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Refractive Intervention

The Impact of Back Optic Zone Design in Orthokeratology on Visual Performance

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Purpose: To evaluate the visual performance in adolescents undergoing orthokeratology (OrthoK) treatment with two different optical zone diameters (OZDs).

Methods: This randomized, double-masked, self-controlled prospective study was conducted at Tianjin Eye Hospital (Tianjin, China) in June 2022. Thirty-six eligible schoolchildren were enrolled and fitted with corneal refractive therapy lenses with two sizes of OZDs (5 mm [5OZ] and 6 mm [6OZ]). Each participant was randomized to wear the 5OZ in one eye and the 6OZ in the contralateral eye. Subjective visual quality was assessed using visual acuity, refraction, contrast sensitivity function, and visual symptoms, and the objective optical quality was assessed using ocular higher order aberrations (HOAs) and modulation transfer function (MTF).

Results: Thirty-five myopic children completed a 1-month follow-up visit. The 5OZ lens induced significantly smaller treatment zone diameters than the 6OZ lens ($P < 0.001$). Subjective visual quality did not differ significantly between the two groups. Compared to baseline, aberrations of Z_4^0, coma-like, spherical-like, and total HOAs in both groups increased significantly ($P < 0.05$). For the 3-mm pupils, spherical aberration in the 5OZ group was significantly higher than that in the 6OZ group ($P < 0.05$). The MTF value of the 6OZ group was significantly higher than that of 5OZ group for 0.3 and 1.5 cycles per degree for the 3-mm pupils ($P = 0.006$ and $P = 0.026$, respectively). However, HOAs or MTF did not differ significantly between the two groups for the 5-mm pupils.

Conclusions: The difference induced by varying OZD was significant only in the smaller pupil condition. The selection of OZD in OrthoK designs in real-world patient management should be done while considering individual pupil size.

Translational Relevance: This study revealed that the objective visual quality of small OZD lenses was only slightly affected for the small pupil size.

Introduction

Orthokeratology (OrthoK) lenses are rigid contact lenses with a reverse geometry designed to reshape the cornea to reduce myopic refractive error and improve uncorrected vision temporarily.[1,2] In recent years, studies have shown that OrthoK can effectively retard myopia progression by 43% to 63% in children, and it has become a major and effective means of myopia control.[3–5]

One of the most commonly accepted theories regarding the anti-myopia mechanism of OrthoK is related to induced relative myopic peripheral defocus (RMPD) and higher order aberrations (HOAs). Preliminary studies have reported a stronger

myopia-inhibiting effect for designs incorporating a smaller back optic zone diameter (OZD), with the proposed mechanism of stronger RMPD and HOAs due to a smaller treatment zone (TZ), on the topographical changes associated with the smaller OZD designs.[6,7] Notably, significant individual variability exists regarding the topographical changes induced by OrthoK lenses, for which lenses with the same OZD do not necessarily induce a consistent corneal TZ. Moreover, the design changes incorporated into the back surface of the lenses may not transfer to induced corneal changes with a 1:1 ratio.[6] Consequently, the OZD of an OrthoK design may not be used as a surrogate marker for the induced corneal changes. Thus, the corneal TZ should be quantified and analyzed for its association with OrthoK-related visual performance and the imposed retinal defocus profile.

OrthoK induces significant flattening of the central cornea and steepening of the paracentral or mid-peripheral cornea, such that the magnitude of flattening in the central 1-mm area of the corneal apex is higher than that in the adjacent areas within the pupil region, resulting in a significantly increased HOA, including spherical aberrations (SAs) and coma aberrations.[8,9] OrthoK lenses designed with smaller OZDs induce higher increases in corneal HOAs and horizontal coma.[10]

Despite the plausible inference that a smaller TZ induced by a smaller OZD may significantly impact visual performance due to higher HOAs, recent studies on reducing the TZ using smaller OZD designs have mainly focused on the effectiveness of delaying myopia progression. In addition, previous studies on visual quality mainly evaluated visual acuity and contrast sensitivity function (CSF).[6] Few studies have evaluated ocular HOAs and the modulation transfer function (MTF) which could objectively describe the optical quality changes after wearing reduced OZD lenses.

This was a 1-year, randomized, self-controlled trial comparing the effect of an OrthoK brand with two sizes of OZDs (5 mm [5OZ] and 6 mm [6OZ]) on myopia progression and visual quality. The participants were randomized to wear the 5OZ in one eye and the 6OZ in the contralateral eye to allow interocular comparison of axial length (AL) elongation and visual performance. Such a self-controlled design effectively minimizes the bias and confounding due to individual variability in the participants' subjective performance. To reduce the impact of myopia progression on visual quality, the current study focused mainly on visual quality 1 month after OrthoK, which reflected plateaued optical correction and relatively stable corneal molding.[11–14] The subjective visual quality was assessed using visual acuity (VA), a visual questionnaire, and the CSF. The objective visual quality was assessed by HOAs and the MTF to better understand the effect of reducing the OZD in OrthoK on the real retinal image quality.

Methods

Study Design

This 1-year, randomized, double-masked, and self-controlled trial was conducted at Tianjin Eye Hospital (Tianjin, China) in June 2022. In this study, each enrolled participant was fitted with corneal refractive therapy (CRT) lenses (Paragon Vision Sciences, Gilbert, AZ) with two OZDs (5 mm and 6 mm). This study adhered to the tenets of the Declaration of Helsinki, was approved by the Ethics Committee of Tianjin Eye Hospital (KY202219), and was registered with Chictr.org.cn (ChiCTR2200061048). The study was explained fully to all of the participants and their guardians, who then signed informed consent forms.

Randomization and Masking

Randomization to determine which eye was fitted with the 5OZ lens and which eye was fitted with a conventional lens was performed using a spreadsheet generator in SPSS Statistics 25.0 for Windows (IBM, Chicago, IL) after the participants and their parents/guardians had met the criteria for lens handling and care procedures. One unmasked person was responsible for group allocation. The participants and examiners were masked to the group allocation during the study period. In addition, the persons who determined the TZ size, decentration, and data analyst were masked.

