Original Article

Temporal and Spatial Flap Variability in Laser *In-Situ* Keratomileusis by Optical Coherence Tomography

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Abstract

Purpose: To study changes in flap thickness made with two different microkeratome heads across different corneal locations using anterior segment optical coherence tomography (OCT).
Methods: In this prospective, non-randomized, consecutive case series, subjects who had their laser *in-situ* keratomileusis (LASIK) flaps made using 90 µm (MSU90) or 130 µm (MSU130) disposable M2 microkeratome heads were examined using OCT. The measurements were performed at three locations (central and 2.5 mm to either side) at 1 day, 1 week, and 1 month postoperatively.
Results: The central flap thickness was 123 ± 15, 130 ± 14, and 127 ± 13 µm, respectively, at 1 day, 1 week, and 1 month postoperatively in the MSU90 group (41 eyes) and 142 ± 20, 147 ± 19, and 143 ± 15 µm, respectively, in the MSU130 group (47 eyes). At 1 month, peripheral flap thickness was 161 ± 17 and 159 ± 13 µm, respectively, at 2.5 mm to the right and left of corneal center in the MSU90 group. The corresponding figures were 170 ± 14 and 167 ± 13 µm, respectively, in the MSU130 group. There was a statistically significant difference between the two groups at all locations ($P < 0.001$). No statistically significant change in flap thickness was detected in either group at any assessment time. There was a partial positive correlation (after controlling for preoperative manifest refractive spherical equivalent) between central flap thickness and preoperative ultrasound central pachymetry ($r = 0.739$, $P = 0.036$) in the MSU90 group but not in the MSU130 group.
Conclusion: Using OCT, changes in flap thickness were minimal in the first month after LASIK. Flap thickness correlated strongly with central corneal thickness if a 90 µm head was used.

Keywords: Flap; Microkeratome; Laser *in-situ* Keratomileusis; Fourier-domain Optical Coherence Tomography

J Ophthalmic Vis Res 2017; 12 (4): 368-73

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Received: 31-08-2016 Accepted: 05-03-2017

Access this article online
Quick Response Code:
Website: www.jovr.org
DOI: 10.4103/jovr.jovr_173_16

INTRODUCTION

Laser *in-situ* keratomileusis (LASIK) is still the most popular procedure performed to correct refractive errors.[1] The wide acceptance of LASIK is mainly based on its postoperative refractive stability and the

How to cite this article: Dawood YF, Al Hassany U, Issa AF. Temporal and spatial flap variability in laser *in-situ* keratomileusis by optical coherence tomography. J Ophthalmic Vis Res 2017;12:368-73.

expected rapid visual recovery.[2] Flap creation by either a mechanical microkeratome or femtosecond laser is the first critical and probably the most important step during LASIK, and precise corneal flap thickness is essential for accurate correction of refraction, especially in eyes with high myopia or a thin cornea.[3]

Flap morphology as related to the type of microkeratome used is an important parameter in modern LASIK surgery.[4] Most mechanical microkeratomes create meniscus-shaped flaps, which are thinner in the central cornea and thicker in the periphery, while femtosecond lasers create planar flaps that are uniformly thick across the cornea[5] and may offer greater biomechanical stability and less change in higher order aberrations.[6]

High variability in flap thickness can increase the risk of long-term plastic changes in the cornea, such as ectasia, in cases where a flap is significantly thicker than expected.[7,8] On the other hand, if a flap is thinner than expected, there is the risk of buttonhole formation.[9] Variability in flap thickness can also have a direct effect on refractive correction because the depth of keratectomy relates to the amount of intraoperative and postoperative bioelastic corneal change, which in turn affects the accuracy of the desired curvature change.[10]

Changes in flap thickness across time and in different locations are not widely studied, especially using newer imaging modalities like optical coherence tomography (OCT). These changes may play an important role in the course of visual recovery, induction of higher order aberrations, and timing of enhancements.[10,11]

In this study, anterior segment OCT was used to monitor the changes in flap thickness made with two different M2 microkeratome heads across different corneal locations over a period of 1 month.

