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Article

Corneal flap thickness in laser in situ keratomileusis using the Moria M2 microkeratome[*1], [*2]

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Abstract

Purpose: To determine the predictability of flap thickness in laser in situ keratomileusis (LASIK) using the Moria M2 microkeratome and identify factors that may be related to variations in flap thickness.

Setting: Laser Vision Correction Center, Bascom Palmer Eye Institute, University of Miami School of Medicine, Miami, Florida, USA.

Methods: Charts of 208 patients having same-day bilateral LASIK using the Moria M2 microkeratome were reviewed. Intraoperative pachymetry was performed routinely. The right eye was always treated first. The same suction ring, stop, microkeratome head (110 μm or 130 μm), and blade were used in fellow eyes. Subtraction pachymetry was used to calculate flap thickness. Other collected data included age, keratometry, corneal diameter, and preoperative spherical equivalent (SE).

Results: With the 110 μm head and slow translation velocity in both eyes, the mean flap thickness was 151.6 μm ± 24.0 (SD) and 148.5 ± 24.3 μm in the right and left eyes, respectively. With the 110 μm head and fast translation velocity in both eyes, the mean thickness was 136.2 ± 25.5 μm and 132.8 ± 23.5 μm, respectively. With the 130 μm head and fast translation velocity, the mean flap thickness was 145.8 ± 25.4 μm and 139.9 ± 25.5 μm, respectively. Flaps were thinner with fast translation velocity, the 110 μm head, and presumably duller blades used in the left eyes. There was a weak but statistically significant inverse correlation between flap thickness and age and between flap thickness and SE. A stronger correlation was found in flap thickness between right and left eyes.

Conclusions: Flap thickness with the Moria M2 microkeratome was variable. Fast translation velocity, a used (presumably duller) blade, and the 110 μm head produced thinner flaps. Given the potential variation in flap thickness (SD 23.5 to 25.5 μm), intraoperative pachymetry might be an adjunctive measure to prevent residual stromal beds that are thinner than planned, especially in patients with high myopia and/or thin corneas.

Article Outline

Laser in situ keratomileusis (LASIK) is an increasingly accepted technique for the surgical correction of refractive errors.[1, 2, 3, 4, 5 and 6] The procedure involves the creation of a hinged corneal flap using a microkeratome. [7 and 8] Consistency of flap thickness is considered a critical feature of a microkeratome. The ability to know how thick the flap actually is affects the degree of myopia that can be corrected, given the current recommendation of leaving at least 250 μm of corneal stromal bed. It is our impression that thin flaps are more prone to the development of striae and are more difficult to manipulate without tearing. Cutting too deeply may leave too little stromal bed for laser ablation and may compromise the structural integrity of the cornea.

The Moria M2 is an automated, new-generation microkeratome. Its advantages include ease of assembly; light weight; narrow design allowing it to fit in small fissures; 2 motors, 1 for translation and 1 for blade oscillation (15000 rpm) (on reverse movement, there is no oscillation); multiple suction rings (−1, 0, +1, +2) that allow the flap diameter to be customized; hinge width adjustment; customized hinge location; low-suction device that can be used to hold the eye; fixed-depth plate that makes it impossible to perforate the eye unless operating on a thin cornea; 2 heads (110 μm and 130 μm) and 2 head translation velocities (fast = 2.1 seconds, SLOW = 3.1 seconds) that allow a wide range of flap thicknesses.

Since its introduction in 2000, no data on the consistency of flap thickness with the Moria M2 microkeratome have been published. This study attempted to determine the predictability of flap thickness in LASIK procedures using the Moria M2 microkeratome and identify factors that may be related to variations in flap thickness.

Patients and Methods

The charts of patients having LASIK by 2 surgeons (W.W.C., S.H.Y.) in our university-based laser vision correction center from September 26, 2001, to April 2, 2002, were reviewed. The names of all patients treated during this period were recovered from the laser logbook. Both surgeons routinely used intraoperative pachymetry to measure central corneal thickness (CCT) before and immediately after cutting the flap.

Only patients having same-day bilateral LASIK using the Moria M2 microkeratome to create superiorly hinged flaps were included. The right eye was always treated first. The same suction ring and stop (following the M2 microkeratome nomogram), microkeratome head, and blade were used in both eyes. Patients in whom it was difficult to obtain satisfactory suction or who had more than 60 seconds of suction time or eccentric flaps were excluded.