Participants

In total, 36 children were recruited for this study according to the following initial inclusion criteria: age between 9 and 12 years; non-cycloplegic spherical equivalent refraction (SER) from −1.00 to −4.00 D; corneal astigmatism ≤ 1.50 D; anisometropia ≤ 1.00 D; and best-corrected monocular visual acuity of 0.0 logMAR or less. The exclusion criteria included abnormal binocular conditions, including strabismus; contraindications to contact lens wear, including history of ocular inflammation or infection; corneal dystrophy; or any systemic and ocular conditions that might affect refractive development.

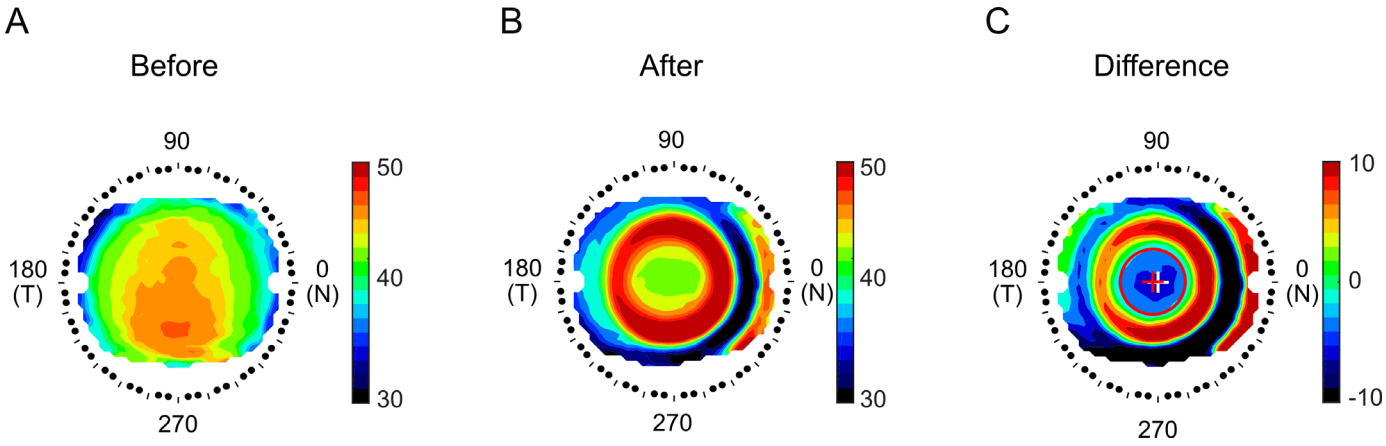

Figure 1. Methods to calculate treatment zone diameter and decentration. (**A**) Tangential topography before lens wear. (**B**) Tangential topography after lens wear. (**C**) Difference map. The *red circle* outlines the treatment zone, the *red cross* indicates the center of the treatment zone, and the *white cross* indicates the cornea center.

Study Procedure

OrthoK Lens Fitting

The OrthoK lenses used in this study were CRT lenses manufactured using Paragon HDS 100 material (Paragon Vision Sciences). The lens features a four-zone design, consisting of a spherical base curve, a sigmoid return zone (RZ), a tangential landing zone, and a periphery system of fixed width that extends to the periphery. The back OZD of each lens was either 6.0 mm or 5.0 mm, and the RZ width was 1.0 mm. Experienced optometrists fitted the participants with the CRT lenses. Participants were first diagnostically fitted with the 6OZ designs in both eyes according to the manufacturer's instructions. For the eyes allocated to wear the 5OZ lenses, the parameters were directly converted from the 6OZ trial lens parameters using the fitting app to ensure the same overall sagittal depth of the lenses between the two OZ selections. The baseline data were measured before CRT initiation. The participants and their guardians were trained on lens application, removal, and daily care processes prior to lens allocation.

Measurements and Follow-Up Visits

VA and Refraction

VA was measured by using the Early Treatment Diabetic Retinopathy Study charts (Series 2000; Precision Vision, Woodstock, IL). Objective refraction under non-cycloplegic conditions was measured three times with an autorefractor (ARK-1; Nidek, Aichi, Japan), and and the average values were used for analyses. Subjective refraction was conducted with maximum plus for maximum VA.

TZ Size and Decentration

Corneal topography was measured using the Medmont E300 corneal topographer (Medmont International, Nunawading, VIC, Australia). Tangential power maps were used to evaluate the lens decentration and TZ size. The difference map was calculated by subtracting the baseline map from the topography obtained at 1-month visits. The central region with a power reduction of more than 0.25 D was identified first, and the boundary points were fitted into a circle using a custom MATLAB program (MathWorks, Natick, MA).[15] This fitted circle was defined as the central TZ, and the diameter of the TZ (TZD) was used to define the TZ size. The distance between the center of the TZ and the corneal vertex was defined as the TZ decentration (Fig. 1). The corneal vertex is the point located at the intersection of the patient's line of sight and the corneal surface. This is represented by the corneal light reflex when the cornea is illuminated coaxially with fixation.[16]

Contrast Sensitivity Function

CSF was measured using the Optec 6500 Vision Tester (Stereo Optical, Chicago, IL) under daytime conditions (luminance level, 85 cd/m^2 without glare; spatial frequencies of 1.5, 3, 6, 12, and 18 cycles per degree [cpd]).

Total Ocular HOAs

Ocular HOAs were measured using an i.Profiler^{plus} (ZEISS, Oberkochen, Germany) for circular apertures of 3 mm and 5 mm without pharmacological pupil dilatation following 10 minutes of dark adaptation. Measurements were repeated at least three times for each eye, and the average values were used for subse-

quent analyses. The Zernike polynomial coefficients of primary vertical coma (Z_3^{-1}), primary horizontal coma (Z_3^1), primary spherical aberration (Z_4^0), and secondary spherical aberration (Z_6^0) were obtained because the magnitudes of the aberrations could directly reflect optical quality.[17] The root mean squares for the fourth- and sixth-order spherical aberrations (spherical-like), third- and fifth-order horizontal and vertical coma aberrations (coma-like), and total HOAs were calculated.

