

Effect of Individualized Ocular Refraction Customization Spectacle Lenses on Astigmatism in Myopic Children

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Abstract

PURPOSE

To evaluate two-year changes in corneal and refractive astigmatism in myopic children wearing individualized ocular refraction customization (IORC) lenses with varying peripheral defocus, and associations with myopia progression.

METHODS

In year 1 of this trial, children aged 8–12 years were assigned to IORC lenses with high (4.50 D), medium (3.50 D), or low (2.50 D) peripheral myopic defocus, or single-vision lenses. After year 1, all switched to high-defocus IORC for 12 more months. Corneal and refractive astigmatism were converted to J0 and J45 vectors. Piecewise linear GEE models with a knot at 12 months estimated annualized changes per period, adjusting for age and sex.

RESULTS

Among 171 children completing 12 months and 161 completing 24 months, corneal J0 increased by 0.087 and 0.068 D/year in years 1 and 2; refractive J0 showed a similar pattern. Corneal J45 remained stable; refractive J45 showed a small negative drift. No significant group-by-time interactions were observed. By 24 months, vector displacement ≥ 0.25 D was 43.9% corneal and 42.2% refractive; ≥ 0.50 D was uncommon (4.7%, 3.4%). Refractive J0 change correlated with axial elongation at 24 months; corneal change showed only a weak association.

CONCLUSION

Over two years, IORC lenses did not induce clinically meaningful or dose-dependent astigmatic changes. The small with-the-rule J0 drift was consistent across groups and phases, suggesting a physiological origin, whereas J45 remained stable. The moderate association between refractive J0 change and axial elongation, without a corresponding corneal association, argues against lens-induced corneal remodeling. These findings support the optical safety of individualized IORC lenses in children.

INTRODUCTION

Myopia has emerged as a major global public health concern, with particularly alarming trends in East Asia, where the prevalence among school-aged children now exceeds 50% in many regions and continues to rise¹. Early onset and rapid progression of myopia substantially increase the lifetime risk of high myopia and vision-threatening complications, including myopic maculopathy, retinal detachment,

glaucoma, and cataract². Identifying effective and well-tolerated interventions to slow myopia progression during childhood is therefore of substantial clinical importance.

Spectacle lenses that impose peripheral myopic defocus have become a key optical strategy for myopia control, owing to their noninvasive nature, ease of prescription, and good tolerability in children. Several designs, including defocus-incorporated multiple-segment, highly aspherical lenslet, and diffusion optics technology, have demonstrated efficacy in slowing axial elongation and refractive progression³. However, a key limitation of most current designs is their reliance on a standardized defocus profile. Given the substantial inter-individual variability in peripheral refraction and ocular shape among children⁴, such a uniform design may not deliver an optimal myopia-control signal for each eye⁵. The individualized ocular refraction customization (IORC) lens addresses this limitation. The IORC lens combines a central distance-correction zone with annularly distributed peripheral defocus micro-lenses, and features a free-form rear surface customized to each child's peripheral refraction, thereby compensating for inter-individual variations in baseline peripheral refractive profile. This personalized approach prevents insufficient or excessive peripheral defocus in children with either baseline peripheral hyperopia or myopia. The myopia control efficacy of this IORC design has been demonstrated in our recent studies^{6,7}.

For myopic children undergoing optical interventions, astigmatism represents a potential confounder and a safety concern. Subtle changes in astigmatism can degrade visual quality and retinal image clarity, and have been implicated in ocular growth regulation⁸. This concern is particularly relevant for peripheral defocus spectacle lenses, as their complex optical designs could generate asymmetric retinal defocus, thereby imposing meridional stress on the cornea⁹. While astigmatic changes have been observed in some myopia-control studies, whether they reflect true corneal remodeling, internal ocular changes, or measurement variability remains debated^{10,11}. Whether peripheral defocus lenses themselves contribute to such changes—particularly in a dose-dependent manner—is also unknown, and requires evaluation in the context of their clinical use.

To address this question, we conducted a two-year longitudinal study. During the first year, myopic children were randomized to high-defocus (IORC-H; 4.50 D), medium-defocus (IORC-M; 3.50 D), or low-defocus (IORC-L; 2.50 D) IORC lenses, or single-vision spectacle lenses (SVL). During the second year, all participants were switched to the IORC-H lens. Because participants received randomized treatments in year 1 but all wore IORC-H in year 2, fitting a single linear trend across the entire study period would be inappropriate¹². We therefore employed a piecewise linear generalized estimating equation (GEE) model, with a knot at 12 months to estimate annualized slopes separately for each period and to test whether the original randomized allocation modified the astigmatic trajectories in either phase¹³. In addition to refractive astigmatism, we quantified corneal astigmatism from total keratometry by vector subtraction, with all components expressed as J0 and J45 power vectors to preserve axis information¹⁴. Measurements were obtained at 3-month intervals for corneal parameters and at 6-month intervals for refraction, allowing us to capture the temporal dynamics of astigmatic change. We hypothesized that

IORC lenses would not induce clinically meaningful, dose-dependent astigmatic changes over the full two-year period, and that any observed changes would primarily reflect physiological variation.

METHODS

Study Design and Participants

This study consisted of a 12-month prospective, randomized, double-masked clinical trial followed by a 12-month extension phase, conducted at West China Hospital of Sichuan University between September 2022 and December 2024. The study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of West China Hospital, Sichuan University (No. 20211191), and registered on ClinicalTrials.gov (ChiCTR2200063036; registration date: 29/08/2022). Written informed consent was obtained from all participants and their parents or legal guardians prior to enrollment.

