J Med Sci 2013;33(4):191-197
http://jms.ndmctsgh.edu.tw/3304191.pdf
DOI:10.6136/JMS.2013.33(4).191

Accuracy of LASIK Flap Thickness Obtained Using 2 Types of Moria M2 Single-use Head Microkeratome Measured Postoperatively by Optical Coherence Tomography

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Background: To investigate the accuracy of corneal flap thickness (FT) and to examine the potential factors that can influence flap thickness obtained using Moria M2 microkeratomes with two kinds of single-use heads. **Methods:** A retrospective review of the records of 90 patients who had undergone LASIK between Jun 2011 and Jan 2012 at Tri-Service General Hospital was performed. Creation of corneal flap was achieved by automated Moria M2 microkeratome with two different types of single-use head (SU90 and SU130). The right eye was operated before the left eye in each patient, using the same blade. Additionally, the corneal flap thickness was measured in all cases using the Fourier-domain anterior segment optical coherence tomography (AS-OCT) one week later. **Results:** The mean central thickness of corneal flap was 114.26±4.49 μm (Range, 106~127 μm) in the SU 90 head and 146.98±3.62 μm (Range, 140~157 μm) in the SU130 head. The difference between the first and second eye operated was not significant. There were no free flaps, incomplete flaps or flaps with buttonholes in any of our cases. **Conclusions:** Moria M2 SU 90 and SU 130 produce accurate, reproducible, safe and cost-effective corneal flap. Thin flaps achieved by both single-use heads did not increase the rate of flap-related complications. Furthermore, AS-OCT is a noncontact, rapid, and repeatable tool for measuring corneal flap thickness and making morphological observations.

Key words: laser in situ keratomileusis (LASIK), corneal flap thickness, keratometry reading, mechanical microkeratome, optical coherence tomography

INTRODUCTION

Creation of an accurate corneal flap is the step most crucial to the success of laser in situ keratomileusis (LASIK) surgery owing to the importance of stromal preservation and surgical planning. In previous studies[1-3], the flap thickness achieved was different from the attempted flap thickness using the mechanical microkeratome. Since the introduction of the femtosecond laser as an alternative to the mechanical microkeratome, thinner and more accurate flaps can be achieved with the advantage of preserving more stroma and potentially reducing the incidence of corneal ectasis.

Received: December 25, 2012; Revised: March 15, 2013; Accepted: March 26, 2013
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The recently developed, automated microkeratomes with single-use head have advantages over the traditional metallic head, such as no need for assembly, enhanced transparency and decreased risk of infection. This current study was performed to evaluate the accuracy of the corneal flap produced using automated Moria M2 microkeratomes with two kinds of single-use head and measured by OCT, and to investigate the potential factors that may influence flap thickness, such as preoperative corneal thickness, preoperative spherical equivalent, patient's age and keratometry readings.

MATERIAL AND METHODS

We performed a retrospective review of the records of 180 eyes of the 90 enrolled patients who had undergone LASIK between Jun 2011 and Jan 2012 at Tri-Service General Hospital. The study protocol complied with the requirements of the the Institutional Review Boards of the Tri-Service General Hospital, Taipei, Taiwan. The study followed the Good Clinical Practice (GCP) guidelines of Taiwan and in accordance with the Declaration of

Helsinki, 1964, and later revisions. The inclusion criteria were no history or slit-lamp evidence of ocular trauma, no ocular surgery or corneal abnormality, no history of systemic or ocular disease that contraindicated LASIK, no use of systemic antimetabolites or immunosuppressants. Besides, if the predicted value of the postoperative residual stromal bed (with the 2 kinds of microkeratomes for calculating) was less than 250 micrometers, the subjects were excluded. Before the operation, use of soft and hard contact lens was suspended for at least 2 and 4 weeks, respectively. All patients underwent a complete preoperative ophthalmological examination including biomicroscopy, measurement of corneal topography and thickness (Obscan), determination of refraction, measurement of intraocular pressure (Topcon Computerized Tonometer CT-60; Topcon Corp, Tokyo, Japan), measurement of uncorrected (UCVA) and best spectacle-corrected visual acuity (BSCVA).

