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Original article

Changes in corneal curvature after wearing the orthokeratology lens



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ABSTRACT

Introduction: The orthokeratology lens (OK lens) is designed to reshape the cornea and correct refraction error. Owing to the convenience of ceasing the use of glasses during the day, the use of the OK lens is increasing in myopic children. In this study, changes in corneal curvature and astigmatism after wearing the OK lens were analyzed.

Methods: This retrospective cohort study included 65 children (130 eyes) who underwent full and regular examinations. None of the participants had any ocular disease other than myopia and astigmatism. The OK lenses used in this study were four-zone, reverse-geometry lenses. The corneal curvature of each patient was checked annually after the patients discontinued daily wearing of the OK lens for 10 days. Student t test and repeated measures analysis of variance (ANOVA) analyses were performed to compare the results.

Results: The radius of corneal curvature showed a progressive annual increase with significant differences, both in the steepest and flattest radius of the corneal curvature (p < 0.001 and p = 0.001, respectively). The mean radius of the steepest and flattest corneal curvature increased significantly from baseline to the following years consecutively (all p < 0.001). Nevertheless, astigmatism did not change significantly in any of the tests.

Conclusion: Corneal curvature changed as the patients grew older. There was a statistically significant increase in the radius of the corneal curvature in the myopic children studied. For correct fit of OK lenses. the radius of the corneal curvature should be regularly checked prior to dispensing a new set of lenses. Copyright © 2013, The Ophthalmologic Society of Taiwan. Published by Elsevier Taiwan LLC. All rights reserved.

1. Introduction

Myopia is the most common ocular disorder, and its prevalence ranges from 20% to 30% in North American, European, and Australian populations^{1–3} and is as high as 70–90% in Asian students.^{4–8} Myopia is associated with increased risk for ocular complications. 9,10 A low to moderate degree of myopia is easily corrected using spectacles or contact lenses. However, a high degree of myopia, while correctable using these optical approaches, is of major concern because of the increased risk for myopia-related pathologies such as chorioretinal degeneration and retinal detachment.^{9,10} Hence, the prevention and control of myopia is a major public health issue. Orthokeratology (OK) uses rigid contact lenses to reshape the cornea in order to temporarily reduce or eliminate refractive error. 11,12 Modern OK using a reverse-geometry design can provide faster, larger, and more predictable refractive changes than the OK lenses introduced in the early 1960s. 13 Overnight OK lenses can provide acceptable vision for daytime activity and decrease the patient's need to wear contact lenses or spectacles. The presumed mechanisms of OK lens-induced myopic reduction include central corneal flattening, thinning of the central corneal epithelium, ^{14–16} thickening of the midperipheral cornea, and peripheral vision hyperopic shift.¹⁷ However, some studies have revealed that OK lenses increase higher-order aberrations of the cornea and decrease contrast sensitivity. 18,19 Despite debate regarding certain safety issues, the use of OK lenses is increasingly popular.¹

The radius of the corneal curvature is important for appropriate fitting of an OK lens, but because OK lenses are generally used on a long-term basis, changes in the corneal curvature that occur with age may lead to inappropriate fitting of lenses. OK lenses thus need

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Table 1Baseline data of patients in the study.

| | OK (mean \pm SD) |
|-------------------------------------|------------------------------|
| Age (y) | 11.82 ± 1.25 |
| Sex (M:F) | 1:0.99 |
| Myopia (D) | $1.5{-}7.5~(4.25\pm1.5)$ |
| Astigmatism (D) (Negative cylinder) | $0 - 2.75 \ (0.75 \pm 0.75)$ |
| UCVA (log MAR) | 0.8 ± 0.45 |
| BCVA (log MAR) | 0.1 ± 0.015 |
| Axial length (mm) | 24.12 ± 1.25 |
| | |

BCVA = best corrected visual acuity; D = Diopter; F = female; log MAR = logarithm of the minimum angle of resolution; M = male; OK = orthokeratology; SD = standard deviation; UCVA = uncorrected visual acuity.

to be refitted regularly owing to changes in refractive power or worn lenses. Nevertheless, the nature of corneal curvature changes and the factors influencing these are still not well defined.²⁰ Some studies have shown that the radius of corneal curvature does not vary significantly with age,^{21,22} but investigations relating to changes in the radius of corneal curvature with age are limited. In this study, corneal curvatures in flat and steep meridians were analyzed to determine the changes in corneal curvature and astigmatism that occur with age to facilitate refitting of OK lenses.

