

# Myopia Control Using Toric Orthokeratology (TO-SEE Study)

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**PURPOSE.** This nonrandomized clinical study aimed to investigate the effectiveness of toric orthokeratology (ortho-k) for myopia control in myopic children with moderate-to-high astigmatism

**METHODS.** We enrolled 80 subjects (aged 6–12 years; ortho-k, 43; control, 37) with myopia of 0.50 to 5.00 diopters (D), and with-the-rule astigmatism of  $-1.25$  to  $-3.50$  D, and unremarkable ocular and general conditions. Data collection, including visual acuity, subjective and objective refraction, axial length, corneal topography, and biomicroscopy examination, was performed every 6 months during the 24-month study period. Results from the right eye or the eye with higher astigmatism were reported.

**RESULTS.** A total of 35 ortho-k and 23 control subjects completed the study successfully. Subjects in both groups demonstrated axial elongation ( $P < 0.001$ ). The average axial elongation at the end of study was  $0.31 \pm 0.27$  and  $0.64 \pm 0.31$  mm in the ortho-k and control groups, respectively ( $P < 0.001$ ). At the end of 24 months, axial elongation in ortho-k subjects was 52% slower than that in the control group. Axial elongation was correlated significantly with the initial age of the subjects ( $P = 0.02$ ) and treatment assigned ( $P = 0.04$ ), but not with sex, initial myopia, initial refractive cylinder, or initial corneal toricity ( $P > 0.08$ ).

**CONCLUSIONS.** Toric ortho-k lenses can slow axial elongation effectively in myopic children with moderate-to-high astigmatism. (ClinicalTrials.gov number, NCT00978692.)

Keywords: toric design, orthokeratology, astigmatism, myopia, myopia control

The prevalence of myopia is high in East Asia (Hong Kong, China, Taiwan, Japan, and Korea).<sup>1–7</sup> Vitale et al.<sup>8</sup> also have reported increasing prevalence of myopia in the United States in recent decades. Hence, preventing or slowing myopic progression has attracted the interest of many clinicians and researchers. For years, researchers have been trying to find an effective method to retard or control the progression of myopia in children.<sup>9–27</sup> These myopia control treatments include bifocal spectacle lenses,<sup>9,25</sup> progressive spectacle lenses,<sup>10,11,20</sup> undercorrection of myopia,<sup>12</sup> rigid contact lenses,<sup>18,19,21</sup> soft bifocal contact lenses,<sup>13</sup> and pharmaceutical agents, such as atropine<sup>14</sup> and pirenzepine.<sup>15–17</sup>

The potential of modern orthokeratology (ortho-k), which uses reverse geometry rigid contact lenses worn overnight to reshape the cornea and, thus, temporarily reducing myopia,<sup>22,24,26–31</sup> for myopia control<sup>22–24,26,27,32</sup> has been confirmed via a 24-month randomized clinical trial.<sup>32</sup> The rate of axial elongation of the eyeball in children wearing ortho-k lenses has been reported to be 32% to 55% slower compared to those wearing single-vision spectacles or soft contact lenses.<sup>22–24,26,27,32</sup> All of these studies used ortho-k lenses of spherical design on low myopes ( $<6.00$  diopters [D]) with low astigmatism. Clinically, corneal astigmatism greater than 1.50 D (with-the-rule) is regarded as unsuitable for spherical ortho-k lenses, because of problems with poor lens centration, and limited or no correction of astigmatism.<sup>33–35</sup> In patients with high corneal astigmatism ( $>1.50$  D), lens decentration is the most common problem with spherical ortho-k lenses, and it can lead to induced astigmatism and poor vision.<sup>34,36</sup> Hence,

spherical ortho-k is not indicated for children with refractive (corneal) astigmatism more than 1.50 D. However, most myopic children also are astigmatic, and the prevalence of astigmatism has been reported to be approximately 21%,<sup>37</sup> and 34%<sup>37,38</sup> in Asian children 3 to 6 and 15 to 17 years old, respectively. Previous myopia control studies using various methods focused mainly on myopic children with no or low amounts of astigmatism. Considering the high prevalence of astigmatism in myopic children, there is a need for a myopia control treatment for myopic children with astigmatism to control progression of myopia, while providing clear unaided vision in the daytime.

Therefore, toric reverse geometry ortho-k designs have been developed and introduced to improve lens centration, as well as for astigmatic correction. While a number of case reports exist on the effectiveness of toric design ortho-k lenses for astigmatic correction,<sup>39–41</sup> to our knowledge there is no published study on the use of toric ortho-k for myopia control in children with moderate-to-high astigmatism.

