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Comparison of Clinical Efficacy of Different Adjustment Methods in Software-Assisted Orthokeratology Lens Fitting for Chinese Children: A Prospective Randomized Controlled Trial

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Abstract

Purpose

To compare the clinical efficacy of three parameter-optimization strategies in software-assisted orthokeratology (ortho-k) lens fitting for Chinese children.

Methods

In this single-blind (participant-masked) prospective randomized controlled trial, 171 myopic children aged 8–15 years who were first-time ortho-k lens wearers (Menicon Z Night) were enrolled between October 2023 and October 2025 at Chongqing Aier Children's Eye Hospital and randomly allocated in a 1:1:1 ratio to three groups (n = 57 each). Group A (control) wore lenses prescribed directly by the fitting software without adjustment; Group B wore lenses prescribed with an over-correction of − 1.50 D; Group C wore lenses prescribed with − 1.50 D over-correction combined with a 40-μm increase in sagittal height and a 1° flattening of the tangential angle. The primary outcomes were uncorrected visual acuity (UCVA), axial length (AL), treatment zone diameter (TZD), and corneal safety over 12 months. Only the right eye of each participant was analyzed.

Results

All 171 participants completed the 12-month follow-up. Baseline characteristics (age, sex, spherical equivalent, and AL) were comparable among the three groups (all $P \geq 0.05$). Fitting success rates were similar (Group A: 100.0%; Group B: 96.5%; Group C: 98.2%; $P = 0.774$, Fisher–Freeman–Halton exact test). At 1 month, mean LogMAR UCVA was 0.00 ± 0.02, 0.03 ± 0.08, and 0.02 ± 0.05 in Groups A, B, and C, respectively ($P = 0.062$), and lens centration was acceptable without significant intergroup differences ($P = 0.373$). TZD was significantly smaller in Group C than in Groups A and B at all visits (1 month: 2.65 ± 0.45 mm vs. 3.28 ± 0.44 mm and 3.16 ± 0.39 mm; all pairwise $P < 0.001$); TZD increased over time in Groups A and B but remained stable in Group C (mixed-effects model, group × time interaction: $\beta = -0.026$ mm/month, $P = 0.007$). Cumulative axial elongation at 12 months was 0.23 ± 0.15 mm (A), 0.21 ± 0.24 mm (B), and 0.13 ± 0.19 mm (C) (overall $P = 0.013$); Group C showed significantly less axial elongation than Group A ($P < 0.001$, LSD post-hoc test; adjusted difference − 0.11 mm, $P = 0.008$, ANCOVA). No serious adverse events occurred (Grade I corneal staining: 1, 0, and 2 eyes; $P = 0.774$).

Conclusion

Software-assisted ortho-k fitting achieved a high fitting success rate (98.2%) in Chinese children. Among the tested protocols, − 1.50 D over-correction combined with a 40-μm increase in sagittal height and a 1°

flattening of the tangential angle produced a smaller and more stable treatment zone and significantly slower axial elongation over 12 months, without compromising visual outcomes or corneal safety.

Trial registration

Medical Research Registration and Filing System, National Health Security Information Platform of China (registration No. MR5026074835). Prospective registration was not required when enrolment began in 2023 the study was registered retrospectively through the platform's supplementary registration procedure. Running title Softwareassisted orthokeratology optimization in Chinese children. Word count Abstract ~ 280 Main text ~ 4,000. Tables 5 Figures 5.

1. Introduction

China has among the highest prevalence rates of myopia worldwide, with a pooled prevalence of 37.7% among children and adolescents and up to 84.8% among those aged 16–18 years in studies conducted after 2013 [5]; early intervention to slow myopia progression and prevent pathological complications is therefore a public health priority [1–6]. Numerous clinical studies have demonstrated the effectiveness of orthokeratology (ortho-k) lenses in slowing axial elongation in children [7,8]. In current practice in China, however, most ortho-k fittings still rely on diagnostic trial lens sets, a procedure that is time-consuming, dependent on clinician experience, and carries a potential risk of cross-infection through reused trial lenses.

With advances in lens design and corneal modeling, software-assisted fitting has become increasingly mature. The Menicon Z Night lens employs a design system that analyzes corneal topography and ancillary data to digitally simulate the eye and determine optimal lens parameters, thereby improving fitting efficiency, reducing cross-infection risk, and shortening patient waiting time. Nevertheless, the parameter algorithm of this system was developed largely on the basis of non-Chinese populations, and clinical evidence validating its default prescriptions in Chinese children remains insufficient.

Myopia progression in Chinese children is rapid, and the demand for effective control is correspondingly high. Studies have shown that increasing the compression factor can enhance myopia control by inducing higher-order aberrations [9,10], and a smaller treatment zone diameter (TZD) enlarges the area of peripheral myopic defocus, which has been confirmed as an important determinant of the myopia-control efficacy of ortho-k lenses [11–13]. By modifying the over-correction and sagittal height of the Menicon Z Night lens, TZD can theoretically be reduced to enhance myopia control. However, quantitative clinical evidence supporting such population-adapted optimization strategies in software-assisted ortho-k fitting is lacking for Chinese children. Therefore, this prospective randomized controlled trial compared three optimization protocols and aimed to identify the most suitable strategy for this population.

2. Materials and Methods

2.1 Trial design and registration

This was a single-center, prospective, three-arm, parallel-group randomized controlled trial conducted at Chongqing Aier Children's Eye Hospital between October 2023 and October 2025. The protocol was approved by the Institutional Ethics Committee of Chongqing Aier Children's Eye Hospital (Approval No. 2023-003-01) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from the legal guardians of all participants. At the time enrolment began (October 2023), prospective trial registration was not required by the institution or by national regulations; the study was subsequently registered retrospectively through the supplementary registration and filing procedure of the Medical Research Registration and Filing System, National Health Security Information Platform of China (registration No. MR-50-26-074835). This report follows the CONSORT 2010 statement.

