Research Square

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Combination of orthokeratology and low-dose atropine for axial length elongation control in myopic children with a poor response to orthokeratology

Bo Wu
Central South University
Zhengfei Yang
Central South University
Jin Xu
Central South University
Fan Yang
Central South University
Huifang Ji
Liaoning Aier Eye Hospital
Xiu Mu
Liaoning Aier Eye Hospital
Yi Wang
Liaoning Aier Eye Hospital
Jiwen Yang
yangjiwen1975@vip.163.com
Central South University

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Abstract

Objectives

To compare the effectiveness of combined treatment comprising low-dose atropine and orthokeratology (OK) in controlling myopia in children with poor responses to OK.

Methods

This retrospective study evaluated 91 children who underwent two years of OK treatment. All the children were 6–12 years old at the start of OK treatment. They all showed a minimum annual increase of 0.3 mm in the first year. In the second year, children receiving 0.01% atropine were categorized into the OKA 0.01% group, those receiving 0.05% atropine into the OKA 0.05% group, and those not receiving atropine into the Mono-OK group.

Results

In the end of the first year, the axial length (AL) in the OKA 0.01% and Mono-OK groups were similar (25.01 mm and 25.29 mm, $P = 0.160$). However, the OKA 0.05% group exhibited a shorter AL (24.54 mm) than both the OKA 0.01% and Mono-OK groups ($P = 0.013$ and $P < 0.001$). After atropine combination therapy, the OKA 0.05% group also exhibited a smaller AL change (0.02 mm/y) than did the Mono-OK group (0.38 mm/y; $P < 0.001$) and OKA 0.01% group (0.27 mm/y; $P = 0.002$), while the difference between the OKA 0.01% and Mono-OK groups was not significant (0.27 mm/y vs. 0.38 mm/y; $P = 0.192$).

Conclusions

For young children with a poor response to OK, the addition of 0.05% atropine could control the progression of axial elongation compared with the combination of 0.01% atropine.

Introduction

Myopia is a major public health concern in China and other East Asian countries, and its prevalence has risen markedly[1–3]. This condition can lead to severe complications including retinal detachment, cataracts, and glaucoma[4]. Children who develop myopia during early school years face a relatively greater risk of developing high myopia[5]. Therefore, slowing the progression of myopia in early childhood is crucial to reduce the risk of developing high myopia.

Orthokeratology (OK) is a clinical technique in which specially designed rigid contact lenses are used to reshape the cornea to temporarily reduce or eliminate refractive error[9]. Studies have shown that OK is effective in slowing myopia progression of myopia[6]. Several studies have indicated that when compared

to spectacle lenses over two years, OK treatment results in a reduction in axial length (AL) elongation of approximately 0.21 mm[7], 0.3 mm[8] and 0.27 mm[9]. Nevertheless, young children may not respond well to OK, as they may continue to experience rapid progression of myopia despite treatment.[10,11] Children with an annual increase in AL of 0.3 mm or more can be identified as rapid progressors[12]. Among those undergoing OK, the proportion of fast progressors was 15%[11].

Recently, a combination of OK and 0.01% atropine was found to be more effective than OK alone in inhibiting AL. Tan et al. reported an additive effect between 0.01% atropine and OK over a two-year period[13,14]. Additionally, two other dosages of atropine (0.125% and 0.025%) were used to control myopia, and it was observed that the combination group exhibited significantly shorter AL progression than the OK group[14]. However, research on the use of atropine in combination with OK in patients who do not respond well to OK alone is scarce. Chen et al. conducted a study investigating the combined effect of OK and 0.01% atropine on axial elongation in children with rapidly progressing myopia, and the results indicated a significant decrease in the annual axial elongation rate compared to that in patients treated with OK alone[15]. Nevertheless, over the following two-year period, the combination treatment did not significantly differ from OK-only treatment[12].

Recent randomized controlled trials have confirmed that 0.05% atropine provides the best efficacy and safety for controlling myopia progression and AL elongation[16,17]. In this retrospective study, we analyzed the combined effect of 0.05% atropine and OK, and compared the results of combining 0.01% atropine with OK. This study aimed to test whether 0.05% atropine in combination with OK is more effective than 0.01% atropine combined with OK in fast progressors to further support that 0.05% atropine could be a first-line combination therapy for children who exhibit poor responses to OK.

