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ORIGINAL RESEARCH

The Effect of Orthokeratology Lens Decentration on Ocular and Biomechanical Measurements

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Purpose: To investigate the effects of orthokeratology (ortho-K) lens decentration on ocular and biomechanical parameters and analyze the correlation of these parameters with decentration distance.

Methods: Thirty eyes of 30 myopic adult subjects, mean age 28.2 years who had worn ortho-K lens for two hours were recruited for this prospective study. Under both the central and eccentric lens fitting conditions, the subjects underwent two rounds of assessments with a week-long interval. The ocular parameters were measured by an IOL Master, whereas the biomechanical parameters were measured by a Corves ST. Differences between measurements were evaluated by one-way ANOVA and a post hoc test. Repeatability was analyzed based on within-subject standard deviation (Sw), repeatability coefficient (RC), intraclass correlation coefficient (ICC), and correlation of variation (CoV). Pearson correlation analysis was employed for correlation analysis.

Results: The ocular parameters showed no significant differences, whereas among the biomechanical parameters, the biomechanical corrected intraocular pressure (bIOP) (95% CI 15.8–16.7 mmHg, 14.7–15.6 mmHg, 14.5–15.5 mmHg for baseline, central and eccentric group) and stiffness parameter at first applanation (SPA1) (95% CI 111.7–122.4, 102.3–113.0, 103.9–115.1 for baseline, central and eccentric group) showed significant changes after ortho-K. In all groups, the ocular parameters showed good repeatability with ICC values greater than 0.95 and CoV values lower than 1.3%. By contrast, the biomechanical parameters showed poor repeatability with low ICC values (ie, below 0.7) for the length of flattened cornea at the first and second applanations (A1L and A2L, respectively) and for velocity of corneal apex at the second applanation (A2V) in the baseline group; for A1L, A2L, and bIOP in the central group; and for A1L and A2V in the eccentric group. The correlation analysis showed the positive relationship in A2L between central and eccentric groups.

Conclusion: Ortho-K lens decentration did not influence the ocular parameters. However, the biomechanical parameters, the bIOP and SPA1 related to corneal thickness changed after ortho-K.

Keywords: orthokeratology, decentration, biomechanical parameters, axial length

Introduction

Myopia has become substantially more prevalent in recent decades, especially in southeast Asian countries, such as China, Korea, and Singapore.[1–3] A study estimated that by the 2050s, 49.8% of the world population will develop myopia and 9.8% will have high myopia,[4] making myopia a global health problem. It develops mostly among children, and its prevalence has increased significantly; moreover, with the increase in educational pressure, myopia tends to develop among younger individuals.[5] Early onset of myopia is associated with rapid disease progression and increased chances of developing high myopia, which may eventually lead to retinal detachment, macular degeneration, and glaucoma.[6,7] Therefore, early myopia control in children is an important approach to minimizing the risk of myopic complications.

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Studies have reported several interventions, including environmental, optical, and pharmacologic approaches, for myopia control in children.[8,9] Among these approaches, optical interventions are the most common myopia control methods given their efficacy; these methods involve the use of orthokeratology (ortho-K) lenses, multifocal contact lenses, and peripheral defocus spectacles.[10] Nevertheless, the mechanism of myopia control remains unclear. The popular hypothesis is that the relative myopic retinal peripheral defocus created by an optical approach can retard axial elongation.[11,12] Animal studies have demonstrated that peripheral myopic defocus can indeed inhibit axial elongation.[13] Given the ability of ortho-K lenses to reduce axial elongation by 43–63% through peripheral myopic defocus created by corneal epithelial remodeling, it is now a commonly used method for myopia control.[14]

Corneal reshaping is a crucial step in ortho-K. Optimal myopia control depends on the perfect reshaping of the corneal epithelium and on the central position of the lens.[15] However, studies showed that central fitting is not always achieved in patients receiving ortho-K, as treatment zone decentration may occur to some extent.[16] Meanwhile, our previous research found that a certain degree of eccentricity of the treatment zone can improve myopia control and can delay axial length elongation,[17] so decentration can also be another strategy to improving myopia control. However, during myopia progression evaluation, the changes in ocular parameter measurements obtained within a short period were not significant, except for a few patients exhibiting rapid disease progression; moreover, differences in the shaping zone caused by decentration may affect a measuring device's alignment. This may affect the judgment of the effectiveness of myopia control. Therefore, evaluating the impact of ortho-K on ocular parameters is necessary when lenses have eccentric fitting. However, the direct decentration fit in children may at risk, we carried out a short-time adult experiments instead. This study is the first to evaluate ocular and biomechanical parameter measurements obtained under different ortho-K lens fitting conditions and examine whether treatment zone decentration affects the accuracy of measurements.