2.2 Participants

A total of 171 children (82 males and 89 females; mean age 10.17 ± 1.82 years, range 8–15 years) who were first-time ortho-k lens wearers were enrolled. Inclusion criteria were: (1) age 8–15 years; (2) spherical myopia − 0.50 to − 4.00 D; (3) astigmatism ≤ − 1.50 D; (4) flat keratometry (Kf) 39.00–48.00 D, with flat K minus the absolute spherical equivalent ≥ 38.00 D; (5) best-corrected visual acuity ≥ 20/20 (LogMAR = 0.0); and (6) absence of keratoconus on corneal topography. Exclusion criteria were: manifest strabismus or other ocular diseases; systemic immune disorders; prior ortho-k lens wear; concurrent use of other myopia-control interventions (e.g., atropine, red-light therapy, defocus spectacles or soft contact lenses, or rigid contact lenses); irregular corneal astigmatism; anisometropia; history of corneal surgery or trauma; reduced corneal sensation; corneal endothelial cell density < 2,000 cells/mm²; and previous intraocular surgery.

2.3 Randomization and allocation concealment

A block randomization design was used. Participants were numbered consecutively by order of consultation, and a random allocation sequence was generated with SPSS 31.0 (IBM Corp., Armonk, NY, USA) using a fixed seed and a block size of six, with two participants assigned to each group within every block. The allocation schedule was generated for the planned sample of 174 participants (29 blocks of six), allowing for the expected dropout rate. Enrolment was closed after 171 participants had been allocated, so the final (29th) block was not completely filled (three of its six slots were used, one in each group), which yielded 57 participants per group. Participants were allocated in a 1:1:1 ratio to Groups A, B, or C, and the allocation sequence was concealed until the lenses were ordered. Group A served as the control group, in which lens parameters were output directly by the fitting software without further optimization. In Group B, lens parameters were generated by the software under an over-correction of − 1.50 DS. In Group C, on the basis of the − 1.50 DS over-correction, the lens sagittal height was further increased by 40 μm and the tangential angle of the reverse curve was flattened by 1°. This was a single-blind trial: enrolled children and their legal guardians were masked to group allocation

(participants did not know which protocol they received), whereas the investigators performing lens fitting and follow-up examinations were aware of the assigned protocol. The investigator who measured TZD from topographic difference maps was not masked to group allocation, which is acknowledged as a limitation. Only the right eye of each participant was included in the analysis; for participants with unilateral myopia, the myopic eye was selected.

2.4 Lens material and design

The Menicon Z Night ortho-k lens (Menicon Co., Ltd., Nagoya, Japan), made of Menicon Z material (Tisilfocon A), was used. The lens has a Dk of 163 (ISO) / 189 (FATT), a center thickness of 0.24 mm, and a reverse-geometry, three-zone tangent design. The reverse curve zone contains three ventilation fenestrations spaced 120° apart, each 0.25 mm in diameter. Lens parameters were determined with the EasyFit software (Menicon Co., Ltd.).

2.5 Examination procedures

All participants underwent a comprehensive pre-fitting ophthalmic examination, including LogMAR visual acuity testing; intraocular pressure measurement with a non-contact tonometer (NT-510, NIDEK, Japan); slit-lamp anterior segment assessment (SLIPS1000, New Vision, China); tear film break-up time with fluorescein strips for dry-eye screening; cycloplegic refraction with an autorefractor (ARK-1, NIDEK, Japan) and phoropter (RT-5100, NIDEK, Japan); axial length measurement with an optical biometer (AL-Scan, NIDEK, Japan); corneal endothelial evaluation with a specular microscope (CEM-530, NIDEK, Japan); Pentacam anterior segment analysis (70700, Oculus, Germany) to exclude keratoconus; Medmont corneal topography (E300USB, Medmont, Australia) for keratometry, eccentricity, and corneal astigmatism; and fundus examination with a scanning laser ophthalmoscope (Daytona P00t, Highsee Technology Co., Ltd., China).

2.6 Lens fitting and follow-up

Corneal topography data were imported into the EasyFit software, and baseline spherical and cylindrical refractive errors, cylinder axis, and horizontal visible iris diameter were entered into the system before lens wear. Lens parameters were adjusted according to the optimization protocol predefined for each group. Follow-up visits were scheduled at 1 day, 1 week, 1 month, 3 months, 6 months, 9 months, and 12 months after lens delivery. At each visit, UCVA, subjective refraction, corneal status (slit-lamp with fluorescein staining), axial length, and corneal topography were assessed. Lens centration was graded on the corneal refractive difference map (A–B map) as centered (decentration ≤ 0.5 mm) or mildly decentred (0.5–1.0 mm), and TZD was measured from the horizontal zero–zero axis of the A–B map.

2.7 Outcome measures

The primary outcomes were cumulative axial elongation and TZD at 3, 6, and 12 months. The secondary outcomes were UCVA at 1 month, lens centration at 1 month, the fitting success rate (defined as successful initial fitting without prescription exchange), and corneal adverse events during the 12-month follow-up.

2.8 Sample size

The sample size was determined a priori for the three-group comparison using a medium effect size (Cohen's f = 0.25), a two-sided significance level of 0.05, and 80% power, which required 53 participants per group (total N = 159). Allowing for an expected 10% dropout rate, 174 participants (58 per group) were planned; 171 participants (57 per group) were ultimately enrolled, which remained above the 53 participants per group required for 80% power.

2.9 Statistical analysis

Statistical analyses were performed with SPSS 31.0. The Kolmogorov–Smirnov test was used to verify normality, and normally distributed continuous variables are presented as mean ± standard deviation (SD). Baseline characteristics and single-time-point continuous outcomes (including LogMAR UCVA at 1 month) among the three groups were compared by one-way analysis of variance (ANOVA), with the least significant difference (LSD) test for post-hoc pairwise comparisons. Categorical variables were compared with the chi-square test or the Fisher–Freeman–Halton exact test, as appropriate. Repeated-measures ANOVA (RM-ANOVA) was used for TZD and axial length across baseline, 1, 3, 6, and 12 months, with within-group paired comparisons against baseline when a significant time effect was found. To account for baseline imbalance in axial length, analysis of covariance (ANCOVA) was applied to axial elongation with baseline AL as a covariate, and a linear mixed-effects model with a random intercept per subject (group × time interaction) was fitted as a sensitivity analysis for both TZD and axial length. Sensitivity analyses were repeated after excluding eyes with $|\Delta AL| > 0.6$ mm at 12 months. A two-sided $P < 0.05$ was considered statistically significant.

