Moria M2 Single Use Microkeratome Head in 100 Consecutive LASIK Procedures

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ABSTRACT

PURPOSE: To evaluate the safety and efficacy of the Moria M2 single use 130 microkeratome head in consecutive laser in situ keratomileusis (LASIK) procedures for correction of myopia and myopic astigmatism.

METHODS: One hundred eyes of 55 patients underwent LASIK in which the flaps were created with the Moria M2 microkeratome using the single use 130 head and excimer laser ablation was done with the Allegretto Wavelight laser. Flap parameters measured were: thickness, diameter, hinge length, and overall quality. Preoperative uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), refraction, wavefront aberrations, and low contrast sensitivity were compared to postoperative values at 6-month follow-up.

RESULTS: Mean flap thickness was 145±17.5 μm, mean flap diameter was 8.5±0.40 mm, and mean hinge cord length was 4.05±0.35 mm. At 6-month follow-up, UCVA improved from 20/200 (±0.24) to 20/18.5 (±0.12) and BSCVA improved from 20/20.5 (±0.18) to 20/17.5 (±0.11).

CONCLUSIONS: The Moria 130 single use head for the M2 microkeratome appears to be safe and effective in performing LASIK procedures. [*J Refract Surg*. 2005;21:xxx-xxx.]

Laser in situ keratomileusis (LASIK) has become the preferred procedure for the correction of myopia and moderate degrees of hyperopia.[1] Its advantages must be weighed, however, against the possible intraoperative corneal flap related complications such as irregular flaps, buttonhole flaps, and free caps,[2-5] as well as postoperative flap complications such as infection and diffuse lamellar keratitis.[6-13] These complications mostly rely on surgeon and microkeratome factors.

Several studies have evaluated the consistency and reproducibility of flap thickness and flap diameter cut by various microkeratomes as well as the induction of wavefront changes.[14-18] This study evaluated the safety and flap consistency of the Moria M2 Single Use 130 microkeratome head (Moria, Antony, France) as well as the postoperative quality of vision and wavefront changes.

PATIENTS AND METHODS

Patient Population

One hundred consecutive LASIK procedures of 55 patients for myopia and/or myopic astigmatism were evaluated. All cases were routine procedures with a wide range of myopia and cylinder correction. Inclusion criteria were myopia of −1.00 to −12.00 diopters (D) and astigmatism up to −5.00 D. Patients with previous corneal surgery, history of herpetic

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The authors have no proprietary interest in the materials presented herein.

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TABLE 1

Mean Flap Dimensions of 100 Eyes Undergoing LASIK With the M2 Single Use 130 Head Microkeratome

Flap Thickness (μm)	Flap Diameter (mm)	Hinge Length (mm)
155±17.5	8.5±0.4	4.05±0.35

eye disease, corneal dystrophy, corneal scarring, keratoconus, severe dry eye, and collagen vascular diseases were excluded.

Preoperative evaluation included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), refraction (manifest, dilated, wavefront refractions), keratometry, slit-lamp examination with fundus evaluation, corneal topography (Orbscan II; Bausch & Lomb, Rochester, NY), and ultrasonic pachymetry (US-1800 Echoscan; Nidek, Achi, Japan).

Operative Technique

A drop of proparacaine 1% (Alcaine; Alcon, Ft Worth, Tex) was instilled into the patient's eye just before the procedure. Eyelids were painted with povidone iodine antiseptic 5% (Betadine; Purdue Pharma L.P., Stamford, Conn), and the eyelashes were isolated with sterile plastic adhesive drapes (Tegaderm; 3M Health Care, St Paul, Minn). The corneal epithelium near the limbus was marked with gentian violet.

The flaps were created with the Moria M2 microkeratome with the single use 130 head; the hinges were positioned superiorly in all cases. A single head-blade assembly was used for both eyes, and the right eye was done first in all bilateral cases. After the microkeratome pass, the corneal flap was reflected and an ultrasound pachymetry measurement of the residual stromal bed was done with the same corneal pachymeter that had been used preoperatively. Three measurements were taken and the median was used. This value was subtracted from the preoperative corneal thickness, and the difference was taken as the corneal flap thickness (subtraction pachymetry). The flap and hinge diameters were also measured intraoperatively with the use of a caliper. Intraoperative flap complications were recorded.

