

Intraocular Pressure Changes in Myopic Patients Undergoing Laser *In-Situ* Keratomileusis and Photorefractive Keratectomy

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ABSTRACT

Objective: To assess the variation in intraocular pressure measurements between Ocular Response Analyzer (ORA) and Goldmann Applanation Tonometer (GAT) in myopic patients undergoing laser assisted *in-situ* keratomileusis (LASIK) and photorefractive keratectomy (PRK).

Study Design: Quasi-experimental study.

Place and Duration of the Study: Armed Forces Institute of Ophthalmology (AFIO), National University of Medical Sciences, Rawalpindi, Pakistan, between September 2020 and 2021.

Methodology: Myopic patients undergoing LASIK and PRK during the study period were selected. Baseline examinations and postoperative follow-ups were carried out to measure intraocular pressure at 1, 3, and 6 months after LASIK or PRK, using Goldmann Applanation Tonometer (GAT) and Ocular Response Analyzer, corneal compensated IOP (ORA IOPcc).

Results: One hundred and thirteen eyes underwent myopic refractive surgery, LASIK (n = 60) or PRK (n = 53). Mean age of patients was 23.6 ± 4.11 years in the PRK group and 24.4 ± 5.94 years in LASIK group. For the PRK group, the GAT IOP value increased at 1-month ($p < 0.001$), decreased at 3-month ($p < 0.001$) and further decreased at 6-month ($p < 0.001$) follow-up postoperatively. In the LASIK group, the GAT IOP value decreased at all time points ($p < 0.001$). In both groups, the mean ORA IOPcc value increased at 1 month ($p < 0.001$), decreased at 3-month ($p < 0.001$) and further decreased at 6-month ($p < 0.001$) follow-up postoperatively. The IOP mean values were generally found to be higher when measured using ORA as compared with GAT.

Conclusion: Corneal refractive surgery markedly decreased IOP. This decrease in IOP was observed more after LASIK than after PRK. ORA was less likely to underestimate the intraocular pressure than GAT.

Key Words: Myopia, Laser *in-situ* keratomileusis, Photorefractive keratectomy, Tonometry ocular, Intraocular pressure.

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INTRODUCTION

Myopia is the sixth most common cause of blindness, with an estimated 80% incidence in Asia alone.¹ Since genetic and environmental variables account for a substantial portion of the aetiology, prevention and therapy are challenging.² Possible consequences include macular degeneration, retinal detachment, and open angle glaucoma in addition to the physical handicap and treatment load.³

The treatment choices include corrective refractive surgery (CRS), contact lenses, and eyeglasses.⁴ The most popular CRS procedures with promising outcome are laser-assisted *in situ* keratomileusis (LASIK) and photorefractive keratectomy (PRK).⁵

Nevertheless, there are changes in the central corneal thickness and corneal hysteresis that affect how intraocular pressure (IOP), a key indicator of glaucoma in myopic patients, is measured.⁶ Myopic patients are at increased risk of developing glaucoma from the use of steroids in the immediate aftermath of surgery.⁷ In addition, 12% of those who had undergone cataract surgery had an increase in IOP caused by steroids.⁵ Therefore, many studies have stressed the importance of taking an accurate IOP reading to detect glaucoma in people who had undergone CRS.

The Goldmann Applanation Tonometer (GAT) is the preferred method for measuring IOP, although after corneal refractive surgery, it has lost some of its durability because of changes in corneal thickness and biomechanical properties. GAT typically measures IOP at a lower level than what are actually present after CRS, necessitating adjustment algorithms.⁸⁻¹⁰

The rationale of this study was to assess the effectiveness of alternative instruments that could measure IOP while taking into account all biomechanical changes without the use of correction formulas. The objective was to assess the variation

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in IOP measurements between ORA and GAT in myopic patients undergoing LASIK and photorefractive keratectomy.

METHODOLOGY

This quasi-experimental study was conducted from September 2020 to 2021 at the Armed Forces Institute of Ophthalmology, Rawalpindi. An approval was provided by Ethics Review Board, before the start of data collection. All patients were briefed about study objectives, procedure, possible risks, benefits, and formal consents were taken to ensure voluntary participation. The minimum required sample size of 113 was calculated using WHO sample size calculator software, considering effect size of 0.8 (mean post-operative IOP difference between two techniques),¹¹ pooled standard deviation of 2.0,¹¹ 95% level of confidence, 80% study power and 10% precision. Non-probability purposive sampling technique was used to select the participants for enrollment in the study.

