


ARTICLE



Agreement of ocular response analyzer cornea compensated IOP with corvis ST biomechanical IOP following Femtosecond Laser-assisted LASIK

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OBJECTIVES: To compare intraocular pressure (IOP) measurement by ORA-IOPcc and Corvis-biOP after femtosecond laser-assisted LASIK (FS-LASIK).

METHODS: In this prospective cohort study, 56 eyes from 56 consecutive patients scheduled for FS-LASIK were enrolled. All patients had IOP measurement with ORA and Corvis ST by two blinded independent expert examiners. IOP examinations were conducted between 8 and 11 A.M. Data were collected at baseline and 3 months after FS-LASIK.

RESULTS: The mean age of the participants was 29.1 ± 6.3 years, and 42 (75%) were female. The average of central corneal thickness (CCT) decreased from $537 \pm 23 \mu\text{m}$ at baseline to $458 \pm 31 \mu\text{m}$ after FS-LASIK. The mean postoperative change of IOP was 0.0 ± 2.1 for biOP and -2.5 ± 3.2 mmHg for IOPcc. The corresponding 95% limits of agreement (LoA) was -4.1 to 4.1 mmHg and -3.8 to 8.8 mmHg, respectively. Both methods showed no significant correlation between ΔIOP and ΔCCT . The 95% LoA between biOP and IOPcc after FS-LASIK was -4.8 to 9.1 mmHg.

CONCLUSIONS: Compared to the ORA-IOPcc, the Corvis-biOP showed less variation after FS-LASIK and might be a more appropriate choice for measuring IOP in this condition. The agreement of biOP vs. IOPcc after FS-LASIK is below the clinically acceptable level, and the two methods could not be regarded as interchangeable.

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INTRODUCTION

The precise measurement of IOP is an essential part of the ocular examination and is crucial for glaucoma detection and monitoring. Traditionally, several devices have been developed to measure IOP, of which the Goldmann applanation tonometry (GAT) has been considered the gold-standard method [1]. Since this method requires direct contact with the cornea and thus poses some risks to the patient (such as corneal epithelial defects or transferring infections), noncontact IOP measurement devices are gaining more popularity for IOP assessment [2]. These devices are also more comfortable for children or uncooperative patients and can be used by less skilled examiners.

Air-puff tonometers use a pulse of air to deflect the cornea and measure the IOP by analyzing the time of corneal applanation [3]. Ocular response analyzer (ORA; Reichert Inc, Depew, NY) and Corvis ST (Oculus Optikgerate GmbH) are air-puff tonometers with additional capabilities of studying corneal biomechanics [4, 5]. Although the GAT readings could be adjusted based on the CCT, both ORA and Corvis ST offer cornea independent IOPs considering a variety of corneal biomechanical properties [4, 5].

The majority of the patients undergoing refractive surgeries are myopic, which is a risk factor for glaucoma [6]. Laser corneal

refractive surgeries are typically cornea-reductive procedures and alter corneal biomechanics [7]. The accuracy of IOP measurements is compromised after these procedures, which increases the risk of IOP underestimation and may lead to missing ocular hypertension or glaucoma [8]. Therefore, a proper approach to an accurate measurement of IOP in these conditions is crucial.

A few studies directly compared the IOP measurement by Corvis ST and ORA after LASIK surgery [9–11]; however, no study reported on the agreement of the corrected IOPs by these devices after LASIK. The purpose of the present study was to assess the effect of femtosecond laser-assisted LASIK (FS-LASIK) on the agreement between ORA-IOPcc and Corvis ST- biOP.

MATERIALS AND METHODS

Patients

In this prospective cohort, 56 consecutive refractive surgery candidates scheduled for FS-LASIK were gathered consecutively from a refractive surgery clinic from May to August 2020. All participants had no ocular condition other than the refractive error, had no previous ocular surgery, and were suitable candidates for refractive surgery based on their refraction and corneal imaging. Patients with systemic diseases such as diabetes, rheumatologic disorders, and thyroid dysfunction were excluded.

