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# The Control Effect of Orthokeratology (Ortho-k) Lenses on Axial Length Elongation in Chinese Children with Myopia

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## ABSTRACT

**Background:** To retrospectively compare axial elongation in children with different degrees of myopia wearing spectacles and undergoing ortho-k treatment.

**Methods:** The medical records of 128 patients who were fitted with spectacles or orthokeratology (ortho-k) lenses in our clinic between 2008 and 2009 were reviewed. Ortho-k group comprised 65 subjects and 63 subjects wearing spectacles were included in the control group. Subjects were also divided into low-myopia, moderate-myopia and high-myopia groups, based on the basic spherical equivalent refractive error. Axial length periodically measured over 2-year of lens wear and changes in axial length were compared between treatment groups and between subgroups with different degrees of myopia.

**Results:** The control group exhibited more changes in axial length than the ortho-k group at both 12 months ( $0.39 \pm 0.21$  mm vs  $0.16 \pm 0.17$  mm,  $p < 0.001$ ) and 24 months ( $0.70 \pm 0.35$  mm vs  $0.34 \pm 0.29$  mm,  $p < 0.001$ ). Axial length elongation was estimated to be slower by about 51% in the ortho-k group. Similar results were found for the subgroups (49%, 59% and 46% reductions, respectively). In the group with low and moderate myopia, the annual increases in axial length were significantly different between the ortho-k and control groups during both the first (Low myopia:  $0.19 \pm 0.17$  mm vs  $0.40 \pm 0.18$  mm,  $p = 0.001$ ; Moderate myopia:  $0.14 \pm 0.18$  mm vs  $0.45 \pm 0.22$  mm,  $p < 0.001$ ) and second (Low myopia:  $0.18 \pm 0.14$  mm vs  $0.32 \pm 0.19$  mm,  $p = 0.012$ ; Moderate myopia:  $0.18 \pm 0.16$  mm vs  $0.34 \pm 0.30$  mm,  $p = 0.030$ ) years. In the high myopia groups, significant differences were only found between the ortho-k and control groups during the first year ( $0.16 \pm 0.18$  mm vs  $0.34 \pm 0.22$  mm,  $p = 0.004$ ). The 2-year axial elongation was significantly associated with initial age ( $p < 0.001$ ) and treatment ( $p < 0.001$ ), but not with gender, initial refractive error, initial axial length, initial corneal curvature.

**Conclusions:** This 2-years study indicates that ortho-k contact lens wear is effective for reducing myopia progression in children with low, moderate and high myopia.

**Abbreviations:** Ortho-K, Orthokeratology; IOP, Intraocular pressure; BCVA, Best corrected visual acuity; AL, Axial length; SER, Spherical equivalent refractive error Competing interests.

## INTRODUCTION

Myopia is one of the most common ocular disorders and has become more prevalent in both adults and children.<sup>1,2</sup> High myopia is associated with increased risks of retinal and vitreous detachments as well as other disorders, such as glaucoma and macular degeneration. High myopia is also associated with increased healthcare costs and ocular-related morbidity.<sup>3</sup> Therefore, many methods have been implemented to try to slow or stop the development of myopia in children.<sup>4</sup> These methods generally fall into two major categories: the topical application of tropicamide<sup>5</sup>, atropine<sup>6</sup>, pirenzepine<sup>7</sup> or some ocular hypotensive agent<sup>8</sup> or optical treatments, such as rigid contact lenses<sup>9</sup>, bifocal spectacle lenses<sup>10</sup> or multifocal spectacle lenses.<sup>11</sup> However, none of these methods are ideal due to limitations in efficacy, safety, economic

feasibility or ease of application. Myopia is a remediable cause of visual impairment<sup>12</sup> and is one of the five priorities set by Vision 2020, the global initiative for the elimination of avoidable blindness, launched by the World Health Organization (WHO).<sup>13</sup>

