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Orthokeratology in controlling myopia of children: a meta-analysis of randomized controlled trials

Xue Li[1†], Meiling Xu[1†], Shanshan San[1†], Lanzheng Bian[1*] and Hui Li[1*]

Abstract

Background Delaying the development and lowering the progression of myopia in children is the focus of current ophthalmology researches. We aimed to evaluate the role of orthokeratology in controlling myopia of children, to provide insights to the clinical treatment and care of children with myopia.

Methods Two investigators searched the The Cochrane Library, Embase, Pubmed, China national knowledge infrastructure, China biomedical literature database, WanFang and Weipu databases for randomized controlled trials(RCTs) on the role of orthokeratology in controlling myopia of children up to November 5, 2022. Two researchers independently searched, screened and extracted the studies according to the inclusion and exclusion standards. RevMan5.3 software was used for statistical analysis.

Results A total of 14 RCTs involving 2058 children were included in this meta-analysis. Synthesized outcomes indicated that orthokeratology improved the uncorrected visual acuity(MD = 0.40, 95%CI: 0.05 ~ 0.74), reduced the diopter change(MD=-3.19, 95%CI: -4.42~-1.95), changes of corneal curvature(MD=-3.21, 95%CI: -3.64~-2.79), the length of ocular axis (MD=-0.66, 95%CI: -1.27~-0.06) and amount of ocular axis change(MD=-0.42, 95%CI: -0.64~-0.21) after 1 year of wearing orthokeratology(all $P < 0.05$). Besides, orthokeratology reduced the diopter change (MD=-3.22, 95%CI: -4.86~-1.58), the length of ocular axis (MD=-1.15, 95%CI: -2.25~-0.06) and the amount of ocular axis change after 2 year of wearing orthokeratology (MD=-0.53, 95%CI: -0.96~-0.11) after 2 year of wearing orthokeratology (all $P < 0.05$). No publication biases were found amongst the synthesized outcomes (all $P > 0.05$).

Conclusions Orthokeratology delays the progression of myopia in children, the long-term effects of orthokeratology need further investigations in future studies.

Keywords Orthokeratology, Myopia, Children, Care

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Background

Myopia is the refractive state in which the light of distant objects is focused in front of the retina when the eye is relaxed. It has become a global public health problem [1]. Myopia is affected by many factors, such as heredity and environment [2]. At present, it can only be controlled clinically. The commonly used methods to correct and prevent myopia include outdoor activities, drugs, wearing frame glasses, hard contact lenses and surgical treatment. In recent years, the control effect of orthokeratology on the development of myopia has been widely recognized. With the increasing number of users, the unique design of orthokeratology lenses and the way of night wear have gradually exposed clinical problems [3–5]. Due to the differences in research quality, there is still a lack of evaluation on myopia control effect of orthokeratology with different treatment duration.

It's been reported that myopia in children is related to severe myopia in adulthood [6, 7]. It is important to control the development of myopia in school age children to reduce the incidence rate of severe myopia in the future [8–10]. There are many studies on the effectiveness of orthokeratology in controlling myopia, but there are differences in follow-up time, research design, research object, etc. This study aimed at these differences, and planned to systematically evaluate the researches on orthokeratology in controlling the development of myopia in school-age children, so as to evaluate the effectiveness of using orthokeratology in the myopia of children, and provide reliable evidences for the clinical treatment and nursing care of myopia in children.

Methods

This meta-analysis and systematic review was conducted following the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement [11].

Literature search

The databases searched in this meta-analysis included: The Cochrane Library, Embase, Pubmed, China national knowledge infrastructure, China biomedical literature database, WanFang and Weipu databases. The retrieval time limit was from the establishment of the database to November 5, 2022. Both the subject words and free words were used for literature search, the retrieval strategy was adjusted according to the specific database. The search strategies were as follows: ("orthokeratology" OR "orthokerological procedure" OR "procedure" OR "orthokerological" OR "procedures" OR "orthokerological" OR "orthokerological lens" OR "ortho-K lens" OR "OK lens" OR "reverse geometry lens") AND ("Myopia" OR "nearsightedness" OR "Near sight" OR "short sight" OR "shortsightedness"). Besides, in order to include more related studies for this meta-analysis, the literatures of relevant reviews and references were searched manually.

Inclusion and exclusion criteria

The inclusion criteria of this meta-analysis were as follows: Children with myopia whose age was 6–18 years old and whose spherical lens was less than −6.00 D and cylindrical lens was less than −1.5D, the follow-up period should be at least one year; the children underwent orthokeratology or frame mirror treatment; related outcomes were reported including axial length, corneal curvature, naked eye vision and diopter et al. the study design should be randomized controlled trial (RCT).

The exclusion criteria of this meta-analysis were as follows: reports including reviews, letters, case reports and comments were excluded; repeated published literature; the full text of literature could not be obtained.

Literature screening and data extraction

Two researchers independently searched, screened, extracted and checked the documents according to the inclusion and exclusion standards. We removed the irrelevant documents by reading the title and abstract, and further read the full text of the retained documents to determine whether they were included. If there was any disagreement between the two researchers, a third researched was invited for discussion to obtain a consistent result.

The two authors extracted data from the original literature, including the author's name, publication time, age, follow-up time, number of eyes, outcome indicators and research conclusions. All differences and disputes are resolved through discussion for reaching consensus.