Surgical technique

The LASIK procedures were performed at our center by the same surgeon (M-C Tai). The automated Moria M2 microkeratome with the control unit ME-LSK Evolution 2 was used for the creation of corneal flaps. There are two kinds of plastic single-use head 90 and 130 microkeratomes, designed to create a 120- and 150-μm flap, respectively. The randomly selected the both eyes of each patient were operated with either plastic single-use head 90 microkeratome or plastic single-use head 130 microkeratome. Prior to the operation, a notepaper representing either Moria M2 SU 90 or Moria M2 SU 130 was randomly picked by the surgeon's assistant. The right eye was operated before the left eye in each patient, using the same blade. The suction ring was chosen according to the manufacturer's recommendations, a nomogram based on the keratometric value. All flaps had a superior hinge. Stromal ablations were performed with a broad beam excimer laser (Visx S4; AMO). Flap morphology was evaluated using an RTVue Fourier-domain anterior segment optical coherence tomography (Optovue, Inc.), which has a depth resolution of 5μm and a speed of 26000 axial scans per second. The scan was centered on the vertex reflection, and the horizontal meridian OCT images with 6 mm in diameter were acquired and analyzed in a blind fashion by the same skilled technician at 1 week postoperatively. Due to poor contrast between the flap and stroma in the central zone, the central corneal flap thickness was interpolated from the paracentral measurements[3] ($\pm$2 mm from the corneal vertex) by semi-automated software (Fig 1). Flap-related complications and post-operative visual acuity were also recorded till 2 weeks after operation. In addition, AS-OCT scanning was performed 3 times with the patients repositioned after each scan.

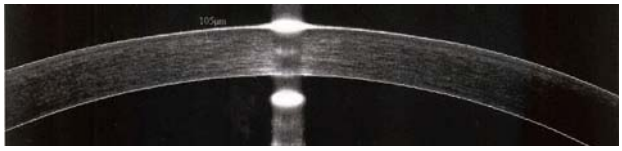

Fig. 1 High-resolution corneal anterior segment optical coherence tomography image showing the flap thickness at measurement$\pm$2mm from the vertex at 1 week postoperatively.

Statistical analysis

The eyes were grouped for statistical analysis according to the type of head used. The mean values and SDs of ages, corneal thickness, flap thickness, preoperative refraction, and keratometric values of 180 eyes were calculated. Statistical analyses were performed using SPSS version 19.0 for windows (SPSS Inc, Chicago, Illinois). Unpaired Student's t-test was used to analyze differences between the two groups (SU 90 and SU 130). Single-variable correlation of flap thickness between preoperative refraction, corneal thickness, keratometric values and age was performed using a Pearson correlation coefficient analysis. A p value of less than 0.05 was considered statistically significant.

RESULTS

A total of 180 consecutive eyes of 90 patients who had undergone LASIK (44 patients treated with Moria M2 SU 90 and 46 patients with Moria M2 SU 130) between Jun 2011 and Jan 2012 at Tri-Service General Hospital were identified. The preoperative values for the two groups are presented in Table 1.

The flap was identified from the stromal bed by its increased internal reflectivity and interface signal peak. This contrast was best seen in the paracentral region ($\pm$2 mm from the vertex) and worse seen near the corneal vertex. The interface peak was clearly visible at 1 week after the operation. In Moria M2 SU 90-treated eyes, the intended corneal flap thickness was 120 μm, and the mean flap thickness was 114.26$\pm$4.49 μm (range, 106-127 μm). In Moria M2 SU 130-treated eyes, the intended corneal flap thickness was 150 μm, and the mean flap thickness was 146.98$\pm$3.62 μm (range, 140-157 μm).

