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Pre-treatment observation of axial elongation for evidence-based selection of children in Hong Kong for myopia control☆,☆☆,★

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ABSTRACT

Purpose: This study aimed to develop evidence-based guidelines for identifying suitable subjects for myopia control using orthokeratology (ortho-k).

Methods: Changes in axial elongation (AE) in the worse eyes of 66 myopic children (myopia between −0.75 and −4.50 D and astigmatism < 2.00D, and aged 6 to < 16 years old) who wore single-vision spectacles for seven months before switching to orthokeratology treatment for another seven months were observed.

Results: AE during ortho-k lens wear was affected by age and rate of progression during spectacle wear. The percentage of subjects with rapid, moderate, and slow AE (equivalent annual myopia progression; rapid: ≥1.00D; moderate: 0.50D to < 1.00D; slow: < 0.50D) during spectacle wear was 36.3%, 33.3% and 30.3%, respectively. Rapid progression was most common in subjects aged less than nine, but 25% of subjects aged 9 to < 13 and 12.5% aged 13 to < 16 also demonstrated rapid progression. All subjects with rapid AE during spectacle wear achieved a significant reduction in eye elongation with ortho-k lens wear. Guidelines for patient selection was proposed based on the initial age and history of myopia progression.

Conclusions: Myopia control is indicated for children at risk of developing high myopia. The suggested guidelines can help practitioners to identify children for whom the benefits outweigh the risks of serious adverse events.

1. Introduction

Myopia is a common ocular refractive disorder usually developing in childhood. In most patients, it will stabilize at a fairly low level and can be easily corrected with conventional contact lenses or spectacles [1]. However, in some patients, myopia will progress rapidly, reaching 6.00D or more [1]. This level of myopia, which is more common in East Asian [2] greatly increases the risk of serious ocular complications in later life, including maculopathy, cataract, and open-angle glaucoma [3]. Thus, intervention to prevent high myopia is crucial to avoid the risk of sight-threatening events. Orthokeratology (ortho-k) has been shown to slow axial elongation in myopic children in Asia, Europe, and North America [4–10]. The procedure involves the application of a rigid lens on the cornea to flatten the cornea and temporarily reduce the myopia. The exact mechanism of myopia control using ortho-k is still under investigation but it is believed to be associated with changes in the peripheral optics of the eyes [11,12].

Although early studies investigating effectiveness of ortho-k for myopia control suggested that axial elongation was associated with the initial amount of myopia in children, with those having lower initial myopia demonstrating faster axial elongation [4], however, the effects of initial age or rate of axial elongation were not considered. Later, a randomized controlled study showed that axial elongation was not actually associated with the initial myopia, but was inversely associated with the initial age of the subjects receiving ortho-k and single-vision spectacles [6]. Similar findings have been reported by other studies [7,8].

Studies of children using spectacles for myopic refractive error correction have suggested that younger children with lower initial myopia have faster myopia progression than older children [13,14]. A

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☆☆ Some of the results of this study were presented at the 4th Asia Orthokeratology and Specialty Lens Conference, 13–14 December 2014 Taipei, Taiwan.

★ An analysis based on results of the right eye only were presentation at the 16th International Cornea & Contact Lens Congress, 8–10 September 2017 Sydney, Australia.

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retrospective study [15] has shown that ortho-k reduced the risk of rapid progression in children undergoing ortho-k compared to those wearing spectacles. For children whose myopia remains low (i.e. not showing progression), other options for myopia correction exist, but ortho-k may be most appropriate for those who are experiencing rapid progression of myopia. Although it is generally agreed that children with a history of rapid myopia progression will benefit more from myopia control interventions, little has been done to measure and investigate this factor in clinical trials on myopia control. Practitioners therefore need evidence-based guidance to identify high risk children who are more likely to progress rapidly towards high myopia, rather than merely offering ortho-k to all children presenting with myopia.

The current prospective study incorporated a monitoring period to determine the initial rate of myopia progression in a group of young subjects in terms of axial elongation before switching them to ortho-k. The primary objective was to develop guidelines for the management of myopia, based on age and progression rate. The current study used ortho-k as the myopia prevention treatment, but use of these guidelines may be applicable to other myopia interventions.