Method

To calculate the sample size for this study, we calculated the sample size use the G-power, as the effect size is 0.5, α is 0.05, power is 0.8, so the calculated sample size is 26. A total of 30 eyes of 30 subjects (19 female and 11 male subjects) were recruited for this prospective study. This study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Qingdao Eye Hospital of Shandong First Medical University (MR-37-24-036573). The potential risks and the purpose of this study were presented to the subjects before the study was initiated, then a written informed consent was obtained from each subject. The inclusion criteria were as follows: older than 18 years, spherical equivalent (SE) of refraction from −0.75 D to −5.00 D, astigmatism up to 1.50 D, without history of contact lens use, without history of ocular surgery and trauma, without systemic/ocular medication use, and demonstrates good compliance with the study protocol.

The subjects initially underwent routine eye examination for visual acuity, intraocular pressure (IOP), axial length, corneal topography, subjective refraction, corneal endothelial cell density, and fundus photography. The ortho-K lens selected for this study was a traditional four-zone reverse geometry rigid lens (Euclid Inc., Charlotte, NC). The base curves (BC) zone is spherical, with a back optic zone diameter (BOZD) of 6.2 mm. Per the manufacturer's instruction, flat keratometry and corneal eccentricity were the basis in choosing the lens for the first trial. After the fluorescein state was evaluated, the lens with a good central position was used to achieve a good fit according to the manufacturer's fitting guidelines. The group subjected to this approach was denoted as the central group. To achieve ortho-K lens decentration, we modified the prescription according to that for a previous central lens with loose of 1.00 D in alignment curve (AC); the subjects could tolerate the discomfort arising from this adjustment (eg If the AC for central position is 42.00 D, then the AC for eccentric position will be selected as 41.00 D). The group subjected to this approach was denoted as the eccentric group. All the subjects wore ortho-K lenses with a target correction of −3.00 D in the trial box.

The lenses were worn for two hours to create a remarkable reshape ring. The wearing of lenses had a one-week interval to allow the cornea to recover its original shape. The parameters measured were axial length (AL), central corneal thickness (CCT), anterior chamber depth (ACD), and lens thickness (LT); measurements were obtained using an IOL Master 700 (Carl Zeiss, Jena, Germany 1.90.38.02). Changes in corneal topography were monitored by a Pentacam® (Oculus, Wetzlar, Germany 6.11r72). Corneal biomechanical parameters were measured using a Corvis-ST (Oculus, Wetzlar, Germany 6.08r30). Measurements were obtained three times using different devices, and only the right eye was selected for this study.

Difference maps of the tangential curvature were created by subtracting the pre-ortho-K map from the post-ortho-K map (with two different treatments). The decentration distance was measured using a MATLAB program based on the difference maps we previously reported.[17] Eight points located around the treatment zone on the difference map with zero refractive power were plotted to define a circular treatment zone. Decentration is defined as the distance between the corneal vertex and the center of the treatment zone.

The data was analyzed by the SPSS software (version 24.0, IBM Corporation, Armonk, NY) and is presented as mean ± standard deviation (SD). The Kolmogorov–Smirnov test was used to check the normality of the data, which was found to be normally distributed ($P > 0.05$). The repeatability of the measurements for the different groups and their differences were analyzed by one-way ANOVA. The Bonferroni was used for post-hoc tests. The indices for repeatability were within-subject standard deviation (Sw), repeatability coefficient (RC), and correlation of variation (CoV). The relationship between groups were analyzed by Pearson correlation. A P value of less than 0.05 indicated statistical significance.

Results

The mean age of the subjects was 28.21 ± 6.20 years. All subjects had completed this study. During the course of this study, none had reported significant discomfort, and no corneal trauma was noted. The treatment zone decentration in the central group measured 0.41 ± 0.18 mm, whereas that in the eccentric group measured 0.91 ± 0.35 mm, and their difference was significant (Supplementary Tables 1 and 2, $P < 0.001$). This result implied that a looser lens fit will lead to a greater lens decentration.

