Original Article

Tonometry by Ocular Response Analyzer in Keratoconic and Warpage Eyes in Comparison with Normal Eyes

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Abstract

Purpose: To compare intraocular pressure (IOP) values measured by ocular response analyzer (ORA) in contact lens-induced corneal warpage, normal, and keratoconic eyes.

Methods: In a prospective, observational case–control study, 94 eyes of 47 warpage-suspected cases and 46 eyes of 23 keratoconic patients were enrolled. Warpage-suspected cases were followed until a definite diagnosis was made (warpage, nonwarpage normal, or keratoconus). ORA tonometry and corneal biomechanics testing were performed for all cases in each visit. We had 2–3 measured corneal-compensated IOP (IOPcc) and Goldmann-correlated IOP (IOPg) for each patient (based on group) with at least 2-week interval.

Results: After following up of warpage-suspected patients, finally 44 eyes of 22 patients had confirmed soft contact lens-related corneal warpage. Forty-six eyes of 23 people were finally diagnosed as nonwarpage normal eyes. Forty-six eyes of 23 known keratoconus patients were also included for comparison. The demographic and refractive data were not different between the warpage and nonwarpage normal groups but were different in the keratoconus group. Both IOPcc and IOPg were statistically different with the highest value in the warpage group followed by normal and keratoconus groups; the same trend was observed in central corneal thickness (CCT). The mean of IOPg was 14.94 ± 2.65, 13.7 ± 2.33, and 10.86 ± 3 and IOPcc was 15.73 ± 2.4, 15.28 ± 2.43, and 14.08 ± 2.55 in the warpage, normal, and keratoconus groups, respectively. IOPg and IOPcc in the warpage group (based on baseline diagnosis) did not regress to become closer to IOP of normal eyes after discontinuation of contact lens in their follow-up visits (*P* value for IOPg and IOPcc trends in the warpage group was 0.07 and 0.09 controlling for CCT, respectively). Both IOPcc and IOPg were significantly lower in keratoconic eyes in comparison with normal eyes. After correction for the confounding effect of CCT, a lower IOPcc in keratoconus versus warpage remained significant ($P = 0.02$).

Conclusion: Both IOPcc and IOPg were statistically different with the highest value in the warpage group followed by normal and keratoconus groups, just like their CCT. After correction for the confounding effect of CCT, there was no statistically significant difference between the three groups in their measured IOPcc and IOPg except for IOPcc in keratoconus versus warpage ($P = 0.02$).

Keywords: Central corneal thickness, Contact lens, Goldmann applanation tonometry, Intraocular pressure, Keratoconus

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Introduction

Contact lens wear prevalence in different surveys has shown to be from 2% to 9% in different populations, and it seems to be increasing for both cosmetic and correcting purposes. Significant contact lens-induced corneal warpage incidence is estimated to be up to 12%, but it highly depends on contact lens material and design.[1-3] On the other hand, it has been

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shown that corneal biomechanics can be affected by corneal warpage.[4]

Corneal warpage is suspected by its typical corneal topography appearance which is bilateral and symmetrical superior flattening and dramatic inferior steepening in the absence of keratoconus clinical features such as characteristic "scissor reflex" and corneal slit-lamp changes. Corneal warpage diagnosis is confirmed after resolution of topographic abnormalities by discontinuation of contact lens wearing.[3,4]

We previously suggested that specific corneal biomechanical indices can help predict the development of corneal warpage.[4] Considering the high prevalence of contact lens use among the general population, especially refractive surgery candidates and highly reported corneal biomechanical changes due to corneal warpage in this population, it seems necessary to work on interpretation of various methods of measuring corneal biomechanics in these patients. It is also important to know the potential limitations of intraocular pressure (IOP) measurement by ocular response analyzer (ORA) in these patients, especially due to higher prevalence of glaucoma in myopic patients who are the majority of soft contact lens wearers.