All the patients presented to out-patient refractive surgical department of AFIO with age of more than 18 years having stable refractive error between -2D and -8D for at least one year, and who were planned for either LASIK or PRK in both the eyes were included in the study. Patients with unstable refractive error, glaucoma, cataract, history of corneal pathologies including scars, dystrophies or opacities were excluded from the study. Patients who wore soft contact lens were asked to discontinue the use of lenses for at least two weeks and were prescribed use of a regular lubricant before the preliminary evaluation.

Patients were divided into two groups. Both groups underwent preoperative examination comprised of detailed history, uncorrected distance visual acuity (UCVA), corrected distance visual acuity (CDVA), cycloplegic refraction, ocular dominance, examination of anterior and posterior ocular segment using slit lamp biomicroscopy, measurement of intraocular pressure (IOP) using GAT (Haag-streit, Bern, Switzerland) and ORA (Reichert Ophthalmic Instruments, Depew, NY). Investigations included pupillometry and topography (Wavelight Topolyzer Vario), tomography (Wavelight Oculyzer II), and aberrometry (Wavelight Analyzer II).

Both the procedures were performed by single experienced surgeon. In LASIK group, 200 KHz Femtosecond laser (Wavelight GmbH, Erlangen, Germany) was used to create a 9mm flap with 100 microns thickness, while spatula was used to manually remove the corneal epithelium in PRK group. Optical zone was set at 6.5mm and wave front optimized ablation profile was selected for all patients. EX 500, 1050 Hz Excimer laser (Wavelight GmbH, Erlangen, Germany) was used in both procedures for stromal ablation. In PRK group, the cornea was exposed to triangular sponge soaked in 0.02% Mitomycin C for about 40 seconds, which was washed thoroughly with normal

saline solution. Soft bandage contact lens was applied at the end of the procedure. Topical antibiotic steroid combination drops (0.3% tobramycin, 0.1% w/v dexamethasone) were prescribed three times a day for two weeks, along with topical lubricants every 2-3 hours. Bandage contact lens was removed on 6th postoperative day in PRK group. Topical antibiotic/steroids were discontinued in LASIK group after two weeks, while in PRK group, fluoromethalone ophthalmic drops were prescribed three times a day for the next two months. Patients of both the groups were advised to use topical lubricants for at least six months.

Postoperative follow-up was conducted at 1 week, 1, 3, and 6 months. Ocular parameters including IOP, and central corneal thickness (CCT), were taken at pre-specified time points. Multiple readings of IOP were taken using both GAT and ORA equipment, and average of the readings were taken.

For statistical data analysis, the data were entered and analysed using IBM SPSS (Version 23.0) data management software. Descriptive statistics were reported as mean and standard deviation for continuous data, while frequency and percentages were reported for categorical data. The ocular outcomes were compared pre and post procedure in patients belonging to the two groups, at pre-specified time points using repeated measures ANOVA with post-hoc Bonferroni correction. Pearson's correlation test was used to correlate the IOP readings measured by two techniques. For comparing the outcomes between the two groups, independent samples t-test was used. A p-value of ≤ 0.05 was considered significant.

RESULTS

A total of 113 eyes of 57 patients were included in the study out of which 60 (53.1%) underwent PRK and 53 (46.9%) underwent LASIK procedure. The mean age was 23.6 ± 4.11 years in PRK group, with 40 (66.6%) males. The mean age was 24.4 ± 5.94 years in LASIK group, with 18 (33.9%) males. Patient demographics, preoperative pachymetry, and IOP values for PRK and LASIK patients are shown in Table I.

Comparison of preoperative intraocular pressure measurement using GAT and ORA equipment, revealed a significant difference in the mean readings, i.e. 14.16 ± 2.25 vs. 15.5 ± 2.72 mmHg, respectively ($p < 0.001$). As for patients belonging to LASIK group, there was a significant difference in mean IOP reading compared between GAT and ORA (IOPcc), i.e. 14.47 ± 2.31 vs. 15.21 ± 2.67 mmHg, respectively ($p = 0.02$). Similarly, for patients belonging to PRK group, there was a significant difference in mean IOP measured with two different equipments, i.e. 13.9 ± 2.19 vs. 15.9 ± 2.74 mmHg, respectively ($p < 0.001$).

