Effectiveness of Overnight Orthokeratology with a New Contact Lens Design in Moderate to High Myopia with Astigmatism

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Background and Objectives

To assess the effectiveness of overnight orthokeratology (OK) in myopia using a new contact lens design over a one-month wearing period.

Materials and Methods

Participants were required to have myopia between -3.00 and -7.50 D and astigmatism ≤ 2.00 D to participate in the study. The participants underwent OK with the White OK lens® (Interjojo, Pyungtek, Korea), which has a 6-curve lens design. Participants were assessed at weeks 1, 2, and 4 using slit-lamp bio-microscopy, and tested for refraction, uncorrected distance visual acuity, and corneal topography. Success was defined as achieving a Logarithm of the Minimum Angle of Resolution (logMAR) ≤ 0.1 .

Results

A total of 46 eligible subjects with a mean age of 23.11 ± 7.89 years were recruited. Baseline logMAR was 1.18 ± 0.30 and a consistent decrease in logMAR was observed from week 1 to week 4. The success rate was 95.35% at week 4. The mean sphere significantly decreased from a mean pre-fitting value of -4.58 ± 1.28 D to a mean value of -0.65 ± 0.69 D at week 4 ($p < 0.0001$). Statistically significant corneal flattening was detected during keratometry at week 4.

Conclusion

Overnight OK with the White OK lens is effective for the correction of moderate and high myopia with astigmatism over a one-month wearing period.

Key words

Myopia; Orthokeratology; Astigmatism

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INTRODUCTION

The prevalence of myopia is up to 70% in Asian populations.^{1,2} Specially, high myopia is a significant risk factor in retinal detachment, glaucoma, and chorioretinal degeneration, which can bring visual impairment.³ To correct myopia, spectacles, contact lens, and keratorefractive surgeries have been applied and low dose atropine, pirenzepine, outdoor activities, and orthokeratology (OK) lens have been used to prevent the progression of myopia.⁴⁻⁸ In OK, myopia reduction occurs through alteration of the anterior corneal shape, whereas myopia control has been hypothesized to be due to myopic defocus at the peripheral retina following changes in the anterior corneal shape.^{9,10}

In overnight OK, specially-designed gas-permeable rigid contact lens worn during sleep is utilized to reshape the front surface of cornea for reduction of myopic refractive errors.¹¹ It reshapes the cornea temporarily by hydraulic forces produced under the rigid contact lens with a reverse geometry design and leads to a reversible myopia correction. OK intends to correct distant vision by flattening of the central cornea and creates the mid-peripheral cornea steeper to focus the image in front of the peripheral retina. These alterations emerge soon after wearing the lens overnight and stabilize after 7-10 days.¹² The mid-peripheral corneal thickening, central corneal flattening, myopic shift of peripheral vision, and central corneal epithelial thinning are thought to result in myopic reduction.^{13,14} However, some reports suggested that OK lens can increase higher-order aberrations and decrease contrast sensitivity.^{15,16}

Many studies revealed that at least 80% myopic reduction can be accomplished for low to moderate myopia.^{17,18} However, full reduction may not be achievable for high myopia.¹⁹ Previous studies evaluated the effectiveness of OK on high myopes and some reported that lens decentration and serious corneal staining tend to develop with increasing target.¹⁹⁻²⁴

It has been reported that correcting moderate to high astigmatism using spherical reverse geometry lens designs in OK is difficult.²⁵ Tahhan et al. showed no significant change in the astigmatism on OK for three months.²⁶ It is thought to be inappropriate for spherical OK to correct with-the rule astigmatism greater than -1.50 D.²⁷ Lens decentration is the most common obstacle with spherical designed OK lens to correct corneal astigmatism because it may result in poor vision and induce astigmatism.

Little information is known about the success rate in correcting higher refractive errors. Thus, the purpose of

this study was to evaluate the effectiveness of OK lens with new contact lens design for the correction of moderate to high myopia with astigmatism over a one-month wearing period. To our knowledge, this is the first study reporting the efficacy of overnight OK with this new design of reverse geometry lens for the correction of moderate to high myopia with astigmatism.

