Influence of orthokeratology lens treatment zone decentration on myopia progression: a systematic review with meta-analysis

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Background: Referring to the myopia control efficacy, the difference between the orthokeratology with decentration (OKD group) and orthokeratology with center-position (OKC group) as control group is not clear currently. Therefore, the aim of this meta-analysis was to investigate the effect of decentration on myopia control efficacy based on existing studies.

Methods: We searched studies in PubMed, Embase and Wanfang up to January 2023 for relative containing the keywords "orthokeratology", "decentration" and their synonyms. Information including axial length measurements and decentration must be available and the included cases should not have obvious complications. The abstract, comment, review, meta-analysis, patent or case reports, studies with no sufficient data or including the combination of other control scheme were excluded. The risk of bias in the included studies was conducted by Newcastle-Ottawa Scale (NOS) and funnel plot. We pooled the mean differences (MDs) between the OKD group and the OKC group for axial elongation.

Results: Six retrospective case control studies and one retrospective self-control study with a total of 624 eyes for OKD group and 343 eyes for OKC group were included for analysis. Although all the included studies indicated that the axial elongation in the severe decentration group (1.0 mm < decentration ≤1.5 mm) was less than that in the moderate group (0.5 mm < decentration ≤1.0 mm), we still uniformly selected the moderate decentration group as the OKD group to improve the persuasiveness of the results. According to the heterogeneity results (I^2=16%, P=0.31), fixed effect model was chosen to get the merged results. One years' MD in axial elongation were −0.06 mm [95% confidence interval (CI): −0.09 to −0.04, P<0.01], indicating that orthokeratology with decentration shows more efficacy in myopia control than orthokeratology with center-position.

Conclusions: Without decreased visual acuity {worse than 0.1 [logarithm of the minimum angle of resolution (logMar)]}, persistent corneal epithelial defects, glare or diplopia, orthokeratology with decentration (≤1.5 mm) showed more efficacy in myopia control than orthokeratology with center-position in children within 1 year.

Keywords: Myopia; orthokeratology; decentration; meta-analysis

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Introduction

The incidence of myopia in children has been increasing recently worldwide. Epidemiological researches showed that the incidence of myopia in students was as high as 80% to 90% in East Asia (1). There is also an increasing prevalence of myopia in children with early on-set and high myopia over recent decades (2-5). If myopia is not well controlled, progression to high myopia is more likely to lead to pathological ocular changes. The complications of high myopia (retinal detachment, peripheral retinal degeneration, choroidal thinning, glaucoma, cataract, etc.) will potentially affect patients' quality of life (6-9).

Myopia can be understood as the size of the eyeball [axial length (AL)] exceeds its required size. Retinopathy caused by high myopia induced by axial elongation has been ranked as the second most frequent cause of low-vision and blindness among adults in China (10-12). Thus, strategies for controlling myopia progression in children, especially slowing axial elongation should be important and noteworthy. Different methods were used to slow down the progression of myopia in children, including orthokeratology (OK), atropine, defocus soft contact lenses and ophthalmic glasses, rigid contact lenses, and outdoor light exposure (13-16). According to systematic review, published controlled studies showed that OK lens wearing was revealed a weighted average of −45.1% change in AL at 2-year follow-up (17).

In OK lens fitting, clinicians have been long taught to have the lens perfectly centered on the corneal geometric center. But in fact, even if after successful lens fitting, different degrees of decentration often occurs. Previous studies used to pay more attention to the myopia control efficacy of OK lenses, and it was started to be reported only in recent years whether the decentration would affect the efficacy.

In this meta-analysis, we aimed to evaluate the efficacy of slowing AL elongation in group of orthokeratology with decentration (OKD group) compared with control [orthokeratology with center-position (OKC group)], based on randomized controlled trials (RCTs), prospective observational and retrospective case control studies. We present this article in accordance with the PRISMA reporting checklist (available at https://pm.amegroups.com/article/view/10.21037/pm-23-20/rc).

Highlight box

Key findings

- Without relevant adverse consequences, orthokeratology with decentration (≤1.5 mm) showed more efficacy in myopia control than orthokeratology with center-position in children within one year [MD in axial elongation were −0.06 mm (95% CI: −0.09 to −0.04, P<0.01)].

