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Corneal Flap Thickness Created by Two different types of femtosecond lasers (WaveLight FS200 and IntraLase FS60)

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ABSTRACT

Background: *The flap creation process is the most serious stage in LASIK surgery, and femtosecond laser was found to be more efficient and safer than mechanical microtome. However, comparison between different devices was not fully addressed.* ***Aim of the work:*** *to compare between Wavelight FS200 and Intralase FS60 as regard to corneal flap creation efficacy and safety.* ***Subjects and methods:*** *The trial included 180 subjects who underwent femtosecond laser for myopia. They were divided into two equal groups; the first included patients allocated for Wavelight FS200; and the second included those allocated for Intralase FS60. All patients underwent a full examination before LASIK surgery (uncorrected distance visual acuity, slit-lamp examination, topography of the cornea, visual acuity, examination of the fundus and ultrasonographic pachymetry). The flat applanation devices of femtosecond laser was used and programmed to a proposed flap thickness of 110 µm. Measurements of the flaps were carried out using RTVue OCT system.* ***Results:*** *the thickness of the flap was significantly thinner in Wavelight FS200 when compared to Intralase FS60. The maximum standard deviation of the mean thickness at different measurement points was ±2µm in Wavelight FS200 group and ±11.9µm in Intralase FS60 group. In addition, the mean flap thickness was significantly reduced in Wavelight FS200 when compared to Intralase FS60 (105.32±1.60 vs 108.86± 2.29 respectively). Finally deviation from intended corneal flap was ≤ 5.0µm in 68.9% of Wavelight group compared to 13.9% in Intralase group, and there was no significant correlation between average flap thickness and any of studied preoperative values, either in Wavelight FS200 or Intralase FS60 groups.* ***Conclusion:*** *Wavelight FS200 seems to be more effective in process of flap creation than IntraLase FS60, although both devices yielded a uniform, regular and planner flaps.*

Introduction

Laser-assisted in situ keratomileusis (LASIK) becomes the most extensively practiced ophthalmology procedure for treatment of myopia, hyperopia and astigmatism, as millions of subjects undergo LASIK each year worldwide. Thus, safety and effectiveness of LASIK are of significant interest for both the ophthalmologist and patients [(1)]**.** Different studies reported that, LASIK is an effective and safe procedure for management of myopia [(2-4)]**.**

The most critical phase in LASIK procedure is the flap creation as it affects the visual outcome of the LASIK procedure. Historically, the process of flap creation changed from mechanically manually-guided microkeratomes to automated microkeratomes, and recently by femtosecond laser [(5)]**.**

There are many FS lasers devices on the marketplace. They included IntraLase (Abbott Medical Optics Inc, Santa Ana, CA, USA), the first femtosecond laser device was announced in the US in 2001 [(6,7)]**;** the Technolas Femtosecond Workstation (Munich, Germany); the FEMTO LDV by Ziemer Ophthalmic Systems (Port, Switzerland), introduced in late 2005; the Visumax by Carl Zeiss Meditec AG (Jena, Germany), presented in second half of 2006 [(8,9)]**;** and the WaveLight FS200 (Alcon Laboratories, Inc., Fort Worth, TX, USA) approved by US FDA (food and drug administration) in 2010 [(10)]**.**

The femtosecond laser photodisruption process is working by two different concepts: low pulse rate (IntraLase and Femtec) and high pulse energy (FEMTO LDV and Wavelight FS200) in both methods, the laser spots generate a possible geometric shape or plane that is then manually dissected to complete the flap foundation process [(8)]**.** During creation of the flap, it is so important to yield a uniform flap with a slight standard deviation from the intended thickness [11-14]. Sufficient residual stromal bed (RSB) thickness is very important to decrease the occurrence of corneal ectasia [15, 16].

Aim of the work
The present series was accomplished to compare between Wavelight FS200 and Intralase FS60 femtosecond lasers as regards the creation of flap, the effect on thickness, safety and uniformity.

Materials and methods
Study area and method
The present study was conducted between January 2017 and January 2020. It included 180 patients who underwent femtosecond laser for correction of myopia. They were allocated into two equal groups (each 90 subjects; 180 eyes); the first group included those who planned to undergo Wavelight FS200; and the second group includes those who planned to undergo Intralase FS60. The protocol of the study was approved by the local research and ethics committee and an informed consent was obtained from all participants before inclusion of the study. Patients with one or more of the following were excluded from the study, diabetes and any other systemic disease affecting the eye, glaucoma, corneal scars, keratoconus, corneal dystrophies and previous ocular surgery.

