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Flap Thickness in Eyes with Ectasia after LASIK

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Abstract

Purpose—To measure central flap thickness in eyes with ectasia after LASIK and to compare these values with estimated anticipated flap thickness based on average published values for each device used for flap creation.

Setting—Emory Vision at Emory University, Atlanta GA, USA

Methods—Confocal microscopic analysis using the Confoscan 3 (Nidek technologies) to measure central flap thickness in eyes with ectasia after LASIK, and evaluation of pre-LASIK records, including basic patient demographics, preoperative corneal topographies, estimated anticipated flap thickness based on published average thickness values, and residual stromal bed thickness (RSB) calculations using both measured and estimated flap thicknesses.

Results—Fifty eyes from 29 patients were evaluated. Average measured flap thickness was $(138 \pm 26 \mu, \text{range } 90 \text{ to } 220 \mu)$. There were no significant differences between measured and estimated flap thicknesses ($138 \text{ vs. } 135 \mu, p = 0.5$) or RSB ($329 \text{ vs. } 332 \mu, p = 0.7$), nor were there any differences in flap thickness between eyes with normal or abnormal corneal topographies. Only one eye had a measured flap resulting in unintended RSB < 250 microns; this occurred in an eye with abnormal topography.

Conclusions—Measured central flap thickness was not thicker than estimated for the vast majority of eyes developing ectasia after LASIK. Thus, excessively thick flaps do not appear to be a major contributing factor to the pathogenesis of ectasia after LASIK.

Postoperative corneal ectasia occurs rarely after LASIK,¹ resulting from corneal biomechanical failure with ultrastructural changes similar to those seen in keratoconic eyes.² This biomechanical failure theoretically arises from two sources: corneas predisposed to postoperative weakening (subclinical-ectatic corneas) being further weakened through surgery, or otherwise normal corneas thinned beyond their point of biomechanical stability from excessive ablation or excessively thick corneal flap creation.

Abnormal preoperative corneal topography is the major risk factor for ectasia after LASIK.^{1,3} However, cases have occurred in eyes with seemingly normal topographies. Excessively thick flaps have been hypothesized as a cause for postoperative ectasia,

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especially in this “normal” population^{4,5}; yet, only rare case reports have actually documented this phenomenon.^{6,7} Flap thickness accuracy and variability has been reported in general LASIK populations, with wide variability in actual obtained flap thickness, but with most flaps being thinner than anticipated by microkeratome plate marking.^{8–11} Therefore, a large number of flaps thicker than calculated would be unusual in any population, including eyes developing ectasia after LASIK.

The purpose of this study was to evaluate central flap thickness in eyes that developed postoperative ectasia, comparing measured to estimated thicknesses, and to correlate these findings with other preoperative parameters, including preoperative corneal topographic patterns.

MATERIALS & METHODS

Confocal microscopic analysis was performed as part of the routine screening protocol for patients with ectasia after LASIK that presented for evaluation for inclusion into the UVX corneal collagen cross-linking clinical trial at Emory University. IRB approval was obtained for this study. Eyes included in this study from that population had preoperative and intraoperative information available for review regarding their LASIK surgery, including age at the time of LASIK, preoperative corneal thickness, preoperative manifest refraction, preoperative corneal topographies, and device type utilized for flap creation, including plate marking for microkeratomes or programmed depth for femtosecond lasers.

Confocal microscopic analysis was performed with the Confoscan 3 (Nidek Co. Greensboro, NC). This device has the capacity to identify the LASIK interface even years after surgery by identifying reflective particles in the interface, which are present in all LASIK flap interfaces¹² [Figure 1]. Flap thickness measurement accuracy is excellent and generally considered to be $\pm 10 \mu$ or less.^{12,13} A series of at least three scans per eye were performed by a single experienced technician (PML) for each eye, and the average of three measurements within a 10 micron range was used as the measured flap thickness. The examiner was blinded to all patient data, including planned flap thickness and type of device used for flap creation.

While overall corneal thickness may be reduced in eyes with ectasia, histopathologic studies have demonstrated that, even in severely ectatic corneas undergoing keratoplasty, overall flap thickness (measured anteriorly-posteriorly) is not significantly different across the flap, that stromal thickness is not different in any regions of the flap, and that epithelial thickness is only affected in the ectatic regions of the flap.² In the eyes included in this analysis, the ectatic process was less severe, and all measurements were taken in the non-ectatic central corneal region. Epithelial hypertrophy can occur after LASIK and influence flap thickness measurements,^{14,15} so epithelial thickness was also evaluated to assess the potential influence of epithelial hyperplasia on flap thickness.

For comparative purposes, estimated flap thicknesses were generated for each eye, utilizing published flap thickness values and standard deviations.⁴ Estimated residual stromal bed thickness (RSB) was obtained by using preoperative central corneal thickness - estimated

flap thickness – programmed ablation depth. Measured RSB was obtained by using central corneal thickness - measured flap thickness - ablation depth.