Modulation Transfer Function

The MTF is a function of the spatial frequency, which displays the loss of contrast between the retinal image and the original scene. The Zernike coefficients were input to a phase plate, which stands for the eye, using Zemax OpticStudio 19.4 (Zemax, Kirkland, WA). Subsequently, the MTF values at spatial frequencies (ranging from 0.3∼30 cpd with an interval of 0.3 cpd) and curves under different pupil diameters were obtained.

Questionnaires

The questionnaire was comprised of four visual performance categories: clarity (distance, intermediate, and near), quality (ghosting and haloes at night), stability when moving (walking up and down stairs and when walking or playing sports), and comfort.[18] The questionnaire was scored on a scale of 1 to 10 for each item (poorest to excellent). An interocular forced-choice comparison was also incorporated for each visual performance question. A copy of the questionnaire used is provided in Supplementary Appendix 1.

Axial Length

AL was measured using the ZEISS IOLMaster 500. Five measurements of AL were taken from each eye, and the average values were used in the analysis. The participants were advised to wear their CRT lenses every night for 8 to 10 hours. Follow-up visits were performed at baseline, 1 day, 1 week, 1 month, and then every 3 months for 1 year. At each follow-up visit, unaided visual acuity (UCVA), best-corrected visual acuity (BCVA), subjective and objective refraction, anterior ocular health, and corneal profiles were measured. CSF was measured at baseline, 1 day, 1 week, and 1 month. HOAs and the questionnaire surveys were conducted at 1 month. AL was measured at baseline, 6 months, and 12 months.

Statistical Analysis

SPSS Statistics 25.0 was used for the data analysis. Quantitative data were tested for normality and are expressed as mean ± standard deviation (SD); the classification data are expressed as the number of cases and percentages. Continuous data with repeated measurements between the two groups were compared using repeated-measures analysis of variance (ANOVA) with the treatment group (5OZ vs. 6OZ) as the independent factor (multivariate tests). For significant outcomes, post hoc comparisons using Bonferroni correction for each pair of visits was subsequently conducted. The paired-samples *t*-test and Wilcoxon matched-pairs signed-rank test were used to compare data between the two groups depending on the data distribution. The χ^2 test was used to compare questionnaire scores at the 1-month follow-up. The questionnaire was assessed using a split-half reliability test and a factor analysis. Statistical significance was considered at $P < 0.05$.

Results

Thirty-five children with myopia (15 boys and 20 girls between the ages of 9 to 12 years; mean age, 10.14 ± 1.15 years) successfully completed the 1-month follow-up visit. Thirty-three children successfully completed the 12-month follow-up visit. One participant dropped out as she chose an alternative myopia correction prior to the allocation of lenses, one subject dropped out because she had poor vision due to insufficient sleep duration, and one subject dropped out because he was not able to follow up on time due

Table 1. Baseline Refraction, Visual Acuity, and Keratometry of Participants

	Mean ± SD		
	5OZ	6OZ	*P*
Sphere (D)	−2.31 ± 0.77	−2.19 ± 0.80	0.155
Subjective SER (D)	−2.59 ± 0.82	−2.43 ± 0.84	0.046*
J0	−0.07 ± 0.21	−0.02 ± 0.17	0.225
J45	0.01 ± 0.27	0.07 ± 0.29	0.315
UCVA	0.73 ± 0.26	0.70 ± 0.30	0.226
BCVA	−0.03 ± 0.04	−0.03 ± 0.04	—
Kf (D)	43.00 ± 1.62	42.96 ± 1.62	0.103
Ks (D)	44.46 ± 1.70	44.46 ± 1.77	0.658
Corneal toricity (D)	1.45 ± 0.44	1.50 ± 0.61	0.764

J0, vector-transformed Jackson cross horizontal; J45, vector-transformed Jackson cross oblique; Kf, flattest keratometry; Ks, steepest keratometry.

*Significant difference between the 5OZ and 6OZ groups.

Table 2. Visual Acuity and Refraction at Baseline and Follow-Up of Participants Wearing 5OZ and 6OZ Lenses

	Mean ± SD					
Group	1 Day	1 Week	1 Month	P_{Group}	P_{Time}	$P_{Group \times Time}$
UCVA						
5OZ	0.15 ± 0.21	0.02 ± 0.14	−0.04 ± 0.08	0.173	<0.001	0.900
6OZ	0.10 ± 0.22	−0.04 ± 0.07	−0.06 ± 0.05			
BCVA						
5OZ	−0.02 ± 0.04	−0.05 ± 0.05	−0.06 ± 0.05	0.816	<0.001	0.882
6OZ	−0.02 ± 0.04	−0.05 ± 0.04	−0.06 ± 0.05			
Subjective SER						
5OZ	−0.64 ± 0.77	−0.12 ± 0.53	0.02 ± 0.42	0.149	<0.001	0.664
6OZ	−0.43 ± 0.65	0.02 ± 0.36	0.11 ± 0.22			
Objective SER						
5OZ	−1.85 ± 1.04	−0.59 ± 1.34	−0.61 ± 1.33	0.420	<0.001	0.273
6OZ	−1.48 ± 0.99	−0.58 ± 1.20	−0.39 ± 1.14			

