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Full Length Research Paper

Intraoperative Ultrasound versus Optical Coherence Tomography (OCT) for Estimation of Flap Thickness in LASIK Surgery

Akram Fekry Elgazzar and Riad Elzaher Hassan Ahmed
Department of Ophthalmology, Damietta Faculty of Medicine, Al-Azhar University, Egypt.

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Corresponding Author:
Akram Fekry Elgazzar
Department of Ophthalmology, Damietta Faculty of Medicine, Al-Azhar University, Egypt.

Background: *Leaving sufficient residual stromal bed thickness is mandatory after LASIK surgery. The flap creation is the main and most important step in LASIK surgery. However, the gold standard method for estimation of laser flap thickness (FT) is controversial.* ***Aim of the work:*** *to compare between intraoperative ultrasound pachymetry and postoperative optical coherence tomography (OCT) for estimation of FT.* ***Patients and methods:*** *The present trial included 20 patients (40 eyes) who scheduled for LASIK surgery to correct myopia. The study was conducted during March 2017 to March 2018. All the patients underwent a full examination before LASIK surgery. Pachymetry was carried out intraoperatively by the ultrasound pachymeter. After completion of each step, the measurements were repeated by a second surgeon. The optical coherence tomography was done by the Visante OCT at one week and at one month postoperatively.* ***Results:*** *The study included 20 patients, their age ranged from 22 to 32 years. Males represented 45%. Observers 1 and 2 reported non-significant differences. However, there was significant increase of FT by OCT at one week and at one month when compared to values registered by ultrasound. In addition, there was proportional (positive), statistically significant correlation between FT measured by ultrasound (intraoperatively) and each of values measured by OCT at one week and at one month.* ***Conclusion:*** *OCT may be a reliable and easily applicable method for estimation of flap thickness in LASIK surgery.*

Keywords: *Intraoperative, Optical Coherence Tomography, LASIK*

Introduction

Laser-assisted in situ keratomileusis (LASIK) is the most common ophthalmology procedure practiced to correct refractive errors [(1)]. The most critical step in LASIK process is the step of flap creation [(2)]. Leaving a sufficient corneal thickness is very important in LASIK surgery, as central corneal thickness is an indicator of healthy cornea [(3)], it is valuable for monitoring of pump function of corneal barrier and endothelium [(4-5)],

Ultrasound pachymetry is the gold standard for measurement of central corneal thickness with advantages of being so easy, fast and suitable to obtain several repeated measures to minimize the error [(6)]. In addition, ultrasound pachymetry had high degree of reproducibility either for intra-operator, inter-operator or inter-instrument [(7)]. However, it is a contact process. It needs contact with the cornea and utilizes the Doppler Effect to estimate the thickness [(5)].

On the other hand, anterior segment-optical coherence tomography (AS-OCT) had the advantages of being non-invasive, non-contact techniques, working by the interferometry principle to detect minute differences in tissue depth. AS-OCT offers a high-resolution, cross-sectional imaging of the cornea with central and peripheral (regional) pachymetry and goniometry of irido-corneal angle [(6)].

Reviewing the literature, there are very few studies comparing between flap thicknesses measurements by ultrasound pachymetry versus AS-OCT. Thus, in this prospective study flap thickness (FT) measurements of AS-OCT was compared with conventional ultrasonic pachymetry.

Patients and methods

The present trial included 20 patients (40 eyes) who underwent LASIK surgery for correction of myopia in the period from March 2017 to March 2018.

The study protocol was approved by the local research and ethics committee of Al-Azhar University, Faculty of Medicine (New Damietta). Before inclusion in the study, the study protocol was explained for each patient separately, and an informed consent was signed by each patient.

Inclusion criteria included: 1) Patients with – 1.25 to -8.5 diopters (D) of spherical myopia and up to -1.5 D for astigmatism; 2) stable refraction for the previous year before surgery.