**Ortho-k contact lens wear is a promising strategy for reducing myopic development in myopic children. Elongation of axial length compared with subjects wearing spectacles was slower by 49%, 59% and 46% for low, moderate and high myopia during 2-year period. Ortho-k treatment would be more beneficial to younger myopic children. Early initiation of ortho-k treatment may be possible to reduce the prevalence of high myopia.**

Vision 2020 also seeks to increase awareness of the growing problem of myopia in children. Although the impact of myopia on quality of life is not as large as the impact from cataracts or other ocular pathologies<sup>14</sup>, the age of onset for refractive errors suggests that this burden may be, in some ways, even greater than that of cataracts.<sup>15</sup>

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If effective treatment strategies can be found to reduce the rate of myopic progression, effects on socioeconomic health caused by myopia, can be profoundly reduced. The specific mechanisms involved in the etiology of myopia are still unclear; however, there are currently three hypotheses regarding the progression of juvenile-onset of myopia. First, it has been hypothesized that a high near-accommodation lag induces abnormal axial growth of the eye<sup>16</sup>, though many studies have found no association between accommodative lag and myopic progression.<sup>17,18</sup> The second hypothesis is based on longitudinal ocular growth data from emmetropic and myopic children and states that mechanical tension, created by the crystalline lens or ciliary body, restricts equatorial ocular expansion and causes accelerated axial elongation.<sup>19</sup> A thickened ciliary muscle<sup>20</sup> and thinned crystalline lens<sup>21</sup> play important roles in maintaining proportional expansion of the globe during eye growth and accelerated axial growth results<sup>22</sup> when the crystalline lens can no longer decrease in power by thinning and stretching.<sup>19</sup> The third hypothesis proposes that myopic eyes are relatively more hyperopic from the peripheral retina to the fovea so that when there are conflicting visual signals in the central and peripheral retina, the peripheral retinal signals dominate axial growth and central refractive development.<sup>22</sup> Longitudinal data, obtained two years prior to the onset of myopia in children who ultimately become myopic, has demonstrated a significant increase in relative peripheral hyperopia, and a relatively more prolate shape.<sup>19</sup> However, this hypothesis remains controversial.<sup>23</sup> Clinicians have been searching for treatments to control the progression of myopia based on these hypotheses, however, few studies have shown clinically significant results.

**Orthokeratology (ortho-k)** is defined as the clinical technique that uses specially designed and fitted rigid contact lenses to reshape the corneal contour to temporarily modify or eliminate refractive error. It was first introduced in the early 1960s<sup>24</sup>, but safety concerns and outcome unpredictability limited its use.<sup>25</sup> Since the mid-1990s, the acceptance of ortho-k has significantly increased, mainly due to huge technological developments in the field of contact lenses, such as the availability of highly-permeable materials<sup>26</sup> and the advent of advanced digital processing technology which uses computer assisted system to achieve optimal lens fitting.<sup>27</sup> A number of recent reports have demonstrated "overnight ortho-k" to be effective for controlling the progression of myopia.<sup>28,35</sup> In fact, several previous studies have reported the efficacy of ortho-k use in those with low to moderate myopia<sup>28,32</sup>, however, few

studies have directly examined the effects of spherical, reverse geometry ortho-k lens designs on axial length elongation in highly myopic children.<sup>35,36</sup> The purpose of the current study was to assess the effectiveness of ortho-k contact lenses in Chinese myopic children with different degrees of myopia over 24 months.

## METHODS

The medical records of children who came to our clinic for vision correction using spectacles or ortho-k were reviewed and pertinent data was retrieved. A total of 128 patients were included, 65 ortho-k treated subjects (ortho-k group) and 63 spectacle-wearing subjects (control group). Each group was designed to achieve 90% power to detect a minimum 0.18 mm (about 0.50D) difference in axial elongation in two years at the 5% level of statistical significance, using group standard deviation of 0.27 mm based on previous studies.<sup>28</sup> The minimal required sample size was calculated to be 49.