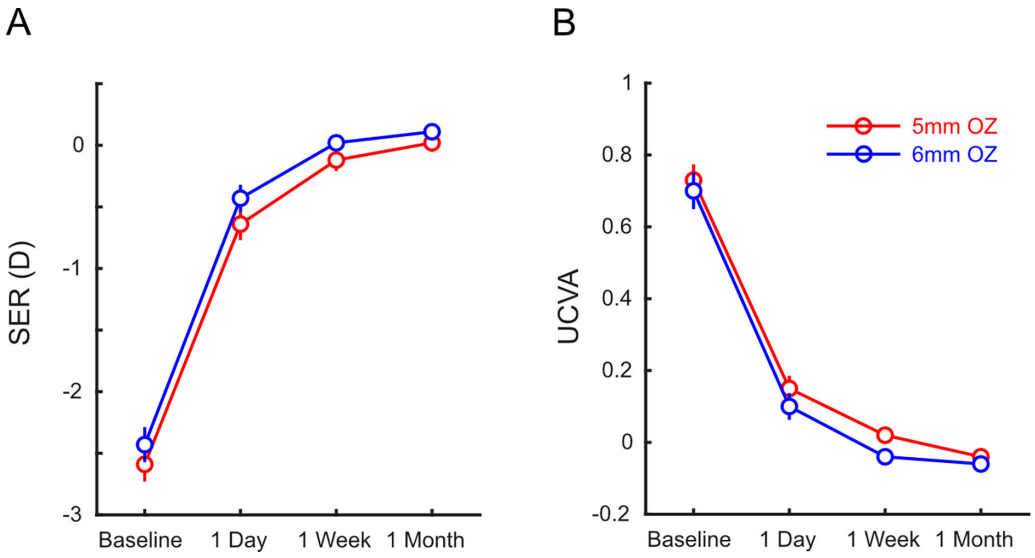

Figure 2. Refraction and visual acuity in participants wearing 5-mm OZ or 6-mm OZ lenses. (**A**) Subjective spherical equivalent refraction (SER). (**B**) Uncorrected visual acuity (UCVA). The *error bars* represent the standard error of the mean.

to COVID-19. Baseline data did not differ significantly between the 5OZ and 6OZ groups ($P > 0.05$) (Table 1).

VA and Refraction

Changes in UCVA, BCVA, and subjective and objective SER at 1 day, 1 week, and 1 month after lens wear are shown in Table 2 and Figure 2. As expected, there were significant effects of time on all four variables for both the 5OZ and 6OZ groups ($P < 0.01$). However, there were no significant differences between the 5OZ and 6OZ groups regarding the changes in UCVA, BCVA, or subjective and objective SER at follow-up (repeated-measures ANOVA, with time, and treatment group as factors; $P > 0.05$).

TZD and TZ Decentration

At 1 month, the TZDs induced by the 5OZ and 6OZ lenses were 2.83 ± 0.57 mm and 3.06 ± 0.41 mm, respectively (Figs. 3A, 3B). This difference was significant ($t = 4.116$, $P < 0.001$). However, TZ decentration did not differ significantly between the two OZDs ($t = -1.797$, $P = 0.082$). The mean TZ decentrations for the 5OZ and 6OZ lenses are shown in Figures 3C and 3D.

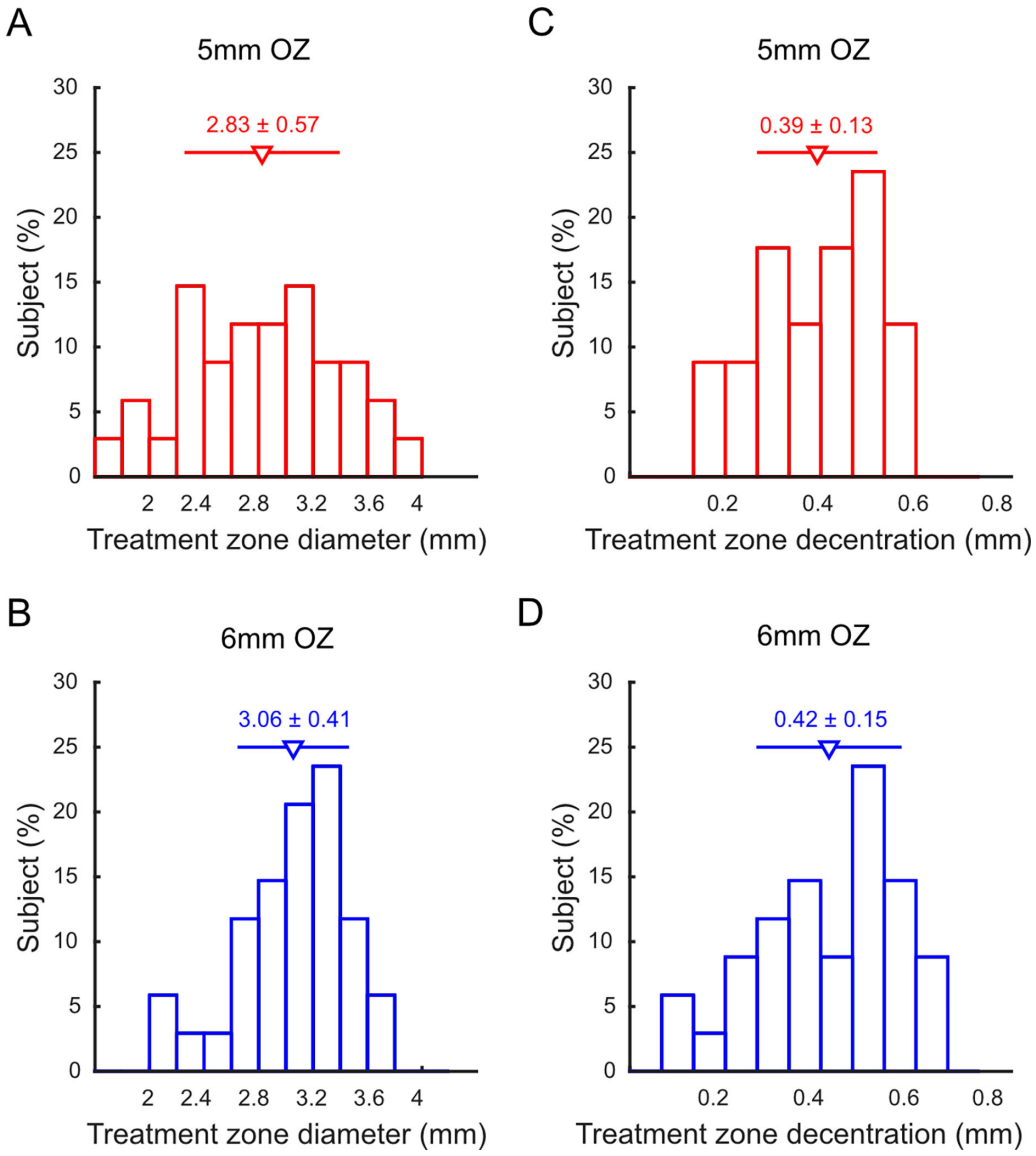

Figure 3. Treatment zone diameter and decentration. (**A**) TZD in participants wearing 5-mm OZ lenses. (**B**). TZD in participants wearing 6-mm OZ lenses. (**C**). TZ decentration in participants wearing 5-mm OZ lenses. (**D**). TZ decentration in participants wearing 6-mm OZ lenses.