What is known and what is new?

- In orthokeratology lens fitting, clinicians have been long taught to have the lens perfectly centered on the corneal. But in fact, different degrees of decentration often occurs.
- In this meta-analysis, we evaluated the efficacy of slowing axial length elongation in group of orthokeratology with decentration compared with control (orthokeratology with center-position).

What is the implication, and what should change now?

- Decentration (≤1.5 mm) without relevant adverse consequences does not require clinicians to worry about the myopia control efficacy, and the continued wearing of OK lenses should be encouraged. But the authors still insist that decentration should not be intentionally created.

Methods

This meta-analysis has been registered on the PROSPERO platform with the ID: CRD42023400966. The protocol can be accessed by the link: https://www.crd.york.ac.uk/PROSPERO/.

Literature research and screening

"Orthokeratology" and "decentration", including their synonyms were used as keywords, and databases including PubMed, Embase and Wanfang (Chinese database) were searched to retrieve the related articles up to January 2023. Manual search was also conducted as a complementary method by reviewing the reference lists and prospective citation search for all retrieved studies. Titles, abstracts and full texts of included articles were then screened according to inclusion and exclusion criteria. All the literature research and screening were performed by two independent researchers. Any disagreement was resolved by discussion with a third researcher.

All related articles were included if they met the following criteria: (I) study samples were patients with acquired myopia without organic disease; (II) studies which focused on the effect on AL by OK lens treatment; (III) information including AL measurements and decentration was available; (IV) the same method was used for AL measurement between two groups; (V) English written articles or Chinese written articles. Studies were excluded if they were: (I) articles with duplicate data; (II) abstract, comment, review, meta- analysis, patent or case reports; (III) study samples with other eye diseases, like amblyopia, cataracts and glaucoma; (IV) studies with no sufficient data; (V) including the combination of other control scheme such as atropine; (VI) including the case of adverse consequences caused by OK {decreased visual acuity; worse than 0.1 [logarithm of the minimum angle of resolution (logMar)], persistent corneal epithelial defects, glare or diplopia}.

Research quality assessments and data extraction

The methodological quality assessment of the included studies was performed by two independent researchers according to the guidelines of the Newcastle-Ottawa Scale (NOS) (for case control studies). This scale uses a star system (with a maximum of ten stars), which is composed of three domains (18): selection of participants (including four items), comparability of study groups (including two items), and the ascertainment of exposure or outcome (including three items, and 'Ascertainment of exposure' contains two stars), which are used to judge the applicability and risk of bias. Each question was answered with quantitative options, asterisked answer represents the low risk of bias and is assigned a score of 1, while answer without asterisk represents a high risk of bias and is assigned a score of 0. Thus, the quality score of study ranged from 0 to 10 stars. Higher scores were indicative of lower risk of bias (19). Studies scoring 7 or more stars were considered to have a low risk of bias, and studies scoring less than 7 stars indicated a high or moderate risk.

Two reviewers independently and jointly extracted information including author, publication year, country or area, sample size, follow-up duration, information on methodology, baseline equivalent spherical error, baseline comparability, the measurement of AL, the definition and measurement of decentration, mean degree of decentration in the test group, mean change in axial elongation. Any discrepancies were resolved by discussion with a third researcher.

Statistical analysis

We performed statistical analyses using Review Manager (version 5.4). The mean difference (MD) and 95% confidence intervals (CIs) were calculated to investigate the differences in axial elongation between OKD and OKC groups. Heterogeneity among studies was tested through Q and I^2 statistics, in which we considered $I^2>50\%$ indicating significant heterogeneity. If $I^2>50\%$, our meta-analysis would use a random-effects model, and a fixed-effects model would be used if $I^2\leq50\%$. Publication bias was assessed using the Funnel plots test. Sensitivity analysis was detected by sequentially eliminating every study. Estimated MD and 95% CI were calculated for the remaining studies to measure the effect of individual studies on pooled MD. The flow diagram, forest plot and funnel plot were drawn by Review Manager (version 5.4). In sensitivity analysis, estimated forest plot of MD after cutting out every study was drawn by StataMP 17.0 (StataCorp LLC, Texas, USA). All the tables were made by Microsoft Word (© 2017 Microsoft, Washington, USA).