2. Methods

In this 14-month prospective cross-over study, low myopic children subjects wearing spectacles were monitored for seven months to determine their progression rate in axial elongation before switching to ortho-k for another seven months. To allow one month of stabilization of ortho-k lenses and six months of monitoring after stabilization of treatment, each phase was monitored for seven months in duration. Rate of axial elongation during the two study phases were determined and compared for subjects in three different age groups: Younger Children (YC) (6 to < 9 years), Older Children (OC) (9 to < 13 years), and Early Adolescents (EA) (13 to < 16 years). The stratification for the YC and OC groups was in accordance with the earlier study by Cho and Cheung [15] for the difference in risk of rapid progression. Axial elongation during spectacle wear phase was divided into three categories: slow (axial elongation < 0.10 mm in seven months; equivalent to < 0.50 D increase in myopia in one year), moderate (axial elongation between 0.10 mm but < 0.20 mm in seven months; equivalent to 0.50 D to < 1.00 D increase in myopia in one year), rapid (axial elongation ≥ 0.20 mm in seven months; equivalent to ≥ 1.00 D increase in myopia in one year [16,17].

Effect of age, gender, refractive error, and axial elongation during spectacle wear phase on reduction in axial elongation after ortho-k lens wear was investigated. Myopia control on reducing rapid progression in the three age groups was evaluated. Results obtained were used to develop guidlines for the identification of children who would benefit from ortho-k treatment.

The study followed the tenets of the Declaration of Helsinki. It was approved by the Ethics Committee of the School of Optometry of The Hong Kong Polytechnic University and registered at ClinicalTrials.gov, number NCT01236755; registration date: November 8, 2010. The study methods were performed in accordance with the approved guidelines of the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University.

2.1. Subjects

Myopic children aged from six to not more than 16 years were recruited. Refractive sphere and spherical equivalent after cycloplegia were between –0.75 to –4.50 D, whilst refractive astigmatism after cycloplegia was not more than 2.00 D (negative cylinder). All subjects recruited for this study had no previous experience in myopia control or contact lens wear and had no contra-indication for ortho-k lens wear. Informed consent was obtained from the subjects and their parents prior to the commencement of the study. They were required to attend nine regular visits in 14 months (see Fig. 1), including five cycloplegic

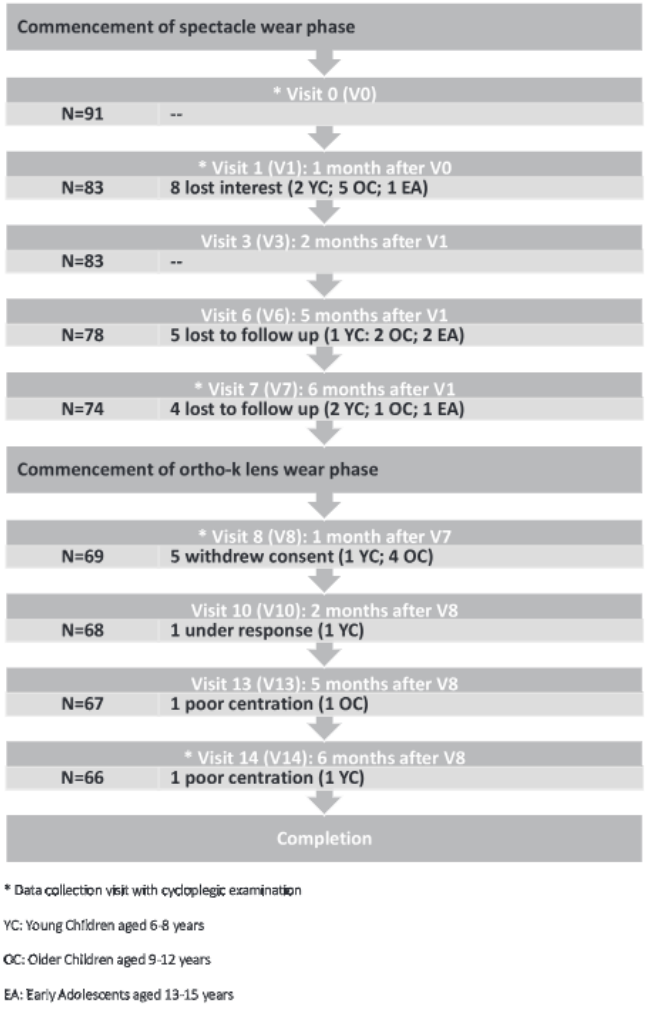

Fig. 1. Study flowchart and reasons for dropout.

data collection visits namely V0, V1, V7, V8 and V14 (number referring to months after commencement of study) and four non-cycloplegic visits namely V3, V6, V10 and V13. The non-cycloplegic visits were arranged to review refraction and vision because of short duration of the study. Additional visits were arranged between V6 and V7 for instruction in lens handling, and V7 and V8 for ortho-k aftercare accordingly.

