Comparison of Corneal Flap Thickness Predictability and Architecture Between Femtosecond Laser and Sub-bowman Keratomileusis Microkeratome in Laser in Situ Keratomileusis.

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Research Article

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Abstract

Purpose of the Study:

The purpose of the study is to assess and compare the corneal flap thickness predictability and uniformity between Visumax femtosecond laser and Moria sub-Bowman keratomileusis microkeratome in laser in situ keratomileusis procedure to correct myopic and myopic astigmatism refractive errors.

Methods:

One hundred eyes from 100 patients, were enrolled in this study. Only one eye (right eye) of each patient was chosen for this study.

They were divided into two groups of equal size (50 each). Target flap thickness was 90 μm.

Flap thickness was measured by anterior segment optical coherence tomography in 7 specified positions at 3 months postoperative.

Results:

For femtosecond laser group, the average central flap thickness (CFT) was 91.35μm ±4.97. There was no statistically significant difference between the target flap thickness and the resultant flap thickness (p=0.12). When the central, nasal and temporal thicknesses in the same flap were compared, there was no statistically significant difference among these measurements (p=0.9).

For the microkeratome group, CFT was 102.18μm±5.63. There was statistically significant difference between the target flap thickness and the resultant flap thickness (p=0.001).The central, nasal and temporal thicknesses were compared and there was a statistically significant difference.(p=0.000).

Conclusions:

Our study is among few studies in the literature comparing femtosecond laser flap to SBK microkeratome flap. Femtosecond laser creates more predicable flap thickness and more uniform flap architecture. It should be the first choice for the patients when the availability and cost is not a problem.

TRIAL REGISTRATION: Trial registration number: NCT04684888. Trial Registration date: December 2020. Registered at www.clinicaltrials.gov.

Introductions:

Laser in situ keratomileusis (LASIK) has become the most popular procedure for refractive errors correction [1, 2]. However, corneal ectasia is a serious complication of LASIK.

One of the critical step of LASIK is the flap creation. The resultant flap thickness is directly related to the residual stromal bed thickness, corneal biomechanics and hence the future risk of ectasia [3].

Recently thin-flap LASIK has been advocated because it allows for more residual stromal bed thickness and thus less risk of ectaisa. Thin flaps are associated with better early postoperative visual and refractive outcomes [4]. However thin-flap LASIK has its own disadvantages. There is greater chance of flap striae and greater risk of button hole formation in thin-flap LASIK [5].

The two available techniques for creating thin-flaps in LASIK are femtosecond laser and sub-Bowman keratomileusis (SBK) microkeratome [5].

The femtosecond laser uses 1043 nm wavelength, a repetition rate of 500 kHz, and 220–580 femtoseconds pulse duration. Each laser pulse produces micro-photodisruption in the tissue. Contiguous, few microns-sized photo-disruptions will create continuous cut in the corneal tissue at precise preset depth. While the mechanical microkeratome uses an oscillating blade to create the corneal flap [6].

The main differences between the femtosecond and mechanical microkeratome flap creation are the resultant flap thickness predictability and architecture[7] .

In this study we compared the flap thickness predictability and architecture in LASIK using Visumax femtosecond laser [Carl Zeiss Meditec AG, Jena, Germany] and Moria One Use-Plus SBK Microkeratome [Moria, Antony, France].

Patients And Methods:

The ethical committee at Al-Kindy College of Medicine University of Baghdad reviewed and approved all the procedures prior to initiation of the study at Eye Specialty Private Hospital. All patients signed an informed consent and the study was conducted in accordance with the tenets of the Declaration of Helsinki.

This is a prospective interventional non-randomized trial. The trial has registered at www.clinicaltrials.gov on December 2020 and the registration number is NCT04684888.

One hundred eyes from 100 consecutive patients, who had myopia or myopic astigmatism refractive errors and were scheduled for laser in situ keratomileusis (LASIK), were enrolled in this study. Only one eye (right eye) of the each patient was chosen for this study. The patients average age was 28.3 years and ranged from 20 to 38 years. The refractive errors spherical equivalent average was – 6.09 diopters of sphere and ranged from – 2 to -6 diopters of sphere.

All the patients had full eye exam and had stable refractive errors for at least one year prior to surgery and all of them had normal topography and tomography measured by Placido-Scheimpflug [Sirius, Costruzione Strumenti Oftalmici, Florence, Italia] and normal corneal epithelial map by anterior segment optical coherence tomography (AS-OCT) system [Optovue Inc, Fremont, California, USA].

The 100 eyes divided into two groups of equal size (50 each) for flap creation with the Visumax Femtosecond laser (FS laser group) and Moria One Use-Plus SBK microkeratome (microkeratome group). Target flap thickness was 90 µm for all patients and for both groups.