At the time when this myopia control study using toric ortho-k was planned, children with moderate-to-high astigmatism were considered contraindicated for ortho-k (spherical design), and there was little evidence on the safety and effectiveness of toric ortho-k for myopic correction in astigmatic children. Without supporting evidence, a randomized study was not warranted and, hence, a nonrandomized study was conducted where parents were allowed to decide which treatment they preferred for their children, the conventional treatment (spectacles) or a new treatment (toric

**TABLE 1.** Inclusion and Exclusion Criteria

Inclusion criteria	
Age	6–12 y
Ethnicity	Chinese
Myopia	0.50–5.00 D
With-the-rule astigmatism	1.25–3.50 D, axis $180 \pm 20$
Anisometropia	: not more than 1.50 D in myopia
Best-corrected monocular visual acuity	equal to or better than 0.10 logMAR
Available for follow-up	for at least 2 y
Exclusion criteria	
Strabismus	at distance or near
Contraindications for contact lens wear and orthokeratology	(e.g., limbus to limbus corneal cylinder, dislocated corneal apex)
Prior experience with the use of soft or rigid lenses, including orthokeratology, or with myopic control	
Systemic or ocular conditions that may affect contact lens wear	(e.g., allergy and medication) or affect refractive development (e.g., Down syndrome, ptosis)

ortho-k). Therefore, the objective of this study was to determine the effectiveness of toric ortho-k lenses for myopia control, in terms of axial elongation, in myopic children with moderate-to-high astigmatism.

## METHODS

This was a nonrandomized clinical study, in that parents of eligible children were allowed to select the treatment option for their children, on a first-come, first-served basis. Subjects were assigned to the other treatment group when the quota for their preferred treatment was filled up. Subjects, aged 6 to 12 years, who satisfied the inclusion criteria (Table 1), with myopia (spherical component) of 0.50 to 5.00 D (inclusive), and with-the-rule refractive astigmatism of 1.25 to 3.50 D were recruited at approximately the same time of the year. All subjects had unremarkable ocular and general health. They were fitted either with ortho-k lenses (study group) or single-vision spectacles (control group). All subjects were followed up biannually for a period of two years. This study was registered at ClinicalTrials.gov, number NCT00978692.

Subjects in the ortho-k group were fitted with Menicon Z Night Toric lenses (NKL Contactlinsen B.V., Emmen, The Netherlands) made of a material of high oxygen permeability (Table 2). All lenses used in this study were replaced annually. Details of the complimentary care solutions, ortho-k fitting, and evaluation procedures have been reported previously.<sup>42</sup> Subjects in the control group were fitted with single-vision spectacles made of CR39 material with refractive index of 1.56 (Hong Kong Optical Lens Co., Hong Kong, China). For all subjects, at each subsequent 6-month visit after baseline visit, ortho-k lenses/spectacles were updated if habitual visual acuity (HVA; for the ortho-k subjects, HVA referred to the unaided visual acuity [VA]) was found to be worse than 0.18 logMAR, or if refractive error (either myopia or astigmatism) increased by 0.50 D or more compared to the previous visit. Ortho-k subjects whose HVA was worse than 0.18 logMAR and could not be improved despite lens modification ( $\times 3$ ) were discontinued. For all subjects, those presenting significant adverse events, or failing to comply with the prescribed procedures despite repeated reeducation or reminders were terminated from the study.

The study complied with the tenets of the Declaration of Helsinki in 2002 and ethics clearance was approved by the Departmental Research Committee of School of Optometry of

**TABLE 2.** Parameters of Z Night Contact Lens Used in This Study

Manufacturer	NKL
Material name	Siloxanylstyrene fluoromethacrylate (tisifilcon A)
Design	Parallel reverse geometry
Dk, barrer	163
Back optic zone radius, mm	7.2–9.50 (0.05 step)
Basic optic zone diameter, mm	6
Overall lens diameter, mm	10.2/10.6/11.0
Tangential angle, deg	50–65 (1 step)
Sagittal depth, mm	0.50–0.99 (0.01 step)
Central thickness, mm	0.24

The Hong Kong Polytechnic University. Consent and assent from parents and subjects, respectively, were obtained after a detailed explanation of the examination procedures and a complete disclosure of the effects of the topical cycloplegic used. Upon completion or withdrawal from the study, ortho-k subjects were required to return all the prescribed ortho-k lenses and solutions to the examiner.

## Examination Procedures

Each subject received a detailed eye examination to confirm normal ocular condition before the commencement of the study. Cycloplegic eye examination was performed at the baseline visit and once every 6 months over a period of 2 years. Before the cycloplegic examination at each data collection visit, high contrast (100%) and low contrast (10%) HVA, and best corrected VA (BCVA) were measured with the Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Precision Vision, La Salle, IL) under normal room lighting condition. Anterior ocular health assessment was performed and any abnormality, if observed, was graded using Efron grading scales.<sup>42</sup> Corneal topography was measured using the Medmont E300 corneal topographer (Version 3.9.3; Medmont Pty. Ltd., Camberwell, Australia) for monitoring changes in the corneal profile during the study period.