Quality assessment

The risk of bias of included RCTs as evaluated using the Cochrane risk of bias assessment instrument [12] by two authors. The bias has been evaluated across four domains: random sequence generation; allocation concealment; blind method; incomplete outcome data and selective reporting. Every domain could be rated as "unclear" OR "low" OR "high" risk of bias accordingly.

Statistical analysis

RevMan5.3 software was used for statistical analysis in this meta-analysis. Continuous results were analyzed by mean difference (MD), and binary variables were evaluated by relative risk (RR). P values and 95% confidence intervals (95% CI) were also obtained. The heterogeneity between studies was tested with I^2 statistic. When $I^2<50\%$ or $P>0.1$, the heterogeneity was considered acceptable, and the MD was combined according to the fixed effect model; On the contrary, if significant heterogeneity ($I^2>50\%$ or $P<0.1$) were considered, a random

effect model was used to combine the data. Besides, we examined the robustness of meta-analysis using sensitivity analysis. P<0.05 was considered that the differences were statistically significant in this study.

Results

RCT selection

The process of RCT selection is presented in Fig. 1. Initially, 194 reports were identified. After removing 12 duplicates, 182 studies remained. By reviewing the title and abstract, 137 unmatched reports were further excluded. Among the remaining 45 reports, 31 studies were removed after reading the full text. Finally, 14 RCTs [13–26] were included in this meta-analysis.

The characteristics of included RCTs

The 14 included RCTs were published between 2012 and 2020. A total of 2058 children were included in this meta-analysis, including 995 children in the orthokeratology group and 1063 children in the control group. All the included RCTs reported that there were no significant differences in the age, gender et al. characteristics. The characteristics of the included RCTs are presented in Table 1.

RCT quality

The quality of included RCTs are showed in Figs. 2 and 3. Some studies that did not explicitly report blinding methods for intervention, outcome measurement personnel, performance bias, and detection bias were rated as "unclear". Other evaluation items were rated as "low risk". Generally, the included RCTs had moderate risk of bias.

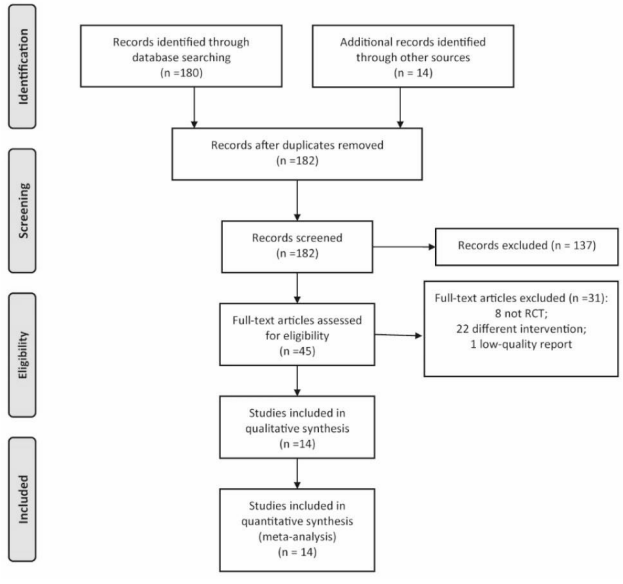


Fig. 1 The flow chart of RCT inclusion

Meta-analysis

The uncorrected visual acuity after 1 year of wearing orthokeratology Five RCTs reported the uncorrected visual acuity after 1 year of wearing orthokeratology, the result had significant heterogeneity (I^2=100%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the uncorrected visual acuity after 1 year of wearing orthokeratology was significantly higher than that of control group (MD=0.40, 95%CI: 0.05~0.74, P=0.02, Fig. 4a).

The diopter change after 1 year of wearing orthokeratology Seven RCTs reported the diopter change after 1 year of wearing orthokeratology, the result had significant heterogeneity (I^2=100%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the diopter change after 1 year of wearing orthokeratology was significantly less than that of control group (MD=-3.19, 95%CI: -4.42~-1.95, P<0.001, Fig. 4b).

The diopter change after 2 years of wearing orthokeratology Four RCTs reported the diopter change after 2 year of wearing orthokeratology, the result had significant heterogeneity (I^2=100%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the diopter change after 2 year of wearing orthokeratology was significantly less than that of control group (MD=-3.22, 95%CI: -4.86~-1.58, P<0.001, Fig. 4c).

The changes of corneal curvature after 1 year of wearing orthokeratology Four RCTs reported the changes of corneal curvature after 1 year of wearing orthokeratology, the result had significant heterogeneity (I^2=92%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the changes of corneal curvature after 1 year of wearing orthokeratology was significantly less than that of control group (MD=-3.21, 95%CI: -3.64~-2.79, P<0.001, Fig. 4d).

The length of ocular axis after 1 year of wearing orthokeratology Eight RCTs reported the length of ocular axis after 1 year of wearing orthokeratology, the result had significant heterogeneity (I^2=99%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the length of ocular axis after 1 year of wearing orthokeratology was significantly less than that of control group (MD=-0.66, 95%CI: -1.27~-0.06, P<0.001, Fig. 5a).

