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Discontinuation of orthokeratology on eyeball elongation (DOEE)

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ABSTRACT

Purpose: To evaluate and compare changes in axial elongation, over a 14-month period, in subjects who discontinued and then resumed ortho-k lens wear with those who continued to wear their lenses or spectacles following a 2-year myopia control study.
Method: This single masked, prospective study recruited subjects who had just completed a 2-year myopia control study. Ortho-k subjects were classified as Group OKc, in which subjects continued ortho-k lens wear for the duration of the study; or Group OKd in which subjects discontinued lens wear for seven months and wore single-vision spectacles (Phase I) and then resumed ortho-k lens wear for another seven months (Phase II). Spectacle-wearing control subjects from the initial myopia control study continued wearing spectacles as control subjects. Axial lengths were measured at scheduled visits using the IOLMaster.
Results: Thirteen, 16, and 15 Control, OKc, and OKd subjects, aged 8–14 years, respectively completed the study. Significant increase in axial elongation was found in OKd subjects only in Phase I but not in Phase II. On resuming lens wear, in Phase II, the rate of axial elongation was no longer significantly different from those of the Control or OKc subjects.
Conclusion: Stopping ortho-k lens wear at or before the age of 14 years led to a more rapid increase in axial length; comparable to those wearing spectacles during the initial 2-year myopia control study, but greater than the Control and OKc group in this study. Axial elongation slowed again with resumed lens wear after six months.

1. Introduction

Orthokeratology (ortho-k), shown to be effective in slowing the progression of myopia [1–8], is now popular for myopia control in children, particularly in East Asian countries where the prevalence of myopia is high [9–12]. Toric ortho-k lenses have also been shown to be effective in reducing high astigmatism [7] and a pilot study using partial correction ortho-k (targeting 4.00D reduction for all high myopic subjects) demonstrated a higher level of myopia control, compared to treatment for low myopes [8], giving improved prognosis for children with high myopia and whose myopia is still progressing.

A survey, conducted in Hong Kong and soliciting parents' perspective on optical methods for myopia control, revealed that ortho-k was the most recognised method for myopia control. When parents were asked about their preferred option *if* all three optical treatments – ortho-k, soft contact lenses, and spectacles, were *equally effective* for myopia control, more parents chose ortho-k over the other treatments [13]. Although safety was a crucial concern, confidence in the treatment and convenience offered were also important considerations when the parents decided on the myopia control method for their children. Children undergoing ortho-k treatment could achieve >50% of myopia reduction after only one overnight lens wear [14–16], which boosted parents' confidence in ortho-k. For most children, the correction of refractive error, after stabilization of treatment, is sufficient to allow freedom from the need of vision correcting aids during the day. Wide publicity of ortho-k treatment in East Asia, including Hong Kong, also reassured parents of its effectiveness for myopia control. While many studies on the effectiveness of ortho-k for myopia control have been published [1–8] less emphasis has been placed on the clinical aspects of this treatment. Common queries from many parents included at what age could their children stop ortho-k lens wear and what would happen when lens wear was ceased. This information is necessary and important as parents do have concerns about permanent dependency on ortho-k once their children had commenced the treatment. It is unknown whether the myopic control effect would dissipate upon discontinuation of the treatment leading to a rebound effect to where the refraction or eyeball length would have been if they had not

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received the treatment (i.e. assuming their myopia was progressing) or, worse still, increased even faster than if they had never had the treatment.

This study aimed to evaluate and compare changes in axial elongation, over a 14-month period, in subjects who continued or discontinued and then resumed ortho-k lens wear following two years of ortho-k lens wear. Axial elongation was compared with control subjects wearing spectacles who had also been monitored over the previous two years.

2. Methods

This study was a single masked, prospective study of 14-month duration. Parents with children participating in the ROMIO [6] and TO-SEE [7] myopia control studies were invited to enroll in this study immediately after their children had completed the myopia control study. The study was approved by the Departmental Research Committee of the School of Optometry of The Hong Kong Polytechnic University and registered at ClinicalTrials.gov, number NCT01236742. Written consent was obtained from both subjects and their parents before study participation. Ortho-k subjects from the initial 2-year myopia control studies who agreed to participate were assigned mainly by randomizing them into two ortho-k groups but due to a few refusals to be randomized, four subjects were allowed to transfer to the group they preferred. The two ortho-k groups were Group OKc where subjects continued ortho-k lens wear for the duration of the study; and Group OKd where subjects discontinued lens wear for seven months and wore single-vision spectacles (Phase I) and then resumed ortho-k lens wear for another seven months (Phase II). All spectacle-wearing control subjects were also invited to continue as control subjects (Group C) and to continue wearing spectacles during the study.

