• Clinical Research •

Changes in corneal biomechanics and intraocular pressure following Femto-LASIK using Goldman applanation tonometry and ocular response analyzer

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Abstract
● **AIM:** To compare intraocular pressure (IOP) measurements before and after laser *in situ* keratomileusis (LASIK) with a femtosecond laser for flap creation using ocular response analyzer (ORA) and Goldmann applanation tonometry, and to identify factors that may influence the preoperative and postoperative IOP.

● **METHODS:** A prospective study conducted on myopic patients who underwent LASIK using a femtosecond laser for flap fashioning. Enrolled patients were evaluated preoperatively, 6wk and 3mo postoperatively for manifest refraction (MR), keratometric (K) readings and central corneal thickness (CCT) using a scheimpflug-based topography. Corneal resistance factor (CRF), corneal hysteresis (CH), Goldmann correlated IOP (IOPg) and corneal compensated IOP (IOPcc) were measured using ORA besides IOP assessment by Goldman applanation tonometry (GAT).

● **RESULTS:** There was a statistically significant decrease in measures of IOPg by 3.35±0.83 mm Hg, followed by GAT which decreased by 2.2±0.44 mm Hg, and the least affected by operation was IOPcc which decreased only by 0.87±0.1 mm Hg after 6wk. After 3mo follow up there was a statistically significant decrease in IOPcc which decreased only by 0.76±0.4 mm Hg, followed by IOP GAT by 1.6±0.5 mm Hg, and the most affected by operation was IOPg which decreased by 2.3±0.3 mm Hg. Correspondingly, there was a statistically significant decrease in CH and CRF after 6wk and 3mo. At 3mo, the preoperative MR and preoperative GAT were prominent significant predictors of the postoperative GAT changes. The prediction equation was subsumed.

● **CONCLUSION:** IOP measurements and corneal biomechanical factors reduce significantly after LASIK with a femtosecond laser for flap creation. The IOPcc values are less influenced by changes in corneal properties than IOPg and GAT, indicating that IOPcc may provide the most reliable measurement of IOP after this procedure.

● **KEYWORDS:** intraocular pressure; laser *in situ* keratomileusis; femtosecond laser; ocular response analyzer; corneal biomechanics; myopia
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INTRODUCTION

Intraocular pressure (IOP) is deemed the most adjustable, substantial risk factor in developing and diagnosis glaucoma[1-2]. Additionally, myopia is another risk factor predominately the high degrees more than 6.00 D and thus those patients are potentially glaucoma suspects[3]. Several studies have documented the alteration in the corneal viscoelastic characteristic after refractive surgery attributing to the corneal flap, altered corneal curvature, decreased corneal hysteresis and corneal thinning[4-5]. This alteration affects the IOP measurement *via* either Goldman applanation tonometry (GAT) or noncontact tonometry. Since any tonometry depends on the corneal biomechanical properties, it yields to uneven falsely measurements before and after the surgery, even if the real IOP is unaltered[6-7]. The ocular response analyzer (ORA) is an

Table 1 Comparisons of manifested refraction, corneal biomechanics, and IOP measure before and after intervention with Femto-LASIK among study group mean±SD

Variables (*n*=40)	Before	After 6wk	After 3mo	*P*
MR, D	-4.85±1.9	-0.48±0.39	-0.54±0.5	<0.001[a], 0.01[b]
CCT, μm	564.6±32.3	405.6±35.4	406.7±35.1	<0.001[a], 0.01[b]
CH, mm Hg	10.56±1.2	8.1±1.3	8.2±1.3	<0.001[a,b]
CRF, mm Hg	11.01±1.9	7.84±1.7	7.9±1.6	<0.001[a,b]
IOPg	14.22±4.03	10.87±3.2	11.92±2.9	<0.001[a], 0.6[b]
IOPcc	14.39±3.2	13.52±3.1	13.63±3.1	<0.001[a], 0.42[b]
GAT	13.5±2.8	11.30±2.4	11.90±1.9	<0.001[a], 0.3[b]

MR: Manifested refraction; CCT: Central corneal thickness; CH: Corneal hysteresis; CRF: Corneal resistance factor; IOPg: Goldmann correlated intraocular pressure; IOPcc: Corneal correlated intraocular pressure; GAT: Goldman applanation tonometry. [a]Before *vs* after 6wk of Femto-LASIK; [b]6wk *vs* 3mo of Femto-LASIK.

appliance, applied for IOP measurement, it provides elaborated data of corneal biomechanics in terms of corneal resistance factor (CRF) and corneal hysteresis (CH). Thus it seems to be more precise than GAT[5].