MATERIALS AND METHODS

Ethics statement

The study was conducted in accordance with the tenets of the Declaration of Helsinki from May 2019 to August 2019. The study protocol and informed consent were reviewed and approved by the institutional review board (IRB) of Dankook university hospital before initiation (IRB#DKUH201903011). The study enrolled subjects at Dankook university hospital and subjects for this study were recruited in accordance with IRB standard for recruitment practices. Written informed consent was obtained from the parents/legal guardians of the minors who are under the age of 19 years, and for other participants, they themselves gave the consent before the start of the study and were explained the methodology of the study and the possible risks that may arise with the use of lens.

Study design and participants

Myopic individuals from 6 to 48 years of age were eligible for inclusion in the study. Subjects were required to have myopia between -3.00 and -7.50 D, cylindrical error ≤ 2.00 D, mean keratometry readings between 39.75 and 46.00 D, horizontal corneal diameter ≥ 11.0 mm, and a best-corrected distance visual acuity (BCVA) of 0.1 logarithm of the minimum angle of resolution (LogMAR). Any participant with history of or existent ocular or systemic pathology that might affect contact lens wear was excluded. Participants were educated to discontinue their contact lens for 2 weeks in case of soft contact lens and for 4 weeks in case of rigid gas-permeable contact lens prior to the baseline examination. Subjects who were noncompliant with test schedule, lost to follow-up, contraindicated to continue OK treatment were excluded from the study.

Lens design and fitting

Subjects received a one-month trial of overnight OK reverse geometry rigid contact lenses. The lens fitted in this study was White OK lens designed and manufactured by the Interjojo Optical Company (Pyungtaek, Korea). The contact lens was manufactured from Acuity 100 (hexa-

focon A) lens material [Dk was 100×10^{-11} [cm² mL O₂]/[s mL mmHg]]. It is an aspheric reverse geometric lens and lens sizes were varied according to the size of cornea. The lens was designed with an overall diameter of 10.2–11.0 mm, and a central thickness of 0.20 mm. When the corneal condition permitted, lens diameter was increased to improve lens centration.

The study lens is a 4-zoned [optical zone, reverse zone, alignment zone and peripheral zone] and 6-curved [base curve (R1), reverse curve (R2, R3), alignment curve (R4, R5) and peripheral curve (R6)] reverse geometry lens. White OK lens is designed to differentiate the reverse zone and alignment zone from other lens to help correct high myopia as well as low and moderate myopia. The reverse zone is wide (1.0–1.3 mm) and consists of two curves (R2, R3). For high myopia or severe steep cornea, the large R2 curve is designed to aid the correction. Two alignment curves are applied (R4, R5). In order to increase the success rate of fitting, reduce the pressure and support the reverse zone, two different e values are applied. The specific characteristics and the schematic drawing of the lens are shown in Table 1 and Fig. 1, respectively. White OK lens was made according to the fitting guide provided by the laboratory with an empirical calculation. The base curve was obtained from the corneal curvature and the spherical equivalent of the participants. Once the trial lens was selected, this selection was sent to the laboratory for its manufacturing. Deep cleaner (I MEDISON, Kwangju, Korea) were used for cleaning the lens. New York define (I MEDISON, Kwangju, Korea) was given to the subjects for storage. No eye drops were prescribed to the participants.

Evaluation and outcome measures

A total of six visits were scheduled for each subject. Participants underwent a comprehensive ophthalmological examination at the screening visit (visit 1), slit-lamp examination after OK lens prefitting (visit 2), and lens was given at following visit (visit 3). Participants were evaluated on weeks 1, 2, and 4 (visits 4–6, respectively). Both eyes of each participant were fitted with the White OK

lens. Refraction, slit-lamp biomicroscopy, and measurement of uncorrected visual acuity (UCVA) for distance vision were performed at each of these visits. UCVA and BCVA were checked on visit 1. Tonometry and Schirmer test were checked on visit 1 and 6. BCVA and UCVA were measured with Hahn's visual acuity chart (Hahn's Co. Ltd, Seoul, Korea) placed 5 m from the subject and converted to logMAR. Autokeratometry and autorefractometry were measured at each visit using autorefractor (Topcon KR-8800, Topcon Inc., Tokyo, Japan). The children were already wearing glasses and BCVA was above 0.1 logMAR so mydriasis optometry was skipped.