Axial length measurements (Zeiss IOLMaster; Zeiss Humphrey Systems, Dublin, CA) were performed by a masked examiner at least 30 minutes after the administration of 1 drop of 0.5% Alcaine, 1 drop of 1% tropicamide, and 1 drop of 1% cyclopentolate, at 5 minutes apart. Axial length measurements were performed according to the manufacturer's instructions. Five consecutive readings were recorded and averaged for analysis.

## Sample Size

This myopia control study was designed to achieve 80% power to detect a minimum difference 0.18 mm (0.50 D) difference in axial length in 2 years at 5% level of statistical significance, using the within group SD of 0.27 mm from our previous report.<sup>22</sup> Based upon these calculations, a sample size of at least 20 subjects would be required for each group.

## Treatment of Data

Statistical analyses were performed using SPSS (ver 18.0; SPSS, Inc., Chicago, IL). Data from the eye with higher astigmatism of each subject were analyzed in this study. Data from the right eye were used if the amount of astigmatism was the same in both eyes. Since all data were distributed normally (Kolmogorov-Smirnov test,  $P > 0.05$ ), parametric tests were used for data analysis. For comparison of baseline data between the two

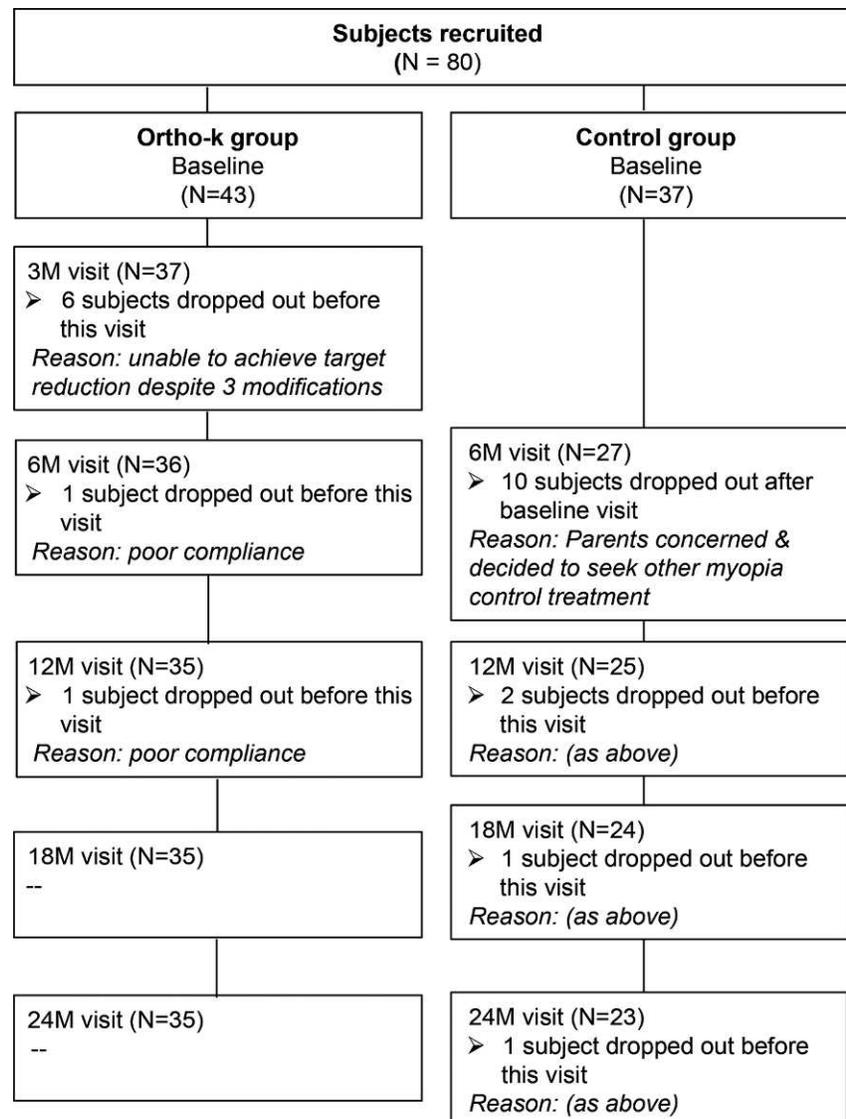


FIGURE 1. Number of subjects (and reasons for) dropping out at different visits.

groups, unpaired *t*-tests were used. Repeated measures ANOVA with post hoc tests were used to compare axial length obtained from the baseline and the 6-monthly visits in the two groups of subjects. Unpaired *t*-tests with Bonferroni correction ( $\alpha \leq 0.01$ ) were used to test for differences between groups. To obtain further insight into the observed treatment effect, crosstab analyses were used to compare the proportions of fast myopia progressors ( $>1.00$  D per year) in the ortho-k and control groups, although each subgroup sample size in these analyses was small. Factors affecting axial elongation, including age, initial myopia, astigmatism, corneal toricity, and treatment, were investigated using stepwise multiple linear regression analysis.