The length of ocular axis after 2 year of wearing orthokeratology Four RCTs reported the length of ocular axis after 2 year of wearing orthokeratology, the result had significant heterogeneity (I^2=100%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the length of ocular axis after 2 year of wearing orthokeratology was significantly

Table 1 The characteristics of included RCTs

RCT	Country	Sample size		Number of eyes		Age(years)	Criteria	Type of orthokeratology	Wearing method	Duration of follow-up(year)
		Orthokeratology group	Control group	Orthokeratology group	Control group					
Bian 2020	China	100	100	100	100	8 ~ 14	Diopter: -0.75~-5.00D; Cis return astigmatism < 1.50D	IV-DF Dream David	Night wear	1
Charm 2013	China	12	16	24	32	8 ~ 16	SEQ refraction at least − 5.75 diopters (D) and myopia − 5.00 D	NA	NA	1
Cho 2012	South Korea	37	41	74	82	6 ~ 10	Myopia degree: 0.50 ~ 4.00D; Astigmatism < 1.50D	NA	NA	2
Dong 2013	China	123	123	236	246	8 ~ 15	Sphere scope: -0.75~-6.00 DS; Range of column mirror − 0.50~-1.50DC	Dream David	Night wear	2
Jiang 2014	China	50	45	90	90	8 ~ 15	Spherical degree 0~-6.00 ODS; Cis return astigmatism 0~-1.50 DC	Hengtai	NA	3
Jiang 2018	China	43	40	86	80	8 ~ 14	SEQ lens diopter: -0.15 ~ − 5.00 D; Range of cis return astigmatism < 150 D	Hengtai	Night wear	2
Li 2016	China	48	48	96	96	8 ~ 18	Diopter: -0.15D~-6.00D; Conforming astigmatism < 1.50 D	NA	NA	1
Li 2020	China	75	75	150	150	12 ~ 18	Diopter: -2.00~-4.30 DS, − 0.50~-1.00 DC	Dream David	Night wear	1
Liu 2018	USA	60	60	60	60	7 ~ 12	Diopter: − 3.50~-6.00 D; Astigmatism<-1.50D	Jingshi Optics	Night wear	1
Lv 2019	China	60	62	60	62	6–15	Diopter: − 2.00~-5.0D; Astigmatism<-2.50D	Dream David	Night wear	1
Tang 2020	China	60	60	98	93	8 ~ 16	SEQ: − 1.50~- 6.00 D; Degree of column mirror < 1.0 0 D	NA	Night wear	1
Zhang 2017	China	80	80	160	160	12 ~ 18	Diopter: 1.00 ~ 5.00; Column mirror range ≤ -1.50 D	NA	Night wear	2
Zhou 2016	China	167	233	334	466	9 ~ 15	Astigmatism<-1.50 DC; SEQ: -2.75 ~ 5.60 DS	Euclid	NA	2
Zhu 2014	China	80	80	160	160	12 ~ 18	Diopter: -1.00~-4.00 DS, < 1.00 DC	NA	NA	1

SEQ, spherical equivalent; NA, not available

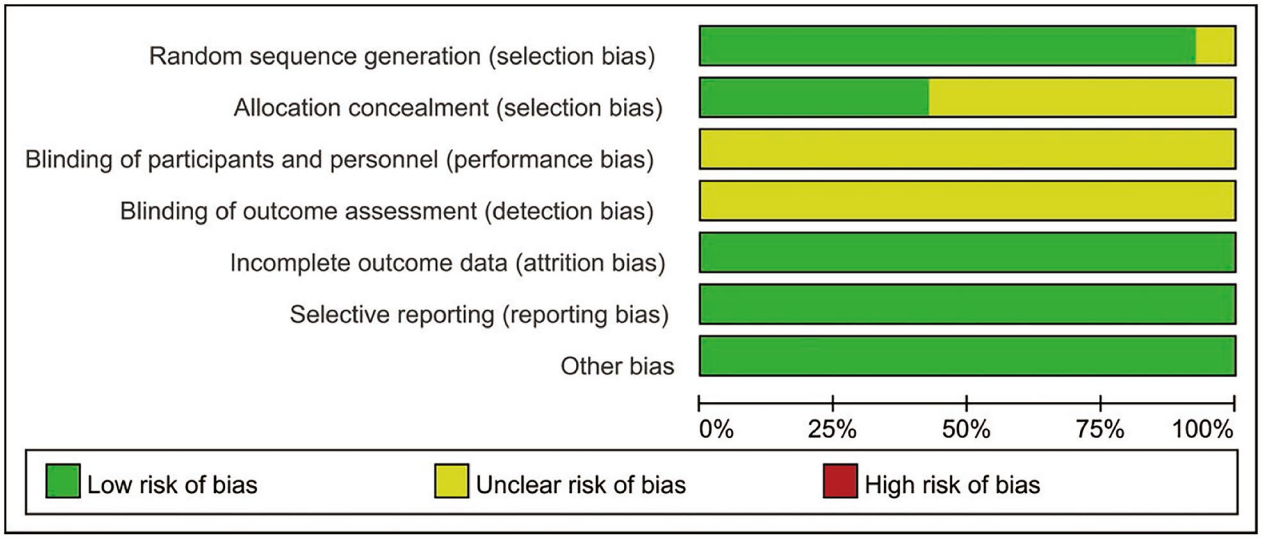


Fig. 2 Risk of bias graph

less than that of control group (MD=-1.15, 95%CI: -2.25~-0.06, P<0.001, Fig. 5b).