Corneal topography was carried out at visit 1 and 6 by Orbscan II (Bausch & Lomb Inc., Salt Lake City, UT). Intraocular pressure (IOP) was evaluated by tonometer (KT-500, KOWA, Tokyo, Japan). Schirmer test was done without anesthesia and the tear volume was measured for 5 minutes. The anterior segment of eye was assessed for injection, neovascularization, edema and fluorescein staining, using slit-lamp biomicroscopy. The lenses were reinserted and lens fitting was evaluated at each visit.

The subjects were evaluated at 30 and 60 minutes after inserting the contact lens, 1 week, 2 week, and 1 month of the use of the lens. During subsequent routine visits, the times for data collection were standardized with respect to lens removal times. Also, the visiting hours and examination times were set to be exact for all subjects. The contact lens fit was thought to be adequate if the lens was centered over the cornea and showed a bull's-eye

Table 1. Specification of White OK lens

Overall lens diameter	10.2-10.6/10.8-11.0 mm
OZ	6.0 mm
OZ + RZ	8.0/8.0-8.4 mm
OZ + RZ + AZ	9.2/9.4/9.6/9.8/10.0 mm
OZ + RZ + AZ + PZ	10.2/10.4/10.6/10.8-11.0 mm
Central thickness	0.20 mm

OZ, optical zone; RZ, reverse zone; AZ, alignment zone; PZ, peripheral zone.

Fig. 1. White-OK lens design. The study lens is 4-zone [optical zone (OZ), reverse zone (RZ), alignment zone (AZ) and peripheral zone (PZ)] and 6-curve [base curve (R1), reverse curve (R2, R3), alignment curve (R4, R5) and peripheral curve (R6)] reverse geometry lens. D1: OZ, D2: OZ + RZ, D3: OZ + RZ + AZ, D4: OZ + RZ + AZ + PZ. CT, Central thickness.

fluorescein pattern with a central feathery touch, mid-peripheral fluorescein pooling, and adequate peripheral edge lift. When the proper lens fit was achieved, over-refraction was performed. All participants were educated how to wear and remove the lens, and were ordered to wear the lens overnight for at least 7 hours during their sleep, while keeping the record of insertion and removal times. If a change in the parameters of lens fitting was necessary, the examination protocol with all the scheduled visits was started again. When participants showed poor topographical changes or insufficient improvement of UCVA, lens parameters were altered throughout the study period. Subjects were asked to report their subjective complaints and satisfaction.

The primary outcome was the success rate of vision correction, defined as $\log\text{MAR} \leq 0.1$ at week 4. Secondary outcomes were the correction of myopia and astigmatism, and the success rate of vision correction, defined as $\log\text{MAR} \leq 0.1$ at week 1, 2, and 4.

Statistical analysis

Categorical variables were presented as number and percentage, while continuous variables were presented as mean and standard deviation. Normally distributed data were expressed as mean $\pm$ standard deviation. After confirming normality (Shapiro–Wilk), the change in each clinical parameter was analyzed using repeated-measures

analysis of variance (RM ANOVA) with Greenhouse-Geisser correction to assess the time course of changes with post hoc test using Bonferroni test. Friedman test was used for not normally distributed data and the Wilcoxon signed-ranked test was used for the post-hoc test. All statistical analyses were performed with SPSS version 22.0 and the level of significance was set at 5%.

RESULTS

A total of 61 participants were screened and 46 eligible participants were enrolled including 19 males and 27 females. Two participants with moderate myopia and one participant with high myopia decided to quit the study during visits 4–6 because they had hard time wearing the lens due to ocular discomfort. Baseline clinical characteristics of participants are shown in Table 2. Only one eye of each participant was included in the study. If both eyes met the inclusion criteria, the right eye was chosen for analysis.

The vision correction success rate ($\log\text{MAR} \leq 0.1$) was 41.86% at week 1, 72.09% at week 2, and 95.35% at week 4 ($p < 0.0001$). A significant decrease in $\log\text{MAR}$ was noted from week 1 to week 4 ($p < 0.0001$). The mean keratometry reading was decreased from week 1 to week 4 and the reduction was statistically significant ($p < 0.0001$). RM ANOVA showed that there was a significant difference in flat keratometry ($F(2.07, 86.8) = 109.08, p < 0.0001$). Post-hoc analysis using Bonferroni test revealed flattening in both vertical and horizontal corneal curvature between baseline and week 4 ($p < 0.0001$). Horizontal corneal curvature showed more flattening than vertical curvature at week 4. Significant improvements of sphere were found ($\chi^2_{(3)} = 108.05, p < 0.0001$). Friedman's test showed that there was a significant difference in cylinder ($\chi^2_{(3)} = 8.85, p = 0.03$) and increase in regard to cylinder was shown (Table 3).