All eligible subjects were prescribed with a pair of single-vision glasses (refractive index 1.56 spherical lenses; Founder Optical Company, Hong Kong) which were used for the first seven months of the study. A pair of ortho-k lenses were ordered (Menicon Z Night or Menicon Z Night Toric ortho-k lenses; NKL Contactlenzen BV, Emmen, The Netherlands), based on the refractive error and corneal topography obtained at V6. Subjects were taught to use ortho-k lenses between V6 and V7.

At V7, seven months after enrollment, ortho-k lenses were dispensed to those who could successfully handle lens insertion, removal, and cleaning. Both the subjects and their parents were given written instructions on proper lens use and care. Complimentary care solutions were provided and bottle solutions were replaced monthly to enhance compliance. Menicon care system products (Menicon Co. Ltd, Nagoya, Japan) were used for daily cleaning (Menicon Spray & Clean), daily disinfection (MeniCare Plus), and weekly protein removal (Menicon Progent), whilst non-preserved unidose artificial tears (Tears Naturale Free, Alcon, Fort Worth, Tx, USA) were used for lubrication prior to lens insertion and in case of lens binding. Subjects were instructed to use normal saline to rinse lenses prior to lens wear and after cleaning with

Table 1
Demographic data and ocular parameters of the worse eyes at the beginning of the study (V0) and before commencement of ortho-k (V7) for the 66 subjects in the three age groups.

Demographic data	Younger Children (6 to < 9 years) (N = 14)	Older Children (9 to < 13 years) (N = 36)	Early Adolescents (13 to < 16 years) (N = 16)	p-value
Median age at V0 (years)	8.10	11.48	13.90	–
Male/Female	3/11	21/15	3/13	0.007[a]
Sphere at V0 (D)	–2.34 ± 0.74	–2.43 ± 0.85	–2.70 ± 0.83	0.43[b]
Cylinder at V0 (D)	–0.32 ± 0.27	–0.34 ± 0.39	–0.50 ± 0.42	0.39[c]
SER at V0 (D)	–2.50 ± 0.74	–2.60 ± 0.89	–2.95 ± 0.91	0.30[b]
Axial length at V0 (mm)	23.94 ± 0.51[#]	24.65 ± 0.80	24.77 ± 0.90	0.008[b]
Sphere at V7 (D)	–3.00 ± 0.86	–2.67 ± 0.90	–2.83 ± 0.90	0.50[b]
Cylinder at V7 (D)	–0.36 ± 0.29	–0.46 ± 0.41	–0.53 ± 0.456	0.66[c]
SER at V7 (D)	–3.18 ± 0.88	–2.90 ± 0.92	–3.09 ± 0.96	0.58[b]
Axial length at V7 (mm)	24.25 ± 0.51	24.79 ± 0.80	24.85 ± 0.93	0.07[b]

p-value: probability values for between-group comparisons using:
[a] Chi-square tests.
[b] One-way ANOVAs.
[c] Kruskal-Wallis tests.
[#] Post-hoc test for one-way ANOVAs: Younger Children: significantly shorter axial length than the Older Children ($p = 0.014$) and Early Adolescents ($p = 0.014$) at V0.

the daily cleaner.

Subjects were required to attend scheduled ortho-k aftercare visits after lens dispensing, that is, one night, one week, two weeks, three weeks, and one month after commencement of lens wear. Refractive correction was considered to be stabilized if changes in corneal topography and refractive error were within 0.25 D in two consecutive weekly visits after optimal effect was achieved, i.e. monocular unaided vision better than 0.10 logMAR without compromising corneal integrity. If target correction could not be achieved or if the refractive change did not stabilize within one month of lens wear, the subjects were required to attend weekly aftercare until an optimal effect could be achieved after lens modification. Subjects would be excluded if optimal ortho-k effect could not be achieved after a maximum of three lens modifications and/or if poor compliance with the use of ortho-k lenses was observed. They were required to return the ortho-k lenses and all unused solutions at the end of the study period.

