

Good reproducibility

Adjustability a plus for microkeratomes

Instruments versatile for anatomically different eyes

By Lynda Charters

Reviewed by Juhani Pietilä, MD

Tampere, Finland—Both the M2 Single Use microkeratome and the M2 microkeratome with the new 90 head (Moria, Antony, France) have been performing well in clinical trials.

The instruments are easy to use because they can be adjusted for anatomically different eyes; they provide good reproducibility in flap thickness and diameter with a small standard deviation; and they are associated with a low rate of microkeratome-related complications, according to two surgeons.

operatively and 1 month postoperatively.

The advantages of these microkeratomes are that the hinge can be positioned anywhere, there are different suction rings for different K values, adjustable hinge lengths can be made with different stop settings, and the instruments have changeable heads to make thicker or thinner flaps.

In this prospective, randomized study, 50 patients, who had not previously undergone a refractive procedure, were included. The randomly



microkeratomes, the investigators reported the following results from the study patients: The flap thicknesses for the M2 Single Use 130 head and the M2 metal 130 head were $147.8 \pm 9.8 \mu\text{m}$ (range, 120 to 170 μm) and $153.4 \pm 13.5 \mu\text{m}$ (102 to 179 μm), respectively. The flap diameters were $9.0 \pm 0.2 \text{ mm}$ (8.3 to 9.6 mm) and $9.1 \pm 0.2 \text{ mm}$ (8.3 to 9.7 mm), and the hinge lengths were $4.2 \pm 0.2 \text{ mm}$ (3.7 to 4.8 mm) and $4.2 \pm 0.3 \text{ mm}$ (3.3 to 4.9 mm) (Table 1).

The complications in the eyes treated with the M2 metal head were epithelial erosion (one eye), epithelium in the edge (one eye), iron particle in the interface (one eye), and bleeding (two eyes). In the eyes treated with the M2 Single Use head the complications were iron particle in the interface (one eye), microstriae (one eye), and bleeding (two eyes).

“The M2 Single Use microkeratome fits in easier on the pivot and it glides

Table 1 Comparison of M2 metallic head versus M2 Single Use head results

50 patients	M2 Single Use 130	M2 Metal 130 Head
Number of eyes	50	50
Flap thickness (μm)	147.8 ± 9.8 (120 to 170)	153.4 ± 13.5 (102 to 179)
Flap diameter (mm)	9.0 ± 0.2 (8.3 to 9.6)	9.1 ± 0.2 (8.3 to 9.7)
Hinge length (mm)	4.2 ± 0.2 (3.7 to 4.8)	4.2 ± 0.3 (3.3 to 4.9)

OT Graphic

Ophthalmology Times / Source: Juhani Pietilä, MD, and Petri Mäkinen, MD

Comparison of results

Juhani Pietilä, MD, and Petri Mäkinen, MD, of the department of ophthalmology, University of Tampere, Tampere, Finland, compared the reproducibility of the flap thickness and diameter of the Moria M2 130 metallic head and the M2 plastic Single Use 130 head microkeratomes and evaluated the complication rate intra-

selected eye was cut with the M2 130 and the other eye with the M2 Single Use 130 microkeratome.

In all cases, the targeted flap thickness was 160 μm , and in all cases the standard keratome advancement speed (speed 2) was used. Using the slower speed, speed 1, would have increased the flap thickness by 10 to 20 μm .

In the comparison of the two

more smoothly over the eye than its metal counterpart," Dr. Pietilä said.

Clinical evaluations worldwide

Other investigators have also evaluated the M2 Single Use 130 head and reported the following results: The target flap thickness in all these studies was 160 μm . In a series of 98 eyes, Professor Chen Yueguo of Beijing, China, reported an average thickness of $159.3 \pm 14.4 \mu\text{m}$ (range, 120 to 195 μm). A. John Kanellopoulos, MD, of Athens, Greece, had a series of

Take-Home Message

The Moria M2 Single Use 130 microkeratome and the M2 with the new 90 head are achieving good results in clinical trials. They can be adjusted for anatomically different eyes, provide good reproducibility in flap thickness and diameter, and have a low rate of microkeratome-related complications.

82 eyes in which he achieved a flap thickness of $152 \pm 14 \mu\text{m}$ (range, 105 to 165 μm).