Participants and Treatment

This study was a retrospective clinical study that followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of the Aier Eye Hospital Group. Written informed consent was obtained from the direct guardians of all participants prior to their enrollment in the study, which involved the use of OK lenses alone or in combination with either 0.01% or 0.05% atropine eye drops.

This study included 91 participants who received orthokeratology lenses for myopia control at Liaoning Aier Eye Hospital from July 2018 to October 2023. The patients were between 6 and 12 years of age when they commenced OK treatment. In the first year of OK treatment, all children showed an annual increase of 0.3 mm or greater in the first year of treatment with OK.

The other inclusion criteria were as follows: cycloplegic auto refraction of -1.00 to -6.00 D; astigmatism less than 2.0 D; unaided daytime vision ≤ 0.1 (logMAR); intraocular pressure within the range of 10 mmHg to 21 mmHg; no previous eye or systemic conditions that might affect vision or vision development; and not receiving any other treatments for myopia progression.

We selected children who used OK for myopia control but experienced an annual increase in AL exceeding 0.3 mm/year in the first year. Children who received combination treatment with 0.01% atropine in the second year were defined as the OKA 0.01% group, and those receiving combination treatment with 0.05% atropine were defined as the OKA 0.05% group. The Mono-OK group included children who continued OK monotherapy without any additional atropine treatment during the second year. The choice of 0.01% or 0.05% atropine was made by the parents, who were given the option to select the concentration they preferred for their child's treatment.

Contact lens

This study included three groups of children who used ProTong OK (Eyebright Co. Ltd., Beijing, China). The lenses were composed of Rofluofocon E, with an oxygen permeability (DK) of 125 (10 – 11 cm^2 × ml O^2)/(s × ml × mmHg)[18]. ProTong OK featured a four-curve design (base curve, reverse curve, alignment curve and peripheral curve), incorporating an aspherical design within each curve. The lens diameter was 10.6 mm, and the back optical zone diameter was 6.0 mm in this study. If the refractive power at different meridian levels at the 8mm diameter of the cornea is measured on the corneal topography and the difference is more than 1D, we will use the astigmatism design lens to make it fit better. Lenses were ordered with over-correction targeted at + 0.75 D ~ + 1.50D. Lenses should be worn for at least 8 hours per night.

Measurements

During each visit, various assessments were conducted, including habitual and best-corrected logMAR visual acuity, corneal topography using the Pentacam device, intraocular pressure measurements with the NIDEK NT-2000 instrument, slit-lamp biomicroscopy, and pupil size measurements using the NIDEK ARK 1 autorefractometer under bright light indoors, the average of three consecutive measurements was taken as the pupil diameter. AL was measured using non-contact optical biometry (IOLMaster; Carl Zeiss Meditec, Dublin, CA, USA). AL and spherical equivalent measurements were standardized for each participant.

Atropine

The concentrations of atropine sulfate used were 0.01% and 0.05% (Aier Eye Hospital Group Co., Ltd., Changsha Aier Eye Hospital). Patients who needed atropine sulfate eye drops were informed about the myopia control effect and possible side effects of different concentrations of atropine sulfate eye drops. Patients and their parents decided whether to use atropine sulfate eye drops and which concentration of atropine sulfate eye drops to choose, and signed the consent form. All the eye drops were free of preservation. Eight hours after the package was opened, atropine was discarded.

The participants were instructed to administer the medication once daily before bedtime, instilling one drop into the conjunctival sac near the outer corner of the ear. After atropine administration, the inner canthus lacrimal sac was pressed with the hand for 3 min. This regimen was followed once every night 30 min before the orthokeratology lens was inserted.

Patients were requested to log any side effects associated with atropine use, such as photophobia and visual blur, during the follow-up visits.

Statistical analysis

Only data from the right eye were used for data analyses. The analysis was conducted using IBM SPSS Statistics for Windows (version 25.0; IBM Corp., Armonk, NY, USA). The normality of the data was assessed using the Shapiro-Wilk test. One-way analysis of variance (ANOVA) and the Least significant difference post hoc test (LSD) were used to compare the differences among the three groups in terms of AL in the second year. The Paired-Samples t Test was used to evaluate the changes in AL between the first and second year in the three groups. Additionally, the one-way ANOVA was used to compare the changes in axial elongation across the three groups in the first and second years. Statistical *P* was set than 0.05.