A spreadsheet was created that included the patients' demographics, surgeon, preoperative simulated keratometry readings and mean keratometry (Orbscan, version 3.0, Bausch & Lomb Surgical), corneal diameter (white to white in Orbscan), preoperative spherical equivalent (SE), M2 head, suction ring and stop, translation velocity of the microkeratome head, and intraoperative pre-flap and post-flap CCT (Advent pachymeter SKU 24-2500, Accutome).

For LASIK, the patient was positioned under the operating microscope of a Visx S3 excimer laser. The CCT was measured 3 times with the ultrasonic pachymeter, and the mean was recorded as the pre-flap thickness. A Moria M2 suction ring was placed on the eye and suction applied. The Moria M2 microkeratome was used to create the flap. The flap was retracted, and the corneal bed thickness was measured 3 times with the ultrasonic pachymeter; the mean was recorded as the post-flap thickness. The refractive ablation was then completed in a routine manner and the flap floated into its primary position.

The flap thickness was calculated by subtracting the post-flap thickness from the pre-flap thickness (subtraction pachymetry). Patients were excluded if a complete set of measurements was not obtained.

Statistical Analysis

Descriptive statistics such as means, standard deviations, and Pearson correlation coefficients are presented. The mean flap thicknesses in right and left eyes were compared with paired *t* tests, and the mean thicknesses with head sizes and translation speeds were compared with *t* tests. An analysis of variance was used to determine whether the difference in flap thickness between right and left eyes was correlated with other variables such as head size or translation speed. Prediction limits (95%) for the flap size in the left eye were computed from the right eye using regression methods.

Results

Two hundred eight patients were included in the study. The mean patient age was 41 years ± 12 (SD) (range 18 to 72 years). The mean preoperative SE was −3.47 ± 3.18 D (range +4.13 to −12.50 D) in the right eyes and −3.56 ± 3.21 D (range +6.13 to −12.00 D) in the left eyes. There was little variation in the thickness across each cornea, suggesting that the microkeratome created a fixed resection, although thickness between cuts differed significantly.

In Table 1, patients are divided by the M2 head and the translation velocity. The 3 major groups were patients operated on with the 110 μm head using slow (30 patients) or fast (43 patients) translation velocity in both eyes and patients operated on with the 130 μm head and fast translation velocity in both eyes (110 patients). Table 2 and Table 3 show the mean and range of flap thickness with the 110 μm head and the 130 μm head, respectively. In both cases, a wide range of cuts was noticed with each microkeratome setting.

Table 1. Patients divided by M2 microkeratome head and translation velocity.

	Number of Patients Per Group				
Head (μm)	OU Fast	OU Slow	OD Fast OS Slow	OD Slow OS Fast	Total
110	43	30	9	10	92
130	110	4	1	1	116
Total	153	34	10	11	208

Fast = fast translation velocity of microkeratome head; OD = right eye; OS = left eye; OU = both eyes; Slow = slow translation velocity of microkeratome head

Table 2. Mean flap thickness with the 110 μm head.

	Mean Flap Thickness ± SD (μm) (Range)		
Eye/Velocity	OD	OS	*P* Value*
OU slow (n = 30)	151.6 ± 24.0 (98–203)	148.5 ± 24.3 (94–208)	.34
OU fast (n = 43)	136.2 ± 25.5 (82–200)	132.8 ± 23.5 (68–174)	.33
OD slow/OS fast (n = 10)	157.1 ± 23.3 (120–189)	134.7 ± 19.2 (112–174)	.003
OD fast/OS slow (n = 9)	148.8 ± 28.5 (120–205)	147.6 ± 26.3 (108–189)	.94

fast = fast translation velocity of microkeratome head; OD = right eye; OS = left eye; OU = both eyes; SLOW = slow translation velocity of microkeratome head

Table 3. Mean flap thickness with the 130 μm head.