2.2. Examination procedures

At the cycloplegic data collection visit, vision and subjective refraction, corneal topography (Medmont E300 topographer, Medmont Pty Ltd, Vermont, VIC, Australia), and slit-lamp biomicroscopy (TOPCON slit-lamp SL7 and TOPCON IMAGEnet system, Topcon Corp., Tokyo, Japan) were performed before cycloplegia, using one drop of 0.5% a proparacaine followed by 1% tropicamide and 1% cyclopentolate, five minutes apart. Push-up test and pupil reflex were performed 30 min after instillation of the eyedrops to ensure effectiveness of cycloplegia. Effective cytoplegia required that a subject must have less than 2.00 D residual accommodation and dilated pupil in each eye before proceeding to the post-cycloplegic examination. Cycloplegic subjective and objective refraction (Shin-Nippon NVision K5001, Shin-Nippon Commerce Inc., Tokyo, Japan), and axial length (IOLMaster; Carl Zeiss Meditec, Inc., CA, US) were measured after pupil dilation and relaxation of accommodation. The assessment of the primary outcome, that is, axial length, was performed by a masked examiner.

2.3. Statistical analysis

Results from the eyes with greater axial elongation in the spectacle wear phase (the worse eye) were used for data analyses. The selection is based on clinical practice that myopia control will be recommended even if only one eye is progressing rapidly. The eyes with greater myopic shift in refractive error were selected if there was no difference in axial elongation in the two eyes. Parametric tests were used for data which followed a normal distribution (refractive sphere, spherical equivalent, and axial length) and non-parametric tests were used for data which demonstrated non-Gaussian distribution (refractive cylinder). Repeated measures ANOVAs comparing axial length at the baseline (V0), at the end of the spectacle wear phase (V7), and at the end of the ortho-k lens wear phase (V14) were used to determine the effect of time (i.e. use of spectacles versus use of ortho-k) on axial length. One-way ANOVAs were used to determine the between-group effect by comparing the changes in axial length among the three groups of subject during spectacle wear, ortho-k lens wear, and the overall 14 months. Post-hoc tests with Bonferroni correction were performed to follow up the significant main effects found in the ANOVAs. Stepwise multiple linear regression was used to study the association between reduction in axial elongation (elongation during ortho-k and elongation during spectacle wear) and the demographic (including age and gender), and ocular (including baseline refractive sphere and cylinder, and baseline axial length) characteristics.

3. Results

Of the 91 eligible subjects recruited, only 66 completed the study: 17 dropped out during the spectacle wear phase due to withdrawal of consent or lost to follow up, and eight dropped out in ortho-k lens wear phase (five withdrew consent due to subjects refusing to wear ortho-k lenses or non-compliance with ortho-k procedures; three due to poor ortho-k response related to poor centration or under response in refractive correction). All subjects, except two, achieved target correction within five weeks of lens wear; the two subjects stabilized after eight weeks of lens wear, after one modification of lens parameters. As the great majority of subjects achieved optimal correction by four weeks, the intervention was deemed to have lasted for seven months for all subjects in the calculation. No significant adverse event was reported and no subject was excluded due to ocular complications.

Table 1 shows the demographic data and baseline ocular parameters of the 66 subjects who completed the study. The majority of subjects were in the OC group (55%). Despite the lack of significant difference in the initial refractive error among the three groups of subjects ($p > 0.30$), subjects in the YC group had shorter initial axial length compared to the other two groups ($p = 0.008$).