Participants were recruited from the ophthalmology and optometry clinics and through online advertisements. The inclusion criteria were: 1) age 8–12 years; 2) cycloplegic SER ranging from -0.75 to -4.00 D; 3) interocular anisometropia ≤ 2.00 D; and 4) best-corrected visual acuity (BCVA) ≤ 0.0 logMAR. The exclusion criteria were: 1) presence of strabismus or binocular vision abnormalities; 2) ocular or systemic abnormalities; and 3) previous myopia control treatment. Participants were randomly assigned to one of four lens groups for the first year: IORC-H (4.50 D), IORC-M (3.50 D), IORC-L (2.50 D), or single-vision spectacle lenses (SVL) as the control group. After completion of the 12-month visit, all participants were switched to the IORC-H lens and followed for an additional 12 months.

Ocular Biometry and Refraction Measurements

The axial length and total keratometry parameters were measured using an IOLMaster 700 (Carl Zeiss Meditec, Jena, Germany). Measurements were obtained at baseline and at 3, 6, 9, 12, 15, 18, 21, and 24 months. At each visit, five consecutive readings were taken and the average value was used for analysis. The total keratometry parameters included flat and steep keratometric powers, together with their corresponding meridian axes.

Cycloplegic refraction was performed at baseline and at 6, 12, 18, and 24 months according to the study protocol. The SER was calculated as spherical power plus half of the cylindrical power. Changes in axial length and SER from baseline were calculated to evaluate myopia progression during the 24-month follow-up.

Calculation of Corneal Astigmatic Vectors

Corneal astigmatism, derived from total keratometry values (tK1, tK2, and tK2 axis), was transformed into Jackson cross-cylinder power vector components (J0 and J45) using the following formulas based on Thibos vector analysis¹⁵:

$$J0 = -\frac{C}{2}\cos(2\alpha)$$

$$J45 = -\frac{C}{2}\sin(2\alpha)$$

where $C = tK2 - tK1$ represents the magnitude of corneal astigmatism, and α is the $tK2$ axis in radians. $J0$ represents the orthogonal astigmatism component at $0^\circ/90^\circ$ (positive values indicating with-the-rule astigmatism; negative values indicating against-the-rule astigmatism), and $J45$ represents the oblique astigmatism component at $45^\circ/135^\circ$. The same formulas were applied to convert cycloplegic refractive astigmatism into $J0$ and $J45$, where C denotes the negative cylinder power and α the cylinder axis.

Statistical analysis

All statistical analyses were performed using SPSS 27 (IBM, Armonk, USA) and Python 3.11 with the Statsmodels package. A two-sided $P < 0.05$ was considered statistically significant. Continuous variables are presented as mean $\pm$ standard deviation (SD), and categorical variables as percentages.

For baseline comparisons, one-way analysis of variance was used for continuous variables, followed by Bonferroni-corrected post hoc pairwise comparisons when the overall test was significant. The chi-square test was used for categorical variables. In addition to baseline characteristics at enrollment, we also compared the four original groups at the 12-month visit (the year-2 baseline) among participants who completed the 24-month follow-up, using the same statistical methods

For longitudinal analyses, we fitted piecewise linear GEE models with a prespecified knot at 12 months¹³, using data from both eyes to maximize statistical power and accounting for inter-eye correlation through participant-level clustering. Follow-up time was parameterized as two annualized spline terms, $t1 = \min(\text{month}, 12)/12$ and $t2 = \max(\text{month} - 12, 0)/12$, so that each coefficient represents the annualized change within the corresponding phase. Models included the randomized group, both spline terms, and their interactions as fixed effects, with adjustment for baseline age and sex. An exchangeable working correlation structure and robust sandwich standard errors were specified. To evaluate whether the original allocation modified the astigmatic trajectories over the two years, we performed a 6-df Wald test of the overall group-by-segmented-time interaction for each outcome. Differences between the year-1 and year-2 slopes were assessed using Wald tests of the corresponding linear contrasts within the same piecewise GEE model. Stage-specific group-by-slope terms were examined secondarily, with Benjamini–Hochberg correction. Separate models were fitted for corneal and refractive $J0$ and $J45$, and for corneal and refractive cylinder magnitude. Additionally, using 0.25 D and 0.50 D as separate thresholds for vector displacement, we compared the proportions of eyes reaching each threshold at 12 and 24 months between groups using logistic GEE models with the same clustering and adjustment.

RESULTS

Demographics and clinical measurements of the participants

A total of 184 children were recruited in this study. Among them, 1 participant was unable to adapt to the IORC lenses, 4 discontinued lens wear due to non-adherence, 3 were lost to follow-up, 1 withdrew due to lens damages, and 3 switched to other myopia control treatments during the study period. The overall non-completion rate was 7.07%. After 12 months of follow-up, 171 participants (mean age 9.50 ± 1.06 years, 89 girls) completed all study assessments. Of these completers, 43, 44, 41, and 44 were in the IORC-H, IORC-M, IORC-L, and SVL groups, respectively. During year 2, a further 10 participants discontinued or were lost to follow-up, and 161 participants (41, 41, 37, and 42 in the IORC-H, IORC-M, IORC-L, and SVL groups, respectively) completed the 24-month visit. Baseline characteristics of the four groups are summarized in Table 1. Considering all participants were switched to IORC-H lenses at 12 months, we additionally examined the year-2 baseline among the 161 two-year completers (Table 1), to assess whether differences present at the start of the second year might influence the subsequent astigmatic trajectories.