## RESULTS

We fitted 43 subjects with ortho-k lenses and 37 control subjects with single-vision spectacles. Only 35 subjects (18 males and 17 females) in the ortho-k group successfully completed the 24-month study (Fig. 1). Of the eight subjects who dropped out, six could not achieve the target reduction in

HVA after 3-month lens wear despite lens modifications (3 times) and two subjects showed poor compliance during the study period, one before the 6-month visit and one before the 12-month visit.

Only 23 subjects (eight males and 15 females) in the control group completed the study; 10 subjects dropped out after the baseline visit, two after the 6-month visit, one after the 12-month visit, and one after the 18-month visit. The main reason for dropout was parental anxiety about the myopic progression in their children. None of the dropouts in either group of subjects was due to ocular adverse events.

No statistically significant differences in baseline values (age, myopia, astigmatism, corneal astigmatism, BCVA, and axial length) were found between those who completed and those who dropped out of the study (unpaired *t*-tests,  $0.14 < P < 0.43$ ). The mean  $\pm$  SD ages of the ortho-k and control subjects who completed the study were  $9.4 \pm 1.4$  and  $8.9 \pm 1.6$  years, respectively, when they commenced this study, and their baseline data are shown in Table 3.

Figures 2A and 2B show the high and low contrast HVA and BCVA of the subjects, respectively. There were no significant differences in the high and low contrast HVA and BCVA during

**TABLE 3.** Baseline Characteristics of Subjects Who Completed the 2-Year Study

	Ortho-k Group, <i>n</i> = 35, 18 Male/ 17 Female	Control Group, <i>n</i> = 23, 8 Male/ 15 Female
Age, y	9.4 ± 1.4	8.9 ± 1.6
Myopia, D	-2.46 ± 1.32	-2.04 ± 1.09
Refractive astigmatism, D	-1.86 ± 0.64	-2.07 ± 0.56
Corneal astigmatism, D	-2.28 ± 0.53	-2.43 ± 0.62
Best-corrected VA, logMAR	0.00 ± 0.05	-0.02 ± 0.03
AL, mm	24.37 ± 0.88	24.18 ± 1.00

Values are mean ± SD. AL, axial length.

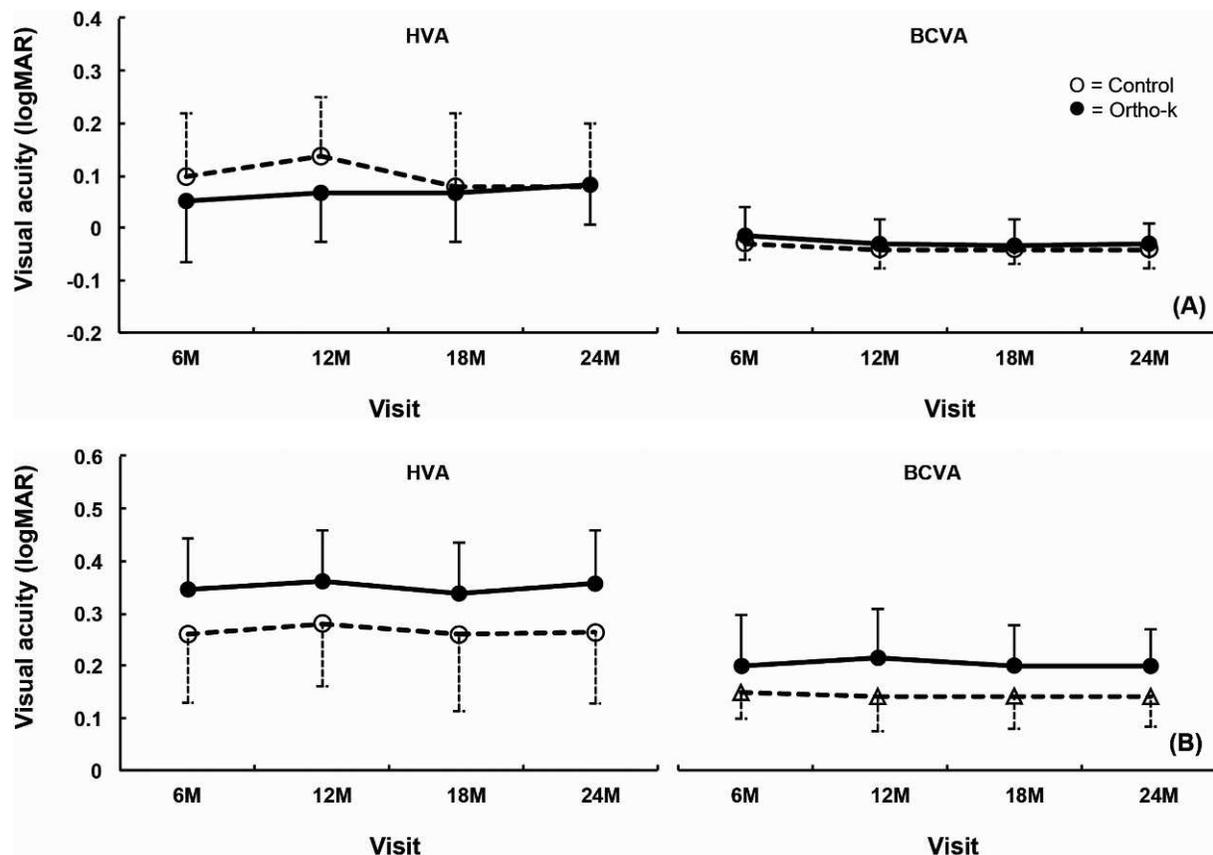
the study period in both groups of subjects (repeated measures ANOVAs with post hoc tests,  $P > 0.05$ ). Changes in high and low contrast HVA and BCVA were not significantly different between the two groups of subjects at any visit during the study (unpaired  $t$ -tests,  $P > 0.01$ ). At the 24-month visit, in the ortho-k and control groups, the mean ± SD high contrast logMAR HVA values were  $0.08 \pm 0.11$  and  $0.08 \pm 0.13$ , respectively, and high contrast logMAR BCVA values were  $-0.03 \pm 0.05$  and  $-0.04 \pm 0.03$ , respectively.

