Taiwan Journal of Ophthalmology 5 (2015) 164–168

Contents lists available at ScienceDirect

Taiwan Journal of Ophthalmology

journal homepage: www.e-tjo.com

Original article

Refractive error, visual acuity, and corneal-curvature changes in high and low myopes with orthokeratology treatment: A Malaysian study

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ARTICLE INFO

Article history:
Received 30 April 2015
Received in revised form
25 July 2015
Accepted 30 July 2015
Available online 12 September 2015

Keywords:
corneal curvature
high myopia
orthokeratology
visual acuity

ABSTRACT

Background/Purpose: The effect of orthokeratology (OK) on low myopia is well known, but there are a few reports on its effect on high myopia. In this study, the parametric changes in high and low myopia as results of wearing OK lenses for a period of 6 months have been analyzed.
Methods: Records of schoolchildren (age 7–17 years) undergoing OK treatment from an optometry clinic were retrospectively reviewed. Data involving refractive errors, uncorrected visual acuity, and corneal curvatures at baseline and after 1 day, 1 week, 1 month, 3 months, and 6 months of OK treatment from 25 patients who fulfilled the inclusion criteria were examined. For the analysis, the participants were arbitrarily divided into two groups comprising high myopia (< −6.00 D) and low to moderate myopia (from −1.00 D to −6.00 D).
Results: Significant reductions of refractive error, improvement in visual acuity, and corneal-curvature flattening were found in all participants after 6 months of OK lens wear compared to the baseline. No significant changes were found in corneal toricity in both high and low to moderate myopic groups. Almost all of these occurred after one night of lens wear in both the high- and low-myopia groups.
Conclusion: The OK lens wear significantly reduced the refractive error and corneal curvature that results in the improvement in visual acuity in both high- and low-myopia groups, and the reduction seemed to occur nearly at the same time despite the difference in initial myopic power. High myopes with refractive power up to −8.25 D would benefit significantly from OK lenses.

1. Introduction

Orthokeratology (OK) is also known as *corneal reshaping* or *corneal refractive therapy* that uses the programmed application of rigid contact lenses to reshape the cornea and temporarily reduce refractive errors.[1,2] Since the introduction of reverse-geometry lens design with high oxygen transmissibility that allows its overnight use for accelerated OK, many studies have shown that OK lenses provide effective means of temporarily reducing low to moderate myopia to ~3.00 D in power.[3–6]

Most OK studies limited the use of high refractive error (< −6.00 D), probably because high-myopia participants seemed to be relatively unsuccessful in OK treatment. There is a significant amount of residual refractive error that results in poor unaided vision after the treatment. Fan et al[7] included young adolescents with pretreatment spherical-equivalent refraction up to −10.75 D in a mix of daily wear and overnight OK lens wear in their study. Over the 6 months' duration, the average myopia reduction was only 3.00 D with maximum reduction < 5.00 D in their participants. The higher pretreatment refractive error and the lens design may explain why the percentage of myopia reduction estimated from their study was relatively low.

Wang et al,[8] in their retrospective study of 46 patients undergoing OK for up to 12 months' period, reported the mean reduction in mild myopia (defined as from −0.50 to −3.50 D) and moderate myopia (defined as from −3.75 to −7.00 D) groups were 0.77 ± 1.14

Conflict of interest: The authors declared no conflict of interest.

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http://dx.doi.org/10.1016/j.tjo.2015.07.006

D and 2.90 ± 1.42 D, respectively. Visual acuity (VA) improved to ≥ 20/40 (6/12) in 95% of their participants in the low-myopia group compared to 75% in the moderate myopic group. Spherical changes were stable after the third month of OK lens wear. There was also a significant increase in astigmatism after 12 months.

In OK, the unaided VA and refractive error follow a pattern of change and recovery similar to that seen in corneal curvature, given that refractive error depends on corneal curvature and unaided VA is based on refractive error.[9] Many studies have shown that most children and young adolescents achieved uncorrected logarithm of the minimum angle of resolution (logMAR) VA of ≥ 0.10 (6/7.5 Snellen) at the end of their study, which lasts all-day long after the OK treatment.[3,6,10]

Myopia reduction is achieved by flattening of the anterior corneal curvature, and this occurred within the first few hours wearing reverse-geometry OK lenses.[11] The flattening resulted in the redistribution of corneal epithelium and stroma tissue that contributed to the refractive changes. Recently, it was reported that myopia reduction is mainly effected by the flattening of the anterior corneal curvatures without the contribution of posterior corneal curvatures.[12]

Studies of OK using reverse-geometry lenses have not reported significant increases in corneal toricity,[3,13,14] possibly because lens centration is maintained more reliably due to the steeper secondary curve of these lenses. Indeed, Soni et al[9] have claimed that OK with reverse-geometry lenses can reduce with-the-rule astigmatism by up to 60%. Mountford and Pesudovs[15] reported an average reduction in corneal toricity of 50% with accelerated OK using reverse-geometry lenses.