In low to moderate myopic participants with myopia between -3.00 and -6.00D , the success rate was 43.24% at week 1, 67.57% at week 2, and 94.59% at week 4. Fried-

Table 2 Baseline clinical characteristics of participants

Characteristics	
Age (years)	23.11 $\pm$ 7.89
Gender (M:F)	19:27
UCVA ($\log\text{MAR}$)	1.18 $\pm$ 0.30
BCVA ($\log\text{MAR}$)	0.00
Sphere (D)	-4.58 ± 1.28
Cylinder (D)	-0.84 ± 0.47

Data presented as mean $\pm$ standard deviation.

UCVA, uncorrected visual acuity; BCVA, best corrected visual acuity; $\log\text{MAR}$, logarithm of the minimum angle of resolution.

Table 3. Uncorrected visual acuity, sphere, cylinder, and keratometry at screening and during follow-up

	Screening (n = 43)	Week 1 (n = 43)	Week 2 (n = 43)	Week 4 (n = 43)	p-value
UCVA ($\log\text{MAR}$)	1.18 $\pm$ 0.30 (0.70, 2.00)	0.30 $\pm$ 0.32 (0, 1.30)	0.13 $\pm$ 0.20 (0, 0.70)	0.06 $\pm$ 0.12 (0, 0.70)	<0.0001*
Sphere (D)	-4.58 ± 1.28 ($-5.50, 0$)	-2.03 ± 1.43 ($-5.50, 0$)	-1.25 ± 0.95 ($-3.50, 0.5$)	-0.65 ± 0.69 ($-3.00, 0.75$)	<0.0001*
Cylinder (D)	-0.84 ± 0.47 ($-2.00, 0$)	-0.90 ± 0.49 ($-2.00, 0$)	-1.01 ± 0.77 ($-3.75, 0$)	-1.17 ± 0.78 ($-3.50, -0.25$)	0.03*
Flat Keratometry (mm)	7.99 $\pm$ 0.23 (7.45, 8.44)	8.29 $\pm$ 0.26 (7.61, 8.84)	8.35 $\pm$ 0.27 (7.74, 8.93)	8.40 $\pm$ 0.28 (7.86, 9.07)	<0.0001**
Steep Keratometry (mm)	7.74 $\pm$ 0.23 (7.22, 8.26)	7.96 $\pm$ 0.29 (7.36, 8.45)	7.98 $\pm$ 0.27 (7.37, 8.47)	7.99 $\pm$ 0.28 (7.35, 8.55)	<0.0001**

Data are presented as mean $\pm$ standard deviation; the range of data was shown in the parenthesis.

UCVA, uncorrected visual acuity; $\log\text{MAR}$, logarithm of the minimum angle of resolution.

*Friedman test, **RM-ANOVA.

man's test showed that there was a significant difference logMAR ($X^2_F(3) = 94.68, p < 0.001$). Post-hoc analysis using Wilcoxon signed-ranked test revealed LogMAR was significantly decreased between baseline and week 4 ($p < 0.0001$). RM ANOVA showed that there was a significant difference in flat keratometry ($F(2.35, 84.55) = 58.24, p < 0.0001$). Post-hoc analysis using Bonferroni test revealed flattening in both vertical and horizontal corneal curvature between baseline and week 4 ($p < 0.0001$). Friedman's test showed that there was a significant difference in sphere ($X^2_F(3) = 77.83, p < 0.001$). Post-hoc analysis using Wilcoxon signed-ranked test revealed significant improvements of sphere between baseline and week 4 ($p < 0.0001$). There was an increase in cylinder at week 4, although Friedman's test showed that there was no significant difference in cylinder ($X^2_F(3) = 2.683, p = 0.443$) (Table 4). 13 participants (38%) of low to moderate myopic group showed clinically significant increase in cylinder (cylindrical error $> 0.50D$). The increase in astigmatism was due to the poor lens centration and reflected in topographic maps.