Harold A. Stein, MD, of Toronto, Ontario, Canada, reported an average flap thickness of $150 \pm 19 \mu\text{m}$ (range, 119 to 200 μm) in 28 eyes, and Richard A. Norden, MD, of Ridgewood, NJ, USA, achieved an average flap that was $160.5 \pm 19.6 \mu\text{m}$ thick (range, 122 to 209 μm) in 31 eyes. Unlike the investigators listed above who used ultrasound pachymetry,

FYI

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Drs. Pietilä and Mäkinen have no proprietary interest in this technology.

Table 2 Clinical studies evaluating the M2 Single Use 130 head in terms of flap thickness

Investigators of the M2 Single Use 130 clinical studies	Measurement technique	Number of eyes	Flap thickness (μm)		
			Average	Standard dev.	Range
Prof. Jorge L. Alio (Alicante, Spain)	Confocal microscopy	15	145.9	18.2	118 to 168
Juhani Pietilä, MD (Tampere, Finland)	Ultrasound pachymetry	50	147.8	9.8	120 to 170
A. John Kanellopoulos, MD (Athens, Greece)	Ultrasound pachymetry	82	152	14.0	105 to 165
Prof. Chen Yueguo (Beijing, China)	Ultrasound pachymetry	98	159.3	14.4	120 to 195
Richard A. Norden, MD (Ridgewood, NJ, USA)	Ultrasound pachymetry	31	160.5	19.6	122 to 209
Harold A. Stein, MD (Toronto, Ontario, Canada)	Ultrasound pachymetry	28	150	19.0	119 to 200



Ophthalmology Times / Source: Juhani Pietilä, MD, and Petri Mäkinen, MD

Table 3 Clinical study evaluating the M2 metal 90 head

184 consecutive eyes	Flap thickness (μm)	Flap diameter (mm)	Hinge length (mm)
M2 metal 90 head	129.3 ± 14.3 (90 to 160)	9.1 ± 0.19 (8.5 to 9.7)	4.24 ± 0.2 (3.8 to 4.8)



Ophthalmology Times / Source: Juhani Pietilä, MD, and Petri Mäkinen, MD

Professor Jorge L. Alio of Alicante, Spain, measured flap thickness with confocal microscopy. The flap thickness with the M2 Single Use 130 was on average $145.9 \pm 18.2 \mu\text{m}$ (range, 118 to 168 μm) in 15 eyes (Table 2).

M2 Microkeratome with 90 head

Drs. Pietilä and Mäkinen also studied the reproducibility of the flap thickness and diameter with the Moria M2 microkeratome with the new 90 head designed to create a 120- μm flap and determined the complication rate during the operation and postoperatively. This microkeratome has similar characteristics to the M2 Single Use and also has two motors—one for oscillation (15,000-rpm blade oscillation) and a second for translation—and four different suction rings to adjust different K values.

This series of patients included 184 consecutive eyes of 100 patients (ages, 19 to 63 years;

mean 31.7 ± 9.9 years) who had spherical refractions ranging from -10.5 to $+4.5$ D, cylinder ranging from 0 to -3.75 D, and K values from 36.75 to 48.4 D (mean, 43.7 ± 2 D).

In this study, suction ring selection using the manufacturer's nomogram was based on the steepest K reading (stop setting always 8 mm). A superior hinge was created in all eyes. In cases in which a bilateral procedure was planned, the right eye was always done first, and the same blade was used in both eyes. The Asclepion MEL 70 excimer laser (Meditec, Jena, Germany) with an active eye-tracker was used in all cases, and in most a 6.5-mm ablation zone was used.

Drs. Pietilä and Mäkinen reported an average flap thickness of $129.33 \pm 14.3 \mu\text{m}$, with a minimum of 90 μm and a maximum of 160 μm . The average flap diameter was 9.1 ± 0.19 mm, with minimum and maximum values of 8.5 and 9.7 mm, respectively. The average hinge

length was 4.24 ± 0.2 mm, with a range of 3.8 to 4.8 mm (Table 3).

The complications reported were an epithelial defect (two eyes), bleeding (15 eyes), and iron particles (two eyes).

Based on these results, "The Moria M2 90 head microkeratome makes thin flaps with good quality, suitable for thin corneas, it is adjustable to anatomically different eyes, and it displayed good reproducibility in flap thickness and diameter with a small standard deviation," Dr. Pietilä stated. "The predictability of this instrument is better than with other microkeratome heads, and importantly, there is a low rate of microkeratome-related complications."

The M2 90 head will be available in plastic only during the first quarter of 2004.

He also pointed out that handling thin flaps requires some experience and that with large flaps, there may be some bleeding from the limbal vessels. **OT**