One-year Effect of Wearing Orthokeratology Lenses on the Myopia Progression

Bei Gao

Shandong University of Traditional Chinese Medicine

Jing Xu

Shandong University of Traditional Chinese Medicine <https://orcid.org/0000-0002-6990-8602>

Guodong Tang

Shandong University of Traditional Chinese Medicine

Chenyong QU

Shandong University of Traditional Chinese Medicine

Dongxue Du

Shandong University of Traditional Chinese Medicine

Jike Song

Shandong University of Traditional Chinese Medicine

Hongsheng Bi (✉ hongshengbi1@163.com)

Shandong University of Traditional Chinese Medicine

Research Article

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Abstract

Background: To Investigate the efficacy of overnight orthokeratology (Ortho-k) for myopia control and the relationship between axial length (AL) changes and different baseline factors.

Methods: This is a retrospective study of 675 myopic patients (Affiliated Eye Hospital of Shandong University of TCM) who received Ortho-k correction between August 2015 and July 2017. These subjects were followed up at least for 12 months. Genders, age, parental refractive status, manifest refractions, cycloplegic refractions, uncorrected and best-corrected visual acuities, power vector of astigmatism, corneal curvature, age at initiation of Ortho-k wear (year), intraocular pressure (IOP), anterior chamber depth (ACD), pupil size (PL), corneal diameter (CD) and AL were obtained for analysis. Correlation and multivariate logistic regression analyses were used to screen for the factors that can improve treatment outcome.

Results: The baseline 675 patients' AL of was 25.12 ± 1.00 mm, and after 12 months of treatment, the AL was 25.30 ± 0.94 mm, and the axial elongation was 0.18 ± 0.22 mm. Univariate analysis of the right-eye independent variable of 675 patients showed a statistically significant association between age at initiation of Ortho-k wear, spherical equivalent refractive (SER), and changes in AL. Regression analysis results show that age at initiation of Ortho-k wear and SER are independent factors with effects on the treatment outcome.

Conclusion: Ortho-k was effective in slowing myopia progression over a one-year follow-up period. Age at initiation of Ortho-k wear, and SER were found to be associated with increased change of AL during follow-up.

Introduction

With the significant increase in the prevalence of myopia, myopia is becoming a public health problem that interferes with the eye health of young children. The prevalence of myopia varies geographically, for example, 30% of the population in Australia ^[1] and North American ^[2] and up to 85% of the East Asia population, especially in Taiwan ^[3,4]. The incidence rate of refractive errors is the highest among the incidence rates of various eye diseases in the world ^[5]. The World Health Organization identified myopia as one of the five leading causes of blindness and visual impairments in the world ^[6].

So far, there are many ways to prevent and control the progress of myopia. These methods generally fall into two major categories: the topical application of tropicamide ^[7], atropine ^[8,9], pirenzepine ^[10], or some ocular hypotensive agent ^[11], or optical treatments, such as rigid contact lenses ^[12], bifocal spectacle lenses ^[13], or multifocal spectacle lenses ^[14].

An orthokeratology lens is a rigid contact lens with a reverse geometry on its back surface ^[15,16]. Overnight wear of the lens flattens the central cornea zone and increases the relative corneal refractive

power in the periphery. This inverted pattern of corneal peripheral refraction induces relative peripheral myopic defocus on the retina, which is considered the working mechanism of the Ortho-k^[17-19].

The concept of Ortho-k was first introduced in the 1950s by Wesley and Jessen as spectacle blur, a phenomenon describing corneal reshaping after wearing hard contact lenses. For its material was poor at oxygen permeation, making long-term wearing infeasible, Ortho-k was more of a novelty back then. In the 1970s, rigid gas permeable lenses improved comfort and safety by allowing more oxygen permeability. However, the lenses remained incapable of effectively correcting myopia until the first reverse geometry lens designed by Richard Wlodyga introduced in 1989, which improved lens centration and myopia correction from -1 diopters (D) to -1.7 D. Up to the present, improvement of Ortho-k mainly involves using higher Dk lens material, different reverse geometry lens designs, and advances in corneal topography^[20].