In 9 high myopic participants with myopia between -6.00 and $-7.50D$, the success rate was 0% at week 1, 44.44% at week 2, and 88.89% at week 4. Friedman's test showed that there was a significant difference in logMAR ($X^2_F(3) = 24.71, p < 0.001$). Post-hoc analysis using Wilcoxon signed-ranked test also revealed that logMAR was significantly decreased at week 4 ($p < 0.0001$). In case of

sphere, significant differences were shown upon Friedman's test ($X^2_F(3) = 25.93, p < 0.001$) and post-hoc analysis using Wilcoxon signed-ranked test at week 4 ($p < 0.0001$). There was an increase in cylinder at week 4, although Friedman's test showed that there was no significant difference in cylinder ($X^2_F(3) = 1.13, p = 0.77$) (Table 5). 6 participants (67%) of high myopic group showed clinically significant increase in cylinder (cylindrical error $> 0.50D$). The increase in astigmatism was due to the poor lens centration and reflected in topographic maps. The incidence of lens decentration was higher in the high myopic subjects.

There were no statistically significant differences between low-moderate myopic participants and high myopic participants in sphere, cylinder, and keratometry at week 4 ($p = 0.07, p = 0.35$, and $p = 0.12$ respectively). There were no significant abnormal results regarding IOP (17.47 ± 2.92 mmHg at screening and 15.97 ± 2.91 mmHg at week 4). There was no significant change in regard to Schirmer test (17.91 ± 7.76 mm at screening and 18.50 ± 7.42 mm at week 4, $p = 0.22$).

Fourteen percent of eyes had ocular pain, twenty-eight percent of eyes had halo and fifty-three percent of eyes had foreign-body sensations. Two high myopic participants were unsatisfied with the White OK lens. One participant of the low to moderate myopia group was found to have conjunctivitis. One participant of the low to moderate myopia group and one participant of the high myopia

Table 4. Uncorrected visual acuity, sphere, cylinder, and keratometry at screening and during follow-up in low to moderate myopic participants

	Screening (n = 34)	Week 1 (n = 34)	Week 2 (n = 34)	Week 4 (n = 34)	p-value
UCVA (LogMAR)	1.05 ± 0.22 (0.52, 1.70)	0.25 ± 0.28 (0, 1.00)	0.14 ± 0.20 (0, 0.70)	0.05 ± 0.13 (0, 0.70)	$<0.0001^*$
Sphere (D)	-3.98 ± 0.71 (-5.75, -3.00)	-1.76 ± 1.32 (-5.00, 0.25)	-1.07 ± 0.99 (-3.50, 1.25)	-0.74 ± 1.04 (-5.50, 0.50)	$<0.0001^*$
Cylinder (D)	-0.79 ± 0.47 (-2.00, 0)	-0.84 ± 0.49 (-1.75, 0)	-0.99 ± 0.84 (-3.75, 0)	-1.07 ± 0.63 (-3.25, -0.25)	0.09*
Flat Keratometry (mm)	8.06 ± 0.24 (7.50, 8.50)	8.32 ± 0.29 (7.59, 8.85)	8.33 ± 0.27 (7.74, 8.85)	8.37 ± 0.27 (7.80, 8.87)	$<0.0001^{**}$
Steep Keratometry (mm)	7.78 ± 0.22 (7.32, 8.26)	8.00 ± 0.29 (7.38, 8.50)	8.00 ± 0.28 (7.50, 8.47)	8.05 ± 0.30 (7.49, 8.55)	$<0.0001^{**}$

Data are presented as mean $\pm$ standard deviation; the range of data was shown in the parenthesis.

UCVA, uncorrected visual acuity; LogMAR, logarithm of the minimum angle of resolution.

*Friedman test, **RM-ANOVA.

Table 5. Uncorrected visual acuity, sphere, cylinder, and keratometry at screening and during follow-up in high myopic participants