We worked previously on corneal hysteresis (CH) and corneal resistance factor (CRF) changes in contact lens-induced corneal warpage.[4] In the present report, we aimed to investigate changes of other corneal biomechanical indices measured by ORA in warpage syndrome: corneal-compensated IOP (IOPcc) and Goldmann-correlated IOP (IOPg). We also aimed to investigate the potential biases of measuring IOP by ORA in corneal warpage compared to normal eyes and IOP measurement trends after resolving warpage.

ORA was introduced in 2004 by Reichert Ophthalmic Instruments, Inc. (Depew, NY, USA). In addition to central corneal thickness (CCT) and corneal biomechanical indices such as CH and CRF, this instrument can also estimate IOP.[5,6] Refractive surgeons have used the ORA to get information about cornea's viscoelastic properties. They have used CH and CRF to diagnose corneal degenerative diseases such as keratoconus, contact lens-induced corneal warpage, and Fuchs' corneal dystrophy.[7-9] Some clinicians also have used them to predict the risk of postrefractive surgery ectasia or to describe postpenetrating keratoplasty corneal changes.[10,11] Furthermore, recent studies have shown that ORA can have an important role in increasing our knowledge in glaucoma pathophysiology.[12-16] Wells *et al*. have shown that in glaucoma patients, lower CH (but not CRF) has been associated with higher optic nerve head surface deformation during artificial IOP spikes. These phenomena have not been shown in control normal eyes.[17] It also has been shown that glaucoma patients with acquired optic nerve head pit have lower CH when compared to other primary open-angle glaucoma patients. CH, which is measured by ORA, could be a sign of susceptibility of the whole eye to deformative changes.[18]

ORA yielded higher IOP measurements in comparison with Goldmann applanation tonometry (GAT), which is known as the gold standard for IOP measurement.[16,19] ORA also provides two IOP values: IOPcc and IOPg. IOPg is an estimation of Goldmann tonometry and is calculated by the average of the inward (P1) and outward (P2) applanation pressures. It has been found that the second applanation (outward) occurs at a lower pressure than the first applanation (inward). IOPcc correlates with both IOP and corneal biomechanical features.[19] To the best of our knowledge, there are few studies to evaluate ORA-based IOP values in prediction of corneal warpage and keratoconus.

Our first aim in this study was to see if IOPcc and IOPg (like other corneal biomechanical indices: CH and CRF) could be used to differentiate corneal warpage from keratoconus or not,[4] though understanding the potential error in IOP measurement by ORA induced by warpage is also interesting.

Clinical utility of ORA in glaucoma management is limited by lack of quality data.[4-12] This transient period has been passed with every new technology such as automated perimetry, optic nerve head OCT imaging, and even GAT. We need studies that help us figure out the ability of ORA in IOP measurement at different clinical situations. In this study, we also tried to compare ORA-measured IOP values in keratoconus and soft contact lens-induced corneal warpage in comparison with normal control eyes. We thought that there might be two hypothetical scenarios for measured IOP change in the warpage group. First, the IOP might be really affected – due to potential effects of long-term contact lens wear such as hypoxia. It has been shown that hypoxia can cause lower IOPs due to decreased oxygenation of ciliary body epithelium. Even lower systemic oxygen saturation levels were associated with lower IOPs as altitude increases in a study by Xie *et al*.[13,14] Second, we were just suspicious about the measurement reliability of ORA-based IOP due to corneal biomechanical changes in these patients. A combination of these two hypotheses can also be considered.

Methods

The protocol of the study was approved by the Ethics Committee of Tehran University of Medical Sciences and adhered to the tenets of the Declaration of Helsinki, and informed consent was obtained from all participants. This study has been done in the Refractive Surgery Clinic of Farabi Eye Hospital. Ninety-four eyes of 47 people who were suspected of soft contact lens-related corneal warpage based on their corneal topographic pattern were enrolled in the study in a case group. Forty-six eyes of 23 known keratoconic patients who had never worn contact lenses were included in the control group of the study. Control patients were selected from the Cornea Clinic of Farabi Eye Hospital.