2.1. Group OKd

At the beginning of Phase I (Spectacle-wear phase), in the RS (Refraction Stabilization) period, subjects were required to wear single-vision spectacles to aid distance vision. They could use their old spectacles from before ortho-k use if the prescription was within ±0.50 DS and ±0.50 DC from the refraction determined at the time of visit, otherwise, a new pair of spectacle lenses was ordered. They were required to return weekly until stabilization of refractive errors was achieved. Refraction was considered stabilized when changes in refractive sphere and refractive cylinder in manifest refraction and change in apical radius in corneal topography between two consecutive visits was 0.25 D or less. Refraction measured after stabilization was used to prescribe a new pair of spectacles which were delivered at Visit I-1 (baseline of Phase I, see Table 1). All subjects were required to wear the fully-corrected spectacles in the daytime during Phase I. They were excluded if they used any contact lenses during Phase I. New ortho-k lenses for these subjects were ordered one month before the end of Phase I (ie. at Visit I-6) and dispensed at the end of Phase I (Visit I-7) before commencing Phase II (Table 1) (Ortho-k phase), in which the subjects were required to wear the lenses every night unless otherwise instructed by their examiner, for example, in cases of illness, sore eyes, or presence of corneal insult. Refractive correction with ortho-k was considered stabilized when changes in manifest refractive sphere and refractive cylinder and change in apical radius in corneal topography between two consecutive visits was not more than 0.25 D. Baseline of Phase II was performed at Visit II-1 and the examination was repeated six months later at Visit II-7.

2.2. Group C and Group OKc

Subjects were required to wear their habitual spectacles (Group C) or ortho-k lenses (Group OKc) at the commencement of Phase I, before Visit I-1. New glasses were prescribed based on the prescription determined at Visit I-0 and new spectacles were delivered at Visit I-1 and if indicated (based on data collected at Visit I-6), at Visit I-7 before commencing Phase II. There was no RS period for these two groups of subjects, but, similar to Group OKd, cycloplegic and non-cycloplegic data correction visits were scheduled accordingly.

All subjects were required to use the prescribed spectacles/ortho-k lenses every day/night unless otherwise instructed. Regular ortho-k aftercare visits (Table 2) were arranged for all ortho-k subjects upon delivery of ortho-k lenses to ensure healthy and safe ortho-k lens wear. The ortho-k effect was reviewed one night, one week, two weeks, three weeks, one month, and every 2–3 months after commencing lens wear. Complimentary contact

Table 1
Data collection visits.

Cycloplegic	Non-cycloplegic	Description	Remark
Phase I			
I-0		Baseline	End of the initial 2-year myopia control study
[RS period: Weekly visits (for Group OKd subjects) to determine stabilization of refraction. Order new orthokeratology lenses/spectacles for the 3 groups of subjects for delivery at Visit I-1 (Prescription for Group C and OKc should not be more than 1 month old)]			
I-1		End of RS period in Phase I for OKd; or 28 (±3 days) after I-0 for OKc and control and for subjects in OKd if RS period was less than 4 weeks	Delivery of glasses for control and OKd and ortho-k lenses for OKc
	I-3	2 (±1 week) after I-I	
	I-6	5 months (±1 week) after I-1	Order new ortho-k lenses/spectacles based on updated Rx for the 3 groups of subjects for Visit I-7 where indicated
I-7		6 months (±1 week) after I-1	Delivery of glasses for control and OKc, and ortho-k lenses for OKd and OKc (if deemed necessary)
Phase II			
II-0		Equivalent to Visit I-7	
II-1		End of RS period for OKd or 28(±3 days) after II-0 for OKc and control and for subjects in OKd if RS period was less than 4 weeks	
	II-3	2 (±1 week) after II-1	
	II-6	5 months (±1 week) after II-1	
II-7		6 months (±1 week) after II-1	

RS – Refraction-Stabilization.
Group OKc – Orthokeratology subjects who continued orthokeratology lens wear for the whole experiment period.
Group OKd – Orthokeratology subjects who discontinued orthokeratology lens wear in Phase I and resumed orthokeratology lens wear in Phase II.