Results

Study selection and quality assessment

As shown in *Figure 1*, a total of 251 studies were found in initial search. After excluding 53 duplicate reports, 198 unrelated studies were screened by reading titles and abstracts. Three articles with only abstract or conference articles, 25 studies that belongs to meta-analysis, review, case report or patent, 67 studies unrelated to the decentration of OK, 81 studies lack of attention to axial elongation, 13 studies lacking control group (orthokeratology with center-position) and 2 studies combined with atropine were excluded. Afterwards, the remaining 7 articles included in this meta-analysis were full text screened, of which 6 were retrospective case control study (20-25) and 1 was retrospective self-control study (26). A total of 624 eyes for OKD group and 343 eyes for OKC group were included for analysis. All the 7 studies were based on China, including 5 articles in English and 2 in Chinese. Four studies followed up for 12 months and the remaining three for 24 months. The articles included were published between 2018 and 2022. The basic characteristics of included studies are listed in *Table 1*.

After checking the three domains, 6 studies got seven or greater scores and one study got six because of the lack of clear statement about baseline comparability between the two groups. The details of quality assessment can be seen in *Table 2*.

Axial elongation

Because three studies were followed up for 2 years in this Meta-analysis, we halved the axial changes in their studies to simulate the average changes in 1 year, and to