Research has disclosed that the transient increased IOP during corneal flap creation significantly affects the ocular blood flow and the retinal vascular perfusion. The limit at which the flow cessation completely relies on both IOP level and as well as blood pressure[8-9]. Therefore, an appropriate IOP monitoring after refractive surgery is pivotal for the early diagnosis of glaucoma. Given the wide prevalence of refractive surgeries and the frequency of glaucoma, it is critically compulsory to estimate the impacts of a laser *in situ* keratomileusis (LASIK) refractive operation on IOP values. Consequently, we conceived this study to compare the IOP measurements before and after LASIK with a femtosecond laser-assisted flap creation (Femto-LASIK) using ORA and GAT and as well to specify predictor factors that may affect IOP before and after the surgery.

SUBJECTS AND METHODS

Ethical Approval The study was designed as a prospective cohort interventional study conducted on 40 eyes of 20 myopic patients underwent Femto-LASIK. Before conducting the study, the study protocol and informed consent were approved by the Ethical Committee of the Faculty Of Medicine, Fayoum University, Egypt (IRB: M188). The Universal Trial Number (UTN) is U1111-1234-4096.

Patients with glaucoma, previous corneal surgery, keratoconus or forme fruste keratoconus, trauma, diabetic eye diseases, connective tissue diseases, pregnancy, and lactation were excluded from the study. Enrolled patients were evaluated preoperatively, 6wk and 3mo postoperatively for manifest refraction (MR), keratometric (K) readings and central corneal thickness (CCT) using a scheimpflug-based topography (Oculus pentacam, Wetzlar, Germany). CRF, CH, Goldmann correlated IOP (IOPg) and corneal compensated IOP (IOPcc) were measured using ocular response analyzer (ORA; Reichert, Inc., Depew, NY, USA) besides IOP assessment by GAT.

The flaps were created by a femtosecond laser apparatus (IntraLaseiFS, abbottMedica Optics, USA). LASIK procedures were performed by a wavefront-optimized ablation excimer laser (WaveLight Allegretto, Alcon, Fort Worth, Texas, USA). After LASIK, patients used topical antibiotics and steroids (gatifloxacin 0.3%, prednisolone acetate 1%) 4 times daily for 1wk then discontinued, furthermore, topical lubricants were used for 3mo.

Statistical Analysis Data were collected and coded in an Excel sheet to facilitate data manipulation. Data analysis was performed using IBM SPSS software (version 20.00, SPSS, Chicago, IL, USA). For qualitative data, the simple descriptive analysis in the form of numbers and percentages performed. For quantitative parametric data, independent *t*-test and paired *t*-test used to compare between two groups, while one way ANOVA test used in comparing more than two groups. Bivariate Pearson correlation test applied to show the association between variables and general linear model to compare the repeated measures. The *P*-value less than 0.05 was considered the cut-off point for test significance.

RESULTS

Twenty patients (40 eyes) included in the current study with the mean age of 25.3±3.7y. The baseline mean MR among the study group was -4.85±1.9 D ranged between -2 and -7 D and the mean CCT was 564.6±32.3 μm ranged between 509 μm and 605 μm. There was a statistically significant decrease in MR and CCT after 6wk and 3mo (*P*<0.05; Table 1).

Regarding K-readings, the mean K1 was 43.2±1.1 D ranged between 41.3 and 45.2 D, and mean K2 was 44.1±0.91 D ranged between 42.7 and 45.8 D. There was a statistically significant decrease in K1 by 3.88 D after 6wk and 3.78 D after 3mo, significant decrease in K2 by 3.77 D at 6wk and by 3.61 D after 3mo (Figure 1).

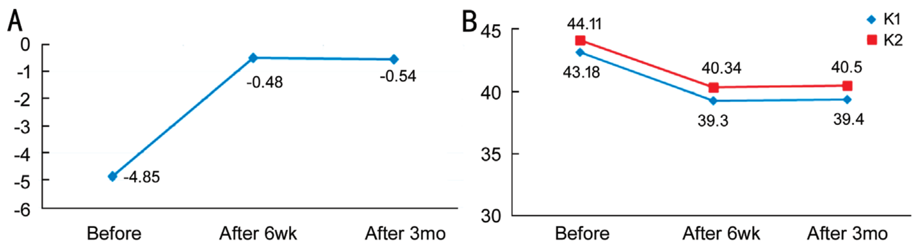

Figure 1 The changes in the study parameters 6wk and 6mo after Femto-LASIK A: Mean manifested refraction measure; B: Mean K1 and K2.