METHODS

This prospective, non-randomized, consecutive case series included subjects who underwent LASIK surgery using an M2 microkeratome (Moria, Anthony, France) and an EC-5000 Quest excimer laser (Nidek, Aichi, Japan) at Jenna Ophthalmic Center in Baghdad, Iraq between November 2011 and December 2011.

Subjects underwent a complete preoperative ophthalmic examination including biomicroscopy, measurement of corneal topography (Galilei, Ziemer, Switzerland), manifest and cycloplegic refractive error, and measurement of uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA).

All subjects met the criteria for LASIK surgery, including age (mean, 29.07 ± 7.28; range, 18 to 42 years), magnitude and stability of the refractive error (range of sphere, -10.00 to +2.00D and range of astigmatism, 0 to -6.00D), and absence of ectasia, dry eye, or any corneal diseases. Subjects with a history of uveitis, glaucoma, cataract, or retinal disease were excluded, as were those who did not had three postoperative visits or valid measurements. The informed consent was obtained from all participants.

The subjects were randomly divided into 2 groups depending on the microkeratome head used, i.e., a 90 μm head (MSU90 group) or a 130 μm head (MSU130 group). These heads are designed to create flaps with a thickness of 120 μm and 150 μm, respectively.

Surgical Procedure

Prior to surgery, topical anesthetic eye drops were instilled. Using the M2 microkeratome with an evolution 3 control unit, flaps were created utilizing single-use plastic heads. The suction ring was selected according to the manufacturer's nomogram and based on steep keratometry readings. Surgery was first performed for the right eye and then the left eye, using the same microkeratome head. All surgeries were performed without complications by the same surgeon (UAH). The M2 microkeratome is a rotational type of oscillating keratome with a pivoting style, which keeps the hinge superior in all cases because it rotates along an incomplete arc in an inferior to superior direction.

Postoperatively, all the subjects were prescribed tobramycin-dexamethasone eye drops and moxifloxacin eye drops four times a day for 1 week and artificial tear preparations for at least 1 month.

OCT Examinations

The RTVue Fourier-domain OCT version 4.0 software system (Optovue, Inc., Fremont, CA, USA) with a corneal adaptor module (CAM) was used in this study. The system works at a wavelength of 830 nm and has a speed of 26,000 axial scans per second. The depth resolution of the system is 5 μm (full-width, half-maximum) in tissue. The CAM produces telecentric scanning for anterior segment imaging using a wide-angle (long) or high-magnification (short) adaptor lens. This study used the wide angle lens, which provides a scan width of 6.0 mm and a transverse resolution of 15 μm (focused spot size). Scans were acquired using a CL-line module centered on the entrance pupil as seen on the real-time OCT image postoperatively at 1 day, 1 week, and 1 month. Flap thickness was then measured using the "Flap Tool" in the RTVue CAM software. The user only has to position the center caliper mark at the flap interface, and the software automatically identifies the anterior and posterior corneal boundaries and outputs the measurements [Figure 1].

Statistical Analysis

The mean values and standard deviations of the OCT flap thickness at various times and location points

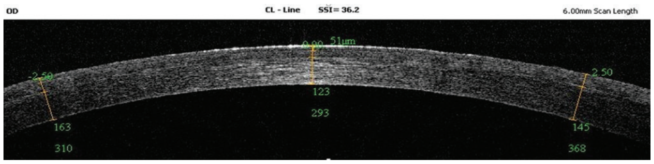

Figure 1. OCT cross section of a corneal line scans showing a LASIK flap. The labels are from top to bottom: transverse location, flap thickness, and bed thickness.

were calculated. Several tests were used to evaluate statistical difference. The paired *t*-test was used for intra-individual comparisons and the independent *t*-test or analysis of variance was used to detect differences between the groups. A *P* value <0.05 was considered to be statistically significant. The data were analyzed using SPSS version 17 software (IBM Corp., Armonk, NY, USA).

RESULTS

Demographics

Eighty-eight eyes (44 subjects, including 31 women) were included in the study. The mean subject age was 29.1 ± 7.28 years. Forty-three eyes were on the right side. There was no statistically significant difference in age, sex, or eye distribution between the study groups.