Nowdays, it has been generally recognized that wearing Ortho-k at night can effectively reduce myopic degree and axial elongation^[21,22]. Five quasi-experimental studies have reported slower myopic progression (by 32-55%) in low-to-moderately myopic children wearing ortho-k lenses compared with those wearing conventional eyeglasses^[23,24] or single-vision soft contact lenses.

A recent meta-analysis study reported that the pooled reduction in axial elongation declined with time, with 55%, 51%, 51%, and 41% obtained after 6, 12, 18, and 24 months of OK lens wear, respectively^[25].

Since the change in AL is small, axial length usually is evaluated once, or at most twice a year, in clinic. Therefore, Ortho-k treatment requires long-term commitment from doctors and patients to see the effect become apparent^[26]. It is of paramount importance to estimate the probability that a patient would achieve effective control in myopic progression before treatment or early during its course.

To this end, efforts have been made to investigate the correlations between axial growth and a variety of parameters at the baseline, including baseline SER, myopia time, diopter, corneal curvature e value, time with Ortho-k. All the above factors are independent factors affecting the effect of Ortho-k^[27-29].

These measurements are nonspecific, indirect, and based on the assumption that their relationships to axial growth are linear, which often leads to contradictory findings and results that are hard to interpret by physicians. The results of the Bingjie Wang's study demonstrated no significant associations between gender, mean corneal power, corneal toxicity, diameter, and pupil size with axial length elongation after Ortho-k lens wear^[30].

This retrospective study aims to investigate whether overnight Ortho-k influences the progression rate of the manifest refractive error of myopic children in a one-year follow-up period, and to investigate the relationship between axial changes and different baseline factors.

Materials And Methods

Materials

This is a retrospective study of subjects who visited Affiliated Eye Hospital of Shandong University of TCM between August 2015 to July 2017. All subjects were deemed suitable for this study and included for analysis according to the inclusion criteria below (Table1). In the end, a total of 675 subjects undergoing overnight Ortho-k treatment were reviewed. The treatment duration was more than 12 months with regular follow-up. To minimize systematic bias, only the data from the right eyes (total 675 eyes) were analyzed, but during the treatment, the left eyes received the same treatment. Although the Ortho-k lens design used in this study was recommended for myopia reduction not more than 6.00 D, we also used this design for subjects with high myopia. If the subject's refractive error was beyond the limit of correction range of Ortho-k lens, the subjects were required to wear spectacles during the day. The investigation was approved by the Ethics Committee of Affiliated Eye Hospital of Shandong University of TCM.

Methods

The pertinent data from examination results were retrieved and rearranged from the medical records of children who used ortho-k lenses for vision correction. Data collected from the patients files include participant demography and visual parameters: gender, parental refractive status (neither parent myopic, one parent myopic and both parents myopic), age at initiation of Ortho-k wear, UCVA (Uncorrected Visual Acuity) (using a standard logarithmic visual acuity chart (GB11533-89, China), diopters, K_{mean} [$K_{\text{mean}} = (K_{\text{flat}} \pm K_{\text{steep}}) / 2$], corneal curvature K_{flat} and K_{steep} (auto-refractor NIDEK ARK-700A, NIDEK, JA-PAN), corneal topography eccentricity value (e-value), AL, ACD, PL, corneal diameter (IOL Master; Carl Zeiss Meditec AG, Jena, Germany), IOP (Non-contact tonometer, NIDEK NT-510, NIDEK, JA-PAN).

Statistical analysis

The primary outcome measure of this study was the change in AL from baseline to the time of review about 12 months. The data of all 675 subjects were included in the analysis and comparison. The SPSS 21.0 software (Chicago, IL, USA) was used for statistical analysis. Measurement data which was distributed normally was expressed as mean $\pm$ standard deviation. Data was expressed in median when the data distribution was abnormally distributed. Data between groups were analyzed with independent sample t test, ANOVA or pearson correlation analysis. Factors that had a statistical significance level of $P < 0.05$ were selected to enter the multivariable regression analysis model using the backward stepwise removal method. The dependent variable was divided into three groups in the regression analysis³¹. The logistic regression model was applied to multivariate analysis, inclusion elimination criteria $\beta \geq 0.05$ and step back screening $P < 0.05$ were regarded as meaningful in the statistical analysis. The strength of association for significant variables is represented using beta values, 95% confidence intervals.