Each group was further divided into three sub-groups based on the basic spherical equivalent refractive error (SER): low-myopia ( $-3.00\text{D} < \text{SER} < -0.50\text{D}$ ), moderate-myopia ( $-6.00\text{D} < \text{SER} \leq -3.0\text{D}$ ) and high-myopia ( $\text{SER} \leq -6.0\text{D}$ ). The ortho-k group selection was based on the inclusion criteria. The medical records of all ortho-k patients seen in our hospital from January 2008 to February 2009 were examined and those that met the inclusion criteria were sorted out. About twenty subjects were then randomly selected for inclusion in each sub-group, according to basic SER. For the control group, we chose all outpatient refractive files that matched inclusion criteria during the same time period as ortho-k patients; about 20 control subjects were randomly each sub-group.

**Inclusion criteria:** Age subjects were 7–14 years of age, visual acuity had no other ocular diseases aside from refractive error and no keratoconus (confirmed by pre-treatment corneal topography) Refractive errors had an intraocular pressure (IOP) of  $<21$  mmHg. Ocular health had an with-the- rule astigmatism (axes  $180 \pm 30$ )  $\leq 1.50$  D had a BCVA (best corrected visual acuity)  $\leq 0.00$  log MAR units in both eyes (Snellen equivalent to 20/20) had no binocular vision problems. Others no medications that might affect refractive development had no history of ortho-k or contact lens wear maintained regularly scheduled visits and completed the 2-year follow-up had no significant deviations during lens wear (criteria only for ortho-k group) discontinued lens wear a total of 30 days or less during the 2 years (criteria only for ortho-k group)

## DISCUSSION

The data from the current study support the theory that ortho-k can reduce progression of myopia by



approximately half compared with traditional spectacle lenses. The major strength of the current study is the inclusion of a greater number of subjects with moderate and high myopia compared to previous studies<sup>30,32</sup>, which allowed the effectiveness of ortho-k lens to be evaluated in those with different degrees of myopia. Cho et al.<sup>28</sup> First reported that an increase in axial length of 0.29 mm in an ortho-k-treated group and of 0.54 mm in a spectacle group over a 2-year period. Since then, similar results have been obtained in several other studies.<sup>29,33</sup> Walline et al.<sup>30</sup> reported that the increase in axial length after 2 years was 0.25 mm in an ortho-k group and 0.57 mm in a control group. Kakita et al.<sup>29</sup> and Santodomingo-Rubido et al.<sup>32</sup> also reported differences in axial length increases between myopic children wearing ortho-k contact lenses and those wearing single-vision spectacles (0.39 mm vs 0.61 mm and 0.47 mm vs 0.69 mm, respectively), over a 2-year period. In a randomised study, Cho and Cheung<sup>34</sup> reported slower axial elongation of 43% in low myopes. Chen et al.<sup>33</sup> reported 52% slower increase in axial length with toric ortho-k. The change in axial length growth between the ortho-k and spectacle groups found in our study is reasonably consistent with previously reported studies, although variations in ethnicity, age and basic refractive error between studies likely affect the rates of myopic progression.<sup>28,34</sup> The prevalence of high myopia (greater than -5.00 D) among Chinese adults (greater than 30 years of age) has been reported to be 2% to 5%<sup>37,38</sup>, whereas the prevalence of high myopia (greater than -6.00 D) among Chinese children, aged 5 to 16, has been reported to be approximately 1.19%.<sup>39</sup>

Pathologic complications, poor vision quality and decreased quality of life are all associated with high myopia. Controlling the rate of myopic progression, thereby reducing the prevalence of high myopia, may result in fewer pathologic complications and improved quality of life.<sup>40</sup> Since children with severe myopia have faster myopic progression<sup>39</sup> in general, it is logical that they would benefit most from a treatment that retards myopic progression. However, information about treatments for high myopia is rare since most studies examining treatments for myopia had been performed in children with low to moderate myopia. In a small study, involving 20 highly myopic children (greater than -6.00 D), myopic progression was found to be significantly reduced after treatment with 0.5% atropine eye drops.<sup>41</sup> A subsequent case-control study indicated that 1% topical atropine was effective in slowing myopic progression in moderately to severely myopic children (initial refractive errors:  $-5.18 \pm 2.05$  D) at the end of 1 year of treatment.<sup>42</sup>

Chen, Cheung and Cho<sup>43</sup> reported no significant increase in axial length of two highly myopic, astigmatic subjects, with histories of myopic progression after they were treated with toric, ortho-k lenses.