	Mean Flap Thickness ± SD (μm) (Range)		
Eye/Velocity	OD	OS	*P* Value*
OU slow (n = 4)	171.5 ± 41.0 (111–199)	160.3 ± 46.2 (92–194)	.25
OU fast (n = 110)	145.8 ± 25.4 (68–205)	139.9 ± 25.5 (69–204)	.008
OD slow/OS fast (n = 1)	154.0	160.0	—
OD fast/OS slow (n = 1)	194.0	184.0	—

fast = fast translation velocity of microkeratome head; OD = right eye; OS = left eye; OU = both eyes; SLOW = slow translation velocity of microkeratome head

With the 130 μm head and fast translation velocity (110 patients), the right flap was thicker than the left in 63% of eyes, the left flap was thicker in 35%, and both flaps were equal in 3% (*P* = .004, sign test). With either microkeratome head and the same translation velocity in both eyes (187 patients), the right flap was thicker than the left in 61% of eyes, the left flap was thicker in 36%, and both flaps were equal in 3% (*P* = .001, sign test).

Table 4 compares flap thickness with fast versus slow translation velocity of the microkeratome head. The fast translation velocity yielded statistically significantly thinner flaps.

Table 4. Mean flap thickness with fast and slow translation velocity of the microkeratome head.

Head (μm)	Mean Flap Thickness ± SD (μm)			
	OD			
	Slow	Fast	*P* Value*	Slow
110	153.0 ± 23.6 (n = 40)	138.4 ± 26.2 (n = 52)	.007	148.3 ± 24.5 (n = 39
130	168.0 ± 36.3 (n = 5)	146.2 ± 25.7 (n = 111)	.07	165.0 ± 41.4 (n = 5

Fast = fast translation velocity of microkeratome head; OD = right eye; OS = left eye; Slow = slow translation velocity of microkeratome head

Table 5 compares flap thickness with the 110 μm and 130 μm heads. The mean flap thickness in both eyes was used for the calculations. The 110 μm head yielded thinner flaps than the 130 μm head. Only patients in whom fast translation velocity was used in both eyes (the larger groups) were included.

Table 5. Flap thickness with the 110 μm and 130 μm heads.

Head (μm)	Mean Flap Thickness ± SD (μm)	
110 (n = 43)	134.5± 21.7	
		P = .041
130 (n = 110)	142.8± 22.8	

Includes only patients with fast translation velocity in both eyes. The mean flap thickness in both eyes was used for calculations.

Figure 1 shows that age was weakly but statistically significantly inversely correlated with flap thickness in the right eyes with the 130 μm head and fast translation velocity ($r = -0.32$, $P = .001$). Results were similar in the left eyes ($r = -0.25$, $P = .007$). Age and SE were also weakly but statistically significantly correlated ($r = 0.37$ in the right eyes, $r = 0.35$ in the left eyes, $P < .001$ in both eyes). The SE was also inversely correlated with the keratometry ($r = -0.18$ in the right eyes, $r = -0.28$ in the left eyes; $P = .031$ in the right eyes, $P = .002$ in the left eyes). The correlation between age and flap thickness was not affected by adjusting for SE and keratometry (partial $r = -0.25$). This analysis was of the right eyes in the 110 patients operated on with the 130 μm head and fast translation velocity in both eyes. The results were similar in the left eyes.

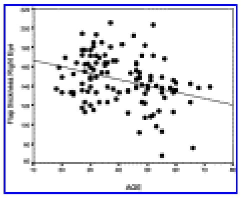 (6K)

Figure 1. (Muallem) Correlation between age and flap thickness with the 130 μm head and fast translation velocity (n = 111) (r = −0.32, P = .001). A similar correlation was found in the left eyes (r = −0.25, P = .007).

Corneal thickness correlated with flap thickness in the left eyes with the 110 μm head and fast (r = 0.44, P = .001) and slow (r = 0.37, P =.020) translation velocities (Figure 2). Similar but not statistically significant results were found in the right eyes with fast (r = 0.23, P =.10) and slow (r = 0.23, P =.15) translation velocities. With the suction rings, there was no correlation between corneal thickness and flap thickness (r = −0.04, r = −0.11, and r = −0.06 for suction rings −1, 0, and +1, respectively; only 6 eyes were done with suction ring +2). This analysis was of the right eyes in the 110 patients using the 130 μm head and fast translation velocity. The results were similar in the left eyes.