2. Methods

This is a retrospective study. Sixty-five patients undergoing regular examinations who had successfully completed the 3-year follow-up examinations were enrolled in this study. Comprehensive ophthalmic examinations were performed prior to treatment and at every visit.

None of the participants had any ocular disease or insult such as retinopathy, prematurity, neonatal problems, a history of genetic disease, or connective tissue disorders associated with myopia, such as Strickler or Marfan syndromes. Clinical examinations included visual acuity, refraction error, slit lamp examination, ocular movements, intraocular pressure, and fundoscopy. Patients with a history of organic eye disease, cataracts, or intraocular surgery were excluded from the study (Table 1). None of the participants had any ocular disease other than myopia and astigmatism. The noncycloplegic subjective vision and cycloplegic objective refraction were recorded. All participants had a visual acuity with distance correction of 0.1 logarithm of the minimum angle of resolution (log MAR; 20/25) or better. Individuals with myopia from 1.5 Diopter (D) to 7.5 D [mean \pm standard deviation (SD), 4.25 \pm 1.5 D] and astigmatism from 0 D to 2.75 D (mean \pm SD, $0.75 \pm 0.75 \; D)$ were included, but cases of extremely high myopia and astigmatism were excluded. Autorefraction (using Autorefractor/Autokeratometer ARK 700A; Nikon, Tokyo, Japan) was conducted on both eyes by experienced optometrists who were trained and certified with respect to the study protocols. The corneal curvature of the flattest and steepest corneal meridians (hereafter referred to as the "flat and steep corneal meridians") was recorded and analyzed. Sixty-five patients (130 eyes) agreed to undergo regular examinations and were included in this study.

The OK lenses used in this study were four-zone, reverse-geometry lenses (Emerald Lenses; Euclid Systems Corp., Herndon, VA, USA, manufactured from Boston XO material; Polymer Technology Corp., Wilmington, MA, USA) with a nominal oxygen permeability (Dk) of 100 \times 10^{-11} cm²/s (mL O₂/mL mmHg). The nominal central thickness of the lenses was 0.22 mm and the diameter was 10.4-11.0 mm. The parameters of the lenses were varied to achieve good centration and a good fluorescence pattern. After the lenses had been dispensed, the patients were advised to wear their OK lenses every night for at least 6-8 consecutive hours. The patients returned for an examination every 3 months and underwent slit lamp examinations for any adverse events. The OK lens fit was evaluated at these visits, and the lenses were replaced if visual acuity was found to have changed by more than 0.3 log MAR (20/ 40) during follow-up. Refraction, visual acuity, axial length, and corneal endothelium cell count obtained prior to the start of the treatment were used as the baseline values, and measurements were performed every 3 months thereafter. The corneal curvature of each patient was checked annually after the patients discontinued daily wearing of the OK lens for 10 days. On each occasion, five successive measurements were taken, and their mean was used as a representative value.

We recorded and compared the change in corneal curvature at baseline and at the 1-year, 2-year, 3-year, and 4-year follow-up. Corneal astigmatism was defined as the absolute difference between the K1 and K2 meridians, where K1 represents the corneal curvature in the flat central radius in the 3.0 mm zone and K2 represents the steep central radius in the 3.0 mm zone. Data are presented as ranges or as mean \pm SD. A paired t test was used to compare the baseline conditions of the two groups and repeated measures analysis of variance (ANOVA) was used to compare the results during the years. A p value < 0.05 was regarded as significant.

3. Results

Sixty-five patients (130 eyes) undergoing regular examinations who had successfully completed the 3-year follow-up examinations were enrolled in this study. Among the 65 patients (33 males and 32 females), their ages ranged from 7 years to 17 years (mean \pm SD, 11.82 \pm 1.25 years). At baseline, their myopia ranged from 1.5 D to 7.5 D (mean \pm SD, 4.25 \pm 1.5 D), and astigmatism ranged from 0 D to 2.75 D (mean \pm SD, 0.75 \pm 0.75 D); log MAR uncorrected visual acuity (UCVA) was between 0.20 log MAR and 1.40 log MAR (mean \pm SD, 0.80 \pm 0.45 log MAR), and axial length ranged from 22.05 mm to 27.05 mm (mean \pm SD, 24.12 \pm 1.25 mm) (Table 1). The mean radius of corneal curvature increased progressively on an annual basis with significant differences between years. The change in mean cornea endothelium cell count was not significantly different during the follow-up years. Using linear regression analysis, we found that myopia increased by 0.28 ± 0.18 D per year in the OK lens user and the UCVA of the OK lens user was 0.2 log MAR (20/30) to $-0.1 \log MAR (20/16)$ at 2 PM