Table 2
Scheduled aftercare visits for orthokeratology subjects.

Commencement of lens wear	The night when the ortho-k treatment commenced or resumed. Within 14 days after the last data collection visit, if applicable,
First overnight visit	The following morning after commencing lens wear. Within 2 h after awakening in the morning.
One-week visit	Seven days (± 3 days) after commencing lens wear. Within 2 h after awakening in the morning.
Two-week visit	Fourteen days (± 3 days) after commencing lens wear. Within 2 h after awakening in the morning.
Three-week visit	Twenty-one days (± 3 days) after commencing lens wear. Within 2 h after awakening in the morning.
One-month visit	Twenty-eight days (± 3 days) after commencing lens wear. Can be in the morning or in the afternoon.
Three-monthly visit	Coincided with data collection visits

lens solutions and lens accessories were also supplied to OKd and OKc subjects during the treatment to ensure compliance with replacement. They also had to complete a daily compliance check list in an ortho-k journal provided. Subjects using ortho-k with residual refractive error more than −0.75DS would be prescribed with a pair of spectacles to be used in the daytime when indicated. They were required to returned the ortho-k lenses at the completion of study at Visit II-7. Weekly review on the regression of refraction and corneal topography would be performed and subjects would be dismissed from the study upon stabilization of changes in refractive error and corneal topography.

2.3. Data collection visits

Cycloplegic (0.5% alcaine followed by 1% tropicamide and 1% cyclopentolate) data collection visits were conducted at the beginning of each phase, after one month, and at the end of each phase. Non-cycloplegic data was collected after three and six months into each phase. To minimize the effect of diurnal variation, data collection visits were scheduled at about the same time of the day for each visit.

Subjective and objective refraction were measured; the latter using the Shin-Nippon NVision-K 5001 open field autorefractor (Shin-Nippon Commerce Inc, Tokyo, Japan). Corneal topography was performed with Medmont E300, Australia) and ocular integrity assessed using a slitlamp (Topcon SL-D7; Topcon Corp., Tokyo, Japan). Axial length measurements were performed by a masked examiner using the IOLMaster (Zeiss Humphrey, Dublin, CA, USA).

2.4. Ortho-k lenses, solutions and spectacles lenses

Menicon Z Night and Night Toric lenses (NKL Contactlenzen BV, Emmen, The Netherlands) were used. Lenses were ordered using the Easy Fit software from NKL. Complimentary solutions (Menicon O2 Care for daily cleaning, Menicare Plus for daily disinfection and Menicon Progent for protein removal, Menicon Co. Ltd, Japan; Tears Naturale Free for eye lubrication, Alcon Hong Kong Ltd) were prescribed to the ortho-k subjects, but subjects had to purchase preserved saline for lens rinsing. All solutions had to be replaced monthly.

Complimentary spectacles lenses (refractive index 1.56 spherical lenses; Founder Optical Company, Hong Kong) were provided, if indicated during the RS period. Once the refraction had stabilized at the end of the RS period, new complimentary spectacle lenses were prescribed. For the Control and OKc subjects, spectacles and new ortho-k lenses, respectively were provided at the commencement of the study.

2.5. Statistical analysis

Statistical analyses were performed using SPSS version 23. Data were first tested to check if they deviated from normality. Oneway ANOVA or Kruskal-Wallis test, as appropriate, was used to test for differences between groups. Changes in axial length between groups, controlled for age and initial axial length, were evaluated using analysis of covariance (ANCOVA), and within groups using repeated measures ANCOVA.

3. Results

A total of 64 ortho-k and 72 control subjects from ROMIO [6] and TO-SEE [7] studies were invited to participate but only 53 agreed. A total of 16, 19 and 18 subjects were recruited for the Control, OKc, and OKd groups, respectively but only 13, 16, and 15 subjects, respectively completed the study. Subjects were 8–14 years old when they commenced this study.