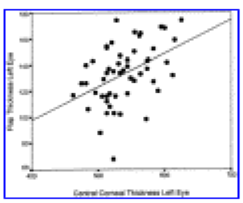 (5K)

Figure 2. (Muallem) Correlation between the preoperative corneal thickness and flap thickness in the left eyes using the 110 μm head and fast translation velocity (n = 53) (r = 0.44, P = .001). A similar correlation was found in the right eyes (n = 39) (r = 0.23, P = .096) and in the left eyes with slow translation velocity (n = 39) (r = 0.37, P = .02).

When fast translation velocity was used in both eyes, a moderate correlation was found between the flap thickness in the right and left eyes with the 130 μm head (r = 0.60, P<.001) (Figure 3). The correlation was similar using the 110 μm head and fast translation velocity (r = 0.57) and the 110 μm head and slow translation velocity (r = 0.75). Prediction of the left eye flap from the right eye flap was poor (Table 6, Table 7 and Table 8).

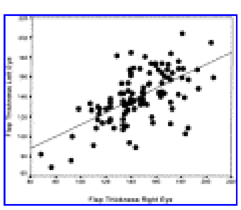 (6K)

Figure 3. (Muallem) Correlation between flap thickness in the right and left eyes using the 130 μm head and fast translation velocity (n = 110) (r = 0.60, P<.001). A similar correlation was

found with the 110 μm head with fast (n = 43) (*r* = 0.57, *P*<.001) and slow (n = 30) (*r* = 0.75, *P*<.001) translation velocities.

Table 6. Prediction of left eye flap from right eye flap with the 130 μm head and fast translation speed in both eyes (n = 110).

Flap Thickness Right Eye (μm)	Predicted Flap Thickness Left Eye (μm)	95% Lower Limit for Left Eye (μm)	95% Up (μm)
125	127	86	
150	142	102	
175	158	117	

Mean thickness in right EYE = 145.8 μm; mean thickness in left EYE = 139.9 μm

Table 7. Prediction of left eye flap from right eye flap with the 110 μm head and fast translation speed in both eyes (n = 43).

Flap Thickness Right Eye (μm)	Predicted Flap Thickness Left Eye (μm)	95% Lower Limit for Left Eye (μm)	95% Up (μm)
125	127	87	
150	140	100	
175	153	112	

Mean thickness in right EYE = 136.2 μm; mean thickness in left EYE = 132.8 μm

Table 8. Prediction of left eye flap from right eye flap with the 110 μm head and slow translation speed in both eyes (n = 30).

Flap Thickness Right Eye (μm)	Predicted Flap Thickness Left Eye (μm)	95% Lower Limit for Left Eye (μm)	95% Up (μm)
125	128	93	
150	147	113	
175	166	132	

Mean thickness in right EYE =151.6 μm; mean thickness in left EYE = 148.5 μm

Discussion

In LASIK, the purpose of the microkeratome is to create a corneal flap of a desired thickness, thus exposing the stroma for laser ablation. The lack of precision in reproducing flap thickness with actual microkeratomes is an important drawback of these instruments. The list of microkeratome models grows, with additional features and designs each year. Despite the innovative advances to obtain more reproducible keratectomies, results show variability in flap thickness (Table 9).[9, 10, 11, 12, 13, 14, 15 and 16] The most frequently used microkeratomes for LASIK are based on the oscillating blade principle. The M2 is an automated microkeratome designed for maximum safety and customized keratectomies. To our knowledge, this is the first study to address factors affecting the predictability of flap thickness with this microkeratome.

Table 9. Flap thickness with different microkeratomes.

First Author (Year)	Number of Eyes	Microkeratome	Flap Thickness (Mean
Jacobs[9] (1999)	93	Moria LSK-One (manual)	159 ± 28
Yi[10] (1999)	69	SCMD (manual)	137.18± 33.66
Choi[11] (2000)	268	Innovatome (automated)	138.8 ± 23.5 148.3 ±
Yildirim[12] (2000)	140	Hansatome (automated)	120.87± 26.39
Durairaj[13] (2000)	102	Chiron Automated Corneal Shaper	105 ± 24.3 125 ± 18.5
Schumer[14] (2000)	370	Nidek MK-2000 (automated)	129 ± 21.8 150 ± 29.6 173 ± 26.9
Sarkisian[15] (2001)	1220	Nidek MK-2000 (automated)	109.33 ± 13.31 (12 eye 15.33 (12 eyes) 145.2 eyes)
Naripthaphan[16] (2001)	200	Nidek MK-2000 (automated)	120.52 ± 16.49 122. 172.71 ± 27.49

Despite its special design for safety and customized keratectomies, the M2 microkeratome created corneal flaps with variable thicknesses. In the larger patient groups, the standard deviation of the mean flap thickness was 23.5 to 25.5 μm. The standard deviations were comparable to those reported with other microkeratomes (Table 9). [9, 10, 11, 12, 13, 14, 15 and 16] The range for all the settings with the M2 microkeratome was wide (Table 2 and Table 3).