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All patients signed the informed consent, and the study protocol adhered to the tenets of the Declaration of Helsinki. The study was approved by the Ethics Committee of Shiraz University of Medical Sciences.

Measurements

All patients had IOP measurements with ORA and Corvis ST. ORA uses corneal hysteresis and corneal resistance factors to calculate IOPcc from Goldmann-correlated IOP (IOPg). Similarly, the Corvis ST calculates bIOP from the crude IOP reading by integrating biomechanical information from the Scheimpflug camera.

All measurements were performed following the manufacturer's guidelines by two blinded independent expert examiners, who were not aware of the measurements by the other operator. To minimize the effects of diurnal fluctuations, all IOP examinations were conducted between 8 and 11 A.M. The order of measurements with ORA or Corvis ST was random to avoid systematic bias, and a 5 min interval was allowed between measurements. Data were collected at baseline and 3 months after FS-LASIK.

Surgical technique

The FS-LASIK procedure was performed by topical anesthesia as described before (the Victus platform; Bausch & Lomb, Inc.) [12]. The flap diameter was 8.5 to 9.5 mm with a maximum thickness of 110–120 μm . Then an excimer laser (TECNOLAS Perfect Vision GmbH; TNEO 317 software version 1.25; Bausch & Lomb) was used to ablate the cornea. Postoperatively, all patients used levofloxacin (Q6H for 1 week) and loteprednol eyedrops (Q6H for 1 week, and tapering till 1 month).

Statistical analysis

Statistical analysis was performed using SPSS software (Version 25.0, SPSS Inc., and Chicago, IL). The normality of the data was tested by the Kolmogorov-Smirnov test, and the similarity of variances was explored by Mauchly's test of sphericity. Data were presented as mean \pm standard deviation. A Paired *t*-test (or Wilcoxon signed-rank test when appropriate) was used to compare pre- versus postoperative measurements. The agreement between devices was assessed using *limits of agreement* and demonstrated by Bland–Altman diagrams. Only data from the right eyes of the patients were used for analysis.

RESULTS

The data from 56 eyes of 56 patients were recorded and analyzed. The mean age of the participants was 29.1 ± 6.3 (range, 21 to 42) years, and 75.0% were female. The preoperative spherical equivalent of refraction ranged from -1.50 to -5.75 D (mean, -3.53 ; SD, 1.09). The average of central corneal thickness (CCT) decreased from 537 ± 23 μm (range, 501 to 582) at baseline to 458 ± 31 μm (range, 397 to 539) after FS-LASIK.

All methods of IOP measurement tended to read lower values after FS-LASIK, except for bIOP, in which the mean of IOP readings did not significantly change (Table 1). The correlations' strength between different pair of methods were variable, with the best correlations found for the measurements from the same device [i.e., IOPg vs. IOPcc and IOP (Corvis) vs. bIOP] in both pre-and postoperative occasions (Table 2). The CCT change after FS-LASIK was directly correlated with IOP reduction after surgery for IOP (Corvis) and IOPg [Pearson correlation coefficient, 0.465 ($P = 0.003$) and 0.554 ($P < 0.001$), respectively], but not for bIOP or IOPcc [0.179 ($P = 0.275$) and 0.241 ($P = 0.134$)].

The mean difference and 95% limits of agreement (95% LoA) of measured IOPs before or after FS-LASIK are summarized in Table 3. The Bland–Altman plots for uncorrected (IOP [Corvis] vs. IOPg) and corrected (bIOP vs. IOPcc) values at baseline and after FS-LASIK are represented in Fig. 1. Preoperatively, the averages of IOP (Corvis) and bIOP were greater than their match from the ORA, and the LoAs were far greater than the clinically acceptable range. After FS-LASIK, the mean of IOP (Corvis) and bIOP were 6.0 and 4.4 mmHg higher than IOPg and IOPcc, respectively. These differences were more evident for lower IOPs. The postoperative LoAs were also well outside the acceptable range.

The Bland–Altman plots for pre- vs. post-LASIK measurements by either bIOP or IOPcc methods are shown in Fig. 2. The 95% LoA for bIOP was delimited within ± 4.1 mm Hg, notably superior to IOPcc, which fluctuated by 8.8 mm Hg after FS-LASIK.

