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Accuracy and Precision in Producing LASIK Flaps: A Comparison of Two Microkeratomes

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Background: To evaluate the consistency of the thicknesses of corneal flaps created with the Amadeus and Moria M2 microkeratomes during laser in situ keratomileusis (LASIK). **Methods:** In this prospective study, 60 eyes underwent LASIK with the Moria M2 microkeratome and 100 eyes were cut using the Amadeus microkeratome. Keratometry readings and refractive errors were measured preoperatively. Corneal thickness was measured with an ultrasonic pachymeter before and during the flap procedure, and the difference was taken to be the flap thickness. Eyes were grouped for statistical analysis according to the order of blade use. The data were analyzed using a two-tailed *t* test and the Pearson correlation coefficient. **Results:** The mean central thickness of the corneal flap was 138.68±20.637μm in the Moria M2 130 group and 127.29± 20.873 μ m in the Amadeus group. There was a negative linear relationship between corneal flap thickness and the preoperative keratometric value in the Moria M2 130 group (r = -0.383, P = 0.002). There was a direct linear relationship between corneal flap thickness and preoperative corneal pachymetry in the Amadeus 140 group (r = 0.287, P = 0.004). Flap thickness was significantly thicker in the first eyes cut. **Conclusions:** Both the Moria M2 130 and the Amadeus microkeratomes produce accurate and repeatable corneal flaps. The Amadeus microkeratome achieved a statistically significantly lower deviation in flap thickness than that of the Moria M2 microkeratome.

Key words: laser in situ keratomileusis (LASIK), corneal flap thickness, central corneal curvature, keratometry reading

INTRODUCTION

Laser in situ keratomileusis (LASIK) has been widely used for the correction of myopia, hyperopia, and astigmatism[1]. Microkeratomes regained popularity in refractive surgery in 1990, when Pallikaris et al.[2] introduced LASIK. With advances in the technology, several new microkeratomes have been introduced. These are expected to create corneal flaps of the desired thickness with safety and consistency. For a successful LASIK operation, it is important to generate a corneal flap of adequate dimensions with the microkeratome. In this study, we evaluated the accuracy and consistency of corneal flap thickness, as well as any possible correlation between central corneal thickness or corneal curvature and the intended flap thickness. We also compared the corneal flap thicknesses achieved using the Moria M2 and Amadeus microkeratomes.

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MATERIALS AND METHODS

This study included 160 consecutive eyes of 81 patients who underwent bilateral LASIK for myopia or myopic astigmatism from July 2003 to August 2004. The criteria for inclusion in the study were: no history or slit-lamp evidence of ocular trauma or ocular surgery (including refractive surgery); no ocular disease; and no use of systemic antimetabolites, corticosteroids, or immunosuppressants. Also excluded were patients who had had any complication during or after LASIK or those who had incomplete data or a lack of follow-up. Soft contact lens use was stopped at least two weeks before the operation and hard lens use at least four weeks before the operation.

All patients gave their written informed consent, as approved by the clinical research committee. A clinical examination before the LASIK treatment included uncorrected visual acuity, best-corrected visual acuity, refrac-

tive error, and slit-lamp biomicroscopy, and the average K value was calculated from preoperative simulated keratoscope readings, which were measured using computerized topography. The central corneal thickness was measured by the surgeon with an ultrasonic pachymeter on the operating table just before the microkeratome pass. The ultrasonic pachymeter was calibrated at regular intervals according to the manufacturer's recommendations. Three measurements were made each time to compare the reproducibility and consistency of the readings. The same operator used the same pachymeter to rule out interobserver differences and interactions between devices. The sterilized pachymeter probe was placed lightly on the center of the cornea, which had been anesthetized with topical proparacaine.

All LASIK procedures were performed using a randomly assigned M2 (Moria, France) or Amadeus (AMO, Irvine, CA, USA) microkeratome and the VISX Star excimer laser system. All procedures were performed by the same operator. Briefly, 1-2 drops of proparacaine hydrochloride 0.5% (Alcaine) were applied to the operative eye twice before surgery. The center of the entrance pupil and the corneal surface were marked to facilitate centering. The suction ring was applied to elevate the intraocular pressure (IOP) above 65 mmHg, which was measured by Barraquer applanation tonometry. After the corneal surface was moistened with balanced salt solution (BSS), the microkeratome head was advanced forward until it reached a stop nut. The Amadeus microkeratome with a 140 μm head or the Moria M2 130 microkeratome was activated to perform the corneal cut. In the Amadeus group, the suction ring was designed to create 140 μ m, and the microkeratome settings were a vacuum of 24.5 mmHg (on full suction), blade oscillation speed of 8000 rpm, and translation speed of 2.5 mm/s. The Moria M2 130 microkeratome head has an intended excision thickness of 160 μ m, and the blade oscillation rate was 15000 rpm. A 9.0 mm diameter flap setting was used and the ablation zone diameter was set at 6.0 mm for all eyes.

