1040-5488/15/9203-0252/0 VOL. 92, NO. 3, PP. 252–257
OPTOMETRY AND VISION SCIENCE

FEATURE ARTICLE ON LINE

Orthokeratology for Myopia Control: A Meta-analysis

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ABSTRACT

Purpose. To conduct a meta-analysis on the effects of orthokeratology in slowing myopia progression.

Methods. A literature search was performed in PubMed, Embase, and the Cochrane Library. Methodological quality of the literature was evaluated according to the Jadad score. The statistical analysis was carried out using RevMan 5.2.6 software.

Results. The present meta-analysis included seven studies (two randomized controlled trials and five nonrandomized controlled trials) with 435 subjects (orthokeratology group, 218; control group, 217) aged 6 to 16 years. The follow-up time was 2 years for the seven studies. The weighted mean difference was −0.26 mm (95% confidence interval, −0.31 to −0.21; $p < 0.001$) for axial length elongation based on data from seven studies and −0.18 mm (95% confidence interval, −0.33 to −0.03; $p = 0.02$) for vitreous chamber depth elongation based on data from two studies.

Conclusions. Our results suggest that orthokeratology may slow myopia progression in children. Further large-scale studies are needed to substantiate the current result and to investigate the long-term effects of orthokeratology in myopia control. (Optom Vis Sci 2015;92:252–257)

Key Words: orthokeratology, myopia, myopia progression, myopia control, axial length, meta-analysis

Myopia has become one of the most common ocular disorders worldwide. The prevalence of myopia is about 20 to 50% in Europe and the United States and is up to 70% or even higher than 80% for young adults in some parts of East Asia.[1–5] High myopia is a risk factor for cataract, glaucoma, myopic retinopathy, and retinal detachment.[6–9] Therefore, it is very important to slow or even stop the progression of myopia in children.

Many researchers are investigating ways to control myopia progression. Several medical treatments have been considered to suppress myopia progression, including topical application of tropicamide,[10] atropine,[11] and pirenzepine.[12] Nevertheless, there have been no ideal therapeutic modalities to effectively prevent myopic progression in light of efficacy, safety, economic feasibility, and ease of application.[2,13] Orthokeratology, an optical correction mainly for correcting low-to-moderate myopia, is showing a potential to reduce the progression of myopia.[14–20] It is reversible and if the patient is unhappy with the treatment, he or she can simply discontinue wearing the lenses.

Axial length (AL) elongation is the most important factor in myopia progression.[21] A number of nonrandomized controlled trials (non-RCTs) have reported that AL elongation in subjects wearing orthokeratology lenses were 36 to 56% slower when compared with that of subjects wearing spectacles.[14,16,17,20] Two recent randomized single-masked studies also reported the efficacy of orthokeratology for slowing axial growth in high and low myopic children.[18,19] These studies suggest that orthokeratology may suppress myopia progression in children, but in general, the sample sizes of these studies were relatively small. Therefore, it would be valuable to conduct a quantitative and systematic summary of the evidence using rigorous methods. In the present study, a meta-analysis was conducted to assess the results from published studies on the efficacy of orthokeratology in myopia control.

METHODS

Search Strategy

To find the relevant literature, PubMed, Embase, and the Cochrane Library were searched. Reference lists of included trials were also searched. There were no language or data restrictions in searching trials. The date of searching databases ended November 16, 2013. The search strategy was based on combinations of

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medical subject headings and free text words and the search terms used were "orthokeratology," "ortho-k," "corneal reshaping contact lens," and "myopia," "nearsight," and "shortsight" in various combinations. Retrieved articles were imported into EndNote X6 (Thomson Reuters, New York, NY) where duplicate articles were manually removed.

Inclusion and Exclusion Criteria

Published studies, regardless of sample size, were included if they (1) were controlled clinical trials, including RCTs and non-RCTs; (2) included myopic patients aged 18 years and younger; (3) compared orthokeratology with control subjects (single-vision spectacles or soft contact lenses); and (4) reported AL elongation or more information relevant to myopia progression, for example, vitreous chamber depth (VCD) elongation. The major reasons for exclusion of studies were (1) review papers, (2) having no control groups, and (3) having no relevant data. We also excluded conference abstracts that had not been published. If duplicated data were presented in several studies, only the largest study was included. Article titles were screened for eligibility by two reviewers (SJK and TK) independently, and abstracts or full texts were reviewed as necessary.