Table 1

Baseline demographics and clinical measurements of the participants at the start of year 1 and year 2.

	IORC-H	IORC-M	IORC-L	SVL	Effect size	P value
Year 1 baseline (n = 171)						
Age (years)	9.37 ± 1.02	9.59 ± 1.06	9.39 ± 1.07	9.63 ± 1.09	0.02 ^a	0.602
Sex (M/F)	21/22	20/24	26/15	15/28	0.20 ^b	0.073
SER (D)	-2.08 ± 0.75	-2.40 ± 0.73	-2.39 ± 0.71	-2.03 ± 0.77	0.04 ^a	0.031
Axial length (mm)	24.35 ± 0.69	24.45 ± 0.69	24.73 ± 0.71	24.32 ± 0.66	0.03 ^a	0.030
Corneal J0 (D)	0.52 ± 0.25	0.49 ± 0.22	0.52 ± 0.28	0.51 ± 0.24	0.00 ^a	0.914
Corneal J45 (D)	-0.13 ± 0.13	-0.08 ± 0.15	-0.05 ± 0.14	-0.12 ± 0.15	0.04 ^c	0.020
Refractive J0 (D)	0.20 ± 0.23	0.23 ± 0.18	0.23 ± 0.20	0.24 ± 0.24	0.00 ^a	0.875
Refractive J45 (D)	-0.06 ± 0.10	-0.02 ± 0.09	-0.04 ± 0.11	-0.05 ± 0.10	0.00 ^c	0.618
Year 2 baseline (n = 161)^d						
Age (years)	10.34 ± 1.04	10.54 ± 1.07	10.41 ± 1.09	10.60 ± 1.08	0.00 ^a	0.693
Sex (M/F)	21/20	17/24	25/12	15/27	0.24 ^b	0.028
SER (D)	-2.26 ± 0.93	-2.71 ± 0.89	-2.90 ± 0.85	-2.60 ± 0.92	0.04 ^a	0.016 ^e
Axial length (mm)	24.49 ± 0.70	24.66 ± 0.75	25.00 ± 0.72	24.68 ± 0.71	0.04 ^a	0.020 ^f
Corneal J0 (D)	0.63 ± 0.30	0.59 ± 0.26	0.60 ± 0.27	0.61 ± 0.25	0.00 ^a	0.953
Corneal J45 (D)	-0.12 ± 0.18	-0.04 ± 0.16	-0.04 ± 0.16	-0.09 ± 0.18	0.02 ^c	0.121
Data are mean ± standard deviation or number (male/female); right-eye data are shown. Effect sizes: ^a omega-squared (one-way analysis of variance); ^b Cramér's V (chi-square test); ^c epsilon-squared (Kruskal–Wallis test). ^d Year-2 baseline was assessed at the 12-month visit among the 161 participants who completed the 24-month follow-up, immediately before all participants were switched to the IORC-H lens; groups refer to the original randomized allocation. Bonferroni-corrected post hoc comparisons: ^e IORC-H vs IORC-L, adjusted <i>P</i> = 0.014; ^f IORC-H vs IORC-L, adjusted <i>P</i> = 0.013 (year-1 baseline: IORC-L vs SVL, adjusted <i>P</i> = 0.045).						

	IORC-H	IORC-M	IORC-L	SVL	Effect size	P value
Year 1 baseline (n = 171)						
Refractive J0 (D)	0.31 ± 0.28	0.32 ± 0.21	0.30 ± 0.23	0.35 ± 0.26	0.00 ^a	0.783
Refractive J45 (D)	-0.08 ± 0.12	-0.04 ± 0.11	-0.06 ± 0.13	-0.06 ± 0.15	0.00 ^c	0.474
Data are mean ± standard deviation or number (male/female); right-eye data are shown. Effect sizes: ^a omega-squared (one-way analysis of variance); ^b Cramér's V (chi-square test); ^c epsilon-squared (Kruskal–Wallis test). ^d Year-2 baseline was assessed at the 12-month visit among the 161 participants who completed the 24-month follow-up, immediately before all participants were switched to the IORC-H lens; groups refer to the original randomized allocation. Bonferroni-corrected post hoc comparisons: ^e IORC-H vs IORC-L, adjusted <i>P</i> = 0.014; ^f IORC-H vs IORC-L, adjusted <i>P</i> = 0.013 (year-1 baseline: IORC-L vs SVL, adjusted <i>P</i> = 0.045).						

Longitudinal Changes in Astigmatic Vector Components

Corneal J0 drifted in the positive (with-the-rule) direction in both years (Fig. 1D). Refractive J0 showed a similar pattern (Fig. 1C). The overall group-by-segmented-time interaction was not significant for either corneal or refractive J0, and none of the stage-specific group-by-slope terms remained significant after Benjamini-Hochberg correction (Table 2).