Table 2 Comparisons of changes in IOP readings between different devices among study group mean±SD

Variables (*n*=40)	Absolute change, 6wk	Average change after 6wk	Absolute change, 3mo	Average change after 3mo
IOPg, mm Hg	-3.35±0.83	-23.56%±5%	-2.3±0.30	-16.17%±5.2%
IOPcc, mm Hg	-0.87±0.1	-6.94%±3%	-0.76±0.4	-5.28%±2.6%
GAT, mm Hg	-2.2±0.44	-16.29%±4%	-1.6±0.50	-11.85%±3.5%
P	<0.001	<0.001	0.01	<0.001

IOPg: Goldmann correlated intraocular pressure; IOPcc: Corneal correlated intraocular pressure; GAT: Goldman applanation tonometry.

The mean IOPg was 14.22±4.03 mm Hg ranged between 10.3 and 17 mm Hg, mean IOPcc was 14.39±3.2 mm Hg ranged between 11 and 18 mm Hg, and mean GAT was 13.5±2.8 mm Hg ranged between 10 and 16 mm Hg. There was a statistically significant decrease in IOPg, IOPcc, and GAT measures after 6wk and 3mo. The mean CH was 10.6±1.2 mm Hg ranged between 8.4 and 13.7 mm Hg, and mean CRF was 11.01±1.9 mm Hg ranged between 7.9 and 15.2 mm Hg. Correspondingly, there was a statistically significant decrease in CH and CRF after 6wk and 3mo (Table 1).

Table 2 shows the IOP changes between different devices among the study group. There was statistically significant much decrease in IOP measures after 6wk in IOPg by 3.35±0.83 mm Hg (23.56%±5% reduction), followed by GAT which decreased by 2.2±0.44 mm Hg (16.29%±4% reduction), and the least affected by operation was IOPcc which decreased only by 0.87±0.1 mm Hg (6.94%±3% reduction). After 3mo follow up there was statistically significant in IOPcc which decreased only by 0.76±0.4 mm Hg (5.28%±2.6% reduction), followed by GAT by 1.6±0.5 mm Hg (11.85%±3.5% reduction), and the most affected by operation was IOPg which decreased by 2.3±0.3 mm Hg (16.17%±5.2% reduction).

Preoperatively, there was a statistically significant negative correlation between IOPg, MR, and K2 (*P*=0.004 and 0.005 respectively) which indicated the decrease in MR, and K2 associated with an increase in IOPg. Also, there was a statistically significant positive correlation with between IOPg, CH, and CRF (*P*<0.001) which indicated an increase in CH and CRF associated with an increase in IOPg before Femto-LASIK intervention. As regard IOPcc, there was a statistically significant negative correlation between IOPcc, MR, K1 and K2 (*P*<0.001, 0.01, and <0.001 respectively) which indicated a decrease in MR, K1and K2 associated with an increase in IOPcc. Also, there was a statistically significant positive correlation between IOPcc with CRF (*P*<0.001) which indicated an increase in CRF will associate with an increase in IOPcc before Femto-LASIK intervention. The preoperative GAT showed a statistically significant negative correlation with MR, K1 and K2 (*P*=0.004, 0.007, and <0.001 respectively) which indicated a decrease in MR, K1 and K2 will associate with an increase in GAT. While it showed a statistically significant positive correlation with CCT (*P*=0.004).

At 6wk, there was a statistically significant positive correlation between IOPg, CH, and CRF (*P*<0.001). IOPcc showed a statistically significant negative correlation with MR, K1, and K2. Also, there was a statistically significant positive correlation between IOPcc and CRF. As regard GAT, there was a statistically significant negative correlation between it and MR, and K2. There was a statistically significant positive correlation between GAT and CCT (Table 3).

After 3mo, there was a statistically significant positive correlation between IOPg and CH and CRF. IOPcc showed a statistically significant negative correlation to K1 and K2. Also, there was a statistically significant positive between IOPcc and CRF. As regard GAT, there was a statistically significant negative correlation between it and K1 and K2. There was a statistically significant positive correlation between GAT and CCT (Table 3).

