

Clinical Efficacy of Toric Orthokeratology in Myopic Adolescent with Moderate to High Astigmatism

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Abstract

Purpose: To observe the efficacy of toric design orthokeratology (ortho-k) for correcting myopia and astigmatism in myopic adolescents with moderate to high astigmatism.

Methods: This was a self-controlled clinical study. Twenty-four subjects (42 eyes) aged 9 to 16 years with myopia of 2.50-6.00 D complicated with rule astigmatism of 1.50-3.50 D were fitted with Lucid Night Toric Ortho-k Lenses (LUCID, KOREA). The changes in uncorrected visual acuity (UCVA), spherical degree, refraction, axial length (AL), and corneal status were assessed at baseline, 1 night, 1 week, 1 month, 3 months, 6 months, and 1 year after the commencement of ortho-k lens wear.

Results: The success rate of the first lens fit was 92.8%. The UCVA after ortho-k wearing was improved significantly compared to the baseline during each visit (all $P < 0.01$), and became stable 1 month after ortho-k. The manifest myopia was significantly reduced from (-3.41 ± 1.27) D to (-0.41 ± 0.37) D by toric ortho-k and the degree of astigmatism from (-1.81 ± 0.53) D to (-0.41 ± 0.39) D after 1 month of lens wear ($P < 0.01$). The mean AL was (24.47 ± 0.91) mm at baseline, which did not significantly differ from (24.49 ± 0.87) mm and (24.48 ± 0.94) mm after 6 months and 1 year, respectively, of lens wear (both $P > 0.05$). Grade 1 corneal staining was observed at 1 week (23.8%), 1 month (21.4%), and 1 year (16.7%) following lens wear, and was improved by lens cleaning, discontinuing lens wear, and moistening the cornea with eye drops. No severe adverse events were reported.

Conclusion: The toric ortho-k lens was effective and safe for correction of low to moderate myopia in children with moderate to high astigmatism. The lens also effectively controlled axial length elongation during 1 year of observation. However, the long-term efficacy remains to be elucidated. (*Eye Science* 2014; 29:209-213)

Keywords: Toric design; orthokeratology; astigmatism; myopia; myopia control

Introduction

Myopia is currently the most common refractive error in Chinese adolescents. Conventional single vision glasses do not effectively prevent the development of myopia or the continuous increase in axial length (AL)^{1,2}. Multiple clinical studies have demonstrated that toric orthokeratology (ortho-k) lenses can effectively prevent the development of low/moderate myopia and reduce the growth rate of vitreous chamber length in patients with progressive myopia³⁻⁶. Adolescent myopia is frequently complicated with corneal astigmatism^{7,8}. However, the conventional ortho-k (OK) lens currently available in China is designed based on the sphere of each zone and is ineffective at correcting moderate/severe astigmatism⁹⁻¹¹. The most common problem is undesirable centralized fitting, which causes a greater severity of astigmatism and lower visual acuity^{10,12}. In this study, adolescent patients with moderate/severe astigmatism or those not treated with conventional OK lens were enrolled and required to wear toric design ortho-k lenses to determine the clinical and correction efficacy of these lenses.

Subjects and methods

Study subjects

The subjects were twenty-four myopic adolescents (42 eyes), 14 females and 10 males, aged 9-16 years, with a spherical equivalent ranging from -2.5 to -6.0 OD, and astigmatism of 1.50-3.50D. Every subject was required to wear conventional ortho-k (OK) lenses in our hospital between February and

July 2013. Participants were not fitted for these conventional OK lenses. Inclusion criteria were the following: The corrected visual acuity in both eyes was ≥ 5.0 as measured by a LogMAR visual acuity chart; no history of wearing corneal contact lens; no ocular pathological changes; no history of ocular trauma or eye surgery; no abnormality in eye position or eye movement. Informed consents were obtained from all adolescents and their guardians. This study was conducted in accordance with declaration of Helsinki and approved by the Ethics Committee of our hospital. The patients' clinical data are shown in Table 1.

Table 1 Patients' data during the first visit (mean \pm SD; $n=42$)

Age (year)	12.4 \pm 2.1
Degree of myopia (D)	3.41 \pm 1.27
Degree of astigmatism (D)	1.81 \pm 0.53
Horizontal curvature (D)	43.10 \pm 1.34
Vertical curvature (D)	45.70 \pm 1.47
Corneal astigmatism (D)	2.27 \pm 0.57
UCVA	4.19 \pm 0.11
BCVA	5.09 \pm 0.07
E value	0.47 \pm 0.21
SAG height difference (μ m)	49.28 \pm 17.84
Intraocular pressure (mmHg)	12.7 \pm 2.1
Axial length (mm)	24.47 \pm 0.91

The lenses used were Lucid Night Toric Ortho-k Lenses(LUCID, KOREA), Toric design (BOSTON, XO),DK:100; lens diameter: 10.6 mm; optic zone diameter: 6.0 mm; lens thickness: 0.23 mm.