Table 1 Preoperative characteristics of patients undergoing LASIK flap creation with Moria M2 SU 90 and SU 130 microkeratomes

Variables	Moria M2 SU 90(n=88)	Moria M2 SU 130(n=92)	Total (n=180)	P value*
Age (y)	29.09±6.44(18~48)	31.67±7.57(23~56)	30.41±7.14(18~56)	0.014
SE (D)	-6.54±2.25(-2.50~-13.50)	-4.94±1.71(-1.75~-9.00)	-5.72±2.14(-1.75~-13.50)	<0.001
CCT (μm)	545.30±41.11(470~653)	552.30±29.55(494~618)	548.88±35.74(470~653)	0.193
Mean K (D)	43.29±1.30(40.2~45.95)	43.96±1.38(40~46.85)	43.63±1.38(40.0~46.85)	0.001
K1 (D)	43.87±1.42(41.1~47.9)	44.51±1.54(40.5~48.4)	44.20±1.51(40.5~48.4)	0.005
K2 (D)	42.71±1.31(39.2~44.9)	43.42±1.30(39.5~46.3)	43.07±1.35(39.2~46.3)	<0.001

CCT = Central corneal thickness, SE = Spherical equivalent, K =keratometry

*The P values of Moria M2 SU 90 and 130 groups were calculated using t test

Table 2 Thickness of corneal flap cut using Moria M2 SU 90 and the Moria M2 SU 130 microkeratomes

Microkeratome group	Flap thickness (μm) Mean ± SD	Range	Mean difference	P value
Moria M2 SU 90 (n=88)	114.26 ± 4.49	106~127	-5.74	<0.001
Moria M2 SU 130 (n=92)	146.98 ± 3.62	140~157	-3.02	<0.001

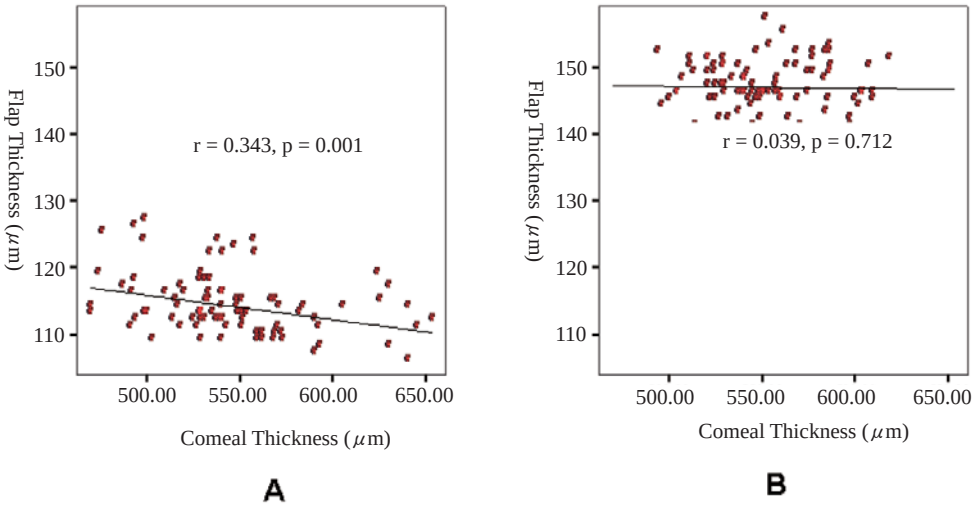

Fig. 2 Graph showing a weakly negative linear relationship between corneal flap thickness and corneal thickness in the SU 90 (A), but no significant correlation in the SU 130 group (B).

The Moria M2 SU 130 group revealed a much smaller deviation from the target thickness (mean difference: SU 90: -5.74, SU 130: -3.02) (Table 2) but both groups showed good precision (Coefficient of Variation: SU 90: 3.93%, SU 130: 2.46%). The second flap cut with the same blade was not significantly thinner for flaps cut with either the Moria M2 SU 90 microkeratome (P = 0.267), showing an average thickness of 114.80 ± 4.54 μm (first) versus 113.73 ± 4.42 μm (second), or the Moria M2 SU 130 microkeratome (P = 0.186), showing an average thickness of 147.48 ± 3.69 μm (first) versus 146.48 ± 3.51 μm (second). Moreover, there were no free or incomplete flaps, or flaps with buttonholes in any of the cases in this study.