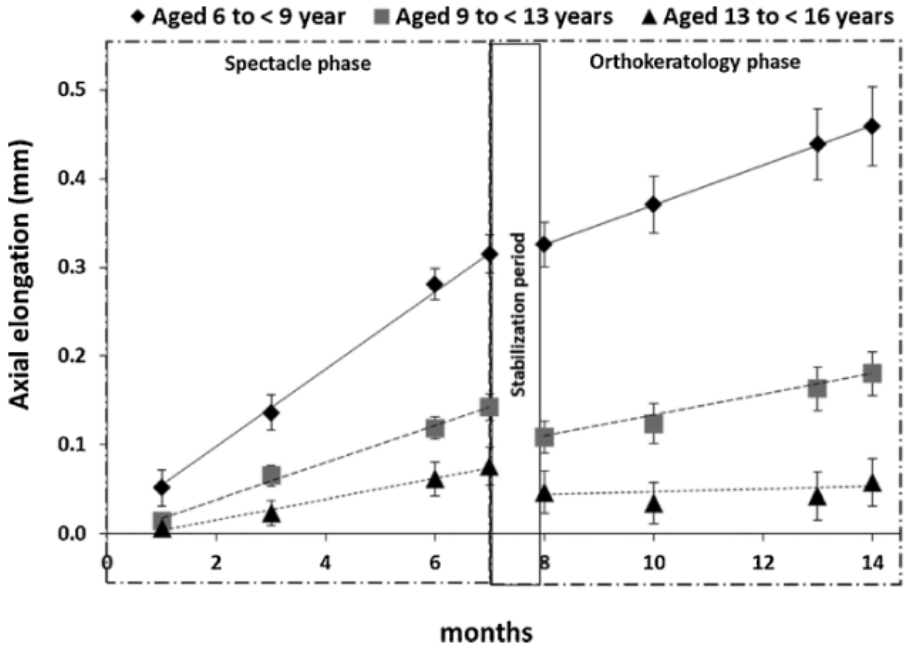

Fig. 2. Axial elongation of subjects in the three sub-groups (each error bar represents one standard error of the mean).

3.1. Axial elongation and myopia control effect

There was a significant increase in mean axial length over the total 14 months for all 66 subjects (Repeated measures, $p < 0.001$) (Fig. 2). Post hoc test revealed that mean axial elongation had significantly increased over both phases of the study ($p < 0.001$), but elongation was significantly slowed by 71% after switching from spectacles to ortho-k for all subjects (Table 2).

The axial elongation was significantly slower in the ortho-k lens wear phase in all the three groups (paired *t*-tests, $p \leq 0.01$). Overall elongation was fastest in the YC group, followed by the OC group (Table 2). The reduction in elongation varied, being much greater in younger children than in older subjects (Table 2). The reduction in elongation (that is, increase in axial length in spectacle wear phase – increase in axial length in ortho-k lens wear phase) was associated with the age groups and the progression during spectacle wear ($F_{2,63} = 19.83$, adjusted $R^2 = 0.37$, $p < 0.001$). However, the reduction was not associated with gender, refractive error, or the axial length at the commencement of ortho-k treatment ($p > 0.21$).

Results using 6-month data (that is, excluding stabilization month) showed similar trends: axial elongation was slowed after ortho-k treatment in all the three groups (paired *t*-tests, $p < 0.016$) with the fastest progression in the YC group and the slowest progression in the EA group (One-way ANOVA, $p < 0.001$). Again, reduction in axial elongation was associated with age group and history of progression ($F_{2,63} = 20.72$, adjusted $R^2 = 0.38$, $p < 0.001$), but not with the other factors being investigated ($p > 0.11$). Therefore, results based on the seven monthly changes were used in the following analyses to reflect the changes during the whole study period.

3.2. Rapid progression before and after orthokeratology

The use of ortho-k for the subjects in YC and OC groups was shown to be protective against rapid axial elongation, as the percentage of subjects progressing rapidly was significantly reduced from 93% to 29% in YC group and from 25% to 0% in the OC group (Table 3). For the EA group, only two subjects (2.5%) displayed rapid progression during spectacle wear phase and both became non-rapid after ortho-k use.

Fig. 3 shows the number of subjects demonstrating slow, moderate, and rapid progression in the two study phases. Among the 46 subjects demonstrating moderate to rapid progression in spectacle wear phase, axial elongation was reduced in 43 subjects during the ortho-k phase, remained unchanged in one, and slightly increased in two subjects. About 68% of these subjects achieved 50% reduction in axial elongation (Table 4). Axial elongation was clinically and statistically reduced by ≥0.10 mm in 7 months in almost 80% and 60% of subjects with rapid

Table 2
Axial elongation (mm) over the study period.

	Change in 7 months on spectacles	Change in 7 months on orthokeratology	Difference in elongation between phases	p-value[++]
All subjects 6 to < 16 years (n = 66)	0.163 ± 0.121	0.047 ± 0.112	–0.116 ± 0.122	**< 0.001**
Younger Children 6 to < 9 years (n = 14)	0.315 ± 0.081[a]	0.144 ± 0.128[a]	–0.171 ± 0.134	**< 0.001**
Older Children 9 to < 13 years (n = 36)	0.143 ± 0.092[b]	0.038 ± 0.092[c]	–0.105 ± 0.110	**< 0.001**
Early Adolescents 13 to < 16 years (n = 16)	0.076 ± 0.086	–0.018 ± 0.081	–0.094 ± 0.130	**0.011**

Significance between groups differences observed in the two study phases (One-way ANOVA, $p < 0.001$). Post-hoc tests with Bonferroni correction show:
[a] Younger Children significantly faster than Older Children ($p \leq 0.003$) and Early Adolescents ($p < 0.001$) in both phases.
[b] Older Children significantly faster than Early Adolescents ($p = 0.044$).
[c] Older Children not significantly different from Early Adolescents ($p = 0.192$).
[++] p-value - probability values for differences between the two phases using paired *t*-tests.