This microkeratome system uses four different suction rings with three different flap-stop adjustments to accommodate various keratometry. The specific nomogram provided by the manufacturer was used in each procedure to select the appropriate ring and flap-stop setting.

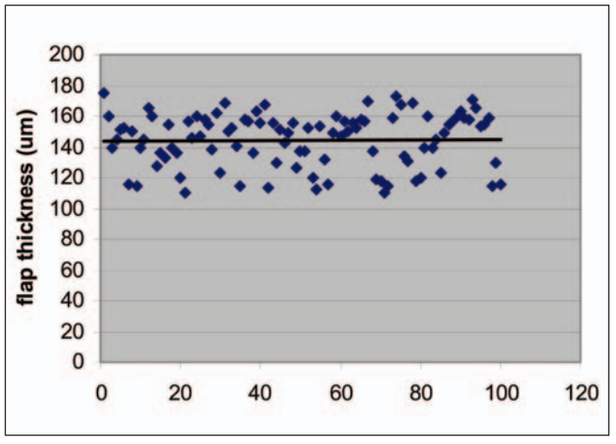

Figure 1. Scatterplot of flap thickness.

The ablations were then performed with the Allegretto Wave excimer laser. After the ablation, the stromal bed was irrigated with balanced salt solution to wash out any debris or epithelial cells. Flap position and centration were checked using the gentian violet pre-markings on the cornea and additionally with a drop of prednisolone acetate 1% (Pred Forte; Allergan, Santa Ana, Calif) to check the flap edge alignment. Patients were examined under a slit-lamp 30 minutes postoperatively to check the corneal flaps.

Postoperatively, patients were given prednisolone acetate 1% and ofloxacin 0.3% (Exocin; Allergan, County Mayo, Ireland) drops 4 times a day for 1 week.

All surgeries were performed by a single surgeon (A.J.K.) in a refractive surgery center in Athens, Greece.

Follow-up examinations were scheduled for 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively. Wavefront measurement was repeated during 6-month follow-up.

Main outcome measures were corneal flap thickness, flap diameter, and hinge cord length. The correlation between flap thickness and preoperative corneal thickness and between flap thickness and keratometry values were tested.

The data were analyzed using Wilcoxon signed rank test, Pearson's correlation, and paired Student *t* test.

RESULTS

This study included 100 eyes of 55 patients with an average age of 32.5±6.83 years. The mean preoperative sphere was 5.25±2.56 D and mean cylinder 1.50±0.78 D. Mean preoperative keratometry was 43.5±1.43 D. Mean corneal thickness was 548±0.34 μm (Table 1).

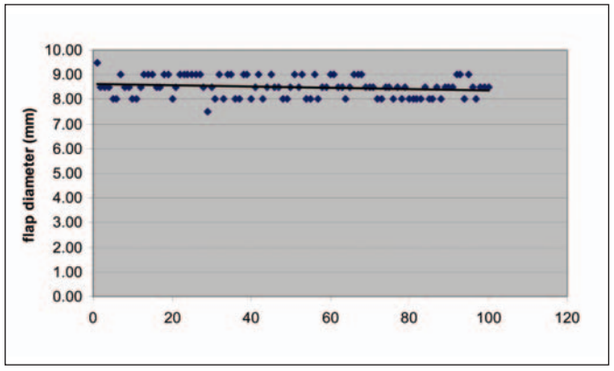

Figure 2. Scatterplot of flap diameter.

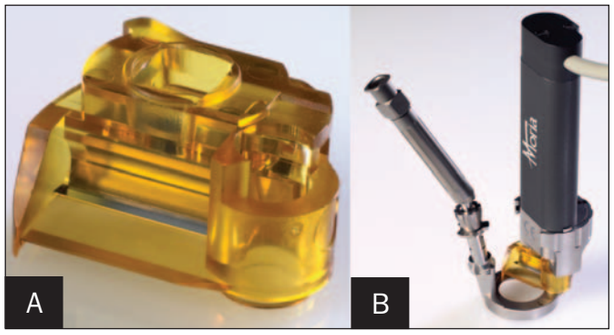

Figure 3. A) Moria M2 130 single use head. B) Microkeratome head assembled onto the motorized hand-piece and suction ring.

The mean flap thickness was 145±17.5 µm (Fig 1), mean flap diameter was 8.5±0.40 mm (Fig 2), and mean hinge length was 4.05±0.35 mm.

