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Changes in the Objective Vision Quality of Adolescents in a Mesopic Visual Environment After Wearing Orthokeratology Lenses: A Prospective Study

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Purpose: This study aimed to investigate changes in objective vision quality in mesopic environments in teenagers with myopia after wearing orthokeratology (OK) lenses.

Methods: This prospective clinical study included 45 patients (80 eyes) who received OK lenses at the First Affiliated Hospital of Jinan University from March 2021 to September 2021. An Optical Path Difference-Scan III refractive power/corneal analyzer was used to determine the corneal topographic parameters (corneal e, corneal Q, surface asymmetry index (SAI), and surface regularity index (SRI)), higher-order aberrations (HOAs), axial length (AL) change, lens decentration, induced astigmatism, target power, and Strehl ratio (SR) in a mesopic visual environment after wearing OK lenses for 6 months. In addition, corneal morphological parameters, HOAs, and SR were analyzed in a mesopic visual environment. Finally, we investigated the correlations among corneal morphology, HOAs, AL change, lens decentration, induced astigmatism, and SR.

Results: The SAI value was significantly higher ($P<0.01$), and the corneal e was significantly lower ($P<0.01$), in a mesopic visual environment after wearing OK lenses for 1 week than baseline. A significant increase was observed in total HOAs and spherical aberrations, compared with before the OK lenses were worn ($P<0.01$). In addition, SR in the mesopic visual environment decreased significantly after wearing the lenses ($P<0.01$). No significant differences were observed ($P>0.05$) among the 1-week, 1-month, 3-month, and 6-month follow-up findings. After 6 months, AL and lens decentration did not differ significantly compared with before ($P>0.05$), whereas induced astigmatism significantly increased ($P<0.05$). Negative correlations were observed between corneal Q, SAI, SRI, HOAs, induced astigmatism, and SR, and positive correlations were found between corneal e, AL change, lens decentration, and SR, after wearing OK lenses.

Key Points: • Wearing orthokeratology lenses significantly altered corneal morphology and HOAs in myopic teenagers within 1 week. • The changes that we observed in the eyes of adolescents with myopia after wearing orthokeratology lenses decreased vision quality in mesopic environments. • Strehl ratio is significantly correlated with multiple parameters, including HOAs, AL change, and lens decentration.

Conclusions: In teenagers with myopia wearing OK lenses, significant changes in vision quality and corneal morphology were observed, leading to increased aberrations and affecting optical imaging quality. Furthermore, SR is significantly correlated with multiple parameters, including HOAs, AL change, and lens decentration.

Registration Number: This study is registered with the United States Clinical Trials Registry under registration number NCT04929119.

Key Words: Orthokeratology lens—Objective vision quality—Corneal morphology—Higher-order aberrations—Axial length—Lens decentration—Strehl ratio.

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The worldwide prevalence of myopia among adolescents is increasing annually.[1] There is a close association between myopia and several eye diseases, such as macular degeneration and glaucoma. In addition, myopia is the leading cause of blindness worldwide. Therefore, preventing and treating myopia are topics of considerable research interest. Myopia can be controlled or corrected by administering low-concentration atropine, undergoing refractive surgery, wearing glasses, wearing defocus lenses, or wearing orthokeratology (OK) lenses.

Orthokeratology lenses induce temporary changes to the eye in the following ways. One achieves corneal reshaping through the mechanical and fluidic effects of wearing the lens, whereas the other is achieved through the pressure exerted by the OK lens.[2] Orthokeratology lenses are usually worn at night to reshape the cornea while sleeping, providing clear vision during the day. This makes wearing an OK lens a popular method for correcting myopia in adolescents,[3] as there is no need to wear glasses during the day.

Despite the fact that OK lenses effectively improve uncorrected visual acuity, however, they can also decrease adolescent patients' objective vision quality in specific visual environments.[4] Based on the ambient luminance, visual environments can be described as photopic, scotopic, or mesopic. In 1983, the International Society of Illumination defined these three types of vision as follows: (1) photopic, or bright, vision occurs with an ambient luminance of $1\times10^{-3}\times10^{4}$ lux, such as sunlight and night-time desk lamps; (2) scotopic, or dark, vision occurs when ambient luminance is below 1×10^{-3} lux, often under dim starry skies; and (3) mesopic vision occurs when ambient luminance is within the range of both bright and dark vision, approximately $0.001\sim3^{3}$ lux. Mesopic vision is the type of vision that is used most often in daily life.[5] As the ambient luminance shifts from bright to dark, the spectral sensitivity curve gradually shifts in the short-wave direction, which is referred to as the Purkinje shift.[6] Because of this shift, a significant increase in lower-order and HOAs in emmetropia is observed in mesopic environments, compromising vision quality and adversely affecting night vision.[7]

Lower-order aberrations, as mentioned above, include myopia, hyperopia, and astigmatism and are defined by having a Zernike coefficient less than 3. In contrast, HOAs (which have a Zernike coefficient ≥3[8,9]) include spherical aberrations, comatic aberrations, and trefoil aberrations. Spherical aberrations occur when light rays that pass through the lens distal from the optical axis come to a focus closer to the lens than light rays close to the optical axis. This results in the peripheral rays converging on a different plane than the more central rays, forming a diffuse light spot on the front of retina. A comatic aberration occurs when a wide beam of light that is not aligned with the main optical axis cannot be focused to a single point through the eye's refractive system, forming a comet-shaped light spot with a bright tail on the front of retina. Trefoil aberrations cause light to diverge in three directions when it passes through the lens, forming a "cloverleaf" shape on the retina. All three of these aberrations can be induced by wearing OK lenses; therefore, adolescents using OK lenses need to be monitored for their potential development. The cornea is the primary source of HOAs in the human eye,[10,11] with spherical aberrations accounting for 90% of all corneal aberrations.[9] Therefore, this study concentrated on the total higher-order and spherical aberrations.

In addition, previous studies have shown that OK lenses can change the rate of curvature, asymmetry, and disrupt surface regularity.[2] Orthokeratology lenses alter corneal morphology to decrease full-eye lower-order aberrations and improve visual acuity in myopic adolescents.[12–14] However, wearing OK lenses results in increased HOAs.[15–17] These parameters are, therefore, also important to monitor in adolescents who use OK lenses.

Previous studies of adolescents who use OK lenses have primarily focused on subjective vision quality[18] and have not evaluated changes in objective vision quality by directly assessing the eye features described above. Furthermore, the correlations between Strehl ratio (SR) and factors such as objective vision quality, axial length (AL) change, lens decentration, and corneal morphology are poorly reported and not comprehensive. Therefore, this study aimed to assess changes in objective vision quality, corneal morphology, and investigate the correlations of SR with the above factors in mesopic environments in myopic adolescents wearing OK lenses. Our findings are expected to explore appropriate indicators to evaluate the effect of OK lenses and to provide real-world data for improving the design of OK lenses to eliminate the associated reduction in objective vision quality.