Data Extraction

Two review authors (SJK and TK) independently extracted the data from articles that met this study's inclusion criteria. Two authors resolved inconsistencies by discussion and consensus. The following data were extracted from articles that met this study's inclusion criteria: name of first author, the year of publication and location of the study, various intervention groups, number of subjects, patient age, sex, duration of follow-up, and the baseline refractive error. The outcome measures were AL elongation and VCD elongation.

Missing SDs were derived from other statistics, such as p values or confidence intervals (CIs) if needed.[22] When a p value was reported as, for example, $p \leq 0.001$, $p = 0.001$ was assumed.[23] The missing SDs were able to be captured from figures using GetData Graph Digitizer 2.24 (available at http://getdata-graph-digitizer.com/index.php).

The methodological quality of the articles was evaluated using the Jadad scale.[24] This validated approach assesses randomization (0 to 2 points), blinding (0 to 2 points), and withdrawals (0 to 1 point) on a five-point scale. This study followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.[25]

Statistical Analysis

Statistical analysis was performed with RevMan 5.2.6 software (Cochrane Collaboration, Oxford, UK). In the present meta-analysis, the effect sizes of each study were presented as weighted mean difference (WMD) with 95% CIs for continuous outcome measures (AL, VCD). The continuous outcome measures were calculated by the inverse variance statistical method of random-effects model. In the inverse variance method, the weight given to each study is chosen to be the inverse of the variance of the effect estimate and is expressed as the percentage of every weight in the overall weight.[23] The statistical heterogeneity was tested by using the

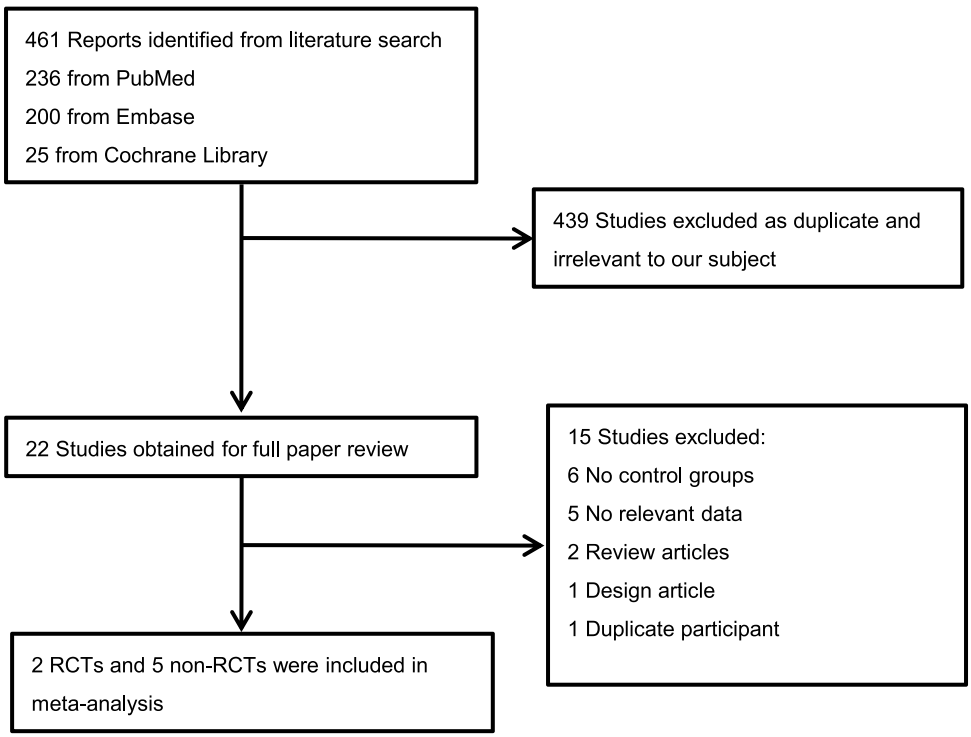

FIGURE 1.
Flowchart of studies included.

