# Higher-Order Aberrations and Visual Performance in Myopic Children Treated With Aspheric Base Curve-Designed Orthokeratology

Changxu Chen, B.S., Wei Ma, M.M.Sc., Jianglan Wang, M.D., Bi Yang, M.D., Tong Liu, B.S., and Longqian Liu, M.D.

**Objectives:** To investigate the impact of aspheric base curve (BC)-designed orthokeratology (ortho-k) (AOK) lenses on higher-order aberrations (HOA) at different pupil diameters and visual performance.

**Methods:** This prospective clinical study included subjects randomized to wear spherical BC-designed ortho-k (SOK) or AOK lenses. The Pediatric Refractive Error Profile (PREP) questionnaire was completed before and after 3 months of lens wear. The Strehl ratio (SR) and root mean square of ocular higher-order aberrations (HOAs), spherical aberration (SA), coma, and trefoil were measured under 4-mm, 5-mm, and 6-mm pupil diameters at baseline and 3-month visits. Corneal topography, uncorrected low-contrast (LC) visual acuity (VA), and high-contrast (HC) VA were measured at baseline and at 1 day, 1 week, 1 month, and 3 month follow-ups.

**Results:** Sixty-five participants completed the study. After 3 months with the ortho-k lens, there were no significant differences in ocular HOA, SA, coma, or trefoil between the SOK group and AOK group at 4-mm, 5-mm, and 6-mm pupil diameters (all P>0.05), except for a significant increase in SA in the AOK group (P=0.01). Stratified analyses showed that the AOK group exhibited greater HOA and SA at 5-mm and 6-mm pupil diameters in the lower myopia subgroup and greater SA at 6 mm in the higher myopia subgroup (all P<0.05). There were no significant differences between the groups in SR, HC VA, LC VA, or PREP scores (all P>0.05).

**Conclusion:** Aspheric BC-designed ortho-k lenses produced a significantly greater SA than SOK lenses, with more significance at lower diopters, without sacrificing subjective visual performance.

Key Words: Myopia—Orthokeratology—Aspheric base curve design— Visual performance.

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From the Department of Optometry and Vision Sciences, West China School of Medicine, Sichuan University (C.C. and T.L.); Laboratory of Optometry and Vision Sciences, West China Hospital, Sichuan University (C.C., W.M., J.W., B.Y., T.L. and L.L.) and Department of Ophthalmology, West China Hospital, Sichuan University, Chengdu, China (W.M., J.W., B.Y., and L.L.).

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C. Chen and W. Ma contributed equally to this work.

Address correspondence to Longqian Liu, M.D., Department of Ophthalmology, West China Hospital, Sichuan University, 37 Guoxue Xiang, Chengdu 610041, China; e-mail: b.q15651@hotmail.com Accepted October 22, 2022.

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M yopia has become a worldwide public health burden, especially in Asia. Longitudinal data suggest that the annual incidence of myopia may be as high as 20% to 30% among schoolaged children.<sup>1</sup> As confirmed by a meta-analysis,<sup>2</sup> orthokeratology (ortho-k) is regarded as an effective optical intervention to slow myopia progression.

Orthokeratology lenses flatten the central curvature and steepen the midperipheral corneal curvature of the anterior surface of the cornea,<sup>3</sup> which is accompanied by significant epithelial thinning of the central and thickening of the total midperipheral corneal thickness,<sup>4</sup> leading to myopic defocus in the peripheral retina. The retina can respond to peripheral optical defocus and regulates growth of the eyeball.<sup>5,6</sup> Myopic control has been hypothesized to be a consequence of myopic defocus of the peripheral retina as a result of changes in the corneal shape.<sup>7–9</sup>

Along with the corneal response after ortho-k, a range of visual performance issues have been observed, including improvements in uncorrected visual acuity (VA),<sup>10</sup> increases in higher-order aberrations (HOA),<sup>11</sup> increases in the objective scatter index,<sup>12</sup> decreases in the Strehl ratio (SR),<sup>12</sup> decreases in contrast sensitivity,<sup>11</sup> and decreases in modulation transfer function (MTF).<sup>12</sup>