Contrast Sensitivity Function

CSFs of the 5OZ and 6OZ lenses are shown in Figure 4. There were significant differences at 1.5, 3, 6, 12, and 18 cpd at all follow-up visits ($P < 0.05$). CSF decreased significantly at each spatial frequency on day 1 and recovered to the baseline level at week 1. However, there were no significant differences in the CSF between the 5OZ and 6OZ groups at each visit.

Higher Order Aberrations

Figure 5 shows the HOAs for the 3-mm and 5-mm pupils, respectively. Compared to baseline, the aberrations of Z_4^0, coma-like, spherical-like, and total HOAs in both the 5OZ and 6OZ groups increased significantly at the 1-month follow-up in both 3-mm and 5-mm pupils ($P < 0.05$). For the 3-mm pupils, the Z_4^0 and spherical-like aberration in the 5OZ group were significantly higher ($t = 2.219$, $P = 0.034$) than those in the 6OZ group ($t = 2.385$, $P = 0.026$). The coma-like aberrations and total HOAs in the 5OZ group were also higher than those in the 6OZ group; the differences were close to being statistically significant (5OZ: $Z = -1.957$, $P = 0.050$; 6OZ: $Z = -1.921$, $P = 0.055$). For the 5-mm pupils, no significant difference in HOAs was observed between the two groups ($P > 0.05$).

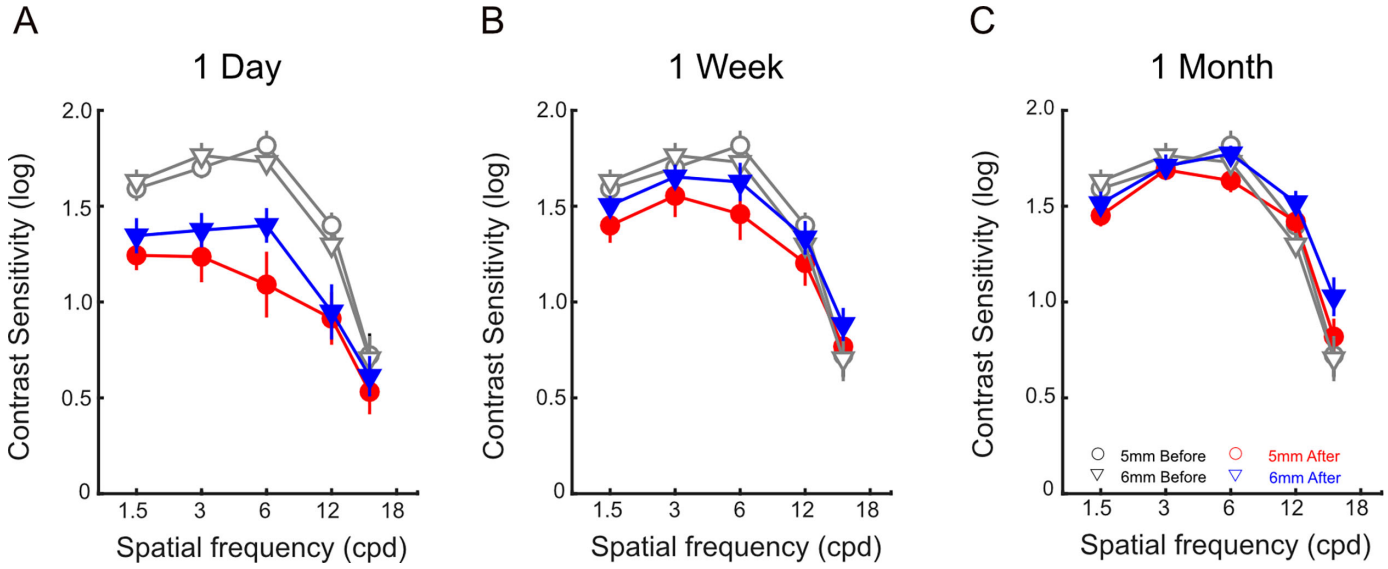

Figure 4. Contrast sensitivity functions. (**A**) One day after lens wear. (**B**) One week after lens wear. (**C**) One month after lens wear. The *error bars* represent the standard error of the mean.