Patients with any history of corneal scarring, corneal diseases, previous corneal surgery, diabetes, and connective tissue disorders were excluded from the study. Our exclusion and inclusion criteria, instrument details, and method of measurement were explained in detail in our previous published work with the same data.[4]

We measured all three groups at baseline and after 2–4 weeks. In the corneal warpage suspect group, patients were asked not to wear their contact lenses for 2–4 weeks and come back to the clinic for reexamination. Refraction, corneal imaging (Orbscan II or Pentacam), and ORA measurements (CH, CRF, IOPcc, and IOPg) were repeated. At this stage, based on the changes in the topographic pattern, the patients were diagnosed as follows: (1) confirmed contact lens-induced corneal warpage – complete resolution, (2) possible contact lens-induced corneal warpage – incomplete resolution, (3) keratoconus, and (4) normal patients with stable irregular topographic pattern.

The criteria for stabilization were defined as (1) manifest refraction changes within 0.50 diopter (D) and (2) keratometry changes within 0.50 D.[4]

Those with suspicious incomplete warpage resolution were requested to wait for 2–4 more weeks, and all the previous examinations were repeated at this follow-up visit. In this stage, patients with normal topography were also defined as confirmed warpage. To reduce variability due to diurnal variations in the IOP, corneal thickness, and CH, all evaluations were performed between 11:00 and 14:00 p.m. At least three acceptable ORA measurements were recorded for each patient, and the mean value was considered for data entry. We had at least 2 measured IOPcc and IOPg for each patient with at least 2-week interval. In the suspected corneal warpage group, some patients had three measurements.

The final categories were based on the consensus of three cornea subspecialists (A.H.B., F.A., and S.F.M.), reviewing all the records as: (1) confirmed soft contact lens-induced corneal warpage, (2) nonwarpage normal, and (3) keratoconus.

Descriptive statistics were used to evaluate the distribution of the data. The normality of the data was tested with Kolmogorov–Smirnov/Shapiro–Wilk test. We used the paired *t*-test to assess the changes within the groups (corneal warpage). As for the difference in the baseline pachymetry, analysis of covariance with adjustment for corneal thickness was used to evaluate the difference between the groups. Considering the possible correlation of the results in two eyes, we applied the generalized estimating equation (GEE) analysis. $P < 0.05$ was considered statistically significant. All statistical analyses were performed with SPSS software (IBM SPSS Statistics for Windows, Version 22.0., Armonk, NY, USA: IBM Corp.).

Results

As it is shown in the study design algorithm of our previous published work,[4] in the case group after follow-up of patients, 44 eyes of 22 patients were found to have confirmed contact lens-related corneal warpage based on three anterior segment expert clinicians' opinion. Forty-six eyes of 23 patients were diagnosed as nonwarpage normal eyes, and two other patients had warpage in only one eye and a nonwarpage normal stable pattern in the other eye. Forty-six eyes of 23 known keratoconus patients were included for comparison as the control group.

The demographic and ophthalmology examination data are shown in Table 1. Case and keratoconic control eyes were statistically different in age, sex, astigmatism ($P < 0.001$), and CCT ($P = 0.004$). Age, CCT, and female-to-male ratio was significantly lower in keratoconic patients in comparison with normal and confirmed warpage group patients, but there was no significant difference between the normal and warpage groups in age, sex, and CCT according to the *post hoc* analysis. *P* values are adjusted for age to avoid bias. Myopic astigmatism average was significantly higher in keratoconic eyes: −3.42 ± 3.14 (mean ± standard deviation [SD]) versus −0.63 and −0.5 in the normal and confirmed warpage groups, respectively. However, there was no statistically significant difference in spherical refractive error, spherical equivalent, and best corrected visual acuity between keratoconic control eyes and normal and confirmed corneal warpage groups ($P = 0.521$, 0.847, and 0.775, respectively). The mean values are shown in Table 1.

Baseline and final IOP values by ORA are shown in Tables 2 and 3, respectively. The Bonferroni method was used for multiple comparisons. The significant values are bolded in Tables 2 and 3.

The mean IOPcc and IOPg in the warpage suspect group were 15.66 ± 2.44 (mean ± SD) and 14.39 ± 2.54 (mean ± SD), respectively. The mean IOPcc and IOPg in the keratoconus group were 14.08 ± 2.55 (mean ± SD) and 10.86 ± 3 (mean ± SD), respectively. Both IOPcc and IOPg were significantly lower in the keratoconic group than the warpage suspect group at baseline ($P = 0.006$ and $P < 0.001$, respectively) [Table 2].