In a recent study using OK lens to slow down myopia, Charm and Cho[16] reported a successful retardation in myopia progression of the participants having myopia higher than 5.00 D, but their target reduction was only 4.00 D, and the highest spherical-equivalent refraction was −5.75 D.

To date, there is limited information in the literature regarding changes in visual parameters after OK treatment in high-myopia participants with a sphere equivalent < −6.00 D. Because there were no reports available on Malaysian studies on the effects of OK treatment among low myopes, we decided to examine and compare the results obtained with high and low myopia in terms of refractive error, corneal curvature, and VA changes after wearing OK lenses for a duration of 6 months.

2. Methods

This was a retrospective study. A total of 30 files of children and adolescents undergoing OK treatment from an optometry clinic were reviewed. Data collected from the patients' files include participant demography and visual parameters: refractive errors, corneal curvatures [simulated keratometry (Sim K) readings along the flattest and steepest meridians], and uncorrected and best corrected logMAR VA. These parameters were documented before the commencement of overnight OK treatment, and post-OK treatment at 1 day, 1 week, 3 months, and 6 months. This study was approved by the Universiti Kebangsaan Malaysia Ethical Committee (Kuala Lumpur, Malaysia; UKM 1.5.3.5/244/NN-175-2009), and followed the tenets of the Declaration of Helsinki.

The inclusion criteria included age between 7 years and 17 years, first time fitted with OK lens, maximum with-the-rule astigmatism of −2.50 DC, able to achieve 0.1 logMAR VA or better in each eye, no systemic or ocular disease affecting the ocular health, not using any systemic or topical medications that could affect the ocular physiology or contact-lens fitting, and no ocular lid or anterior segment abnormalities for which contact-lens wear could be contraindicated. They must be successfully fitted with OK lenses for a period of 6 months and had worn their lenses for at least 6 hours nightly, especially before the follow-up visits. Of all the files, 25 participants met the inclusion criteria. For the analysis, the participants were arbitrarily divided into two groups in this study, which comprised the high-myopia group with sphere equivalents < −6.00 D and the low-to-moderate-myopia group with sphere equivalents ≥ −6.00 D.

The OK data were collected by the practitioner within 2 hours after lens removal at the 1st day of overnight wear and the following post-OK visits. The manifested refractive error and residual subjective-refraction results at every visit were recorded. VA was measured using the Early Treatment of Diabetic Retinopathy Study charts with a lighted box of luminance (85 cd/m^2). It was a high-contrast VA logMAR chart with a testing distance of 4 m. VA was recorded as logMAR with Snellen VA equivalents. Corneal-topography measurements were taken using the corneal topographer, Tomey TMS-4 (Tomey Co., Aichi, Japan), with at least three measurements obtained from each eye before the OK treatment and after the OK lens wear at each follow-up visit. Data retrieved included Sim K readings along both the flattest (Sim K_{flat}) and steepest (Sim K_{steep}) meridians. The average Sim K readings were also recorded at every visit.

All participants used the same lens type and design throughout the OK treatment. The OK lens was manufactured by Global-OK Vision, San Diego, USA. It was made of Optimum Extra (Roflufocon D) material with a high oxygen permeability (DK) value {oxygen permeability: 100×10^{-11} cm^2/sec [mL O_2/(mL × mmHg)]}.

The data recorded for this study were analyzed using SPSS version 20.0 (IBM Corp., New York, NY, USA). All data were tested using Shapiro–Wilk tests before the statistical analysis for normality ($p > 0.05$). Repeated-measures analysis of variance (ANOVA) with $p = 0.05$ was used to examine the visual-parameter changes from the baseline over the 6 months' study period. Paired t tests with Bonferroni correction (to minimize any type 1 error) were used to test for differences between any two consecutive visits. For all the parameters (5 comparisons), $p < 0.01$ (0.05/5) was considered significant. The relationship between change in refractive error and change in unaided VA was examined by Pearson correlation analysis.