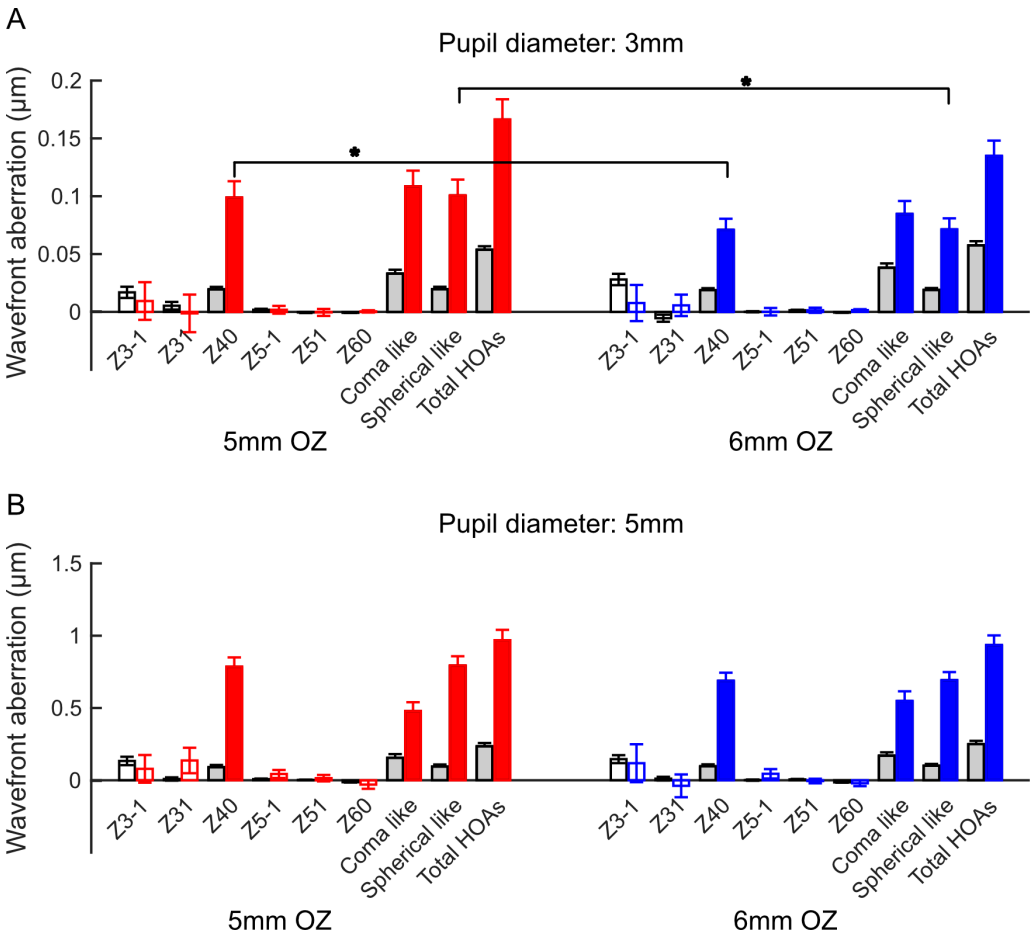

Figure 5. (**A**, **B**) Root mean squares (RMS) of high-order aberrations for the 3-mm pupil condition (**A**) and the 5-mm pupil condition (**B**). *Open bars* indicate no significant difference before and after lens wear. *Filled color bars* indicate significant differences before and after lens wear. The *error bars* represent the standard error of the mean.

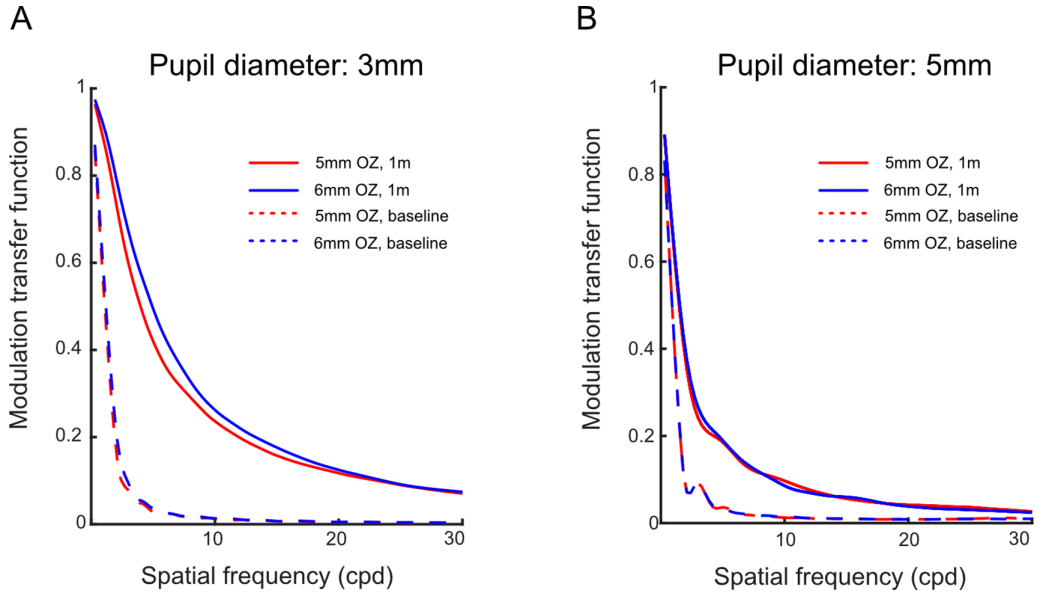

Figure 6. (**A**, **B**) Modulation transfer functions measured for the 3-mm pupil condition (**A**) and the 5-mm pupil condition (**B**).

Modulation Transfer Function

After the lenses were worn for 1 month, the MTF values for each spatial frequency of both the 5OZ and 6OZ groups significantly increased in both 3-mm pupils and 5-mm pupils ($P < 0.05$) (Fig. 6). However, the MTF values at each spatial frequency for 5-mm pupils were significantly lower than those for 3-mm pupils in both groups ($P < 0.05$). For 3-mm pupils, the MTF values for 0.3 and 1.5 cpd for the 6OZ group were higher than those of the 5OZ group for 0.3 and 1.5 cpd, and the difference was statistically significant (6OZ: $Z = -2.743$, $P = 0.006$; 5OZ: $Z = -2.225$, $P = 0.026$). For 5-mm pupils, there were no significant differences between the 6OZ group and 5OZ groups in the MTF values for all spatial frequencies ($P > 0.05$).

Questionnaire

The split-half reliability coefficient was 0.771, and the Kaiser–Meyer–Olkin value was 0.693, indicating that the validity of the questionnaire was acceptable. Vision clarity, quality, stability, and comfort at 1 month did not differ significantly between the two groups ($P \geq 0.083$) (Table 3). However, in a forced-choice comparison, a higher percentage of children reported that their 6OZ lens-wearing eye experienced better vision than their 5OZ lens-wearing eye (Fig. 7).

AL Elongation

At the 1-year visit, the mean AL elongation was significantly less in the 5OZ group (0.19 ± 0.15 mm) than in the 6OZ group (0.26 ± 0.15 mm; $P < 0.01$).