All the patients underwent a full examination before LASIK surgery. This examination comprised uncorrected distance visual acuity, slit-lamp examination, topography of the cornea, visual acuity, examination of the fundus and ultrasonographic pachymetry. The femtosecond laser flat applanation devices were used and programmed to a planned flap thickness of 110 µm. In first group, the flap was produced by WaveLight FS200 femtosecond laser. The laser energy was 0.8 µJ with replication frequency of 200 kHz. The duration of pulse was about 350 femtoseconds. The line and spot separations were 8.0 µm. The side cut angle was 90^o, canal width was 1.5 mm, hinge width was 0.6 mm and hinge angle were 60^o. In the second group, the flap was created using IntraLase FS60 femtosecond laser. The laser energy was set at 0.75 µJ and the repetition frequency set at 60 kHz. The pulse duration was set between 600 and 800 femtoseconds. Superior hinged flaps were fashioned by 8.5 mm diameter. The line and spot separations were 8.0 µm. The side cut angle set at 90^o, hinge angle of 50^o. The start depth of the pocket is 180µm and the pocket width was 0.2 mm. Ablations were done by the Visx S4 excimer laser, after the flap was lifted up in the second group and Alcon WaveLight EX500 excimer laser in the first group with a 0.5-mm transition zone and 6.0-mm optical zone.

Measurements of the LASIK flaps were carried out using RTVue OCT system. The CAM-L scan configuration of the anterior module of the cornea to obtain scans of the cornea through a diameter of 8.0 mm for cross line analysis. The scan was centered on the vertex reflection, and 0^o, 45^o, 90^o, 135^o planes OCT pictures were obtained and analyzed 1wk after surgery. The thickness of the flap was measured at 9 points in each plane in 4 different OCT pictures (1.0, 2.0, 3.0 mm and center from the midpoint and the peripheral zone of the flap). Center was recognized as the range of ±0.5 mm from the apex of the flap and peripheral zone, as the range within ±0.5 mm from the edge of the flap edge.

Data analysis: numerical data were expressed as mean±SD, while categorical data were expressed as count and percent. All tests carried out by statistical package for social sciences, version 22 (IBM®, SPSS®, Chicago, USA). Independent samples student (t) -test was used to analyze data consistent with normal distribution. Chi square was used for non-numerical data (categorical data). A p value less than 0.05 was approved as a statistically significant.

Results
In the present study, patient age ranged from 24 to 35 years, and there was no significant difference between both groups (26.88±1.93 vs 27.32±2.34 years). In addition, there was no significant difference between both FS200 and FS60 group as regard to patient gender (males represented 40% and 44.4% respectively). Furthermore, both groups were comparable as regard to spherical equivalent, central corneal thickness and corneal curvature. However, there was statistically significant decrease of UCVA in FS60 when compared to FS200 (1.13±0.092 vs 1.31±0.09 respectively) one week after surgery (Table 1)

Table (2) represents corneal flap thickness in different meridians and at different distances from flap vertex, and at all these points, flap thickness is significantly thinner in Wavelight FS200 when compared to Intralase FS60. The maximum standard deviation of the mean thickness at different measurement points was ±2µm in Wavelight FS200 group and ±11.9µm in Intralase FS60 group, denoting that flap was uniform and regular in both groups. However, the flap in FS200 was more significantly regular and uniform

In addition, the average flap thickness was significantly reduced in Wavelight FS200 when compared to Intralase FS60 (105.32±1.60 vs 108.86± 2.29 respectively). Moreover, the mean central flap thickness was significantly lower in FS200 when compared to FS60 groups (105.05±1.72 vs 111.25±10.20 respectively). Finally, the mean central corneal flap thickness was significantly reduced in Wavelight FS200 when compared to Intralase FS60 (105.05±1.72 vs 110.93±0.982 respectively). Moreover, both mean flap deviation and mean central corneal flap deviation than intended flap was significantly lower in Wavelight FS200 than Intralase FS60. Finally, deviation from intended corneal flap was ≤ 5.0µm in 68.9% of Wavelight group compared to 13.9% in Intralase group (Table 3). There was no significant correlation between average thickness of the flap and any of studied preoperative values, either in Wavelight FS200 or Intralase FS60 groups (Table 4).

