ABSTRACT

PURPOSE: To evaluate the accuracy and consistency of corneal flap thickness, horizontal diameter, and hinge size with the Moria M2 90-µm single use head (Moria, Antony, France).

METHODS: Fifty-two myopic patients (104 eyes), mean age 32.6 years, underwent bilateral LASIK with a superior hinged flap using the Moria M2 microkeratome (90-µm single use head). Prospective evaluation included flap thickness (subtraction method), diameter, hinge size, interface particles, intraoperative complications, and visual recovery.

RESULTS: The mean preoperative spherical equivalent refraction was 5.72 ± 2.59 diopters (D) (range: 2.88 to 10.75 D) and 5.84 ± 2.73 D (range: 3.13 to 9.38 D) for right and left eyes, respectively. The mean preoperative central pachymetry was 548 ± 24 µm and 547 ± 25 µm for right and left eyes, respectively. The mean preoperative steepest K was 44.12 ± 1.28 D and 44.41 ± 1.27 D for right and left eyes, respectively. Corneal diameter (white to white) was 12.0 ± 0.4 mm and 11.9 ± 0.4 mm for right and left eyes, respectively. The mean postoperative flap thickness was 109 ± 18 µm (range: 67 to 152 µm) and 103 ± 15 µm (range: 65 to 151 µm) for right and left eyes, respectively. The mean postoperative flap diameter was 9.4 ± 0.3 mm (expected mean according to the nomogram given by the company was 9.5 mm). The mean postoperative hinge chord was 4.4 ± 0.4 mm (expected mean 4.2 mm). No interface particles were detected on slit-lamp examination.

CONCLUSIONS: The Moria M2 90-µm single use head is safe with good predictability for LASIK flap creation. [J Refract Surg. 2006;xx:xxx-xxx.]
Sonomed, Lake Success, NY), and corneal diameter (white-to-white distance; Canon autorefractometer; Canon Medical Systems, Irvine, Calif). All pachymetry measurements were done by the same individual (A.N.I.).

The mean preoperative spherical equivalent refraction was \(-5.72 \pm 2.59\) dioptries (D) (range: \(-2.88\) to \(-10.75\) D) in the right eye and \(-5.84 \pm 2.73\) D (range: \(-3.13\) to \(-9.38\) D) in the left eye. The mean preoperative steepest K was 44.12 \(\pm 1.28\) D in the right eye and 44.41 \(\pm 1.27\) D in the left eye. Mean pachymetry was 548 \(\pm 24\) µm (range: 491 to 595 µm) in the right eye and 547 \(\pm 25\) µm (range: 490 to 603 µm) in the left eye, whereas mean white-to-white corneal diameter in the right eye was 12 \(\pm 0.4\) mm (range: 11 to 12.5 mm) and 11.9 \(\pm 0.4\) mm (range: 11 to 12.5 mm) in the left eye.

All patients underwent primary LASIK in both eyes by the same surgeon (A.I.M.) using the Allegretto Wave excimer laser (WaveLight Technologies, Erlangen, Germany). Inclusion criteria were myopia between \(-2.00\) and \(-10.00\) D, \(<3.0\) D of corneal astigmatism, (manufacturer’s guideline), and age \(\geq\)18 years. Exclusion criteria included history of corneal dystrophy or herpetic eye disease, topographic evidence of keratoconus or warpage from contact lenses, corneal scaring, glaucoma, severe dry eye, and collagen vascular diseases.

LASIK procedures were performed in a standardized manner. One drop of proparacaine 0.5% (Alcaine; Alcon, Ft Worth, Tex) was instilled in each eye 5 minutes and just before the procedure. This was followed by a povidone-iodine (Betadine) preparation of the eyelids. Eyelashes were isolated by a drape, and a speculum with suction was placed into the operative eye. The cornea was marked with a corneal marker using gentian violet staining. The microkeratome settings (suction ring, flap stop) were chosen according to the steepest K (manufacturer’s nomogram), aiming for the maximum flap diameter. The Moria M2 90-µm single use head was used for a desired cut depth of 120 µm and a superior hinge. The standard speed of pass (“speed 2”: 15,000 rpm, 2 seconds of cutting time) was used in all cases. One single use head was used in both eyes of each patient (the right eye was always done first), and the head was discarded upon completion of the procedure. After the microkeratome pass, the flap was lifted and central ultrasound pachymetry of the residual stromal bed was performed. Three measurements were taken and the mean value was subtracted from the preoperative corneal thickness. This difference was considered the flap thickness (subtraction pachymetry). After performing the laser ablation, the flap was floated back into position, and the stromal bed was irrigated with balanced salt solution. Flap alignment was checked using gentian violet premarkings on the cornea, and a striae test was performed to ensure proper flap adherence.

Using one drop of prednisolone acetate 1%, which clearly identified the outline of the flap furrow in its whole circumference, as well as the exact dimensions of the hinge chord, the measurements were taken with the use of a surgical caliper.

All patients were examined 60 minutes after surgery to check flap adherence. Postoperatively, they were given flurbiprofen sodium 0.03% (Ocufluor; Allergan, Irvine, Calif) drops 4 times a day for 2 days, dexamethasone 0.1% + tobramycin 0.3% (Tobradex, Alcon) drops 4 times a day for 2 weeks, and sodium hyaluronate 0.18% (Vismed; TRB Chemedica, Newcastle under Lyme, United Kingdom) drops hourly for 1 month. Patients were instructed to wear protective eye shields at night and to return the following day and on postoperative day 3.

Statistical analysis was done using two-tailed Student t test for independent events and linear correlation.

