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Study of Accuracy of Corneal Flap Thickness by Using Femtosecond Laser Technology

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ABSTRACT

Background- LASIK is the most popular surgery to correct the refractive errors nowadays. It is proved to be safe, effective and well predictable. It is important to produce a uniform flap with a narrow SD from the intended thickness. The Integrated optical pachymetry is a convenient and useful feature of the EX500 excimer laser which can be used to measure flap thickness intraoperatively.**Objectives:** this study aimed to detect the accuracy of Allegretto Wavelight FS200™ platform in creation of different corneal flap thicknesses. **Patients and Methods:** sixty eyes of 30 myopic patients were included in our study, the patients were operated by 2 different surgeons from June 2017 till December 2017. The patients were distributed randomly into 3 studied groups. **Group I** (20 eyes with intended fs flap 100um), **group II** (20 eyes with intended fs flap 110um) and **group III** (20 eyes with intended fs flap 120um). All participants were subjected to full medical history taking, uncorrected distance visual acuity, slit-lamp microscopy, corneal topography using oculus® pentacam device, manifest and cycloplegic refraction, corrected distance visual acuity, fundus bio-microscopy examination using 90 D lens.

Results: in this study 100μm thickness group (**Group A**) showed the lowest difference between the mean result and the intended flap (-0.35um) followed by the 120um group (**Group C**) with difference of (-2.9um) between the mean result and the intended flap thickness followed by the 110μm group (group B) with the highest difference (-3.45um) from the intended flap thickness.

Conclusion: the flaps made with the Wavelight FS200 femtosecond laser were predictable and uniform more predictable in **group A** than **in group C** and B, but with no statistical significance between the three studied groups (P=0.402).

Keywords: femtosecond laser, LASIK, allegretto Favelight FS200™ , EX500 optical pachymetry.

INTRODUCTION

Laser *in situ* keratomileusis (LASIK) has become the most popular approach in the world for the correction of refractive errors including the correction of myopia, hyperopia, and astigmatism [(1)].The first phase of LASIK, the creation of corneal flap, is the most critical step of LASIK, and it affects the visual outcome of the whole procedure[(2)].

The technological evolution of flap creation has emerged from automated microkeratomes to most recently femtosecond (FS) laser technology [(3)].The corneal flap thickness is directly related to LASIK predictability and safety, therefore, methods that improve the predictability and minimize the degree of variation in corneal flap thickness are worthy of attention [(4)]. Recently the femtosecond laser technology has been widely used , which has provided an alternative option for flap creation since the introduction of the IntraLase™ (Abbott Medical Optics, Santa Ana, CA, USA) in 2001 [(5)]. In the femtosecond (FS) laser technology, FS laser photodisrupts tissue at a preset depth and produces microcavitation bubbles consisting of water and carbon dioxide. The expansion of these bubbles separates the corneal lamellae and forms a resection plane [(6)]. It is important to produce a uniform flap with a narrow standard deviation (SD) from the intended thickness to obtain an appropriate residual stromal thickness during LASIK [(7)]. Sufficient residual stromal bed (RSB) thickness is Important to reduce the likelihood of corneal ectasia [(8)]. Femtosecond-LASIK flaps that are too thin may be prone to gas breakthrough or lifting complications, such as flap tears, striae, or buttonhole formation [(9)].

Corneal thickness can be measured by several methods as ultrasound pachymetry,optical pachymetry, pentacam and optical coherence tomography [(10)]. Intraoperative measurements may help surgeons determine the accuracy of programmed versus achieved flap thickness (FT) [(11)]. The WaveLight® EX500 (Alcon Laboratories, Fort Worth, TX, USA) has built-in optical pachymetry that is generally quick, easy to use, and does not interrupt the cadence of surgery. Previous studies have shown similar residual stromal bed (RSB) values when comparing measurement with intraoperative optical pachymetry and ultrasound pachymetry [(11)].

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PATIENTS and METHODS

Sixty eyes with Myopia were included in this prospective, randomized, interventional study. These cases were operated in Al Watani Eye Hospital during the period from June, 2017 till December, 2017. The Candidates were distributed randomly on 3 studied groups. **Group I** (20 eyes with intended fs flap 100um), **group II** (20 eyes with intended fs flap 110um) and **group III** (20 eyes with intended fs flap 120um). All participants were subjected to full medical history taking, uncorrected distance visual acuity, slit-lamp microscopy, corneal topography using oculus® pentacam device , manifest and cycloplegic refraction, corrected distance visual acuity, fundus bio-microscopy examination using 90 D lens. Candidates with hyperopia, age was less than 18 or more than 45 years , previous corneal surgeries or corneal opacities, thinnest point less than 490um , average K is less than 40 or more than 48 Diopters were excluded from this study .

Statistical Analysis

The collected data were revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (SPSS 20). Data were presented and suitable analysis was done according to the type of data obtained for each parameter.

i. Descriptive statistics:

1. Mean, Standard deviation (± SD) and range for parametric numerical data, while Median and Interquartile range (IQR) for non parametric numerical data.
2. Frequency and percentage of non-numerical data.

ii. Analytical statistics

1. One-Sample T Test was used to test whether the mean of a single variable differs from a specified constant.
2. ANOVA test was used to assess the statistical significance of the difference between more than two study group means.