Refractive Data

Using vector analysis, the preoperative manifest spherical equivalent refractive error was -5.63 ± 2.51 D in the MSU90 group and −2.6 ± 2.52 D in the MSU130 group ($P < 0.05$). Postoperatively, there was no statistically significant difference in spherical or astigmatic error between the two groups [Table 1].

Measurements of OCT Thickness

The preoperative OCT central corneal pachymetry was 536.91 ± 25.78 µm in the MSU90 group and 552.16 ± 20.21 µm in the MSU130 group ($P = 0.028$). Postoperatively, within each group there was a statistically significant difference in flap thickness profile measured at various locations, with thinner values measured centrally resulting in a meniscus-shaped flap ($P < 0.01$).

In the MSU90 group, the mean central flap thickness was 122.59 ± 15.6 µm on day 1 and 127.03 ± 12.99 µm at 1 month postoperatively ($P = 0.083$); the corresponding values were 141.91 ± 19.63 µm and 145.13 ± 14.77 µm in the MSU130 group, respectively ($P = 0.5$). The difference in mean flap thickness between the two groups was statistically significant at all locations ($P < 0.001$). No statistically significant changes in flap thickness were detected within each group at any of the assessment time points. There was a partial positive correlation (after controlling for preoperative manifest refractive spherical equivalent) between central flap thickness and preoperative ultrasound central pachymetry ($r = 0.739$, $P = 0.036$) in the MSU90 group but not in the MSU130 group.

Postoperative OCT changes in flap thickness, the residual stromal bed, and epithelial thickness at the various assessment points did not reach statistical significance in either group [Table 2]. Comparison of the peripheral measurements within each group did not show any statistically significant differences at different time points; for example, in the MSU90 group, flap thickness at 2.5 mm was 161.17 ± 16.26 µm and at −2.5 mm was 159.34 ± 12.72 µm at 1 month ($P = 0.393$).

In the MSU90 group, the intended corneal flap thickness was 120 µm and the mean central flap thickness was 126.51 ± 14.49 µm; the corresponding values in the MSU30 group were 150 µm and 143.96 ± 18.51 µm, respectively. Eyes in the MSU130 group revealed a smaller deviation from the target thickness (mean difference +6.51 in the MSU90 group and −6.04 in the MSU130 group; Table 3) but both groups showed good precision (coefficient of variation 11.45% in the MSU90 group and 12.86% in the MSU130 group). The second flap cut was not significantly thinner than the first flap cut using the same blade with either the MSU90 or the MSU130 microkeratome.

DISCUSSION

In this study, there were no significant changes in flap thickness for up to 1 month after LASIK surgery using Fourier-domain OCT. Several processes are in play during the early postoperative period, i.e., resorption of fluid introduced by intraoperative irrigation, a biomechanical hydration shift, modulation of epithelial thickness in response to laser ablation, and a change in interface reflectivity. The present study demonstrated minimal variability of changes in flap thickness at different locations during the first month after LASIK surgery. This means that within each group, no statistically significant temporal or spatial flap variability was present during the study period.

This study also demonstrated good accuracy and reproducibility of central flap thickness with both microkeratomes. Moreover, the precision of flap thickness in terms of the coefficient of variation and the accuracy of flap thickness in terms of mean difference were acceptable in both groups. On the basis of the above findings, both microkeratomes appeared to produce accurate and reproducible corneal flaps. There are a number of microkeratomes in clinical use and their most common characteristic is the creation of a flap thinner than what intended.[12–14] However, in our present study, the mean central corneal flap thickness in the MSU90

Table 1. Refractive data for MSU90 and MSU130 groups

	MSU90		MSU130	
	Preoperative	Postoperative	Preoperative	Postoperative
Sphere	-4.32±4.30	-0.07±1.84	-2.03±4.2*	0.21±1.55
Cylinder	-2.62±-3.58	-0.24±-1.48	-1.15±-3.36	-0.39±-1.34
Preoperative CDVA	-0.07±0.12		-0.06±0.16	
Postoperative UDVA		-0.098±0.119		-0.076±0.167
Surgically induced MRSE*	-5.18±2.08		-2.4±2.34	
SIRC*	-2.46±-3.61		-0.76±-2.97	