I^2 statistic. The statistical heterogeneity was considered significant when the I^2 statistic was greater than or equal to 50%. Because patient characteristics, region, the baseline refraction error, and other confounding factors were not consistent between studies, we further performed sensitivity analysis to examine the influence of various exclusion criteria on the overall pooled estimate. We also investigated the influence of a single study on the overall pooled estimate by omitting each study in turn. The sensitivity analysis was only performed for changes in AL because of the small number of studies reporting changes in VCD. The pooled effect sizes were considered significant when the 95% CI of WMD did not cross zero. We did not analyze publication bias because of the limited number of studies.

RESULTS

Search Results

A total of 461 studies were identified by the initial database search, of which 439 studies were excluded because they were duplicates or irrelevant to our subject. The remaining 22 full-text studies were carefully reviewed for more detailed evaluation, and 15 of them were excluded. Thus, two RCTs[18,19] and five non-RCTs[14–17,20] published from 2005 to 2013 were included in the final meta-analysis. Fig. 1 shows the process of filtering articles to determine their appropriate value for inclusion in the meta-analysis.

Characteristics and Quality of Trials

A total of 435 subjects (orthokeratology group, 218; control group, 217) aged 6 to 16 years were included in the present meta-analysis. The basic characteristics of the included studies are described in Table 1. Among these seven studies, five studies[14,16,18–20] were performed in East Asia, one study was performed in Europe,[17] and one study was performed in America.[15] All studies included reported the AL, and two studies also reported VCD. The follow-up time was 2 years for the seven studies. The quality assessment of studies included in this meta-analysis is presented in Table 1.

Meta-analysis

The gold standard for determining myopic progression is the elongation of AL[26]; hence, we selected the AL changes as the first outcome measure. As the SDs in the article by Walline et al.[15] were missing, we derived the SDs from the p values using the method reported by Wiebe et al.[22] We also captured missing SDs from the study by Santodomingo-Rubido et al.[17] from published figures using GetData Graph Digitizer 2.24. The results showed that AL increased with time in both orthokeratology and control subjects. At 2 years follow-up, the AL elongation of the orthokeratology group was significantly slower than that of the control group (WMD, −0.26 mm; 95% CI, −0.31 to −0.21; $p < 0.001$) (Fig. 2). We performed sensitivity analysis to test the robustness of

TABLE 1.
Characteristics of studies included in the meta-analysis

Study	Region	Design	Control group	No. eyes (OK/control)	Age, y	Sex (F/M)	Refraction error, D	Follow-up, y	Jadad score
Charm 2013[19]	Hong Kong	RCT	Single-vision spectacles	28 (12/16)	8–11	NA	SER: at least −5.75 Myopia: >−5.00	2	4
Chen et al. 2013[20]	Hong Kong	Non-RCT	Single-vision spectacles	58 (35/23)	6–12	OK: 17/18 Control: 15/8	Myopia: −0.50 to −5.00 Astigmatism: −1.25 to −3.50	2	1
Cho et al. 2005[14]	Hong Kong	Non-RCT	Single-vision spectacles	70 (35/35)	7–12	OK: 19/16 Control: 19/16	SER: −0.25 to −4.50 Astigmatism: <−2.00	2	1
Cho and Cheung 2012[18]	Hong Kong	RCT	Single-vision spectacles	78 (37/41)	6–10	OK: 18/19 Control: 19/22	Myopia: −0.50 to −4.00 Astigmatism: <−1.25	2	4
Kakita et al. 2011[16]	Japan	Non-RCT	Spectacles	92 (42/50)	8–16	OK: 21/21 Control: 28/22	SER: −0.50 to −10.00 Astigmatism: <−1.50	2	1
Santodomingo-Rubido et al. 2012[17]	Spain	Non-RCT	Single-vision spectacles	53 (29/24)	6–12	NA	Myopia: −0.75 to −4.00 Astigmatism: <−1.00	2	1
Walline et al. 2009[15]	United States	Non-RCT	Soft contact lens	56 (28/28)	8–11	OK: 13/15 Control: 11/17	Myopia: −0.75 to −4.00 Astigmatism: <−1.00	2	1

OK, orthokeratology; SER, spherical equivalent refractive error; NA, data not available; M, male; F, female.