All subjects were able to comply with the instruction on lens wear, i.e. at least eight hours a day and at least five hours a week, either using spectacles or ortho-k lenses.

The baseline refractive errors of the subjects before they commenced ROMIO/TO-SEE studies and before and during this study are shown in Table 3. All OKd subjects achieved stabilization of refraction within six weeks after ceasing lens wear in Phase I and within five weeks after commencement of lens wear in Phase II.

Table 3
Demographic data of the three groups of subjects.

	Control (N = 13)	Okc (N = 16)	Okd (N = 15)	P value
Baseline (before commencing initial 2-year myopia control studies[#]) (retrospective data)				
SER (D)	−2.12 ± 0.81	−2.42 ± 0.92	−2.36 ± 1.06	0.676*
Axial length (mm)	24.07 ± 0.79	24.26 ± 0.89	24.61 ± 0.90	0.255*
Baseline (before commencing current study)				
Age (years, median (range))	11.0 (9–13)	11.0 (9–12)	10.0 (10–14)	0.479**
Axial length (mm)	24.69 ± 0.88	24.72 ± 0.90	24.94 ± 0.89	0.704*

P value – probability values from * One-way ANOVA; **Kruskal-Wallis test.
[#] ROMIO[6]/TO-SEE[7] studies.

At Visit I-0, all pertinent data, except for age, were normally distributed ($p > 0.05$). No significant differences in age, initial Rx, initial axial length and axial length were found among the three groups of subjects (age: Kruskal-Wallis test, $p = 0.479$; AL: one-way ANOVA, $0.255 < p < 0.704$). At the end of Phase I, after adjusting for age and initial axial length before commencing this study, significant differences in axial elongation were found among the three groups of subjects (ANCOVA, $p = 0.041$). However, these differences were not observed in Phase II (ANCOVA, $p = 0.945$) (Table 4). Post hoc with LCD tests indicated that the differences in Phase 1 were between OKd and the other two groups of subjects (Control vs OKd, $p = 0.027$; OKc vs OKd, $p = 0.030$). Axial elongation in OKd group was faster than those of Control and OKc subjects in this phase. Changes in axial length (unadjusted) during the different phases of the study are shown in Fig. 1. The graph shows wide and overlapping standard deviations at each visit within groups, indicating large variations.

4. Discussion

This is the first study to investigate the effects of discontinuation and resumption of ortho-k lens wear in children. The results of this study showed a faster axial elongation in OKd group compared to those of OKc and Control in Phase I of the study. We believe that this is the first longitudinal study to address the concerns of dependency on ortho-k once children commenced treatment and effect on refraction after discontinuation of lens wear. Although the sample sizes were relatively small and therefore the power of the study was limited, some interesting observations were noted.

In Phase I, axial elongation of OKd subjects was faster when lens wear was terminated after two years of ortho-k lens wear. The rate appeared to be similar to that of progression of control subjects wearing spectacles during the initial myopia control studies (ROMIO [6]/TO-SEE [7]) (see Fig. 2). Since OKd subjects were aged 10 to 14 years when they commenced participation in this study, the results of this study suggested that ortho-k treatment should not stop at the age of 14. So, if termination of treatment at 14 years old is not recommended, when should it be terminated? The COMET group (COMET study [17]) evaluated the age of myopia stabilization of children of different ethnic groups. They monitored the refraction of the subjects over 11 years and, based on seven refraction assessments, they reported that the age of stabilization of myopia for Asian subjects was 16 years old. However, it should be noted that at age 16, the proportion of their Asian subjects with estimated stable myopia was about 60%, that is to say, the myopia of 40% of the subjects were still progressing, *albeit* at a slower rate.

Another interesting observation that may be observed in Fig. 2 is that axial elongation after resuming lens wear in Phase II (month 31–38) was slower than the rate before stopping lens wear (before month 24). It appears that after stopping lens wear for six months, resuming lens wear led to much slower axial elongation, although it is unclear why. Possibly, the myopia progression mechanism was disrupted due to the interrupted lens wear pattern. Nevertheless, if the rate continued to be slower, with continued lens wear for another 12 months, OKd subjects may eventually have a much lower increase in axial length than if they did not stop lens wear.