The amount of ocular axis change after 1 year of wearing orthokeratology Four RCTs reported the amount of ocular axis change after 1 year of wearing orthokeratology, the result had significant heterogeneity (I^2=99%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the amount of ocular axis change after 1 year of wearing orthokeratology was significantly less than that of control group (MD=-0.42, 95%CI: -0.64~-0.21, P<0.001, Fig. 5c).

the amount of ocular axis change after 2 year of wearing orthokeratology Three RCTs reported the the amount of ocular axis change after 2 year of wearing orthokeratology, the result had significant heterogeneity (I^2=99%, P<0.001), then random effect model was applied for data analysis. The synthesized result indicated that the amount of ocular axis change after 2 year of wearing orthokeratology was significantly less than that of control group (MD=-0.53, 95%CI: -0.96~-0.11, P<0.001, Fig. 5d).

Publication bias

The funnel plots are presented in Figs. 6 and 7. The dots were evenly distributed in the funnel plots, and the Egger test results indicated that there were no publication biases in the synthesized outcomes (all P>0.05).

We examined the robustness of meta-analysis using sensitivity analysis by excluding the RCTs one by one, the synthesized results did not statistically change, indicating that the synthesized outcomes were robust.

Discussions

Myopia is a global health and social problem. The occurrence and development of the disease mainly occurs in children and adolescents. Therefore, the control of myopia has focused on children and adolescents. Myopia, especially high myopia, usually leads to serious consequences, including glaucoma, macular degeneration, retinal detachment and cataract, which may lead to irreversible visual impairment in later life [27–29]. At the same time, high myopia is related to the reduction of vision related quality of life, and has a significant socio-economic impact [30, 31]. Compared with previous meta-analyses [32, 33], this study has included more sample size and analyzed outcomes. The results of this meta-analysis have showed that compared with the frame lens, the naked vision, corneal curvature, diopter, axial length and their changes of the patients with the corneal plastic lens are statistically different, and the myopia control effect are better than the frame lens. Orthokeratology is a beneficial to control the myopia progression of children, which is a good option for myopia control and care.

At present, the measures to control the progress of children's myopia include pharmacology, environment, surgery and optics [34–36]. The drug control of myopia mainly uses atropine. 0.01% atropine can reduce refractive error by about 45%. Compared with the control group, the axial control effect is not obvious, but the side effects and reactions after drug withdrawal are less, 1% atropine may reduce myopia progression by 60%~80% [37]. The extension of outdoor activities and the reduction of children's schoolwork burden are more effective in the primary prevention of myopia [38]. Wearing frame glasses is a common means to control myopia. However, because of the distance between the lens and the apex of

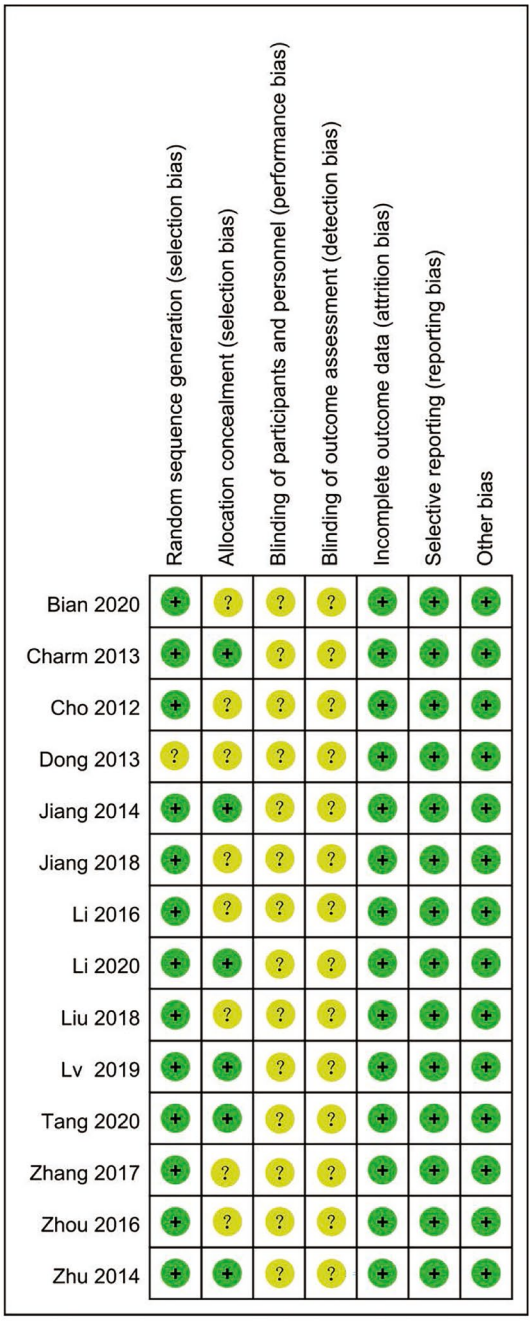


Fig. 3 Risk of bias summary

the cornea, the image magnification is bound to change. The lens itself also limits the field of vision, and this phenomenon is more obvious in myopic eyes with higher degrees [39]. Compared with frame glasses, Orthokeratology has unique advantages. The distance between the lens and the eye is reduced, it can minimize the magnification reduction of the retinal image caused by high refraction [38, 40]. However, it must be noted that there is a lack of corneal topography analysis after orthokeratology to define the optical effect of the molding on peripheral defocus from each study. Contrary to soft multifocal or glasses, the visual impact on peripheral defocus of orthokeratology can vary with the brand and the fitter philosophy.