3. Results

The demographic data are presented in Table 1. There were no significant differences in data from the right and left eyes of the participants in spherical equivalent refraction (SER), uncorrected visual acuity, best-corrected visual acuity, anterior Sim K_{flat}, and Sim K_{steep} (t tests, SER, best-corrected visual acuity, anterior Sim K_{flat}, and Sim K_{steep}, respectively, $p > 0.05$; uncorrected visual acuity, paired t test, $p > 0.05$); therefore, for the subsequent analysis, only data from the right eye were analyzed. There were significant differences in the baseline refraction values between the high and low to moderate myopic groups ($p < 0.05$; t test).

3.1. Refractive error

The average change in refraction ($n_{total} = 25$ participants) during the 6 months' treatment duration for high ($n = 10$) and low to moderate myopic ($n = 15$) groups is shown in Fig. 1. After 6 months of post-OK lens wear, the refractive error in both groups was significantly reduced from the baseline readings (ANOVA, $p < 0.001$). High myopes showed a greater significant change on myopia reduction from the baseline value compared to the low to moderate myopes (ANOVA, $p < 0.05$).

In the high-myopia group, the spherical-equivalent refractive error reduced from an average of −7.11 ± 0.79 D − −0.18 ± 0.31 D

Table 1
Demographical data of the participants ($n = 25$) at the baseline visit.[a]

	High-myopia group		Low-to-moderate-myopia group	
Age (y)	13.60 ± 3.10 (range: 8–17 y)		13.00 ± 3.25 (range: 7–17 y)	
Sex (male/female)	2/8		5/10	
Race	8 Chinese, 2 Indian		15 Chinese	
Eye	Right	Left	Right	Left
SER (D)	−7.11 ± 0.79	−7.19 ± 1.05	−3.91 ± 1.01	−4.33 ± 1.81
Refractive sphere (D)	−6.63 ± 0.66	−6.70 ± 1.16	−3.65 ± 1.14	−4.00 ± 2.27
Refractive cylinder (D)	−0.98 ± 0.79	−1.08 ± 0.82	−0.52 ± 0.62	−0.93 ± 1.50
UCVA	1.34 ± 0.11	1.33 ± 0.14	0.83 ± 0.18	0.96 ± 0.38
BCVA	0.11 ± 0.52	0.11 ± 0.51	−0.05 ± 0.08	−0.01 ± 0.13
Sim K_{steep} (D)	44.20 ± 1.50	44.26 ± 1.47	44.02 ± 1.19	44.09 ± 1.34
Sim K_{flat} (D)	42.58 ± 1.77	42.55 ± 1.69	42.77 ± 1.17	42.70 ± 1.17
Corneal toricity (D)	−1.62 ± 1.11	−1.71 ± 1.05	−1.25 ± 0.57	−1.39 ± 1.14

Data are presented as mean ± standard deviation.
BCVA = best-corrected visual acuity; SER = spherical-equivalent refraction; UCVA = uncorrected visual acuity.
[a] Spherical-equivalent refraction, uncorrected and best-corrected logarithm-of-the-minimum-angle-of-resolution visual acuity, and simulated-keratometry readings along the flattest (Sim K_{flat}) and steepest (Sim K_{steep}) meridians.

after 6 months of overnight lens wear. In this group, the largest spherical-equivalent reduction was observed after an overnight wear, and continued until the 1st week of wear with a spherical-equivalent value reaching −0.41 ± 1.13 D (paired t tests, $p < 0.01$). No further significant change was observed over subsequent visits (paired t tests, $p > 0.01$). In the low-to-moderate-myopia group, myopia was reduced from the baseline value of −3.91 ± 1.01 D−−0.27 ± 0.75 D after 6 months. The largest spherical-equivalent-refraction reduction was observed after the 1st night of lens wear (paired t tests, $p < 0.01$), and appeared to stabilize since no significant myopia reduction was observed over subsequent visits (paired t tests, $p > 0.01$).

3.2. Visual acuity

Fig. 2 shows the uncorrected logMAR VA for both high and low to moderate myopic groups, which improved after different periods of OK lens wear. Statistically significant improvements in unaided VA were found relative to the baseline in all the participants over the 6 months of lens wear for both myopic groups (ANOVA, $p < 0.05$). For both the high- and low-myopia groups, the VA stabilized after 1 day of wearing OK lenses ($p < 0.01$). No more significant changes in the VA were seen between the subsequent visits ($p > 0.01$). The unaided VA after 6 months of lens wear in high and low to moderate myopes were −0.07 ± 0.10 and 0.01 ± 0.16, respectively.