Mean ± SD low contrast HVA values for the ortho-k and control groups were  $0.36 \pm 0.15$  and  $0.27 \pm 0.14$ , respectively, and low contrast BCVA values were  $0.20 \pm 0.08$  and  $0.14 \pm 0.05$ , respectively.

Figure 3 shows the refractive errors of the subjects at different visits during the study period. For the ortho-k

subjects, there was a significant change in myopia and astigmatism over time (repeated measures ANOVA; myopia,  $P < 0.001$ ; astigmatism,  $P < 0.001$ ), but this was only due to significant decreases at the 6-month visit. Myopia reduced from  $2.46 \pm 1.32$  D (baseline) to  $0.18 \pm 0.37$  D (6-month, paired  $t$ -tests,  $P < 0.001$ ) while astigmatism reduced from  $-1.86 \pm 0.64$  D (baseline) to  $-0.37 \pm 0.39$  D (6-month, paired  $t$ -tests,  $P < 0.001$ ). Myopia and astigmatism at subsequent visits were not significantly different in the ortho-k group (repeated measures ANOVA (6-, 12-, 18-, 24-month; myopia,  $P = 0.06$ ; astigmatism,  $P = 0.83$ ). For the control subjects, the amount of myopia increased with time at every 6-month visit (repeated measures ANOVA,  $P < 0.001$ ). Myopia increased gradually from  $2.04 \pm 1.09$  D at baseline to  $3.17 \pm 1.22$  D at the 24-month visit (paired  $t$ -tests,  $P < 0.001$ ). Astigmatism remained unchanged during the study period (repeated measures ANOVA,  $P = 0.07$ ). It was  $2.07 \pm 0.56$  D at baseline and  $2.10 \pm 0.51$  D at the 24-month visit (Fig. 3).

Changes in axial length during the study period are shown in Figure 4. Subjects in both groups demonstrated significant axial elongation (repeated measures ANOVA; ortho-k,  $P < 0.001$ ; control,  $P < 0.001$ ). Axial elongation was significantly slower in the ortho-k group than in the control group at every 6-month visit (unpaired  $t$ -tests,  $0.01 < P < 0.001$ ). The mean ± SD increase in axial length in ortho-k subjects was  $0.33 \pm 0.05$  mm less than the control subjects at the end of the 24-month study period (Table 4). The levels of reduction of myopia progression compared to the spectacle-wearing control group were 61%, 58%, 53%, and 52% after 6, 12, 18, and 24 months of ortho-k lens wear.



**FIGURE 2.** High contrast (A) and low contrast (B) HVA and BCVA logMAR visual acuities at different visits during the study period (HVA logMAR VA in orthokeratology subjects = unaided VA). Each error bar represents 1 SD. M, month.