Myopia is the result of genetic and environmental factors, and its pathogenesis and progression mechanism are still unclear. At present, the mainstream mechanisms include regulation mechanism, hyperopic defocusing mechanism, etc [41, 42]. The stimulating effect of peripheral hyperopia defocus on central axial myopia [43]. It has been reported that in the later stage, significant differences in axial length and peripheral retinal morphology are found between people with progressive myopia and those with stable myopia [44]. Previous research [45] shows that myopic defocusing can slow down the progress of myopia. The principle of orthokeratology to control myopia is based on defocusing theory. Compared with the traditional monocular frame glasses that may increase the peripheral hyperopia defocusing, orthokeratology changes the central shape of the cornea, promotes the migration of corneal epithelial cells, inhibits hyperopia defocusing, and provides myopia defocusing for the peripheral retina through the mechanical pressure of the flat base arc designed in inverse geometry and the negative pressure suction of the tear under the reverse arc [46, 47]. For astigmatic patients, the progression of myopia is not related to the initial astigmatism, but related to the way of myopia control [48]. Therefore, the rational use of orthokeratology can effectively control the development of myopia in children.

It's been reported that the intraocular pressure measured by non-contact intraocular pressure after orthokeratology is lower than the actual value, and is significantly related to the thinning of central corneal thickness after wearing glasses [49]. Previous study [50] has measured intraocular pressure with dynamic contour tonometer before and after wearing, there is no significant difference. They have believed that there is no effect on actual intraocular pressure after orthokeratology. Myopia is one of the risk factors of glaucoma. For patients who use non-contact tonometer to recheck intraocular pressure, they may miss the early stage of glaucoma, so they should be alert in clinical work [51]. Previous study [52] has found that Goldmann related intraocular pressure and corneal compensated intraocular pressure decreased one week after orthokeratology, and have become stable after reaching the minimum one week. The mechanism of this decrease in intraocular pressure may be that the base arc of the lens contacts the center of the friction cornea, and the compression force of the eyelids produces a continuous massage force on the eyeball, forcing the aqueous humor to drain faster, so that the intraocular pressure decreases [53]. Therefore, orthokeratology is a safe means to prevent and control myopia, but improving the visual