The linear regression model analysis was conducted to explore the prediction power of different variables to IOPg, and IOPcc, it illustrates that there were statistical significance predictors of IOPg to CH and CRF measure. It illustrated that there were statistical significance predictors of IOPcc to preoperative CH, CRF measure, and IOPcc (Table 4).

The linear regression model analysis was also conducted to explore the prediction power of different variables to GAT, it

Table 3 Correlation between IOP with other preoperative variables after Femto-LASIK at 6wk and 6mo

Variables	After 6wk from Femto-LASIK						After 3mo from Femto-LASIK					
	IOPg		IOPcc		GAT		IOPg		IOPcc		GAT	
	R	*P*	*R*	*P*	*R*	*P*	*R*	*P*	*R*	*P*	*R*	*P*
MR, D	-0.12	0.3	-0.33	0.002	-0.30	0.007	-0.07	0.5	-0.17	0.1	-0.17	0.1
CCT, μm	-0.09	0.7	0.04	0.7	0.55	<0.001	0.006	0.7	0.005	0.9	0.64	<0.001
CH, mm Hg	0.44	<0.001	-0.03	0.8	-0.09	0.4	0.45	<0.001	-0.07	0.5	0.007	0.8
CRF, mm Hg	0.83	<0.001	0.45	<0.001	-0.08	0.5	0.79	<0.001	0.38	<0.001	0.006	0.7
K1, D	-0.09	0.4	-0.39	<0.001	-0.21	0.06	-0.15	0.2	-0.41	<0.001	-024	0.03
K2, D	-0.09	0.4	-0.39	<0.001	-0.23	0.04	-0.13	0.3	-0.39	<0.001	-0.23	0.03

MR: Manifested refraction; CCT: Central corneal thickness; CH: Corneal hysteresis; CRF: Corneal resistance factor; IOPg: Goldmann correlated intraocular pressure; IOPcc: Corneal correlated intraocular pressure; GAT: Goldman applanation tonometry.

Table 4 Liner regression analysis to determine the prediction power of different variables for IOPg and IOPcc among study group

Measures	IOPg 3mo			IOPcc 3mo		
	B coefficient	Standard error	*P*	*B* coefficient	Standard error	*P*
Constant	7.4	1.5	<0.001	7.4	2.6	0.006
Pre MR	0.03	0.06	0.7	0.07	0.07	0.4
Pre CH	-1.5	0.2	<0.001	-1.1	0.3	0.002
Pre CRF	1.8	0.2	<0.001	0.7	0.3	0.009
Pre IOPg	0.04	0.08	0.7	-	-	-
Pre IOPcc	-	-	-	0.69	0.1	<0.001

MR: Manifested refraction; CCT: Central corneal thickness; CH: Corneal hysteresis; CRF: Corneal resistance factor; IOPg: Goldmann correlated intraocular pressure; IOPcc: Corneal correlated intraocular pressure; GAT: Goldman applanation tonometry. Prediction equations: IOPg=7.4+(-1.5×CH)+(1.8×CRF); IOPcc =7.4+(-1.1×CH)+(0.7×CRF)+(0.69×pre-IOPcc).

illustrates that there were statistical significance predictors to preoperative MR and GAT measure (Table 5).

Table 5 Liner regression analysis to determine the prediction power of different variables for IOP (GAT) among study group

Measures	GAT 3mo		
	B coefficient	Standard error	*P*
Constant	5.6	4.1	0.2
Pre MR	0.31	0.05	<0.001
Pre CCT	-0.002	0.003	0.4
Pre mean K	-0.06	0.08	0.5
Pre GAT	0.77	0.03	<0.001

MR: Manifested refraction; CCT: Central corneal thickness; IOP: Intraocular pressure;GAT: Goldman applanation tonometry. Prediction equation: GAT=5.6+(0.31×MR)+(0.77×pre-GAT).

DISCUSSION

GAT, the golden standard for IOP measurement, theoretically requires a regular spherical ocular surface with an exemplary CCT measured 520 micrometers to flatten a 3.06 mm of the corneal surface. As expectant, after LASIK, the IOP (GAT) reduces than the baseline values according to CCT changes[10-11].

There is a robust correlation between the IOP changes, corneal thickness changes, and the ablation depth. Corneal ablation causes a steady reduction in the tonometric measurement by about 1.6 mm Hg either in myopic or hyperopic ablations, however, myopic patients may exhibit an extra decrease in IOP values by 0.029±0.003 mm Hg owing to the central corneal ablation[12].