	Screening (n = 9)	Week 1 (n = 9)	Week 2 (n = 9)	Week 4 (n = 9)	p-value
UCVA (LogMAR)	1.57 ± 0.31 (1.00, 2.00)	0.62 ± 0.35 (0.22, 1.30)	0.25 ± 0.25 (0, 0.70)	0.11 ± 0.07 (0.05, 0.30)	$<0.0001^*$
Sphere (D)	-6.69 ± 0.50 (-7.50, -6.00)	-3.47 ± 1.04 (-5.50, -2.00)	-2.06 ± 0.79 (-3.25, -1.00)	-1.06 ± 0.54 (-1.75, -0.25)	$<0.0001^*$
Cylinder (D)	-1.06 ± 0.39 (-2.00, 0)	-1.14 ± 0.42 (-2.00, -0.75)	-1.08 ± 0.50 (-2.00, -0.25)	-1.58 ± 1.14 (-3.50, -0.25)	0.2857*
Flat Keratometry (mm)	8.00 ± 0.27 (7.45, 8.38)	8.39 ± 0.32 (7.65, 8.68)	8.55 ± 0.30 (7.97, 8.93)	8.58 ± 0.34 (7.98, 9.07)	$<0.0001^{**}$
Steep Keratometry (mm)	7.76 ± 0.25 (7.22, 8.12)	7.96 ± 0.25 (7.44, 8.24)	8.02 ± 0.26 (7.69, 8.31)	7.97 ± 0.20 (7.70, 8.32)	$<0.0001^{**}$

Data are presented as mean $\pm$ standard deviation; the range of data was shown in the parenthesis.

UCVA, uncorrected visual acuity; LogMAR, logarithm of the minimum angle of resolution.

*Friedman test, **RM-ANOVA.

group had conjunctival hyperemia. One participant of the low to moderate myopia group showed corneal staining at week 1 and one participant of the high myopia group showed corneal staining at week 4. None of the staining episodes required any clinical intervention. Edema and neovascularization was not observed at any time during follow-up. No serious adverse events were observed during our study.

DISCUSSION

There are increased numbers of clinical studies evaluating the efficacy of overnight OK employing different designs of reverse-geometry lens.²⁶⁻³⁰ In this study, overnight OK using White OK lens revealed clinically significant improvement in UCVA and myopic refractive error throughout the follow-up period for the correction of moderate to high myopia. The mean UCVA decreased to 0.06 ± 0.12 log MAR and the mean sphere was reduced by 3.93 ± 1.06 D. Tahhan et al. compared different overnight OK lens in one-month follow-up study and found out all studied lenses have similar results on reduction of myopic refractive error.²⁶ In our study, 41.86% of refractive effect occurred after the week 1, 72.09% after 2 weeks and about 95.35% after 4 weeks of lens wear. Other studies showed that 50% of the refractive effect was evident after 1 h of lens wear, and 75-80% of the refractive effect was apparent after a single night of lens wear, and the full effect was revealed in 7-10 days.^{26,31} This suggests that remodeling or redistribution of the anterior corneal layers occurs very rapidly in response to the pressures exerted by reverse-geometry lens.³¹ Changes in epithelial thickness do appear to occur more gradually over a 28-day period which Swarbrick et al. found significant changes between days 7 and 14 and again between days 14 and 28 both centrally and peripherally.³² Previous studies included subjects with refractive error between -1.00 to -4.00 D low to moderate myopes but our study included not only low to moderate myopes but also high myopes. This may be the reason why the success rates were slower to manifest with the White OK lens compared with previous studies.

There are some theories accounting for the mechanism of OK. Initial corneal response to OK and changes in the anterior corneal morphology lead to refractive effect.³² In other studies, there was the change in apical corneal power because of the flattening of the central cornea which showed a strong correlation with the refractive change, and 43-78% of the refractive change was thought to be related to the central corneal flattening.^{17,28} In our

study, using the topography, we noticed a significant flattening in the central cornea compared to baseline which revealed a strong correlation with the refractive change that was consistent with previous studies.

Previous study reported another lens that has hexa-curve reverse geometry lens design, which is similar to the White OK lens, based on a biconic model that attempts to mold the periphery of the cornea with a minimum compression in the center of the lens.³³ The difference between this lens and White OK lens is differing lens geometry and lens behavior during overnight.