Table 2
Piecewise linear generalized estimating equation analysis of two-year astigmatic trajectories

Astigmatic component	Year-1 slope, D/year (95% CI)	Year-2 slope, D/year (95% CI)	P (group × time)
Corneal J0	0.087 (0.071 to 0.102)	0.068 (0.054 to 0.083)	0.942
Corneal J45	-0.000 (- 0.011 to 0.010)	0.008 (- 0.003 to 0.019)	0.188
Refractive J0	0.094 (0.079 to 0.108)	0.070 (0.057 to 0.084)	0.535
Refractive J45	-0.025 (- 0.031 to - 0.019)	-0.024 (- 0.030 to - 0.018)	0.980
Corneal cylinder magnitude	0.169 (0.139 to 0.199)	0.139 (0.111 to 0.168)	0.875
Refractive cylinder magnitude	0.200 (0.170 to 0.230)	0.155 (0.127 to 0.184)	0.628
Slopes are annualized changes estimated from piecewise linear generalized estimating equation models (knot at 12 months; both eyes; participant-level clustering; exchangeable working correlation; robust standard errors; adjustment for baseline age and sex). Year-1 and year-2 slopes are shown for the SVL reference group. <i>P</i> (group × time) is the overall 6-df Wald test of the group-by-segmented-time interaction; group terms in year 2 represent the original randomized allocation, because all participants wore IORC-H lenses during year 2.			

Corneal J45 remained essentially flat throughout the follow-up (Fig. 1F), whereas refractive J45 showed small negative drifts of approximately -0.02 to -0.03 D/year (Fig. 1E). Astigmatism magnitude increased gradually in all groups (Fig. 1A and 1B). None of the overall group-by-segmented-time interactions was significant for J45 or astigmatism magnitude.

Endpoint Changes and Vector Displacement

Endpoint analyses of refractive and corneal astigmatism included 342 eyes (171 participants) at 12 months and 322 eyes (161 participants) at 24 months. At 12 months, the mean change in corneal J0 was 0.10 ± 0.15 D and the mean corneal vector displacement was 0.18 ± 0.12 D; 19.7% and 1.8% of eyes showed a displacement of ≥ 0.25 D and ≥ 0.50 D, respectively. At 24 months, the mean change in corneal J0 was 0.17 ± 0.17 D, the mean vector displacement was 0.24 ± 0.14 D, and the corresponding proportions increased to 43.9% and 4.7%. Refractive astigmatism showed a similar pattern (12 months: mean $\Delta J0 = 0.09 \pm 0.11$ D, with 20.2% showing a displacement ≥ 0.25 D; 24 months: $\Delta J0 = 0.16 \pm 0.15$ D, with 42.2% and 3.4% showing displacements ≥ 0.25 D and ≥ 0.50 D, respectively). In logistic GEE analyses, the odds of exceeding either displacement threshold did not differ significantly among groups at either time point, except for a nominally higher odds of a corneal vector displacement of ≥ 0.25 D at 12 months in the IORC-H group versus the SVL group (odds ratio 2.92, 95% CI 1.23–6.95, $P = 0.016$; overall group effect $P = 0.062$).

Association Between Astigmatic Change and Axial Elongation

Correlations with axial elongation were examined using right-eye data. The mean axial elongation was 0.24 ± 0.19 mm at 12 months and 0.41 ± 0.28 mm at 24 months ($n = 161$ right eyes). The change in refractive J0 was moderately correlated with axial elongation at both 12 months ($r = 0.39$, $P < 0.001$) and 24 months ($r = 0.39$, $P < 0.001$), and these associations remained significant after adjustment for age, sex, and baseline values (standardized $\beta = 0.51$, 95% CI 0.26–0.76, and $\beta = 0.55$, 95% CI 0.27–0.83, respectively; both $P < 0.001$; Fig. 2A and 2B). The change in corneal J0 was not correlated with axial elongation at 12 months ($r = 0.12$, $P = 0.131$, $n = 160$ right eyes) but showed a weak association at 24 months ($r = 0.25$, $P = 0.001$, $n = 159$ right eyes; adjusted $\beta = 0.32$, 95% CI 0.10–0.54, $P = 0.005$; Fig. 2C). No significant associations were observed for J45 (all $P > 0.05$). Corneal and refractive astigmatism were moderately to strongly correlated at 24 months, both in absolute terms (J0: $r = 0.77$; J45: $r = 0.61$) and in their 24-month changes ($\Delta J0$: $r = 0.59$; $\Delta J45$: $r = 0.34$; all $P < 0.001$; Fig. 3).

DISCUSSION

In this two-year randomized clinical trial, we evaluated whether IORC spectacle lenses with three levels of peripheral myopic defocus induced clinically meaningful changes in corneal or refractive astigmatism in myopic children. We found that J0 drifted slightly but consistently in the with-the-rule direction in both the corneal and refractive domains, at approximately 0.07–0.09 D per year; however, the group-by-segmented-time interaction was not significant for any outcome, indicating that this drift was independent of both lens wear and defocus dose. Meanwhile, J45 remained essentially stable

throughout the follow-up, and although astigmatism magnitude increased gradually, a two-year vector displacement of ≥ 0.50 D occurred in fewer than 5% of eyes. Furthermore, the change in refractive J0 was moderately correlated with axial elongation, whereas the corresponding corneal change showed at most a weak association, and the corneal and refractive changes agreed only moderately with each other. Collectively, these results support our hypothesis that IORC lenses do not induce clinically meaningful, dose-dependent astigmatic changes, and suggest that the small J0 drift observed over the two-year period is physiological in origin. Each of these findings is discussed in turn below.