Results

Patient and treatment characteristics

The data of the myopic teenagers were summarized in Table 2. Data comprised 675 subjects (312 male and 363 female). The age at initiation of Ortho-k wear ranged from 7 years to 24 years (mean $\pm$ SD, 11.71 $\pm$ 2.58 years). The SER ranged from 0.00/-0.25 to -10.13 D. The initial baseline eye axial of the group was 25.12 $\pm$ 0.995 mm. After 12 months of wear, the AL was 25.30 $\pm$ 0.94 mm—the AL change was 0.18 $\pm$ 0.22 mm.

Univariate analysis

Univariate analysis results of the independent variables in the right eyes of all subjects showed statistically significant associations between age at initiation of Ortho-k wear, SER and Baseline AL with AL change ($P<0.05$). Of the 675 patients, patients with larger initial wearing age, greater SER and larger baseline AL showed that smaller increases in AL.

In this study, there was a moderately negative correlation between baseline age and the rate of axial elongation ($r=-0.476$, $p<0.001$). Older patients who wear Ortho-k lens later had smaller AL change (Fig.1). During the duration of lens wear, there is a moderately positive statistical relationship between the SER and the rate of axial elongation ($r=0.344$, $p<0.001$), subjects with greater SER when wearing Ortho-K had less length change at 12 months (Fig.2). Baseline AL demonstrated a moderate relationship with the axial elongation ($r=0.340$, $p<0.001$), with a greater baseline AL associated with a greater degree of the axial elongation (Fig.3).

The results of this study showed that gender, UCVA, parental refractive status, K_{mean} , IOP, corneal curvature e value, PL, and corneal diameter were not associated with axial elongation after Ortho-k lens wear.

Multivariable analysis

According to the regression analysis of the right eye, age at initiation of Ortho-k wear and SER are independent factors with effects on the treatment outcome (Table 3). Based on the results of the univariate analysis, regression analyses did not show any statistically significant relationship between the baseline AL and axial elongation after Ortho-k lens wear.

Discussion

In the past few decades, the use of orthokeratology treatment worldwide has become more popular because of its effectiveness in the correction of myopia and the resolution of associated safety issues [32]. Ever since orthokeratology has been reported to inhibit myopia progression [33,34], Several studies in recent years have now demonstrated the benefit of ortho-k over other treatment modalities in assisting to reduce axial length growth and thereby slow the rate of myopia progression in children [35,36]. The data from the present study support the theory that the ortho-k lens can effectively control myopia by

inhibiting axial elongation. The data from the present study support the theory that the ortho-k lens can effectively control myopia by inhibiting axial elongation. The children with myopic progression less than the average annual growth (axial elongation ≤ 0.18 mm per year or ≤ 0.50 D per year) were considered as slow progressors^[31]. After 12 months' follow-up, the mean axial elongation of our study was 0.18 ± 0.22 mm.

The main aims of this study were to evaluate which of these factors effect AL change and myopia progression, and our results would be beneficial in the selection of suitable subjects for ortho-k to inhibit myopic progression as well as correct myopia. In this study, 12 baseline factors were included. We demonstrated that the age at initiation of ortho-k wear and SER are significantly associated with AL growth and myopia progression in ortho-k.

It was found that the axial length is related to the initial age at baseline^[37], and studies have shown that axial elongation slows with age^[38]. As shown in Figure 1, the greater the baseline age in this study, the smaller the axial elongation.

The ROMIO study suggested that baseline age may reflect the rate of myopia progression, with younger children shown to undergo faster rates of axial elongation, which has also been proposed by others previously^[37,39].

The current study found that ages of 7 to 8 years which was the age when myopia became the refractive state with the highest prevalence^[40,41].