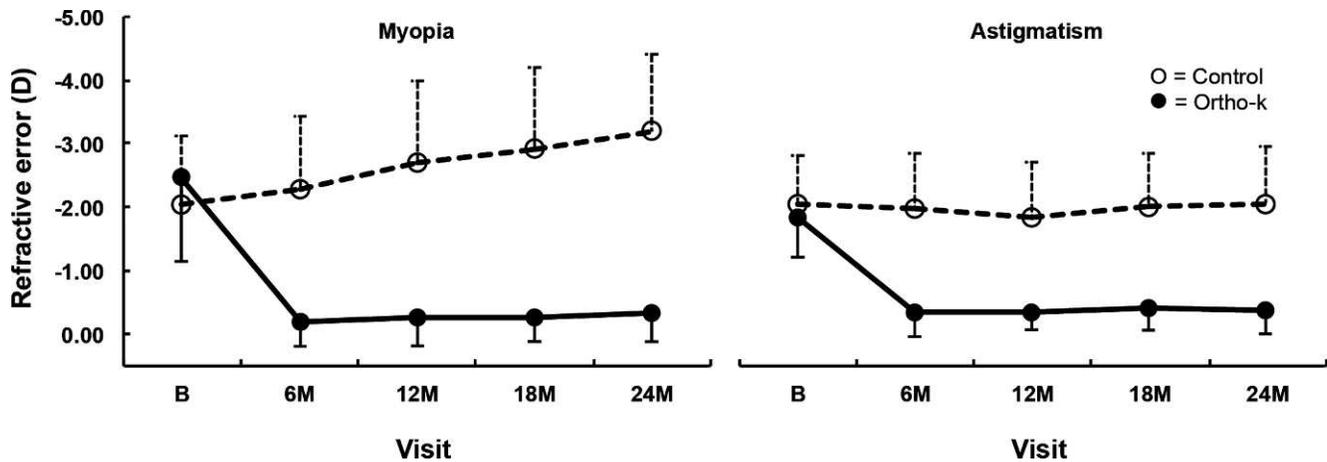


FIGURE 3. Cycloplegic subjective refractive error changes at different visits during the study period. Each error bar represents 1 SD. B, baseline.

At the end of the 24-month monitoring period, seven subjects in the control group demonstrated fast myopic progression (myopic progression exceeding 1.00 D per year or axial elongation  $> 0.36$  mm per year), while only one subject in the ortho-k group had fast myopic progression. The odds of becoming fast progressors was 14.9 times greater in children wearing single-vision spectacles than those wearing ortho-k lenses (95% confidence interval [CI], 1.7–131.3; Fisher's exact test,  $P = 0.005$ ). Stepwise multiple linear regression analysis showed that among the predicting factors, axial elongation was correlated significantly with the initial age of the subjects (standardized  $\beta = -0.30$ ,  $P = 0.02$ ) and treatment assigned (standardized  $\beta = -0.36$ ,  $P = 0.04$ ). However, axial length elongation was not affected by sex, initial myopia, initial refractive cylinder, or initial corneal toricity (partial  $r$ ,  $-0.36$ – $0.22$ ,  $P > 0.08$ ).

No significant adverse event was observed in either group of subjects. Only mild corneal staining (grade 1) was observed in both groups of subjects at different visits (Table 5) and most were in the inferior cornea. There were no changes in the incidence of inferior corneal staining over time in the ortho-k group (17%–23%). However, in the control group, the incidence of inferior corneal staining was lower at the 24-month visit (baseline to 18 month visits, 14%–20%; 24 month visit, 9%). The incidence of mild central corneal staining was not common in either group of subjects; two observations in the control group and five observations in the ortho-k group over the 24-month study period. Superior and nasal corneal

staining in the control group was rare, and no corneal staining was observed in the temporal cornea of the control subjects. Incidences of mild corneal staining in the peripheral corneal regions appeared to increase after ortho-k lens wear, especially in the inferior cornea. No lens binding was reported after 1 month of lens wear.

## DISCUSSION

To our knowledge, this is the first longitudinal clinical study to investigate the effectiveness of toric design ortho-k for controlling myopic progression in myopic children with moderate-to-high amounts of astigmatism. Our results showed that toric design ortho-k effectively corrected myopia and astigmatism, providing the ortho-k subjects with high and low contrast unaided visual acuities comparable to the HVA of the control subjects after stabilization of ortho-k treatment. There have been reports of consistent reductions in contrast sensitivity, including low contrast BCVA, and the area under the log contrast sensitivity function after the commencement of ortho-k lens wear.<sup>43–45</sup> These researchers also have reported significant increases in higher-order aberrations with ortho-k lens wear, which was consistent with the reduced contrast sensitivity finding. However, our results did not agree with their findings, as we observed consistently no changes in low contrast BCVA over time (Fig. 2B). The differences in findings between studies may be due to different methodologies (e.g., different charts used, dilated versus nondilated pupil, lighting) used, and our subjects were children, whereas previous reports were on adults. Toric design ortho-k lenses also can slow myopic progression in children with myopia and moderate-to-high astigmatism.

Reports discussing the relationship between myopia and astigmatism are scarce.<sup>37,46</sup> Saw et al.<sup>46</sup> reported no difference in the increase in myopia between astigmats (astigmatism  $> 0.50$  D) and nonastigmats in children 6 to 11 years old, but they did not investigate the association between initial astigmatism and myopic progression. Fan et al.<sup>37</sup> reported an association between astigmatism and myopic progression among Asian children aged 3 to 6 years old, but it appeared that their subjects were mostly hyperopes. Unfortunately, they did not provide further information about the myopic and astigmatic progression in their subjects.

