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Analysis of Thin Microkeratome Flap Architecture using a Fourier Domain Optical Coherence Tomography

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Abstract

Purpose—To assess the corneal architecture and reproducibility of laser in situ keratomileusis (LASIK) flap thickness created by the Amadeus II mechanical microkeratome using Fourier domain optical coherence tomography (OCT).

Methods—Anterior segment Fourier domain OCT (Optovue RTVue-100, Optovue Inc, Fremont, CA) was used to analyze the morphology of 58 LASIK flaps created with the Amadeus II microkeratome 140 μ m head (Ziemer Ophthalmic Systems AG, Port, Switzerland), with the ML7090CLB blade (Med-Logics, Inc, Laguna Hills, CA), at 2 weeks postoperatively. Flap thickness was assessed at 10 points across the central 6mm of the cornea (horizontal and vertical meridians). The postoperative central corneal flap thickness measured by Fourier domain OCT was compared with intraoperative ultrasound (US) pachymetry measurements.

Results—There was no significant difference between central flap thickness measured by intraoperative pachymetry (107.2 $\pm$ 14 μ m) and postoperative OCT (111.7 $\pm$ 11 μ m; $p=0.07$, correlation coefficient=0.86). Fourier domain OCT measurements demonstrated functionally planar flap architecture (SD of thickness across the flap= 4.9 μ m, SD range across the flap= 2 to 9 μ m) for the microkeratome flaps.

Conclusions—The Amadeus II microkeratome with Med-Logics blades created thin, reproducible, functionally planar flaps as measured by the Fourier domain OCT. Central flap thickness measured by intraoperative US pachymetry was equivalent to that measured 2 weeks postoperatively by OCT.

Both mechanical microkeratomes and femtosecond lasers are currently utilized for LASIK flap creation. Femtosecond lasers have reported advantages of creating thinner, more reproducible flaps with a more nearly planar flap architecture than is typically obtained with older generation mechanical microkeratomes.^{1–6} Newer mechanical microkeratomes have also shown highly reproducible thin flaps, as determined by central thickness measurements, and comparable visual outcomes^{7,8}; however, less is known about overall flap architecture with these microkeratomes.

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LASIK flap thickness and morphology can be evaluated with regional ultrasound pachymetry, high-resolution anterior segment ultrasound, and both time-domain and Fourier-domain ocular coherence tomography (OCT).^{9,10} Central corneal thickness and LASIK flap thickness measurement comparisons using time-domain and ultrasound pachymetry have been reported, with most studies finding good correlation between techniques but consistently thinner measurements obtained with time-domain OCT.^{11–13} To our knowledge, no central or regional flap thickness comparisons between Fourier-domain OCT and ultrasound pachymetry have been reported.

The purpose of this study is two-fold: to compare and correlate ultrasound pachymetry central flap thickness measurements with Fourier-domain OCT, and to analyze and describe flap thickness architecture created with the Amadeus II mechanical microkeratome.

PATIENTS AND METHODS

Patients

Patients undergoing LASIK from May to June 2009 at Emory Vision (Atlanta, GA) were the subjects of this retrospective, consecutive eye analysis. Institutional review board approval was obtained for this review.

Surgical Technique

All surgical procedures were performed by one of two experienced surgeons (JBR or RDS). LASIK flaps were created with the Amadeus II microkeratome (Ziemer Ophthalmic Systems AG, Port, Switzerland) with a 140µm head, 9.0mm or 9.5mm suction rings (used according to white-to-white corneal measurements) with Med-Logics blades (ML7090CLB, Med-Logics, Inc, Laguna Hills, CA). Intraoperative pachymetry was measured before applying the microkeratome and after flap creation to the stromal bed with a DGH-550 Pachette ultrasonic pachymeter. This is done routinely on all LASIK cases, each “measurement” is an average of ten measurements, and this process is repeated twice for each eye. A standard deviation of less than 2 microns per ten measurements and less than 5 microns difference between measurement sets is tolerated. Ablation was performed with the WaveLight Allegretto Eye-Q 400Hz excimer laser (Alcon Laboratories, Inc., Fort Worth, TX).

Anterior segment Fourier domain OCT

A Fourier domain (spectral-domain) OCT device (Optovue RTVue-100, Optovue Inc, Fremont, CA) with a scan rate of 26 000 axial scans per second, axial resolution of 5 µm, transverse resolution of 15 µm and an add-on lens (CAM-L mode: 6.0–2.0 mm) was used to assess the corneal flap morphology two weeks postoperatively. Patients were asked to fixate on the target light source and consecutive images were acquired with the patient’s forehead and chin stabilized by a headrest. Images were obtained in triplicate to determine the repeatability of the thickness measurements with this method. The posterior edge of the LASIK flap was determined by direct visualization of the area of increased reflectivity corresponding with the flap-stroma interface. The flap tool of the high-resolution cross-line scan of the add-on lens was used to measure the flap thickness. The anterior surface of the

cornea and the flap-stroma interface was used as anatomical landmarks to measure flap thickness. All measurements were performed by the same examiner (KMR).