Most published OK studies enrolled participants with low spherical equivalent refractive errors and low astigmatism. The percentage of myopic reduction accomplished by White OK lens was similar to those reported in other studies for low to moderate myopes.^{15,18} Horizontal corneal curvature showed more flattening than vertical curvature at week 4. 13 participants (38%) of low to moderate myopic group and 6 participants (67%) of high myopic group showed clinically significant increase in cylinder (cylindrical error > 0.50 D). The increase in astigmatism was due to the poor lens centration and reflected in topographic maps. The incidence of lens decentration was higher in the high myopic subjects. High myopic subjects may need a lens replacement with different lens parameters according to the altered corneal profile for myopic and astigmatic correction. Long-term study to evaluate the change of refractive cylinder power is necessary. For high myopes, our study with White OK lens showed a success rate of 88.89% at 4 weeks of lens wear. There are fewer publications on high myopia. Zhou et al. investigated the long-term clinical effects of OK lens in high myopia and reported that visual acuity was some degree improved compared to pre-fitting.²⁴ The spherical diopters during the first two years after wearing OK lens were significantly reduced and kept stable in the long-term observation.²⁴ Charm and Cho revealed partial reduction OK was successfully applied to high myopia with no significant changes in ocular health after one month of lens wear.¹⁹ For high myopia or steep cornea, the large R2 curve of White OK lens is designed to provide larger capacity for high myopia since the epithelial cells are compressed centrally and expanded in the midperiphery. In addition, White OK lens helps to adhere to the cornea improving lens centration and aids the mid-peripheral tear reservoir to permit more oxygen created under the steeper curve of the lens. Also, the current study observed the symptom changes for one month and found out that the overnight use of White OK lens can effectively correct high myopia.

Superficial corneal staining was thought to be hypoxic and mechanical in nature. Previous study showed clinically insignificant corneal staining in 77.4-90.3% of eyes.²⁸ In our study, one participant of the low to moderate myopia group showed corneal staining at week 1 and one participant of the high myopia group showed corneal staining at week 4. None of the staining episodes required any clinical intervention. Asymptomatic corneal pigmented arc was reported in overnight OK.³⁴ The abrupt local discontinuity in corneal curvature that allow pooling of tears under the lens' reverse curve with the decrease in the rate of normal epithelial exfoliation is thought to be the cause of this pigment deposition.³⁵ The incidence and intensity of corneal pigmented arc is thought to be associated with the overall duration of lens wear, and it disappears after halting overnight OK lens wear. Previous study reported that the incidence OK-associated pigmented arc increases from 17% after 3 months of lens wear to over 90% after 12 months of lens wear.³⁵ In our study, one participant was found to have conjunctivitis and four participants had conjunctival hyperemia. No corneal pigmented arc was observed during the study. The subjects who were not familiar with OK lens might have rubbed their eyes due to the foreign body sensation, or inappropriate lens removal might have irritated their eyes. All cases of conjunctival hyperemia and conjunctivitis were observed during week 1 and 2, and disappeared at week 4. The most serious complication of OK is microbial keratitis. Almost one-third of the cases was associated with *Acanthamoeba*, and was related to the use of tap water.³⁶ Inappropriate patient selection, insufficient education of patient, usage of unsuitable material of lens, storage of lens in nonpreserved saline or tap water, empirical lens fitting were related to the development of keratitis. In our study, microbial keratitis or any other serious adverse event due to OK lens wear was not seen in any eye.

Previous study compared subjective complaints of soft contact lens and OK lens in mild myopia and soft contact lens wear was related to better visual acuity and less glare, while symptoms of dryness, itching, and awareness of lens, limitations of daily activity, and dependence on refractive correction were less bothersome with OK lens wear.³⁷ In our study, all patients were satisfied with the modality.

The limitation of this study is the lack of long-term follow-up and control group. Although the results of this study obviously indicate that overnight OK with the White OK lens can effectively correct myopia, long-term follow-up studies with control group is required.

In conclusion, overnight OK with the White OK lens is

effective for the correction of moderate and high myopia with astigmatism improving unaided visual acuity over a one-month wearing period.

CONCLUSION

Overnight OK with the White OK lens – a 4-zoned and 6-curved reverse geometry lens – has been proven effective for the correction of moderate and high myopia with astigmatism over a one-month wearing period, showing a success rate of 95.35% and significant corneal flattening in keratometry at week 4.

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Not applicable.

CONFLICT OF INTEREST

Kyong Jin Cho is an editorial board member of the journal but was not involved in the review process of this manuscript. Otherwise, there is no conflict of interest to declare.

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AUTHORS' CONTRIBUTIONS

Study concept and design (KJC); collection, management, analysis, and interpretation of data (KJC,YP,JKK); and preparation, review, or approval of the manuscript (KJC,YP,HK). All authors read and approved the final manuscript.

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