3. Results

3.1 Baseline characteristics

All 171 participants (57 per group) completed the 12-month follow-up with valid data (Fig. 1). The three groups were comparable at baseline in age (10.46 ± 1.84, 10.26 ± 1.76, and 9.79 ± 1.82 years for Groups A, B, and C, respectively; P = 0.131), sex distribution (26:31, 28:29, and 28:29 male:female; P = 0.911), spherical power (P = 0.573), spherical equivalent (P = 0.618), flat and steep keratometry (P = 0.138 and P = 0.144), corneal eccentricity (P = 0.399), and axial length (24.52 ± 0.68, 24.45 ± 0.65, and 24.35 ± 0.68 mm; P = 0.395). The distribution of cylinder axis differed marginally across groups (P = 0.051). All baseline comparisons are summarized in Table 1.

Table 1
Baseline characteristics of the three groups.

Variable	Total (n = 171)	Group A (n = 57)	Group B (n = 57)	Group C (n = 57)	Statistic	P*
Age, years	10.17 ± 1.82	10.46 ± 1.84	10.26 ± 1.76	9.79 ± 1.82	F = 2.05	0.131
Sex, M/F	82/89	26/31	28/29	28/29	χ^2 = 0.19	0.911
Spherical power, D	−1.69 ± 0.68	−1.76 ± 0.70	−1.65 ± 0.61	−1.65 ± 0.71	F = 0.56	0.573
Cylindrical power, D	−0.49 ± 0.45	−0.53 ± 0.36	−0.54 ± 0.45	−0.42 ± 0.50	F = 1.19	0.306
Cylinder axis, °	100.29 ± 82.74	114.04 ± 78.18	111.06 ± 79.99	79.12 ± 85.89	F = 3.03	0.051
Spherical equivalent, D	−1.91 ± 0.70	−1.98 ± 0.73	−1.90 ± 0.65	−1.86 ± 0.73	F = 0.48	0.618
Flat K, D	42.54 ± 1.19	42.33 ± 1.17	42.52 ± 1.18	42.77 ± 1.20	F = 2.00	0.138
Steep K, D	43.70 ± 1.28	43.51 ± 1.28	43.61 ± 1.30	43.96 ± 1.24	F = 1.96	0.144
Eccentricity	0.65 ± 0.10	0.64 ± 0.10	0.66 ± 0.11	0.64 ± 0.10	F = 0.92	0.399
Axial length, mm	24.44 ± 0.67	24.52 ± 0.68	24.45 ± 0.65	24.35 ± 0.68	F = 0.94	0.395

Data are mean ± SD unless otherwise indicated. *P from one-way ANOVA for continuous variables and chi-square test for sex. K, keratometry.

3.2 Fitting success rate

All 171 participants completed the initial lens fitting. Three participants required prescription exchange: two for frequent lens displacement and one for poor wearing comfort. The overall fitting success rate was 98.2% (168/171), and the rates were 100.0% (57/57), 96.5% (55/57), and 98.2% (56/57) in Groups A, B, and C, respectively, with no significant difference among groups (P = 0.774, Fisher–Freeman–Halton exact test; Table 2).

Table 2
Fitting success rate in the three groups.

Group	Total (n)	Success (n)	Failure (n)	Success rate (%)	P value*
Group A	57	57	0	100.0	0.774
Group B	57	55	2	96.5	
Group C	57	56	1	98.2	

*P from the Fisher–Freeman–Halton exact test across the three groups.

3.3 UCVA, lens centration, and corneal safety at 1 month

At 1 month, daytime UCVA had stabilized in all three groups. The mean uncorrected LogMAR UCVA was 0.00 ± 0.02 (median 0.00) in Group A, 0.03 ± 0.08 in Group B, and 0.02 ± 0.05 in Group C, with no statistically significant difference among groups (P = 0.062; Kruskal–Wallis P = 0.053). Corneal A–B maps demonstrated acceptable lens centration in all subjects; centration grading (centered vs. mildly decentred: 57/0, 55/2, and 54/3 eyes in Groups A, B, and C) did not differ significantly among groups (P = 0.373, Fisher–Freeman–Halton exact test). During the 12-month follow-up, Grade I corneal epithelial staining occurred in 1 eye (1.8%) in Group A, 0 eyes in Group B, and 2 eyes (3.5%) in Group C, without a significant intergroup difference (P = 0.774). No Grade II or higher staining, microbial keratitis, or other serious adverse events occurred (Table 3, Fig. 4).

Table 3
Visual, centration, and safety outcomes.

Parameter	Group A (n = 57)	Group B (n = 57)	Group C (n = 57)	P value
LogMAR UCVA at 1 month	0.00 ± 0.02	0.03 ± 0.08	0.02 ± 0.05	0.062*
Lens centration at 1 month, centered / mildly decentred	57 / 0	55 / 2	54 / 3	0.373**
Grade I corneal staining during follow-up, n (%)	1 (1.8)	0 (0.0)	2 (3.5)	0.774**

UCVA, uncorrected visual acuity. Data are mean ± SD or n (%). *One-way ANOVA. **Fisher–Freeman–Halton exact test.

3.4 Axial length

Cumulative axial elongation is summarized in Table 4 and Fig. 2. At 3 months, elongation was 0.07 ± 0.07, 0.04 ± 0.09, and 0.01 ± 0.08 mm in Groups A, B, and C, respectively (overall P = 0.003); Group C showed significantly less elongation than Group A (P < 0.001, LSD test), with no significant A–B or B–C differences. At 6 months, elongation was 0.12 ± 0.10, 0.11 ± 0.13, and 0.05 ± 0.13 mm (overall P = 0.004); Group C differed significantly from both Group A (P = 0.001) and Group B (P = 0.014). At 12 months,

elongation was 0.23 ± 0.15, 0.21 ± 0.24, and 0.13 ± 0.19 mm (overall P = 0.013); Group C showed significantly less elongation than Group A (P = 0.001) and Group B (P = 0.048). Axial elongation followed the order Group A > Group B > Group C at all time points.