IOP was measured postoperatively at 1, 3, and 6 months after LASIK and PRK, using GAT and ORA (IOPcc) and the values were compared with baseline preoperative value.

Table I: Comparison of baseline characteristics of patients belonging to PRK and LASIK group (n=113).

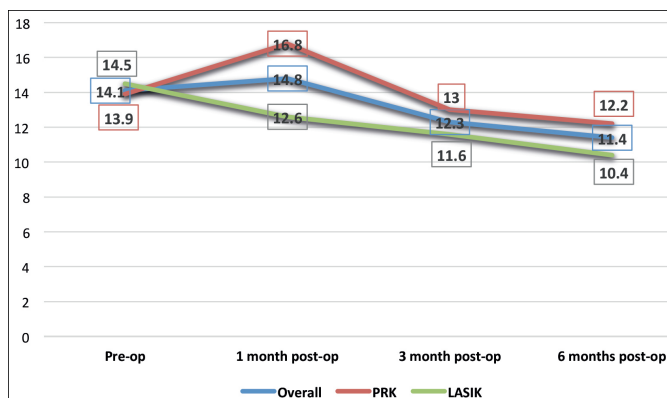
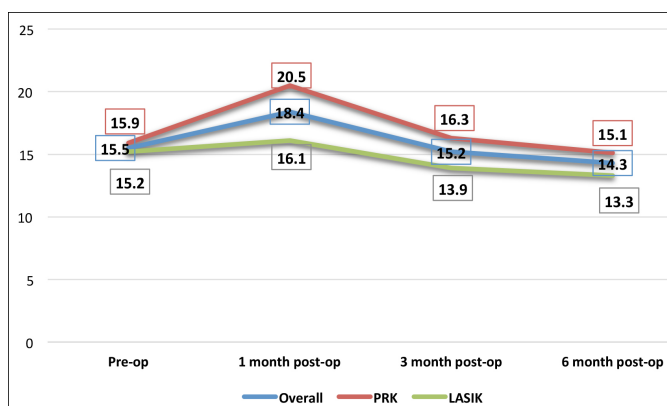
Variable	PRK (n=60)	LASIK (n=53)	p-value
Age (years)	23.6 ± 4.11	24.4 ± 5.94	0.405*
Gender			0.001**
Male	40 (66.6%)	18 (33.9%)	
Female	20 (33.3%)	35 (77.3%)	
Preoperative Pachy, μ m	536.63 ± 26.53	545.11 ± 28.61	0.105*
Preoperative IOP (GAT), mmHg	13.9 ± 2.19	14.47 ± 2.31	0.180*
Preoperative IOPcc (ORA), mmHg	15.92 ± 2.74	15.21 ± 2.67	0.170*

*Independent samples t-test, **Chi-square test.

PRK = Photorefractive keratectomy, LASIK = Laser in-situ keratomileusis, Pachy = Corneal pachymetry, IOP = Intraocular pressure, GAT = Goldmann Applanation Tonometer, ORA = Ocular Response Analyzer, μ m = Micro meter, IOPcc = Intraocular pressure corneal compensated.**Table II: Comparison of mean IOP values measured using GAT and ORA (IOPcc) at various time points.**

Study Group	Time point	GAT		ORA (IOPcc)		P*
		Mean	SD	Mean	SD	
Overall (n=113)	Pre-op IOP	14.1	2.25	15.5	2.72	<0.001
	Post-op 1 month IOP	14.8	4.69	18.4	5.14	<0.001
	Post-op 3 month IOP	12.3	2.47	15.2	2.95	<0.001
	Post-op 6 month IOP	11.4	2.09	14.3	2.56	<0.001
PRK (n=60)	Pre-op IOP	13.9	2.19	15.9	2.74	<0.001
	Post-op 1 month IOP	16.8	5.20	20.5	5.67	<0.001
	Post-op 3 month IOP	13.0	2.61	16.3	3.01	<0.001
	Post-op 6 month IOP	12.2	2.01	15.1	2.82	<0.001
LASIK (n=53)	Pre-op IOP	14.4	2.30	15.2	2.60	0.129
	Post-op 1 month IOP	12.6	2.7	16.0	3.04	<0.001
	Post-op 3 month IOP	11.6	2.10	13.9	2.28	<0.001
	Post-op 6 month IOP	10.4	1.77	13.3	1.83	<0.001

*Independent samples t-test.