Table 1 compares the AL, CCT, ACD, and LT values for the baseline, central, and eccentric groups. No differences in these ocular parameters were noted among the three groups ($P > 0.05$). Table 2 shows the repeatability of the ocular parameter measurements obtained from the different groups by an IOL Master. The results demonstrated good repeatability; the COV values were all less than 1.3%, and the CCT values showed less deviation in the eccentric group than in the baseline and central groups. The ICC values for all the parameters were greater than 0.95. These results showed that short-term wearing of ortho-K lenses had no influence on the ocular parameters.

Tables 3–5 show the repeatability of the measurements for corneal biomechanical parameters in the baseline, central, and eccentric groups, respectively. In most biomechanical parameters, repeatability was lower in the baseline group than in the treatment groups. Although the ICC for A1L was higher in the baseline group than in the treatment groups, the result still indicated poor repeatability; moreover, low ICC values (ie, below 0.7) were observed in the length of flattened cornea at the first and second applanations (A1L and A2L, respectively) and velocity of corneal apex at the second applanation (A2V) in the baseline group, in A2L and biomechanical IOP (bIOP) in the central group, and in A2V in the eccentric group. A significant difference was observed between the bIOP and stiffness parameter at first applanation (SPA1) measurements ($P < 0.05$, Table 6); a post hoc test further showed a difference in bIOP values between the baseline and treatment groups ($P < 0.001$), whereas no difference was observed between the treatment groups ($P > 0.05$). Similarly, differences in SPA1 values were observed only between the baseline and treatment groups ($P = 0.034$), indicating that such a difference was associated with the absence or presence of treatment.

Table 7 shows the association between eccentric distance and other parameters. After ortho-K, the velocity of corneal apex at the first applanation (A1V) ($P = 0.012$) and radius value of central concave curvature at highest concavity (Radius) ($P = 0.015$) in the central group were negatively correlated with decentration, whereas AL was positively

Table 1 The Difference of Ocular Parameters in Different Groups

	Baseline		Central		Eccentric		F	p	Partial η^2
	Mean±SD	95% CI	Mean±SD	95% CI	Mean±SD	95% CI			
AL (mm)	25.04±0.97	24.67, 25.40	25.01±0.99	24.63, 25.37	25.03±0.98	24.66, 25.37	0.010	0.990	0.0502
CCT (mm)	525.84±29.12	514.97, 536.71	536.89±30.60	525.45, 548.31	533.33±31.36	521.62, 545.04	1.033	0.360	0.0566
ACD (mm)	3.57±0.25	3.48, 3.67	3.56±0.25	3.47, 3.66	3.56±0.26	3.46, 3.66	0.015	0.985	0.175
LT (mm)	3.81±0.24	3.72, 3.90	3.82±0.24	3.73, 3.91	3.83±0.24	3.73, 3.92	0.056	0.945	0.0719

Abbreviations: AL, axial length; CCT, central corneal thickness; ACD, anterior chamber depth; LT, lens thickness.

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Table 2 The Repeatability of Ocular Parameters in Baseline, Central and Eccentric Groups

		Sw	RC	Mean	SD	CoV (%)	ICC
Baseline	AL	0.01	0.03	25.04	0.97	0.041	1.000
	CCT	6.78	18.79	525.84	29.12	1.2904	0.948
	ACD	0.02	0.07	3.57	0.25	0.7727	0.988
	LT	0.05	0.13	3.81	0.24	1.3201	0.960
Central	AL	0.01	0.02	25.01	0.99	0.0337	1.000
	CCT	6.78	18.81	536.89	30.60	1.2646	0.952
	ACD	0.02	0.07	3.56	0.25	0.6959	0.991
	LT	0.03	0.10	3.82	0.24	0.9657	0.977
Eccentric	AL	0.03	0.08	25.03	0.98	0.1248	0.999
	CCT	5.01	13.90	533.33	31.36	0.941	0.975
	ACD	0.04	0.12	3.56	0.26	1.1798	0.975
	LT	0.03	0.092	3.83	0.24	0.8664	0.983

Abbreviations: Sw, within-subject standard deviation; RC, repeatability coefficient; CoV, correlation of variation; ICC, intraclass correlation coefficient; AL, axial length; CCT, central corneal thickness; ACD, anterior chamber depth; LT, lens thickness.