A positive correlation was noted between flap thickness and preoperative corneal thickness ($P<.01$). A negative correlation was noted between preoperative average keratometry and resulting flap thickness ($P<.01$). Both were tested using Pearson's correlation.

At 6-month follow-up, UCVA improved from 20/200 (±0.24) to 20/18.5 (±0.12) and BSCVA improved from 20/20.5 (±0.18) to 20/17.5 (±0.11) ($P<.01$, Wilcoxon signed rank test). Of the 100 eyes, 92% saw ⩾20/20, 47% saw ⩾20/15, and 31% attained 20/10.

No major flap complications occurred.

DISCUSSION

We previously reported our clinical experience with the Allegretto Wave excimer laser and the M2 microkeratome with the standard reusable head for myopia and myopic astigmatism (Stein and A.J. Kanellopoulos, unpublished data 2003). In this study, we used the same surgical technique, but instead of the standard reusable M2 microkeratome head, we used the single use 130 head.

Creating the corneal flap is one of the most critical steps for a successful LASIK procedure. Areas of concern for the LASIK surgeon are microkeratome sterilization, assembly, and blade handling. Several studies have reported diffuse lamellar keratitis and infectious keratitis complications related to the microkeratome sterilization process and major fluctuations or deviations of flap parameters due to microkeratome head wear and tear.[2-17]

The concept of a disposable microkeratome has been investigated and brought to clinical practice by a number of manufacturers. None of these has been commercially successful because of inadequate design choice and plastic material. The disposable microkeratome has several significant advantages over a conventional reusable microkeratome head. First, sterilization is not necessary, as it is distributed sterile by the manufacturer. This avoids possible contamination by microbial pathogens and bacterial endotoxins from the autoclave water and sterilizing trays.[6,7,10-13] Second, no wear and tear occurs, as a new head is provided for every patient. Third, minimal technical manipulation and assembly is required, as the microkeratome blade is preassembled with the disposable head. This reduces the possibility of human error in blade insertion and microkeratome assembly. And lastly, the single use head is made of translucent plastic, which facilitates easier placement and locking of the head onto the suction ring and allows better visualization of the procedure. The surgeon can take advantage of the translucent head to guide it directly on to the stylus (Fig 3).

The M2 130 in this series cuts consistent flaps with the diameter of 8.5±0.40 mm. The standard deviation ±17.5-µm in flap thickness in this study compares closely to the findings of ±23.5 µm in a previous study by Miranda et al[14] with the standard (re-usable) M2 110.

We found a positive correlation between the preoperative eventual flap thickness and the preoperative corneal thickness. Patients who had thicker preoperative pachymetry tend to have thicker corneal flaps. An inverse correlation was noted between preoperative keratometry and flap thickness. Corneas with higher keratometry tend to have thinner flaps. These associations are in contrast to previous studies dealing with the same microkeratome by Miranda et al[14] and other microkeratomes,[17] where they report no correlation between the preoperative corneal thickness, keratometry, or patient age.

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AUTHOR QUERIES per Dr Waring

The title has been changed. Okay as edited?
Original: Prospective Evaluation of the M2 Single Use 130 Head in 100 Consecutive LASIK Procedures
Edited: Moria M2 Single Use Microkeratome Head in 100 Consecutive LASIK Procedures

Please be consistent when describing the equipment throughout. Should it be referred to as the Moria M2 Single Use 130 Microkeratome Head or the Moria 130 Single Use Head for the M2 microkeratome?

Please indicate if the 130 head is intended to give a 130-µm thick flap.

Please provide the dates of the surgeries.

Was 100% follow-up achieved at 6 months for all 100 eyes enrolled in the trial initially?

How were the average visual acuities attained? How did you measure visual acuity and what visual acuity chart was used?

You state no major complications occurred. What minor complications occurred?

Please identify when and where you previously reported the "unpublished data."

Please provide Stein's first initial and the month of the unpublished data.

Please provide detailed figure captions, ie, interpret what is shown.

Please indicate where the cutting blade is on Figure 3.

Table 2 has been omitted.

Making conclusions about contrast sensitivity and corneal aberrations and attributing them to the microkeratome seems inappropriate when the majority of those changes would be induced by the excimer laser ablation itself. Your paper is about the microkeratome, and therefore I limited your conclusions to findings with the microkeratome specifically, and not conclusions that combine the outcome of the microkeratome and the excimer laser, as your paper is not about the overall outcomes in this series of eyes based on the laser itself.