The relationship between the baseline astigmatism and axial elongation of our subjects was analyzed, and our result showed no correlation between these two factors. Since the current study did not include children with low astigmatism, to have

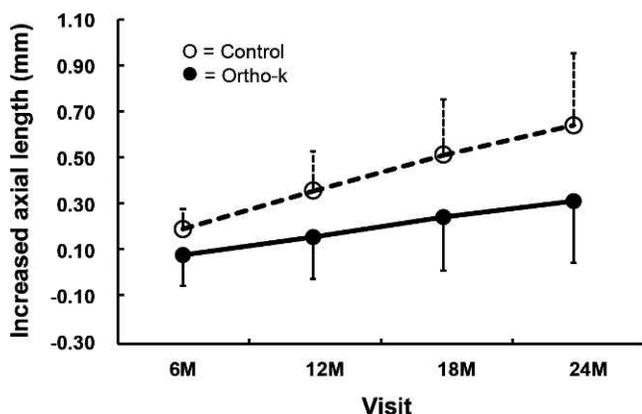


FIGURE 4. Changes in axial elongation (mean  $\pm$  SD) at different visits during the study period. Each error bar represents 1 SD.

**TABLE 4.** Increases in Axial Length in Orthokeratology and Control Subjects at Different Visits During the Study Period

	Orthokeratology, mm, <i>n</i> = 35	Control, mm, <i>n</i> = 23
6 mo	0.07 ± 0.13	0.19 ± 0.08
12 mo	0.15 ± 0.18	0.36 ± 0.16
18 mo	0.24 ± 0.23	0.51 ± 0.24
24 mo	0.31 ± 0.27	0.64 ± 0.31

Values are mean ± SD.

better understanding of the effect of astigmatism on myopic progression in children, we compared our results to those obtained from the ROMIO study,<sup>52</sup> which was a randomized clinical trial on the use of ortho-k for myopia control in myopic children with no or low astigmatism. TO-SEE and ROMIO studies were conducted concurrently at the same location by the same research group. The inclusion criteria of the two studies differed in age (up to 10 years old in ROMIO and up to 12 years old in TO-SEE) and refractive astigmatism (“low astigmats,” refractive [corneal] astigmatism of less than 1.25 D in ROMIO study; “moderate-high astigmats,” refractive [corneal] astigmatism 1.25 D or more in the TO-SEE study). There were no significant differences in the initial myopia among the four groups of subjects (low or moderate-high astigmats fitted with ortho-k or spectacles, 1-way ANOVA,  $F_{3,132} = 1.30$ ,  $P = 0.28$ ). We used analysis of covariance to adjust the effect of age and initial myopia, and to test for differences between low astigmats and moderate-high astigmats wearing ortho-k lenses or single-vision spectacles. There were no differences in the axial elongation between the low and moderate-high astigmats wearing single-vision spectacles (1-way ANCOVA,  $F_{1,60} = 0.20$ ,  $P = 0.66$ ) or ortho-k lenses (1-way ANCOVA,  $F_{1,68} = 0.28$ ,  $P = 0.60$ ). The 24-month axial elongations were  $0.63 \pm 0.26$  and  $0.65 \pm 0.31$  mm in low astigmats and moderate-high astigmats, respectively, wearing single-vision spectacles, and were  $0.36 \pm 0.24$  and  $0.33 \pm 0.28$  mm in low astigmats and moderate-high astigmats, respectively, wearing ortho-k lenses. That is, myopic progression was not affected by the initial refractive astigmatism of the eye, but by the method of vision correction given to the subjects.

Corneal complications associated with any contact lens wear can lead to vision impairment and potential blindness.<sup>47</sup> Many clinicians/researchers are concerned with the potentially increased risk involving overnight wear of contact lenses.<sup>48–50</sup> Microbial keratitis in ortho-k lens wear has been reported in case studies,<sup>51,52</sup> but not in clinical studies, which usually require and may involve a higher standard of care given to the subjects. Clinical studies on ortho-k for myopia control published to date, including the current study, have shown no severe adverse events that left permanent damage to the eye or vision.<sup>23,24,26,32</sup> That is, with stringent management protocol (e.g., proper education and review on lens handling, and lens care products and procedures, frequent aftercare visits, education, and reeducation of patients and parents, and delivery of written and verbal instructions), complications associated with ortho-k lens wear can be minimized. Santodomingo-Rubido et al.<sup>48</sup> reported adverse events, such as contact lens-induced peripheral ulcer and conjunctivitis, but they also reported that the conditions “are not considered to be serious, are similar to those reported with other contact lens types, and can be managed easily in clinical practice.”