The results of this study indicated that taking short break of limited period from lens wear did not adversely affect axial elongation if lens wear was later resumed. This information is important for practitioners and parents; they can be assured that allowing their child to take a break from lens wear in case of illness or travelling, may not affect the overall outcome of the treatment.

Table 4
Six-monthly increases (mean (SE)) in axial length (mm), adjusted for age and axial length before commencing the study.

	Control (N = 13)	Okc (N = 16)	Okd (N = 15)	P value
Phase I	0.082 (0.022)	0.087 (0.020)	0.153 (0.021)	0.041
Phase II	0.064 (0.015)	0.068 (0.013)	0.059 (0.014)	0.901

P value – probability values from ANCOVA.

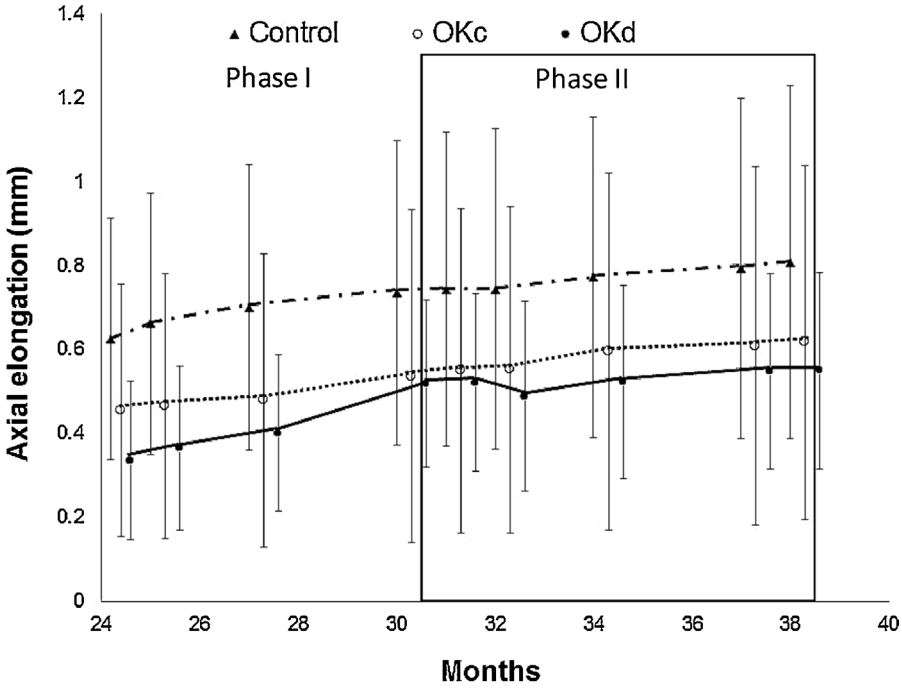

Fig. 1. Axial elongation of the subjects at each visit over 14 months (starting at month 24, as current study commenced following completion of a 2-year myopia control study). Control – continued to wear single vision spectacles in both Phases of the study; OKc – continued to wear orthokeratology lenses in both Phases of the study; OKd – ceased orthokeratology lens wear for 6 months (Phase I) and then resumed lens wear in Phase II.
Data points shown in the graph are staggered to allow easier view of the error bar. Each error bar represents one standard deviation.