*Statistically significant difference. CDVA, corrected distance visual acuity; UDVA, uncorrected distance visual acuity; MRSE, manifest spherical equivalent refraction; SIRC, surgically induced refractive cylinder

Table 2. Flap and residual stromal bed thickness (RST) measured centrally (point 0), and 2.5 mm to either side on a horizontal line during the postoperative course. Epithelial (EPI) thickness was measured centrally

	Flap			RST			EPI
MSU90 group							
	-2.5	0	2.5	-2.5	0	2.5	
1 day	159.76±16.02	122.59±15.6	158.73±20.7	383.47±32.82	348.71±32.57	379.85±29.71	52.84±3.25
1 week	164.41±11.37	129.41±14.04	165.76±15.97	377.47±38.41	339.32±31.95	373.65±32.39	53.57±3.34
1 month	159.34±12.72	127.03±12.99	161.17±16.26	371.48±35.72	332.79±32.77	364.33±30.78	53.23±2.92
Mean	161.38±13.71	126.51±14.49	162.25±18.34	377.65±36.25	340.5±32.31	372.76±30.89	53.23±3.2
ANOVA	0.141	0.083	0.163	0.42	0.147	0.141	0.462
MSU130 group							
	Flap			**RST**			**EPI**
	-2.5	0	2.5	-2.5	0	2.5	
1 d	173.13±20.67	141.91±19.63	170.80±19.58	393.66±25.79	378.05±26.46	392.02±42.98	53.89±4.27
1 w	174.22±20.16	147.67±18.90	173±18.54	388.37±23.39	368.34±24.38	385.77±21.01	54±3.86
1 m	168.50±14.02	145.13±14.77	168.38±14.77	395.13±24.84	376.33±26.01	393.47±24.88	54.19±4.89
Mean	171.79±18.76	143.96±18.51	171.66±17.68	390.27±25.25	371.58±29	390.04±33.49	53.74±4.1
Analysis of variance	0.315	0.5	0.733	0.449	0.083	0.825	0.867

P-value for analysis of variance is shown

Table 3. Thickness of central corneal flap cut using Moria M2 90 μm (MSU90) and the Moria M2 130 μm (MSU130) blade microkeratomes

Microkeratome group	Flap thickness (μm) Mean±SD	Mean difference	*P*
Moria M2 SU90 (*n*=41)	126.51±14.49	+6.51	<0.001
Moria M2 SU130 (*n*=43)	143.96±18.51	-6.04	<0.001

group was greater than the intended thickness. Previous studies[15–17] showed that the standard deviation of flap thickness achieved by mechanical microkeratomes was in the range of ±20 to ±40 μm.

The improved standard deviation seen in our study may be attributable to better design of the microkeratome, selection of appropriate suction rings, and accuracy/reproducibility of OCT measurements. Although thinner flaps are prone to buttonholes and require more complicated handling during surgery, no incomplete flaps, buttonholes, or other microkeratome-related flap complications were observed in our study.

To determine the preoperative factors associated with corneal flap thickness, we investigated the correlation between corneal flap thickness and the preoperative spherical equivalent, age, keratometry, and central corneal thickness, respectively. We found a positive correlation between central flap thickness and preoperative central pachymetry in the MSU90 group but not in the MSU130 group. This finding is in agreement with some previous studies.[12,13] The explanation for this correlation may be the fact that a thicker cornea is more compressible in the superficial corneal area than a thinner cornea.[18]

The discrepancies between our results and previous findings[12,13] may be attributed to differences in the methods used to measure corneal thickness (OCT vs. ultrasonic pachymetry) or in assessment times (first postoperative day vs. immediately after creation of the flap). The anticipated errors[19] with the measurement technique using ultrasound pachymetry to measure central corneal thickness before and after flap creation and then calculating flap thickness indirectly have led investigators to use the OCT as a tool for measuring postoperative flap thickness.[20,21]

Another common issue that arises with microkeratomes concerns the discrepancy in flap thickness between the first and second eye when the same blade was used for both eyes. David et al[22] showed that reuse of microkeratome blades created significantly thinner flaps on the second cut. Although our study demonstrated a slightly thinner flap in the second cut, the difference did not reach statistical significance, as was seen in previous studies.[12,13] Some authors postulated that the reason for the thinner flap obtained in the second cut was the increased dullness of the blade following the first cut.[23,24]