There was a strong negative correlation between the change in spherical equivalent and the change in unaided VA after 6 months of overnight lens wear (Fig. 3), which was statistically significant (Pearson correlation coefficient, $r = -0.94$, $n = 14$, $p < 0.01$).

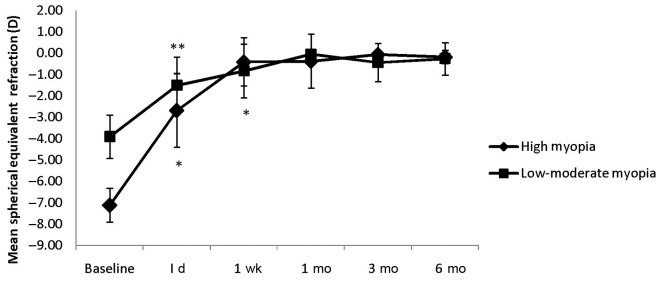

Fig. 1. Change of refractive error for both high-myopia and low-to-moderate-myopia groups at every visit. Error bars indicate standard deviation. *,** Significances of $p < 0.01$ for the high-myopia and low-to-moderate-myopia groups, respectively (the residual refraction is significantly different compared with previous visits).

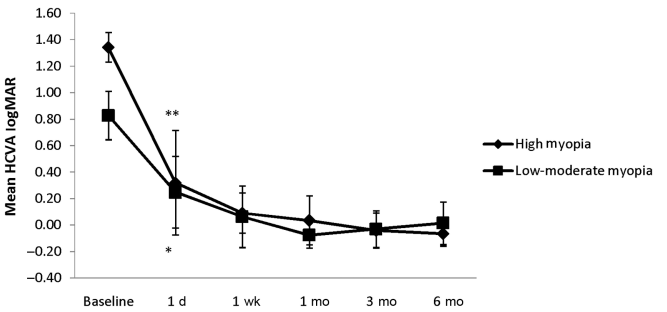

Fig. 2. Unaided high-contrast logarithm-of-the-minimum-angle-of-resolution visual acuity for both high-myopia and low-to-moderate-myopia groups at every visit. *,** Significances of $p < 0.01$ for the high-myopia and low-to-moderate-myopia groups, respectively (the residual refraction is significantly different compared with previous visits). logMAR = logarithm of the minimum angle of resolution; HCVA = high contrast visual acuity.

3.3. Corneal topography

Fig. 4 shows the reduction in corneal power along the steepest and flattest meridians for both high and low to moderate myopic groups after different periods of OK lens wear. In both groups, the Sim K along the steepest (Sim K_{steep}) and flattest meridians (Sim K_{flat}) after OK lens wear was flatten significantly over time compared to the baseline (ANOVA, $p < 0.001$). For the high-myopia group, the corneal flattening along both meridians appeared to stabilize by the first week of lens wear (paired t test, $p < 0.01$). No

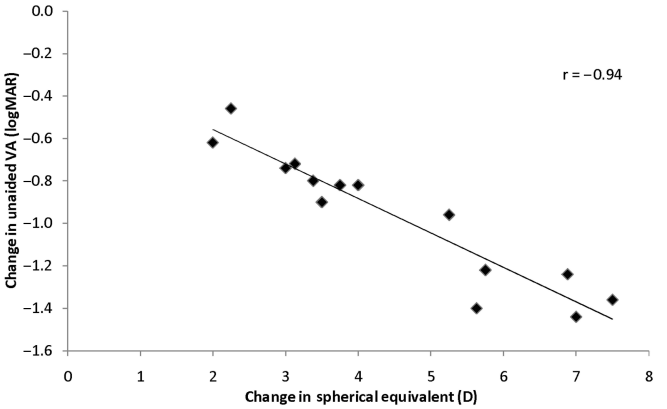

Fig. 3. The relationship between the change in spherical equivalent and the change in unaided visual acuity after 6 months of overnight lens wear. logMAR = logarithm of the minimum angle of resolution.