Table 3. Subjective Ratings (1–10 Scale in 1-Point Steps, Poorest to Excellent) While Wearing 5OZ and 6OZ Lenses at 1 Month

Variable	Description	Mean ± SD		*Z*	*P*
		5OZ	6OZ		
Vision clarity	Distance	9.66 ± 0.80	9.80 ± 0.47	−1.000	0.317
	Intermediate	9.69 ± 0.76	9.83 ± 0.38	−1.134	0.257
	Near	9.89 ± 0.40	9.94 ± 0.24	−1.000	0.317
Vision quality	Ghosting	9.77 ± 0.60	9.83 ± 0.38	−0.378	0.705
	Halo at night	9.34 ± 1.24	9.43 ± 1.20	−1.732	0.083
Vision stability when moving	Walking up and down stairs	9.80 ± 0.58	9.86 ± 0.49	−1.000	0.317
	Walking or playing sports	9.69 ± 0.80	9.80 ± 0.47	−1.342	0.180
Comfort	—	8.86 ± 1.61	8.89 ± 1.63	−1.00	0.317

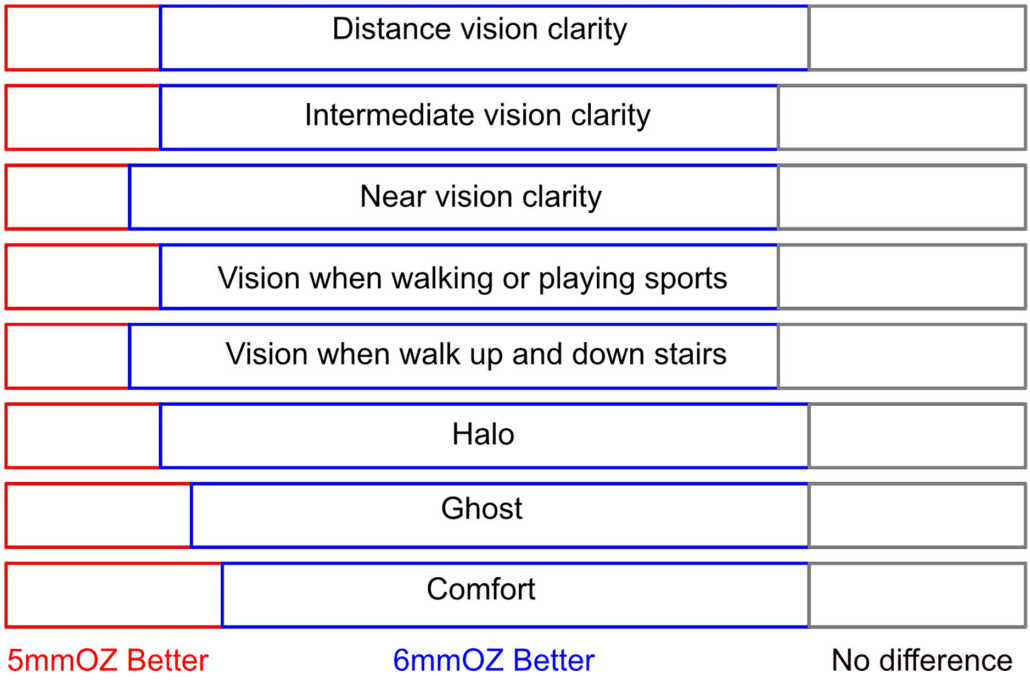

Figure 7. The proportion of eyes with better subjective visual perception in the forced-choice comparison.

The 5OZ lens reduced AL elongation by 0.07 mm/yr (27%) compared to the 6OZ lens.

Discussion

To our knowledge, this was the first self-controlled study to compare the interocular differences in visual performance with varying OrthoK designs for each eye. After 1 month, there were no significant differences in VA, residual refraction, visual symptoms, or CSF between the 5OZ and 6OZ groups. The optical quality, evaluated by HOAs and MTF, was slightly lower in the 5OZ group than in the 6OZ group under the 3-mm pupil condition. Significantly less AL elongation in the 5OZ group than in the 6OZ group was observed after 12 months.

The UCVA improved significantly as early as 1 day after wearing both designs, and the residual refraction decreased significantly in both groups. However, there was no significant difference in UCVA and residual refraction at 1 day, 1 week, and 1 month after both designs were worn, consistent with previous reports.[6,18] Consistent with previous studies,[11] VA and residual refraction at 1 week and 1 month were not significantly different, suggesting a plateaued optical correction and relatively stable corneal molding at 1 week after treatment initiation. The results confirm the validity of visual performance evaluations at 1 month to fully reflect the impact of treatment-induced differences. The improvement in BCVA in the two groups might be due to a practice or learning effect due to the frequent follow-up visits, a finding that was also found in the study by Lam et al.[19]

As predicted, the 5OZ design induced a significantly smaller TZD than the 6OZ design, with a mean difference of 0.24 mm, which was similar to the result of Carracedo et al.[6] Both results indicate a ratio much smaller than 1:1 between the OZD design difference and the corneal TZD change. However, these results differ from those of other studies that have used vision shaping treatment (VST)-designed lenses and have reported a ratio closer to 1:1 between OZD changes and TZD differences.[20] Several factors may contribute to this discrepancy. First, the quantification of TZD may differ across studies. In our study, the TZ was defined as the area enclosed by points of zero dioptric changes on subtractive topographical maps, which were highly variable depending on tangential or axial display or the image acquisition platform (i.e., placido-based vs. Scheimpflug image–based) and the model of the topographers. Second, the algorithms used in each study to extract topographical data and quantify the size of TZD were also different. In the present study, a custom MATLAB program was used to identify the boundary at less than 0.25 D on the differential topographic map and calculate the diameter of the fitting circle in the TZ, an approach that differs from other studies.[15] Further studies are required to validate the comparability of

different TZ definitions and measurements. Finally, OZD change has been treated as an independent variable in the majority of the studies, which may have been confounded by other parameter changes coupled with OZD changes. Specifically, for VST designs, a reduction in the OZD is usually accompanied by an increase in the asphericity of the base curve and changes in the width, radius, and asphericity of the reverse curve and the width of the alignment curves. Univariate analysis to show correlation between the OZD and TZD changes was insufficient for causal inference due to the inevitable associated changes in other lens parameters. In addition to the OZD modification, accompanying changes, especially in the reverse geometry region of the VST lenses, should be reported and included in the statistical analysis to better understand the underlying mechanism of the induced TZD changes.