In the current study, we found no significant adverse events in both groups of subjects. Although ortho-k lens wear tended to increase the incidence of corneal staining in the peripheral cornea, the staining observed was considered to be mild, as depth of staining was mostly superficial (grade 1) and the

**TABLE 5.** Percentages of Mild Corneal Staining (Not More Than Grade 2) at Different Corneal Locations in Orthokeratology and Control Subjects at Different Visits

Location	Baseline, %	6-mo, %	12-mo, %	18-mo, %	24-mo, %
Ortho-k, <i>n</i> = 35					
Central	0	0	2.9	5.7	5.7
Inferior	22.9	17.2*	17.2*	17.1	17.1
Superior	2.9	5.7	8.6	14.3	8.6
Nasal	0	5.7	0	2.9	5.7
Temporal	0	2.9	5.7	2.9	0
Control, <i>n</i> = 23					
Central	2.9	0	0	2.9	0
Inferior	20.0	20.0	14.3†	17.1	8.6
Superior	2.9	0	0	5.7	2.9
Nasal	0	2.9	0	0	0
Temporal	0	0	0	0	0

Grading is based on Efron's scale.<sup>43</sup>

\* One subject showed grade 2 corneal staining.

† Two subjects showed grade 2 corneal staining.

average incidence was less than 10%. The situation was similar to wearing any other types of daily wear soft contact lenses.<sup>53</sup> Such minor ocular problems can be monitored and managed easily by early detection and treatment, such as use of artificial tears for lubrication.

Poor lens cleaning procedure and poor lens hygiene may increase the risk for infection in ortho-k patients as lenses are worn overnight. Therefore, providing careful and specific education in the care of ortho-k lenses to parents and children is important to minimize complications in ortho-k lens wear.

Lens binding has been reported to be the most common nonvisual problem in ortho-k lens wear<sup>33,54,55</sup> and is a risk factor for corneal staining. However, in the current study, no lens binding was reported after 1 month of lens wear. The low incidence of lens binding may be due to the use of fenestrated lenses<sup>56</sup> and application of artificial tears to the eye before lens removal. All ortho-k subjects were required to remove the lens from each eye using their fingers instead of a lens remover. These steps may have aided lens mobility after waking up and minimized lens binding.

In ortho-k, the reshaped cornea changed relative peripheral refraction of the myopic eyes from relative hyperopia to relative myopia, and this appears to be consistent with the suggestion that relative peripheral hyperopia drives myopic progression.<sup>57</sup> However, further evidence is required before any firm conclusion can be made on the mechanism of myopia control in ortho-k. The effectiveness of ortho-k for myopia control, in terms of axial elongation, has been reported to range from 32% to 55%.<sup>22,23,26,27,32</sup> To our knowledge, the only randomized longitudinal clinical trial published to date on ortho-k for myopia control reported 43% effectiveness.<sup>32</sup> Axial elongation of subjects wearing toric ortho-k lenses was 52% slower compared to subjects wearing spectacles in our study. However, as this was a nonrandomized study, systematic bias cannot be ruled out. In our study, the odds of children having fast progression in myopia (more than 1.00 D per year) were reduced with the use of ortho-k lenses. However, no conclusive evidence can be drawn on this issue from this study, as only eight subjects demonstrated fast progression. Our results also may be affected by selection bias, since the number of subjects with faster progression may not have been balanced at the beginning of the study without randomization. A randomized clinical trial would have provided better evidence on the effectiveness of using toric ortho-k for myopia control in myopic children with significant astigmatism.

Another potential limitation is that it is unknown if the treatment effect continues after year 2. We believe that a randomized clinical trial now is warranted, in light of the evidence from this study, to confirm the effectiveness of toric ortho-k for myopia control.

Apart from being effective and safe, a good myopia control treatment also should provide convenience for children's daily activities. If the treatment is causing inconvenience or problems, a high dropout rate would be expected. The dropout rates in ortho-k ranged from 6%<sup>27</sup> to 30%<sup>23</sup> in previous studies. In our study, the dropout rates were 19% (8/43) and 38% (14/37) in the ortho-k and control groups, respectively. The reasons for dropouts in the two groups of subjects differed. All dropouts in the control group were initiated by the parents. They were concerned and worried about the myopic progression in their children, and decided to withdraw from the study to seek myopia control treatment for their children. On the other hand, dropouts in the ortho-k group were initiated by the investigators, either because of the unsatisfactory ortho-k lens wear that affected the daytime vision (six of eight subjects) or noncompliance to the study protocol (stopped lens wear from time to time without notifying the investigator), which affected the daytime vision and, therefore, the results of myopia control (two subjects). The dropout results may be an indication that parents in Hong Kong are very concerned about myopic progression in their children, and are eager to seek effective treatment to slow myopia. However, not all children are suitable to wear ortho-k lenses and even those who had good response in the beginning may not continue to show good or satisfactory responses with continued lens wear. Good ocular and visual responses require combined efforts from the practitioners, the children, and their parents. Subjects wearing ortho-k lenses who completed the study had comparable visual quality to those wearing single-vision spectacles, but enjoyed the additional benefit of convenience from spectacle-free vision in the daytime.

## CONCLUSIONS

This nonrandomized study has provided evidence that toric ortho-k lenses can provide clear unaided vision for myopic children with moderate-to-high astigmatism, and can slow axial elongation effectively in these children.

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