Table 4
Cumulative axial elongation from baseline in the three groups.

Time point	Group A (n = 57)	Group B (n = 57)	Group C (n = 57)	Overall P (ANOVA)	Post-hoc (LSD)
Baseline AL, mm	24.52 ± 0.68	24.45 ± 0.65	24.35 ± 0.68	0.395	—
ΔAL at 3 months, mm	0.07 ± 0.07	0.04 ± 0.09	0.01 ± 0.08	0.003	A vs. C: P < 0.001
ΔAL at 6 months, mm	0.12 ± 0.10	0.11 ± 0.13	0.05 ± 0.13	0.004	A vs. C: P = 0.001; B vs. C: P = 0.014
ΔAL at 12 months, mm	0.23 ± 0.15	0.21 ± 0.24	0.13 ± 0.19	0.013	A vs. C: P = 0.001; B vs. C: P = 0.048

AL, axial length. Data are mean ± SD. Post-hoc comparisons by LSD test; only significant pairs are listed (all other pairs P > 0.05). ANCOVA with baseline AL as covariate and mixed-effects sensitivity analyses are reported in the Results text.

Because baseline AL was slightly, albeit non-significantly, different among the groups, ANCOVA was performed with baseline AL as a covariate. The model-estimated differences in 12-month axial elongation were − 0.110 mm for Group A vs. Group C (Bonferroni-adjusted P = 0.008) and − 0.084 mm for Group B vs. Group C (Bonferroni-adjusted P = 0.064). In the linear mixed-effects model, the group × time interaction was significant for Group C versus Group A (β = −0.008 mm/month, P < 0.001), whereas Group B did not differ from Group A (P = 0.529), confirming a consistently slower elongation rate in Group C. In the sensitivity analysis excluding eyes with |ΔAL| > 0.6 mm at 12 months (three eyes), 12-month elongation was 0.22 ± 0.13, 0.21 ± 0.17, and 0.13 ± 0.19 mm (overall P = 0.006), and both A vs. C (P = 0.002) and B vs. C (P = 0.021) remained significant.

3.5 Treatment zone diameter

TZD followed the order Group A > Group B > Group C at every visit (Table 5, Fig. 3). At 1 month, TZD was 3.28 ± 0.44, 3.16 ± 0.39, and 2.65 ± 0.45 mm in Groups A, B, and C, respectively (overall P < 0.001); at 3 months, 3.40 ± 0.44, 3.32 ± 0.42, and 2.66 ± 0.49 mm (P < 0.001); and at 6 months, 3.40 ± 0.45, 3.38 ± 0.46, and 2.63 ± 0.49 mm (P < 0.001). Post-hoc tests showed that TZD in Group C was significantly smaller than in both Groups A and B at all visits (all P < 0.001), whereas Groups A and B did not differ at any visit (all P > 0.10). Within groups, TZD increased significantly from 1 to 6 months in Group A (mean change + 0.12 mm, paired P = 0.007) and Group B (+ 0.23 mm, P < 0.001) but remained stable in Group C (− 0.02 mm, P = 0.641). In the mixed-effects model, the between-group TZD difference for Group C versus Group A was − 0.63 mm (P < 0.001), and the group × time interaction confirmed a significantly

divergent time course (Group C slope − 0.026 mm/month vs. Group A + 0.022 mm/month, P = 0.007; Group B slope + 0.021 mm/month above Group A, P = 0.026).

Table 5
Treatment zone diameter (mm) in the three groups.

Time point	Group A (n = 57)	Group B (n = 57)	Group C (n = 57)	Between-group P*
1 month	3.28 ± 0.44	3.16 ± 0.39	2.65 ± 0.45	< 0.001
3 months	3.40 ± 0.44	3.32 ± 0.42	2.66 ± 0.49	< 0.001
6 months	3.40 ± 0.45	3.38 ± 0.46	2.63 ± 0.49	< 0.001
Within-group change 1 → 6 months, P**	0.007	< 0.001	0.641	

Data are mean ± SD. *One-way ANOVA at each time point; LSD post-hoc tests showed Group C vs. A and Group C vs. B all P < 0.001, while Group A vs. B was not significant at any visit (all P > 0.10). **Paired t-test for TZD change from 1 to 6 months within each group. RM-ANOVA and mixed-effects model results are reported in the Results text.

4. Discussion

The myopia-control efficacy of ortho-k lenses is determined by the interaction between lens design parameters and inherent corneal factors, including corneal curvature, eccentricity, and biomechanics. Based on the Menicon Z Night software-assisted fitting system, this randomized controlled trial systematically compared three optimization protocols with respect to myopia control, treatment zone morphology, visual outcomes, and safety in Chinese children. The main findings are threefold. First, the fully software-driven default protocol (Group A) achieved a high fitting success rate and good visual outcomes, confirming the clinical viability of software-assisted fitting. Second, over-correction of −1.50 D alone (Group B) did not significantly reduce TZD or axial elongation relative to the control. Third, the triple-parameter strategy (Group C) — −1.50 D over-correction combined with a 40-μm increase in sagittal height and a 1° flattening of the tangential angle — produced a smaller and longitudinally stable treatment zone and significantly slower axial elongation over 12 months, without compromising visual performance or corneal safety.

4.1 Mechanism of the smaller and more stable treatment zone in Group C

The superior performance of Group C in forming a smaller and temporally stable treatment zone can be explained by the combined effects of over-correction, elevated sagittal height, and a modified tangential angle.

(a) Limitations of over-correction alone. Theoretically, increasing lens over-correction enhances central corneal flattening and favors formation of a smaller treatment zone. In the present trial, however, Group

B, which received standardized −1.50 D over-correction, showed no significant difference in TZD compared with the unadjusted control Group A. This suggests that the EasyFit algorithm may apply compensatory parameter adjustments — such as automatic modification of sagittal height — when over-correction is increased, offsetting the intended narrowing effect. Adjustment of over-correction alone therefore appears insufficient to reshape the treatment zone in routine software-assisted fitting.