The positive J0 drift observed in all four groups indicates a slight steepening of the vertical corneal meridian relative to the horizontal one. The drift was small in absolute magnitude, below the 0.50 D generally regarded as clinically meaningful for astigmatic change¹⁶. This positive J0 drift is the opposite direction to that reported by Qin et al.¹⁷ in a large longitudinal study of Chinese school-age children. Several differences may explain this discrepancy. First, their long-term observation covered the full transition from childhood to adolescence, whereas our two-year follow-up focused on a narrower window around puberty, during which J0 may still be increasing before declining later in adolescence¹⁸. Second, their observational design captured natural refractive development, whereas our trial involved optical interventions that may have modulated the physiological trajectory, even without dose-dependent effects. Crucially, the SVL group showed a J0 drift similar in magnitude and direction to that of the IORC groups, with no significant group-by-time interaction for any outcome. This suggests that the positive J0 drift is unlikely to be lens-induced, but rather a physiological change during this developmental window¹⁹.

The two-phase design provides further support for this interpretation: the year-2 slope did not differ significantly from the year-1 slope even though all participants had switched to the IORC-H lens, and the year-2 trajectory did not differ according to the original randomized allocation. This internal control indicates that the drift was independent of both lens wear and defocus dose. We therefore consider the with-the-rule J0 drift to be primarily age-related physiological change rather than a treatment effect.

The J45 represents the oblique astigmatic component and is considered more sensitive to irregular or asymmetric corneal changes²⁰. In our study, corneal J45 remained essentially flat over the two years, whereas refractive J45 showed only a small negative drift of approximately -0.02 D per year. These findings are consistent with those from other myopia control studies^{21, 22} and support the clinical safety of the IORC design—particularly given that oblique astigmatism is generally more visually disruptive than regular astigmatism. The gradual increase in cylinder magnitude, accompanied by a stable J45, indicates that the astigmatic change occurred along the principal meridians without axis rotation toward oblique orientations, a pattern characteristic of regular physiological change. This interpretation is further supported by the vector displacement data. Although 43.9% of eyes showed a corneal vector displacement of ≥ 0.25 D by 24 months, only 4.7% reached ≥ 0.50 D, and the odds of exceeding either threshold did not differ significantly among lens groups. Notably, at 12 months, the IORC-H group showed a higher odds of achieving a corneal vector displacement of ≥ 0.25 D compared with the SVL

group. However, this finding should be interpreted with caution: the overall group effect was not significant, the difference did not persist at 24 months, and the nominal significance did not survive adjustment for multiple comparisons. Thus, this finding does not constitute evidence of a lens-related effect on corneal astigmatism, nor does it support a dose-dependent response.

The absence of any dose–response relationship across the 2.50, 3.50, and 4.50 D defocus levels is consistent with findings from studies on diffusion optics technology lenses^{23, 24} and lenslet-array-integrated designs¹⁴. In contrast, Xu et al.¹⁰ reported that highly aspherical lenslet lenses were associated with increasing astigmatism, with 23.6% of wearers showing an annual cylinder progression of ≥ 0.50 D. We consider that differences in lens design may explain this discrepancy. The highly aspherical lenslet lenses employ concentric rings of lenslets that create a spatially discontinuous peripheral defocus profile with abrupt optical gradients²⁵. Because ocular growth is regulated by local retinal defocus signals in a regionally selective manner²⁶ through retina-to-scleral signaling pathways²⁷, such an asymmetric optical input could theoretically impose meridional imbalances on anterior segment growth. The IORC lens, in contrast, uses an individualized free-form back surface customized to each child’s measured peripheral refraction, ensuring a smooth transition from the central correction zone to the peripheral defocus zone and thus a more symmetric defocus signal⁶. Consistent with this design feature, the stability of J45 in our cohort supports the absence of such asymmetric corneal effects. Moreover, the year-2 phase revealed that uniformly exposing all participants to the highest defocus level neither accelerated the J0 drift nor destabilized J45, suggesting that the IORC lenses do not induce a dose-dependent effect on astigmatism progression, and supporting the safety of this lens design.

We next examined whether these astigmatic changes were related to myopia progression. Refractive J0 change was moderately correlated with axial elongation, whereas the corresponding corneal change showed only a weak association, and the two domains agreed only moderately with each other. The dissociation between corneal and refractive J0 suggests that the refractive J0–axial elongation relationship is not driven by corneal remodeling alone. A more plausible explanation involves the compensatory role of internal optics, particularly the crystalline lens, which partially offsets corneal astigmatism²⁸. This compensation is highly prevalent in children and may be modulated during axial elongation²⁹, as internal astigmatism itself has been associated with myopic traits such as axial length and spherical equivalent. Thus, the association between refractive J0 change and axial elongation likely reflects coordinated physiological adjustments of the entire optical system, encompassing both corneal and internal components, during emmetropization, a process in which astigmatism and ocular growth are known to interact³⁰. From a practical standpoint, the astigmatic changes observed were too small and too uniform across groups to confound the evaluation of myopia-control efficacy, nor do they raise a safety concern that would warrant a change in prescribing practice on the basis of astigmatism alone.