As it is shown in Table 3, both IOPcc and IOPg were statistically different, with the highest value in the confirmed warpage group followed by normal and keratoconus groups, just like their CCT. IOPg was 14.94 ± 2.65, 13.7 ± 2.33, and 10.86 ± 3 and IOPcc was 15.73 ± 2.4, 15.28 ± 2.43, and 14.08 ± 2.55 in the confirmed warpage, normal, and keratoconus groups, respectively. Therefore, we decided to control CCT effect on IOPcc and IOPg measurements [Table 4]. After CCT control, there was no statistically significant difference between the three groups in their measured IOPcc and IOPg except for IOPcc in keratoconus versus confirmed warpage ($P = 0.02$).

We also tried to check IOPcc and IOPg trends in warpage diagnosed eyes to see if there is any statistically significant change by improving warpage and corneal deformities after discontinuing contact lenses. We had at least 2 measured IOPcc and IOPg for each patient with at least 2-week interval. In the corneal warpage suspect group, some patients had three measurements. As shown in Table 5, there was no statistically significant trend in IOP by improving warpage. IOPg and IOPcc in the warpage suspect group (based on baseline diagnosis) did not regress to become closer to IOP of normal eyes in their follow-up visits (*P* value for IOPg and IOPcc trends

Table 1: Demographic and ophthalmology examination data based on final diagnosis

Parameter	Total	Group			*P*
		Keratoconus	Normal	Warpage (confirmed)	
Age, mean±SD	23.8±3.8	21.3±2.9	25.5±4.3	25±2.8	<0.001†
Sex (%)					
Female	43 (66.2%)	8 (34.8%)	16 (80.0%)	19 (86.4%)	<0.001*
Male	22 (33.8%)	15 (65.2%)	4 (20.0%)	3 (13.6%)	<0.001
SPH, mean±SD	−3.39±2.47	−2.98±3.83	−3.55±1.35	−3.55±1.99	0.521§
Cyl, mean±SD	−1.4±2.31	−3.42±3.14	−0.58±1.35	−0.66±1.13	<0.001§
SE, mean±SD	−4.11±2.73	−4.79±4.31	−3.84±1.33	−3.88±2.19	0.847§
BCVA					
LogMAR, mean±SD	0.95±0.6	0.86±1.11	0.99±0.05	0.99±0.04	0.775§
CCT, mean±SD	534±51	469±60	535±27	552±50	0.004§

†Based on ANOVA. *Based on Chi-square test, §Based on GEE analysis. SPH: Sphere, SE: Spherical equivalent, Cyl: Cylinder, BCVA: Best corrected visual acuity, CCT: Central corneal thickness, SD: Standard deviation, GEE: Generalized estimating equation, ANOVA: Analysis of variance, LogMAR: Logarithm minimum angle of resolution

Table 2: Intraocular pressure values by ocular response analyzer measurements according to the baseline diagnosis

	Total	Group		Difference	95% CI		*P*§
		Warpage (suspect)	Keratoconus		Lower	Upper	
IOPcc							
Mean±SD	15.29±2.55	15.66±2.44	14.08±2.55	1.73	0.51	2.95	**0.006**
Median (range)	14.99 (11.2-20.9)	15.3 (11.3-20.9)	13.63 (11.2-20.02)				
IOPg.1							
Mean±SD	13.57±3.03	14.39±2.54	10.86±3	3.46	1.95	4.96	**0.000**
Median (range)	13.34 (5.6-21.6)	13.81 (9.7-21.6)	10.82 (5.6-17.15)				
CCT							
Mean±SD	542±47	551±39	480±60	75	29	121	**0.001**
Median (range)	548 (423-639)	549 (453-639)	463 (423-600)				

§*P* for changes based on linear GEE. IOP: Intraocular pressure, IOPcc: Corneal-compensated IOP, IOPg: Goldmann-correlated IOP, CCT: Central corneal thickness, CI: Confidence interval, SD: Standard deviation, GEE: Generalized estimating equation