The patients were given the choice to select one of two flap creation methods, after explaining the benefits, risks, complications and the cost differences between the two procedures. All the patients were candidate for both flap creation methods. There were no statistically significant differences between the patients characteristics in both groups. The patients characteristics are shown in Table 1.

Table 1
Preoperative patients characteristics of the two groups

Group	Age (Years)	SE Refraction (D)	CCT (µm)	Mean Keratometry	CHD (mm)
FS laser group (n = 50)	28.8 ± 3.8	− 6.26 ± 2.83	528.50 ± 31.42	43.8 ± 13.2	11.83 ± 0.23
Microkeratome group (n = 50)	27.8 ± 2.9	-5.92 ± 3.2	538.09 ± 25.18	44.2 ± 11.8	11.79 ± 0.34
P -value	0.701	0.321	0.401	0.51	0.730
SE: Spherical equivalent, CCT: Central corneal thickness, CHD: Corneal horizontal diameter.					

Flap thickness was measured by anterior segment optical coherence tomography (AS-OCT) in 7 specified positions on each flap at 3 months postoperative in each eye. One central and three points on each sides along the horizontal meridian were measured. The three points on nasal and temporal sides were located 1mm, 2mm, 3mm respectively from the center. Therefore total central 6 mm diameter of the flap was measured as shown in Fig. 1.

The primary outcome measure was to compare the accuracy and predictability of flap thickness and also the uniform nature of the flap between the two groups. The secondary outcome measures were to compare the postoperative uncorrected visual acuity and mean spherical refractive errors.

All surgeries were performed by single experienced surgeon under topical anesthesia (Tetracaine eye drop 0.5%). For FS laser group, the flap parameters were 90 µm thickness, 8.8 mm flap diameter, and 90º side cut angle. The hinge was nasally located with the hinge width of 3.45 mm and hinge angle of 50º. The laser parameters were 500 kHz and 160 nJ energy.

For microkeratome group, the flap thickness was set to 90 µm thickness, 9.00 mm flap diameter. The hinge was also nasally located.

The excimer laser ablation was performed by MEL90 [Carl Zeiss, Meditec, Germany] in both groups after flap creation. A 6.5 mm optical zone and 8.00 ablation zone was used. Automatic iris-registration and

pupil-tracking systems were activated before photo-ablation.

Minitab version 16 (Minitab Ltd, Coventry, UK) was used for statistical analysis. The correlation between the parameters was evaluated by Pearson correlation. A paired T-test was used for comparing parameters of the same group. For comparing two independent means of two groups, two-sample T-test was used. One sample T test was used for evaluation of predictability. A statistically significant difference was considered when p-value < 0.05. All data expressed as mean ± SD.

Results:

There was no statistically significant difference between the patients characteristics in both groups. The patients characteristics are shown in Table 1.

For FS laser group, the average central flap thickness (CFT) was 91.35µm ± 4.97. There was no statistically significant difference between the preoperative target flap thickness and the postoperative resultant flap thickness (p = 0.12) as shown in Table 2. This indicates that the resultant flap thickness is accurate and predictable as intended. When the central, nasal and temporal thicknesses were compared in the same flap, there was no statistically significant difference among these measurements (p = 0.9). This reflects the uniform and regular architecture of the flap and it indicates the configuration of the flap is planner shape. Preoperative central corneal thickness, corneal horizontal diameter, refractive errors were not related to the CFT (p = 0.25, 0.12, 0.41 respectively).

Table 2
Predictability of Central Flap Thickness

Central Flap Thickness (µm)			
Groups	Predicted Thickness	Central Flap Thickness (3 months postop)	p-value
FS laser group (n = 50)	90	91.35 ± 4.94	0.12
Microkeratome group (n = 50)	90	102.18µm ± 5.63	0.001

For the microkeratome group, the average CFT was 102.18µm ± 5.63. There was statistically significant difference between the preoperative target flap thickness and the resultant flap thickness (p = 0.001) as shown in Table 2. Therefore the resultant flap thickness in this group is less predictable. The central, nasal and temporal flap thicknesses were compared and there was a statistically significant difference.(p = 0.000). This reflects less uniform and regular architecture of the flap and it indicates that the configuration of the flap is more meniscus shape. The pre-operative central corneal thickness found to be directly correlated to the CFT (p = 0.002). The corneal diameter and refractive errors were not correlated (p = 0.5, 0.09 respectively).

We also compared the flap thickness in the FS laser group with the flap thickness in the microkeratome group and found that difference between the two groups was statistically significant (p-value = 0.000) as shown in Table 3.