Table (1): Patient characteristics at inclusion of the study and UCVA after LASIK

Variable		Wavelight FS200	IntraLase FS60	Test	p
Age		26.88±1.93; 24-33	27.32±2.34; 24-35	1.35	0.17(ns)
Sex	Male	36(40.0%)	40(44.4%)	0.36	0.54(ns)
	Female	54(60.0%)	50(55.6%)		
SE		-5.68±1.52	-5.95±1.69	1.61	0.11(ns)
CCT (µm)		552.16±32.49	555.69±36.53	0.96	0.33(ns)
CC (D)		44.46±2.60	44.12±2.68	1.23	0.21(ns)
Intended flap (µm)		110	110	-	-
UCVA		1.31±0.09	1.13±0.092	***18.20***	***<0.001****

SE: spherical equivalent before LASIK; CCT: central corneal thickness; CC: corneal curvature: UCVA: uncorrected visual acuity

Table (2): Flap thickness in studied populations at different points of measurement

		-peri	-3mm	-2mm	-1mm	center	1mm	2mm	3mm	+peri
0°	FS200	106.1±1.7	104.1±1.6	105.1±1.7	104.1±1.6	105.1±1.7	104.1±1.6	106.1±1.7	105.1±1.7	106.1±1.4
	FS60	110.8±10.8	110.6±10.8	111.7±11.9	111.2±11.7	111.7±10.9	111.1±10.7	111.1±10.8	111.6±10.4	111.6±11.0
45°	FS200	106.1±1.7	104.9±1.7	105.2±1.8	104.1±1.5	105.1±1.7	104.8±1.8	106.1±1.7	105.7±1.9	106.1±1.5
	FS60	111.8±10.7	111.4±11.0	111.4±11.0	112.1±10.3	111.3±10.3	109.9±10.6	112.2±10.7	111.6±10.7	111.7±11.1
90°	FS200	106.2±1.8	104.9±1.8	105.2±1.9	104.1±1.5	105.1±1.7	104.8±1.8	106.1±1.8	105.7±2.0	106.2±1.5
	FS60	111.8±10.4	110.3±10.5	110.3±10.8	110.2±10.7	109.6±10.8	109.8±11.0	111.9±11.0	111.4±11.2	111.6±11.2
135°	FS200	106.3±1.9	105.0±1.8	105.3±1.9	104.2±1.6	105.2±1.7	104.9±1.9	106.1±1.8	105.8±2.0	106.4±1.6
	FS60	110.7±8.7	111.6±11.3	111.7±11.3	111.4±11.3	111.1±9.4	111.7±11.0	112.4±11.5	111.6±11.4	111.2±9.7

NB: in all measurements, there was significant decrease of corneal flap thickness in Wavelight FS200 when compared to corresponding measurement in intrLase FS60. ±1.0 mm: Point 1.0 mm from flap vertex; ±2.0 mm: Point 2.0 mm from flap vertex; ±3.0 mm: Point 3.0 mm from flap vertex; Center: Range of ±0.5 mm from flap vertex; ±Peri: Range within 0.5 mm from the flap rim (approximately 3.75 to 4.25 mm from flap vertex).

Table (3): Comparison between groups as regard to flap parameters

		Wavelight FS200	Intralase FS60	Test	p
Mean flap thickness		105.32±1.60	111.25±10.20	***7.68***	***<0.001****
Mean central flap thickness		105.05±1.72	110.93±9.82	***7.80***	***<0.001****
Mean flap deviation		4.67±1.60	9.44±3.99	***14.89***	***<0.001****
Mean central flap deviation		4.86±1.69	8.72±4.56	***16.64***	***<0.001****
Deviation from Intended flap	≤ 5.0µm	124(68.9%)	25(13.9%)	***162.8***	***<0.001****
	5.1-10.0 µm	55(30.6%)	55(30.6%)		
	10.1-15.0 µm	1(0.6%)	99(55.0%)		
	15.1-20.0 µm	0(0.0%)	1 (0.6%)		

Table (4): Correlation between mean flap thickness and preoperative data in each group

	Wavelight FS200		Intralase FS60	
	r	p	r	p
Corneal curvature	0.06	0.37	-0002	0.97
Central corneal thickness	0.19	0.11	-0.12	0.11
SE	-0.07	0.31	0.015	0.84
Age	0.04	0.71	0.03	0.77

Discussion

Femtosecond laser invention has reformed corneal refractive surgery and it is widely accepted all over the work. This wide acceptance returns to its flexibility, accuracy, safety and reproducibility. The creation of corneal flap during LASIK surgery remains the major application of femtosecond laser **[17,18].** Commercially, there are different machines of femtosecond laser, which are different in many aspects (such as pulse energy, pulse frequency, laser pattern, contact interface, and additional features), that can affect the process of flap creation. Flap shape, thickness, regularity and uniformity in different meridians remain a matter of the study **[19].** Thus, the present trial was done to investigate such parameters in patients underwent LASIK surgery by two different femtosecond lasers. The first is wavelight FS200 and Intralase FS60. It included 180 patients who were divided into two equal groups, one used wavelight FS200 (first group) and second group used Intralase FS60.