(b) Core effect of 40-μm sagittal height elevation. Elevating the sagittal height directly increases the tear-film thickness between the reverse curve and the cornea (Figure 5b). The thicker tear layer generates stronger negative suction, concentrating the reshaping force within the reverse zone. Sagittal height is a critical parameter governing lens centration and the magnitude of corneal remodeling [14]. The present study quantifies this effect in vivo and identifies the 40-μm elevation as the core factor facilitating treatment-zone narrowing.

(c) Synergistic effect of 1° tangential-angle flattening. Flattening the tangential angle of the reverse curve shifts the lens–cornea contact points inward toward the corneal apex (Figure 5c). This shift restricts outward migration of central corneal epithelial cells and promotes epithelial redistribution within the reverse zone, forming a broader and steeper peripheral defocus ring. Together with the elevated sagittal height, the modified tangential angle synergistically stabilizes the lens–cornea relationship and the resulting treatment zone.

4.2 Treatment zone size and axial myopia control

The present findings support the mechanistic chain of "smaller treatment zone → stronger peripheral myopic defocus → slower axial elongation." Group C yielded an average TZD of approximately 2.65 mm, compared with approximately 3.40 mm in Group A and 3.15 mm in Group B. Under natural photopic pupil conditions (typically 4–6 mm), a smaller treatment zone allows a larger proportion of the pupil area to be covered by the peripheral myopic defocus ring, generating a stronger retinal "stop signal" [16]. Our results are consistent with Pauné et al. [15], who reported that smaller back optic zone diameters were associated with slower axial elongation, and with Hiraoka et al. [17] and Zhong et al. [18], who found that narrower treatment zones and steeper peripheral defocus profiles were associated with superior myopia control. The magnitude of the present effect also agrees with the VOLTZ randomized trial, in which a 0.72–0.92 mm smaller treatment zone corresponded to 0.13 mm less axial elongation over one year [13].

In the present cohort, the intergroup TZD difference between Group C and Group A was approximately 0.75 mm, corresponding to a 12-month axial elongation difference of 0.10 mm (0.23 mm vs. 0.13 mm), i.e., approximately 0.13 mm less axial elongation per 1 mm reduction in TZD. While this cross-sectional comparison cannot establish causality, the magnitude is compatible with prior reports [11,12,15] and further verifies that fine adjustments of sagittal height and tangential angle can narrow the treatment zone, enhance peripheral defocus within the pupil, and ultimately slow axial growth.

4.3 Clinical value of software-assisted fitting and population-adapted optimization

Group A represented a standardized, fully software-dependent fitting mode, offering clear clinical advantages: elimination of cross-infection risk from trial lenses, improved fitting efficiency, and reduced dependence on individual clinician experience. The default algorithm of the Menicon Z Night system, however, was developed primarily on non-Chinese populations and may not fully match the ocular characteristics of Chinese myopic children, in whom early onset and rapid progression make maximized myopia control a clinical priority. The default software fitting balances visual quality and myopia control rather than prioritizing myopia prevention. The present study addresses this gap by proposing a practical, quantifiable, population-adapted modification protocol (40-μm sagittal height increase plus 1° tangential-angle flattening) that is readily implementable within the existing software workflow and generalizable in principle to other intelligent fitting systems.

4.4 Corneal safety

Although the Group C protocol generates a more concentrated reshaping force, no severe ocular complications occurred during the 12-month follow-up, and the incidence of Grade I corneal staining did not differ among groups (P = 0.774). Two mechanisms may underlie this safety profile. First, the elevated sagittal height increases central tear clearance, partially counterbalancing the compressive effect of −1.50 D over-correction. Second, the EasyFit algorithm enforces a minimum tear-layer thickness of 10–15 μm for all generated lenses, a safety constraint that is difficult to guarantee with conventional trial-lens fitting. Because the protocol alters the magnitude and distribution of the reshaping force, however, long-term safety beyond 2 years requires further verification in larger cohorts.

4.5 Limitations

Several limitations should be acknowledged. First, this was a single-center trial with 171 participants, which may restrict generalizability; multi-center validation is warranted. Second, the 12-month follow-up is insufficient to assess long-term durability of the effect. Third, only children with low to moderate myopia (−0.50 to −4.00 D) were enrolled, so the applicability to higher myopia remains unverified. Fourth, the optimization magnitudes (40 μm and 1°) were fixed empirical values without a dose-gradient design. Fifth, the mechanistic inference is based on indirect phenomenological evidence; direct markers of peripheral defocus (e.g., choroidal thickness measured by OCT) were not obtained. Sixth, TZD was measured manually from topographic difference maps by an investigator who was not masked to group allocation; although participants were masked to treatment, the absence of masking at the measurement step may introduce observation bias, and automated TZD algorithms or masked reading should be used in future trials. Finally, prospective trial registration was not required when enrolment began in October 2023; the study was therefore registered retrospectively through the supplementary registration and filing procedure of the national platform (No. MR-50-26-074835), and this should be considered when interpreting the evidence.

5. Conclusion

In Chinese children undergoing software-assisted ortho-k fitting, a triple-parameter optimization — −1.50 D over-correction combined with a 40-μm increase in sagittal height and a 1° flattening of the tangential angle — produced a smaller and more stable treatment zone and significantly slower axial elongation over 12 months, with visual outcomes and corneal safety comparable to the default software fitting. This quantifiable, readily implementable strategy offers a population-adapted pathway for individualized myopia control with intelligent ortho-k fitting systems.

Declarations

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee of Chongqing Aier Children's Eye Hospital (No. 2023-003-01); written informed consent was obtained from legal guardians.

Consent for publication: Not applicable.

Availability of data and materials: The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: Sen Wang and Zonghan Zhou are employees of Menicon (Dalian) Medical Technology Co., Ltd. The manufacturer did not provide free lenses, materials, or any other form of material support, and the collaboration with the manufacturer was limited to research. The remaining authors declare no competing interests.

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Authors' contributions: Z.L. and D.T. contributed to participant enrolment and the collection of clinical records; Z.L. performed the statistical analysis; G.Z. was responsible for patient follow-up management; S.W. was responsible for data entry; Z.Z. and Y.H. conceived and designed the study; Z.Z. coordinated and supervised the entire project; Y.H. supervised the conduct of the study and is the guarantor of this work, taking responsibility for the integrity of the data and the accuracy of the data analysis. Y.G. was responsible for the software-based output of lens parameters. All authors read and approved the final manuscript.