MATERIAL AND METHODS

Study Population

Forty-five consecutive patients (80 eyes), including 25 females, who received OK lenses at the First Hospital of Jinan University from March 2021 to September 2021 were included in this prospective self-controlled study. The general patient characteristics are presented in Table 1. Customized OK lenses were produced based on the patients' ocular features (AL, refractive error, corneal topography). The patients were required to wear OK lenses for no less than 8 hr per night. The following inclusion criteria were applied: (1) patient age 8∼18 years; (2) intention to wear OK lens; (3) informed consent provided by the patients themselves and their guardians; (4) equivalent spherical refraction ≤-6.00 D, ≥-0.05 D, and regular astigmatism ≤1.5 D; and (5) intraocular pressure (IOP) of less than 23 mm Hg. The exclusion criteria were as follows: (1) patients with concurrent corneal diseases, such as active keratitis, corneal dystrophy, keratoconus, and nubecula; (2) those with a history of corneal surgery or corneal trauma; (3) those with other concurrent ocular diseases, such as various inflammatory diseases (dacryocystitis, xerophthalmia, and uveitis), glaucoma, fundus disease, ocular tumor, ocular trauma, manifest strabismus, and any ocular diseases affecting visual function; and (4) those with a previous history of contact lens or contact lens care solution allergy. Informed consent was obtained from the patients and their guardians to participate study after they received an explanation of the treatment principle, wearing method, and complications associated with OK lenses. This study is registered with the United States Clinical Trials Registry under registration number NCT04929119.

Evaluation of Vision Quality and Corneal Topography

All outcomes were measured using an Optical Path Difference (OPD)-Scan III refractive power/corneal analyzer (OPD-SCAN III; Nidec Corporation, Ltd, Aichi, Japan). This instrument combines Placido topography and retinoscopy imaging, which can measure corneal curvature, pupil diameter, spherical or columnar powers, aberrations, and optical functions.[19] The OPD-SCAN III has a large measurement range, with a diameter of up to 9.5 mm, enabling accurate measurement of wavefront aberrations, including total ocular aberrations, corneal aberrations, and intraocular aberrations. In addition, this instrument assesses 11,880 data measurement

TABLE 1. *Descriptive Statistics (Mean±SD) of the Myopic Teenagers Included in This Study*

	Range	Mean	SD
Age (years)	8 to 18	10.62	2.52
Corneal curvature K1 (D)	40.30 to 46.92	42.88	1.30
Corneal curvature K2 (D)	41.80 to 48.06	43.87	1.51
Equivalent spherical lens (D)	−0.75 to −5.25	−2.81	1.27
Axis length (mm)	23.16 to 26.52	24.58	0.54
Corneal thickness (μm)	500 to 633	556.09	28.43
Intraocular pressure (mm Hg)	11 to 20	16.04	2.38

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points when analyzing corneal topography and can adjust the lighting to imitate different luminance conditions.

To control the experimental lighting conditions, sunlight was blocked from entering the room. Ambient illumination intensity was adjusted using a light source and measured using a Sekonic L-308DC light meter (Sekonic Corporation, Ltd, Tokyo, Japan). To create photopic, mesopic, and scotopic lighting situations, illuminance was adjusted to greater than 100, 3～10, and less than 0.5 lux, respectively.[20] For mesopic lighting conditions, the illuminance was adjusted to 3.5 lux, and patients were allowed to acclimate to the lighting conditions for 10 to 15 min before any measurements were taken.

During the recruitment phase of the study, a basic examination was performed under a slitlamp to assess each patient's ocular condition and diagnose other ocular diseases, such as conical cornea and ocular inflammation. Subsequently, a noncontact IOP meter (Canon TX-20; Canon Medical Systerms, Inc, CA) was used to record the patients' IOPs. Next, for all patients who were included in the study, a normal pupillary reflex in response to light was confirmed, after which the patients were allowed to sit in a dark room for 15 min. Subsequently, each patient's basic information was verified and inputted into the OPD-SCAN III. The patients were asked to open their eyes wide and look at the image that appeared before them to completely expose the cornea and pupil, where tear film stability is maintained. The examiner then focused the instrument on the eye, and measurements were taken automatically after alignment (3～5 measurements per eye). When measuring the corneal e and Q, the diameter of measurement should be 12.0 mm. Higher-order aberrations (total higher-order, spherical, coma, trefoil, corneal higher-order, and intraocular HOAs), corneal morphological parameters (corneal e, corneal Q, SAI, and SRI), and SR are automatically determined by the analyzer. For an eye to be included in the study, the following criteria needed to be met: (1) offset value less than 2.0; (2) corneal measurement zone greater than 8 mm; and (3) uniform tear film. We screened patients with $\geq$20 Placido rigs and pupil diameters of $\geq$4 mm. Also, central corneal thickness was measured by the specular microscope (CEM-530; Nidek, Inc, CA). Then, the examiner focused the instrument on the center of eye, and instrument automatically identified the center of the cornea (3 measurements per eye). In addition, each eye underwent three AL measurements using the Optical Biometer AL-Scan (Nidek, Inc, CA).[21] Then, we recorded data pertaining to corneal morphological parameters, aberrations, optical function, and basic ocular conditions, such as anterior corneal surface curvature, posterior corneal surface curvature, central corneal thickness, AL, and degree of lens sphericity.

Paralytic drugs, such as compound tropicamide eye drops, were not administered to the patients during the examination. In addition, because some studies show that mydriatics can affect detection of HOAs,[22] especially spherical aberration, and that the pupil requires 4～6 hr after administration of a mydriatic to recover its normal function, OPD-Scan III examinations were performed on a different day than the initial basic examination. The same experienced clinical ophthalmologist, who is skilled in operating the OPD-Scan III, performed all of the examinations.

Orthokeratology Lenses

The OK lenses used in our study were Arcoflex with Boston EM lenses (Alpha Corporation Inc, Nagano, Japan) that have an oxygen transmission coefficient value of 78×10^{-11} (cm/s) [(mLO_2/(mL×h PA)], an optical zone diameter of 6.00 mm, a reversal arc diameter of 7.20 mm, and a central thickness of 0.22 mm. Customized OK lenses were fabricated based on each patient's ocular features, including corneal topography, eye axis, and refraction. Arcoflex OK lenses are fourth-generation reverse geometry lenses made of hard, breathable materials. Target power is calculated based on the initial refractive error and individual patient considerations to ensure optimal visual outcomes. In the next 6 months, refractive power change should be derived from the changes in the refractive power map obtained through corneal topography (ATLAS 500; Carl Zeiss Meditec AG, Jena, Germany).