Previous studies on the relationship between higher-order aberration and myopia progression suggested that the magnitude and direction of HOA may act as a signal to regulate eve growth.<sup>13–15</sup> Lau et al.<sup>13</sup> found a significant negative association between the root mean square (RMS) of total HOAs and axial elongation in Hong Kong children. Cheng et al.<sup>14</sup> observed the axial length growth of the eye in myopic children wearing soft daily disposable contact lenses with spherical design (control) versus with positive spherical aberration (SA) design. Their results indicated that the soft contact lens with positive SA could inhibit axial elongation of the eye. Lau et al.<sup>15</sup> found that after ortho-k, the RMS of ocular SA increased by approximately 9 times, which increased most among ocular HOA. After adjusting for known confounding factors, higher RMS values of total HOA and SA were associated with slower axial elongation. These findings indicated that the increase in HOA, particularly SA, may be a potential mechanism to retard axial growth in ortho-k treatment.

The base curve (BC) plays an important role in changing corneal curvature, inducing peripheral defocus and ocular HOA. Theoretically, the aspheric BC may cause a steeper shaping effect in the midperipheral portion of the cornea, which could induce more HOA, especially SA, thereby may realize a better effect of myopia control, compared with the spherical BC. The optic differences between these two designs of BC zone were displayed in Figure 1. FIG. 1. Lens design of SOK and AOK. AOK, aspheric BC-designed ortho-k; BC, base curve; RC, reverse curve; SOK, spherical BC-designed ortho-k

The main purpose of this study was to investigate the effect of the aspheric BC design on ocular HOA and to evaluate its effect on visual performance including higher-order SR, low-contrast (LC) VA, high-contrast (HC) VA, and the Pediatric Refractive Error Profile (PREP) questionnaire.

# **METHODS**

#### Study Design

This prospective, randomized, controlled, single-masked trial aimed to compare visual performance in two groups of school-aged children wearing spherical BC-designed ortho-k (SOK) lenses and aspheric BC-designed ortho-k (AOK) lenses. This study was approved by the Ethics Committee on Biomedical Research, West China Hospital of Sichuan University, registered with chictr.org.cn (ChiCTR2000040990), and conducted at the Department of Ophthalmology of West China Hospital, Sichuan University, following the tenets of the Declaration of Helsinki.

#### Subjects

Seventy Chinese subjects were recruited through advertisements in the outpatient department between December 2020 and July 2021 at the West China Hospital of Sichuan University (Chengdu, China). The inclusion criteria were as follows: age between 8 and 12 years, myopic spherical refractive error between-0.75 and-4.00 D, with astigmatism≤1.50 D, anisometropia≤1.00D, Best corrected VA 0.10 (logarithm of minimal angle of resolution [logMAR]) or better in both eyes, symmetrical corneal topography with corneal astigmatism less than 1.50 D in either eye, no history of myopia control treatment, and no contraindications to contact lens wear. None of the participants had previously received ortho-k treatment. All subjects were warned of the potential risks of infection and inflammation. The periodicity and frequency of regular follow-up visits were also recorded. All participants and their parents or guardians signed written consent forms before participation. Data were collected from both eyes; however, only data from the right eye were analyzed to avoid statistical problems associated with the lack of independence of ocular aberrations between fellow eves.16,17

#### Interventions

The subjects were fitted with ortho-k lenses (Eyebright, Beijing, China) with a four-zone reverse-geometry lens design. The regular design of the lens used in two groups consists of a central BC with a 6.2-mm optic zone diameter, a 0.8-mm wide reverse curve, a 0.9-mm wide alignment curve, a 0.5-mm wide peripheral curve, and a +0.75 D Jessen factor. The lenses were manufactured using a fluorosilicone-acrylate material with a gas permeability of  $125 \times 10^{-11}$  (cm<sup>2</sup>×mLO<sub>2</sub>)/(s×mL×mm Hg). Differences existed only in the BC design. The absolute value of the equivalent radius of



curvature around the BC zone of the lens is smaller than the absolute value of the radius of curvature at the center of the BC zone of the lens. The BC zone uses a positive Q-value, which is a fixed value for all myopic patients. The lenses were fitted in accordance with the manufacturer's instructions. Lenses would be replaced if any of the following modifications was observed: (1) poor corneal response, (2) poor lens fit (lens decentration>1.0 mm), (3) poor vision (uncorrected VA was worse than 0.1 logMAR in either eye after 1-month wear), and (4) poor refraction correction effect (residual myopia<-0.50 D in either eye after 1-month wear). If the poor condition did not improve after replacement, the subjects would be asked to terminate the lens wear.