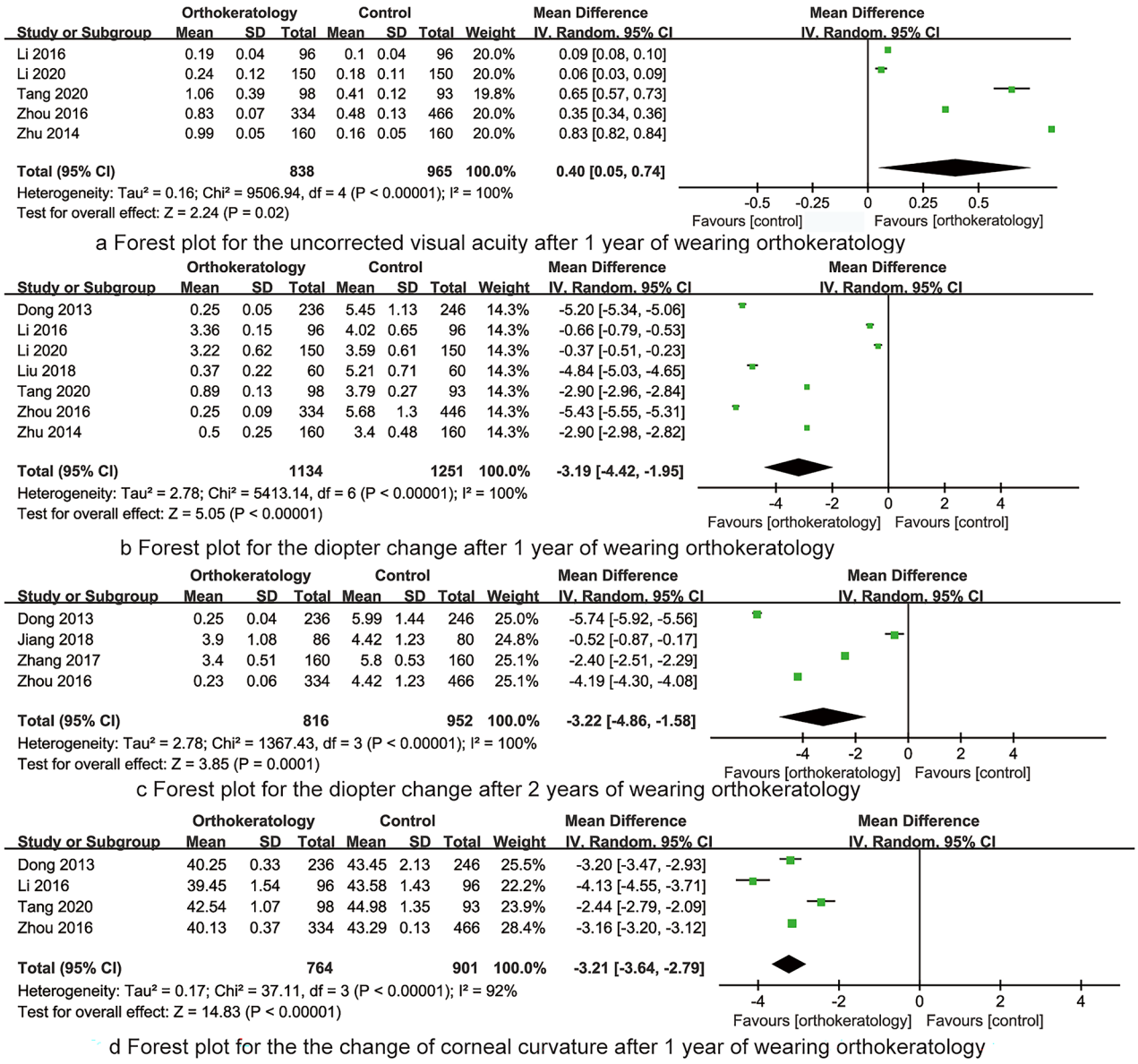


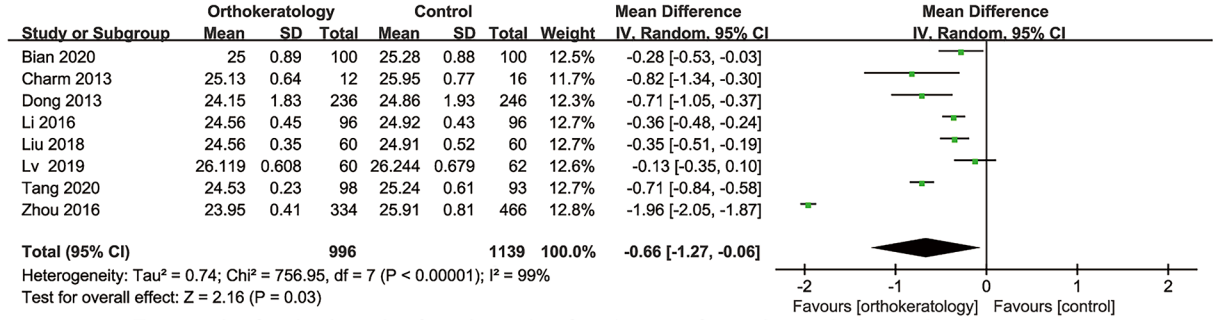
Fig. 4 The forest plots for synthesized outcomes

quality of the lens optical area, reducing corneal irritation, improving tear circulation and tear film stability are the improvement directions of orthokeratology [54–56]. For myopic patients, it is very necessary to follow up regularly and strengthen lens care.

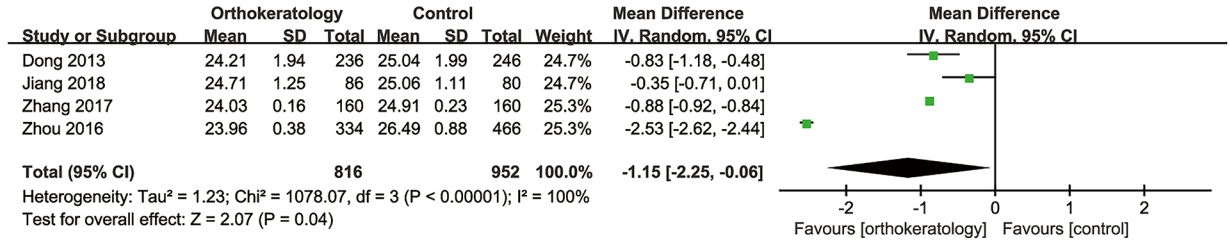
There are some limitations in this study that are worth considering. Firstly, fewer high-quality documents are included, and the possibility of bias and error is increased; Secondly, there is too large I^2 amongst the results, yet we can not perform the subgroup analysis limited by the reported data. Thirdly, we only include Chinese and English literature, which may have some language bias; Finally, the number of included RCTs and the sample size were limited, and extrapolation of the meta-analysis results was limited to some extent. Future studies with rigorous design from different areas are needed to evaluate the effects of orthokeratology in myopia control.

Conclusions

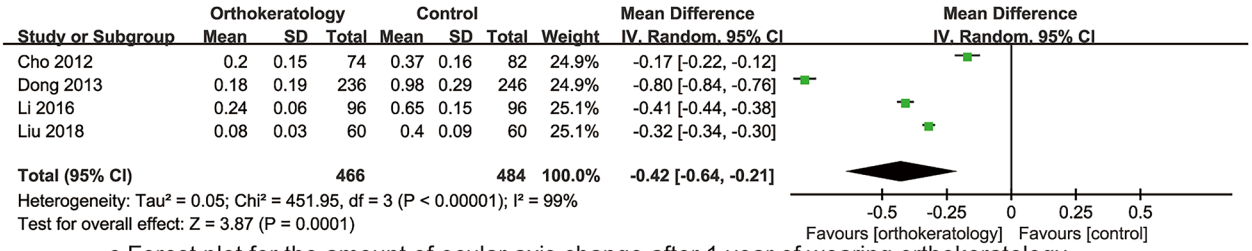
In conclusion, existing evidences have showed that orthokeratology has a positive effect on slowing down the development of myopia in children. Whether there are differences in the long-term efficacy and safety of OK for children of different ethnic groups, as well as the efficacy of different OK for patients with different myopia and different ages, still needs to be further verified by a large sample of high-quality RCTs.