Study Outcomes

The primary outcomes assessed in this study were HOAs, induced astigmatism, AL change, lens decentration, target power, and SR. Higher-order aberrations include spherical, comatic, and trefoil aberrations: spherical aberration and comatic aberrations have the greatest impact on central vision and vision quality and account for 90% of all corneal aberrations, whereas trefoil aberrations have a lesser impact on vision quality.[23] Strehl ratio is an objective indicator of the optical imaging quality of the human eye. Because of diffraction and scattering effects, light that enters the human eye forms a point on the retina. The point spread function (PSF) reflects the shape and focus of this point within an optical system that has an aberration. The SR is commonly used to describe this response function and refers to the ratio of the peak value of the PSF of an optical system with an aberration to the peak value of the PSF of an ideal optical system. A lower SR value indicates low objective vision quality because of increased HOAs when SR$<$0.8 (see Figure S1, Supplemental Digital Content 1, http://links.lww.com/ICL/A296).

The secondary outcomes assessed in this study were indicators of corneal morphology, including corneal e, corneal Q, SAI, and SRI values. Corneal e is a sensitive indicator of corneal morphology: as the central area of the cornea becomes steeper and the peripheral area becomes flatter, the e value increases. Corneal Q reflects the degree of inconsistency between the curvature of the center and periphery of the cornea; in normal eyes, the corneal Q value is less than 0, indicating that the cornea gradually flattens from the center to the periphery, resembling a prolate ellipse. The SAI is a measure of abnormal changes in symmetrical corneal refractive power. A normal SAI value is 0.3 ± 0.1 D; as the corneal surface becomes more asymmetric, the SAI increases, and values greater than 0.5 are considered abnormal. The SRI refers to the optical quality of the central area of the cornea and evaluates whether the distribution of corneal refractive power is smooth or regular. A normal SRI value is 0.05 ± 0.03 D; the more regular the corneal surface, the smaller the SRI value, and values greater than 0.8 are considered abnormal.

Statistical Analysis

Data analysis was conducted for both eyes of all patients in our study. SPSS 25.0 (IBM) was used to perform all statistical analyses. Descriptive statistical analysis, including calculation of means, standard deviations, and maximum and minimum values, was performed to assess the basic ocular features of the participants. Univariate analysis of variance (ANOVA) with repeated measurement was used to compare differences between corneal e values, SAI, total HOAs, spherical aberrations, and SR in each participant's eyes in a mesopic visual environment before and after wearing OK lenses. Spearman analysis was used to analyze the

TABLE 2. *Pairwise Comparisons and the Difference Between the Mean Values at Baseline, 1 Week, 1 Month, 3 Months, and 6 Months*

		Changes in Corneal Morphology								Changes in Higher-Order Aberration						Changes in SR	
		Corneal e		SAI		Corneal Q		SRI		HOA		Spherical		Coma			
Baseline		0.406 (0.374, 0.428)		0.354 (0.333, 0.375)		−0.177 (−0.202, −0.152)		0.392 (0.339, 0.445)		0.153 (0.133, 0.173)		0.023 (0.017, 0.028)		0.057 (0.049, 0.065)		0.254 (0.206, 0.302)	
1 week	*Versus* baseline	−1.422 (−1.531, −1.312)	$P<0.05$	0.162 (0.095, 0.230)	$P<0.05$	1.336 (1.136, 1.537)	$P<0.05$	0.447 (0.362, 0.533)	$P<0.05$	0.209 (0.160, 0.258)	$P<0.01$	0.160 (0.124, 0.196)	$P<0.01$	0.195 (0.138, 0.251)	$P<0.01$	−0.183 (−0.243, −0.122)	$P<0.01$
	Versus 1 month	0.063 (−0.077, 0.202)	$P>0.05$	−0.020 (−0.107, 0.067)	$P>0.05$	−0.087 (−0.392, 0.218)	$P>0.05$	−0.032 (−0.141, 0.077)	$P>0.05$	−0.007 (−0.085, 0.071)	$P>0.05$	0.031 (−0.010, 0.073)	$P>0.05$	−0.004 (−0.084.0.075)	$P>0.05$	0.003 (−0.023, 0.028)	$P>0.05$
	Versus 3 months	0.029 (−0.098.0.156)	$P>0.05$	−0.041 (−0.123, 0.041)	$P>0.05$	−0.050 (−0.305, 0.205)	$P>0.05$	−0.058 (−0.149, 0.033)	$P>0.05$	−0.036 (−0.090, 0.018)	$P>0.05$	−0.013 (−0.090, 0.063)	$P>0.05$	−0.005 (−0.079, 0.069)	$P>0.05$	0.011 (−0.013.0.035)	$P>0.05$
	Versus 6 months	0.032 (−0.078.0.195)	$P>0.05$	−0.026 (−0.121, 0.054)	$P>0.05$	−0.064 (−0.295, 0.216)	$P>0.05$	−0.050 (−0.150, 0.051)	$P>0.05$	−0.015 (−0.054, 0.022)	$P>0.05$	−0.003 (−0.087, 0.066)	$P>0.05$	−0.004 (−0.069, 0.081)	$P>0.05$	0.007 (−0.025, 0.031)	$P>0.05$
1 month	*Versus* baseline	−1.485 (−1.590, −1.379)	$P<0.05$	0.182 (0.117, 0.248)	$P<0.05$	1.423 (1.198, 1.649)	$P<0.05$	0.480 (0.396, 0.563)	$P<0.05$	0.217 (0.160, 0.273)	$P<0.01$	0.129 (0.100, 0.158)	$P<0.01$	0.199 (0.151, 0.248)	$P<0.01$	−0.185 (−0.235, −0.135)	$P<0.01$
	Versus 3 months	−0.034 (−0.156, 0.087)	$P>0.05$	−0.021 (−0.110, 0.068)	$P>0.05$	0.037 (−0.238, 0.312)	$P>0.05$	−0.026 (−0.128, 0.077)	$P>0.05$	−0.029 (−0.099, 0.042)	$P>0.05$	−0.045 (−0.114.0.024)	$P>0.05$	0.000 (−0.071, 0.071)	$P>0.05$	0.009 (−0.013.0.031)	$P>0.05$
	Versus 6 months	−0.005 (−0.026, 0.062)	$P>0.05$	−0.011 (−0.089, 0.094)	$P>0.05$	0.007 (−0.203, 0.230)	$P>0.05$	−0.031 (−0.103, 0.067)	$P>0.05$	−0.012 (−0.064, 0.061)	$P>0.05$	−0.034 (−0.248.0.063)	$P>0.05$	0.005 (−0.094, 0.062)	$P>0.05$	0.013 (−0.013.0.041)>	$P>0.05$
3 months	*Versus* baseline	−1.450 (−1.548, −1.352)	$P<0.05$	0.203 (0.133, 0.274)	$P<0.05$	1.386 (1.177, 1.595)	$P<0.05$	0.505 (0.418, 0.593)	$P<0.05$	0.245 (0.191, 0.300)	$P<0.01$	0.174 (0.113, 0.234)	$P<0.01$	0.199 (0.148, 0.250)	$P<0.01$	−0.194 (−0.257, −0.131)	$P<0.01$
	Versus 6 months	−0.002 (−0.033, 0.052)	$P>0.05$	0.000 (−0.073, 0.051)	$P>0.05$	0.011 (−0.301, 0.250)	$P>0.05$	−0.015 (−0.085, 0.033)	$P>0.05$	−0.031 (−0.055, 0.022)	$P>0.05$	−0.030 (−0.081.0.043)	$P>0.05$	0.003 (−0.087, 0.060)	$P>0.05$	0.010 (−0.015.0.069)	$P>0.05$
6 months	*Versus* baseline	−1.460 (−1.672, −1.203)	$P<0.05$	0.198 (0.122, 0.239)	$P<0.05$	1.380 (1.068, 1.637)	$P<0.05$	0.499 (0.320, 0.556)	$P<0.05$	0.202 (0.166, 0.330)	$P<0.01$	0.170 (0.119, 0.201)	$P<0.01$	0.201 (0.143, 0.251)	$P<0.01$	−0.178 (−0.209, −0.134)	$P<0.01$
Composite comparison of 1 week, 1, 3, and 6 months	*Versus* baseline	−1.457 (−1.521, −1.364)	$P<0.05$	0.192 (0.174, 0.226)	$P<0.05$	1.380 (1.207, 1.510)	$P<0.05$	0.508 (0.442, 0.525)	$P<0.05$	0.228 (0.184, 0.257)	$P<0.01$	0.175 (0.133, 0.229)	$P<0.01$	0.200 (0.169, 0.228)	$P<0.01$	−0.162 (−0.206, −0.142)	$P<0.01$