The OCT scans were centered on the vertex of the cornea and horizontal and vertical cross section images were acquired. The flap thickness was assessed at 10 points across the central 6 mm of the cornea (horizontal and vertical meridians at 0 mm, 1.5 mm and 2.5 mm, 3.0 mm to the vertex) [Figure 1]. The regularity and morphology of the flaps were assessed by evaluating the standard deviation of the corneal thickness across the flap within the central 6 mm. The postoperative central corneal flap thickness was compared to intraoperative ultrasound (US) pachymetry measurements.

Visual acuity, both uncorrected (UCVA) and distance corrected (DCVA), and manifest refraction spherical equivalent (MRSE) were recorded at three months postoperatively. Eyes with intended undercorrection for monovision were excluded from UCVA and MRSE analysis but were included in DCVA analysis.

Data analysis

Statistical analysis included Student's t-tests to evaluate differences between groups, Pearson correlation coefficient, and multivariate analysis to compare peripheral to central measurements. P values less than 0.05 were considered significant.

RESULTS

There were 58 eyes from 30 consecutive patients analyzed. Patient demographics are found in Table 1. All eyes in the study had uneventful LASIK without flap complications.

There were no clinically or statistically significant differences and excellent correlation between central flap thickness measured by intraoperative US pachymetry [$107.2 \pm 14 \mu\text{m}$, range 78 to $136 \mu\text{m}$ ($60 \mu\text{m}$)] and postoperative OCT [$111.7 \pm 11 \mu\text{m}$, range 94 to $132 \mu\text{m}$ ($40 \mu\text{m}$); $p=0.07$, correlation coefficient=0.86].

Fourier domain OCT measurements demonstrated functionally planar flap architecture across the flap [Figure 1] with an average standard deviation of measurements across the flap of $4.9 \mu\text{m}$ (SD range across the flap 2 to $9 \mu\text{m}$) [Table 2]. The greatest average deviation from the center measurement to any location was 6.2 microns. No flap deviated more than 20 microns from the center thickness in any direction, and in multivariate analysis there was no significant difference between central and peripheral measurements for each flap ($p>0.05$). No significant differences in flap thickness were found between right and left eyes at the central or any paracentral/peripheral location [Table 3].

At three months, average UCVA was 20/18.8 (SD = 3, range 20/15 to 20/25) for 48 eyes targeted for Plano (10 were targeted for near), average DCVA was 20/17.6 (SD = 2.5, range 20/15 to 20/20) for all 58 eyes, and MRSE was 0.02 D (SD = 0.32 D, range -0.63 to +0.50) for the 48 eyes targeted for Plano.

DISCUSSION

Consistently thin, reproducible, functionally planar flaps are created with the Amadeus II microkeratome used with Med-Logics blades. These flap thickness, flap architecture, and predictability of flap thickness parameters are equivalent to the ranges reported for flaps created with femtosecond lasers.^{3,4,14,15}

In an article by Reinstein and colleagues¹⁵ that provides a summary of multiple reports on femtosecond central flap thickness results, there is a wide range of accuracy (mean absolute deviation from intended flap thickness) from 0.4 to 40 microns, as well as a wide range of central flap thicknesses from each report (range 22 to 84 microns). Based on previous studies from our group regarding this microkeratome and blade combination,^{16, 17} we anticipated the flap thickness to be $107 \pm 12 \mu\text{m}$, which is essentially identical to the results presented herein, and our reported range of central thicknesses (60 microns as measured with ultrasound pachymetry, 40 microns as measured with OCT) falls well within the reported ranges for femtosecond flaps.

Flaps created with this microkeratome/blade combination produced functionally planar flaps, with approximately 6 microns average deviation from central to peripheral measurements, average standard deviation across all flaps of less than 5 microns, and no peripheral measurements greater than 20 microns thicker than central measurements for any flap. These flap parameters are consistent with those reported for the Schwind Carriazo-Pendular mechanical microkeratome⁷ and femtosecond lasers⁴⁻⁷ and superior to those reported for the Moria M2⁷ and Zyoptix XP³ mechanical microkeratomes.

We found excellent correlation between flap thickness measured intraoperatively with ultrasound pachymetry and postoperative flap thickness measured with high resolution OCT. High correlation between US pachymetry and time domain anterior segment OCT (Visante OCT) central corneal thickness measurements has already been described.^{10,13,18} However, the time domain OCT measurements were reproducible and constantly less compared to US pachymetry. Furthermore, although corneal measurements with time domain and Fourier domain OCT were significantly correlated, the Fourier Domain OCT was superior in terms of intersession reliability.¹⁹ The images in Fourier domain OCT systems are acquired up to 100 times more quickly when compared to the standard time-domain OCT devices.²⁰ Therefore, the improved correlation between ultrasound and OCT images in this study is not surprising.