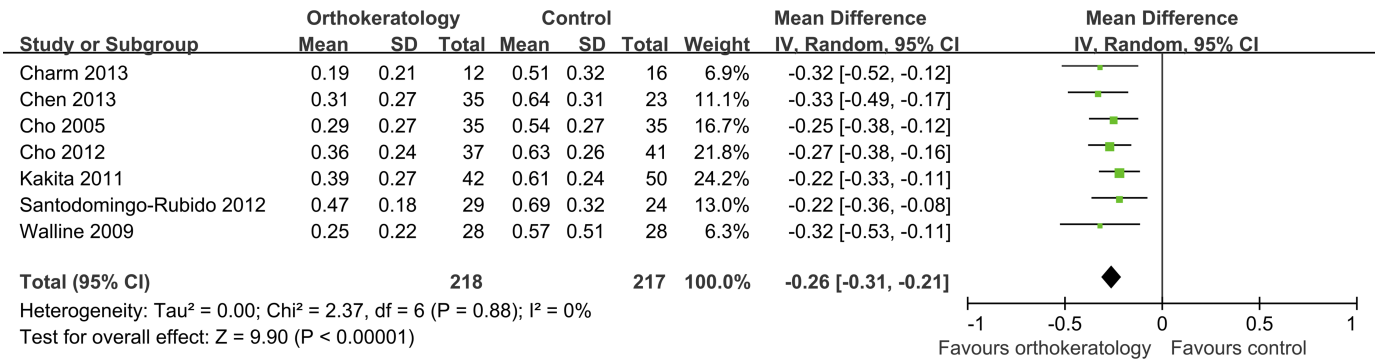

FIGURE 2.

Forest plot of AL elongation in the orthokeratology group and the control group. A color version of this figure is available online at www.optvissci.com.

the results. Table 2 shows the results of sensitivity analysis based on various exclusion criteria for AL. All groups in Table 2 showed insignificant heterogeneity: $I^2 \leq 50\%$, $p \geq 0.10$. We also assessed the influence of individual studies on the combined risk estimate by sequentially excluding each study in turn to test the stability of the main results. The exclusion of any single study did not materially alter the overall combined WMD, which ranged from −0.25 mm (95% CI, −0.31 to −0.20; $p < 0.001$) to −0.27 mm (95% CI, −0.33 to −0.22; $p < 0.001$).

Two studies reported VCD,[14,15] which increased with time in both groups of subjects. The VCD changes in the orthokeratology group were significantly slower than those in the control group (WMD, −0.18 mm; 95% CI, −0.33 to −0.03; $p = 0.02$) (Fig. 3).

DISCUSSION

The major purpose of the present meta-analysis was to evaluate the efficacy of orthokeratology in myopia control. Our meta-analysis suggests that compared with control, orthokeratology may effectively reduce the elongation of AL to a certain extent, with mean differences of −0.26 mm in 2 years. Moreover, the difference between orthokeratology and control in VCD elongation was −0.18 mm in 2 years. Exclusion of any single study and sensitivity analysis based on various exclusion criteria did not materially alter the pooled results, which added robustness to our main result.

Some early reports[27–29] described apparent effectiveness of overnight orthokeratology for arresting the progression of myopia. Subsequently, retrospective and prospective studies provided further evidence in support of the effectiveness of treatment. These results indicated that orthokeratology could suppress myopia progression with mean difference for AL elongation between orthokeratology and control ranging from −0.22 to −0.33 mm in 2 years.[14–20] In our study, the meta-analysis that combined seven studies with 435 subjects (orthokeratology group, 218; control group, 217) indicated a similar result and confirmed the efficacy of orthokeratology for myopia control.

The mechanism by which orthokeratology might control myopic eye growth is still debatable. It has been proposed that relative peripheral hyperopic defocus in myopes may trigger axial elongation.[30,31] Recent animal studies indicate that form deprivation that is limited to the peripheral retina can produce myopic eye growth in monkeys, despite ablation of the fovea with an argon laser.[32] In human studies, myopic eyes experience more relative hyperopia in the periphery, on average, than hyperopic and emmetropic eyes.[33] Furthermore, results from the CLEERE (Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error) study indicated that children who become myopic have more relative hyperopic peripheral refractive error than emmetropic children 2 years before the onset of myopia.[34] Therefore, peripheral hyperopia may act as a signal for increased eye growth. The correction of peripheral hyperopia may be the mechanism of orthokeratology in the suppressing of myopic eye growth. In orthokeratology, the central cornea is flattened, reducing the axial myopia, whereas the midperipheral cornea remains relatively steeper, leading to relative peripheral myopia in myopic eyes. The peripheral myopia created by orthokeratology reduces peripheral hyperopic defocus, and this may reduce the visual feedback for eye elongation, leading to slower myopic progression.[35–37] In contrast, the CLEERE group's later study[38] found that hyperopic relative peripheral refractive error was not a significant risk factor for the onset of myopia as a whole. However, the association between more hyperopic relative peripheral refractive error and

TABLE 2.