Table 3: Intraocular pressure values by ocular response analyzer measurements according to the final diagnosis

	Keratoconus (confirmed)	Normal	Warpage	*P*§	*P*1	*P*2	*P*3
IOPcc							
Mean±SD	14.08±2.55	15.28±2.43	15.73±2.4	**0.013**	**0.004**	0.060	0.108
Median (range)	13.63 (11.2-20.02)	14.74 (11.3-20.9)	15.8 (11.8-20.55)				
IOPg.1							
Mean±SD	10.86±3	13.7±2.33	14.94±2.65	**<0.001**	**<0.001**	**<0.001**	0.345
Median (range)	10.82 (5.6-17.15)	13.25 (9.7-19.2)	14.66 (10.8-21.6)				
CCT							
Mean±SD	480±60	542±26	562±48	**0.005**	**0.002**	**0.001**	0.83
Median (range)	463 (423-600)	548 (489-593)	556 (453-639)				

§*P* for changes based on GEE, *P*1: Keratoconus versus normal adjusted for multiple comparisons based on Bonferroni method, *P*2: Keratoconus versus warpage adjusted for multiple comparisons based on Bonferroni method, *P*3: Comparison of normal versus warpage adjusted for multiple comparisons based on Bonferroni method. IOP: Intraocular pressure, IOPcc: Corneal-compensated IOP, IOPg: Goldmann-correlated IOP, CCT: Central corneal thickness, GEE: Generalized estimating equation, SD: Standard deviation

in the warpage group was 0.07 and 0.09 with CCT control, respectively).

Discussion

Analysis of the demographic data showed no significant differences in age, sex, and refractive error (sphere, spherical equivalent, and astigmatism) between patients who suffered from warpage and normal participants without warpage. However, the participants in the keratoconus group were younger with a higher male-to-female ratio, thinner corneas, and higher myopic astigmatism [Table 1].

Although this finding could be predicted because of our selection method which was to include documented keratoconus patients who never used contact lenses in our control group, it might

Table 4: Intraocular pressure *P* values by ocular response analyzer measurements according to the final diagnosis adjusted for central corneal thickness

	P[§]	*P*1	*P*2	*P*3
IOPcc	0.02	0.11	0.02	0.53
IOPg.1	0.03	0.96	0.11	0.09

[§]*P* for changes based on GEE, *P*1: Comparison of keratoconus versus normal adjusted for multiple comparisons based on Bonferroni method adjusted for CCT, *P*2: Comparison of keratoconus versus confirmed warpage adjusted for multiple comparisons based on Bonferroni method adjusted for CCT, *P*3: Comparison of normal versus confirmed warpage adjusted for multiple comparisons based on Bonferroni method adjusted for CCT. IOP: Intraocular pressure, IOPcc: Corneal-compensated IOP, IOPg: Goldmann-correlated IOP, CCT: Central corneal thickness, GEE: Generalized estimating equation

Table 5: Intraocular pressure trends in the warpage group based on final diagnosis

	Mean±SD	*P* value without CCT control	*P* value with CCT control
IOPg	14.89±1.01	0.66	0.8
IOPg2	14.83±2.19		
IOPg3	15.37±2.02		
IOPcc	16.16±0.92	0.79	0.65
IOPcc2	15.92±1.74		
IOPcc3	16.60±0.88		

Numbers stand for patients visits. In the warpage suspect group, patients had two to three different intraocular pressure measurements in three different visits with at least 2-week interval. IOP: Intraocular pressure, IOPcc: Corneal-compensated IOP, IOPg: Goldmann-correlated IOP, CCT: Central corneal thickness, SD: Standard deviation

have resulted in some biases in our findings.[20-22] For example, it has been shown that corneal stiffness parameters such as CCT and age can affect ORA measurements. These two parameters were different in our case and control groups that might be a source of bias.[23] To avoid this bias, we tried to control CCT and age effect on IOPcc and IOPg measurements. Controlling age effect did not make any change; however, there was no statistically significant difference between the three groups in their measured IOPcc and IOPg after controlling for CCT, except for IOPcc in keratoconus versus confirmed warpage.