DISCUSSION

This study revealed that the bIOP by Corvis ST could read up to 9.0 mm Hg higher than the ORA-IOPcc after FS-LASIK. This difference is far greater than the clinically acceptable threshold (usually referred to as 3 mm Hg), and therefore, these two methods should not be used interchangeably.

The FS-LASIK procedure seems to have no meaningful effect on the agreement of the two methods, and the greater absolute value of the agreement range remained around 9–10 mm Hg (Fig. 1). The weak agreement of IOPcc and bIOP implies that either or both methods might not be an accurate method for post-LASIK IOP measurements. The Bland–Altman plots suggested that the bIOP overestimation compared to IOPcc was more notable for lower IOPs. The same pattern was observed with ORA IOPg vs. uncorrected IOP of the Corvis ST in both virgin and operated corneas (Fig. 1). The observed systematic difference could be due to the different methods each device uses in measuring Goldmann-correlated IOP rather than corrected IOPs (IOPcc or bIOP).

As previously noted, the bIOP showed a better agreement than IOPcc for pre- vs. post-LASIK measurements. The mean difference of bIOP measurements obtained before and after FS-Lasik was almost zero, while the IOPcc tended to read lower values (average, 2.5 mm Hg) postoperatively, particularly for higher IOPs. As claimed by the manufacturers, the corrected IOP measurements by these devices should not be affected by corneal refractive surgeries. The results of the current study suggest a better performance of bIOP compared to IOPcc.

Table 1. Comparison of mean IOP measurements by different methods before vs. after FS-LASIK.

	Before	After	<i>P</i> -value
IOPg by ORA	16.9 \pm 3.7	11.7 \pm 2.8	0.001
IOPcc by ORA	17.4 \pm 3.8	14.9 \pm 2.4	0.001
IOP by Corvis	19.5 \pm 2.8	17.7 \pm 2.1	0.001
bIOP by Corvis	19.7 \pm 2.5	19.7 \pm 2.0	0.626

All values are in mmHg.

Significant *P* values are marked as boldface letters.

Table 2. Correlation of IOP measurements between different methods before (Underline letters) vs. after (Boldface letters) FS-LASIK.

	IOPg by ORA	IOPcc by ORA	IOP by Corvis	bIOP by Corvis
IOPg by ORA		0.828 ($P < 0.001$)	0.578 ($P < 0.001$)	0.508 ($P < 0.001$)
IOPcc by ORA	<u>0.765 ($P < 0.001$)</u>		0.415 ($P = 0.002$)	0.423 ($P = 0.002$)
IOP by Corvis	<u>0.563 ($P < 0.001$)</u>	<u>0.480 ($P < 0.001$)</u>		0.939 ($P < 0.001$)
bIOP by Corvis	<u>0.503 ($P < 0.001$)</u>	<u>0.527 ($P < 0.001$)</u>	<u>0.930 ($P < 0.001$)</u>	

All pairwise comparisons are analyzed by Pearson correlation coefficient.

Table 3. Agreement of IOP measurements between different methods before (Underline letters) vs. after (Boldface letters) FS-LASIK.

	IOPg by ORA	IOPcc by ORA	IOP by Corvis	biOP by Corvis
IOPg by ORA		0.5 (-3.8 to 4.8)	2.6 (-3.4 to 8.6)	2.7 (-3.6 to 9.0)
IOPcc by ORA	<u>3.2 (-0.4 to 6.9)</u>		2.0 (-5.1 to 9.1)	2.1 (-4.8 to 9.1)
IOP by Corvis	<u>6.0 (1.3 to 10.7)</u>	<u>2.8 (-1.8 to 7.3)</u>		0.1 (-1.7 to 2.0)
biOP by Corvis	<u>7.9 (3.0 to 12.9)</u>	<u>4.7 (0.4 to 9.0)</u>	<u>2.0 (0.4 to 3.5)</u>	

Data are presented as mean difference (95% limits of agreement) in mmHg.

