Corneal Flap Thickness in Laser in Situ Keratomileusis Using Moria M2 130 Micron Single Use Plastic Head and It's Relationship with Age, Corneal Thickness, Keratometry and Refraction

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Abstract

Purpose: To determine the predictability of flap thickness in laser in situ keratomileusis (Lasik) using the newly introduced disposable plastic head intended to make 130 micron flaps. To identify relationship of obtained flap thickness with different variables like preoperative corneal thickness, spherical equivalent refraction, mean keratometry, age of the patient and size of the microkeratome ring used during the procedure.

Design: Prospective non-comparative interventional case series.

Method: Sixty four eyes of thirty six patients underwent laser in situ keratomileusis. In all cases Moria M2 microkeratome with single use 130 micron head was used to create the flap. Manufacturer provided nomogram were used for suction ring selection. Laser ablation was performed with Allegretto Wavelight Eye-Q 400 Htz excimer laser. Central flap thickness was calculated by subtraction pachymetry using DGH-500 pachymeter. The obtained flap thickness was correlated with the age of the patient, preoperative pachymetry, spherical equivalent refraction, mean keratometry, and size of the keratometry ring.

Results: Mean flap thickness obtained was 130.7 ± 27.35 μm (range 69 to 188 μm). Flap thickness directly correlated with preoperative pachymetry (p= 0.001*). There was no correlation between flap thickness and age, mean keratometry, spherical equivalent refraction or the suction ring size.

Conclusion: The Moria M2 130 μm single use head gives flaps with wider standard deviation than previously reported . We recommend that the target flap thickness should be set at 160 μm for residual bed calculation. In patients with calculated residual stromal bed of less than 275 μm intra-operative pachymetry should be performed.

Key Words: central corneal thicness, pentacam, ultrasound pachymetry, specular microscopy

The preservation of Bowman's membrane and the rapid visual rehabilitation associated with LASIK has made the procedure the first choice of many refractive surgeons and patients. Creation of corneal flap is the most critical step for successful lasik procedure. Flap complications such as irregular astigmatism, button hole and free cap can lead to loss of best corrected visual acuity (BCVA).[1-4]

Consistency of flap thickness is crucial for any microkeratome. Very thin flap are more difficult to manipulate and can lead to stria. Unexpectedly thick flaps can compromise corneal stability by reducing the residual stromal bed thickness to less than 250 μm and can result in corneal ectasia. Several studies have mentioned a difference in achieved flap thickness from the attempted flap thickness using the different microkeratome. Most studies showed achieved flap being thinner than the attempted one[5-9] . This study determines the predictability of flap thickness

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in laser in situ keratomileusis using the recently introduced Moria M2 single use plastic head of 130 micron and to identify the factors that may be related to variation in flap thickness.

PATIENTS AND METHODS

This was a prospective non-comparative interventional case series. Sixty four eyes of thirty six patients with myopia and myopic astigmatism underwent conventional lasik using Eye-Q Allegretto Wavelight excimer laser by the same surgeon (M.A.F). All flaps were created using the Moria M2 microkeratome with single use plastic head with intended flap thickness of 130 μm. Patients of either sex with myopia or myopic astigmatism with no systemic or ocular disease and no history of previous ocular surgery were included in the study. Preoperatively uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA) and cycloplegic refractions were recorded. Complete slit lamp and fundus examination was performed. Corneal topography was performed with topolyzer (Wavelight Technologies, Erlangen, Germany). Central keratometry readings were measured with TOPCON autokerato and refractometer (Topcon Inc, Japan). Preoperative corneal thickness and intraoperative stromal thickness was measured using ultrasonic pachymeter (DGH technologies, USA) and an average of three readings was used for calculation. Similar regimen of preoperative medication was used in all the patients. Each patient received two drop of ofloxacin (Oflox, Allergan Inc, USA) and three drops of local anesthetic benoxinate hydrochloride (Novasin, Novartis pharma gmbh, Switzerland) in half hour before surgery. Conjunctival cul de sac was sterilized with 10% povidon iodine solution diluted 50:50 with balanced salt solution. After placement of lid speculum three central pachymetry readings were recorded at the fixation light reflex. Cornea was marked with gention violet and washed with few drops of BSS. Excess water was wiped with merocel sponge. All flaps were created using the Moria evolution-2 console and M2 hand piece. M2 hand piece consists of two separate motors, one each to oscillate the blade and move the head forward (Moria, France). 130 micron disposable plastic head with pre-implanted steel blade (Moria Inc. France) was used to create flap of intended thickness of 130 micron by using fast pass speed. Suction ring and microkeratome stop was selected according to the manufacturer's nomogram (Moria, France). Suction ring was gently placed on the eye surface and suction was started after the full vacuum was achieved as seen on main console microkeratome head was placed on the pivot and locked by sliding the latch. All the flaps were made using the fast pass speed. After the flaps were lifted central stromal bed thickness was measured using the pachymetry probe. Every effort was made to take the preoperative and intra-operative pachymetry readings by directing the patient to look at the fixation light and applying the probe on the fixation light shadow in order to ensure the same measurement point. Case of uncooperative patients or where three readings could not be taken was excluded. After stromal bed thickness measurement laser ablation was performed with Allegretto Wavelight Eye-Q excimer laser (Wavelight Technologies, Erlangen, Germany).