Several limitations should be acknowledged. First, the second year was not randomized; all participants received IORC-H, so year-2 between-group comparisons reflect original allocation and possible carryover effects. Although the piecewise model partially accounts for this and the absence of slope change

argues against a strong carryover effect, the lack of a concurrent control group limits causal attribution of year-2 trajectories. Future studies with extended randomized periods or crossover designs would help separate treatment effects from developmental changes. Second, the sample size was calculated for myopia progression, not astigmatic outcomes; small lens-specific effects on J0 or J45 may have been undetected. Future studies specifically powered for astigmatic vectors would be valuable. Third, total keratometry, while more comprehensive than anterior keratometry alone, does not allow separate analysis of anterior and posterior corneal astigmatism, which partially compensate for each other³¹. Dedicated corneal tomography in future studies could better delineate the contribution of each surface to overall astigmatic change. Fourth, the single-center cohort of Chinese children aged 8–12 years may limit generalizability. Future multi-center studies across diverse populations would help confirm the generalizability of these findings.

CONCLUSION

In conclusion, over two years of follow-up, IORC spectacle lenses did not induce clinically meaningful changes in corneal or refractive astigmatism across the three defocus levels. The small with-the-rule J0 drift was uniform across groups and study phases, consistent with age-related physiological change, whereas J45 remained stable throughout. The moderate association between refractive J0 change and axial elongation was not observed for corneal J0, indicating that it does not reflect lens-induced corneal remodeling. These findings support the long-term optical safety of the individualized IORC design with respect to astigmatic changes and suggest that the use of these lenses for myopia control in children is not associated with clinically meaningful astigmatic effects.

Declarations

DATA AVAILABILITY

The data supporting the findings of this study are available from the corresponding author, Longqian Liu, upon reasonable request.

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AUTHOR CONTRIBUTIONS

G.H., Y.W. and L.L. conceived and designed the study. G.H. and Y.W. wrote the manuscript. G.H. and Q.C. analyzed the data. S.L. and J.K. acquired the data. G.H. contributed figures. L.L. obtained funding. L.L., G.H. and Y.W. had overall responsibility. X.C. and L.L. contributed to the paper and discussion of the results. All authors read and approved the final manuscript.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

ETHICS AND CONSENT TO PARTICIPATE DECLARATIONS

Human subjects were included in this prospective, randomized, double-masked clinical trial. The study was approved by the institutional review board of West China Hospital, Sichuan University, and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants and their parents or legal guardians prior to enrollment.