#### Sample Size

The sample size was determined based on previous studies and the results of a pilot study. The samples in most previous studies<sup>11,16–19</sup> of HOA included fewer than 50 eyes. The results of the pilot study showed that the SOK lenses induced an increase of  $0.64\pm0.36 \,\mu\text{m}$ , whereas the AOK lenses induced an increase of  $0.88\pm0.25 \,\mu\text{m}$  in the RMS of SA. To achieve a power of 80% at  $\alpha$ =0.05 and allow for a dropout rate of 20%, a sample size of 35 was required for each group according to the pilot study. Based on this information, a sample size of 35 people in each group was recruited, resulting in a total of 70 participants.

## **Randomization and Masking**

Randomization into the SOK and AOK groups was performed using an interactive web response system in a 1:1 ratio after the subjects met the criteria. During the randomization procedure, SOK and AOK groups were paired with matching gender, age, and refractive errors. The random allocation sequence was performed by the same practitioner who was involved in the follow-up visits. The subjects were blinded to the lens design during the study period.

# **Examination Schedules and Procedures**

The examinations were performed before lens wear (baseline). Follow-up and additional data collection were performed 1 day, 1 week, 1 month, and 3 months after commencing lens wear. Measurements were taken within 4 hr of lens removal.

#### **Corneal Topography**

Corneal topography was obtained using the Topographic Modeling System (Tomey Corporation, Nagoya, Japan) at 1 day, 1 week, 1 month, and 3 months after commencing lens wear. At each follow-up visit, each eye was measured four times, and the highest-quality image was selected and saved. Power difference maps were calculated by subtracting the baseline tangential curvature map from the 3-month tangential curvature map. Based on previous studies,<sup>20,21</sup> eight points were plotted on power difference maps surrounding the central flattened area, on which the

power was  $0\pm0.05$  D. These points were loaded into a MATLAB program to calculate the best-fitting circle. The magnitude of decentration was calculated as the distance between the center of the best-fitting circle and the center of the entrance pupil.

#### Visual Acuity

Uncorrected and corrected VA values were obtained throughout the study. However, to reflect the daily VA after lens wear more realistically, uncorrected VA was used in these analyses. Highcontrast (>90%) and LC (10%) VAs were measured using Early Treatment Diabetic Retinopathy Study charts (Precision Vision, Woodstock, IL) under photopic lighting conditions (400 lx). Low-contrast VA was measured first, followed by HC VA in the order of the right eye and then the left eye. Visual acuity was assessed 1 day, 1 week, 1 month, and 3 months after commencing lens wear. The results were expressed as logMAR, from 1.00 to -0.30 with 0.02 as the interval.

# **Pediatric Refractive Error Profile Questionnaire**

The PREP questionnaire was completed at the baseline and at the 3-month visits. The questionnaire consists of 26 questions in 10 categories. The original PREP questionnaire was translated into Chinese following the instructions for PREP.<sup>22</sup> This was used with the subjects at baseline. For the subjects wearing ortho-k lenses after 3 months, the questionnaire (PREP-OK) was minimally modified by substituting the word "glasses"/"When I wear my glasses" with "ortho-k"/"After I wore ortho-k lenses" to deal with the same issues. The same 26 questions were used for both questionnaires. Subjects were asked to read the 26 statements in the questionnaire and to select the most suitable option based on "strongly agree," "agree," "neutral," "disagree," or "strongly disagree," according to their subjective feelings. The scoring method used in this research was conducted in accordance with previous research methods related to PREP.<sup>22-25</sup> Each question was assigned a score of 100 (excellent quality of life) to 0 (poor quality), and the score for each category was the average score of all questions in that category. The overall PREP score is the average of all 26 statements.