Main out come measure was corneal flap thickness which was measured by subtracting the mean value of the intraoperative pachymetry from the mean value of the preoperative pachymetry. Statistical soft ware SPSS 10.0.7 for windows was used to calculate Pearson's correlation between the factors and paired

Table 1. Demography of the Study

Number of Patients	36 (28 bilateral, 8 unilateral
Number of Eyes	64
Age	27.38 +/- 7.33 (min 19, max 46)
Sex	15 male, 21 female
Mean Pre-operative Spherical Equivalent	-3.19 ± 1.87 D (range -0.25 to -6.25 D)
Mean Pre-operative Keratometry	42.8 ± 1.44 D (range 39.6 to 46.6 D)
Mean pre-operative Corneal Thickness	550 ± 29.5 μm (range 486 to 611 μm)

Table 2. Correlation Coefficients of Variables vs Flap Thickness

Variable	Mean (SD)	Correlation Coefficient	P Value
Spherical equivalent	-3.19 ± 1.87 D	-0.009	0.472
Corneal thickness	550 ± 29.5 μm	0.419	0.001*
Age	27.38 ± 7.33 yr	0.085	0.313
Keratometry	42.8 ± 1.44 D	-0.112	0.191
Ring Size	-1 to +2	-0.022	0.433
Sex		-0.231	0.091

sample t test with a confidence interval of 95% was done to compare the means between the two eyes. A p value of < 0.05 was considered significant.

RESULTS

The study included sixty four eyes of 15 men and 21 women with a mean age of 27.38 ±7.33 years. Eight of the patients had unilateral surgery done. Mean pre-operative spherical equivalent refraction was -3.19 D ± 1.87 D (range -0.25 D to -6.25 D). Mean pre-operative keratometry was 42.8 ± 1.44 D (range 39.6 to 46.6 D). Mean pre-operative corneal thickness was 550 μm ± 29.5 μm (range 486 – 611 μm) Table 1. No intra-operative complication was recorded. With the attempted thickness of 130 μm the mean flap thickness obtained was 130.7 ± 27.35 μm (range 69 to 188 μm). The actual flap thickness was not significantly different from the attempted flap thickness but showed significantly high variation among the cohort. In bilaterally treated cases, the mean flap thickness for the right eye was 131.3 μm ±29.5μm and for the left eye flap thickness was 132.3 ±25.4 μm. The difference in the flap thickness between the two eyes was statistically insignificant p = 0.832.

Flap thickness showed a strong co-relation with pre-operative corneal thickness (r = 0.419, p = .001*). There was no correlation found with spherical equivalent refraction, preoperative keratometry, ring size, age and sex (r = -0.009, -.112, -.022,.085 and -.231 respectively) Table.2.

DISCUSSION

The single use head is considered advantageous over the reusable as it is easier to use and no assembly is required. Availability of pre-sterilized and pre-assembled microkeratome head eliminates the possibility of contamination from autoclave water and sterilization tray. Thus it have the possibility to minimize the risk of diffuse lamellar keratitis and infectious keratitis related to microkeratome[10-12], a possibility that has yet to be proved[13]. Moria M2 disposable heads are single block plastic heads with pre loaded steel blade similarly manufactured reusable steel heads with insert able blades has shown to cut flaps thicker than the heads were intended to cut. Muallem MS et al in their study showed that reusable steel head of 130 micron using fast translation gives mean flap of 145.8 μm ±25.4 μm[14]. In another study Pietila et al comparing Moria reusable and single use 130μm head with intended flap thickness 160 μm found thinner flaps than the head were intended to cut. Mean flap thickness obtained in their study was 153μm ± 13.3μm (range: 102 to 179) by reusable 130μm head and 148μm ± 9.8 (range: 120 to 170) by single use 130μm head[15]. Kanellopoulos et al in their series of 100 consecutive eyes using Moria M2 singe use head with intended flap thickness 160 μm found mean flap thickness of 145μm ± 17.5μm[13]. Aslanides et al[16] and Huhtala et al[17] reported thinner than the intended flap in their series using M2 single use head with intended flap thickness 120 μm. In our small cohort study we found mean flap thickness of 130.7μm that was closer to the intended flap thickness of 130μm but the SD (±27.35μm) and range (69 to 188μm) was wider than in to previously mentioned studies. Flap thickness in our study directly correlated with the preoperative corneal thickness (Fig: 1), which is comparable with to other studies.[5,16,18,19] No correlation was found between the flap thickness and age, sex, keratometry, or spherical equivalent refraction Table 2. In our study

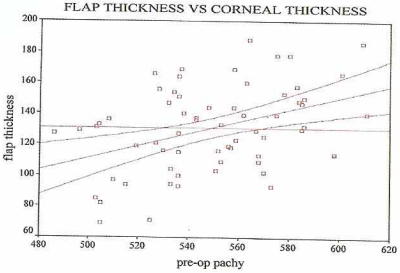

Figure 1. Scattergram demonstrating the correlation between fap thicknesses and pre-operative corneal thickness.

we did not find statistically significant difference in the flap thickness between the two eyes that make it safer to use the same head in two eyes. The difference in the flap thickness, obtained by the same type of machine, as mentioned in different studies[9,14,18] signifies that there could be surgeon specified factors that can affect the thickness of flaps. With the larger standard deviation in flap thickness obtained with Moria single use 130 micron head it deems necessary to measure the intraoperative flap thickness in patients with larger corrections and border line calculated residual stromal bed thickness.

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