The radius of the steepest corneal curvature in the right eyes was 7.85 \pm 0.30 mm, 7.91 \pm 0.29 mm, 7.94 \pm 0.29 mm,

 Table 2

 Comparison of the radius of corneal curvature measurement during the years (right eye).

| | Baseline (mm) | 1 st year (mm) | 2 nd year (mm) | 3 rd year (mm) | 4 th year (mm) | p^* |
|--|---|----------------------------------|---|---|----------------------------------|-----------------|
| Steepest corneal meridians Flattest corneal meridians | $\begin{array}{c} 7.85 \pm 0.30 \\ 7.67 \pm 0.30 \end{array}$ | $7.91 \pm 0.29 \\ 7.70 \pm 0.31$ | $\begin{array}{c} 7.94 \pm 0.29 \\ 7.74 \pm 0.32 \end{array}$ | $\begin{array}{c} 7.96 \pm 0.12 \\ 7.76 \pm 0.22 \end{array}$ | $7.98 \pm 0.18 \\ 7.78 \pm 0.12$ | <0.001 0.001 |

Data are presented as mean \pm standard deviation (SD).

^{*} Repeated measures analysis of variance (ANOVA).

Table 3Comparison of the mean of the radius of corneal curvature (the average between the steepest and flattest corneal meridians) during the years (right eye).

| Difference between year and previous year | Mean of corneal curvature \pm SD | <i>p</i> * |
|--|---|-----------------------------------|
| 1 st year and baseline 2 nd year and 1 st year 3 rd year and 2 nd year 4 th year and 3 rd year | $\begin{array}{c} -0.06177 \pm 0.05630 \\ -0.03208 \pm 0.04298 \\ -0.00500 \pm 0.05994 \\ -0.06556 \pm 0.06100 \end{array}$ | <0.001 0.025 0.760 0.012 |

^{*} Paired t test.

SD = standard deviation.

 7.96 ± 0.12 mm, and 7.98 ± 0.18 mm in the baseline, $1^{\rm st}$ year, $2^{\rm nd}$ year, $3^{\rm rd}$ year, and $4^{\rm th}$ year, respectively. The radius of the flattest corneal curvature in the right eye was 7.67 ± 0.30 mm, 7.70 ± 0.31 mm, 7.74 ± 0.32 mm, 7.76 ± 0.22 mm, and 7.78 ± 0.12 mm in the baseline, $1^{\rm st}$ year, $2^{\rm nd}$ year, $3^{\rm rd}$ year, and $4^{\rm th}$ year, respectively (Table 2). All of these changes were significantly different (p < 0.001 and p = 0.001; Table 2).

The between-year differences of the mean of the radius of corneal curvature (the average between the steepest and flattest corneal meridians) of right eyes were also significantly different except in the $3^{\rm rd}$ year and the $2^{\rm nd}$ year (p < 0.001, 0.025, 0.760, and 0.012, respectively; Table 3).

The average of the mean of the radius of corneal curvature (the difference between the steepest and flattest corneal meridians) of right eyes compared to baseline were all significantly different (all p < 0.001; Table 4).

Nevertheless, astigmatism was not changed significantly in any of the tests in this study. The differences between the steepest (S) and flattest (F) corneal meridians (S-F) were insignificant between the years (Table 5).