All the patients underwent a full examination before LASIK surgery. This examination consisted of measurement of uncorrected distance visual acuity, slit-lamp examination, topography of the cornea, visual acuity, examination of the fundus and ultrasonographic pachymetry. All LASIK surgeries were performed without complications, by the WaveLight ALLEGRETTO Eye-Q laser system (WaveLight Inc, Sterling, Va) and microkeratome (Advanced Medical Optics Inc., Santa Ana, CA, USA). The intended FT was set to 110µm. Pachymetry was carried out intraoperatively by the ultrasound pachymeter (SP-100; Tomey Corp, Nagoya, Japan) of central cornea before the microkeratome cut and after lifting of the flap. If excess fluid on the ocular surface was found, it was removed by a dry merocel sponge, before the application of suction ring. Then, ultrasound pachymeter was used to contact the central corneal surface in a perpendicular plane and measurements were repeated until three consecutive measurements with a variation <5µm were obtained. Five drops of balanced salt solution were applied for lubrication of the corneal surface when suction activated. Then, the microkeratome cut was carried out, and the flap was lifted. By a similar maneuver, measurements of central corneal bed thickness were obtained. The average of the three measurements was used for analysis. The difference of the two readings represented the central FT. These measurements were averaged and the average was included in the subsequent analysis. After completion of each step, the measurements were repeated by a second surgeon and documented. The OCT was done by the Visante OCT (Carl Zeiss Meditec, Jena, Germany). OCT was carried out by obtained two high resolution "high res corneal" scans for each eye by an examiner who was not included in the subsequent FT analysis. The examination enclosed 10 mm in length and 3 mm in depth and 512 axial scans. Before conduction of the scan, polarization was adjusted manually. The data was then analyzed to give a compound image. Images were stored for later analysis. The OCT examination was repeated after 1 weak and 1 month postoperative by the same examiner. Each scan was investigated by two different researchers. Both were blinded to the examination of the other and blinded to intraoperative ultrasound measurements, and each of them examined the images independently.

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). Kolmogorov-Smirnov test was used to test normality of means and standard deviations. When data were normally distribution, the two tailed independent samples student (*t*) -test was used. Chi square was used for non-numerical data (categorical data). Correlation between measurements was estimated by Pearson's correlation coefficient, and Bland-Altman plots were constructed to estimate the agreements between measurements. The limits of agreement were defined as the mean difference of two measurements± (1.96 * standard deviation). A p value less than 0.05 were approved as a statistically significant.

Results

Table (1) presented the preoperative data of studied populations; it included 20 patients, their age ranged from 22 to 32 years, the mean (±SD) age was 26.35 (±2.79) years. Males represented 45% (9 patients). The preoperative sphere ranged from -7.0 to -2.5, the mean was -4.83±1.3 (D), while preoperative astigmatism ranged from -1.5 to -0.10, the mean was -0.74±0.31 (D). Table (2) showed the central corneal thickness (CCT) and FT measurement by intraoperative US and postoperative OCT at one week and one month, and revealed that, there was significant difference between observer 1 and observer 2 as regard to any of measurements. However, there was statistically significant increase of FT measured by OCT at one week and at one month when compared to values registered by ultrasound. The difference between OCT at one week and at one month was not significant either for observer 1 or 2. In the present study, there was proportional (positive), statistically significant correlation between FT measured by ultrasound (intraoperatively) and each of values measured by OCT at one week and at one month. On the other hand, there was inverse (negative) significant correlation between ultrasound-OCT difference and each of OCT at one week and at one month postoperatively (Table 3). The 95% confidence interval of the level of agreement of FT between ultrasound and OCT one month postoperatively was (-2.61 to -14.47), while for OCT (one week, one month), it was -4.07 to 4.35) (Figures 1 and 2).