All statistics in this table present for Mean, 95% confidence interval.

HOA, higher-order aberration; SAI, surface asymmetric index; SRI, surface regular index; SR: Strehl ratio.

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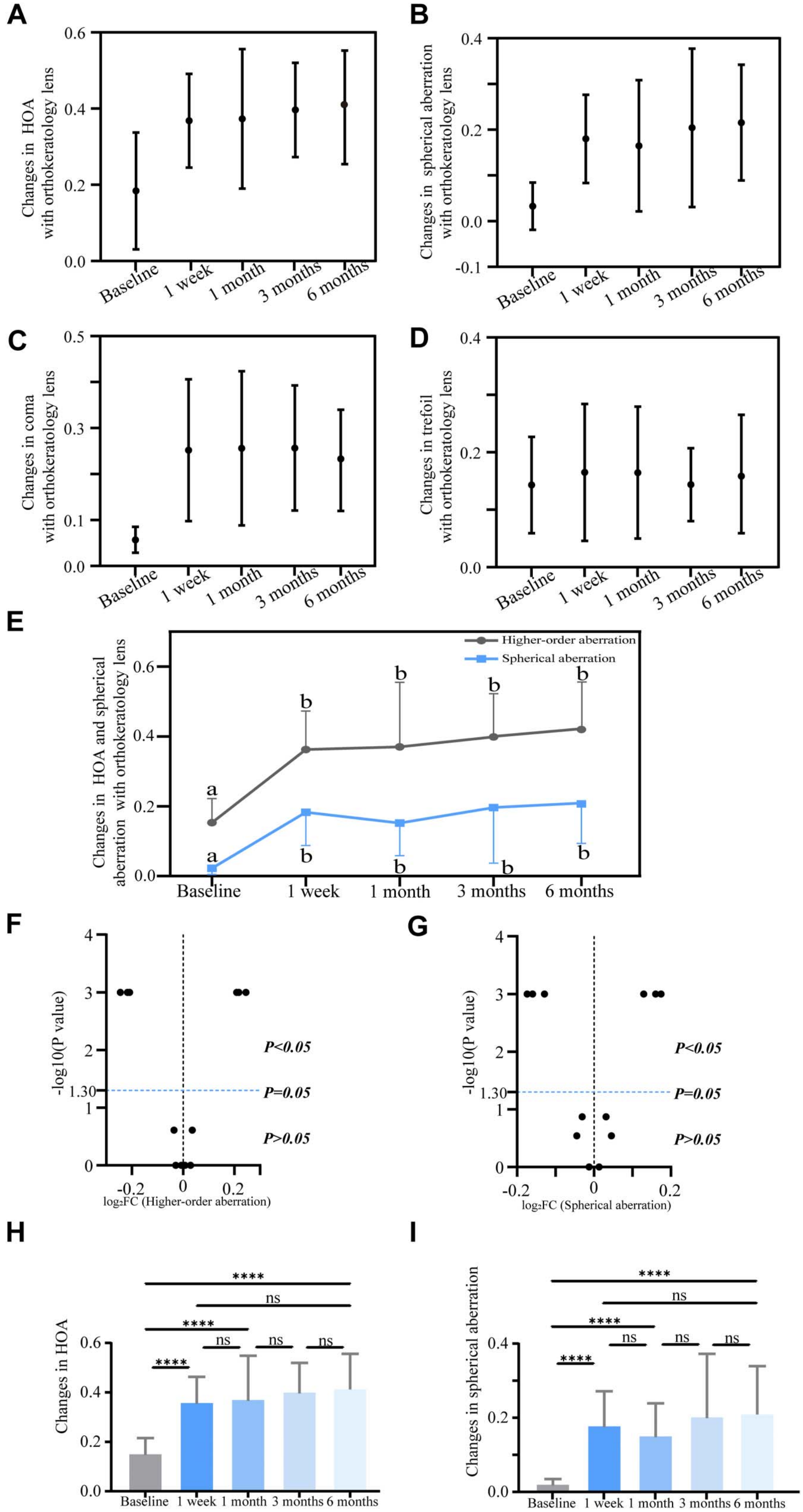

FIG. 1. (A–D) Changes in HOAs and spherical, comatic, and trefoil aberrations after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses. (E) Changes in HOAs and spherical aberrations after wearing OK lenses. "a" represents the baseline, whereas "b" indicates a statistically significant difference compared with "a." There is no statistically significant difference between data points that are both marked with "b." Error bar: standard deviation. (F, G) Volcano plots presenting pairwise comparisons between baseline and after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses. The horizontal axis shows the logarithmic ratio ($\log_2$ fold change) between HOAs, spherical aberrations, and baseline. The vertical axis shows the $-\log_{10}$(*P* value), and $-\log_{10}$(*P* value=0.05) is approximately equal to 1.30. Higher values on the vertical axis correlate with lower *P* values, and values less than 0.05 (shown above the dashed blue line) were considered to be significant. (H, I) Post-hoc analyses of (H) HOAs and (I) spherical aberrations. ****, $P<0.01$, ns, not significant ($P>0.05$). HOA, higher-order aberration; OK, orthokeratology.

correlation between corneal parameters, aberrations, AL change, lens decentration, induced astigmatism, and SR in a mesopic visual environment. The descriptive statistical analysis results are expressed as the mean±SD. Statistical significance was set at $P<0.05$.