RESULTS

Patient demographics are listed in Table 1. LASIK was performed between 1997 and 2008, with 40 eyes (80%) having LASIK before 2003. Twenty-one patients (42 eyes) had all data available for both eyes, while 8 patients had data available for only one eye, either due to insufficient preoperative records (4 patients), prior corneal transplant in the fellow eye (3 patients), or unilateral ectasia development (1 patient). Among the 21 patients with bilateral data, 16 had abnormal topographic patterns in one or both eyes, while 5 patients (10 eyes) had symmetric or only mildly asymmetric patterns bilaterally. Example topographies from this “Normal Topography” group are shown in Figures 2 & 3. Three eyes from two patients developed ectasia after hyperopic LASIK; in each of these eyes preoperative topography was abnormal.

LASIK flaps were created with three different microkeratome models and one femtosecond laser, including 8 with an Automated Corneal Shaper (ACS; Bausch & Lomb, Rochester, NY) with a 160 micron plate, 35 with a Hansatome (Bausch & Lomb, Rochester, NY) with either a 160 (18) or 180 (17) micron plate, 6 with a Moria M2 (Moria, Antony, France) with a 130 micron plate, and 1 with the Intralase femtosecond laser (Abbott Medical Optics, Santa Ana, CA) set at 110 microns depth.

To generate estimated flap thicknesses, published values from a variety of studies for each microkeratome utilized were averaged and standard deviations generated.⁴ The following flap thickness estimates were generated: Hansatome 180 plate = $140 \pm 23 \mu$, Hansatome 160 plate = $130 \pm 20 \mu$, Moria 130 plate = $160 \pm 25 \mu$, ACS 160 plate = $120 \pm 20 \mu$, Intralase = $110 \pm 10 \mu$.^{4, 16}

Overall flap thickness results are listed in Table 2. There was no significant difference between estimated and measured flap thickness (135μ vs. 138μ , $p=0.5$). Epithelial thickness profiles were of normal thickness and distribution. There were 17 eyes with measured flap thickness more than 10 microns thicker than estimated, including 7 created with the Hansatome 180 plate, 4 with the Hansatome 160 plate, 4 with the ACS, 1 with the Moria M2, and 1 with the Intralase. The greatest deviations from average included 7 eyes between 30–40 μ thicker than estimated (Hansatome 180 and 160 plates, ACS, and Intralase), 1 eye 50 μ thicker (Hansatome 180) and one eye 100 μ thicker (ACS). [Figure 4].

There were no differences in central corneal thickness or any flap thickness parameters between eyes with normal and abnormal topography [Table 3]. Eyes with normal topographies were significantly younger, more myopic, and had significantly lower estimated and measured RSB. Only one eye had an unintended RSB less than 250 microns in each group.

DISCUSSION

In this study the rate of excessively thick flap creation (greater than 2 standard deviations above average) was rare in eyes that developed ectasia after LASIK in this study group. There were no differences between average measured thickness and average published flap thicknesses from normal populations. Most flaps (82%) were within one standard deviation from estimated average thickness, and only 2 eyes had flaps greater than 2 standard deviations above normal, both of these occurring in patients with abnormal preoperative topography. Flap thickness parameters, including average central thickness, range, and relationship to planned thickness, was equivalent to that reported for contemporaneous patients undergoing uneventful LASIK that did not develop ectasia.^{8,9,11} Further, there were no differences in flap thickness between eyes with or without topographic abnormalities. These results suggest that thick flaps are an uncommon cause of ectasia after LASIK, and corneas predisposed to biomechanical weakening (ectasia-susceptible corneas), even those not detectable with current technology, are a likely a much more significant factor in the development of ectasia than are excessively thick flaps in otherwise normal corneas.

In the small subgroup of 10 eyes with normal topographies, patients were younger, more myopic, and had lower calculated and measured RSB than patients with abnormal topographies. No eyes in this group had between-eye corneal thickness asymmetry of more than 10 microns, a recently suggested risk factor for ectasia.¹⁷ One eye had a measured RSB less than 250 microns, which was similar to the abnormal topography group. Further, there were no differences in flap morphology in this subgroup; therefore, excessive flap thickness did not appear any more important in this subgroup than in the whole study population.

There are potentially significant limitations to the interpretation of this data. These include accuracy of flap thickness measurements, potential alterations to flap thickness measurements over time, and the limitation of measuring only central flap thickness.

As mentioned in the Methods section, the confocal microscope has good accuracy in identifying the flap interface and obtaining measurements even years after surgery. While these measurements may not be as exact as other modalities obtained immediately after surgery, we feel that they do provide a useful approximation of actual flap thickness at the time of surgery.