The microkeratome was assembled and tested before each procedure. After the flap was made, the microkeratome and suction ring were removed, the hinged flap was lifted with a cannula, and the stromal bed thickness was measured with the ultrasonic pachymeter immediately after the cut. The flap thickness was determined by subtracting the stromal bed thickness from the preflap thickness. The flap was replaced in its original position after ablation with the excimer laser, and the interface was irrigated with BSS to remove all particles, debris, and epithelial cells. The flap was then centered for proper alignment.

All patients were examined by slit-lamp biomicroscopy one hour after the procedure. Eyes were grouped for statistical analysis according to the blade use. The effects of preoperative corneal thickness, keratometry values, and blade reuse on flap thickness were evaluated. The data were evaluated using a two-tailed *t* test and Pearson correlation coefficient analysis. A *P* value of 0.05 or less was considered significant.

Table 1. Preoperative variables

Variables	Moria M2 160 group (n=60)	Amadeus 140 group (n = 100)	Total(n=160)	P value*
Age	30.80±7.06	31.08±7.67	30.98±7.43	0.818
Spherical equivalent (D)	-5.740±1.568	-6.750±2.442	-6.371±2.206	0.002
Keratometry reading (D)	43.287±1.421	43.867±1.443	43.649±1.458	0.014
Central corneal thickness(μ m)	566.92±30.22	554.34±32.99	559.06±32.46	0.015

*The P values were calculated from the Moria M2 160 group data and the Amadeus 140 group data by t test.

Table 2. Thickness of the corneal flap cut using the Moria M2 and Amadeus microkeratomes

Microkeratome group	Flap thickness (μ m) Mean ± SD	Range	Mean difference	*P* value*
Moria M2 group (160 head) (n=60)	138.68 ± 20.637	97-189	-21.32	< 0.001
Amadeus group (140 head) (n=140)	127.29 ± 20.873	74-173	-12.71	< 0.001

*The Amadeus microkeratome showed a statistically significantly and clinically relevant lower deviation from the device's target value and a distinctly lower deviation than that of the Moria M2 microkeratome (P = 0.001, mean difference = -11.39).

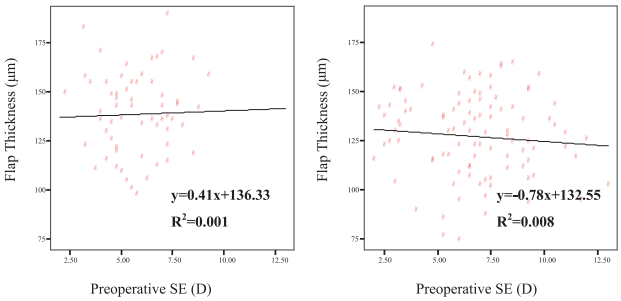
Table 3. Mean flap thickness (μ m) (±SD) cut using the Moria M2 and Amadeus microkeratomes

Microkeratome group	Eye cut	No. eyes	Mean ± SD	Mean difference	P value*
Moria M2 group (160 head) (n = 60)	first	42	141.79 ± 20.567	10.34	0.075
	second	18	131.44 ± 19.458		
Amadeus group (140 head) (n = 140)	first	63	132.27 ± 19.494	13.46	0.002
	second	37	118.81 ± 20.648		

*Comparing the first and second eyes cut.

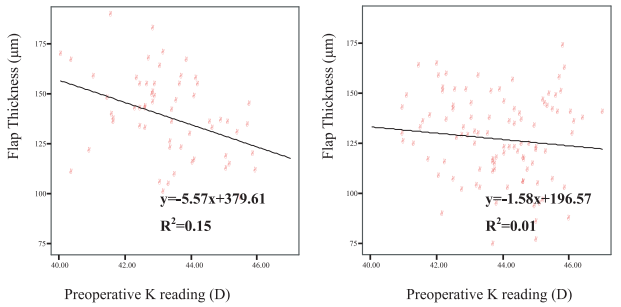
RESULTS

One hundred sixty consecutive eyes of 81 patients (49 women and 32 men) were enrolled in this study. The mean (±SD) patient age was 30.98±7.43 years (range, 19-47 years). The mean spherical equivalent (SE) refraction was -6.371±2.206 diopters (D) (range, -2.00 to -13.00 D), the mean keratometry reading was 43.649±1.458 D (range, 40.05-47.00 D), and the mean central corneal thickness



A B

Fig. 1 Graph showing no correlation between flap thickness and preoperative SE in the Moria M2 group (A) or the Amadeus group (B).