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Figures

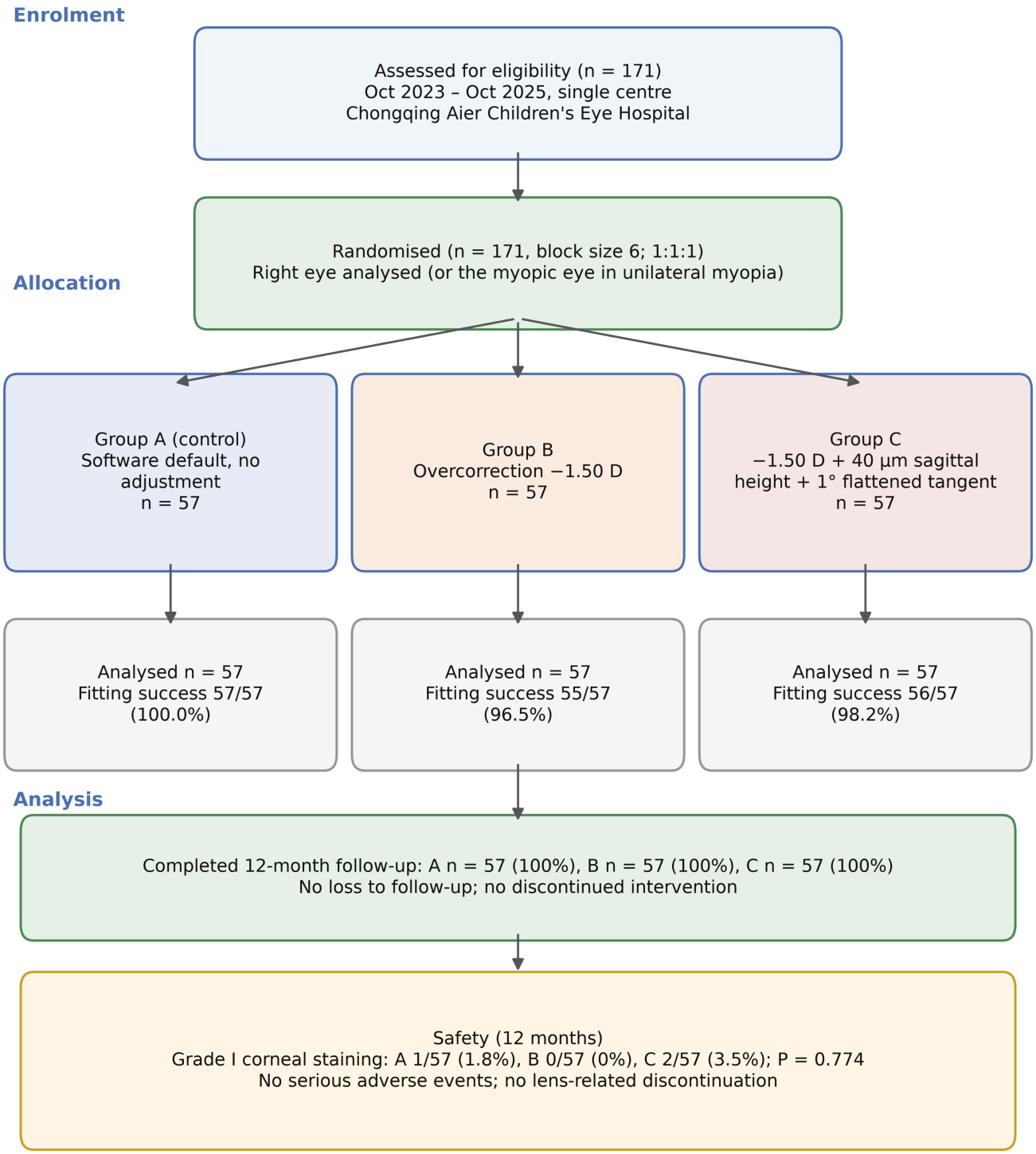


Figure 1

CONSORT flow diagram of participant enrollment, allocation, follow-up, and analysis.

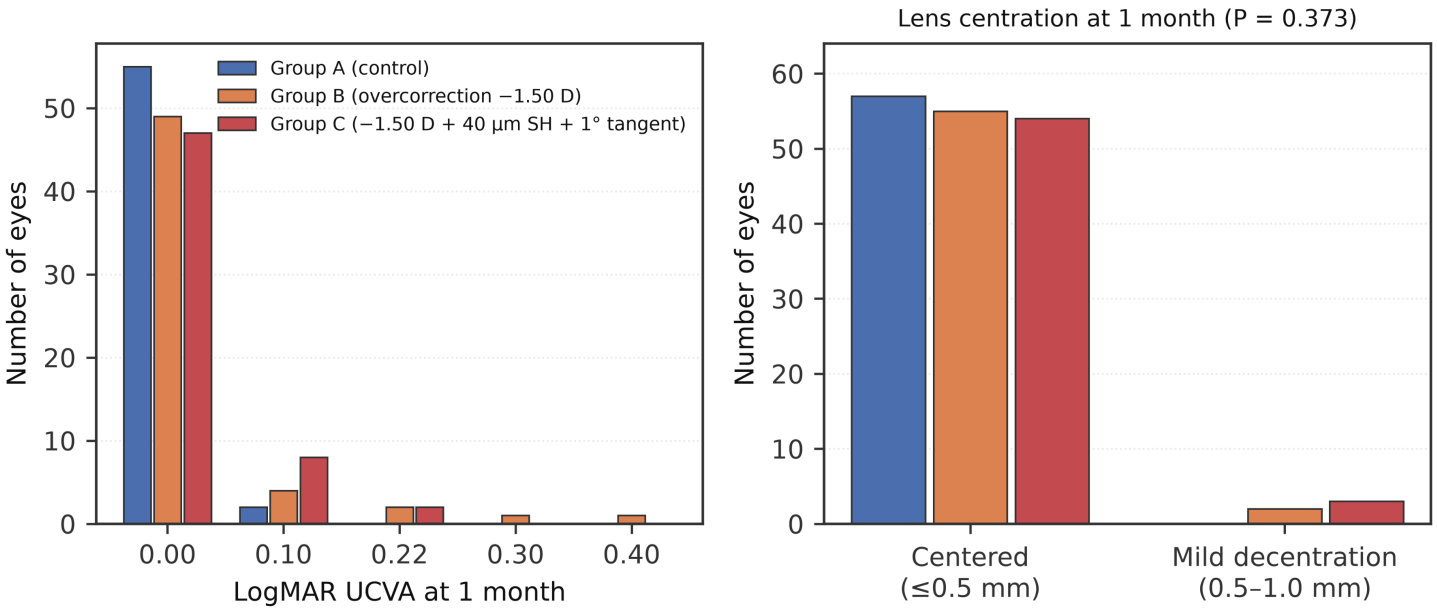


Figure 2

Uncorrected LogMAR visual acuity and lens centration outcomes at 1 month by group.