Table 3
Subjects with rapid (7 months increase ≥0.20 mm) and not rapid axial elongation in the two phases of the study.

	N	Spectacles	Orthokeratology	RR (95%CI)	p-value
Younger Children (6 to < 9 years)	14				
Rapid		13 (93%)	4 (29%)	0.31 (0.13–0.71)	**0.006**
Not rapid		1 (7%)	10 (71%)		
Older Children (9 to < 13 years)	36				
Rapid		9 (25%)	0 (0%)	0.05 (0.00–0.87)	**0.040**
Not rapid		27 (75%)	36 (100%)		
Early Adolescents (13 to < 16 years)	16				
Rapid		2 (13%)	0	0.20 (0.01–3.86)	0.287
Not rapid		14 (88%)	16 (100%)		

RR: relative risk of rapid progression after ortho–k treatment.
CI: confidence interval.
p-value: probability value for significance of relative risk; bold values indicate significant difference.

and moderate progression, respectively (Table 4). The remaining 20 subjects demonstrating slow progression in spectacle wear phase were aged nine or above (i.e. in OC and EA groups) and had a non-significant response to ortho-k. About 45% of the 20 slow progressors achieved 50% reduction in axial elongation, but only 10% of them demonstrated significant reduction in elongation (≥0.10 mm in 7 months) (Table 4).

4. Discussion

This study has confirmed the beneficial effects of ortho-k on slowing the rate of axial elongation as shown in previous studies [4–10]. In contrast to cohort and randomized control trial in which subjects received either conventional spectacles or ortho-k treatment, this study compared the rates of elongation of individual subjects during both spectacle wear and use of ortho-k lenses. The results revealed that ortho-k reduced overall axial elongation and these effects were most dramatic in the YC and OC groups, as the axial growth had already slowed considerably in most of the subjects in the EA group. It is tempting to use percentage reduction in axial elongation as an indicator of success of myopia control therapy, but it is important to observe the actual reduction in growth with respect to clinical relevance. It is generally accepted that axial elongation of 0.09 mm is equivalent to an increase in myopia of 0.25D [18]. Thus, if a slow progressor has an increase of 0.028 mm, achieving a high percentage reduction may not be clinically significant, whereas in a rapidly progressing subject, even a smaller percentage reduction could have a far greater clinical impact. For example, axial growth in one YC subject reduced from 0.31 to 0.16 mm (48% reduction) over the two study phases, whilst the axial elongation of an EA subject reduced from 0.06 to 0.02 mm (67% reduction). The treatment appears to have had a greater effect in the EA subject, but the amount of change is not clinically significant.

4.1. Development of guidelines for myopia control using ortho-k

It was observed that growth rate was not equal in all age groups, which was reflected in the range of changes in axial length as seen in Fig. 2. In particular, in the YC group, all subjects showed rapid axial elongation, with only one exception having moderate elongation (Fig. 3). It could be suggested that all young children presenting with myopia should be immediately offered an intervention [19]. However, in the current study, as about 10% would be slow or moderate progressors, delaying commencement allows the growth rate to be determined before considering the management of an individual child. This permits an informed decision to be made as to whether ortho-k should be recommended. As rapid myopia progression is known to increase the risk of long-term adverse events and this progression can be reduced by interventions, it would be unethical not to offer advice to parents of children whose refractive error is increasing. However, providing the best information to make that decision prevents an unnecessary risk of serious adverse events to the child and a high financial burden to the parents. For older children, where the percentage of slow/moderate progressors is higher, this wait-and-see period becomes even more useful and also prevents parents being railroaded into a major commitment, which may not be necessary. The information collected in these two study phases provide evidence for practitioners to communicate and understand the subsequent management plan with the parents.