Table 3 The Repeatability of Biomechanical Parameters in Baseline

	Sw	RC	Mean	SD	ICC
A1L	0.29	0.82	2.16	0.33	0.419
A1V	0.01	0.02	0.15	0.01	0.884
A1IOP	1.02	2.83	16.76	1.91	0.885
A2L	0.36	1.00	1.88	0.39	0.406
A2V	0.03	0.09	−0.26	0.04	0.587
A2IOP	0.95	2.65	16.31	1.40	0.780
PD	0.13	0.36	4.93	0.27	0.906
RADIUS	0.53	1.47	6.68	0.75	0.754
DA	0.05	0.16	1.08	0.10	0.869
CCT	11.82	32.74	552.44	30.85	0.947
DaRatio	0.16	0.44	4.24	0.35	0.920
IR	1.40	3.89	8.90	1.87	0704
ARTH	24.79	68.67	476.86	98.58	0.978
SPA1	9.07	25.13	117.11	15.99	0866
CBI	0.08	0.24	0.05	0.12	0.721

Abbreviations: Sw, within-subject standard deviation; RC, repeatability coefficient; CoV, correlation of variation; ICC, intraclass correlation coefficient; A1L, length of flattened cornea at the first applanation; A1V, velocity of corneal apex at the first applanation; A2L, length of flattened cornea at the second applanation; A2V, velocity of corneal apex at the second applanation; A1IOP, intraocular pressure at the second applanation; A2IOP, intraocular pressure at the second applanation; PD, distance of two apex at time of highest concavity; RADIUS, radius of the highest concavity; DA, deformation amplitude; DaRatio, the ratio of deformation amplitude; CCT, central cornea thickness; IR, integrated radius; SPA1, stiffness parameter at first applanation; ARTh, Ambr´osio's relational thickness horizontal; CBI, Corvis biomechanical index.

Table 4 The Repeatability of Biomechanical Parameters in Central Group

	Sw	RC	Mean	SD	ICC
A1L	0.33	0.93	2.22	0.35	0.228
A1V	0.01	0.02	0.16	0.01	0.836
A1IOP	0.79	2.19	15.79	1.77	0.925
A2L	0.31	0.87	1.98	0.36	0.504
A2V	0.02	0.06	−0.27	0.04	0.874
A2IOP	1.27	3.52	15.07	1.65	0.680
PD	0.76	2.12	5.08	0.79	0.929
RADIUS	0.58	1.62	6.60	0.85	0.776
DA	0.04	0.12	1.11	0.11	0.951
CCT	5.80	16.08	560.82	31.04	0.966
DaRatio	0.16	0.46	4.08	0.34	0.912
IR	10.29	28.52	10.23	10.51	0.909
ARTH	37.92	105.05	469.25	117.60	0.964
SPA1	5.88	16.30	109.57	15.63	0.949
CBI	0.07	0.21	0.09	0.18	0.935

Abbreviations: Sw, within-subject standard deviation; RC, repeatability coefficient; CoV, correlation of variation; ICC, intraclass correlation coefficient; A1L, length of flattened cornea at the first applanation; A1V, velocity of corneal apex at the first applanation; A2L, length of flattened cornea at the second applanation; A2V, velocity of corneal apex at the second applanation; A1IOP, intraocular pressure at the second applanation; A2IOP, intraocular pressure at the second applanation; PD, distance of two apex at time of highest concavity; RADIUS, radius of the highest concavity; DA, deformation amplitude; DaRatio, the ratio of deformation amplitude; CCT, central cornea thickness; IR, integrated radius; SPA1, stiffness parameter at first applanation; ARTh, Ambr´osio's relational thickness horizontal; CBI, Corvis biomechanical index.

correlated with decentration (P = 0.01). In the eccentric group, a positive relationship was found in A2L (P = 0.025). While compared the central and eccentric groups, only the A2L showed positive relationship (P = 0.005). This finding indicates that ortho-K lenses only induce changes in several parameters when combined with corneal reshaping.