Table (1): Preoperative data of studied populations

		Statistics
Age		26.35±2.79; 22-32
Sex	Male	9(45.0%)
	Female	11(55.0%)
Preoperative sphere		-4.83±1.33; -7.0 to -2.5
Preoperative astigmatism		-0.74±0.31; -1.5 to -0.10

Table (2): FT at different points by the two observers

	Observer (1)	Observer (2)	t	p
CCT	538.85±26.95	538.77±27.27	0.01	0.99(ns)
Flap thickness (US)	108.90±2.39	109.17±2.69	0.48	0.63(ns)
Flap thickness (OCT 1 week)	123.80±6.33#	123.37±5.98#	0.30	0.75(ns)
Flap thickness (OCT 1 month)	123.65±6.80#	123.23±6.97#	0.26	0.79(ns)
Difference between two OCT measurements	0.15±2.16	0.13±2.16	0.03	0.97(ns)

Mean value of OCT measurements	123.72±6.48	123.30±6.41	0.28	0.77(ns)
Ultrasound- OCT difference	-14.82±6.06	-14.13±6.10	0.51	0.61(ns)
Mean value of OCT and US measurements	116.31±3.83	116.24±3.85	0.08	0.93(ns)

#: significant increase of OCT and pachymetry FT.

Table (3): Correlation between OCT and ultrasound FT

	OCT at one Week		OCT one month		US-OCT difference	
	r	p	r	p	r	p
Flap thickness (US)	0.23	0.044*	0.42	<0.001**	0.06	0.56
OCT at one week			0.95	<0.001**	-0.95	<0.001**
OCT at one month	0.95	<0.001**			-0.87	<0.001**
US-OCT difference	-0.950	<0.001**	-0.870	<0.001**		

** Significant difference at p < 0.05, and ** significant difference at p value < 0.01*

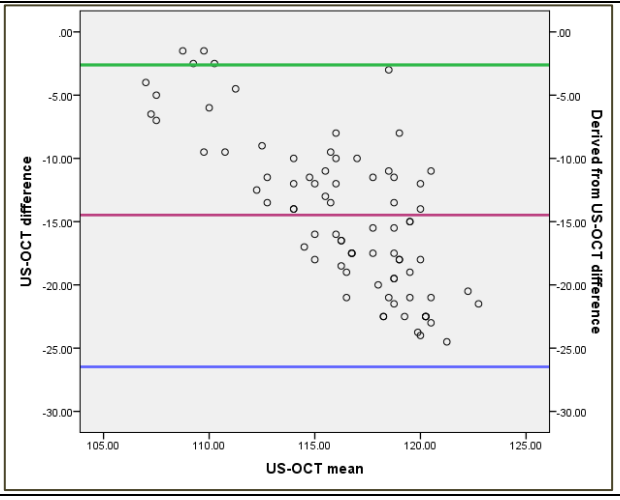

Fig (1): Bland-Altman plot of ultrasound- OCT at one month difference, against the mean of ultrasound and OCT at one month. Horizontal lines denote mean and 95% limits of agreement.

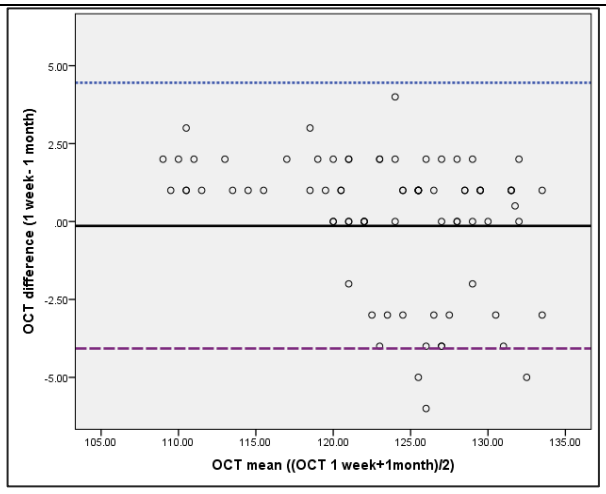

Fig (2): Bland-Altman plot of OCT at one week and at one month difference, against the mean of OCT at one week and at one month.