Results of sensitivity analysis

	No. studies	No. OK	No. control	WMD (95% CI), mm	p
Total	7	218	217	−0.26 (−0.31 to −0.21)	<0.001
Study type					
RCT	2	49	57	−0.28 (−0.38 to −0.19)	<0.001
Non-RCT	5	169	160	−0.25 (−0.31 to −0.19)	<0.001
Total sample size					
≥50	6	206	201	−0.26 (−0.31 to −0.20)	<0.001
≦50	1	12	16	−0.32 (−0.52 to −0.12)	0.001
Region					
Asia	5	161	165	−0.26 (−0.32 to −0.21)	<0.001
Europe and America	2	57	52	−0.25 (−0.37 to −0.13)	<0.001

OK, orthokeratology.

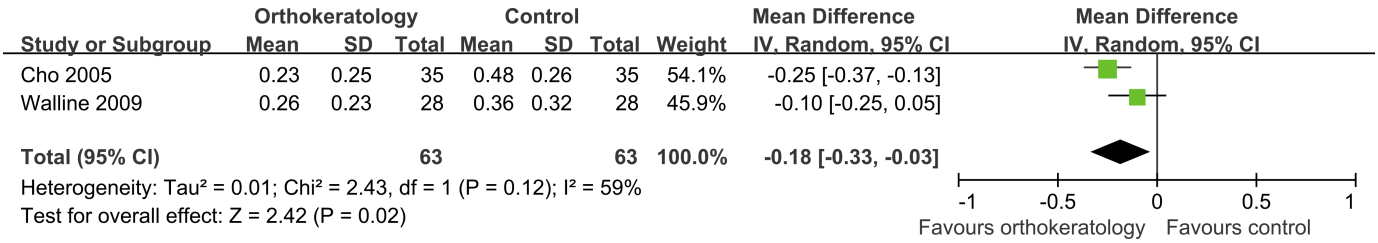

FIGURE 3.

Forest plot of VCD elongation in the orthokeratology group and the control group. A color version of this figure is available online at www.optvissci.com.

the risk of the onset of myopia varied by ethnic group, with Asian American children having the highest risk. Thus, whether relative peripheral hyperopic defocus acts as an important mechanism by which orthokeratology might control myopia progression is still uncertain. Furthermore, researchers have found that many other factors may influence the effectiveness of myopia control with orthokeratology, including corneal relative peripheral power change,[39] levels of parental myopia,[40] and pupil sizes.[41] All factors mentioned above serve to remind us that the mechanism by which orthokeratology might control myopic eye growth may be complex.

This study has several limitations. First, our analysis was based on only seven studies (two RCTs and five non-RCTs) with relatively small sample sizes, thus limiting the reliability of the results. Second, the targeted population varied greatly, and study protocols and designs differed. These factors may have potential effects on our results. Third, the study by Walline et al.[15] was included in this meta-analysis, although soft contact lenses were used as control. Moreover, most trials included in the present meta-analysis were performed in Asia, and only two studies[15,17] were conducted outside this region in America and Spain.

Further studies should focus on the following two points. First, although RCTs for orthokeratology are difficult to carry out, using RCTs can leave little room for bias, and the results of RCTs are more convincing. Therefore, future large-scale RCTs to investigate the effects of orthokeratology on myopia progression are still important. Second, because the mechanism of myopia progression is still debatable, additional animal and human studies will be needed to further elucidate the potential biological mechanisms that are involved.

In conclusion, our meta-analysis suggests that orthokeratology can reduce the progression of myopia to a certain extent. The results of this meta-analysis should be interpreted with caution because of the limitations discussed above. Further large-scale studies are needed to substantiate the current results and to investigate the long-term effects of orthokeratology in myopia control.

ACKNOWLEDGMENTS

This study was supported by the National Natural Science Foundation of China (81173440) and the Shandong Traditional Chinese Medicine Science and Technology Development Plans Project (2011-130). Jun-Kang Si and Kai Tang contributed equally to this work.

Received February 17, 2014; accepted October 10, 2014.

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