Using the results of this study, with reference to observations in clinical practice, guidelines were constructed and are shown in Fig. 4. If no records of myopia progression are available, a short period of monitoring is required to make an informed decision for myopia management. Progression of myopia may be determined using either increase in axial length or refractive error, as appropriate. If progression is slow, results of the current study indicated that there is

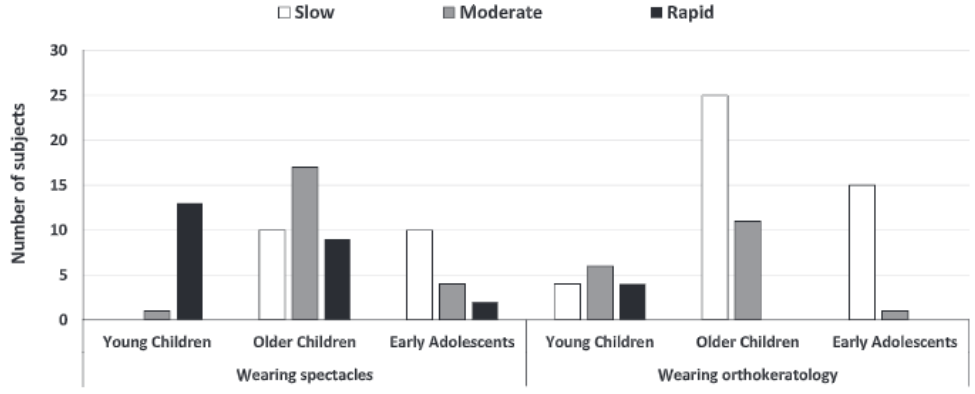

Fig. 3. Number of subjects with slow (axial elongation < 0.10 mm in 7 months), moderate (axial elongation 0.10 to < 0.20 mm in 7 months) and rapid (axial elongation ≥0.20 mm in 7 months) in the spectacle wear and orthokeratology lens wear in the three sub-groups.

Table 4
Comparison of changes in axial length (mm) between spectacle wear and orthokeratology lens wear periods, with respect to the rate of progression during spectacle wear phase. The mean reduction and mean percentage of reduction in axial length, the percentage of subjects with reduction more than 50%, and the percentage of subjects with reduction of 0.10 mm or more were shown.

Progression	N	Spectacles	Orthokeratology	Reduction	% reduce	p-value	MC ≥ 50%	AER ≥ 0.10
Rapid	24	0.291 ± 0.077	0.094 ± 0.124	0.197 ± 0.116	71 ± 41	< 0.001	67%	79%
Moderate	22	0.156 ± 0.030	0.025 ± 0.101	0.121 ± 0.094	88 ± 70	< 0.001	68%	59%
Slow	20	0.028 ± 0.044	0.015 ± 0.090	0.014 ± 0.074	36 ± 151	0.422	45%	10%

p-value: probability values for differences in axial elongation between the two phases.
% reduce: Percentage of reduction in axial elongation.
MC ≥ 50%: Percentage of subjects with reduction in axial elongation more than 50%.
AER ≥ 0.10: Percentage of subjects with reduction in axial elongation ≥ 0.10 mm in 7 months (equivalent to ≥ 0.50 D in 1 year).

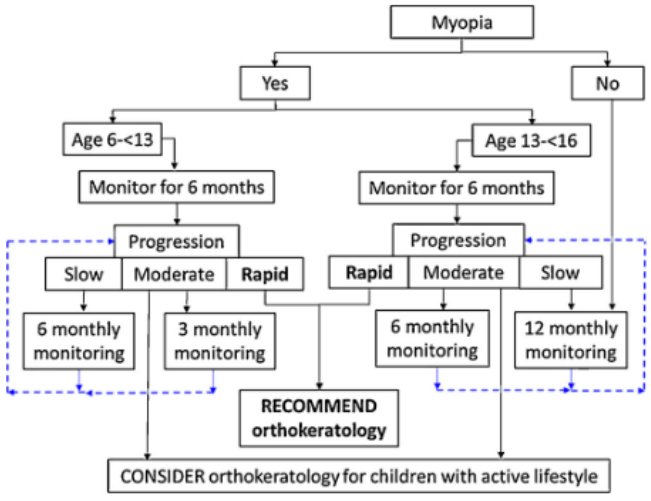

Fig. 4. Guidelines for myopia control management for children aged 6 to < 16 years. Definition of progression: slow (axial elongation < 0.10 mm in 7 months), moderate (axial elongation 0.10 to < 0.20 mm in 7 months) and rapid (axial elongation ≥ 0.20 mm in 7 months).

apparently little justification for the use of ortho-k, as these subjects are unlikely to develop high myopia. In contrast, for children whose myopia is progressing moderately, a decision can be made reflecting both the continuing growth and the life style of the child. For active children, as they can enjoy unaided daytime vision as in other contact lens wear [20,21], as well as possibly slowing axial elongation, ortho-k treatment may be considered. Whilst for less active children, a further monitoring period of 3–6 months, depending on age, may be appropriate before deciding to undertake myopia control.