Regarding the optical quality comparison, HOAs significantly increased at 1 month in both groups, especially the Z_4^0, coma-like, and spherical-like aberrations, a finding that has also been reported in previous studies.[7–9] The Z_4^0 and spherical-like aberrations in the 5OZ group were significantly higher than those of the 6OZ group under the 3-mm pupil condition but not the 5-mm pupil condition. A plausible explanation is a potential saturating effect due to the interactions between pupil size and the location of the paracentral corneal steepening, a major source of the induced HOAs in the OrthoK treatment. Light rays entering an OrthoK-treated eye can be generally grouped as central or on-axis rays, which pass through the central corneal treatment zone, and peripheral or off-axis rays, which pass through the paracentral corneal steepening region. When the paracentral steepening is more peripheral relative to the pupil border, part of the peripheral rays are blocked by the pupil, and the induced HOAs are significantly influenced by the pupil size. However, in the case of a smaller treatment zone with a smaller OZ design, paracentral steepening is more central, and consequently the induced HOAs are less affected by changes in pupil size when they are larger than the threshold diameter. Consequently, differences in the HOAs induced by the two OZ designs are diminished for larger pupils.

The MTF values of the 5OZ lens at 0.3 and 1.5 cpd were lower than those of the 6OZ lens under the 3-mm pupil condition but not the 5-mm pupil condition. MTF reflects the transmission ability of the optical system of the human eye to different spatial frequency components and is related to the imaging quality of the retina: the lower the MTF, the worse the visual quality. MTF is mainly affected by aberration, diffraction, and pupil diameter.[21] Genetic studies have shown that the retinal contrast signal is abnormally increased in children with high-grade myopia locus mutations, which may lead to high myopia.[22,23] Further, wearing a new spectacle lens designed with diffusion optical technology can effectively delay myopia progression by reducing the contrast of the retina[24]; the results of this study are contrary to those of some studies, especially for form deprivation myopia.[25,26] Hence, the role of retinal contrast signals in refractive development warrants further investigation. Also, whether or not the reduction of MTF under the 3-mm pupil condition leads to better myopia control requires further study.

Interestingly, despite the OZD-specific decreases that were found in the objective measures of image quality, such as HOAs and MTF under the 3-mm pupil condition, the CSF and subjective symptoms such as vision clarity, quality, stability, and comfort, based on the standard questionnaire, were not affected by OZD. However, when a forced-choice questionnaire was employed, a higher percentage of participants preferred vision in the eye treated with the 6OZ design, suggesting the importance of properly designed questions for the detection of subtle differences in subjective performance variables.

The argument behind the effort of inducing a smaller TZD was based on the finding that HOAs induced by OrthoK treatment are protective against myopia progression, and preliminary studies have reported a potential dose-dependent response such that a smaller TZD was associated with better axial inhibiting effects.[7,8,20] In our study, the non-significant difference in induced HOAs between the two OZD designs in the larger pupil condition suggests a potential interaction between TZD and pupil size in the axial inhibiting effect of OrthoK. The reduced TZDs in patients with larger pupil size may not benefit from a stronger "myopia-controlling dosage" while suffering from reduced visual quality; therefore, pupil size is an important factor when considering the OZD design in the lens. Based on recent research on AL elongation and HOAs, smaller OZD-designed lenses may be more beneficial to children with small pupil size.[7] However, clinicians may not need to utilize the smaller OZD-designed lens for children with large pupil sizes, as similar effects of myopia control and better visual quality may be achieved with traditional OZD lenses.

Considering the dynamic nature of pupil behavior under various lighting conditions and accommodative demands, future studies are warranted to include dynamic pupillometry so that not only the static pupil size under fixed lighting but also the velocity and

contraction amplitude are included to further study the interactions between corneal changes related to OrthoK and the dynamic pupil changes on induced changes in retinal image quality and myopia-inhibiting signals.[27] In addition, most current OrthoK designs are rotationally symmetric which, if lenses are fitted properly, results in a TZ centered on the cornea rather than on the pupil. Given the presence of clinically significant angle kappa in the majority of pediatric patients with myopia, further efforts in OrthoK design advancement could be devoted to a pupil-centered design in the optical zone of the lens while maintaining the overall lens centration on the cornea to optimize the visual performance of the treatment and its impact on myopia control.[28]

Consistent with previous studies, this study showed that lenses designed with a smaller OZ can achieve better myopia control.[29,30] However, in the present study, the 5OZ lens reduced AL elongation by 0.07 mm/yr (27%) compared with the 6OZ lens, which was less than the mean difference between the 5OZ and 6OZ groups found in the study by Li et al.[29] (0.14 mm/yr, 52%) and the study by Ding et al.[30] (0.11 mm/yr, 42%).

This study had several advantages. First, the self-controlled study design was most effective in minimizing the bias and confounding due to the individual variability of the study participants, which was especially important in the evaluation of the subjective performance of the treatment such as the quantification of visual performance and comfort. Furthermore, a forced-choice questionnaire was included to allow for better differentiation of small interocular differences, which may not be possible using the standard questionnaire. Second, the parameters of the 5OZ design were directly converted from the diagnostic fitting of the 6OZ lenses to ensure that the same overall sagittal depth as its 6OZ equivalent was utilized so that the interocular differences observed were due to the design difference without confounding due to varying fitting physiology.

In conclusion, this study compared the effects of different OZD-designed OrthoK lenses on visual performance, including subjective and objective visual qualities. Compared with a large OZD, a small OZD caused higher spherical aberration and slightly affected the objective visual quality under a small pupil size condition; however, there was no difference under a large pupil size condition. These results indicate that, for children with a large pupil size, small OZD lenses could be applied while considering visual quality. In clinical management, the individual pupil size should be considered in the application of customized OrthoK lenses.

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