The study was done after approval of ethical board of Ain Shams University and an informed written consent was taken from each participant in the study.

RESULTS

Comparing the demographic and clinical data of all groups **(Table 1)** showed no statistical significant differences between the three studied groups regarding gender (P=0.26). **Table 2** showed comparison between the 3 studied groups regarding age where no statistical significant differences were observed between **group A & group B** (P=0.17) and between **group B & group C** (P=0.6), while there was a statistical significant difference between **group A & group C** (P=0.04).

Regarding spherical equivalent, there were no statistical significant differences between the three studied groups **(Table 3)**. Regarding K1, K2 readings, there were no statistical significant differences between the three studied groups (**Table 4).**

Regarding preoperative corneal thickness, no statistical significant differences were observed between the three studied groups (**Table 5).**

Table 6 showed comparison between flap thickness measured by EX500 and the planned flap thickness in **group A**, where mean flap was 99.65 um with SD ±6.34 from the mean, the difference between the mean flap and the intended flap was found to be -0.35 (-3.31 - 2.61) (P=0.808) where this difference was not statistically significant . **Table 7** showed comparison between flap thickness measured by EX500 and the planned flap thickness in **group B,** where mean of flap was 106.55 um with SD ±7.06 from the mean, the difference between the mean flap and the intended flap was found to be -3.45 (-6.75 - -0.15) (P=0.042) although this difference was statistically significant it was not clinically significant. **Table 8** showed comparison between flap thickness measured by EX500 and the planned flap thickness in **group C,** where mean of flap was 117.10 um with SD ±9.35 from the mean, the difference between the mean flap and the intended flap was found to be -2.9 (-7.27 - 1.47) (P=0.181), where this difference was not statistically significant . By comparing the 3 studied groups regarding their accuracy, there was no statistical significance between them.

Table 1: showing comparison between the 3 studied groups regarding gender

	Group A	Group B	Group C	P value	chi-square
Males	2	2	4	0.26	2.73
Females	8	8	6		

Table 2 showing comparison between the 3 studied groups regarding age

	Group A	Group B	Group C	A Vs B	A Vs C	B Vs C
Age (years)	Mean ± SD	Mean ± SD	Mean ± SD	p value		
	26.28 ± 5.65	29.23 ± 7.61	30.46 ± 6.98	0.17	0.04	0.60

Table 3: showing comparison between the 3 studied groups regarding spherical equivalent

	Group A	Group B	Group C	A Vs B	A Vs C	B Vs C
Spherical equivalent (Diopters)	Mean + SD	Mean + SD	Mean + SD	p value		
	-3.56 ± 1.59	-3.71 ± 1.40	-3.31 ± 1.72	0.75	0.64	0.43

Table 4: showing comparison between the 3 studied groups regarding K1 and K2

	Group A	Group B	Group C	A Vs B	A Vs C	B Vs C
	Mean ± SD	Mean ± SD	Mean ± SD	p value		
K1 reading	42.87 ± 1.80	43.28 ± 1.41	43.05 ± 1.44	0.43	0.74	0.60
K2 reading	43.71 ± 1.75	44.09 ± 1.45	44.00 ± 1.67	0.45	0.59	0.85

Table 5: showing comparison between the 3 studied groups regarding preoperative corneal thickness

	Group A	Group B	Group C	A Vs B	A Vs C	B Vs C
Preop thickness (µm)	Mean + SD	Mean + SD	Mean + SD	p value		
	570.70 ± 37.73	553.95 ± 21.46	553.40 ± 24.95	0.09	0.10	0.94

Table 6: comparison between flap thickness measured by EX500 and the planned flap thickness in group A

Flap thickness By EX500		Planned Flap	Difference (95% CI)	One Sample t test	
Mean	±SD			p value	Sig
99.65	6.34	100	-0.35 (-3.31 - 2.61)	0.808	NS

Table 7: comparison between flap thickness measured by EX500 and the planned flap thickness in group B

Flap thickness By EX500		*Planned Flap*	*Difference (95% CI)*	*One Sample t test*	
Mean	*±SD*			*p value*	*Sig*
106.55	7.06	110	-3.45 (-6.75 - -0.15)	0.042	S

Table 8: comparison between flap thickness measured by EX500 and the planned flap thickness in group C

Flap thickness By EX500		*Planned Flap*	*Difference (95% CI)*	*One Sample t test*	
Mean	*±SD*			*p value*	*Sig*
117.10	9.34	120	-2.9 (-7.27 - 1.47)	0.181	NS

Table 9: comparison between the different planned flaps regarding the difference between planned flap and actual flap thickness measured by EX500