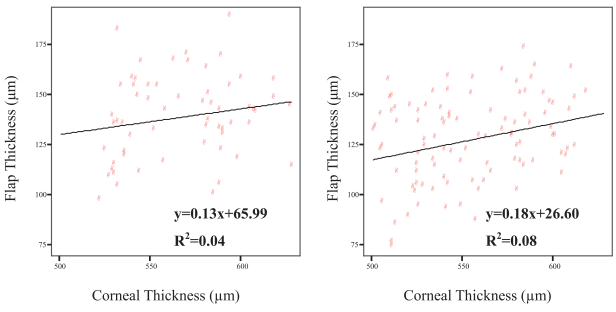
A B

Fig. 2 Graph showing a negative linear relationship between corneal flap thickness and preoperative keratometric values in the Moria M2 group (A), but no significant correlation in the Amadeus group (B).

was 559.06±32.46 μm (range, 501-628 μm). These preoperative values for the two groups are shown in Table 1.

The mean central thickness of the corneal flap was 138.68±20.637 μm (range, 97-189 μm) in the Moria M2 group and 127.29±20.873 μm (range, 74-173 μm) in the Amadeus group (Table 2). The Amadeus group demonstrated a statistically significantly lower deviation from the target thickness (mean difference: Amadeus -12.71, Moria M2-21.32; P < 0.001) and also a lower deviation than that of the Moria M2 group.

Figures 1, 2, and 3 show the relationships between corneal flap thickness and preoperative SE, preoperative keratometric value, and preoperative corneal pachymetric value, respectively, in the Moria M2 and Amadeus groups. No significant correlation was found between the corneal flap thickness and preoperative SE in the Moria M2 group (r = 0.031, P = 0.813) or in the Amadeus group (r = -0.091, P = 0.367) (Fig. 1). There was a negative linear relationship between corneal flap thickness and preoperative



A B

Fig. 3 Graph showing a linear correlation, with low significance, between baseline central corneal thickness and flap thickness in the Moria M2 group (A), and a statistically significant correlation in the Amadeus group (B).

keratometric values in the Moria M2 group (r = -0.383, P = 0.002), and no significant correlation in the Amadeus group (r = -0.109, P = 0.28) (Fig. 2). There was a direct linear relationship between corneal flap thickness and preoperative corneal pachymetry in the Amadeus group (r = 0.287, P = 0.004). A trend toward a correlation between flap thickness and preoperative central corneal thickness was observed in the Moria M2 group (r = 0.188, P = 0.151), although it was not significant (Fig. 3).

Table 3 shows the mean (±SD) flap thicknesses (μm) cut using the Moria M2 and Amadeus microkeratomes. The second flap cut with the same blade was not significantly thinner for flaps cut with the Moria M2 microkeratome (P = 0.075), with an average thickness of 141.79±20.567 μm (first) versus 131.44±19.458 μm (second), but was significantly thinner for flaps cut the with the Amadeus microkeratome (P = 0.002), with an average thickness of 132.27±19.494 μm (first) versus 118.81±20.648 μm (second).

DISCUSSION

An ideal microkeratome for LASIK should consistently create a corneal flap of the desired thickness, thus exposing the stroma for laser ablation. The factors that determine the corneal flap thickness have yet to be studied. In general, the thickness of the flap plays a role in determining its stability. The thinner the flap, the less stable it is and the easier it wrinkles, which may lead to irregular astigmatism and loss of vision. On the other hand, a thicker flap could lead to a weakened cornea, because corneal strength is determined predominantly by the thickness of the remaining stromal bed after ablation[3-4]. Variables previously shown to correlate with corneal flap thickness include preoperative cor-

neal thickness, microkeratome gap width, preoperative keratometry values, microkeratome blade oscillation and translation velocities, reuse of the microkeratome blade, and vacuum setting. Studies have evaluated different microkeratome systems and reported variable results[5-12].