A recent randomized study showed that ortho-k lenses effectively slowed myopic progression in high myopes. In that study, which axial length elongation was reported to be 63% slower in children treated with partial correction ortho-k lenses compared to children wearing spectacles.<sup>35</sup> In the current study axial length elongation was found to be 46% slower in the high myopic ortho-k group compared with the spectacle group. Although full reduction was not achieved in the current study with current ortho-k lens designs, ortho-k was shown to be effective to slow myopic progression during the 24-month period of lens wear in subjects with low, moderate and high myopia.

Previous studies have reported that subjects with higher baseline SERs benefited the most from ortho-k treatment.<sup>29,30</sup> However, in this study, subjects with all degrees of myopia demonstrated similar therapeutic benefits from ortho-k, specifically in retarding axial growth. The results of the current study are in agreement with previous studies in that there is a significant negative correlation between initial age and the change in axial length after 24 months of ortho-k treatment. This result is supported by observations in 3 other recent studies.<sup>31,33,34</sup> Hence, we concurred with Cho and Cheung<sup>34</sup> that younger myopic children will benefit more from ortho-k treatment than older myopic children.

The annual axial elongation in the current study in high myopia group was 0.16 and 0.18 mm in the first and second years, respectively, in the ortho-k subjects, and was 0.34 and 0.27 mm, respectively, in the control subjects. Our results had little difference with the annual growth in the first year as reported by Charm J and Cho P<sup>35</sup>, whose results showed relatively better myopic control in the first year of the study period (80% slower) compared with the second year (38% slower), while the value in current study was only 53% in the first year and 33% in the second year. This difference may be due to the different inclusion criteria in age of the two studies (8-11 years of age in Charm J and Cho P's study and 7-14 years of age in our study). But the tendency of reduced myopic control effect in high myopia was same and this phenomena was also occurred in low and moderate myopia in current study. This may be due to the slowing of myopic progression in the control group.<sup>31,35</sup> Another explanation may be the adaptation of subjects to the signal that slows myopic progression in the ortho-k group.<sup>34</sup>



However, information on the effectiveness of ortho-k was only available over a 2-year period. It remains to be seen whether ortho-k lenses should be worn continually, what treatment duration will optimize the reduction in myopic progression. Further studies are needed to address these questions.

One limitation of this study is that this was a retrospective study. Factors may affect myopic progression, such as peripheral refractive status, accommodative lag, pupil size, retinal image quality, a history of parental myopia, were not recorded in either group. A second potential limitation is that, although there were already some articles about the short-term changes in ocular biometry after discontinuation of orthokeratology<sup>44,46</sup>, it is unknown whether the rate of axial elongation will be maintained after cessation of ortho-k treatment<sup>47</sup> or whether a rebound phenomenon will occur as reported in the atropine study.<sup>48</sup> Further studies, including a longer follow-up period after cessation of treatment are required to answer these questions (especially in high myopia). Third, only one ortho-k lens spherical design was used in our study.

There are a number of different lenses aimed at controlling myopia in moderate to high astigmatic and high myopic children<sup>43</sup>, such as the toric reverse geometry lens, which provides good lens centration on toric corneas. Further investigation is warranted to address the long-term safety and myopia control efficacy in these specially designed ortho-k lenses.

## CONCLUSION

In conclusion, ortho-k contact lens wear is a promising strategy for reducing myopic development in myopic children. Elongation of axial length compared with subjects wearing spectacles was slower by 49%, 59% and 46% for low, moderate and high myopia during 2-year period. Ortho-k treatment would be more beneficial to younger myopic children. Early initiation of ortho-k treatment may be possible to reduce the prevalence of high myopia.

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