4. Discussion

OK may be defined as a temporary reduction in myopia induced by the application of rigid contact lenses.²³ The essential feature of accelerated OK is the reduction of myopia by the application of appropriately fitted reverse-geometry gas-permeable lenses, which reduce corneal eccentricity and flatten the apical radius of the cornea.²⁴ Good fit and centralization of OK lenses can afford good vision quality and stable peripheral vision, although cannot avoid high order aberrations completely, which is also important for decreasing the progression of myopia. Changes in corneal curvature with age are strongly suspected but have not been conclusively proved.²² In this study, a significant increase in the radius of corneal curvature was observed compared with previous years (paired ttest). Repeated measures ANOVA also revealed a tendency toward an annual increase in corneal curvature. The radius of corneal curvature increased every year (Tables 3 and 4). Moreover, after 4 years there were still significant differences when compared with the baseline (prior to treatment). Only the radius of the corneal

Table 4The differences in the mean of the radius of corneal curvature (the average between the steepest and flattest corneal meridians) compared to baseline (right eye).

| Difference between year and previous year | Mean of corneal curvature \pm SD | <i>p</i> * |
|--|---|--------------------------------------|
| 1 st year and baseline 2 nd year and baseline 3 rd year and baseline 4 th year and baseline | $\begin{array}{c} 0.06177 \pm 0.05630 \\ 0.07344 \pm 0.07997 \\ 0.07963 \pm 0.05905 \\ 0.15409 \pm 0.08046 \end{array}$ | <0.001 <0.001 <0.001 <0.001 |

^{*} Paired t test.

curvature of the 3rd year did not increase significantly as compared with the 2nd year; this may be due to the changes of the years being very small, but the increasing tendency of the radius of corneal curvature was still evident and should not be overlooked.

Curvature changes are more complex than a simple molding of the corneal curvature, and the radius of corneal curvature is influenced by many factors, including gender, sclera biomechanical properties, race, and eyelid tightness.^{20,25} A previous study revealed that astigmatism changes are more reliable in men than in women, and a with-the-rule astigmatism can change into an against-the-rule astigmatism. However, changes in astigmatism often happen after mid-life, and may be due to changes in eyelid tightness that occur at this age, which would clearly not be expected in the present study. The astigmatism diopter did not change significantly during the study period even though significant changes in corneal curvature were observed; that is, the steepest and flattest corneal curvatures all changed and were set up in the same direction. Consequently, the changes in the radius of corneal curvature observed in this study may be due to axial elongation during growth, but more studies are needed to confirm these findings.

Many previous studies evaluated age-related variations in ocular parameters and these revealed that axial length, anterior chamber depth, and white-to-white distance increase from age 2 years to 19 years. ^{26,27} As for corneal curvature, a few studies have shown that this increases with age, but this has not been confirmed. The present study findings may provide a useful index for fitting OK lenses.

One major limitation of our study is that the corneal curvature was checked every year after the use of OK lenses had been discontinued for 10 days; 10 days may not have been sufficient time for the myopia diopter to completely recover to the baseline condition. However, the patients often relied on the OK lenses for everyday vision and could not discontinue using OK lenses for 4–6 weeks, a period proven to be sufficient for restoration of corneal curvature to the baseline condition. Nevertheless, in clinical practice during the 4 years, changing the prescription of newly fitted OK lens to increased radius of corneal curvature was suitable for patients. Besides, the rate of increase of corneal curvature may be different at different ages. Therefore, a larger, age-stratified study sample is required in future studies.

According to the results shown in Tables 3 and 4, the "average" of the corneal curvature change every year compared well with previous years. We suggest that a recheck of the corneal curvature prior to dispensing a new set of OK lenses is important. According to the data in Table 5, the "differences" of the steepest and flattest cornea curvature of individual patients were insignificant, that is, the corneas are becoming flatter with age in the OK lens-wearing patients but the cornea-induced astigmatism does not change significantly after wearing OK lenses. The changes in astigmatism of the general population not using OK lenses were not within the scope of this study; this area needs further investigation.

Proper fitting and good centration of OK lenses are essential for OK lens users to have good visual quality during the day time. In

Table 5The differences in the steepest (S) and flattest (F) corneal meridians (S—F; right eye).

| | S–F corneal meridians, mean \pm SD (mm) | p* |
|--|---|----------------|
| 2 nd year and baseline 3 rd year and 2 nd year | $\begin{array}{c} 0.00917 \pm 0.01328 \\ 0.00571 \pm 0.00965 \end{array}$ | 0.504 0.564 |
| 4 th year and 3 rd year | 0.01333 ± 0.02205 | 0.562 |

^{*} Paired t test.

SD = standard deviation.

SD = standard deviation

this study, corneal curvature changed with age. There were statistically significant increases in the radius of corneal curvature in myopic children according to increasing age. In order to appropriately fit OK lenses, it is reasonable to perform regular corneal curvature examinations and to check the radius of corneal curvature regularly and carefully prior to dispensing a new set of OK lenses.

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