Measurements were obtained using a composite refractometer (BURTON 7500-I, Spain), auto-refractometer (NIDEK ARK-510A, Japan), optical biometry device (IOLMaster, Zeiss, Germany), and corneal topography device (TMS-4, TOMEY, Japan).

Methods

Routine examination included: UCVA, medical optometry, slit-lamp examination, eye axial length measurement, tear function test, corneal curvature, corneal topography, non-contact intraocular pressure, and funduscope examination. Other ocular diseases were excluded. The FK and degree of astigmatism of the trial ortho-k lens was determined by FK, E value, and SAG height difference revealed by

corneal topography. The parameters of the ortho-k lens were confirmed by centralized fitting, shifting degree, fluorescence imaging, and optometry. During the trial lens wear, each child was required to wear the optimal ortho-k lens and close their eyes for 30 min; the changes in corneal topography were then observed. Subjects who presented with apparent lens eccentricity due to eyelid morphology and nasal and temporal corneal asymmetry were excluded from the OK lens treatment. The subjects were required to wear OK lenses for 8 to 10 h every night unless instructed otherwise by the examiner and to attend aftercare visits scheduled after the first overnight, and at 1 week, 1 month (each visit within 2 h after waking up in the morning), and 3, 6, 12 months after commencing lens wear. The parameters including UCVA, residual refractive power, corneal status, and corneal topography were re-examined. The AL was measured at 6 and 12 months after ortho-k. All tests were performed by assigned ophthalmologists in the morning within 2 h after lens removal. The glasses were changed when refractive power was increased by 0.50 D.

Statistical analysis

SPSS 16.0 statistical software was utilized for data analysis. A paired t-test was conducted for statistical comparison. $P < 0.05$ was considered as statistically significant.

Results

The success rate of good lens fitting for the first lens was as much as 92.8% (39/42). The remaining 3 eyes obtained good lens fitting after parameter adjustment. Good centralized fitting was observed in most cases by corneal topography, as illustrated in Figures 1-4.

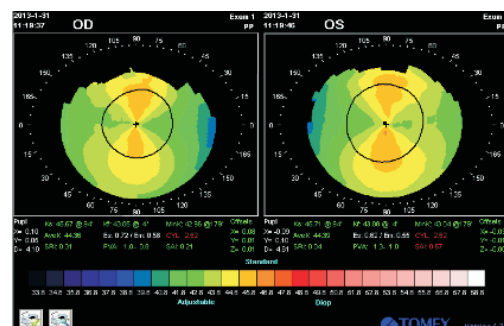


Figure 1 Corneal topography before lens wear

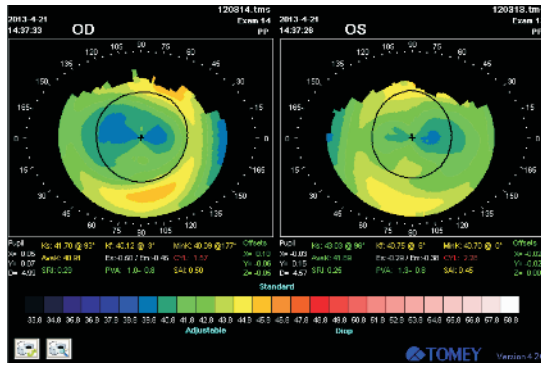


Figure 2 Corneal topography at 3 months after lens wear

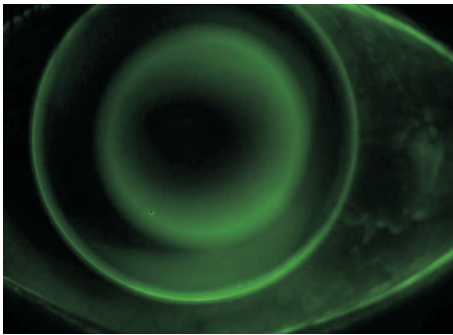


Figure 3 Fluorescent images of conventional ORTHO-K

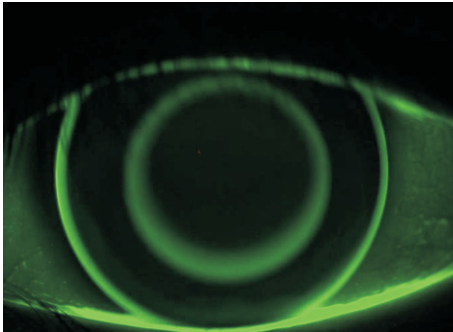


Figure 4 Fluorescent images of toric design ORTHO-K

Changes in UCVA: UCVA before ortho-k was 4.19 ± 0.11 and 4.62 ± 0.13 , 4.89 ± 0.12 , 4.96 ± 0.14 , 5.03 ± 0.11 , and 5.01 ± 0.15 at 1 night, 1 week, and 1, 6, and 12 months after ortho-k, respectively. The initial UCVA and those at 1 night, 1 week, and 1 month after ortho-k were significantly enhanced (all $P < 0.05$) and became stable at 1 month later. Changes in BCVA (Table 2): BCVA prior to ortho-k was 5.09 ± 0.07 and decreased to 5.07 ± 0.08 at 1 year after ortho-k. No statistical significance was observed ($P > 0.05$). Figure 5 shows the changes in UCVA.