Discussion

Ortho-K can inhibit myopia progress by reshaping the cornea, forming a flatter optical zone and a sharper treatment zone. Corneal deformation may inevitably influence corneal parameters, such as cornea biomechanics.[18] A reshaped corneal epithelium may not align at the center, but decentration of the reshape zone can enhance myopia control;[17] however, when the reshape zone aligns with optical zone, the irregular cornea could influence the measurement of ocular parameters. This study applied two ortho-K fitting conditions to simulate the central and eccentric reshaping of the cornea, and repeatability and difference between these groups were further evaluated. It could provide a new opinion of myopia control with Ortho-K.

The results for the central, eccentric, and baseline groups showed no significant differences in anterior ocular parameters, including AL, CCT, ACD, and LT. However, the CCT values increased after ortho-K, a result that does not align with conventional view that ortho-K could reshape the cornea by compressing the epithelium. Wan et al found that the CCT decreased after a week-long treatment with ortho-K.[19] Another study reported that the CCT was thinner after 6 months of treatment and that recovery was noted after one month of withdrawal.[20] Another meta-analysis demonstrated that the CCT decreased significantly from day 1 to day 7.[21] We speculated that the difference is related to corneal edema due to the 2-hour wearing of the lenses. A similar trend was observed in the central and eccentric groups, demonstrating that the difference was due to ortho-K and not due to optical zone decentration. This is because the setting used in the eccentric group was conservative enough to avoid the potential risk of corneal trauma or oxygen deficit.

Table 5 The Repeatability of Biomechanical Parameters in Eccentric Group

	Sw	RC	Mean	SD	ICC
A1L	0.49	1.37	2.23	0.49	0.280
A1V	0.01	0.02	0.16	0.01	0.846
A1IOP	0.86	2.38	15.85	1.98	0.930
A2L	0.34	0.95	1.98	0.45	0.703
A2V	0.06	0.16	−0.26	0.06	0.515
A2IOP	0.77	2.15	15.20	1.36	0.864
PD	0.11	0.30	5.03	0.26	0.934
RADIUS	0.56	1.56	6.73	0.97	0.860
DA	0.04	0.11	1.11	0.11	0.953
CCT	5.82	16.13	561.73	31.54	0.967
DaRatio	0.14	0.41	4.05	0.34	0.932
IR	0.481	1.35	9.04	1.13	0.931
ARTH	31.69	87.78	487.40	130.31	0.980
SPA1	6.71	18.61	107.73	15.17	0.926
CBI	0.06	0.17	0.06	0.13	0.918

Abbreviations: Sw, within-subject standard deviation; RC, repeatability coefficient; CoV, correlation of variation; ICC, intra-class correlation coefficient; A1L, length of flattened cornea at the first applanation; A1V, velocity of corneal apex at the first applanation; A2L, length of flattened cornea at the second applanation; A2V, velocity of corneal apex at the second applanation; A1IOP, intraocular pressure at the second applanation; A2IOP, intraocular pressure at the second applanation; PD, distance of two apex at time of highest concavity; RADIUS, radius of the highest concavity; DA, deformation amplitude; DaRatio, the ratio of deformation amplitude; CCT, central cornea thickness; IR, integrated radius; SPA1, stiffness parameter at first applanation; ARTh, Ambr´osio's relational thickness horizontal; CBI, Corvis biomechanical index.

The decentration of an ortho-K lens might not induce measurement errors compared when the lens is centrally positioned. As for the biomechanical parameters, differences were observed in bIOP and SPA1; a post hoc test further showed that a difference was found only between the baseline group and the treatment groups, whereas the treatment groups showed no significant difference. Joan et al evaluated the changes in various biomechanical characteristics of the cornea following mid- and long-term ortho-K treatments.[22] Adult subjects were scheduled for follow-up visits after wearing ortho-K lenses for one night, one week, and three months, and differences were found in the deformation amplitude ratio at 2 mm (DARatio_2 mm), integrated Radius (IntRad), Ambrósio's Relational Thickness Horizontal (ARTh), Corvis Biomechanical Index (CBI), and Tomographic Biomechanical Index (TBI). They concluded that the changes in these parameters were probably a response to the changes in pachymetry and tomography. Zhang et al conducted an observational study on the differences in corneal biomechanical parameters induced by ortho-K in children with myopia at six time points.[23] They observed differences in the deformation amplitude ratio at 2 mm (DAR2), integrated inverse radius (IIL), CBI, and Corvis biomechanical index for the Chinese population (cCBI); after integrating covariates (CCT, SimK, and bIOP), they also found a noticeable difference in SPA1. They concluded that the primarily attributions of ortho-K wearing are the alterations in corneal thickness and morphology. In the present study, differences were observed only in bIOP and SPA1. SPA1 is an indicator of corneal stiffness during the first applanation; thus, the result demonstrates that short-term wearing of ortho-K lens affects corneal stiffness. However, this effect is attributed to ortho-K treatment and not to the eccentricity of the treatment zone. This finding may be due to the measurement area covered by Corvis ST: the measurement area measures 3 mm in diameter; for the eccentric group, the decentration distance is 0.91 mm compared with 0.41 mm for the central group. The decentration of the measurement zone may not induce the primarily reshape zone enter the measurement zone and influence the measurement. This means that the main cause of the changes in biomechanical parameters is the ortho-K-induced corneal reshaping and not ortho-K decentration.