RESULTS

Patient Characteristics

Forty-five patients (80 eyes) who met the inclusion criteria, of which 25 (56%) were females, were included in this study. The mean age of the patients was 10.62±2.52 years (range, 8–18 years). All patients exhibited right eye corneal curvature (K1) values of 43.18±1.13 D, right eye corneal curvature (K2) values of 43.69±1.56 D, left eye corneal curvature (K1) values of 42.57±1.24 D, left eye corneal curvature (K2) values of 44.16±1.55 D, right eye spherical equivalents of −2.75±1.32 D, left eye spherical equivalents of −2.83±1.20 D, right AL of 24.51±0.76 mm, and left AL of 24.94±0.87 mm (Table 1). Eight patients did not complete the 6-month follow-up and were, therefore, excluded. Ultimately, 74 eyes were included in the study (see Table S1, Supplemental Digital Content 1, http://links.lww.com/ICL/A298).

Effect of Orthokeratology Lenses on Higher-Order Aberrations

To determine whether wearing OK lenses induces the development of HOAs in adolescents, we compared the number of aberrations in participants before and at several timepoints after wearing OK lenses at night. Total HOAs, spherical aberrations, and comatic aberrations in a mesopic visual environment were significantly more common after wearing OK lenses ($P<0.05$) (Table 2) (Fig. 1A–C, E–I). Participants exhibited significantly more HOAs before wearing OK lenses and after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses ($P<0.01$) (Fig. 1H). As the sphericity hypothesis was not met, the Bonferroni post hoc test method based on the Bonferroni correction for significance was used for pairwise comparison between groups. The total HOA after 1 week of wear was significantly higher than before wear ($P<0.01$). The total HOA after 1 month of wear was significantly higher than before wear (Table 2).

Next, we performed composite comparisons of HOAs and spherical aberrations before wearing OK lenses and after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses, respectively. The statistical results of HOAs and spherical aberrations are listed in Table 2. The difference in spherical aberrations between the four datasets was statistically significant ($P<0.01$).

Subsequently, we performed a pairwise comparison between groups. The spherical aberration at 1 week was significantly higher than before wear ($P<0.01$). In addition, spherical aberration at 1 month was significantly higher than before (Fig. 1I). Spherical aberration before wear and at 1 month, 3 months, and 6 months of wear were then subjected to composite comparison. The difference between the means before wear and after 1 week, 1 month, 3 months, and 6 months of wear was significant ($P<0.01$) (Table 2). Comatic aberrations after wearing OK lenses increased, and its pairwise comparison between groups was statistically significant ($P<0.01$) (Table 2). There were no statistically significant differences in HOAs, spherical aberrations, or comatic aberrations after 1 week, 1 month, 3 months, and 6 months of wear ($P>0.05$) (Fig. 1F–I), or in trefoil aberrations after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses compared with baseline ($P>0.05$) (Fig. 1D).

Taken together, these findings show that wearing OK lenses overnight induced HOAs in myopic adolescents.

Effect of Orthokeratology Lenses on Strehl Ratio

Given that OK lenses appeared to affect aberrations in our patients, we next evaluated vision quality by determining the SR before and after wearing OK lenses. We found that the SR in a mesopic visual environment decreased significantly ($P<0.01$) after wearing OK lenses, as demonstrated by univariate ANOVA with repeated measurement (Table 2) (Fig. 2A–C). The SR decreased significantly from baseline to after 1 week of wearing OK lenses and remained relatively constant until the 6-month follow-up (Table 2). The difference in SR before wear and after 1 week, 1 month, 3 months, and 6 months of wear was statistically significant ($P<0.01$) (Table 2). The SR after 1 week of wear was significantly lower than that before wear by 0.183 ($P<0.01$). In addition, the SR after 1 month was significantly lower than that before wear by 0.185 (Table 2).

Next, we performed a composite comparison of the SR before and after 1 week, 1 month, 3 months, and 6 months of wear and found that the difference between the mean values before and after wear was 0.162 (Fig. 2C). There was no statistically significant difference in SR after 1 week, 1 month, 3 months, and 6 months of wear ($P>0.05$) (Table 2) (Fig. 2B).

Taken together, these findings suggest that OK lens use significantly lowers visual acuity in a mesopic visual environment in adolescents, as indicated by a decrease in the SR.

Effect of Orthokeratology Lenses on Axial Length, Lens Decentration, and Induced Astigmatism

To evaluate myopia control after wearing OK lenses, we next evaluated AL, lens decentration, and induced astigmatism before and after lens wear. The AL and lens decentration at 6 months showed no statistically significant differences compared with before ($P>0.05$). However, the study found that induced astigmatism was significantly higher than before ($P<0.05$) (see Figure S2, Supplemental Digital Content 1, http://links.lww.com/ICL/A297).

Effect of Orthokeratology Lenses on Corneal Morphology

Next, we sought to determine whether wearing OK lenses affects corneal morphology in adolescent patients. To do this, we evaluated indicators of corneal symmetry (SAI), smoothness (SRI), and curvature (corneal e and corneal Q) before and after wearing OK lenses overnight for up to 6 months. Although the SAI, SRI, and corneal Q values increased significantly ($P<0.05$) after wearing OK lenses, the corneal e decreased significantly ($P<0.05$). The statistical results of corneal morphology were listed in Table 2 and Figure 3 (A,B). No statistically significant differences were observed in the corneal e and SAI values after 1 week, 1 month, 3 months, and 6 months of wear ($P>0.05$) (Table 2).