A weak correlation was found between corneal flap thickness and corneal thickness in the Moria M2 SU 90 group (r = -0.335, P = 0.001) but no significant correlation in the M2 SU 130 group (r = -0.025, P = 0.812) (Fig. 2). There was a weak correlation between corneal flap thickness and preoperative spherical equivalent in the M2 SU 90 group (r = 0.276, P = 0.009) but no significant correlation in the M2 SU 130 group (r = 0.0004, P = 0.997) (Fig. 3). Moreover, corneal flap thickness showed no correlation with age (r = 0.061, P = 0.572 in M2 SU 90 group; r = 0.134, P = 0.202 in M2 SU 130 group) (Fig. 4) or preoperative keratometry K_1 (r = 0.04, P = 0.709 in M2 SU 90 group; r = 0.087, P = 0.074

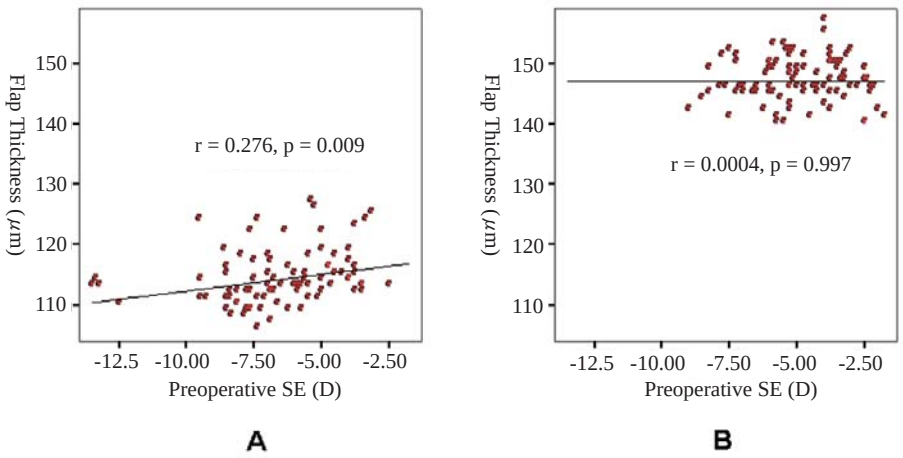

Fig. 3 Graph showing a weakly direct linear relationship between corneal flap thickness and preoperative spherical equivalent in the M2 SU 90 group (A), but no significant correlation in the SU 130 group (B).

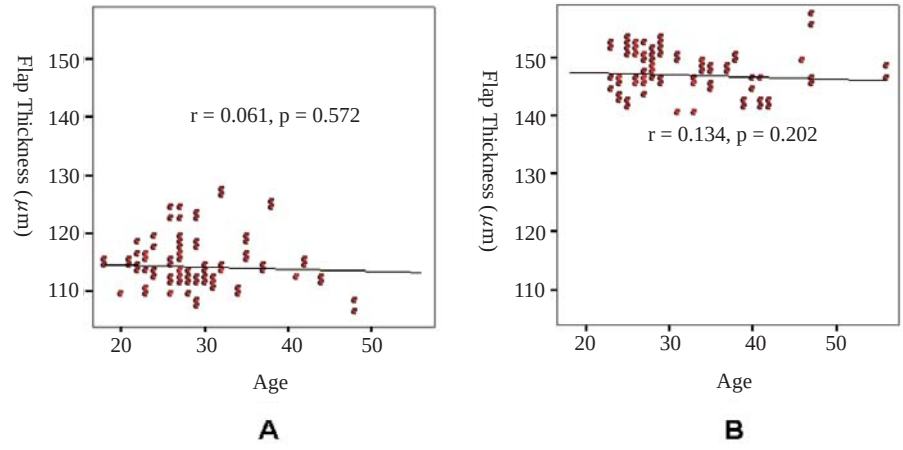

Fig. 4 Graph showing no correlation between flap thickness and age in the SU 90 group (A) or the SU 130 group (B).

in M2 SU 130 group) (Fig. 5) in the two groups.