**Figure 1: Comparison of intraocular pressure, preoperatively and 1, 3, 6 month postoperatively, using GAT.****Figure 2: Comparison of intraocular pressure IOPcc preoperatively and 1, 3, 6 month postoperatively, using ORA.**

Overall, it was observed that GAT IOP values for all patients decreased postoperatively at 1-month, further reduced at 3-month and 6-month compared to baseline. For patients belonging to PRK group, the GAT IOP value increased at 1-month, decreased at 3-month and further decreased at 6 month postoperatively. For patients belonging to LASIK group, the GAT IOP value decreased at all-time points 1, 3, 6-month postoperatively as shown in Figure 1.

Similarly, it was observed that ORA IOPcc values for all patients in both the groups increased postoperatively at 1 month, decreased at 3 months and further decreased at 6 months postoperatively as shown in Figure 2.

The differences in the mean IOP compared pre and postoperatively at 1, 3, 6 months' time points, using GAT and ORA (IOPcc). A significant difference was observed in mean IOP values overall ($p < 0.001$), in PRK group ($p < 0.001$) and in LASIK group ($p < 0.001$) measured via GAT at different time points. On the other hand, a significant difference in mean IOPcc values was observed ($p < 0.001$) in PRK group ($p < 0.001$), whereas no significant difference was observed in mean IOPcc in LASIK group ($p = 0.076$) measured via ORA at different time points.

Table II shows the comparison of mean IOP values measured by GAT and ORA (IOPcc), overall, in PRK and LASIK groups at various time points. A significant difference was observed in mean IOP value measured via GAT and ORA at preoperative ($p < 0.001$), 1-month ($p < 0.001$), 3-month ($p < 0.001$), and 6-month ($p < 0.001$) postoperatively. Table II provides a

detailed comparison of GAT and ORA (IOPcc) between PRK and LASIK group level. The mean values were generally found to be higher when measured using ORA (IOPcc) as compared with GAT.

Upon correlating IOP with central corneal thickness (CCT) and refractive error at baseline, no significant correlation was found between IOP GAT and CCT ($r = 0.164$, $p = 0.083$), IOP GAT and UCVA ($r = 0.042$, $p = 0.659$) or IOPcc ORA and CCT ($r = -0.058$, $p = 0.543$) and IOPcc ORA and UCVA ($r = 0.032$, $p = 0.739$). Similarly, at 3-month postoperative follow-up, a significant weak positive correlation was found between IOP GAT and CCT ($r = 0.189$, $p = 0.045$), while no significant correlation was observed between IOP GAT and UCVA ($r = -0.157$, $p = 0.097$) or between IOPcc ORA and CCT ($r = -0.003$, $p = 0.979$), and IOPcc ORA and UCVA ($r = -0.025$, $p = 0.792$). At 6-month follow-up, a significant weak positive correlation was found between IOP GAT and CCT ($r = 0.231$, $p = 0.014$) while no significant correlations were found between IOP GAT and UCVA ($r = -0.053$, $p = 0.579$) or IOPcc ORA and CCT ($r = 0.019$, $p = 0.844$) or IOPcc ORA and UCVA ($r = -0.078$, $p = 0.411$).

DISCUSSION

It is well-established that corneal refractive surgery results in many changes in the anterior eye segment and a lot of biologic parameters lose their accuracy. IOP is known to get reduced post-refractive surgery, when measured using the GAT or other equipment including pneumotonometer, dynamic contour tonometer (DCT), non-contact tonometer and tonopen, etc. During an eye examination, the intraocular pressure is regularly measured and follow-ups are recommended. Inaccurate low readings might postpone the identification of glaucoma, especially in myopic eyes where the evaluation of the optic disc and the visual field can be quite challenging. The reduction in IOP in eyes undergoing corneal refractive surgery had been addressed in a number of ways by various researchers.