# Total Ocular Higher-Order Aberrations and Strehl Ratio

Total ocular HOA was measured under cycloplegia using the i-Trace wavefront aberrometer (Tracey Technologies Inc., Houston, TX). Before the cycloplegic examination, four drops of 0.5% tropicamide, applied 5 min apart, were instilled in each eye. Cycloplegic measurements were performed on the eyes after 30 min when there was no pupillary response, and the amplitude of accommodation was no more than 2.00 D at 0.50 m distance. Data were acquired under an autoacquisition model with scan zone diameters set to 4, 5, and 6 mm. The Strehl ratio is the area under the MTF curve. The Strehl ratio with low-order aberration corrected by software was collected to ensure that SR was affected only by HOA. Strehl ratio and RMS of ocular HOA, SA, coma, and trefoil were collected at baseline and 3-month visits. Previous studies have found that increases in HOA are correlated with the degree of myopic correction.<sup>11,26</sup> In this study, a stratified analysis was performed with refractive error stratification. The separation was based on the midpoint between -0.75 and -4.00 D, with -0.75 to -2.25 D being defined as the lower myopia subgroup and -2.50 to -4.00 D being defined as the higher myopia subgroup.

#### **Statistical Analysis**

All statistical analyses were performed using SPSS (version 22.0; IBM Corporation, Armonk, NY). Baseline data between the two BC design groups were compared using the chi-squared test for sex. Unpaired t tests or Mann–Whitney U tests were used to analyze variables including age, VA, refraction, RMS of ocular HOA, SR, and PREP questionnaire scores between the two groups. Paired t tests or Wilcoxon tests were used to analyze the measurement differences from before to after lens wear. Repeated-measures analysis of variance was used to examine the changes in HC and LC VA throughout the study and included a within-subject factor of time (baseline, 1-day, 1-week, 1-month, and 3-month visits), a between-subject factor of BC design (aspheric and spherical), and their interactions. P values of less than 0.05 were considered to be statistically significant.

# RESULTS

Seventy subjects met the recruitment criteria and were randomized into the SOK (n=34) and AOK groups (n=36). However, two subjects in the SOK group were excluded because of poor vision (1) and poor lens fit (1), and three subjects in the AOK group were excluded due to poor vision (1), loss to follow-up (1), and poor lens fit (1), leaving 65 subjects included in the final analysis. Thirty-two participants were fitted with SOK lenses, consisting of 17 boys and 15 girls with a median (range) age of 9.21 (8.25–11.79) years. Thirty-three subjects were fitted with AOK lenses, consisting of 19 boys and 14 girls with a median (range) age of 9.57 (8.14–11.85) years.

 
 TABLE 1.
 Demographics and Baseline Data of the Subjects (Median [Range] or Mean±SD)

	SOK (n=32)	AOK (n=33)	Р
Age, yrs	9.21 (8.25–11.79)	9.57 (8.14–11.85)	0.64
Male/female	17/15	19/14	0.72
VA, logMAR			
LC	0.12 (0.08–0.24)	0.14 (0.06–0.30)	0.20
HC	-0.03 (-0.12-0.04)	-0.04 (-0.10-0.06)	0.88
Refraction, D			
Myopia	$-2.41\pm0.85$	$-2.38\pm0.77$	0.89
Astigmatism	-0.50 (-1.00-0.00)	-0.50 (-1.00-0.00)	0.73
SER	$-2.60\pm0.91$	$-2.59\pm0.85$	0.95
SR at 4 mm	0.27 (0.13–0.58)	0.23 (0.08–0.83)	0.08
SR at 5 mm	0.09 (0.05–0.25)	0.08 (0.03-0.56)	0.10
SR at 6 mm	0.04 (0.01–0.15)	0.04 (0.01–0.14)	0.30
RMS at 4 mm, µm			
HOA	0.14±0.05	0.14±0.05	0.88
Coma	0.10±0.05	0.10±0.05	0.86
SA	0.04±0.02	0.04±0.03	0.68
Trefoil	0.05 (0.03-0.17)	0.05 (0.01–0.15)	0.29
RMS at 5 mm, µm			
HOA	0.22±0.07	0.25±0.09	0.20
Coma	0.15±0.08	0.18±0.11	0.29
SA	0.07±0.03	0.07±0.04	0.70
Trefoil	0.08 (0.03-0.19)	0.09 (0.01–0.16)	0.76
RMS at 6 mm, µm			
HOA	0.35±0.12	0.40±0.17	0.22
Coma	0.23±0.13	0.27±0.14	0.29
SA	0.10±0.07	$0.11 \pm 0.08$	0.63
Trefoil	0.13 (0.02-0.32)	0.13 (0.02–0.61)	0.42

AOK, aspheric BC-designed ortho-k; HC, high contrast; HOA, higher-order aberration; LC, low contrast; logMAR, logarithm of minimal angle of resolution; RMS, root mean square; SA, spherical aberration; SER, spherical equivalent refraction; SOK, spherical BC-designed ortho-k; SR, Strehl ratio; VA, visual acuity Table 1 displays the demographic details and baseline data of the subjects, including baseline VA, refraction, SR, and RMS of ocular HOA, SA, coma, and trefoil when the scan zone diameter was set to 4, 5, and 6 mm. There were no significant differences between the two groups in any of these metrics (all P>0.05).