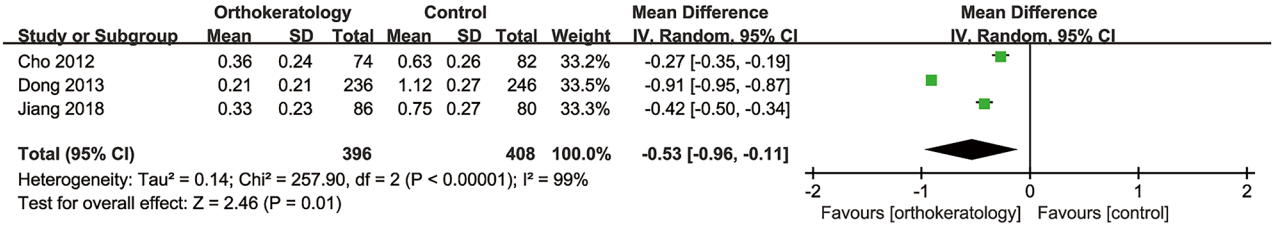
a Forest plot for the length of ocular axis after 1 year of wearing orthokeratology



b Forest plot for the length of ocular axis after 2 year of wearing orthokeratology



c Forest plot for the amount of ocular axis change after 1 year of wearing orthokeratology



d Forest plot for the amount of ocular axis change after 2 year of wearing orthokeratology