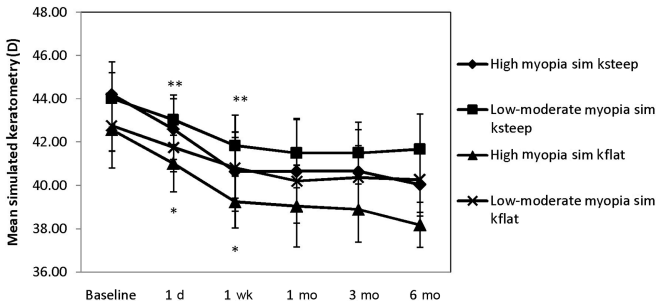

Fig. 4. Simulated keratometry along the steepest and flattest meridians (D) in both high-myopia and low-to-moderate-myopia groups at every visit. Error bars indicate standard deviation. *,** Significances of $p < 0.01$ for the high-myopia and low-to-moderate-myopia groups, respectively (paired t test; the residual refraction is significantly different compared with the previous visit).

further significant flattening was observed ($p > 0.01$) beyond 1 week of lens wear. For the low-to-moderate-myopia group, Sim K_{flat} was flattened and appeared to stabilize after an overnight of lens wear, whereas Sim K_{steep} stabilized within 1 week of lens wear (paired t test, $p < 0.01$). No further significant flattening was observed ($p > 0.01$) in subsequent visits.

3.4. Topographic corneal toricity

The change in corneal toricity over the 6 months of OK lens wear was demonstrated in Fig. 5. There was no significant change in the corneal toricity with time in both groups of participants (ANOVA, $p > 0.05$). In all the participants, corneal toricity is not significantly different compared to the mean at previous visits during the OK lens wear (paired t test, $p > 0.01$). The corneal toricity after 6 months of lens wear in high and low to moderate myopes were -1.86 ± 1.12 D and -1.41 ± 0.75 D, respectively.

4. Discussion

The effect of OK lens in low myopia is well known. The results of our study on low myopia up to −6.00 D in power concur with most previous studies. Myopic power was reduced to almost zero at the end of the 6 months' study after wearing OK lenses. Surprisingly, the results of our study on high myopia also follow the same pattern with low myopia, with most of the changes occurring within 24 hours after wearing OK lenses overnight. In this study, the mean change in refractive error of the high-myopia participants was 6.93 ± 0.92 D at 6 months of post-OK lens wear from the baseline value of -7.11 ± 0.79 D. The high-myopia participants achieved a final residual spherical equivalent of -0.18 ± 0.31 D. For the high myopes, the largest reduction in myopia occurred after one night of OK lens wear, and this stabilized after 1 week. Our study showed

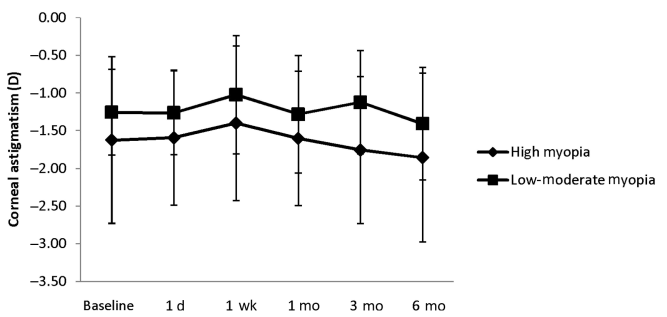

Fig. 5. Corneal toricity (D) in both high-myopia and low-to-moderate-myopia groups at every visit. Error bars indicate standard deviation.

that high myopes with power range −6.25–−8.25 D can be successfully treated with OK lenses worn nightly. Koffler and Smith[17] used Paragon HDS 100 paflufocon D OK lens that has the same DK value as our lens, and also included myopic participants that have a refractive-error range similar to ours and reported a myopia reduction of 5.80 ± 1.80 D in their participants. However, there were only two participants with a refractive error < −6.00 D in the study. At the baseline, their participants' refractive errors range from −1.00 D to −7.75 D. They also concluded that participants between −1.00 D and −6.00 D refractive error with up to 1.50 D of astigmatism can expect a good outcome with OK lenses. The outcome of our results among the low-myopia group concurred with their results and also with many other studies reported earlier.[4,6,18]

In a retrospective study, Wang et al[8] examined the data of participants that have undergone overnight OK using Contex OK-3 design with a spherical power up to −7.00 D and astigmatism < 2.00 D. For the analysis, they divided their data into two groups of mild myopia (0–−3.5 D) and moderate myopia (−3.75–−7.00 D). They noted a mean change of 0.77 ± 1.14 D in the low-myopia group, and 2.90 ± 1.42 D in the moderately myopic group after 1 year of OK treatment. The reduction of sphere reached its maximum only in the 3rd month and fluctuated slightly thereafter. The mean spherical change was only 51% less than its baseline value. In both our high- and low-myopia groups, the mean change in refractive error relative to the baseline is > 93%, and almost all these changes occurred within 1 day (low myopes) and 1 week (high myopes) of OK lens wear. Although the outcome of our results seems better than Wang et al,[8] we could not compare them directly since we have strict inclusion criteria, different classifications of low and high myopia, as well as different lens designs and materials that may have contributed in part to the outcome.