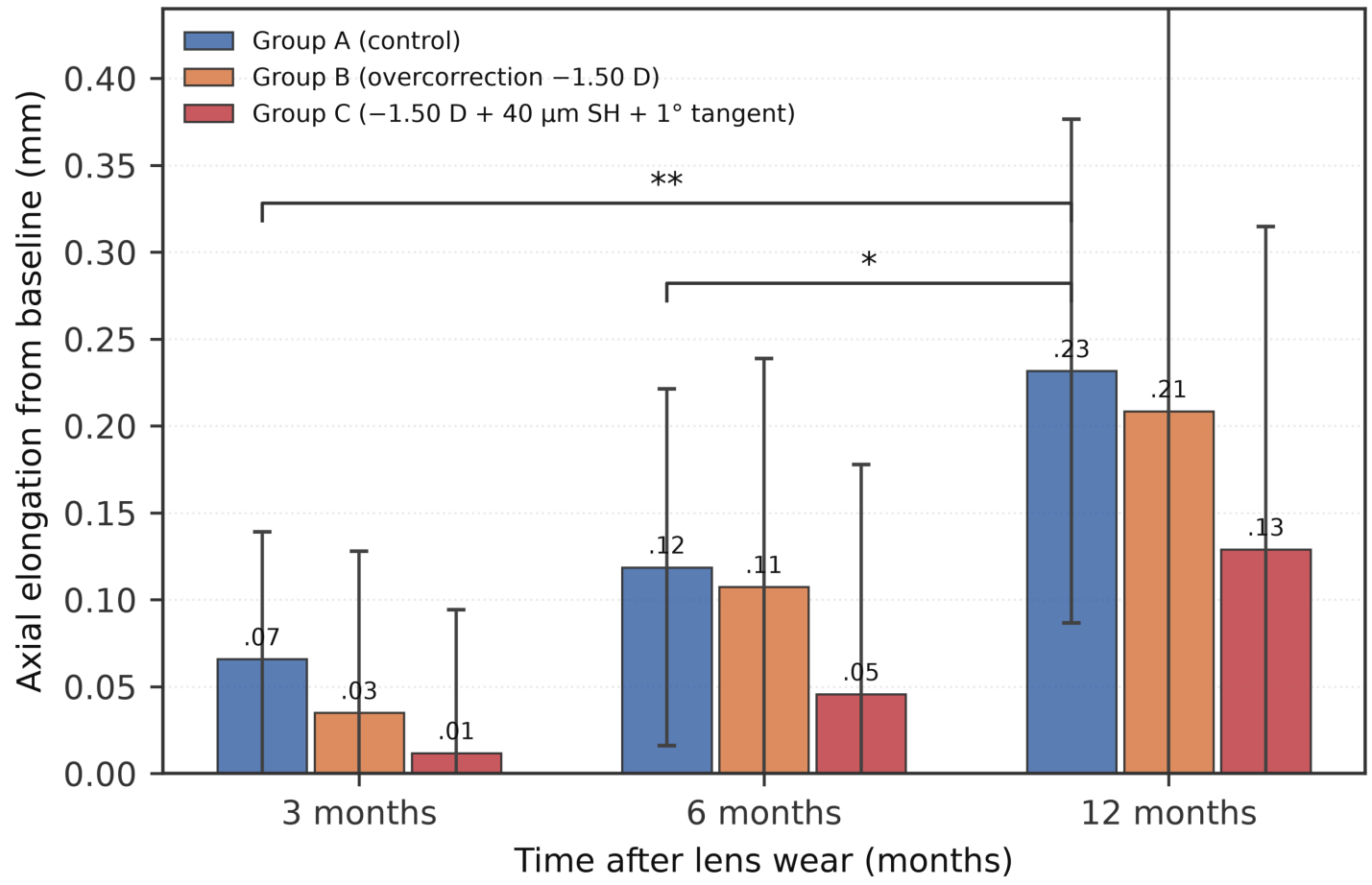


Figure 3

Cumulative axial elongation (mean ± SD) at 3, 6, and 12 months in Groups A, B, and C.