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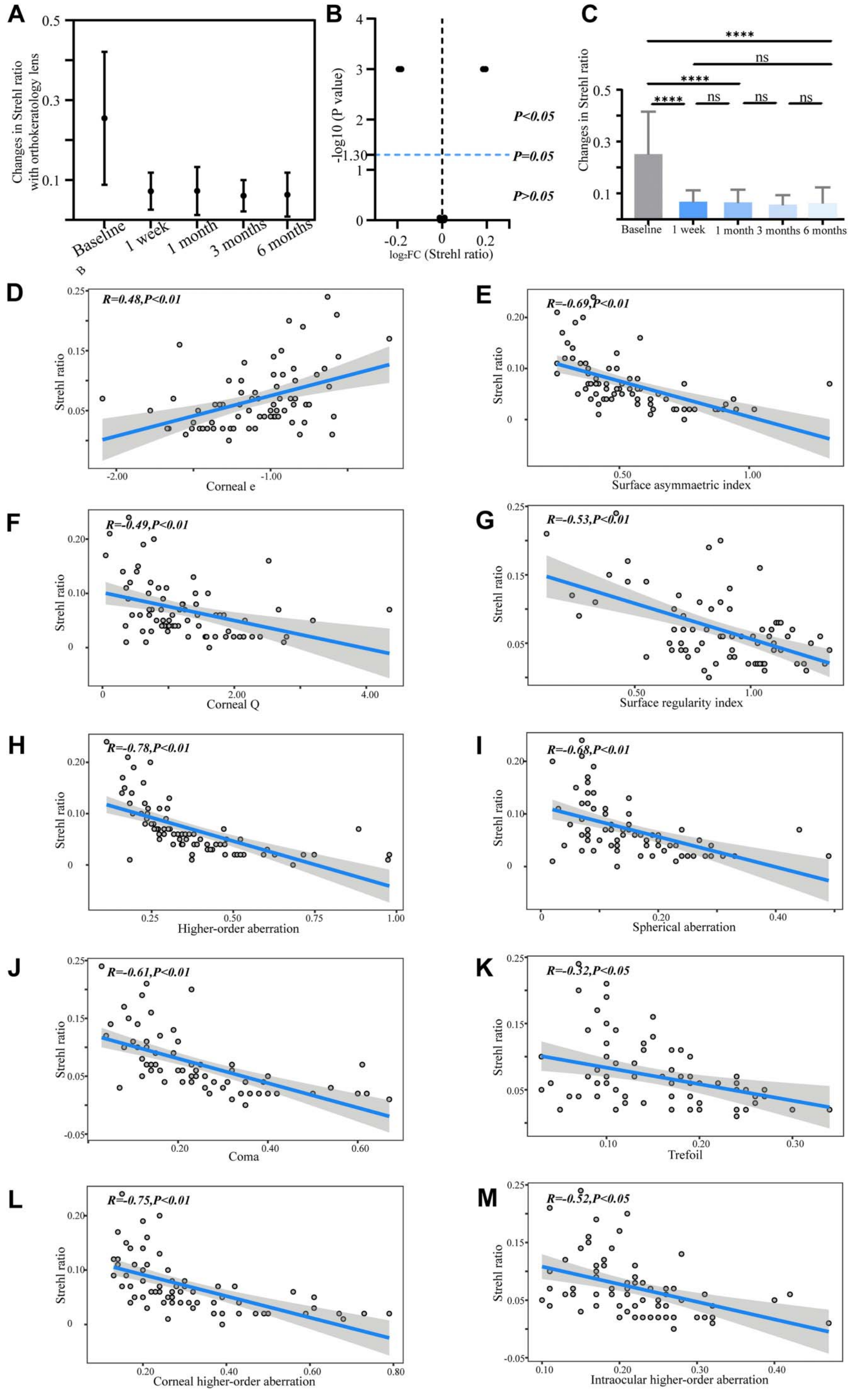

FIG. 2. (A) Changes in SR after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses. (B) A volcano plot presenting pairwise comparisons of SRs between baseline and after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses. (C) A post-hoc analysis of SR. ****, $P<0.01$, ns, not significant ($P>0.05$). (D–M) Spearman linear correlation analyses between surface asymmetric index, corneal Q, surface regularity index, total HOAs, spherical aberrations, comatic aberrations, trefoil aberrations, corneal HOAs, intraocular HOAs, and SR, showing negative correlations after 6 months of wearing orthokeratology lenses (r=0.69, r=−0.49, r=−0.53, r=−0.78, r=−0.68, r=−0.61, r=−0.32, r=−0.75, r=−0.52, respectively; $P<0.05$), with a 95% confidence interval. HOA, higher-order aberrations; OK, orthokeratology; SR, Strehl ratio.

Interactions Among Objective Measures of Vision Quality Affected by Wearing Orthokeratology Lenses

After 1 month of wearing OK lenses, we performed Spearman correlation analyses. The results showed a moderate positive correlation between corneal e value and SR, with a related coefficient of 0.48 ($P<0.01$) within a 95% CI, in teenagers who wore OK lenses for 6 months in a mesopic visual environment (Fig. 2D); the Spearman linear correlation among SAI, corneal Q, SRI, HOA, spherical aberration, comatic aberration, trefoil aberration, corneal HOA, intraocular HOA, and SR showed a negative correlation at 6 months (Fig. 2E–M). Furthermore, correlations between SR and refractive power changes and target power were performed, and their relative plots are shown in Figure 4. We found that the SR was strongly correlated to target power and refractive power changes, with related coefficients of −0.72 and −0.65,

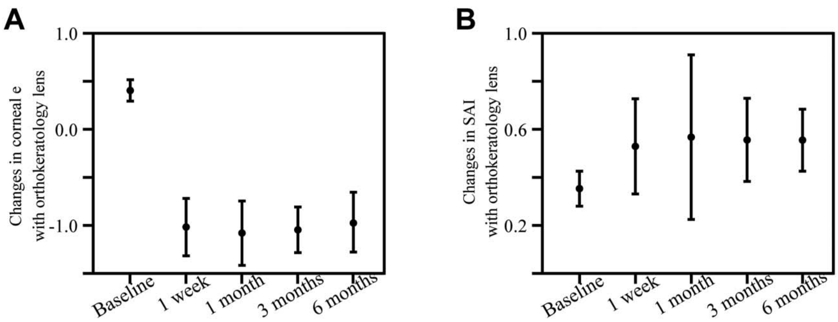

FIG. 3. (A, B) Changes in corneal e and SAI after 1 week, 1 month, 3 months, and 6 months of wearing OK lenses. OK, orthokeratology; SAI, surface asymmetry index.

respectively ($P<0.01$). Therefore, the SR was strongly correlated to SAI, HOA, corneal HOA, and target power and moderately correlated with corneal Q, SRI, spherical aberration, comatic aberration, trefoil aberration, intraocular HOA, and refractive power changes. Also, we have performed correlations between AL change, lens decentration, induced astigmatism, target power, and SR. We found positive correlations between AL change, lens decentration, and SR with related coefficients of 0.66 and 0.59, respectively ($P<0.01$), after 6 months of wearing OK lenses in a mesopic visual environment (Fig. 5).

DISCUSSION

This prospective clinical study investigated the effects of wearing OK lenses in mesopic visual environments on corneal morphological parameters (including corneal e, corneal Q, SRI, and SAI values), ocular HOAs (including total HOA, spherical aberration, comatic aberration, and trefoil aberration), AL change, lens decentration, induced astigmatism, and SR in adolescents. Significant changes in objective vision quality were observed, and these changes remained stable after 7 days. The changes in ocular surface morphology increased higher-order, spherical, and comatic aberrations. In addition, the SR decreased significantly with wear. Optical imaging quality in these patients was also affected by the changes in corneal morphology. Finally, the decrease in SR was significantly associated with reductions in the SAI, total HOAs, spherical aberrations, comatic aberrations, corneal HOAs, induced astigmatism, target power, and refractive power changes.