Changes in residual refractive power: the degree

Table 2 Comparison of AL before and after ortho-k (means \pm s, mm)

	Baseline	6 months	12 months
AL	24.47 ± 0.91	24.49 ± 0.87	24.48 ± 0.94
T value		0.024	0.021
P		0.978	0.981

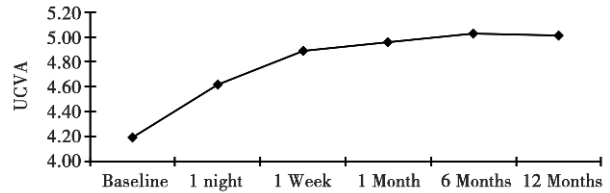


Figure 5 Changes in UCVA before and after ortho-k

of myopia was $-3.41 \pm 1.27D$ before ortho-k, and $-1.74 \pm 1.07D$, $-0.81 \pm 0.57D$, $-0.41 \pm 0.37D$, $-0.39 \pm 0.38D$, and $-0.37 \pm 0.36D$ at 1 night, 1 week, and 1, 6, and 12 months after ortho-k, respectively. Statistical significance was observed before and after ortho-k (all $P < 0.05$). The myopia degree was decreased by 87.9% at 1 month after ortho-k and tended to stabilize after 1 month. The degree of astigmatism was $-1.81 \pm 0.53D$ before ortho-k and $-0.78 \pm 0.57D$, $-0.54 \pm 0.42D$, $-0.41 \pm 0.39D$, $-0.35 \pm 0.34D$, and $-0.36 \pm 0.37D$ at 1 night, 1 week, and 1, 6, and 12 months after ortho-k, respectively. Statistical significance was observed before and after ortho-k (all $P < 0.05$). The degree of astigmatism was decreased by 77.3% at 1 month after ortho-k and tended to stabilize after 1 month, as illustrated in Figure 6.

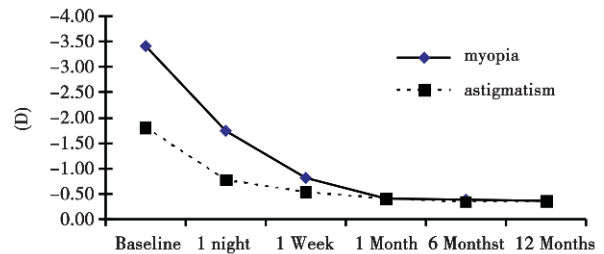


Figure 6 Changes in residual refractive power before and after ortho-k

Changes in corneal astigmatism: the corneal astigmatism was $2.27 \pm 0.57D$ before ortho-k and $2.02 \pm 0.46D$, $1.72 \pm 0.57D$, $1.48 \pm 0.47D$, $1.31 \pm 0.58D$, and $1.27 \pm 0.43D$ at 1 night, 1 week, and 1, 6, and 12 months after ortho-k, respectively. Statistical significance was observed before and after ortho-k (all $P <$

0.05), as shown in Figure 7.

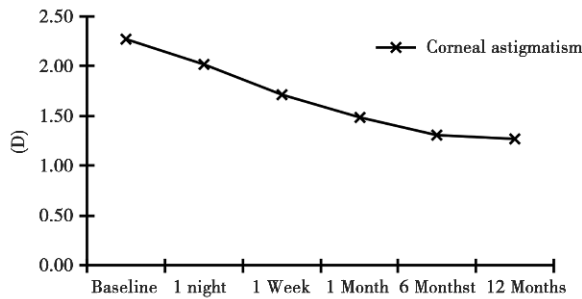


Figure 7 Changes in corneal astigmatism before and after ortho-k

Changes in AL: the axial length was (24.47 ± 0.91) mm prior to ortho-k and (24.49 ± 0.87) mm and (24.48 ± 0.94) mm at 6 months and 1 year after ortho-k. No statistical significance was observed before and after ortho-k (all $P > 0.05$), as illustrated in Table 2.