Results

A total of 91 participants were included in the study: 32 participants (32 eyes) were in the OKA 0.01% group, 30 participants (30 eyes) were in the OKA 0.05% group, and 29 participants (29 eyes) were in the mono-OK group. No statistically significant differences were observed in baseline age, SE, gender among the three participant groups. The baseline AL analysis of the three groups of participants revealed that the AL in the mono-OK group was longer than that in the OKA 0.05% group (P = 0.028). However, there were no significant differences in AL between the mono-OK group and the OKA 0.01% group (P = 0.245), nor between the OKA 0.01% group and the OKA 0.05% group (P = 0.271). The demographic characteristics of the three groups are presented in Table 1.

Table 1
The demographic description of the study participants

		Mono-OK, n = 29	OKA 0.01%,n = 32	OKA 0.05%,n = 30	ANOVA / Kruskal—Wallis H / χ^2	
					F/ H / χ^2	*P*
Age	M ± SD	8.70 ± 1.09	8.82 ± 1.32	9.07 ± 1.25	0.621	5.39
SE	Median	-2.38	-2.50	-1.75	1.716	0.424
	(Q1,Q3)	(-2.75, -1.50)	(-3.25, -2.00)	(-2.69, -1.25)		
AL	M ± SD	24.35 ± 0.73	24.14 ± 0.73	23.94 ± 0.65	2.495	0.088
Male	N(%)	14(29.8%)	18(38.3%)	15(31.9%)	0.436	0.804

SE, spherical equivalent; AL, axial length; ANOVA, one-way analysis of variance

The AL in the three groups were compared pairwise within the group (LSD) : OKA 0.05% group vs. mono-OK group, $P = 0.028$; OKA 0.05% group vs. OKA 0.01% group, $P = 0.271$; OKA 0.01% group vs. mono-OK group, $P = 0.245$.

Comparison of axial length.

After one-year of OK lens treatment, the AL values of the participants in all three groups increased. The AL in the mono-OK group was longer than that in the OKA 0.05% group (P = 0.042), but there were no significant differences in AL between the mono-OK group and the OKA 0.01% group (P = 0.346), nor between the OKA 0.01% group and the OKA 0.05% group (P = 0.249).There was no statistically significant difference in the increase among the three groups (P = 0.545).

In the second year after the treatment, The AL values did not differ significantly between the OKA 0.01% group and the mono-OK group ($P = 0.160$); however, the AL in the OKA 0.05% group was significantly lower than that in the OKA 0.01% and mono-OK groups (OKA 0.05% vs. 0.01%, $P = 0.013$; OKA 0.05% vs. Mono-OK, $P < 0.001$) (Table 2 and Fig. 1).

Table 2
Comparison of axial length among the three groups.

Baseline	Mono OK (M ± SD)	OKA 0.01% (M ± SD)	OKA 0.05% (M ± SD)	F	*P*
	24.35 ± 0.73	**24.14 ± 0.73**	**23.94 ± 0.65**	**2.495**	**0.088**
12 month	24.91 ± 0.73	24.74 ± 0.69	24.54 ± 0.63	2.143	0.123
24 month	25.29 ± 0.79	25.01 ± 0.78	24.54 ± 0.65	7.684	0.001

The pairwise comparisons of AL values among the three groups after 12 months (LSD): OKA 0.05% group vs Mono-OK group *P* = 0.042; OKA 0.05% group vs OKA 0.01% group, *P* = 0.249; OKA 0.01% group vs Mono-OK group *P = 0.346.*

The pairwise comparisons of AL values among the three groups after 24 months (LSD): OKA 0.05% group vs Mono-OK group *P* < 0.001; OKA 0.05% group vs OKA 0.01% group, *P* = 0.013; OKA 0.01% group vs Mono-OK group *P = 0.160.*

Compared to the first year, the second year showed a decrease in AL change in all three groups. (P < 0.001). Additionally, the OKA 0.05% group exhibited a significantly smaller AL change in the second year compared to both the Mono-OK group (P < 0.001) and the OKA 0.01% group (P = 0.015). However, no significant difference in AL change was observed between the OKA 0.01% and Mono-OK groups (P = 0.066).(Table 3).