In our study, both IOPcc and IOPg in keratoconic eyes were lower than the normal and confirmed warpage groups. Even with GAT, measured IOP in keratoconic eyes is lower than normal.[24] This might be due to lower CCT and CH in keratoconic patients.

Özcura *et al*. have shown that dynamic contour tonometry seems to be the most accurate instrument for IOP measurements in keratoconus because it is least affected by CCT and corneal radius of curvature.[25] In this study, we can tell inferentially that ORA-measured IOPs are affected by CCT. The lower the CCT, the lower the ORA-measured IOP values (correlation coefficient of IOPg in the keratoconus group was 0.87, $P = 0.02$). This may be a red flag that shows us ORA cannot be the instrument of choice for measuring IOP in keratoconus; however, this hypothesis should be evaluated by other studies and could not be confirmed by the methodology of this study.

Finally, we think that manometric studies and long-term longitudinal prospective studies are needed to show ORA-measured IOP correlation with glaucoma development to optimize the clinical utility of ORA in glaucoma management.

Our other aim in this study was to see if IOPcc and IOPg could be clinically useful modalities to detect corneal warpage. Are they useful to differentiate warpage from keratoconus before refractive surgery? Based on our study, IOPg could be a potential factor that can help us differentiate them ($P < 0.001$). However, IOPcc did not show this capability ($P = 0.060$). Clinicians may also be able to use this difference in IOPg as a factor added to other corneal biomechanical features for predicting the development of corneal warpage in those who wish to use contact lenses. Further longitudinal and prospective research studies in this regard are needed.

Interestingly, despite the fact that our first theory was "those who develop warpage are possibly more similar to keratoconus patients", we found that participants with documented corneal warpage were more similar to the normal (nonwarpage) group than the keratoconus group in IOPcc and IOPg [Table 3].

The idea of using IOPg for differentiating contact lens-induced corneal warpage from keratoconus is a novel idea. Although we have shown that patients with corneal warpage have higher IOP, the reverse is not necessarily true, and future longitudinal studies with different designs are needed to investigate their relationship. More importantly, in this study, we showed the potential false measurement of ORA-based IOP in warpage (possible overestimation of IOP) and keratoconic eyes (possible underestimation of IOP) that could be an important applicable point in a clinic; however, it needs to be proven in future longitudinal studies.

On the other hand, as shown in Table 5, with improvement of corneal warpage, IOP measurements did not change significantly. As mentioned previously, we suggested two different potential mechanisms that ORA-based measured IOP could be affected in corneal warpage patients. First, the IOP might be truly affected due to potential effects of long-term contact lens wear such as hypoxia. Second, the measurement validity of ORA-based IOP due to corneal "biomechanic" changes in these patients might be under question. The fact that we did not see returning to normal group IOP values after contact lens discontinuation might be either due to primary difference in the biomechanics properties of those participants who are susceptible to warpage or due to "permanent" effects of the contact lens on the cornea. These theories should be further evaluated in future studies.

In this study, we did not have one normal group with no history of the contact lens use at the beginning of the study. We also did not compare our measured IOPs with GAT, which is the gold standard of IOP measurement. This study did not include rigid gas permeable (RGP) contact lenses.

Further studies also are required on the corneal structure and histology of these three groups, including one normal group with no history of contact lens use and/or another group with keratoconus diagnosis and contact lens wearing history, to prove our findings and find biological explanations for these differences. We also recommend similar studies for RGP and/or scleral contact lenses.

The other limitation of the study was a short follow-up period of 4–6 weeks in the corneal warpage group to assess IOP trends in them. We had borderline *P* values for IOP trend (*P* value for IOPg and IOPcc trends in the warpage group was 0.07 and 0.09, respectively). With a longer follow-up period, these *P* values could be significant.

ORA measures the corneal biomechanics and IOP in the central cornea while most striking warpage changes occur in eccentric locations. This can reduce the chance to detect the full magnitude of changes.

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Conflicts of interest

There are no conflicts of interest.

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