Table 6 The Difference of Biomechanical Parameters in Different Groups

	F	p	Partial η^2
A1L	0.713	0.493	0.0502
A1V	0.810	0.448	0.0566
A1IOP	2.864	0.062	0.175
A2L	1.046	0.356	0.0719
A2V	0.711	0.494	0.05
A2IOP	99.18	<0.001	0.8802
PD	1.338	0.268	0.0902
RADIUS	0.222	0.801	0.0162
DA	0.983	0.378	0.0679
CCT	0.832	0.438	0.0581
DaRatio	2.927	0.059	0.1782
IR	1.117	0.332	0.0764
ARTH	0.190	0.827	0.0139
SPA1	3.504	0.034	0.2061
CBI	0.592	0.555	0.042

Abbreviations: Sw, within-subject standard deviation; RC, repeatability coefficient; CoV, correlation of variation; ICC, intraclass correlation coefficient; A1L, length of flattened cornea at the first applanation; A1V, velocity of corneal apex at the first applanation; A2L, length of flattened cornea at the second applanation; A2V, velocity of corneal apex at the second applanation; A1IOP, intraocular pressure at the second applanation; A2IOP, intraocular pressure at the second applanation; PD, distance of two apex at time of highest concavity; RADIUS, radius of the highest concavity; DA, deformation amplitude; DaRatio, the ratio of deformation amplitude; CCT, central cornea thickness; IR, integrated radius; SPA1, stiffness parameter at first applanation; ARTh, Ambr´osio's relational thickness horizontal; CBI, Corvis biomechanical index.

Table 7 The Correlation Between Eccentric Distance and Other Parameters

	Central-Baseline		Decentral-Baseline		Decentral-Central	
	R	P	R	P	R	P
A1L	0.061	0.749	−0.158	0.404	−0.315	0.090
A1V	−0.454*	0.012	−0.274	0.142	0.127	0.504
A1IOP	0.202	0.284	−0.026	0.890	−0.234	0.214
A2L	0.045	0.814	0.408*	0.025	0.496**	0.005
A2V	−0.007	0.971	0.163	0.389	−0.058	0.759
A2IOP	0.102	0.590	−0.101	0.596	−0.209	0.267
PD	−0.129	0.497	−0.170	0.370	0.242	0.198
RADIUS	−0.438*	0.015	−0.048	0.799	−0.030	0.876
DA	0.081	0.672	0.071	0.709	0.186	0.326
CCT	0.017	0.929	0.166	0.380	0.070	0.711
DaRatio	−0.047	0.803	−0.242	0.198	−0.015	0.936
IR	0.146	0.441	−0.151	0.427	0.233	0.214
ARTH	0.072	0.705	−0.133	0.485	−0.061	0.750
SPA1	0.136	0.473	0.111	0.560	−0.138	0.468
CBI	0.160	0.399	0.092	0.631	0.231	0.220

(*Continued*)

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Table 7 (Continued).

	Central-Baseline		Decentral-Baseline		Decentral-Central	
	R	P	R	P	R	P
AL	0.462*	0.010	−0.195	0.301	−0.106	0.576
CCT (IOLMASTER)	0.086	0.650	0.327	0.078	−0.104	0.583
ACD	0.222	0.239	−0.104	0.583	−0.179	0.343
LT	−0.252	0.179	−0.049	0.799	0.188	0.320

Notes: *Represents the relationship is significant at P<0.05, **represents the relationship is significant at P<0.01.