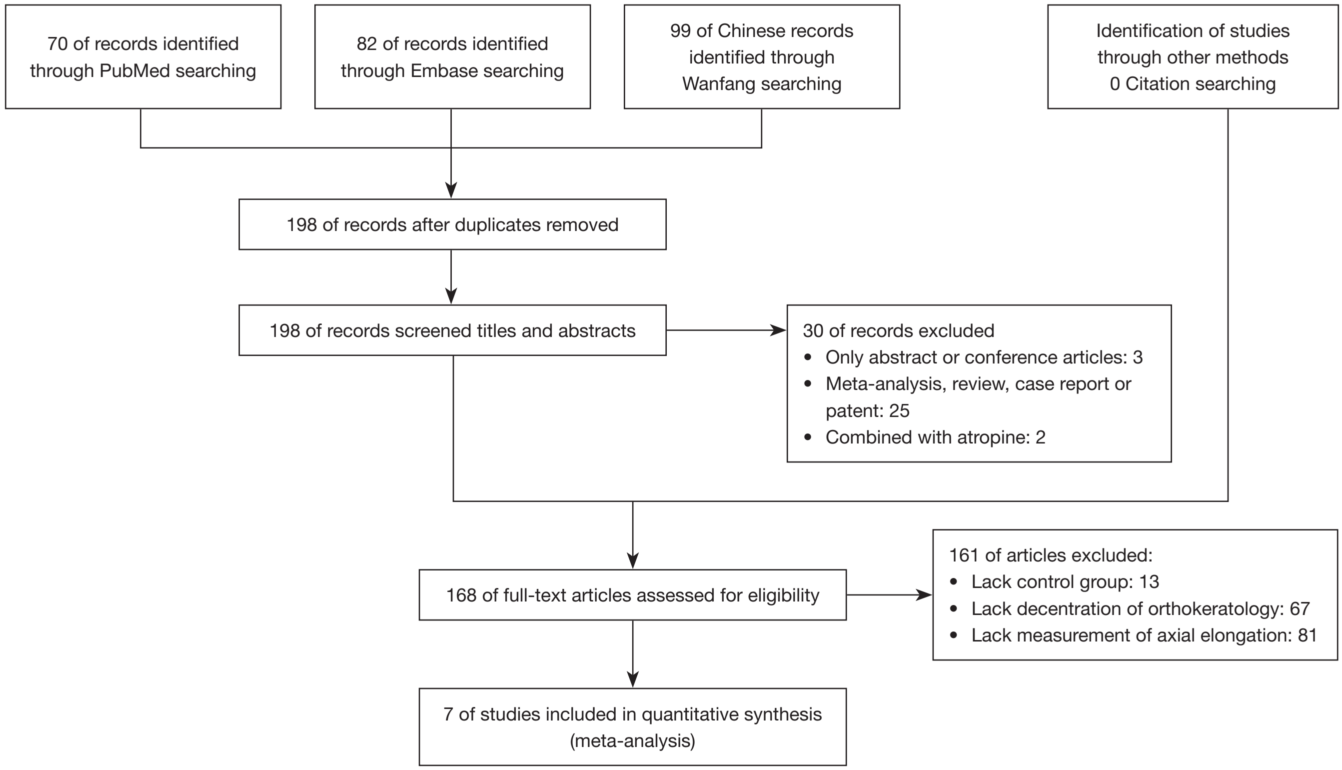

Figure 1 A flow diagram of the included studies eligible for this meta-analysis.

make the efficacy of axial elongation consistent. Most of the seven studies included three groups: the control group (decentration ≤0.5 mm), the moderate decentration group (0.5 mm < decentration ≤1.0 mm) and the severe decentration group (1.0 mm < decentration ≤1.5 mm). Although all the include studies indicated that the axial elongation in the severe group was less than that in the moderate group, we still uniformly selected the moderate decentration group as the OKD group to improve the persuasiveness of the results. According to the heterogeneity results (I^2=16%, P=0.31), fixed effect model was chosen to get the merged results. As shown in *Figure 2*, the MD (95% CI) of change in AL between OKD group and OKC group was −0.06 mm (95% CI: −0.09 to −0.04; P<0.01) in 1 year, indicating that orthokeratology with decentration shows more efficacy in myopia control than orthokeratology with center-position.

Publication bias

According to the symmetrical plots in funnel plot (*Figure 3*), no publication bias was found in this meta-analysis.

Sensitivity analysis

A sensitivity analysis was performed to detect the stability and reliability of our meta-analysis. As shown in *Figure 4*, cutting out of every study did not significantly affect the pooled MD and the result was robust.

Discussion

The decentration of orthokeratology

In orthokeratology lens fitting, clinicians should basically try to locate the OK lens centered on the corneal center. However, in fact, the situation of decentration still happens frequently. As for the definition of decentration, most studies in this meta-analysis chose the distance between the center of treatment zone and the pupil center. At present, there is no unified plan on how to measure the decentration, because there is no intelligent program completely separated from manual operation. However, as long as the measurement methods between the two groups are consistent, the comparison results can be considered accurate.

According to existing research, about 10–30% of the

Table 1 The basic characteristics of included seven studies

Study	Country or area	Study design	Follow-up (months)	Age (years)	Baseline SE(D) (OKD group)	Definition of decentration* and the methods of decentration measurement	Baseline comparability (mainly difference of lenses, baseline age and AL, etc.)	AL measurement	Design and material of OK lenses	Degree of decentration in OKD group (mm), mean ± SD
Gangyue Wu 2018, (20)	China	Retrospective case control	24	8–15	Unclear	A >0.5 mm; control ≤0.5 mm; method: unclear	Unclear	Lenstar	Brand: unclear; four-zoned reverse-geometry design (diameter: 10.0–11.2 mm); material: Boston XO	0.75±0.15
Guo Li 2021, (21)	China	Retrospective case control	12	7–17	−3.06±1.47	B >0.5 mm; control ≤0.5 mm; method: displayed by corneal topography (TMS-4, Tomey, Nagoya, Japan)	All P>0.05	IOL-Master	Brand: Hengtai; four-zoned reverse-geometry design (diameter: 10.2–11.0 mm); material: Boston Equalens II	0.68±0.44
Lu Sun 2022, (22)	China	Retrospective case control	12	9–19	−3.10±1.20	A >0.5 mm; control ≤0.5 mm; method: inhouse developed computer program (Python)	All P>0.05	IOL-Master	Unclear	0.71±0.13
Minfeng Chen 2022, (23)	China	Retrospective case control	24	8–14	−3.64±1.14	A >0.5 mm; control ≤0.5 mm; method: Image software (National Institutes of Health, Bethesda, MD, USA)	All P>0.05	IOL-Master	Brand: Euclid; four-zoned reverse-geometry design (diameter: 10.2–11.2 mm); material: Boston Equalens II	0.84±0.25
Shuxian Zhang 2022, (24)	China	Retrospective case control	12	8–15	−3.18±1.18	A >0.5 mm; control ≤0.5 mm; method: displayed by corneal topography (TMS-4, Tomey, Nagoya, Japan)	Only astigmatism, and cornea keratometry P<0.05	IOL-Master	Brand: Euclid; four-zoned reverse-geometry design (diameter: 10.0–11.2 mm); material: Boston Equalens II	0.76±0.13
Ziyang Chen 2020, (25)	China	Retrospective case control	24	6–18	−3.32±1.29	C >0.5 mm; control ≤0.5 mm; method: displayed by corneal topography (the corneal front surface section) (Italy, CSO Sirius)	All P>0.05	IOL-Master	Brand: Euclid; four-zoned reverse-geometry design (diameter: 10.2–11.2 mm); material: Boston Equalens II	Unclear
Anken Wang 2019, (26)	China	Retrospective self-control	12	8–13	−2.58±1.15	A >0.5 mm; control ≤0.5 mm; method: software (Photoshop 6.0, Adobe Systems, USA)	All P>0.05	IOL-Master	Brand: Lucid or Alpha; four-zoned reverse-geometry design (diameter: 10.0–11.0 mm); material: Boston EN or Boston XO	0.73±0.25