Thickness difference		*Mean ± SD*	*Median (IQR)*	*Range*	*ANOVA*	
					p value	*sig.*
Planned flap	100	-0.35 ± 6.34	-0.5 (-5.5 - 3)	-10 - 14	0.402	NS
	110	-3.45 ± 7.06	-3 (-9 - 1)	-14 - 12		
	120	-2.9 ± 9.34	-3 (-12 - 5.5)	-16 - 12		

DISCUSSION

LASIK is the most popular surgery to correct the refractive errors nowadays, which is proved to be safe, effective and well predicable [12]. The critical step of LASIK is to make a thin and uniform lamellar cornea flap [12]. At present, flap can be created with a mechanical microkeratome or femtosecond laser. A previous study had shown that femtosecond laser flaps are of uniform thickness and planar-shape [13]. Several studies have compared femtosecond lasers and the mechanical microkeratomes for corneal flap creation and found that the FS laser may yield better safety, reproducibility, and predictability [14]. It is important to produce a uniform flap with a narrow SD from the intended thickness. A relatively thin corneal flap increases the incidence of flap related complications including a free, irregular, incomplete, buttonhole or lacerated flap. A relatively thick corneal flap increases the risk of corneal ectasia [15].

The femtosecond laser has revolutionized the way corneal flaps are created during LASIK surgery. Accurate FT creation may have importance in visual quality, prevention or avoidance of striae, epithelial ingrowth, and ease of flap lifting at primary or enhancement surgeries [16]. Our study included 60 eyes of 30 myopic patients, 8 males and 22 females, with age ranged from 20.83 to 44 years with mean 28.66 ± 6.91 and spherical equivalent ranged from -0.75 D to -7.00 D with mean -3.53 ± 1.56, with preoperative corneal thickness ranged from 511 to 637 um with mean 559.35 ± 29.54 um. In our study we used the integrated optical pachymeter in Allegretto Wavelight EX500 (Alcon Laboratories Inc, Ft Worth, Texas) to measure corneal flap thickness intraoperatively to assess the FS200 (Alcon Laboratories Inc, Ft Worth, Texas) accuracy to form a flap with narrow deviation from the intended flap in the different flap thicknesses (100,110,120 um).We considered ultrasonic pachymetry, while useful, to be less than ideal for intraoperative measurements during LASIK. Our concerns included risk of introduction of contaminants or even infectious agents into the interface, interruption of the surgical cadence and possible challenges with technical aspects of the measurement itself, including exact centration and perpendicularity of the probe [17].

A previous study had shown similar residual stromal bed (RSB) values when comparing between measurement with intraoperative optical pachymetry and ultrasound pachymetry [18]. It was found that the 100 μm thickness group (group A) showed mean Flap thickness of 99.65 with the lowest SD of ± 6.34 μm which was not statistically significant (P=0.808) ,while the 110um group (**Group B)** showed mean flap thickness of 106.55 with SD of ±7.06 although it was statistically significant (P=0.042) it was not clinically significant ,while the 120μm group (**Group C)** showed mean flap thickness of 117.10 with SD of ±9.34 which was not clinically significant (P=0.181) .

Qian *et al*. compareed corneal flaps created by wavelight FS200 vs intralase FS60 with intended flap 110um , the mean flap thickness was 105.71±4.72 μm in the Wavelight FS200 group[19].

Regarding the accuracy, the 100 μm thickness group (group A) showed the lowest difference between the mean result and the intended flap (-0.35um) followed by the 120 um group (**Group C**) with difference of -2.9um between the mean result and the intended flap thickness followed by the 110μm group (group B) with highest difference of -3.45um from the intended flap thickness. We found that the actual corneal flap was within 5 um from the intended flap in 60 % of patients in group A (100um thickness group) , 50 % in group B (110um thickness group) , 30% in **group C** (120um thickness group) , while the flap was within 10 um from the intended flap in 35 % in group A , 25 % in **group B** , 30 % in **group C**, while the flap thickness was within 20 um from the intended flap in 5 % of patients in **group A** , 25 % in **group B** , 40 % in **group C**.

In a previous study, the deviation of less than 5 μm in the wavelight FS200 group with intended flap of 110um was 57.72%. The deviation of more than 20 μm was 0.2% measurements [19]. According to these results corneal flaps in **group A** were more predictable and more accurate than **group C** and corneal flaps in **group C** was more predictable and more accurate than **group B.**

STUDY LIMITATIONS

The number of eyes was not conclusive being only 60 eyes. There was probably a selection bias due to the place of sampling being patients asking for LASIK in a private hospital with 2 different surgeons.

Capturing optical pachymetry measurements intraoperatively can be affected by small pupil size and opacities, such as an opaque bubble layer. This can increase the time it takes to capture a measurement, which could lead to drying of the

flap and RSB and artificially low measurements. This is only a short-term study of corneal flap thickness created by wavelight FS200 in three different thickness groups. Long-term outcomes needed to be done to explore the consequence of the different corneal flap created.

CONCLUSION

The corneal flaps made with the wavelight FS200 femtosecond laser were predictable more predictable in **group A** than **group C** and **B,** but with no statistical significance between the three studied groups.

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