Table 3
Comparison of the changes in axial length

Yearly increase	Mono OK (M ± SD)	OKA 0.01% (M ± SD)	OKA 0.05% (M ± SD)	F	P
First	0.56 ± 0.12	0.60 ± 0.19	0.60 ± 0.19	0.610	0.545
Second	0.38 ± 0.20	0.27 ± 0.35	0.02 ± 0.36	10.401	< 0.001
T (Paired-Samples t Test)	-4.952	-4.732	-7.355		
P	< 0.001	< 0.001	< 0.001		

The AL changes in the second year were compared pairwise within the group (LSD) : OKA 0.05% group vs. mono-OK group, *P* < 0.001; OKA 0.05% group vs. OKA 0.01% group, *P* = 0.002; OKA 0.01% group vs. mono-OK group, *P = 0.192.*

Side effects

Following combination treatment, the pupil size in the OKA 0.05% group significantly increased compared to baseline measurements (T =−12.596, P < 0.001; Table 4). Spearman correlation analysis revealed no significant association between changes in pupil diameter and axial length (AL) progression in the second year for either the OKA 0.01% group (P = 0.259) or the OKA 0.05% group (P = 0.315).

Table 4
Comparison of photopic pupil diameter

		M(SD)	95%CI	T	*P*
OKA 0.01%	Pre-drug	6.24(0.55)	(6.06,6.48)	-0.860	0.234
	Post-drug	6.38(0.62)	(6.18,6.64)		
OKA 0.05%	Pre-drug	6.27(0.57)	(6.06,6.49)	-12.596	< 0.001
	Post-drug	7.08(0.56)	(6.88,7.29)		

After the use of atropine eye drops, some patients in the OKA 0.01% and OKA 0.05% groups had complications of photophobia and near vision difficulty in the early stage, and the incidence of OKA 0.05% group was higher (OKA 0.01% vs. OKA 0.05%, 9.38% vs. 53.33%). But most of them disappeared within 1 month. After 3 months, only 4 patients still had mild photophobia, but it was relieved and could be tolerated.

Discussion

In this retrospective study, 0.05% atropine in combination with OK was significantly more effective in managing myopia than 0.01% atropine in combination with OK and OK monotherapy. Therefore, a combination treatment comprising 0.05% atropine and OK is important for children with a poor response to OK.

Our study revealed that the change in AL after combination treatment (0.02 mm/y) in the OKA 0.05% group was significantly smaller than that before combination treatment (0.60 mm/y). Our findings demonstrate that the OKA 0.05% group exhibited significantly slower axial elongation during the two-year follow-up period. While previous studies have established that axial growth naturally decelerates with age[19,20], the observed reduction in axial length progression between the first and second years was substantially greater in the OKA 0.05% group compared to the mono-OK group. This significant treatment effect persisted after accounting for age-related changes, providing compelling evidence that the enhanced efficacy stems from the combined therapeutic mechanism of orthokeratology and low-dose atropine. Furthermore, the OKA 0.05% group demonstrated a significantly greater reduction in axial elongation compared to the OKA 0.01% group, with annual progression rates of 0.02 mm/y versus 0.27 mm/y, respectively. This difference was further reflected in the final 2-year axial length measurements (24.54 mm vs. 25.01 mm), indicating superior myopia control efficacy with the higher atropine concentration. These findings suggest that the enhanced therapeutic effect observed in the OKA 0.05% group may be attributed to the increased pharmacological potency of 0.05% atropine, consistent with

previous reports [16]. Supporting this observation, Li et al. [21] noted that younger pediatric patients often require higher atropine concentrations (0.05%) to achieve optimal myopia suppression. Therefore, for children aged 8–12 years exhibiting suboptimal response to orthokeratology alone, adjunctive therapy with 0.05% atropine may provide superior efficacy compared to lower-dose (0.01%) regimens.