Fig. 5 The forest plots for synthesized outcomes

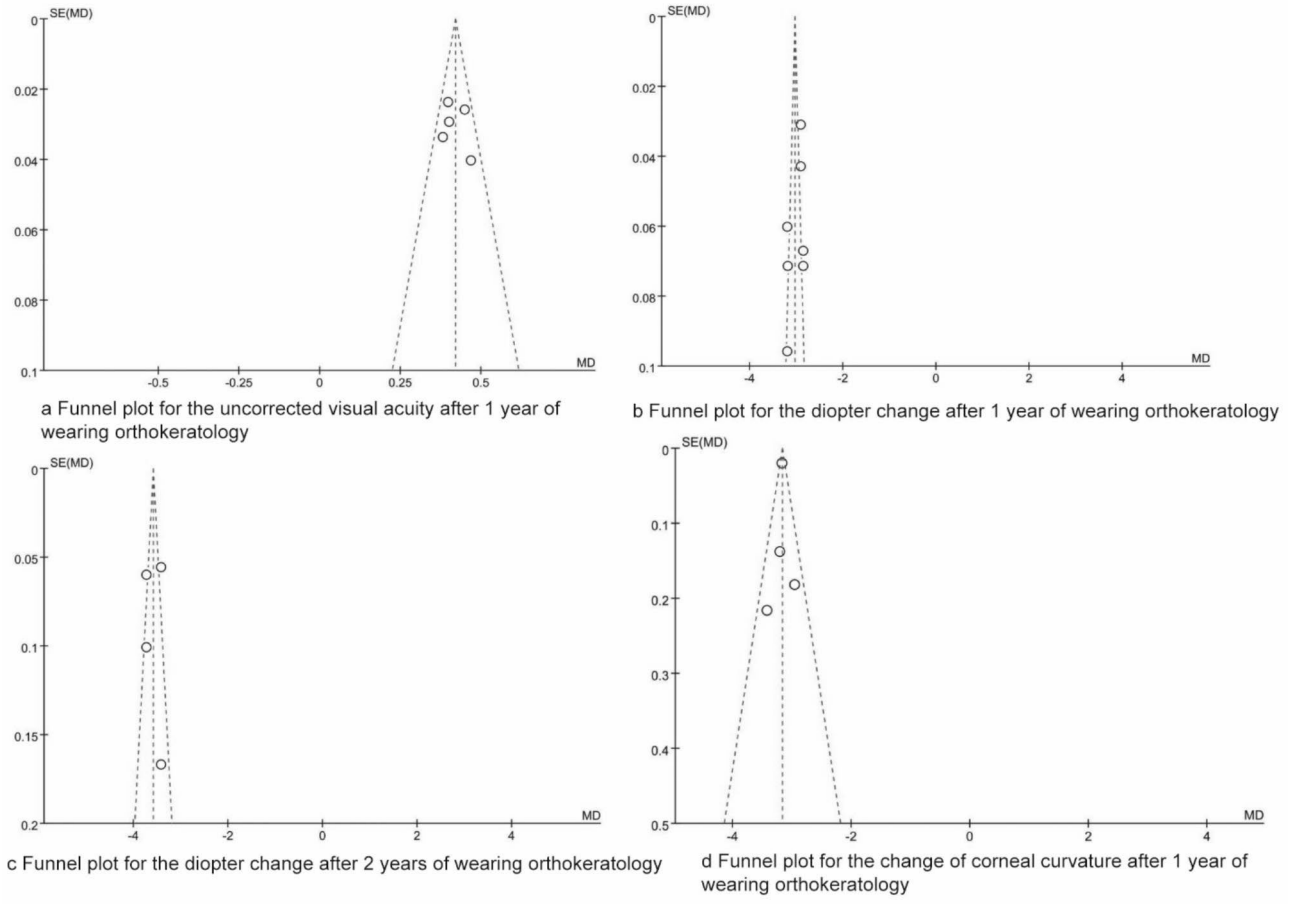


Fig. 6 The funnel plots for synthesized outcomes

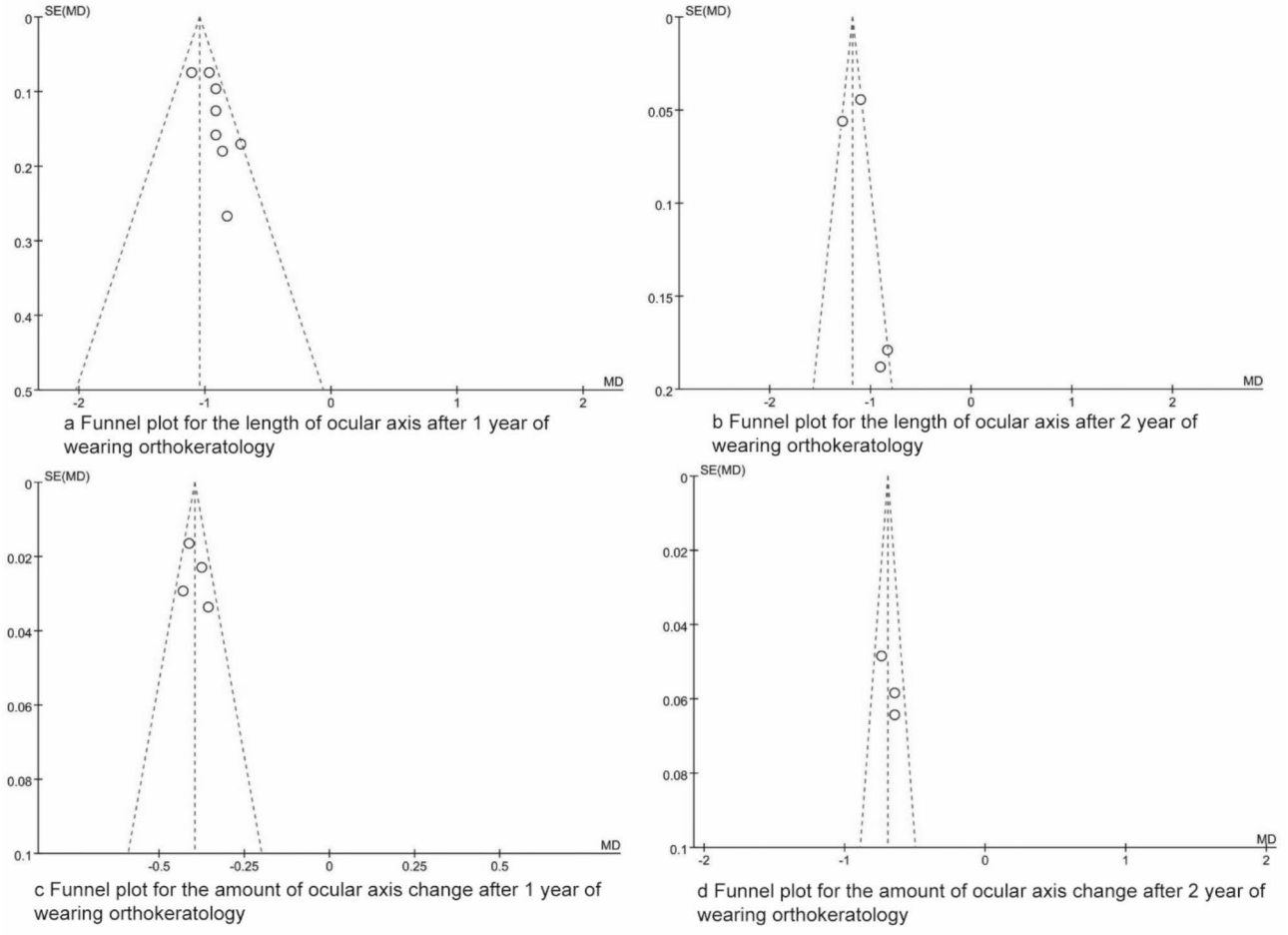


Fig. 7 The funnel plots for synthesized outcomes

Abbreviations

RCTs	Randomized controlled trials
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
MD	Mean difference
RR	Relative risk
CI	Confidence interval

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None.

Author contributions
L B, H L designed research; X L, M X, S S, L B, H L conducted research; X L, M X analyzed data; X L, H L wrote the first draft of manuscript; L B had primary responsibility for final content. All authors read and approved the final manuscript.

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Data Availability
All data generated or analyzed during this study are included in this published article.

Declarations

Competing interests
The authors declare no competing interests.

Consent for publication
Not applicable.

Ethics approval and consent to participate
In this study, all methods were performed in accordance with the relevant guidelines and regulations. Ethics approval and consent to participate are not necessary since our study is a meta-analysis.

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