# Total Ocular Higher-Order Aberrations and Strehl Ratio

After 3-month ortho-K lens wear, there was no significant difference in decentration distance between the SOK group and AOK group  $(0.50\pm0.22 \text{ mm vs}. 0.42\pm0.17 \text{ mm}, P=0.11)$ . Table 2 shows the SR and RMS of HOA, SA, coma, and trefoil at pupil diameters of 4, 5, and 6 mm after 3 months of lens wear. For SR, there were no significant differences between the groups at baseline and 3 months after lens wear in the 4-mm, 5-mm, and 6-mm scan zones (all P>0.05). For ocular HOA, there were no significant differences in ocular HOA, SA, coma, or trefoil between groups at 4-mm, 5-mm, and 6-mm pupil diameters (all P>0.05), except for a significant increase in SA in the AOK group ( $0.70\pm0.34$  vs.  $0.90\pm0.28$ , P=0.01).

The results of stratified analysis are presented in Table 3. For subjects in the lower myopia subgroup, there were no significant differences in the RMS of HOA, SA, coma, or trefoil between the two groups at a pupil diameter of 4 mm (all P>0.05). However, significantly higher RMS values of HOA and SA were observed in the AOK group when the scan zone was fixed at 5 and 6 mm (all P<0.05). There were no statistically significant differences in RMS values for coma and trefoil between the groups when the scan zone was fixed at 5 and 6 mm (all P<0.05).

For subjects in higher myopia subgroup, significant differences were found only in the RMS of SA at a pupil diameter of 6 mm ( $0.89\pm0.33$  vs.  $1.11\pm0.22$ , P=0.03). The remaining RMS values were not significantly different at the 4-mm, 5-mm, or 6-mm scan zones (all P>0.05).

#### Low-Contrast and High-Contrast Visual Acuity

Supplemental table 1, Supplemental Digital Content 1, http:// links.lww.com/ICL/A249, summarizes the VA at baseline and at the four follow-up time points in the two groups. After wearing the lens for 1 week, the logMAR values for the two groups reached the level of baseline best-corrected VA in both the LC and HC conditions and tended to be stable. No statistically significant differences were observed between the two groups at any time point (all P>0.05).

# Pediatric Refractive Error Profile Questionnaire Scores

Supplemental table 2, Supplemental Digital Content 2, http:// links.lww.com/ICL/A250, presents the PREP scores for the 26 questions for the two groups. There were no significant differences between baseline and 3-month visit in near vision, symptoms, or handling before and after lens wear in either group (all P>0.05). Significantly higher scores were found at 3 months than at baseline in far vision, appearance, satisfaction, activities, academics, peer perception, and overall scores in both groups (all P<0.05). In addition, a higher overall vision score compared with baseline was found only in the AOK group (P=0.01). No significant differences were found between the groups in any aspects or overall scores at baseline or at the 3-month visit (all P>0.05).

 TABLE 2.
 SR and RMS of HOA, SA, Coma and Trefoil at 4, 5, 6 mm

 Pupil Diameter After 3 Months Lens Wear (Median [Range] or

 Mean±SD)

	•		
	SOK (n=32)	AOK (n=33)	Р
RMS at 4 mm, µm			
HOA	0.33 (0.13–1.16)	0.33 (0.11-0.96)	0.74
Coma	0.29 (0.05-1.01)	0.26 (0.01-0.85)	0.44
SA	0.16 (0.05-0.41)	0.15 (0.01-0.37)	0.91
Trefoil	0.06 (0.01-0.28)	0.06 (0.01-0.27)	0.68
RMS at 5 mm, µm			
HOA	0.67 (0.31–2.21)	0.89 (0.43–1.97)	0.35
Coma	0.50 (0.17-2.01)	0.74 (0.23-1.79)	0.59
SA	0.41±0.18	0.46±0.14	0.18
Trefoil	$0.09 \pm 0.04$	0.10±0.05	0.89
RMS at 6 mm, µm			
HOA	1.29 (0.64-3.15)	1.54 (0.79–2.98)	0.12
Coma	1.05 (0.44-2.80)	1.15 (0.28-2.74)	0.25
SA	0.70±0.34	0.90±0.28	0.01
Trefoil	0.16 (0.05-0.62)	0.13 (0.03-0.32)	0.06
SR at 4 mm	0.05 (0.01-0.17)	0.06 (0.01-0.35)	0.44
SR at 5 mm	0.02 (0.00-0.08)	0.02 (0.00-0.09)	0.79
SR at 6 mm	0.00 (0.00-0.02)	0.00 (0.00-0.04)	0.72