A microkeratome makes a corneal flap of consistent thickness, determined by the type of microkeratome plate. Although most microkeratomes consistently create reproducible corneal flaps, they still produce large variations in corneal flap thickness. In our study, the mean corneal flap thickness was 138.68 μm in the Moria M2 group. The standard deviation of 21.32μm was clinically insignificant. On the other hand, the mean corneal flap thickness in the Amadeus group was 127.29$\pm$20.873μm. Therefore, both the Moria M2 microkeratome and the Amadeus microkeratome appear to produce accurate and reproducible corneal flaps. In previous studies using a conventional microkeratome with a 160μm plate in human eyes, Perez-Santonja et al.[13] reported that the instrument created flaps with a mean thickness of 141.1μm. Yi and Joo[9], Ömür Ö. Uçakhan[14], and Yildirim et al.[7] reported that the SCMD, SKBM and Hansatome microkeratomes, respectively, produced thinner flaps than were specified by their respective manufacturers. In this study, we found that both microkeratomes tended to cut flaps on corneas that were thinner than predicted. With respect to the deviations in flap thickness, the Amadeus microkeratome worked more precisely than the Moria M2 microkeratome in our study.

To determine the preoperative factors associated with corneal flap thickness, we studied the relationship between corneal flap thickness and the preoperative SE, keratometry reading, and central corneal thickness. There was no correlation between preoperative refractive error and corneal flap thickness in either group (Table 1). A statistically positive association was demonstrated between corneal flap thickness and preoperative central corneal thickness in the Amadeus microkeratome group. A linear correlation, with low significance, between the baseline central corneal thickness and flap thickness in the blade Moria M2 group was also observed. Huang et al.[15] found that corneal flap thickness increased with preoperative central corneal thickness when the Moria M2 microkeratome was used. However, Miranda and coauthors[16] have reported no significant correlation with the same type of microkeratome. Yi and Joo[9] reported the same finding with the SCMD manual microkeratome. Yildirim et al.[7] and Maldonado et al.[17] reported a similar finding with the Hansatome microkeratome, but Jacob et al.[6] failed to find such a relationship with the Moria LSK-One manual microkeratome. Yi and Joo[9] believed this was due to the compression of the cornea by the elevated IOP after the application of the suction ring. Thicker corneas are proposed to be more compressible, resulting in thicker flaps.

In this study, an inverse correlation was observed between preoperative keratometric values and corneal flap thickness in the Moria M2 group, but there was no such relationship in the Amadeus group. Yi and Joo[9] and Jacobs et al.[5] found no significant correlation between mean corneal curvature and flap thickness. In their study of flap thickness using the Moria LK One microkeratome, Jacobs et al.[1] questioned the relationship between flap thickness and preoperative average keratometry. In a study of flap thickness using the Hansatome automated microkeratome, Yildirim et al.[7] also questioned this relationship. Although they demonstrated that accurate and repeated cuts almost approached the attempted resection, they could not show a significant correlation between preoperative corneal curvature and flap thickness. In another study, Flanagan et al.[18] demonstrated an inverse correlation with the ACS microkeratome. A significant positive correlation between preoperative corneal curvature values and flap thickness with the SKBM microkeratome was also observed.

In previous studies[5,19,20], the reuse of microkeratome blades caused less predictable and less reproducible results relative to the results when a new blade was used for each cut. The limited reuse of microkeratome blades in this study caused, on average, a flap that was 10.34μm thinner in the Moria M2 group and a flap that was 13.46 μm thinner in the Amadeus group in the consecutive eye, without associated complications. The LASIK flaps on the second eyes cut with the same blade were significantly thinner when the 140 μm head of the Amadeus microkeratome was used. In a study of the Amadeus microkeratome, David et al.[21] demonstrated that the reuse of microkeratome blades produced significantly thinner LASIK flaps on the second eye cut. This knowledge allows the surgeon to make a corneal flap with confidence in the predictability of the corneal thickness. This study also provides good clinical evidence that the LASIK flap should be made first on a thicker preoperative central cornea or on the less myopic eye. This ensures that more posterior tissue is preserved for further laser ablation.

In conclusion, the thickness of the corneal flaps made by the Moria M2 and the Amadeus microkeratomes is variable and thinner than that suggested by the manufacturers. There was no relationship between corneal flap thickness and the degree of myopia, but there was a positive correlation between corneal flap thickness and preoperative corneal thickness in both groups and a negative correlation with preoperative keratometry readings in the Moria M2

group. With both microkeratomes, the reuse of the microkeratome blades produced significantly thinner LASIK flaps on the second eyes cut with the same blade.

These results were based on the evaluation of only two microkeratomes, and we were unable to compare them with results from other microkeratomes. Therefore, further study should be conducted to compare the results obtained with a variety of microkeratomes. Most importantly, however, clinical studies are required to assess flap thickness accuracy, which seems to be relevant to the calculation of residual corneal thickness, a crucial factor in preventing keratectasia after LASIK[22,23].

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