DISCUSSION

The incidence of microkeratome-related flap complications has been reported to range from 0.3% to 1.9%.[4-6] In addition, iatrogenic keratectasia is one of the long-term major complications after LASIK. Therefore, creating an accurate and thin corneal flap to preserve as thick as possible the residual corneal bed is critical in LASIK surgery. In the current study, the mean corneal flap thickness in the Moria M2 SU 90 group was 114.26 μm. The standard deviation of 4.49 μm was clinically insignificant and the same conclusion can be made for the Moria M2 SU130 group. Moreover, the precision in flap thickness in terms of Coefficient of Variation (SU 90: 3.93%, SU 130: 2.46%) and the accuracy in flap thickness in terms of mean difference (SU 90: -5.74, SU 130: -3.02) are great in both groups. According to the findings above, both groups appeared to produce accurate and reproducible corneal flaps. Besides, there are plenty of microkeratomes in clinical use and their most common characteristic is thinner flap thickness achieved than intended[7-9], agreement with our current study. Previous studies[1,2,10] showed that the standard deviation of flap thickness achieved by mechanical microkeratomes was in the range of ±20 to ±40. The improvement in standard deviation of our study may be attributed to the learning curve of the procedure or better design of microkeratome. Furthermore, thin flaps are prone to buttonholes and necessitate more complicated handling during surgery. However, in our study, incomplete flaps, buttonholes and other microkeratome-related flap complications were not observed.

To determine the preoperative factors associated with corneal flap thickness, we investigated the correlation between corneal flap thickness and the preoperative SE, age, keratometry K_1 power and central corneal thickness, respectively. We found a weak correlation between flap thickness and central corneal thickness and a weak correlation between flap thickness and preoperative spherical equivalent only in the M2 SU 90 group. However, in previous studies[7,8], a positive correlation between flap thickness and central corneal thickness was found. Furthermore, Pietila *et al.*[7] found a tendency towards thinner flaps created by Moria M2 SU 130 with higher keratometric K_1 value in myopic eyes, but the difference was not significant. Huhtala *et al.*[8] reported that increasing thickness of flaps produced by Moria M2 SU 90 was associated with flatter keratometric power K_1 in

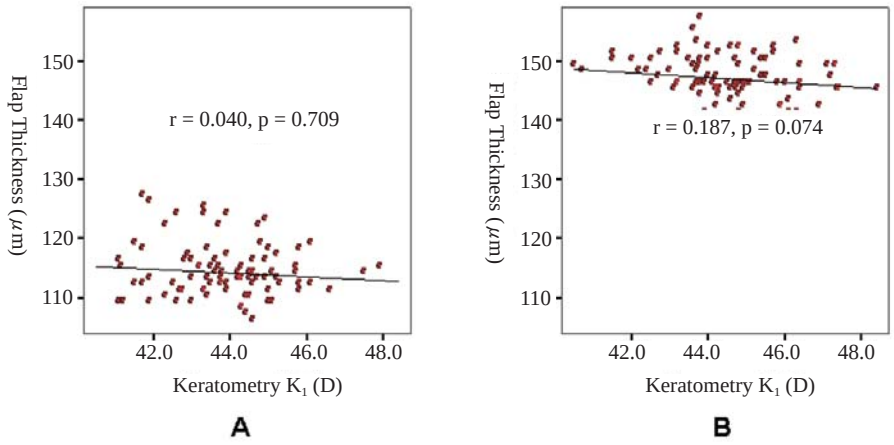

Fig. 5 Graph showing no correlation between flap thickness and preoperative keratometry K1 in the SU 90 group (A) or the SU 130 group (B).

hyperopic eyes but not in myopic eyes. In addition, a negative correlation between patient's age and corneal flap thickness was also noted in that study. The discrepancies between our results and previous findings[7,8] may be attributed to the dissimilar methods adopted (OCT vs. ultrasonic pachymetry) or the different time points (1 week after operation vs. immediately after flap creation) of flap measurement. The anticipated errors[11] with the measurement technique using ultrasound pachymetry and the subtraction method of calculating flap thickness have led investigators to use the OCT as a tool for measuring postoperative flap thickness.[12,13] Fourier-domain anterior segment OCT provides noncontact high-resolution corneal cross-sectional images. We have recently reported that AS-OCT provided excellent reproducibility and quantitative parameters in the anterior chamber angle.[14] In this study, we also confirmed previous results[15] that routine measurement of flap thickness with OCT was recommended at 1 week postoperatively, when the measurement was most precise and edema has resolved. Moreover, the mean corneal flap thickness in both groups of our study was less than that in previous studies.[7,8] Such difference may be due to too dry residual stromal bed after flap creation or compression of residual stromal bed when making measurement, thus increasing the pachymetry-derived flap thickness.