Flap thickness measurements were obtained in many cases years after the development of ectasia, leading to the concern that flap morphology may be altered and generate unreliable results. We feel this likely has minimal impact on the obtained results, as the two most important issues affecting flap thickness over time in this ectasia population are epithelial remodeling after LASIK and stromal or epithelial thinning due to ectasia. All flap thickness measurements in this study were obtained centrally, not in the region of the ectatic process, and epithelial thickness measurements obtained in this study are comparable to those reported after myopic LASIK.^{12–15} Further, we have previously reported that the flap is unaffected by the ectatic process in the non-ectatic regions, and in the ectatic regions only epithelial thickness is reduced²; therefore, we believe these flap thickness values to be reasonably accurate despite the number of years between surgery and measurement.

Most ectasia cases in this study had abnormal topographies by today's standards; thus only a limited number of eyes with relatively normal topographies were available for review. Further, flap thickness evaluation with confocal microscopy only allows for central flap thickness measurements with out adequately evaluating overall flap architecture. Irregular flaps, with thicker peripheral depths, could theoretically negatively impact corneal biomechanics, and these would not have been identified by this study. The ideal future study population would include only eyes without topographic abnormalities and with a full analysis of flap architecture. Nevertheless, the fact that flap thickness did not differ between eyes with and without topographic abnormalities nor between this population and contemporaneous uneventful LASIK populations suggests that these flap architecture features likely do not play a significant role.

Despite the fact that excessively thick flaps appear rare, thicker than average flaps did occur with a variety of devices, including both microkeratomes and the Intralase femtosecond laser. Although femtosecond lasers and modern microkeratomes create thinner flaps with improved predictability^{10, 18–22} thicker than expected flaps can still occur with any device.²² Therefore, we recommend using average flap thickness plus 2 standard deviations for preoperative planning of residual stromal bed thickness and diligence with measuring flap thicknesses, especially in cases with potentially borderline RSB.

In summary, based on the findings of this study, it appears that, while excessively thick flaps can occur, this mechanism is unlikely to be a major contributing factor to the pathogenesis of ectasia after LASIK.

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Figure 1.
Confocal Microscopic image demonstrating reflective particles in the LASIK flap interface.

Figure 2.

Preoperative topography of the right (A) and left (B) eye of one patient from the normal topography subgroup.

Figure 3.
Preoperative topography of the right (A) and left (B) eye of a second patient from the normal topography subgroup.

Figure 4.

Graph demonstrating relationship between estimated and measured flap thickness. Each microkeratome type is identified by a unique color and symbol and oriented along the Y-axis by estimated flap thickness values based on published averages. The central “mean” line indicates points were estimated and measured thicknesses are identical. The two lighter blue lines indicate one and two standard deviations thicker than average values.

Table 1

Patient Demographics

	Number/Average	Range
Eyes	50	
Patients	29	
% Males	54%	
Age (yrs)	35 ± 9 y	21 to 56 y
Preoperative CCT	528 ± 36 μ	458 to 619 μ
Preoperative MRSE	−4.1 ± 2.6 D	+2.50 to −9.38 D

CCT = central corneal thickness

MRSE = manifest refraction spherical equivalent

Table 2**Flap and Residual Stromal Bed Thickness Measurements**

Flap Thickness	Average	Range	P value
Estimated*	135± 12μ	110 to 160 μ	<0.5 [#]
Measured**	138 ± 26μ	90 to 220 μ	
# > 150 μ	13 (26%)		
# > 180 μ	2 (4%)		
# > 10 μ above planned	5 (10%)		
Epithelial Thickness	43 ± 10μ	25 to 60 μ	
Residual Stromal Bed			
Estimated*	332± 40μ	269 to 466 μ	0.7 ^{###}
Measured**	329 ± 49μ	231 to 506	
# Measured < 250 μ	2 (4%)		

* Estimated = published average values for microkeratome and femtosecond lasers utilized in this study

** Measured = average values measured by confocal microscopy

[#] P value = comparison between calculated and measured flap thickness

^{###} P value = comparison between residual stromal bed thickness based on calculated and measured flap thickness

Table 3

Comparisons Between Normal and Abnormal Topography Groups

	Abnormal Topography (n=40)	Normal Topography (n=10)	P value*
Age (y)	36 ± 8 μ	29 ± 10 μ	0.05
CCT	527 ± 37 μ	530 ± 36 μ	0.8
MRSE (D)	-3.5 ± 2.4 D	-6.6 ± 1.7 D	0.0001
Flap Thickness			
Estimated	135±13μ	134± 5μ	0.6
Measured	137 ± 28μ	138 ± 18μ	0.9
Epithelial Thickness	42 ± 9μ	47 ± 10μ	0.2
Residual Stromal Bed			
Estimated	338± 42μ	307± 27μ	0.008
Measured	336 ± 49μ	302 ± 41μ	0.04
# < 250 μ (estimated)	0	0	
# < 250 μ (measured)	1 (3%)	1 (10%)	0.3

CCT = central corneal thickness

MRSE = manifest refraction spherical equivalent refraction