The results showed that the ocular parameters, namely, AL, CCT, ACD, and LT, demonstrated good repeatability, wherein their ICC values were all above 0.95 and their CoV values were less than 1.3%. No significant differences were observed between the baseline and treatment groups. Shu et al compared the effect of ortho-K on the precision of measurements in children by using a new swept-source optical coherence tomography optical biometer.[24] Comparing AL, ACD, and corneal diameter (CD), they found that the ICC values were above 0.95 and the CoV values were below 1.23%. In another study, Ardoy used swept-source optical coherence tomography and partial coherence interferometry biometers to compare the repeatability and agreement of measurements in myopes.[25] They found that the ortho-K group showed low repeatability for cornea-related parameters, such as mean keratometry. The results for the baseline and central groups also supported the conclusion that ortho-K had a comparable effect on the repeatability of ocular parameters; in some parameters, the treatment groups showed better ICC than the baseline group, although the difference is not significant. The results showed that ortho-K decentration did not influence the AL, ACD, CCT, and LT measurements. No error in the measurement values were noted, as the measurement area of the IOL Master was 2.5 mm in diameter in the corneal apex at the center. While the diameter of the back optic zone of ortho-K is usually 5.0–6.0 mm, the decentration distance of the treatment zone created in the eccentric group was only 0.91 mm. Thus, the actual borderline of the back optic zone was larger than 2.0 mm toward the apex, still larger than the measurement area of devices with a 1.25 mm radius. However, the flatter of center cornea reduced the gradient of corneal shape that may reduce the measurement error with tiny eye movement in measurement.

Ortho-K might have influenced the corneal pachymetry-related parameters. The variations in the repeatability of corneal biomechanical parameters were higher than those observed in the ocular parameters. In the baseline group, A1L, A2L, and A2V showed poor repeatability; poor repeatability was also observed in A1L, A2L, and bIOP in the central group and in A1L and A2V in the eccentric group; the ICC values in all groups were below 0.7. Different parameters showed different trends: the repeatability of A1L decreased after ortho-K, and A2L showed the highest repeatability in the central group and the lowest repeatability in the eccentric group. Nevertheless, these parameters all had unacceptable repeatability. Generally, the parameters related with biomechanics were more stable after ortho-K, whereas the parameters related with corneal shape were more varied. A similar result for repeatability after ortho-K was reported in our previous study.[26] Corneal biomechanical parameters demonstrated a good repeatability, except A1L and A2L. This result may be due to the intrinsic differences of the parameters; A1L and A2L are related to corneal pachymetry and tomography, wherein ortho-K lens can more easily affect cornea morphology; by contrast, biomechanical parameters such as SPA1 seem much stable. Other researchers share the same view, that is, ortho-K is more likely to cause changes in parameters related to corneal thickness.[27,28] Moreover, the correlation results demonstrated that decentration correlated only to some corneal thickness parameters, such as A1V and A2L. These differences in results are caused by ortho-K itself, and they have nothing to do with ortho-K decentration.

This study has several limitations. First, the decentration distance of the optical zone was still short. A conservative eccentric fitting was used to avoid the risk of corneal trauma caused by ortho-K decentration. Given that children commonly receive ortho-K and given the differences between adults and children, children may be better candidates for similar studies. Therefore, further studies must use larger decentration distance to ensure safety. The more sample size is essential to detect small effect of decentration. So it will give a further interpretation of decentration fitness in related ocular measurements of a larger children group with a more wearing time.

Conclusion

The decentration of ortho-K lenses did not influence the measurement of ocular parameters in adult, namely, AL, CCT, ACD, and LT. These parameters remained stable despite ortho-K decentration after 2-hour ortho-K wear. For the biomechanical parameters, differences were observed in SPA1 and bIOP. Thus, more attention should be given to parameters related to corneal thickness during biomechanical evaluations. The patients with 0.9 mm decentration may not influence the ocular parameters, however the larger decentration still merit attention especially in corneal biomechanics.

Data Sharing Statement

Data are available upon reasonable request. It is available from the corresponding author.

Ethics Approval Statement

The study was approved by the Ethics Committee of the Qingdao Eye Hospital of Shandong First Medical University (MR-37-24-036573) in accordance with the Declaration of Helsinki.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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