AOK, aspheric BC-designed ortho-k; HOA, higher-order aberration; RMS, root mean square; SA, spherical aberration; SOK, spherical BC-designed ortho-k; SR, strehl ratio

#### DISCUSSION

To the best of our knowledge, this is the first study to combine objective and subjective parameters to evaluate visual performance associated with AOK lenses. We have shown that the AOK lenses resulted in a greater RMS for SA at a 6-mm pupil size after 3 months of lens wear than the SOK lens. Stratified analyses showed that the AOK group exhibited greater HOA and SA at 5-mm and 6mmmm pupil diameters in the lower myopia subgroup and greater SA at 6 mm in the higher myopia subgroup. In addition, there were no significant differences between the groups in SR, HC VA, LC VA, or any aspects of PREP scores.

Numerous studies have reported that ortho-k lenses could significantly increase corneal and ocular HOA,<sup>11,18,27,28</sup> especially the positive shift of SAs and coma aberrations.<sup>28,29</sup> Previous studies have suggested that the increase in HOA, SA, and coma may have a better effect on retarding the growth of the axial length.<sup>15,30,31</sup> The aspheric BC design can theoretically increase HOA, especially SAs, compared with the spherical design. Although previous studies of aberrations have tended to focus on a single pupil diameter, this study increased the range of aberration measurements, that is, fixing pupil diameters at 4, 5, and 6 mm, to present more comprehensive results.

Encouraging results showed that AOK lenses resulted in significantly greater RMS of SA at 6-mm pupil diameter than SOK lenses. However, no significant differences in HOA, SA, coma, or trefoil were found at pupil diameters of 4-mm and 5-mm pupil diameters. In general, the pupil diameter is approximately 4 mm during the day.<sup>32</sup> To ensure that AOK lenses do not affect the wearer's visual performance during the day, the HOA of AOK lenses at the 4-mm pupil diameter should not be significantly different from that of SOK lenses. Simultaneously, AOK lenses need to have a higher HOA in more peripheral areas to induce a better myopia control effect, which may be a potential reason why AOK lenses can ensure good visual performance while also optimizing myopia control.

This study represents the preliminary results of a 1-year study focusing on whether an aspheric BC design could result in better

	Lower Myopia			Higher Myopia		
	SOK (n=17)	AOK (n=17)	Р	SOK (n=15)	AOK (n=16)	Р
RMS at 4 mm, µm	. ,					
HOA	0.29±0.09	0.32±0.16	0.46	0.46 (0.21–1.16)	0.33 (0.20-0.96)	0.22
Coma	0.23±0.09	0.24±0.16	0.73	0.40 (0.05–1.01)	0.27 (0.10-0.85)	0.11
SA	0.12±0.05	$0.15 \pm 0.08$	0.25	0.20 (0.09-0.41)	0.17 (0.01–0.37)	0.26
Trefoil	0.05 (0.03-0.16)	0.06 (0.01–0.15)	0.47	0.09±0.07	0.09±0.06	0.93
RMS at 5 mm, µm						
HOA	0.62±0.22	0.79±0.24	0.03	1.19±0.52	$1.01 \pm 0.34$	0.26
Coma	0.46 (0.25–1.00)	0.56 (0.23–1.18)	0.05	$1.01 \pm 0.52$	0.80±0.34	0.19
SA	0.29±0.10	0.41±0.09	< 0.01	0.54±0.16	0.52±0.16	0.71
Trefoil	0.09±0.03	0.09±0.03	0.94	0.10±0.05	0.10±0.07	0.86
RMS at 6 mm, µm						
HOA	1.06±0.31	1.29±0.31	0.04	1.93±0.75	1.92±0.47	0.98
Coma	$0.81 \pm 0.31$	$1.01 \pm 0.33$	0.07	1.60±0.72	1.47±0.55	0.56
SA	0.53±0.26	0.70±0.17	0.03	0.89±0.33	$1.11 \pm 0.22$	0.03
Trefoil	0.16±0.07	$0.12 {\pm} 0.06$	0.09	0.19 (0.07–0.62)	0.15 (0.05–0.32)	0.23