In this study, fast translation velocity of the microkeratome head produced thinner flaps. A similar inverse correlation between the speed of the microkeratome advancement and the resulting corneal flap thickness has been reported.[17] It seems the faster the translation speed of the microkeratome head, the less corneal tissue is engaged and cut as a flap.

As expected, the 110 μm head produced thinner flaps than the 130 μm head. This makes the 110 μm head and fast translation speed a more viable option for thinner corneas and/or higher degrees of myopia, in which leaving a 250 μm stromal bed may be more of a concern to the surgeon. Although there is no scientific evidence to support the 250 μm bed as the minimum optimal amount, leaving as thick a bed as possible should be the universal standard of care for every patient.

Flap thickness was significantly thinner in the left eye when the 130 μm head and fast translation velocity were used in both eyes (Table 3). A similar trend (not statistically significant) was noticed with the 110 μm head when the same translation velocity was used in both eyes (Table 2). The use of the same blade in both eyes, which was presumably somewhat blunted when used in the left eye, may explain these results.

The correlation of age with flap thickness was weak. Age was also weakly correlated with SE (older patients treated with LASIK tend to be more hyperopic with higher SEs), and SE was weakly inversely correlated with keratometry (hyperopic patients have flatter corneas). It seems that flatter corneas tend to yield thinner flaps. However, adjusting for SE and keratometry did not substantially affect the correlation between age and flap thickness.

Further studies may be warranted to confirm this correlation.

A weak correlation of flap thickness with corneal thickness was found. A similar correlation between flap thickness and CCT is reported in studies with different microkeratomes.[10, 11 and 12] Several surgeons have found a similar correlation between CCT and flap thickness with the M2 microkeratome (R. Stein, MD, "Automated Microkeratome Makes Flap Creation Simple, Safe," Ophthalmology Times, January 1, 2003, page 16; S. Updegraff, MD, "Intraoperative Pachymetry Essential as Flap Thickness Varies," Ophthalmology Times, December 15, 2001, pages 26–27; D. Dhaliwal, MD, "New Microkeratome Produces Consistent Flaps," Ocular Surgery News, November 15, 2001, pages 74–75). However, Jacobs and coauthors [9] failed to find this relationship with the Moria LSK-One manual microkeratome.

In a previous study at our facility (unpublished data), we found the standard deviation for the Carriazo-Barraquer (CB) manual microkeratome to be about 18 μm. This lower standard deviation could be explained by the existence of a dovetail on the CB suction ring that engages the microkeratome head, minimizing its degree of freedom when rotating around its axis. The absence of this dovetail from the Moria M2 microkeratome suction ring may result in a higher degree of head freedom during rotation around its axis, allowing a wider range of possible tissue engagements and cuts. Subsequently, a wider range of flap thickness might be expected. A special design to fit such a dovetail to the M2 suction ring may help lower the standard deviation for this microkeratome.

In conclusion, in this study, flap thickness with the Moria M2 microkeratome was variable. There was a trend toward thinner flaps with the 110 μm head, fast translation speed, thinner CCT, increasing age, and surgery in the second eye. No such effect was found for the corneal diameter.

One should determine the mean, standard deviation, and potential range for his or her microkeratome. The data can be used preoperatively to calculate the probability of having enough residual stromal bed to perform an ablation. In addition to being a vital tool for individual case management, intraoperative ultrasound pachymetry may be important for long-term evaluation of technique and instrument quality. It can determine intraoperatively whether there is enough stroma to safely perform an ablation or modify the planned ablation. It can also determine intraoperatively whether there is enough residual stroma to perform enhancement in the bed. Hence, we strongly recommend the routine use of intraoperative ultrasound pachymetry in LASIK procedures.

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