Another common issue of microkeratomes concerning the discrepancy in flap thickness between the first and second eye also occurred when the same blade was used for both eyes. David *et al*.[16] showed that the reuse of microkeratome blades created significantly thinner flaps on the second cut. Our study demonstrated a slightly thinner flap in the second cut, which was consistent with previous findings.[7,8] Some authors postulated that the reason for thinner flap obtained in the second cut was the increased dullness of the blade following the first cut.[17,18]

The newly developed femtosecond lasers were designed to produce thinner flaps, with closer range of thickness around the mean. Salomao *et al*.[19] obtained a standard deviation of flaps to be ± 14.5 μm using the IntraLase femtosecond laser. The standard deviation was comparable with that obtained using the two kinds of mechanical microkeratomes in our study (SU90: ± 4.49 and SU130: ± 3.62), meaning that Moria M2 SU 90 and SU 130 microkeratomes could also effectively produce thinner flaps with a smaller standard deviation in more eyes with relatively thinner corneas. In contrast to the high-priced IntraLase femtosecond laser device and the extra charges to the patients using femtosecond laser, either Moria M2 SU 90 or SU 130 produce accurate, reproducible, safe and cost-effective corneal flap. Moreover, Moria M2 SU 130 could be more precise and accurate than Moria M2 SU 90 although the difference was not significant. However, with the advantages of preserving more stromal tissue and potentially reducing the incidence of corneal ectasis, M2 SU 90 could create thinner and accurate flaps (but not superior to M2 SU 130) and thus more suitable for the patients with thinner central corneal thickness.

There were some drawbacks that need improvement in our present study. First, because our study was a retrospective study with relative small patients, when they were divided into groups, analysis of the data was limited to one factor at a time. Therefore, we were unable to benefit from an interaction analysis of factors. Such as the result of factors correlated the flap thickness was not totally compatible with the previous studies[7,8] and the rate of LASIK flap complication might be underestimated, as the incidence of actual microkeratome-related flap complications had been reported to range from 0.3% to 1.9% in previous literature[4-6] but none in our study. A large prospective study is required to establish more statistically powerful results. Second, because poor contrast between the flap and stroma in the central zone but best in the paracentral region as an intrinsic limitation by the

corneal geometry, the central corneal flap thickness was interpolated from the paracentral measurements to lower the effect of flap thickness variation[3] and was only along the horizontal meridian of the cornea. As the previously study[20] state, in order to avoid false measurement and misinterpretation of the flap data that might be caused by interference from the upper eyelid or by superior location of the hinge-pocket complex, the horizontal meridian was concentrated. However, the horizontal profile only is not enough to determine the homogeneity of the whole flap; flap profile shown on vertical and oblique scans should be included in future studies.

CONCLUSION

This study revealed that automated microkeratome Moria M2 with SU 90 and SU 130 heads could produce accurate, reproducible, safe and cost-effective corneal flap. Furthermore, they did not increase the rate of flap-related complications, showing results comparable with those created using femtosecond laser. Moreover, anterior segment OCT is a noncontact, rapid, and repeatable tool for measuring corneal flap thickness and making morphological observations.

ACKNOWLEDGEMENTS

A. This study was supported by funding from Tri Service General Hospital (TSGH-C100-1-SO4).
B. The authors contributed to the manuscript and study as follows: CM Liang, JT Chen and DW Lu collected data, reviewed the literature and writing part of the manuscript. YC Chou was responsible for analysis and interpretation of data and writing part of the manuscript. YS Chou was the chief editor and MC Tai was the surgeon and corresponding author.

DISCLOSURE

A. The authors have no additional financial disclosures.
B. The article has not been presented in a meeting.
C. The authors have no financial or proprietary interest in a product, method, or material described herein.

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