TABLE 3.	RMS of HOA, SA, Coma, and	Trefoil at 4-mm, 5-mm, a	nd 6-mm Pu <sub>l</sub>	pil Diameters After	3 Months of Lens	Wear in Lower Myopia and
		Higher Myopia Subgroup	os (Median [ŀ	Range] or Mean±S	D)	

AOK, aspheric BC-designed ortho-k; HOA, higher-order aberration; RMS, root mean square; SA, spherical aberration; SOK, spherical BC-designed ortho-k

myopia control effects. The results of the stratified analyses indicate that changing the optical design of ortho-k lenses, especially the BC area, to an aspheric design can significantly induce more HOA and SA after lens wear. In addition, these results may indicate that the aspheric BC design is more effective in controlling myopia in patients with lower myopia, whereas previous studies have shown that smaller axial length elongation was associated with a greater baseline spherical equivalent myopic refractive error.<sup>33,34</sup> The results of axial length elongation is still being collected and will be published in the future. The current study did not find a significant difference between the two groups in coma, which may have been due to the similar degree of lens decentration in the two groups, as Hiraoka et al.<sup>26</sup> presumed that the main cause of coma was decentration.

Strehl ratio and MTF are objective parameters that reflect the level of image quality in the presence of wavefront aberrations.<sup>35</sup> The SR is defined as the ratio of the peak diffraction intensities of a measured eye to those of the aberration-free eye,<sup>36</sup> which provides an accurate quantification of the area under the MTF curve for an objective analysis. Liu et al.<sup>12</sup> demonstrated that ortho-k lenses would lead to a decrease in SR. Similar results were obtained in this study. However, there was no significant difference between the groups, suggesting that AOK did not have a significant effect on SR relative to SOK.

Ortho-k lenses can immediately improve uncorrected VA, even just after a single night of wearing. Uncorrected HC VA stabilized after 7 to 30 days of use and reached the baseline level of best corrected VA.<sup>10,37</sup> Low-contrast VA has been shown to be slightly worse than baseline levels when stabilized.<sup>29,37–39</sup> However, this study demonstrated that both uncorrected HC and LC VA could reach the level of baseline best-corrected VA after 1 week of ortho-k and remained stable within 0.04 logMAR (two letters) fluctuations. Further studies are needed to confirm whether LC VA is affected by wearing ortho-k lenses.

Regarding the PREP questionnaire, significantly higher scores for far vision, appearance, satisfaction, activities, academics, peer perception, and overall were found in both groups than at baseline. Similar results were also found in other studies.<sup>23,25</sup> This study has once again verified that compared with spectacle lenses, ortho-k lenses are highly praised by wearers in those aspects. However, there were no significant differences between the groups before or after ortho-k. This suggests that AOK does not significantly affect the subjective dimension of PREP relative to that of SOK.

This study suggests that aspheric BC design lenses may contribute to improved myopia control effects in lower myopia, and for the higher myopia group, aspheric design also helps to increase SA, which may also improve myopia control effect. However, there are two limitations in this study. First, only ocular HOAs were analyzed for convenience and conciseness, without distinguishing between the cornea and intraocular, and each item was not statistically analyzed by Zernike polynomial expansion. Second, for the analysis of objective and subjective visual performance, only typical qualifications, such as HOAs, SR, VA, and PREP questionnaire, were selected. Other qualifications that could have been used, such as MTF cutoff frequency, objective scatter index, and contrast sensitivity function, were not included in this study. These two limitations will be investigated further with larger sample sizes in the subsequent studies. In addition, how AOK lenses affect corneal mechanics, corneal thickness, and retinal peripheral defocus will also be investigated in the future.

# CONCLUSION

Aspheric BC designed ortho-k lenses produced a significantly greater SA than SOK lenses, with more significance at lower diopters, without sacrificing subjective visual performance.

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