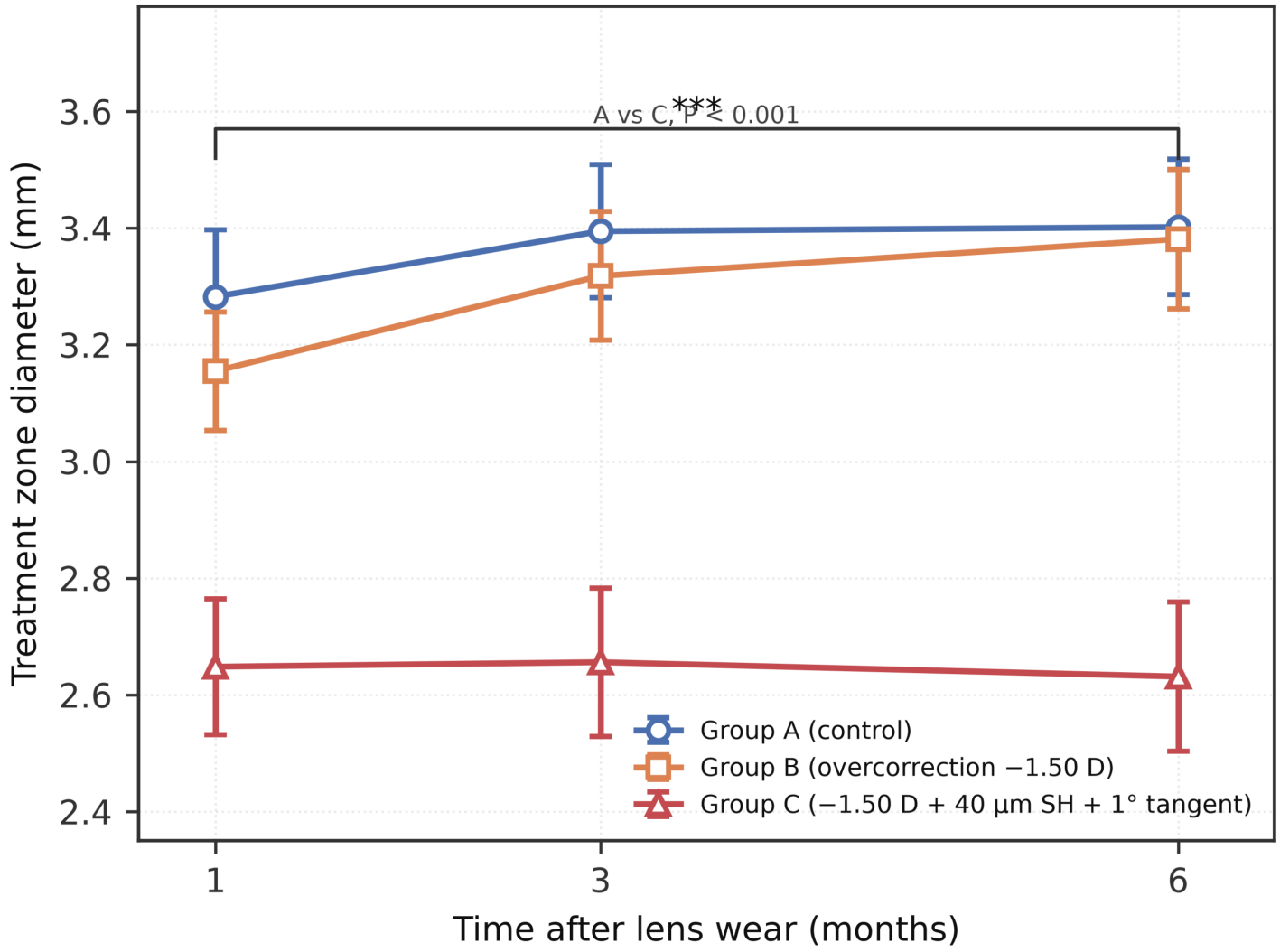


Figure 4

Treatment zone diameter over time (mean ± 95% CI) in the three groups. Group C maintained a significantly smaller and stable treatment zone throughout follow-up.

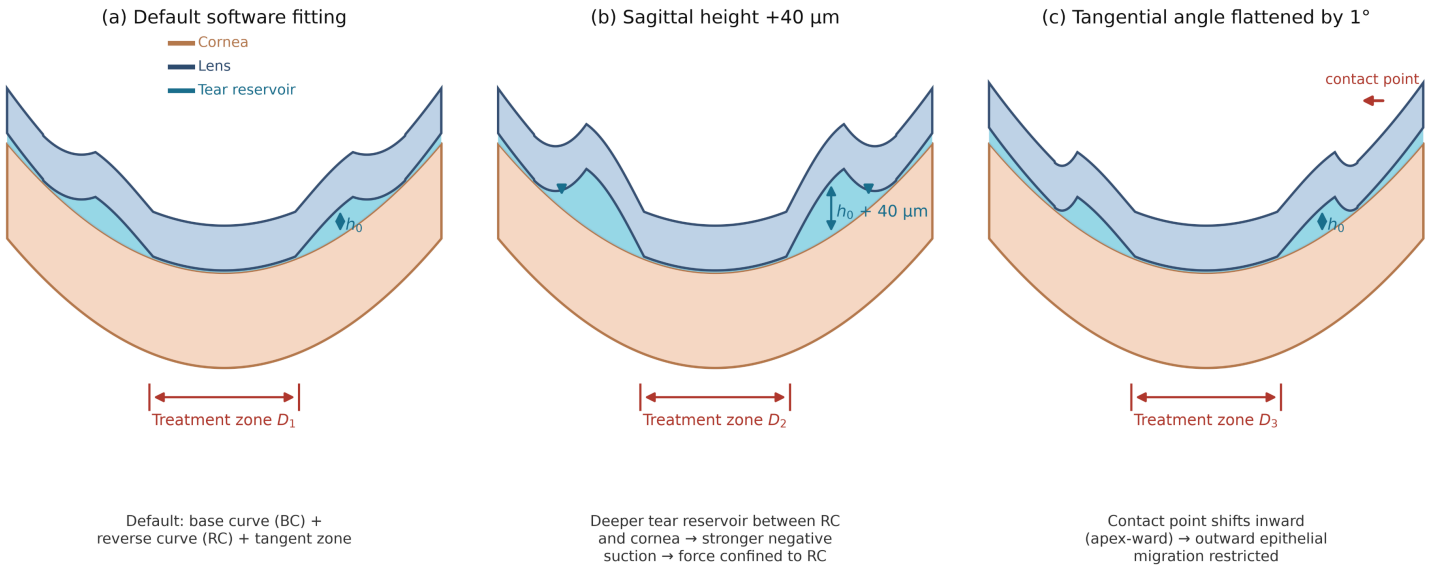


Figure 5

Schematic diagrams of the lens–cornea relationship in software-assisted ortho-k fitting. (a) Default fitting: the reverse-geometry lens rests on the cornea with a thin tear reservoir (h_0) and treatment zone D_1. (b) A 40-µm increase in sagittal height deepens the tear reservoir between the reverse curve and the cornea, generating stronger negative suction that confines the reshaping force to the reverse zone and narrows the treatment zone (D_2). (c) Flattening the tangential angle by 1° shifts the lens–cornea contact point inward toward the corneal apex, restricting outward epithelial migration and further stabilizing the treatment zone (D_3).