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Figures

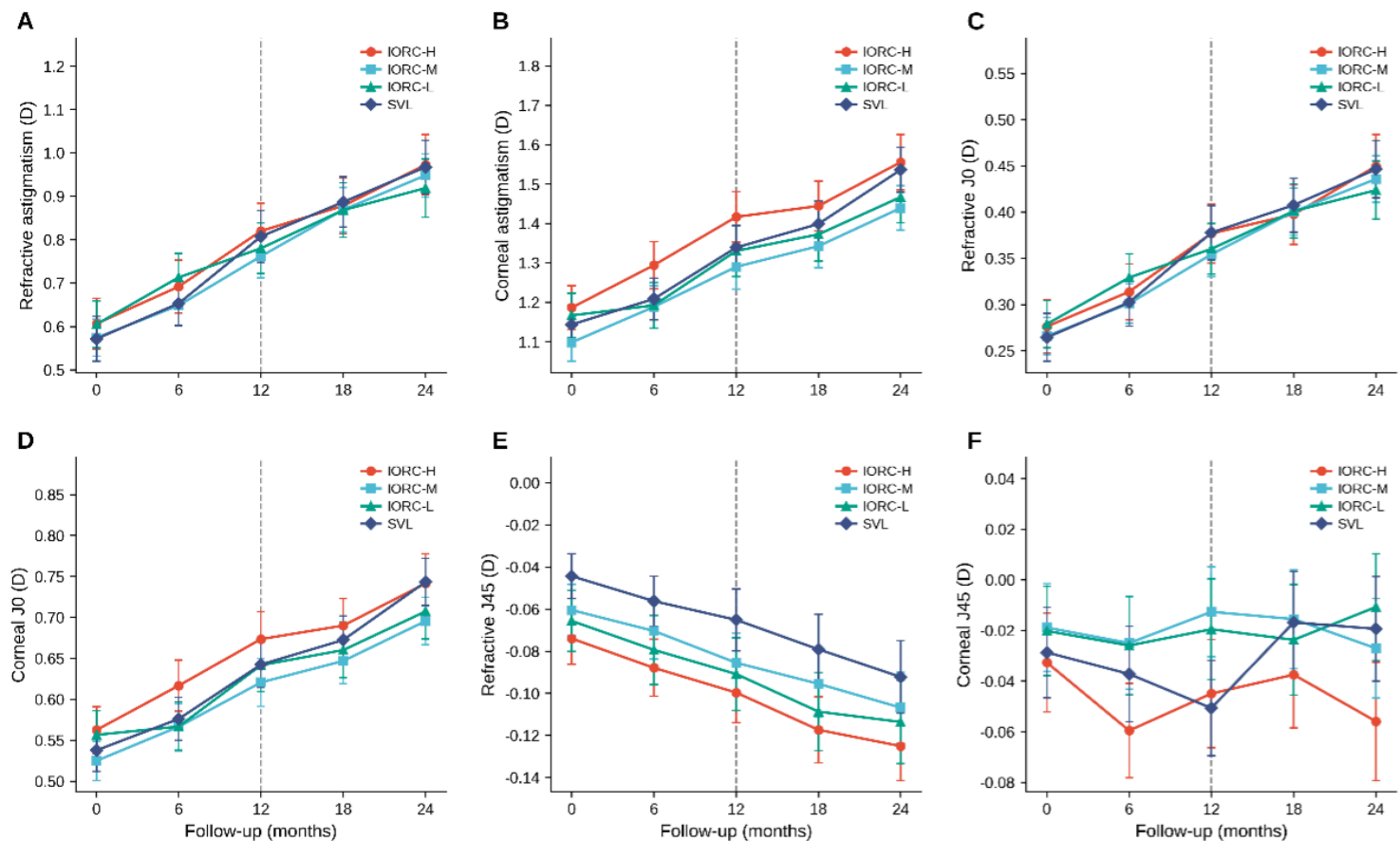


Figure 1

Observed two-year trajectories of astigmatism outcomes according to the randomized group. (A) Refractive astigmatism magnitude (absolute cylinder power). (B) Corneal astigmatism magnitude (total keratometry-derived cylinder power). (C) Refractive J0. (D) Corneal J0. (E) Refractive J45. (F) Corneal J45. Symbols and error bars indicate group means $\pm$ standard errors computed from both eyes at each visit. The vertical dashed line marks the 12-month visit, after which all participants were switched from their assigned lens to the IORC-H (4.50 D) lens. Group trajectories beyond this point therefore reflect the original randomized allocation rather than concurrent treatment.

IORC-H, IORC-M, and IORC-L = individualized ocular refraction customization lenses with 4.50, 3.50, and 2.50 D of peripheral myopic defocus, respectively; SVL = single-vision lenses.

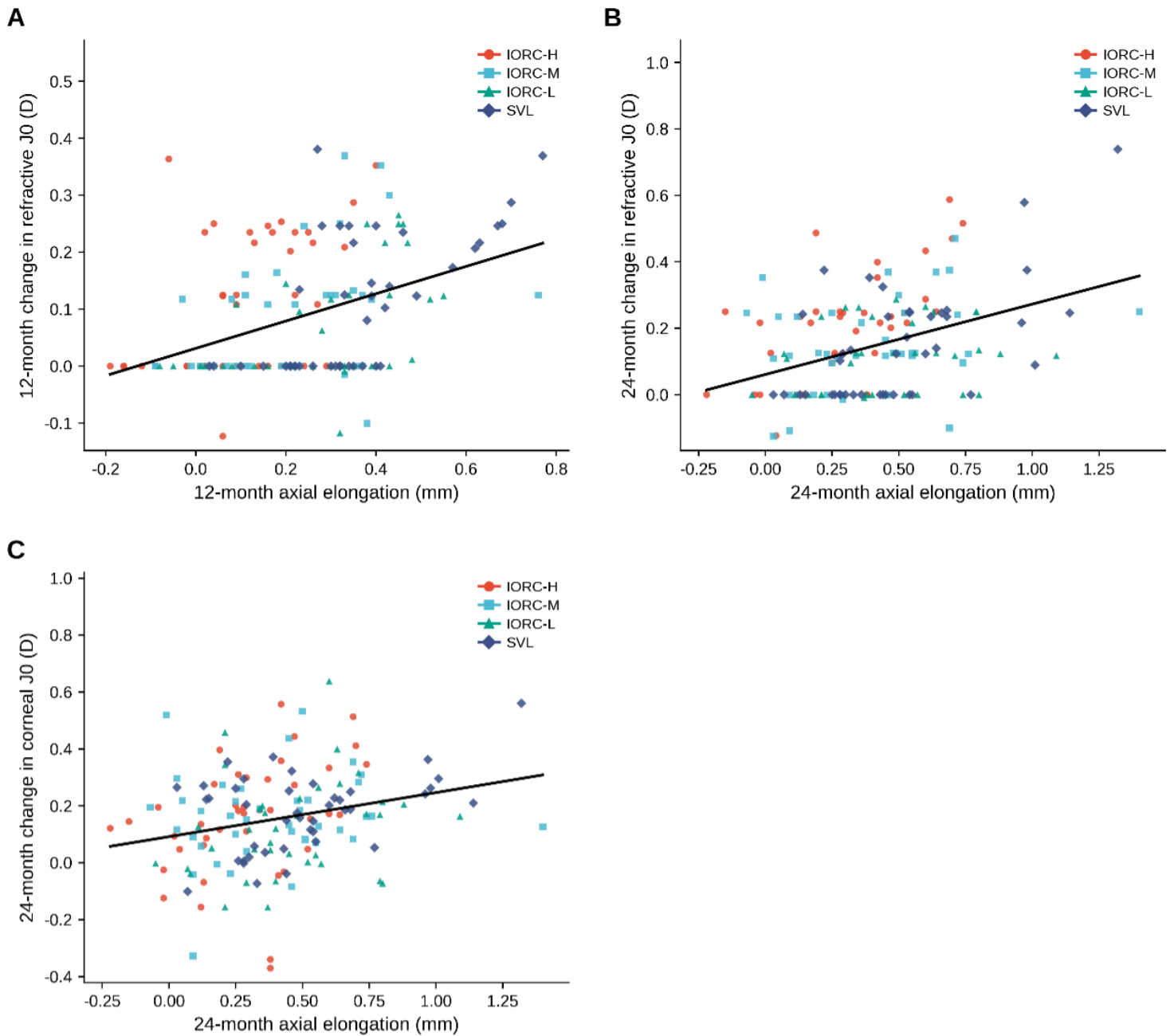


Figure 2

Statistically significant associations between changes in J0 and axial elongation (right eyes). (A) Twelve-month change in refractive J0 versus 12-month axial elongation ($r = 0.39$, $P < 0.001$). (B) Twenty-four-month change in refractive J0 versus 24-month axial elongation ($r = 0.39$, $P < 0.001$). (C) Twenty-four-month change in corneal J0 versus 24-month axial elongation ($r = 0.25$, $P = 0.001$). Solid lines represent ordinary least-squares fits. Each panel also reports the standardized regression coefficient (β) adjusted for age, sex, and baseline values. Marker colors and shapes denote the original randomized group.