*, A: distance between the center of treatment zone and the pupil center; B: distance between the center of defocus ring and the pupil center; C: distance between the center of treatment zone and the corneal center. SE(D), equivalent spherical error (diopter); AL, axial length; OK, orthokeratology; OKD, orthokeratology with decentration; SD, standard deviation.

Table 2 Quality assessment for case control studies included in the meta-analysis using Newcastle-Ottawa Quality Assessment Scale

Study	Selection				Comparability	Exposure			Score
	Is the case definition adequate	Represent-activeness of the cases	Selection of controls	Definition of controls		Ascertainment of exposure	Same method of ascertainment for cases and controls	Non-response rate	
Anken Wang 2019	*	*		*	**	*	*	*	8
Gangyue Wu 2018	*	*		*		*	*	*	6
Guo Li 2021	*	*		*	**	*	*	*	8
Lu Sun 2022	*	*		*	**	*	*	*	8
Minfeng Chen 2022	*	*		*	**	*	*	*	8
Shuxian Zhang 2022	*	*		*	*	*	*	*	7
Ziyang Chen 2020	*	*		*	**	*	*	*	8

*, low risk of bias and is assigned a score of 1, while answer without * represents a high risk of bias and is assigned a score of 0. **, the comparability including two items (main factors like age and minor confounding factors), so it may contain two asterisks.

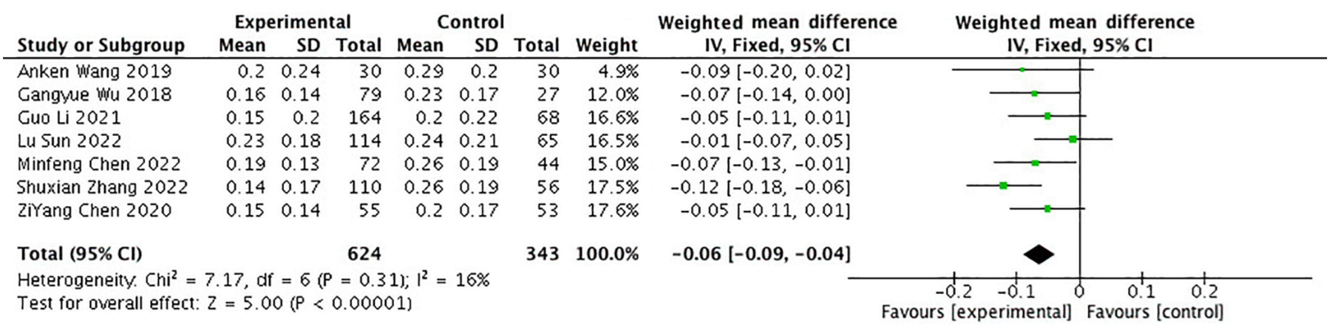

Figure 2 Forest plot of weighted mean difference between OKD group and OKC group in annual axial elongation according to included 7 studies. SD, standard deviation; IV, inverse variance; CI, confidence interval; OKD, orthokeratology with decentration; OKC, orthokeratology with center-position.