According to our study findings, total ocular HOAs and spherical aberrations began to increase significantly after 1 week of wear, which is consistent with previous studies.[24–26] Wearing OK lenses results in morphological and structural changes to the cornea, as evidenced by a decrease in corneal e values and an increase in SAI after wearing OK lenses.[27–29] The corneal alterations induced by wearing OK lenses make it more challenging to focus peripheral light entering the eye than light entering near the same angle as the optical axis because of increased corneal asymmetry because of a more convex peripheral cornea and irregularities in the temporal cornea.[15,30,31] As a result, the magnitude of light projected on the retina in the same plane increases, thereby increasing total higher-order and spherical aberrations. Central vision in mesopic visual environments is primarily mediated by cone cells in the central retina. However, as the ambient luminance decreases, the rod cells of the peripheral retina are continuously activated, and peripheral vision becomes crucial for achieving clear vision.[32,33] Therefore, in patients with peripheral corneal myopic drift wearing an OK lens, the amount of light that enters the eye in mesopic visual environments is insufficient, resulting in peripheral light entering the eye away from proximal light. This results in greater scatter and decreased brightness on the peripheral retina, increasing total HOAs and spherical aberrations and, to some extent, affecting the wearer's vision quality. With improved living standards and lifestyle changes, people today are exposed to mesopic visual environments for longer periods than they were in the past. Myopic patients wearing OK lenses are more sensitive to shorter wavelengths of light than longer wavelengths of light in mesopic visual environments. Nevertheless, long-wavelength high-pressure sodium lamps are currently the most frequently employed for street illumination. In addition, the human eye can better visualize dark objects on a bright background than bright objects on a dark background.[34] Thus, OK lens wearers should theoretically have better vision quality under current road lighting conditions than in nonmesopic visual environments. However, long-wavelength lighting affects peripheral vision, which, to some

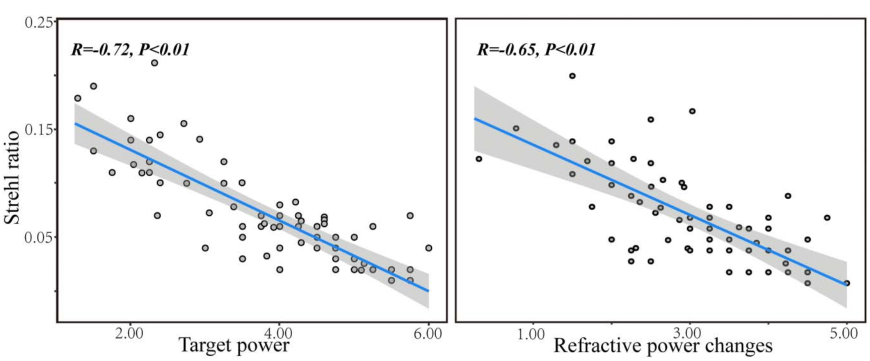

FIG. 4. Spearman linear correlation analyses between target power, refractive power changes, and SR, showing negative correlations after 6 months of wearing orthokeratology lenses (r=−0.72, r=−0.65, respectively; $P<0.01$), with a 95% confidence interval. SR, Strehl ratio.

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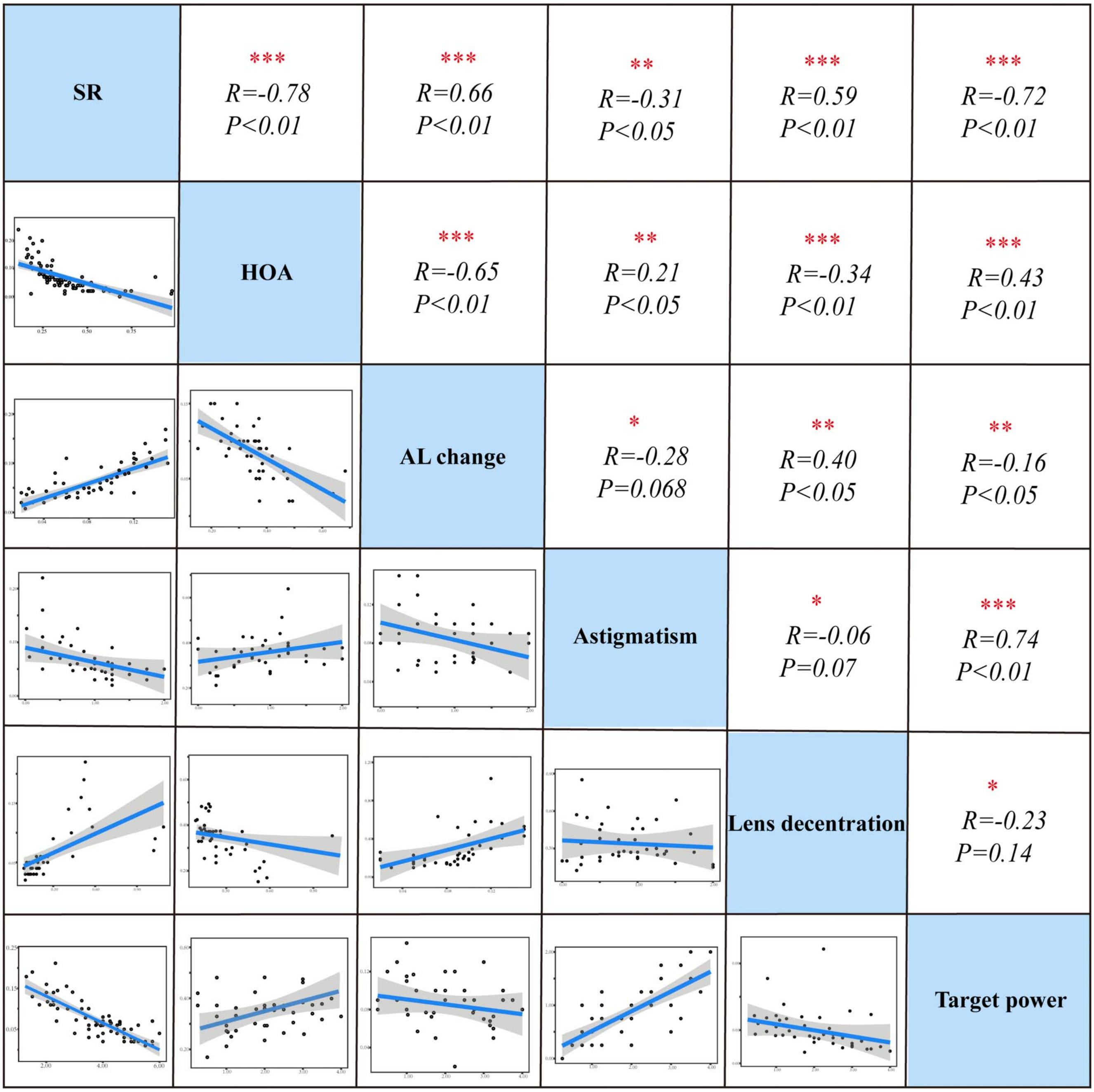

FIG. 5. Spearman linear correlation analyses among SR, HOAs, AL change, induced astigmatism, lens decentration, and target power, showing positive correlations between AL change, lens decentration, and SR after 6 months of wearing OK lenses (r=0.66, r=0.59, respectively; $P<0.05$), with a 95% confidence interval. ***, $P<0.01$, **, $P<0.05$, *, $P>0.05$. AL, axial length; HOA, higher-order aberration; OK, orthokeratology; SR, Strehl ratio.

extent, results in a loss of vision quality and generation of the night-time glare phenomenon. However, the exact mechanism underlying this phenomenon remains unclear.