The reduction in refractive error in both groups of high and low myopes was also reflected in the final VA achieved by the end of 6 months. The high myopes achieved a final acuity of −0.07 logMAR (6/4.8 Snellen) compared to 1.38 ± 0.09 at the baseline. This is almost the same as the final acuity achieved by the low to moderate myopes (0.01 ± 0.16 logMAR) in our study. After 6 months of OK lens wear, 88% of the high-myopia participants achieved a VA of 0.0 logMAR (6/6 Snellen) or better, whereas 82% of the low to moderate myopic participants achieved a VA of 0.0 logMAR (6/6 Snellen). Our results seem better than Wang et al[8] who reported 95% of their low-myopia group (defined as −0.75–−3.50 D) achieved a VA of 0.3 logMAR (6/12 Snellen), and only 75% of the moderate myopic group (−3.75–−7.00 D) achieved 0.3 logMAR by the end of 1 year of lens wear. This could be due to the improvement of much more highly oxygen-permeable lens materials and a different lens design that led to the successful fitting of OK lens in our groups of participants. Walline et al[3] used Paragon corneal refractive therapy, which has the same DK value like ours (DK value of 100) in their participants, and they also achieved an unaided logMAR VA of 0.08 ± 0.15 (~6/7.5 Snellen) at 6 months of lens wear. Lum and Swarbrick[19] have demonstrated that an increase in the lens Dk/t not only provides physiological advantages, but most importantly enhanced the clinical outcomes of overnight OK.

In this study, we found a good correlation between uncorrected VA and refractive error (Fig. 3). This is in agreement with many studies reported previously where flattening of the cornea resulted in improvement in VA.

The change in refractive error reflects the changes in corneal shapes. The average changes of corneal power along a flat meridian after 6 months from the baseline were -4.57 ± 1.39 D and -2.28 ± 1.01 D in the high myopes and low to moderate myopes, respectively. Corneal flattening was stabilized by 1 week of lens wear in all the participants, and this concurred with many other studies.[4,8,11,20,21]

The mean changes of cornea toricity were −0.67 ± 1.48 DC and −0.01 ± 0.60 DC in the high and low to moderate myopic groups, respectively. There were no significant differences in toricity over the 6 months' duration of OK lens wear in both groups. Our finding was in agreement with Kang et al,[22] Sridharan and Swarbrick,[23] Cheung et al,[24] and recently by Chou et al[25] who reported no significant change in corneal toricity after an overnight OK wear. The spherical central base-curve radii on the contact lens flatten both principal meridians of the cornea almost equally; thus, corneal toricity was not significantly altered throughout the treatment (Soni et al[9]). However, Wang et al[8] reported an increase in astigmatism in the moderately myopic group of participants. Many studies on the astigmatism change in OK lens wear are not comparable because the studies vary in the nature of astigmatism being investigated (corneal vs. refractive), the parameters used for describing astigmatism (refractive error vs. aberration), and the differences in the participant inclusion criteria.

In summary, the OK lens wear significantly reduced the refractive error and flattened the corneal curvature that resulted in an improvement in VA in both the high and low-myopia participants. The end point of residual refraction in both groups seemed to occur at the same time, despite the difference in initial myopic power. Overnight OK using modern reverse-geometry lens designs is an effective nonsurgical method for both refractive correction and clear unaided vision in high-myopia children (range from −6.25 D to −8.25 D) with maximum refractive astigmatism of −2.50 DC. The spherical OK lens designs used in this study neither induce nor reduce corneal toricity. The main limitation in this study is the limited number of participants in the high-myopia group. Further researches on a larger sample size are needed to provide a better understanding of the efficacy and safety of OK treatment, particularly among high-myopia children.

Acknowledgments

The authors acknowledge receipt of the Ministry of Science, Technology and Innovation grant 060102-SF0604.

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