Table 3
Comparison between central flap thickness in both groups

Central Flap Thickness (µm)		
Groups	Predicted Thickness	Central Flap Thickness (3 months postop)
FS Laser group(n = 50)	90	91.35 ± 4.94
Microkeratome group(n = 50)	90	102.18µm ± 5.63
p-value		0.000

There were no statistically significant difference between the uncorrected visual acuity (p = 0.91) and mean spherical equivalent refractive error (p = 0.92) between the two groups as shown in Table 4.

Table 4
Comparison between the visual acuity and refraction in both groups

Groups	**Preop SE (D)**	**Postop SE (D)**	**scVa preop**	**scVa postop**
FS laser group (n = 50)	-6.26 ± 2.83	0.75 ± 0.12	1.0 ± 0.2	0.22 ± 0.1
Microkeratome group (n = 50)	−5.92 ± 3.23	+ 0.81 ± 0.2	1.2 ± 0.15	0.23 ± 0.13
p-value	0.321	0.91	0.82	0.92
SE: Spherical equivalent, Preop: Preoperative, Postop: Postoperative,				
scVa: Uncorrected Visual acuity.				

Discussions:

Research on flap thickness and architecture and its effects on postoperative performance have gained more attention in recent years.

Corneal flap creation is an important step of LASIK procedure. Creating thin flaps is becoming more popular in LASIK procedure. Flap thickness predictability and flap uniformity and homogeneity is an important benefit of thin-flap LASIK. Thin-flap LASIK has excellent visual and refractive outcomes. It allows for more refractive errors correction as it allows for more residual stromal bed thickness. The predictability of flap thickness in addition to more residual stromal bed thickness incorporate into the better safety profile of thin-flap LASIK procedures. Thin-flap LASIK is not without disadvantages however. It has more risk of striae and button holes formation in the flap.

The two available tools for creating thin-flap in LASIK procedure are femtosecond laser and newer mechanical microkeratome system which is Moria One Use-Plus SBK microkeratome. Both can create thin and uniform flaps. In our study we compared the flap thickness predictability and uniformity between the two techniques. We found that the femtosecond laser produces more accurate and predictable flap thickness. It also creates a more uniform flap.

There are few papers in the literature comparing corneal flap in LASIK created by femtosecond laser and Moria One Use-Plus SBK microkeratome. On the other hand, there are several papers comparing femtosecond laser flap to conventional (non-SBK) microkeratome.

Zhai Chag-bin et al, in their 161 eyes of 81 patients study, demonstrated that Intralase femtosecond laser and Moria One Use-Plus microkeratome created a more uniform, regular and more accurate flap than Moria M2 [4]. They did not find significant differences between the femtosecond laser and SBK microkeratome in the central measurement of thickness of the flap. However they stated that the accuracy of femtosecond laser flap is better than SBK microkeratome flap in the peripheral zones of the flap. Therefore they concluded at the end of their study that the flaps created by the femtosecond laser are safer, more accurate, and have better visual quality.

Zhang J et al, compared the Visuamax femtosecond laser flap to Moria SBK microkeratome flap similar to our study. In their 120 eyes study they found that Visumax femtosecond laser flap is more planner and more uniform than Moria SBK which is in agreement to our study [5]. However they found no statistically significant difference in the predictability of corneal flap thickness between the two techniques. This finding is different than what we concluded in our study. One of the reasons for this disagreement could be the fact that we used anterior segment OCT for measuring the flap thickness while they used ultrasonic pachymetry. Kim et al, reported that OCT is more reliable than ultrasound pachymetry in measuring the central corneal flap thickness [8]. Another reason could be because they performed their measurements intra-operatively, therefore the compression factor and the amount of hydration of the corneal stroma could have affected the readings.

The preoperative corneal thickness was directly related to corneal flap thickness in the microkeratome group. This was not the case in FS laser group. Therefore some parameters should be adjusted according to the preoperative corneal thickness when using SBK microkeratome to increase the safety in LASIK.

Our study found no difference in visual and refractive outcomes at three months postoperatively between the two groups. However the limitation of this conclusion is that we did not study the aberrations and quality of life of the patients between the two groups.

In conclusion, Visumax femtosecond laser creates more predicable flap thickness and more uniform architecture of the flap than Moria SBK microkeratome in LASIK. It should be the first choice for the patients when availability and cost is not a problem.

There are several limitations in our study. The sample size is not large enough. The study was not randomized and not blinded. However it adds more agreement to the few available studies that compare the femtosecond laser to the SBK microkeratome in thin-flap LASIK.

Declarations

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Authors Contribution: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by all authors. All authors read and approved the final manuscript.

Ethical Declarations: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of at Al Kindy College of Medicine University of Baghdad. Informed consent was obtained from all individual participants included in the study.

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Figures

Figure 1

AS-OCT of flap thickens taken at 7 points.