IORC-H, IORC-M, and IORC-L = individualized ocular refraction customization lenses with 4.50, 3.50, and 2.50 D of peripheral myopic defocus, respectively; SVL = single-vision lenses.

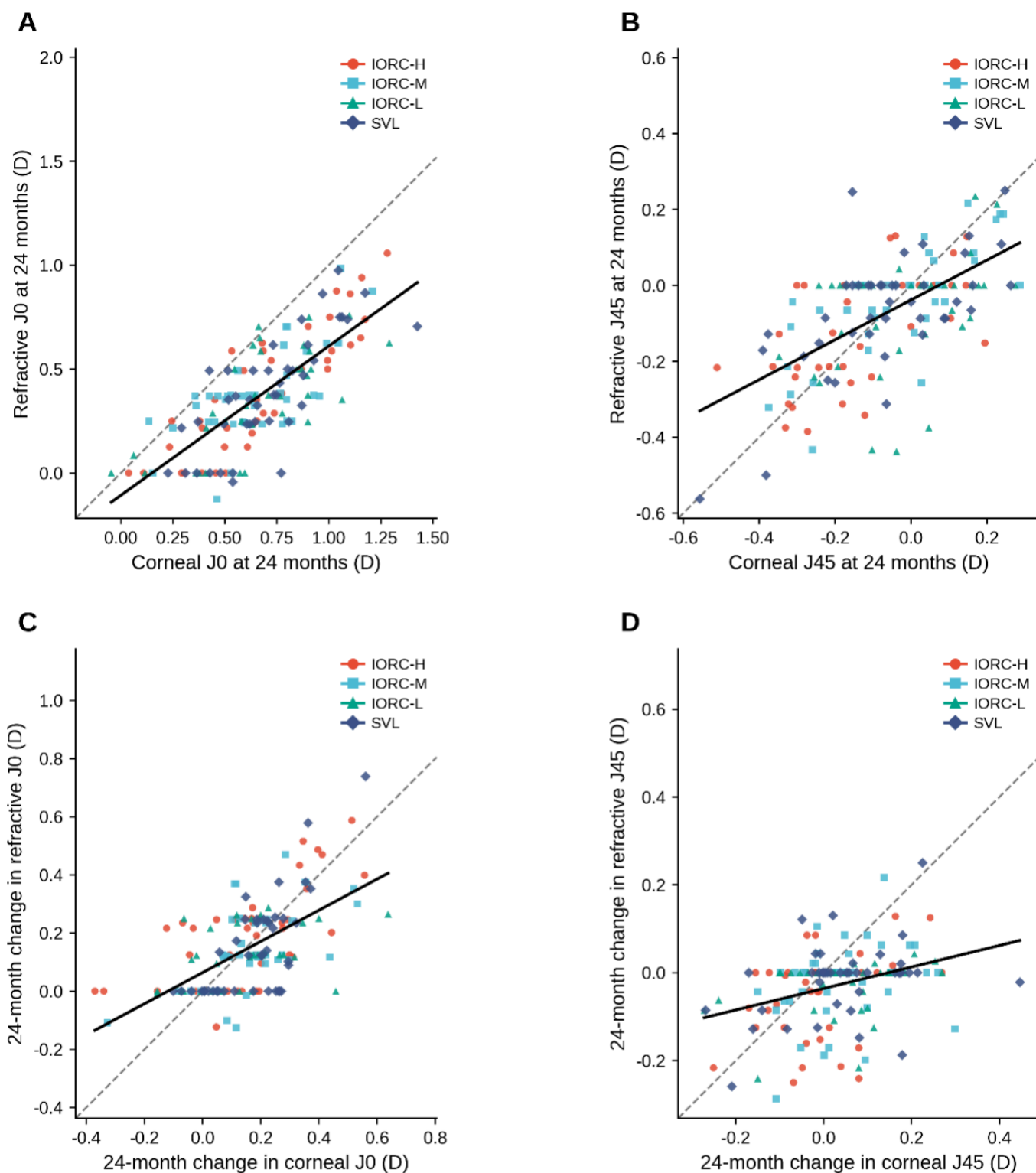


Figure 3

Consistency between corneal and refractive astigmatism at 24 months (right eyes). (A) Absolute J0 ($r = 0.77$, $P < 0.001$). (B) Absolute J45 ($r = 0.61$, $P < 0.001$). (C) Twenty-four-month change in J0 ($r = 0.59$, $P < 0.001$). (D) Twenty-four-month change in J45 ($r = 0.34$, $P < 0.001$). Solid lines represent ordinary least-squares fits, and dashed grey lines indicate the line of identity. Corneal J0 values derived from total keratometry were systematically larger than refractive J0 values, whereas the 24-month changes agreed

more closely between the two domains. Marker colors and shapes denote the original randomized group.

IORC-H, IORC-M, and IORC-L = individualized ocular refraction customization lenses with 4.50, 3.50, and 2.50 D of peripheral myopic defocus, respectively; SVL= single-vision lenses.