The newly developed femtosecond lasers were designed to produce thinner flaps, with a closer range of thickness around the mean. Salomao et al[25] obtained a standard deviation in flap thickness of ±14.5 μm using the IntraLase femtosecond laser. This standard deviation was relatively comparable with that obtained using the two kinds of mechanical microkeratomes in our study. In contrast with the high-priced IntraLase femtosecond laser device and the extra charges to the subjects using femtosecond laser, the MSU90 and MSU130 can both produce an accurate, reproducible, safe, and cost-effective corneal flap.

Moreover, in the current study, although the difference in precision was not statistically significant between the two groups, the 130 μm microkeratome produced a flap thinner than intended flap thickness compared to the 90 μm microkeratome. However, with the advantages of preserving more stromal tissue and potentially reducing the incidence of corneal ectasia, the MSU90 could create thinner and more accurate flaps and thus be more suitable for subjects with thinner central corneal thickness.

Using a similar OCT system, Kanellopoulos and Asimellis[26] found that the corneal epithelium was thickened centrally and paracentrally after myopic LASIK, that the maximum epithelial thickening occurred in an annular area about 3–4 mm in diameter, and that the central epithelial thickening and amount of LASIK correction were statistically correlated (1.39 μm/D for the mid-peripheral region). The authors hypothesized that epithelial hyperplasia might be caused by a thinned cornea that was biomechanically unstable. This hypothesis was also supported by a study of changes in epithelial thickness after collagen cross-linking.[27] Thus, the changes in epithelial thickness could be a response to focal curvature changes[28] in addition to alterations in corneal biomechanical properties. In this study, no significant changes in corneal epithelial thickness were detected during the period of measurement.

There were some drawbacks in our present study. First, because measurements of variation in flap thickness was only along the horizontal meridian of the cornea, other regional flap/epithelial thickness changes may not have been detected. Horizontal line scanning and measurement was selected in order to avoid false measurement and misinterpretation of the flap data that might be caused by interference from the upper eyelid or by changes influenced by the superior location of the hinge.[29] However, the flap profile on vertical and oblique scans should be included in future studies. Second, our study included a relatively small number of subjects, so a large prospective study is required to establish more statistically powerful results.

Although the LASIK flap interface was better visualized in 1-day and 1-week postoperative OCT images than later on in the study, the flap is detected best by OCT in the pericentral zone, where the stromal bed signal is low, bringing out the contrast in the higher flap internal reflectivity and the flap interface peak. The contrast is poor near the corneal vertex (diameter >2 mm), where the interface reflections are overwhelming and both flap and bed internal reflectivities are high. In the transitional and peripheral zones (diameter >5 mm), the signal is low in all corneal layers and frequent lid shadowing makes measurements less reliable. These contrast variations are brought by the variation in incidence angle as the OCT beam is scanned across the corneal dome. This is an intrinsic limitation for OCT flap measurement because of the corneal geometry. We partially circumvented this problem by taking scans centered on the pupil center rather than on the corneal vertex which offsets the increased reflectivity seen in some scans.

In conclusion, flap thickness can be monitored via high-resolution non-contact optical technology anterior segment OCT, allowing both central and regional pachymetry. With anterior segment OCT, the thickness of different layers of the cornea, including the epithelium as well as total corneal thickness, can be measured. Moreover, anterior segment OCT has the overwhelming advantages over ultrasonic pachymetry and confocal microscopy of being non-contact and non-invasive. A limitation of AS-OCT is that the boundaries between the flap and stroma become ambiguous with time, increasing the examiner's subjectivity.[30] Thus, flap thickness measurements at 1 week after LASIK were recommended for evaluating the performance of the microkeratomes. There was no statistically significant temporal and spatial flap variability with the two different M2 microkeratomes during the first month after LASIK surgery that may influence both biomechanical and optical properties. Further study of the clinical impact of flap morphology is warranted.

Financial Support and Sponsorship

Nil.

Conflicts of Interest

There are no conflicts of interest.

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