Previous studies have suggested that increased pupil diameter induces higher-order aberrations at the retinal plane, which may subsequently modulate refractive development. These optical modifications have been proposed to collectively contribute to axial length regulation[22]. However, our findings demonstrate no significant association between pupil size and axial elongation. Pharmacologically, atropine exerts its effects through competitive antagonism of muscarinic acetylcholine receptors (mAChRs). The reduced AL progression in the OKA 0.05% group likely reflects mAChR-mediated regulation of retinal signaling pathways and scleral extracellular matrix remodeling both critical to ocular biomechanics [23]. While these complementary mechanisms provide a pathophysiological rationale, the precise synergistic interactions between optical and biochemical pathways require rigorous investigation through controlled mechanistic studies.

In the present study, axial elongation during the second year did not significantly differ between the OKA 0.01% and mono-OK groups. This contrasts with Tan et al.'s investigations demonstrating additive effects for 0.01% atropine combined with orthokeratology over both one- and two-year periods [24]. Xu et al. similarly reported enhanced myopia control efficacy with combination therapy versus orthokeratology monotherapy[25]. Critically, however, neither Tan's nor Xu's study cohorts specifically comprised rapid progressors. When evaluating this clinically challenging subgroup, Chen et al. observed no additive effect when supplementing established orthokeratology with 0.01% atropine after 12 months [12]— a finding mirroring our results in comparable patient profiles.

Our study demonstrated significantly faster baseline axial elongation rates than previously reported in pre-intervention cohorts[10,11], attributable to three key factors: First, intentional participant selection for accelerated progression profiles. Second, the cohort's younger age distribution—a recognized risk factor for rapid myopia progression[26]—as younger children exhibit greater susceptibility to axial elongation even with orthokeratology treatment[7,27]. Third, the relatively low baseline refractive error. Notably, existing literature has established that eyes with lower baseline myopia demonstrate accelerated axial elongation during orthokeratology treatment[7,28], it may also account for the progressive reduction in axial elongation observed in our mono-OK group, with significantly slower progression rates during the second treatment year compared to the first.

The incidence of side effects in the OKA 0.01% group was 9.38%, consistent with the findings of Wei et al., who also noted a low incidence of adverse effects in children administered 0.01% atropine[29]. An increase in the dosage of atropine resulted in a corresponding increase in the occurrence of side effects[30]. In our study, 53.33% of the children in the OKA 0.05% group exhibited side effects, which was higher than that of the OKA 0.01% group, and lower than that of the Yam et al.'s study, which reported

75.8% adverse events in the 0.05% group[16]. Despite the high rate of side effects in the OKA 0.05% group, no serious adverse events were observed in our study, and most side effects disappeared within one month.

This study has several limitations that should be acknowledged. First, the retrospective design may introduce selection bias in data collection. Second, potential confounding factors including variations in children's growth rates, near work duration, and outdoor activity time could influence myopia progression, but these data were not systematically collected in our study. Third, the treatment efficacy was only evaluated over a one-year period, and longer-term follow-up would be valuable to assess sustained effects.Furthermore, previous studies have reported myopic rebound after atropine cessation[31], and the differential rebound effects between 0.01% and 0.05% atropine concentrations require further investigation. Additionally, baseline AL differences existed between the mono-OK and OKA 0.05% groups, which might affect our conclusions. However, it should be noted that the OKA 0.05% group showed better AL control despite having shorter baseline AL, suggesting that the combination of orthokeratology with 0.05% atropine may indeed provide superior myopia control efficacy.

In conclusion, the use of 0.05% atropine in combination therapy effectively controlled myopia in children who exhibited poor response to OK. Its efficacy was better than that of a combination of 0.01% atropine. Moreover, this treatment has no serious side effects; therefore, a combination of 0.05% atropine can be considered clinically for children with poor responses to OK.

Declarations

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Availability of data and material:

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions:

Design of the study (Bo Wu, Zhengfei Yang, Jiwen Yang), conduct of the study, data collection, analysis, and interpretation (Bo Wu, Zhengfei Yang, Jin Xu, Yi Wang, Xiu Mu), writing the manuscript (Bo Wu, Zhengfei Yang), critical revision of the manuscript (Zhengfei Yang, Bo Wu, Fan Yang, Jin Xu), supervision (Jiwen Yang).