Results of the present work, revealed that, both groups were comparable as regard to patient characteristics, spherical equivalent before LASIK, central corneal thickness and corneal curvature. However, there was statistically significant decrease of UCVA in FS60 when compared to FS200 (1.13±0.092 vs 1.31±0.09 respectively) one week after surgery. In addition, flap thickness was significantly thinner in Wavelight FS200 when compared to Intralase FS60 at all meridians, and at different points of measurement, although both flaps were uniform and regular with significantly better regularity in Wavelight FS200 group.

A thin flap is preferable in LASIK surgery to ensure a thicker residual stroma, especially in myopic eyes. In addition, thinner flap reduced the interference of running nerves within the corneal stroma, with subsequent decrease of postoperative dry-eye [20]**.** Thus, the intended flap thickness in the present work was 110µm. However, the too thin corneal flap (<90 µm) may be associated with complications such as flap slippage, striae, irregular flap, buttonholes, and corneal haze [21-22]**.**

On the other hand, thicker flaps in treatment of myopia (>140µm) were considered too thick, and may associated with residual stroma, and leading to iatrogenic corneal ectasia [23,24]**.** The values of achieved corneal flap thickness in the present work did not reach both extremes (<90 µm or >140µm) ensuring the right selection of 110µm as an intended flap.

Results of the present trial are in agreement with **Liu *et al*.** [14] who reported that, the mean central thickness of the flap and the mean flap thickness in WaveLight FS200 group were thinner than in Intralase FS60 group. In addition, results of the present study are in accordance with previous work by **Kanellopoulos and Asimellis** [25] who reported that, the flap thickness variability (deviation than intended flap thickness) was reduced for the FS200 group than for the FS60 group. The FS200 flaps were more uniform, with an average thickness variability of 4.84 ± 1.88µm, whereas variability was 8.48 ± 4.23 µm for the FS60 group.

The possible explanation for such results can be due to the different intraoperative gas-venting methods and/or different – active (FS200) versus passive (FS60) – intraoperative suction techniques. In addition, differences in the stabilizing power to the cornea during flap creation, may also lead to tissue separation bias [25]**.**

Zhou *et al*. [26] conducted a study to estimate the thickness of flaps founded by the Intralase FS60 femtosecond and reported that Intralase flaps with an intended thickness of 110 were actually achieved a mean of 110.5±2.9µm. These results are better than that achieved in the present work. In addition, **Zhang *et al*.** [10] carried out another study to measure the flaps originated by the Intralase FS60 femtosecond laser and reported that Intralase flaps with an intended thickness of 110µmwere actually a mean of 109.34±7.57µm. These results are closer to the present work than results of Zhou *et al*. [12]

Interestingly, **Huhtala *et al*.** [5] carried out a meta-analysis compared many types of FS lasers for LASIK surgery and revealed that, there is no significant variability in the loss of ≥2 Snellen lines of CDVA, no significant difference in the mean spherical equivalent within ±0.5D between FS lasers. On the other hand, IntraLase and WaveLight SF200 had the least intraoperative complication; with the most frequent is the lamellar keratitis. IntraLase FS60 kHz, Visumax, and WaveLight FS200 never had postoperative complications.

In the present work, there was no statistically significant correlation between achieved mean corneal flap thickness and preoperative data. These results are comparable to those reported by **Kim *et al*.** [27] who reported that, no significant correlations were found between the actual thickness of the flap and preoperative variables. In addition, **Sutton and Hodge** [28] found that, there was no significant correlation between keratometry and mean thickness of the flap, or between preoperative pachymetry and mean flap thickness.

In the present work, flap was uniform and regular in both groups, with better results in Wavelight FS200 group. These results are comparable to previous works indicating the effectiveness and safety of femtosecond laser in general. The flaps created by femtosecond laser are more predictable and planner with low intra- and post-operative complications [29,30]**.**

Conclusion

In conclusion, both femtosecond laser devices were very effective and safe in flap making. However, WaveLight FS200 femtosecond laser has a statistically higher accuracy in planar flap creation. It was associated with more uniform and regular flap. No preoperative variables correlate with achieved mean flap thickness.

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