It has been observed that there are seasonal differences in rates of axial elongation in most ethnic groups with lower growth rate in the summer months [22]. However, it was noted that such differences did not reach statistical significance in children of Asian background [22], or Japanese children [23].

Longer monitoring period for 13–16 years-old children is suggested as growth tended to have slowed down in this group. If growth continues, ortho-k treatment can be commenced. For any child with a record of rapid progression or demonstrating rapid axial growth during the monitoring period, immediate myopia control treatment is recommended. After commencing treatment, a six monthly follow up to determine the myopia control effect and decide whether to continue would be prudent.

The proposed guidelines may be applicable to all myopia control interventions and are based on two pertinent clinical data: age and refractive error/axial elongation. In the current study, history of progression was determined by axial elongation, but this can be replaced by refraction in clinical practice. Further research may allow for modifications to the guidelines applicable to individual regions, ethnicities, and clinical practice.

4.2. Proposed guidelines for myopia control management

As myopia control with ortho-k improves unaided daytime vision, it is popular with parents as a form of vision correction. However, ortho-k also involves higher risk of serious complications than other myopia control treatment [24,25] and therefore, should not be undertaken without due consideration of both the child's ability and willingness and parent's ability to provide supervision and support for the child. The dropout rate in the current study shows that ortho-k may not be suitable for all children, as some are unable to tolerate lens wear or unwilling to attempt lens use [5,9]. Whilst ortho-k can help to control myopia progression, it does need to be recognized that careful monitoring after fitting is essential [26], to ensure early termination of the treatment for children with poor response to reduce the unnecessary risk of ocular complications and improve safety [27]. The cost of myopia control interventions is relatively high, therefore, a cost effective management plan to select the best candidates and aid decision making would be beneficial to both parents and practitioners. The guidelines in Fig. 4 aim to help practitioners and parents make a clinical decision on initiation of treatment.

The current management plan for myopia control is indicated for children aged six to 16 years. Although the sample size for the YC and EA groups were not large, the guidelines were derived based on progression and response observed in the whole group of subjects. Age is important in that younger children are mostly likely to be rapid progressors, but rapid progression can occur in all age groups. As was noted in the study, a few adolescents may be still progressing rapidly. Thus, the decision needs to be taken based on the progression rate rather than the age alone. The six-month run-in period helps the practitioners to identify children with rapid progression and initiate treatment in a timely manner for those with higher likelihood of developing high myopia. Whilst this study did not include children younger than six years old, younger children do need to be screened for early onset of myopia, as knowledge of early rapid progression would allow for timely intervention.

It is believed that the proposed guidelines are the first to take into account the progression rate based on the axial elongation. Prescribing trends and basis for choice of treatment in large sample of practitioners worldwide were recently investigated and it was observed that a wide range of parameters were taken into account when making a decision [28]. However, there was little evidence-based approach adopted by the practitioners and it was noted that there was a need for the development of clear guidelines for myopia interventions [28]. Recently, guidelines for myopia control have been proposed based on familial risk, behavioral management, and choice of intervention in which both the benefits outweigh the risks and myopia progression is reduced by at least 50% [29]. Genetics is regarded as a risk factor for the prevalence of myopia, rather than a predictor for the severity of the myopia [30,31]. Although it is well recognized that increased outdoors activities reduces the onset of myopia [32,33], it may not reduce myopia progression [34]. The final provision of the guideline was the choice of effective intervention whilst reducing risk of adverse events to the

child. Ortho-k has been shown to be effective and the proposed guidelines would limit the intervention to those children who would benefit most.

The risk of myopia may be increased in lower income families [35] who may be unable to afford regular eye examination and myopia control treatment for their children. Government or other assistance with the cost of this treatment could help these children avoid the consequence of high myopia in later life. Preventing sight threatening consequences of high myopia can reduce the burden of care on society for the vision impaired.

In conclusion, this study has shown that identification of rapid progression of myopia is the most important pre-condition for strong recommendation of ortho-k treatment, as all rapid progressors benefitted from the treatment. It was observed that younger children were most likely to display rapid progression, but screening older children and even early adolescents may reveal some to be still progressing rapidly. The proposed structural management plan for myopia control allows identification of appropriate subjects for myopia control. Its use by practitioners could help to improve the professional standard for treatment by use of an evidence-based decision process. Adoption of this management plan could improve the cost and safety of myopia control using ortho-k.

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