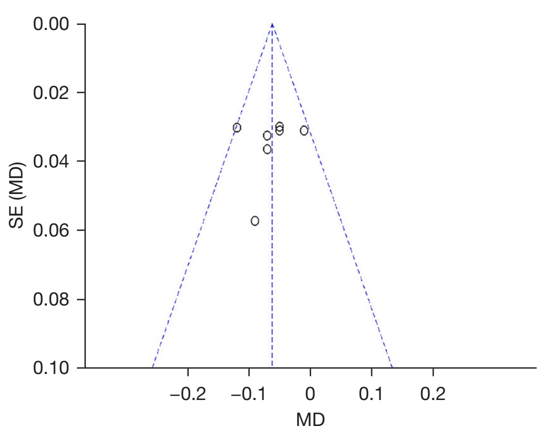

Figure 3 The funnel plot about included seven studies. SE, standard error; MD, mean difference.

OK lens wearers were observed decentration (27-29). There are also studies on the causes of decentration, such as paracentral corneal asymmetry (30), nasal-temporal and superior-inferior quadrants asphericity (Q-value) (31), surface asymmetry index of cornea (32) and amounts of corneal toricity (33,34), and in our opinion these can be classified as different criteria for evaluating corneal asymmetry. Another reason familiar to clinicians is the lateral force to the cornea generated by the eyelids, which is very difficult to quantify, so there is no report at present.

At present, there is no unified measurement method for decentration, and it is mainly through the corneal topography at present. Finding the distance from the center of pupil to the center of the treatment zone through the

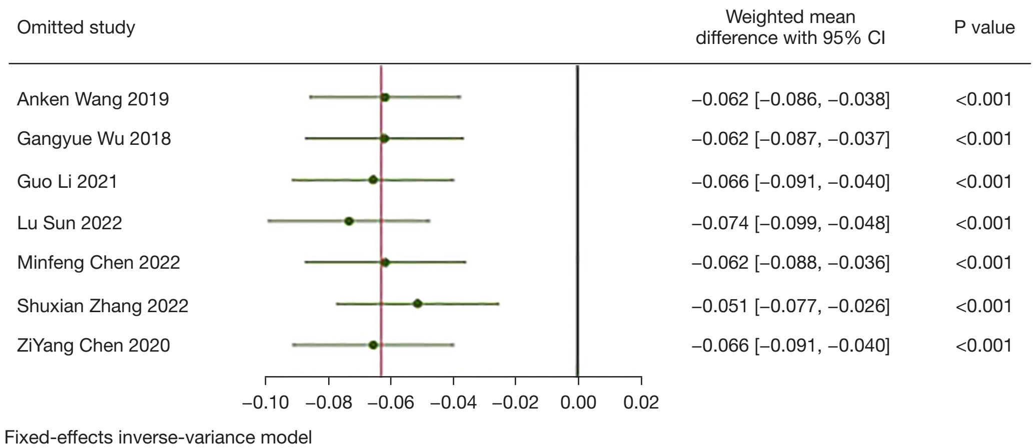

Figure 4 Estimated forest plot of weighted mean difference between OKD group and OKC group in annual axial elongation after cutting out every study. CI, confidence interval; OKD, orthokeratology with decentration; OKC, orthokeratology with center-position.

tangential map is selected by more scholars (20,22-24,26). It is expected that more accurate and unified automated decentration measurement software will emerge or that decentration can be measured directly and precisely by fluorescein pattern assessment in the future. Even if the measurement methods between each experimental group and the control group were the same for all the studies involved, it would still have an impact on the results of this meta-analysis.