The pairwise comparisons were arranged as follows: biOP – IOP (Corvis); biOP – IOPcc; biOP – IOPg; IOP (Corvis) – IOPcc; IOP (Corvis) – IOPg; IOPcc – IOPg.

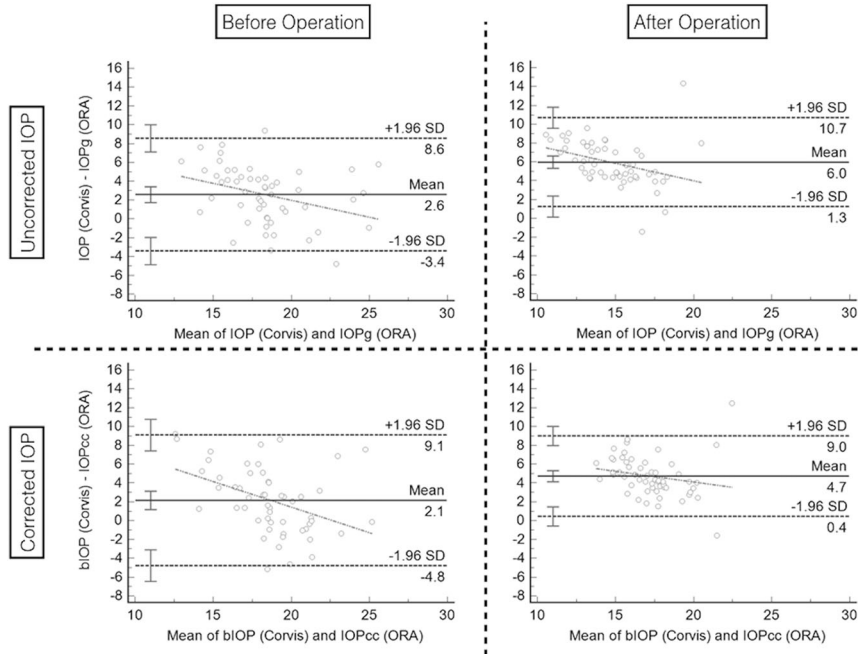


Fig. 1 Agreement analysis of biOP vs. IOPcc. Bland-Altman plots showing the agreement between uncorrected (top row) or corrected (bottom row) IOP measurements with Corvis ST and the ORA at baseline (left column) and three months after (right column) FS-LASIK.

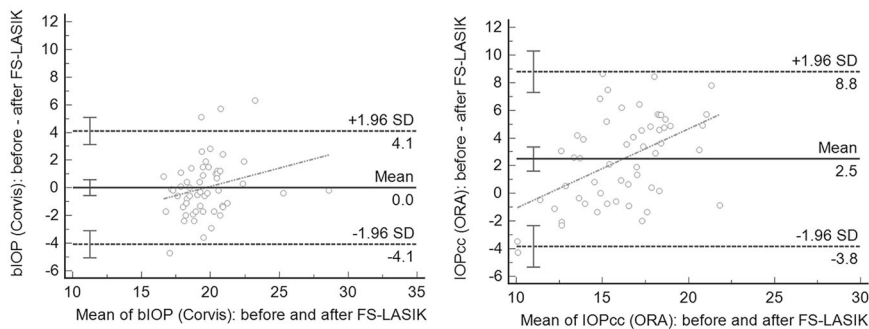


Fig. 2 Agreement analysis of Pre vs. Post FS-LASIK IOP measurements. Bland-Altman plots representing the pre- vs. post-operative agreement of biOP by Corvis ST (left) vs. IOPcc by the ORA (right).

One of the methods of IOP adjustment is to tune GAT readings based on the CCT. This approach uses nomograms that were adopted from virgin corneas with various CCTs. In corneal refractive surgery, however, the corneal reduction is accompanied by more complex biomechanical changes due to the changes in Bowman layer (the backbone of the cornea). Therefore, in post-LASIK eyes, the CCT-corrected GAT might not provide a valid standard reference to be compared with biOP and IOPcc. Considering the inherent accuracy limitations of air-puff tonometers, integrating biomechanical data from Corvis ST or ORA with GAT readings might be a viable method to precisely measure the IOP after refractive surgery.