Corneal staining: the incidence of grade 1 staining of corneal epithelia observed after ortho-k: 23.8% at 1 night after OK lens wear, 19.0% at 1 week, 21.4% at 1 month, and 16.7% at 1 year. These symptoms could be alleviated by discontinuing ortho-k, OK lens cleaning, or administration of levofloxacin or recombinant human bovine basic fibroblastic growth factor eye drops as necessary. No corneal infection, lens binding, or severe lens shifting was observed.

Discussion

Orthokeratology is a special type of rigid corneal contact lens with reverse-geometry lens design. It can lightly press the cornea, causing a gradual reshaping that temporarily reduces refractive errors¹³. In clinical practice, the ortho-k lens is mainly designed based on the four zones: Base, Reverse, Alignment, and Peripheral zones.

The scope of orthokeratology treatment includes a degree of myopia 1.00-5.00 D, degree of astigmatism < 1.50 D, and corneal FK value ranging from 41.50 to 44.00 D¹⁴. However, the conventional OK lens fails to achieve ideal lens fitting and reshaping effects for patients with moderate/severe astigmatism. The reasons include: 1) the difference in horizontal and vertical corneal curvature causes significant discrepancy in terms of toric corneal surface

morphology; 2) the difference between corneal central and peripheral curvature; 3) a large area of corneal astigmatism; 4) corneal astigmatism involved in a peripheral position. The toric ortho-k lens, by contrast, is designed based on the difference in mid-peripheral corneal curvature. Both the reverse and alignment zones are designed to the toric surface, such that neither the reverse zone nor the alignment zone has a circular section. Instead, it consists of zone segments with a different radius of curvature to form a toric surface, which is more suitable for corneas with irregular morphology and provides better lens fitting^{15,16}. In this study, the success rate of good centralized fitting of the first ortho-k lens was 92.8%, higher than that of the conventional OK lens¹⁰, whereas it was similar to that of the toric lens reported by Chen¹⁷. The corneal astigmatism was gradually decreased after ortho-k, suggesting that the toric design lens is able to improve the lens fitting of eyes with moderate/high corneal astigmatism.

In this study, the UCVA of 42 eyes was gradually improved after toric design ortho-k and the highest increase was observed 1 week after lens insertion, indicating that the lens provides the best corneal reshaping effect during this period. After 1 month of ortho-k, the increase in UCVA became mild and stable, suggesting that the effect of corneal reshaping is gradually steady and long-lasting. The BCVA did not significantly differ before and after ortho-k. After ortho-k, the residual degree of myopia and degree of astigmatism and corneal astigmatism were gradually decreased and became stable after 1 month of ortho-k.

The changes in AL are the important index when evaluating the progress of myopia^{3,6,18}. Pauline Cho and colleagues found that OK lenses could significantly delay the increase in AL. The LORIC study conducted in Hong Kong⁴ revealed that the AL was increased by 0.16 mm on average after 1 year of conventional sphere design ortho-k treatment, significantly reduced by 53% compared to the control group, and increased by 0.29 mm on average after 2 years of treatment, significantly reduced by 42% compared to the control group. The ROMIO study³ demonstrated that the mean increase in AL was 0.2 mm after 1-year sphere design ortho-k treatment, increased by 0.36 mm after 2-year therapy, and signif-

icantly decreased by 52% compared with the control group. The TO-SEE study¹⁸ revealed that the AL was increased by 0.15 mm on average after conventional astigmatism design ortho-k treatment for 1 year, significantly reduced by 58% compared with the control group, and increased by 0.31 mm on average after 2-year therapy, significantly reduced by 52% compared to the control group. In this study, the AL was not altered after 1-year of toric design ortho-k lens correction, hinting that the myopia did not progress, probably resulting from the strict inclusion criteria. The cases who presented with apparent lens eccentricity due to eyelid morphology and nasal and temporal corneal asymmetry were excluded from this study. During the 1-year follow up, good lens fitting was observed in all patients and no evident lens eccentricity was seen, hinting that good centralized fitting of ortho-k lenses plays a pivotal role in controlling the increase of AL and delaying the progress of myopia.

In this study, grade I staining was observed in the corneal epithelial cells after ortho-k and recovered by conservative treatment. The incidence of corneal staining was lower when compared with the findings of previous studies¹⁰, which was probably related to the modified lens design, good centralized fitting, and no lens binding. The lens design has relatively good safety, showing no corneal infection or severe complications during the subsequent follow up.

Limitations

No control group was included in this study. The sample size was relatively small. The follow up lasted only 1 year. Consequently, the long-term effect of toric design ortho-k lens treatment remains to be investigated.

Conclusions

The toric design ortho-k lens can significantly improve centralized fitting of the lens. It was effective and safe in correcting low to moderate myopia in adolescents with moderate to high astigmatism. The lens could also effectively control axial length elongation during the 1 year of observation. The myopia did not progress during the 1 year treatment. However, the long-term clinical efficacy remains to be further evaluated.

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