RESULTS

The mean flap thickness for all eyes was 106 \(\pm 17\) µm, being 109 \(\pm 18\) µm (range: 67 to 152 µm) in the right eye and 103 \(\pm 15\) µm (range: 65 to 151 µm) in the left eye (Figs 1 and 2). The difference was not statistically significant (\(P=0.08\)). The mean flap diameter was 9.4 \(\pm 0.3\) mm (range: 8.5 to 9.9 mm) and the mean hinge chord size was 4.4 \(\pm 0.4\) mm (range: 3.8 to 6 mm) (Figs 3 and 4).

The relationship between flap thickness and preoperative corneal pachymetry is demonstrated in Figure 5. A statistically significant correlation (\(R^2=0.49\), \(P<0.0001\)) showed that thicker corneas produce thicker flaps. None of the other tested parameters, such as age, flat K, steep K, or preoperative spherical equivalent refraction, showed any correlation with flap thickness.

No intraoperative complications occurred in this series. No interface particles were observed on slit-lamp examination. Mean UCVA (logMAR) on postoperative day 1 was 0.10 \(\pm 0.09\) (range: 0.30 to \(-0.08\)) and 0.05 \(\pm 0.08\) (range: 0.28 to \(-0.08\)) on postoperative day 3.

DISCUSSION

A crucial step during LASIK is the creation of a hinged corneal flap due to the potential complication that may occur and cause the postponement of the procedure. The precision in reproducing flap thickness is significant when planning and performing LASIK surgery. A thin flap is generally desirable because it reveals a thicker stromal bed for the ablation, although it is more difficult to manipulate and more prone to...
complications such as folds or striae. Given the current recommendation of leaving at least 250 µm\(^4,13\) of residual corneal tissue, a thinner flap allows the correction of a larger amount of myopia. Therefore, a thin LASIK flap theoretically decreases the risk of corneal ectasia. On the other hand, the risk of flap irregularities, buttonholes, and epithelial defects may increase when thinner flaps are created.\(^14\)

The concept of a disposable microkeratome has been investigated and introduced in clinical practice by a number of manufacturers, but it was not until the first encouraging results with the Moria M2 single use 130 head\(^15\) had it been shown that with an adequate design or plastic material choice, the increased flap-related complications with other disposable microkeratomes\(^16\) can be overcome.

This study evaluates the safety and efficiency of the Moria M2 90-µm single use head. The M2 90-µm single use head is a disposable unit made of plastic with several advantages over a conventional reusable
whereas all flaps thinner than 89 µm occurred in corneas that were thinner than 550 µm prior to surgery. None of the other tested parameters, such as age, flat K, steep K, or preoperative spherical equivalent refraction, showed any correlation with flap thickness.

The mean flap diameter was 9.4±0.3 mm and the mean hinge chord size was 4.2±0.4 mm, which were close to the expected values according to the manufacturer’s nomogram (9.5 mm and 4.2 mm, respectively). A larger flap diameter with a small hinge allows a larger ablation zone, reduces the risk of ablating the hinge, and can be significant in completing the procedure in cases with eccentric flaps. On the other hand, it increases the risk for intraoperative bleeding in cases of neovascularization of the peripheral cornea, as in chronic contact lens users.

Although several interspersed interface particles were observed in a previous confocal microscope study after LASIK with the Moria microkeratome,31,32 no interface particles were noted on slit lamp examination in the present study.

The Moria M2 90-µm single use head seems to cut thinner flaps than the expected values according to the manufacturer’s nomogram (9.5 mm and 4.2 mm, respectively), although with a large range (65 to 152 µm). The M2 90-µm single use head seems to cut thinner flaps with smaller variability, comparable not only to other Moria heads14,15,17-21 but also to other microkeratomes with different heads.17,19,20,22-26

The mean flap thickness in the second (left) eye was approximately 5.5% thinner than in the first (right) eye (103±15 µm compared to 109±18 µm), which is in agreement with other studies.17,19,20 Although no statistically significant difference (P=0.08) was noted between the first (right eye) and second (left eye) cut, this may change with a larger number of eyes.

There was a trend showing that thicker corneas produce thicker flaps, which is comparable to other studies.20,22,23,25,27-30 Corneas as thin as 500 µm and as thick as 589 µm produced flaps with thicknesses between 90 and 133 µm. However, all flaps thicker than 133 µm were observed in corneas thicker than 550 µm.
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<th>Flap Thickness With the Moria M2 Single Use Head/Aslanides et al</th>
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**AUTHOR QUERIES**

Please clarify the manufacturer of the C-Scan. Is the full company name Technomed Arnold-Sommerfeld-Ring1?

Please provide the manufacturer (and its location) of Betadine.

What is meant by “can be significant” in the following statement?

A larger flap diameter with a small hinge allows a larger ablation zone, reduces the risk for ablating the hinge, and can be significant in completing the procedure in cases with eccentric flaps.

**AUTHOR QUERIES PER DR WARING**

Please revise your conclusion in the Abstract and Discussion, which currently states that the instrument gives good predictability for flap thickness, but you have a standard deviation of approximately 17 µm with a range of approximately 70 µm. That does not qualify for “good predictability.” In addition, the microkeratome cuts approximately 15 µm thicker than the stated 90 µm, although your desired cut depth was 120 µm, which acknowledges this disparity.

You begin your Discussion by mentioning flap folds and striae and irregularities. You do not discuss these topics in your Results. Please comment on the number of eyes that had flap folds or striae or irregularities, including those that needed some type of postoperative adjustment.

In your Discussion, you note that there is a “large range (65 to 152 µm),” and yet your Abstract and Conclusion state that the unit is accurate. Please remove allusions to accuracy, and in your Abstract Conclusion and Discussion conclusion please indicate the actual range.