Bao et al. assessed four methods of IOP measurement (including biOP and IOPcc) in 65 patients before and 3 months after FS-LASIK [10]. In the low to moderate myopia group, the Δ biOP was 0.47 mm Hg ($P = 0.120$), and the Δ IOPcc was 3.76 mm Hg ($P < 0.001$), closely correlated to our results (0.0 and 2.5 mm Hg, respectively). They found the greater absolute value of the 95% LoA as 3.9 mm Hg for biOP (4.1 in ours) and 6.0 mm Hg for IOPcc (8.8 in our study). They reported no significant correlation between Δ CCT and Δ biOP or Δ IOPcc, similar to our results. In agreement with the present study, Bao and colleagues concluded that the biOP was less influenced by the corneal changes after FS-LASIK than the IOPcc, and biOP might

be a better option for post-refractive surgery IOP measurement [10]. Chen et al. reported the IOP changes 3 months after three different kinds of refractive surgeries, including FS-LASIK ($n = 50$) [9]. The Δ IOP was notably lower for bIOP (1.21 mm Hg, $P = 0.0013$) than IOPcc (3.94 mm Hg, $P < 0.001$). The greater absolute value of the 95% LoA was 4.59 and 7.28 mm Hg for bIOP and IOPcc, respectively. Their findings were also comparable to ours, which further confirmed the validity of our results.

As previously noted, GAT generally underestimates IOP after refractive surgeries due to the changes in corneal thickness and biomechanics. The respective averages of GAT IOP, bIOP, and IOPcc measured after FS-LASIK were 10.21 ± 2.04 , 12.66 ± 1.79 , and 11.83 ± 1.65 mm Hg in Bao et al., [10] and 9.95 ± 2.16 , 12.53 ± 1.78 , and 11.64 ± 1.65 mm Hg in Chen et al. [9]. Differences in post-LASIK IOP measurement between GAT and noncontact methods should be considered in clinical decision making.

This prospective study sought to determine a reliable range of agreement between Corvis ST and ORA IOP measurements in eyes that have undergone FS-LASIK. The ranges we have determined may be referred to for clinical purposes within similar populations. As mentioned above, we did not have an available standard method of IOP measurement in post-LASIK eyes to be compared with Corvis ST and ORA. The present study was primarily designed to find the agreement range between bIOP and IOPcc and could not determine the accuracy of either method. Previous similar studies did not report on the agreement between these two methods. This information is essential to conclude on the clinical interchangeability of them. The results of this study could be used for similar patients of the same age group, baseline refractive error, and CCT; and may not be generalized to other populations.

In conclusion, the Corvis-bIOP showed weak agreement with ORA-IOPcc before and after FS-LASIK surgery, and the two methods could not be used interchangeably. Compared to IOPcc, the bIOP method showed less variation after the operation and might be the superior method for measuring IOP in eyes with previous FS-LASIK.

Summary box

What was known before

- Corneal refractive surgeries such as FS-LASIK alter the corneal structure and thus usual methods for measuring IOP become inaccurate in this condition.
- Both ORA-IOPcc and Corvis-bIOP claim that they can remove the confounding effect of the operated cornea on the measurement of IOP. However, there is no study to report their agreement after corneal refractive surgeries.

What this study adds

- The Corvis-bIOP showed less variability than ORA-IOPcc after the FS-LASIK procedure and maybe a more appropriate choice to be considered for IOP measurement in this condition.
- The mean difference (and 95% LoA) of bIOP vs. IOPcc after FS-LASIK was 2.1 (−4.8 to 9.1) mmHg, and though the two methods could not be considered interchangeable.

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AUTHOR CONTRIBUTIONS

Conception or design: RS, RR, MHN; Data acquisition: GE, KS; Data analysis: MHN; Data interpretation: RS, RR, MZ, MG; Drafting: RS, RR, GE, MZ, KS, MG, MHN; Critical revising: RS, RR, MZ, MHN; Final approval: RS, RR, GE, MZ, KS, MG, MHN.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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