Our findings showed that the SR was significantly lower after wearing OK lenses, indicating a significant decrease in ocular imaging quality, which is consistent with the findings of Sun et al.[24–26] In addition, a previous study evaluated ocular imaging quality using a two-channel vision quality analysis system in individuals who wore OK lenses.[35] Their findings revealed that, at 1-month follow-up, the SR values had decreased significantly, and the patients' imaging quality had deteriorated.[27] In addition, in this study, we found a positive correlation between the corneal e value and SR.[36,37] After wearing OK lenses, the corneal e value increased, and the SR value decreased. This decrease in SR was because of morphological changes induced in the cornea by wearing OK lenses, as evidenced by erratic alterations in corneal morphology and an increase in the corneal e value.[2,28] Meanwhile, some studies have found that there is a correlation between corneal curvature and aberration, but they only measured corneal curvature and did not perform a correlation between corneal curvature and SR.[38] Other studies have found that total HOA had a negative correlation with SR,[39] but the researchers have not divided the HOA into types and performed correlative analysis separately. We chose more corneal morphological parameters, which reflect corneal morphology more accurately than previous reports. Therefore, the extensive structural changes to the cornea and lower SR values observed after wearing OK lenses suggest that this treatment approach results in poorer vision quality in adolescent patients with myopia in mesopic visual environments.

Furthermore, we find that SR has correlations with most ocular parameters, such as SAI, corneal Q, HOA, target power, refractive power changes, AL change, lens decentration, and induced astigmatism. After wearing OK lenses for 6 months, our study found that there was a decrease in AL change and no significant change in lens decentration. We also found significant correlations between target power, lens decentration, and AL change. It has been found that AL change is not only related to the initial AL[40] but also to the lens decentration and target power, which can also affect the changes in AL. However, lens decentration remained stable even after wearing OK lenses, indicating that it was not affected by the OK lenses. Because of the impact of AL change, patients with poor myopia control are more likely to increase lens decentration. Also, the induced astigmatism has experienced an increase, primarily owing to the target power, which also has a consequential impact on the HOAs. Although correlations have been identified between spherical refraction (SR) and various parameters, such as AL change and lens decentration, the utilization of SR as an indicator of visual function and myopia control necessitates further investigation. The ambiguity persists regarding the extent to which SR influences visual function. Nevertheless, investigating SR continues to be a crucial research pathway for evaluating the efficacy of myopia control in clinical practice, and its impact on visual function may need to be analyzed along with subjective visual evaluations and other related symptoms.

We set a shorter follow-up period and found that, in a mesopic visual environment, the corneal e value decreased significantly after wearing OK lenses, and the most significant decrease in corneal e value was observed after 1 week of wearing OK lenses, which is inconsistent with findings from previous studies.[27–29] However, no significant change in corneal e value was observed at 1-month follow-up compared with after 1 week of wearing OK lenses. According to Yin et al.,[28] no significant changes were observed in corneal e values at 1-month, 3-month, and 1-year follow-up compared with before wearing OK lenses, which differs from our findings. Our study brought this change forward to the first week, which shows that the OK lens has a significant effect after the first week when it comes to myopia control. The Oculus Pentacam system was used in most previous studies, which could only acquire 25 or 50 images that contain 500 measurement points on the corneal surface.[41] Compared with it, the OPD-Scan III used in this study has a larger measuring range and contains 11,880 measurement points on the corneal surface to make the results more precise and realistic.[42] Therefore, our findings indicate that wearing OK lenses increased corneal asymmetry, decreased corneal surface regularity, and flattened the corneal surface in adolescent patients. Furthermore, these effects advanced to the first week and did not increase over time. We speculate that the reason for this apparent discrepancy could be related to the oxygen permeability coefficient of the OK lenses used in the two studies. Our study used OK lenses with lower oxygen permeability coefficients, which resulted in insufficient oxygen supply to the cornea, causing edema of the corneal epithelium and leading to changes in corneal morphology.[43] Another potential explanation is our use of the OPD-SCAN III, which can measure corneal morphology on a larger scale and produce more accurate results than other means of assessment. Future studies should explore the reasons for this apparent discrepancy in study findings.

Although we noted significant changes in corneal e value, total HOAs, spherical aberrations, and SAI in adolescent patients after wearing OK lenses, these changes are not necessarily permanent. Kobayashi et al., in their study on corneal morphology and OK lenses, reported that corneal morphology returned to its before-wear state within 1 to 6 months after patients stopped wearing OK lenses[44,45] and, therefore, does not impact the patient's long-term vision quality. Kobayashi et al.[45] also followed patients wearing reverse geometry OK lenses for 52 weeks and reported that the lenses not only increased uncorrected visual acuity but also increased corneal irregularities. As mentioned in our research, negative correlations between AL and HOA and spherical aberration are similar to previous study[46]; it means that the HOA increases after wearing orthokeratology lenses, and it can make the AL of myopia patients increase slowly to control myopia lot better. We believe that even though the visual function mildly decreases, the treatment objectives are being still met. Nevertheless, future studies need to assess the duration of the changes induced by OK lens wearing in adolescent patients to ensure that the benefits are not outweighed by long-term deficits.

Our study also had some limitations. First, a total of 74 eyes were included in the study, but the samples are still insufficient and no large-scale studies have been conducted. Therefore, it is necessary to conduct a multicenter, large-sample clinical study to make up for the shortcomings of this study. Second, considering the typical 1-year recommended treatment period for OK lenses, the 6-month duration of the conducted research might limit the conclusiveness of the findings. This discrepancy in study duration versus recommended treatment length could affect the interpretation of the results. Third, this study only focused on the objective visual quality, and the data of subjective visual evaluations are incomplete. In addition to investigating subjective symptoms or visual acuity with the OCULUS Binoptometer, evaluating the correlation between SR and subjective visual to guide patients is meaningful. Therefore, to more accurately analyze the reliability of SR, more large-sample, multicenter, multiethnic, multiregional clinical studies are required.

CONCLUSION

In summary, we observed significant changes in objective vision quality in teenagers with myopia wearing OK lenses in mesopic visual environments, and these changes remained stable after 1

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week. The changes in ocular surface morphology increased higher-order, spherical, and comatic aberrations. Optical imaging quality in these patients was mainly affected by the changes in corneal morphology and aberrations. Furthermore, SR is significantly correlated with multiple parameters, including HOAs, AL change, lens decentration, and target power. Given these significant correlations, SR may emerge as a nonnegligible factor in the comprehensive evaluation of myopia control strategies in clinical practice.

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