Ethics approval:

This study adhered to the tenets of the Declaration of Helsinki. This study was

approved by the Liaoning Aier Hospital Review Board.

Consent for publication: Not Applicable

Conflict of Interest declaration: The authors have declared that no competing interests exist.

Consent to participate: Written informed consent was obtained from the direct guardians of all participants prior to their enrollment in the study, which involved the use of OK lenses alone or in combination with either 0.01% or 0.05% atropine eye drops.

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Figures

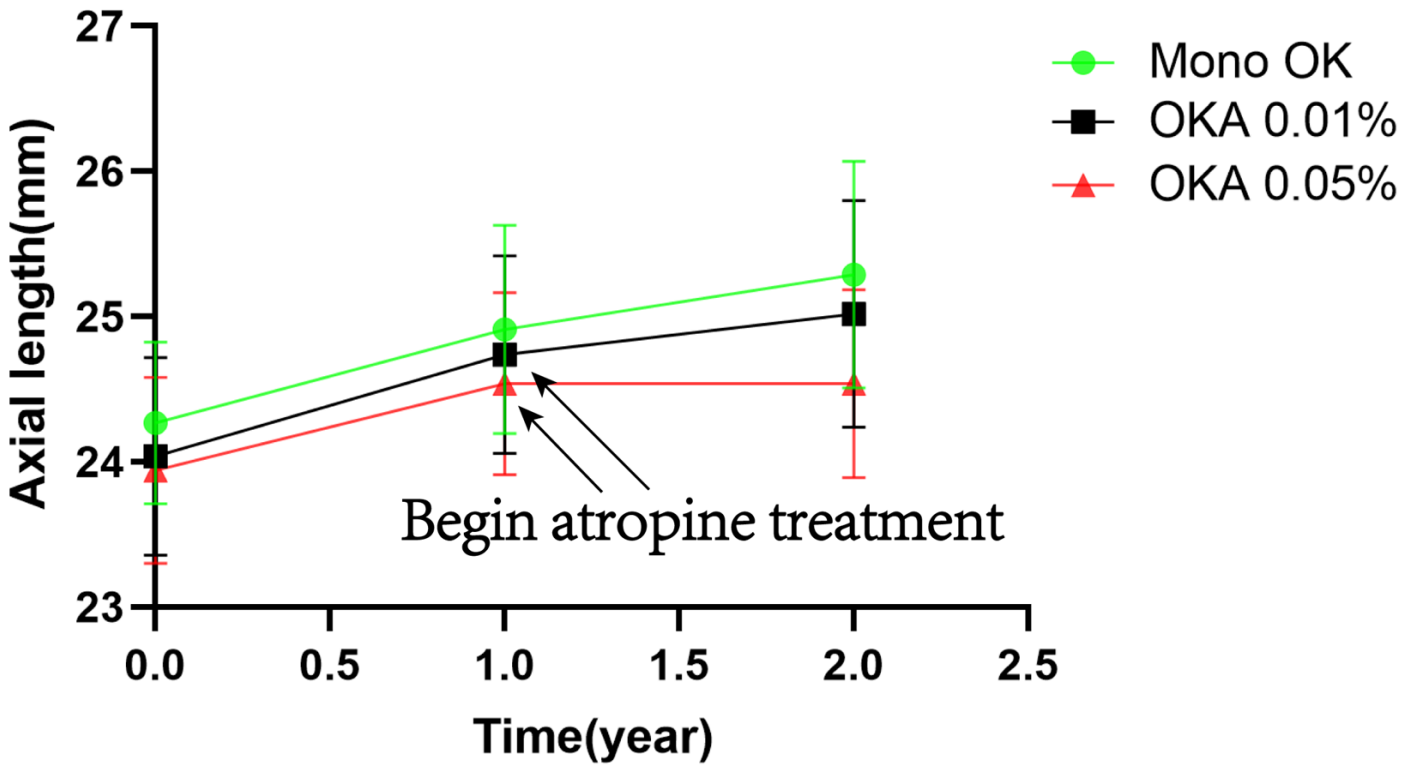


Figure 1

Mean and SD of axial length in Mono OK, OKA 0.01%, and OKA 0.05% groups.