In the present study, the authors compared the changes in IOP observed among patients undergoing PRK and LASIK. The IOP was measured using two different equipments and readings were compared at 1, 3, and 6 months postoperatively. A change in IOP was noted postoperatively among patients undergoing PRK and LASIK surgery. Generally, the IOP measurements increased at the first follow-up month, while reduced in subsequent months postoperatively among all patients irrespective of the type of surgery. The comparison of GAT and ORA revealed that higher intraocular measurements were noted using ORA as compared to GAT.

In a study conducted by Lanza *et al.*, it was reported that at 6-month follow-up, the IOP was significantly reduced ($p = 0.01$) when measured using five different instruments including ORA, GAT, dynamic contour tonometry (DCT), Corvis ST (CST), and rebound tonometry (RT).¹² Compared to

all others, GAT displayed the largest reduction and strongest association with changes in corneal parameters. It was concluded that after myopic refractive surgery, each examined instrument displayed a substantial underestimate of IOP. Similar results were observed in the current study, where intraocular values reduced in both surgery types using two sets of instruments.

In another study conducted by Iglesias *et al.*, the authors compared Goldmann convex tonometer IOP measurements 12 months after myopic refractive surgery with GAT, and ORA standard equipment.¹³ It was concluded that IOP evaluated with Goldmann convex tonometer 12 months after surgery showed a good correlation with GAT prior to surgery, suggesting a potential alternate method for monitoring IOP by following this procedure. This study has found better results with ORA as compared to GAT.

In a study conducted by Ang *et al.*, IOP was compared using three different instruments and the findings were correlated with corneal parameters.¹¹ It was concluded that after myopic refractive surgery *via* LASIK and PRK technique, the IOP dropped in all three tonometer instruments, with the biggest reduction in GAT. The least amount of change was seen in CVS.-bIOP between preoperative and postoperative IOP measurements. In the LASIK group, only the percentage change in MRSE was linked with the percentage change in CVS.-bIOP. Similar results were observed in the present study, where GAT instrument depicted greater reductions in IOP as compared to the comparator instrument.

In a systematic review and meta-analysis reported by Zhang *et al.*, it was concluded that IOP reduced in majority of the patients undergoing myopic refractive surgeries.¹⁴ In comparison to IOP measured with GAT, IOP measured by ORA was found to be less reliant on the central corneal thickness, and it might be closer to the genuine IOP. It was also concluded in the present study that IOP measured by ORA depicted more realistic results as compared to GAT.

In a study conducted by Fakhraie *et al.*, 348 eyes were studied to check the changes in intraocular pressure following myopic refractive surgeries, and it was concluded that IOP rise following PRK surgery is more likely to occur in eyes with higher baseline IOP and lower baseline CCT; hence, these eyes need to be examined more frequently.¹⁵ Same results were reported in this study with IOP raised in PRK group immediately after the surgery as compared to LASIK.

Chen *et al.* conducted a study on 144 eyes undergoing refractive surgery to check the performance of four tonometer equipment to detect changes in IOP postoperatively.¹⁶ It was concluded that IOP decreased significantly postoperatively in a similar manner in all types of surgeries, but the measurements were found to be significantly lower in ORA and further lower in GAT.

CONCLUSION

IOP increased immediately after myopic refractive surgery but decreased 3 to 6 months postoperatively in both LASIK and PRK. This decrease in IOP was observed more after LASIK than after PRK. In comparison of tonometers, it was found that IOP was significantly lower with GAT as compared to ORA, and ORA is more likely to give a realistic estimate of IOP than GAT. However, long term follow-up is required to fully understand the corneal biomechanics and its effect on IOP.

ETHICAL APPROVAL:

An approval (No. 215/ERC/AFIO) was granted by the Hospital Ethical Review Committee on 21st February 2020.

PATIENTS' CONSENT:

All patients gave informed consents to participate in the study.

COMPETING INTEREST:

The authors declared no competing interest.

AUTHORS' CONTRIBUTION:

SH: Concept, design of work, and data interpretation.

YWB: Drafting of work, data analysis, and critical revision.

MI: Final approval of manuscript.

AAS: Data acquisition.

All authors approved the final version of the manuscript to be published.

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