Discussion

The flap creation is the most important step of LASIK surgery aiming to leave sufficient residual stromal bed thickness ≥ 250µm to prevent the development of keratectasia after surgery [8-10]. The residual stromal bed thickness of cornea is usually calculated by subtracting the expected flap thickness (FT) from the CCT by ultrasound pachymetry [11-12], and subtracting stromal bed thickness from corneal thickness equals the FT, which can be also measured by OCT postoperatively [13].

Intraoperative pachymetry had many disadvantages; 1) the risk of contamination by the direct contact of ultrasound probe to the stromal bed; 2) less precession associated with the manual application of the two measurements. In addition, the values of flap and stromal bed thickness may be not available when needed at a subsequent time for planning for repeated surgery or avoidance of complications. On the other hand, OCT is non-contact method of measurement, with advantages of easy use, ability to evaluate the morphology of the flap, precise FT measurement and better visualization of flap-stromal bed interface [14,15]. However, studies comparing both techniques of measurements are scarce.

The present study was designed to measure the FT estimated by two different methods (intraoperative pachymetry and postoperative OCT), and to investigate inter-observer variability of both techniques. Results of the present work revealed that, values of FT measured by OCT up at one week and one month postoperatively were significantly increased when compared to values registered by intraoperative ultrasound both for observer 1 (123.80± 6.33, 123.65 ± 6.80 vs 108.90 ± 2.39 respectively) and observer 2 (123.37 ± 5.98, 123.23± 6.97 vs 109.17± 2.69 respectively). No significant difference was found between observer 1 and observer 2 for any of registered measurements.

Results of the present work are comparable to those reported by **Cheng et al.** [16] who reported that, there was statistically insignificant difference among the interobserver OCT measurements and good agreement between the two scans interpreted by the two observers was noted, and the OCT FT was significantly thicker than by ultrasound. In another study, **Li et al.** [17] showed that the central FT in 24 eyes was 143±14 µm by OCT and 131±17 µm by ultrasound 1 week after LASIK. The ultrasound FT was thinner than intended which in agreement with previous studies [18-20]. For example, **Rocha et al.** [18] found the FT was 107.2±14 µm, which they used

AMADEUS with, intended FT of 140 µm. On the other hand, **Jackson et al.** [21] found a mean FT of 153.0±18.0 for intended FT of 140 µm. This contradiction can be explained by many factors affect corneal FT during LASIK surgery including the model of microkeratome, thickness of the plate, mean preoperative pachymetry, the order of surgery steps, the serial number of the head, the lot number of the blade and the surgeon experience [22- 23].

In the present work, the 95% level of agreement of FT between ultrasound and OCT one month postoperatively was (-2.61 to -14.47), while for OCT (one week, one month), it was -4.07 to 4.35). These results mean that, there was low discrepancy between OCT and ultrasound. However, the agreement between OCT measurements is better than that of US-OCT. These results are in contradiction to that reported by **Sun et al.** [14] who reported that, there was wide discrepancy between OCT and ultrasound FT measurements (-5.40 to 42.10), and they explain their results by hydration shift of cornea, with increased water content in the corneal stromal bed just before application of ultrasound probe. Thus corneal bed thickness measured at this time is larger than the actual value. This explains the statistically significant decrease of ultrasound than OCT flap thickness in the present work.

On the other hand, after cutting of corneal flap, it is under low tensile strain and will absorb water and become thicker [24-26]. In addition, epithelial hyperplasia after LASIK for myopia [27] could be a contributing factor. Both these factors participate in thicker FT measured by postoperative OCT at one week and at one month.

Furthermore, **Dawood et al.** [28] reported that, there were no significant changes in FT for up to one month after LASIK surgery using Fourier-domain OCT.

In summary, results of the present work revealed that, OCT is a reliable and easily applicable method for estimation of FT in LASIK surgery. It could substitute the intraoperative ultrasound pachymetry.

Conflict of interest: none

Financial disclosure: none to disclose

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