While there does not appear to be any significant difference between thick and thin flap LASIK in terms of visual acuity,^{17, 21, 22} the advantages of a thin, planar LASIK flap include greater residual stromal bed thickness and a presumed increased corneal biomechanical stability that may be similar to that of surface ablation.^{23, 24} A non-uniform meniscus-shaped flap can lead to deeper disruption of collagen lamellae in the corneal periphery; these observations explain why the risk for ectasia may therefore be greater with deeper ablations into the posterior stroma, as unexpectedly thick flaps and meniscus-shaped flaps produce a deeper disruption of collagen lamellae and can contribute to the development of ectasia after LASIK.

In this study only the central 6mm of the corneal flap was studied; therefore, it is possible that there were greater differences between the far periphery and the central thicknesses. However, we believe it is unlikely that these far peripheral measurements would be significantly thicker than central measurements given the regularity of the flap from central through the 6mm diameter. Further, we believe that potential differences in the far periphery of the flap would be unlikely to have clinical significance because the corneal stroma is inherently thicker in these more peripheral areas. Nevertheless, this is an area that warrants further specific study.

In conclusion, new generation thin flap microkeratomes create consistently thin, reproducible, planar LASIK flaps with excellent visual outcomes.

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Figure 1. Spectral-domain (Fourier domain) optical coherence tomography of thin LASIK flap for myopia, revealing a uniform flap thickness and planar architecture throughout the central and paracentral cornea (A) and at the superior and inferior flap edge (B).

Table 1

Patient Demographics.

Demographics	Avg (SD)	Range
Age (yrs)	35 (6.8)	23 to 56
Sex # male eyes (% male)	32 (55%)	
Preoperative		
DCVA (Snellen)	20/18.2	20/15 to 20/25
MRSE (D)	-3.88 (1.82)	-0.25 to -6.5
US CCT (?m)	557.3 (29.9)	499 to 614

DCVA = distance corrected visual acuity

MRSE = manifest refraction spherical equivalent

D = diopters

US CCT = Ultrasound Central Corneal Thickness

Table 2

OCT Measured Flap Thickness Comparisons Across the Flap

	Central	V Inf 2.5	V Inf 1.5	V Sup 1.5	V Sup 2.5	H - 2.5	H - 1.5	H + 1.5	H + 2.5
Average	111.7	115.2	112.6	113.6	117.9	116.6	112.6	113.4	117.8
SD	11.1	11.7	11.0	11.3	10.1	12.4	11.4	11.0	11.0
Min	94	92	91	95	98	96	92	92	95
Max	136	138	135	138	142	146	140	137	145
P		0.09	0.7	0.6	0.02	0.03	0.7	0.4	0.003

P = p values as compared from the center

V Inf 2.5: measurement taken 2.5mm inferior to vertex

V Inf 1.5: measurement taken 1.5mm inferior to vertex

V Sup 1.5: measurement taken 1.5mm superior to vertex

V Sup 2.5: measurement taken 2.5mm superior to vertex

H - 2.5: measurement taken 2.5mm nasal to vertex

H - 1.5: measurement taken 1.5mm nasal to vertex

H + 1.5: measurement taken 1.5mm temporal to vertex

H + 2.5: measurement taken 2.5mm temporal to vertex

Table 3

Regional Flap Thickness Comparisons Between Right and Left Eyes

Measurement region	OD	OS	P value
Central	113.7	109.7	0.16
V Inf – 2.5	116.9	113.5	0.27
V Inf – 1.5	114.4	110.8	0.27
V Sup – 1.5	114.8	109.7	0.16
V Sup – 2.5	119.8	112.3	0.38
H – 2.5	118.8	116.0	0.16
H – 1.5	115.2	114.3	0.17
H + 1.5	115.3	111.5	0.19
H + 2.5	120.4	115.2	0.08
SD across flap	4.9	4.8	0.89

V Inf 2.5: measurement taken 2.5mm inferior to vertex
 V Inf 1.5: measurement taken 1.5mm inferior to vertex
 V Sup 1.5: measurement taken 1.5mm superior to vertex
 V Sup 2.5: measurement taken 2.5mm superior to vertex
 H – 2.5: measurement taken 2.5mm nasal to vertex
 H – 1.5: measurement taken 1.5mm nasal to vertex
 H + 1.5: measurement taken 1.5mm temporal to vertex
 H + 2.5: measurement taken 2.5mm temporal to vertex
 SD – standard deviation