In this study, the SER was associated with AL growth. Figure 2 shows that the larger the baseline SER, the smaller the axial elongation. While, Cho and Cheung^[25] and Charm and Cho^[42] observed that SER at baseline was not associated with AL growth in myopic patients reported no relationship between them. The discrepancy might be due to the differences in the contact lens design^[43] and their effects on peripheral refraction of the eye. Reasons for variation in results between studies regarding correlation between SER and AL increase need further discussion. This research not only determined the baseline factors affecting the AL growth during ortho-k wearing, but also laid a more stable foundation for preventing and controlling juvenile myopia.

The major strength of this study was that the sample size contained is relatively large, a wide range of myopia, and there are more baseline factors. This large sample size and baseline factors allow greater statistical power to detect any significant relationships between the various factors and AL in myopia progression. Certain limitations existed in the present study. It was a retrospective study, but had no control group to compare the results of the Ortho-k wearing children to. Another limitation is that the follow-up time is not long enough to observe long-term results.

Conclusions

The current study confirms that the factors closely related to axial growth in this study include the age at initiation of Ortho-k wear, the SER, and the ACD. Based on this, it provides a reliable basis for clinicians to better predict the effect of wearing Ortho-K.

Declarations

Disclosure statement

The authors declare no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Tables

Table 1. Inclusion criteria for data collection.

Inclusion criteria	
Age	greater than 7 years old
Refractive errors	SER $\leq$ -6.00D, flat meridian corneal curvature $\leq$ 50.00D, corneal astigmatism $\leq$ -2.00 D, BCVA $\leq$ 0.00 logMAR units in both eyes (Snellen equivalent to 20/20) and IOP within normal range (IOP<21mmHg).
Ocular healthy	no Ortho-k treatment contraindications, no ocular, systemic pathologies, history of ocular trauma, surgery, previous Ortho-k treatment, or use of contact lenses
Others	follow-up period greater than 5 month with sufficient clinical data
SER=spherical equivalent refractive BCVA =best corrected visual acuity Log MAR=log Minimal Angle of Resolution IOP=intraocular pressure	

Table 2. Baseline data description of Ortho-k subjects and univariate analysis results.

Groups	Value	T/peason/ANOVA	P
Male/Female	312/363	-1.204	0.229
Age at initiation of Ortho-k wear (yr)	11.71±2.58	-0.476	0.000
UCVA	0.30±0.15	0.073	0.060
SER (D)	-3.80	0.344	0.000
Parental refractive status	0.98±0.77	1.426	0.241
K _{mean}	43.30±1.40	0.054	0.158
IOP (mmHg)	16.64±3.18	-0.016	0.695
ACD (mm)	3.70±0.21	-0.066	0.086
Corneal curvature e value (D)	0.55±0.91	0.011	0.811
PL (mm)	6.19±0.89	-0.037	0.348
Corneal diameter (mm)	12.02±0.69	-0.014	0.726
Baseline AXL (mm)	25.12±0.995	-0.340	0.000
AXL after one year (mm)	25.30±0.94		

Table 3. Multivariable regression analyses of baseline factors on AL change.

Groups	B value	Wald	OR	P value	95% Confidence interval	
Age _{initiation of Ortho-k wear} (yr)	-0.382	86.608	0.683	0.000	-0.462	-0.301
SER (D)	0.147	3.953	1.158	0.047	0.002	0.091
Baseline AXL (mm)	-0.108	0.899	0.898	0.343	-0.331	0.115

Figures

Figure 1

Older patients who wear Ortho-k lens later had smaller AL change (Fig.1).

Figure 2

During the duration of lens wear, there is a moderately positive statistical relationship between the SER and the rate of axial elongation ($r=0.344$, $p<0.001$), subjects with greater SER when wearing Ortho-K had less length change at 12 months (Fig.2).

Figure 3

Baseline AL demonstrated a moderate relationship with the axial elongation ($r=0.340$, $p<0.001$), with a greater baseline AL associated with a greater degree of the axial elongation (Fig.3).