The AL elongation

This is the first meta-analysis of the efficacy of decentration in slowing axial elongation of myopia children wearing OK lens. A total of 967 children (624 in OKD *vs.* 343 in OKC) from 6 retrospective case control studies and 1 retrospective self-control study were included for analysis. Our meta-analysis proved that OKD is more effective in slowing axial elongation than OKC in 1 year with a statistically significant difference: −0.06 mm (95% CI: −0.09 to −0.04; $P<0.01$) ($I^2=16\%$, $P=0.31$). Because we uniformly selected the moderate decentration group as the OKD group, our results are relatively convincing. But to be honest, such a gap may not be so obvious when turned into myopia diopter, generally speaking, it means that progression of myopia may be suppressed nearly by 0.5 diopter in 3 years.

The exact mechanism underlying the myopia control effect of orthokeratology is not fully understood and the main current hypothesis are the peripheral defocus provoked by mild-peripheral steepening in cornea and the higher-order aberrations that cannot be corrected with a conventional sphero-cylinder lens after orthokeratology (35,36). Additionally, the reason for the slower axial elongation caused by decentration is still under exploring and the existing relevant researches are as follows: a larger treatment zone decentration was associated with a larger summed relative corneal refractive power in the central cornea (27), which can be divided into 3 Fourier components more specifically: a mean (F0), a single-cycle sinewave (F1) and a double-cycle sinewave (F2) and F1 was correlated with decentration significantly (37). The decentration was also associated with a more oblate retinal shape (38).

Adverse consequences of decentration

Obvious decentration of orthokeratology may cause glare, double vision and other discomfort because of the reduced visual quality, such as induced additional corneal high order Zernike coefficients, increased ocular higher-order aberrations, and lower contrast sensitivity (29,39-41).

This meta-analysis did not contain the adverse consequences of decentration, because all the included studies have excluded the cases with adverse consequences. So strictly speaking, the results of this meta-analysis was based on the absence of adverse consequences {decreased visual acuity [worse than 0.1 (logMar)], persistent corneal epithelial defects, glare or diplopia}.

Attitude to the decentration

Because of the unpredictability of the decentration itself, and the unpredictability of the resulting complications, the authors still insist that decentration should not be intentionally created. The conclusions of this study suggest that a decentration of less than or equal to 1.5 mm without relevant adverse consequences does not require clinicians to worry about the myopia control efficacy, and the continued wearing of OK lenses should be encouraged. As for the better myopia control efficacy caused by decentration, it can be applied to the modified lens design by further studies clarifying the mechanism of this phenomenon.

Limitations

As the first meta-analysis on decentration of orthokeratology, the quantity and quality of the literature we included still need to be strengthened, although we conducted a relatively extensive search of the databases. None of the studies we included have been followed up for more than 2 years, and all of them were from China, so this analysis has certain limitations in terms of time and region. In general, smaller increases in AL are associated with older age according to previous studies (42,43). So, the large age ranges of the subjects included in this study may affect the reported degree of axial elongation and the results of this study. Based on current research, different lens designs may have an impact on the efficacy of myopia control (44,45), and the different lens designs involved in this study may reduce the validity of the results. All of the study included were retrospective, and may bring bias in the selection of cases by the authors. But frankly, there is great uncertainty in the occurrence of decentration, and it is difficult to truly achieve double blind or triple blind, so the implementation of RCT research in this regard is extremely difficult.

Conclusions

In summary, without decreased visual acuity [worse than 0.1 (logMar)], persistent corneal epithelial defects, glare or diplopia, orthokeratology with decentration (≤1.5 mm) showed more efficacy in myopia control than orthokeratology with center-position in children after 1 year. According to this result, a decentration of less than or equal to 1.5 mm without relevant complications does not require clinicians to worry about the myopia control efficacy, and the continued wearing of OK lenses should be encouraged. More studies with long-term follow-up data are expected to draw a more precise conclusion.

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Footnote

Reporting Checklist: The authors have completed the PRISMA reporting checklist. Available at https://pm.amegroups.com/article/view/10.21037/pm-23-20/rc

Peer Review File: Available at https://pm.amegroups.com/article/view/10.21037/pm-23-20/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://pm.amegroups.com/article/view/10.21037/pm-23-20/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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