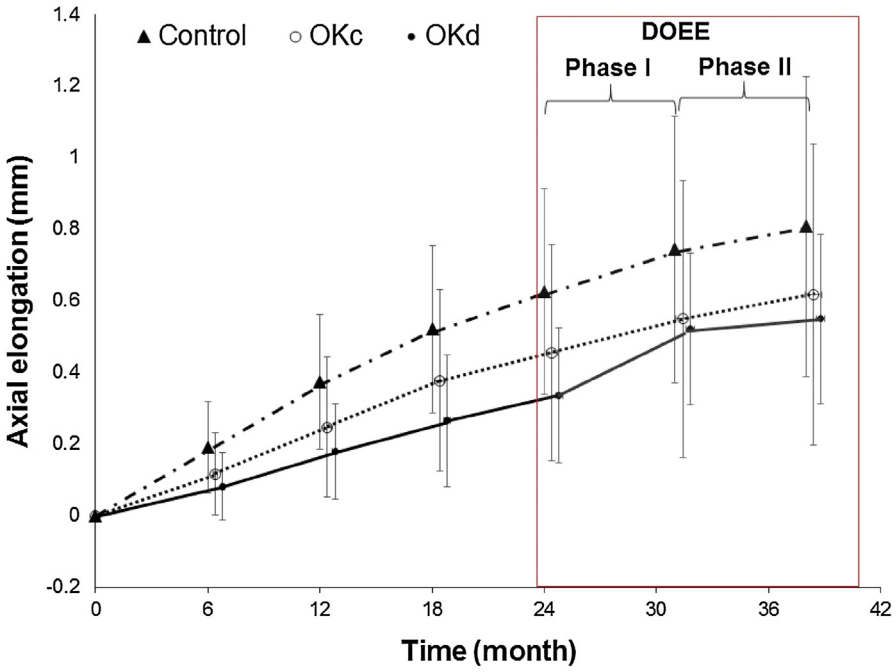

Fig. 2. Axial elongation of the subjects at each visit, including data (retrospective) from subjects' initial 2-year myopia control study. Control – continued to wear single vision spectacles in both Phases of the study; OKc – continued to wear orthokeratology lenses in both Phases of the study; OKd – ceased orthokeratology lens wear for 6 months (Phase I) and then resumed lens wear in Phase II.
Data collection visits for the three groups of subjects were the same but data points shown in the graph are staggered to allow easier view of the error bar. Each error bar represents one standard deviation.

The results of this study suggest a potential option for parents who ask if their children could stop lens wear after two years of myopia control. Practitioners could suggest ceasing lens wear for six months, and monitor eyeball elongation every three months. If the axial elongation rate increased, then they should resume lens wear after six months.

Randomisation of subjects into OKd and OKc groups was initially attempted but abandoned after a few parents refused to participate in the study if their children were assigned to OKd group. Although clinical trials involving children often encounter difficulties with subject recruitment and retention, this study encountered more difficulties than most in enrolling subjects for several reasons. The most important reasons for refusal of subjects to stop ortho-k lens wear were fears of losing the benefits of the initial 2-year myopia control treatment and the need for vision correction in the daytime once they stopped lens wear. Many subjects were reluctant to participate in this study because of the need to attend frequent scheduled visits and the necessity of cycloplegic examination as the drug used affected their near work for at least a day; about 16–19% of subjects dropped out of the study for these reasons.

Compliance with lens wear and care was carefully monitored throughout the study. Subjects were requested to withdraw from the study if any of the following occurred: persistent corneal staining (>Grade 2 in Efron's scale [18]); non-compliance with study protocol (e.g. wearing contact lenses during the discontinuation period or rarely use ortho-k lenses during the lens wear period).

Clearly there are problems both with recruitment of subjects leading to a small sample size and inability to completely randomize subjects into different groups. However, the study does show a significant different in rates of axial elongation during the period of discontinuation of lens wear, which can be reversed by resumption. We believe that any other study including similar groups of subjects is likely to encounter similar difficulties.

From experience, once children are undergoing successful ortho-k treatment, parents are reluctant to stop as the treatment because, apart from being effective in slowing myopia progression, it also allows their children to be free from the need to wear any vision correction in the daytime, bringing convenience to daily activities for their children. The major concern of parents commencing ortho-k treatment is not knowing when they can discontinue the treatment. About 50% of the ortho-k subjects continued to wear ortho-k lenses after the study. It is hoped that these subjects and those who have discontinued can be contacted at a later date for assessment of their ocular parameters.

In summary, axial elongation appeared to speed up when ortho-k lens wear was terminated after two years of ortho-k lens wear, before or at the age of 14. The rate of elongation was similar to those wearing spectacles during their 2-year myopia control study, but more rapid than either the control and OKc group in this study.

The results of this study suggest that early termination of ortho-k treatment may not be recommended and, in case of discontinuation, it would be prudent to continue to monitor axial elongation after stopping lens wear for at least 6 months and to resume lens wear if rapid axial elongation was observed during the discontinuation period.

Conflicts of interest

None.

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