The changes in IOP values are incompatible from one study to another. Some studies reported a trivial change[13] while others recorded IOP reduction of more than 5 mm Hg[14]. Most of the previous studies revealed the underestimation in IOP values after LASIK[15-16], while few studies investigated the biomechanical changes after the femtosecond laser which has been accessible for flap creation in LASIK procedure[5,17-18].

Even though the baseline IOPg, IOPcc, and GAT did not exhibit a significant difference in our study, the postoperative IOP values were considerably different, that elucidates the pivotal impact of LASIK on IOP. Our study demonstrated that refractive surgery causes a significant lowering of IOP by diverse degrees between the different devices at 3mo. IOPcc reduced by 0.76 mm Hg, GAT reduced by 1.6 mm Hg, and IOPg reduced by 2.3 mm Hg.

Consistency with our results, Shin *et al*[5] established that significant variation in postoperative IOPg, IOPcc, and GAT. The absolute changes and percentage changes in GAT and IOPg were super than changes in IOPcc after Femto-LASIK. They have concluded comparable results for our results with convergent percentage changes. While Hosny *et al*[19] reported a significant decline in the postoperative IOP GAT by 5 mm Hg and in IOPcc by 2.9 mm Hg after femto small incision lenticule extraction (SMILE) surgery.

In the present study, by 3mo, there was a statistically significant decrease in CH and CRF by 2.36 mm Hg and 3.11 mm Hg respectively. Our results coincided with Hosny *et al*[19] who found a significant decline in both CH and CRF after the SMILE procedure, they concluded this decline was directly proportionate to the lenticule thickness. As well, Dou *et al*[20] found that the postoperative CH and CRF decreased considerably in both SMILE and LASEK groups after surgery. However, CH values increased at 3mo after surgery. Contrastingly to our findings, Uzbek *et al*[18] concluded an insignificant change in both CH and CRF after femtosecond laser-assisted flap creation. They deduced that the changes might be chiefly due to laser ablation and so femtosecond laser-assisted flap creation may prompt biochemical changes linked to the lowering in corneal stiffness.

Currently, there was a statistically significant decrease in CCT with a statistically significant positive correlation with between GAT and CCT after Femto-LASIK intervention. In agreement with our results, two other previous studies concluded a significant correlation between preoperative GAT and CCT[5,19]. Contrastly, Vandewalle *et al*[21] founded that IOP readings from Icare tonometer were in accordance with those from GAT, whereas there was no correlation between the IOP measurements and CCT.

In our study, there was a positive correlation between IOPg and CH, CRF before and after Femto-LASIK surgery and positive correlation between IOPcc and CRF before and after Femto-LASIK surgery. As well, the preoperative MR and preoperative GAT were powerful predictors of GAT at 3mo. The linear regression model analysis revealed that preoperative CH and preoperative CRF were significant predictors to IOPg whereas preoperative CH, preoperative CRF, and preoperative IOPcc were also influential predictors to IOPcc at 3mo. Comparably, Shin *et al*[5] founded that the preoperative CH and CRF significantly predicted postoperative IOPcc and IOPg values.

We postulated prediction paradigm for post-LASIK IOP by theoretical prediction equations. Creation of a prediction model is important but it yields little additional clinical values except if there is confirmation through validation studies. So our initial formerly results for predicting the IOP changes after LASIK require further argument by rigorous randomized controlled clinical trials to minimize the bias towards a particular device.

One limitation of our study is the lack of comparing IOP measurements using dynamic contour tonometry (DCT) with that of GAT because of the unavailability of the device. DCT is a relatively new IOP measuring device, designed to be less affected by CCT or corneal curvature and assumed to be an accurate method of IOP measurement in patients undergoing refractive surgeries[22]. Hence, this is possible to be motivating for a future study to compare the pressure measurements of the three devices (GAT, ORA, and DCT).

In conclusion, IOP measurements and corneal biomechanical factors reduced significantly after Femto-LASIK. The IOPcc values were less influenced by changes in corneal properties than were IOPg and GAT, indicating that IOPcc may provide the most reliable measurement of IOP after this procedure. We further identified factors that may predict the postoperative IOP measurements and changes. However, there is a necessity for further studies with a larger sample size to validate this theory.

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