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VISUAL AND CORNEAL CHANGES IN OVERNIGHT ORTHOKERATOLOGY USING MENICON Z LENSES – A MALAYSIAN STUDY

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Abstract: Reverse geometry lens is a specially designed orthokeratology (OK) lens used to treat myopia. Menicon Z night OK lens is unique because software supplied by the manufacturer generates its parameters. No reports have been published on its effectiveness in reducing myopia among young Malay adults. This prospective study involved young Malay adults 22.5 ± 1.2 years old. Participants who met the inclusion criteria were fitted with OK lenses and the following parameters were measured at baseline: Refractive errors, visual acuity and corneal curvatures. Participants were asked to sleep with the lenses and remove them in the morning before re-examining them at 24 hours, one week, one month and six months. Repeated measure analysis of variance was carried out to find any significant differences in the parameters measured over the six months. The correlation was also done between refractive error, corneal curvatures and visual acuity. Significant reductions in refractive error, corneal curvatures and improvement in visual acuity were found during the six months. The greatest change occurred after 24 hours of lens wear. There was no change in corneal toricity. Changes in refractive error correlated significantly with visual acuity and corneal curvatures. In conclusion, the OK lenses significantly flattened corneal curvature and reduced refractive power to almost zero, which improved visual acuity in young Malay adults. Myopes with low refractive power who want to be free from spectacles may benefit from this alternative myopic management.

Keywords: Orthokeratology, myopia, Malays, corneal curvature, visual acuity.

Introduction

The prevalence of myopia is increasing worldwide, especially among Asians (Aller, 2014; Sankaridurg & Holden, 2014). It is refractive and the actual cause is not known. High myopia poses risks that may lead to visual impairment and blindness. The prevalence of myopia among Malays adults is relatively lower than other Asian populations (Pan *et al.*, 2015). However, there are significant increases in the prevalence of myopia among young adult Malay males in Singapore aged 16-25 years old, from 64.9% in 1996-1997 to 70.7% in 2009-2010 (Koh *et al*., 2014).

Many treatments are available to correct myopia and orthokeratology (OK) treatment is one of the optical corrections for myopia. The OK treatment uses a specially-design rigid gas permeable contact lens to correct myopia. It reduces the refractive power to almost Plano and lets the person see clearly without any optical correction (Swarbrick, 2006). The OK lens can be used as an alternative treatment for adults who do not want to wear spectacles or are intolerant to conventional contact lenses. Adults with active lifestyles requiring spectacle freedom and those in a specific profession such as divers or athletes may also benefit from OK treatment. Unlike any other refractive treatments, OK lens effects on the cornea are reversible and wearers can discontinue wearing the OK lenses if they are dissatisfied with the outcome (Kobayashi *et al*., 2008).

The benefits of the OK lens in improving vision are well established (Nichols *et al.,* 2000; Cho *et al*., 2005; Swarbrick *et al*., 2015; Liong *et al*., 2015). OK treatment done in Malaysia involving a group of younger population (age 8-17 years old) has been reported and the results showed a reduction of myopia to almost Plano power was achieved within a day of wearing the OK lenses (Mohd-Ali *et al*., 2014; Liong *et*

al., 2015). The effects on corneal curvature and visual acuity of OK treatment on young Malay adults have not been reported. The OK treatment may be the same but this needs reaffirmation.

There are a few brands of OK lenses available in the Malaysian market such as Boston and Pentagon lenses but the Menicon Z Night lens was newly introduced in 2015 and there is no study yet which has reported on its effect on the Malaysian population. The Menicon Z Night lens has some unique features. Its parameters are determined by the software Easyfit and no trial fitting is involved in determining the parameters of the OK lenses. By putting in values for refraction and topography derived from clinical measurements, the software automatically assesses whether potential participants are suitable for OK treatment and generates suitable parameters that give the desired amount of myopia reduction. The software also helps in troubleshooting and improving lens fittings upon delivery. Few studies have reported using the Menicon Z Night lens with promising results comparable in performance with other established OK lenses (Santodomingo-Rubido *et al*., 2012; Chan *et al*., 2012; Chen & Cho, 2012; Santodomingo-Rubido *et al.,* 2013). Several retrospective studies were done in Malaysia that showed the OK lenses were effective in myopia treatment but used the conventional fitting methods with other established brands of OK lenses (Mohd-Ali *et al.,* 2014; Liong *et al.,* 2015). There are no available studies yet that report the effect of myopia treatment among Malaysians using the Menicon Z Night lens. Therefore, this study aims to examine changes in refractive error, unaided visual acuity and corneal curvature after wearing the Menicon Z-Night lens for six months among young Malay adults. Malays ethnicity was chosen because no study has reported on the effect of OK on Malays and ocular biometric comparison studies have shown differences in ocular parameters between Malays and other ethnicities in Malaysia (Ramlee & Goh, 2012).

Materials and Methods

This prospective study was approved by the Ethical Committee of the Universiti Teknologi MARA (REC 286/16) and followed the tenets of the Declaration of Helsinki.

Participants

Participants were recruited through advertisements posted around Puncak Alam Campus and by personal invitation. The sample size was calculated using G power version 3.1. Based on previous studies on the effects of OK on corneal curvature (Chan *et al.,* 2008), the effect size is equal to one, α (Type I error) set at 0.05, power of the study at 95% and the sample size calculated equal to 16. The drop-out rate was estimated to be about 25%. Therefore, the actual sample required is equal to 20.

The inclusion criteria included age between 18-25 years, of Malay ethnicity (both parents are Malay), first time fitted with an OK lens, a refractive error in the range of -1.00 to -4.50 Dioptre, astigmatic power of -1.50 Dioptre or less and able to attain visual acuity of 6/6 or better in each eye. Participants who wore soft contact lenses were asked to stop wearing their lenses for four weeks before the baseline measurement. Participants must not have any history of systemic and ocular diseases, not use any systemic or ocular medications that could affect ocular physiology and contact lens fitting, had no lid and anterior segment abnormalities that may contraindicate successful contact lens wear.

Measurements

Baseline visual acuity (VA) was measured using a Snellen chart projector (Huvitz Chart Projector CCP-3100, Korea) with room luminance kept at 130-215 lux. Snellen notation was then converted into a Log of minimum angle of resolution (Log MAR) units using a converter calculator (http://www.myvisiontest.com/log MAR.php). Retinoscopy was performed without dilation and refined subjectively. Corneal curvatures along the horizontal and vertical meridians were measured using the Tomey TMS-4 topographer

(Tomey, Japan). Measurements were made on both the right (RE) and left eye (LE).

Orthokeratology Lenses

The lens was manufactured by Menicon Co Ltd (Japan) and is the only Hyper DK GP lens material approved by the FDA for up to 30 days of continuous wear. It was made of a hyper-permeable copolymer of siloxane styrene and fluoro-methyl-acrylate material with high oxygen permeability (DK) value of 163 x 10-11 (cm2/sec) [mL02/ (mL•mmHg)]. The lens underwent surface treatment to allow maximum wettability and high resistance against breakage and scratches.

Standard Fitting Evaluation of Orthokeratology Lenses

Assessments of the Z-night lens fitting were based on the fluorescein pattern of the lens seen through a slit lamp and cobalt blue filter. Dynamic lens assessment included good centration and adequate movement with a smooth response. Due to the existence of the fenestration point, active tear flow under the lens created tear bubbles. Tears will be seen to flow in and out of the fenestration point and are considered as having good tear exchange. The size and number of air bubbles vary with blinking but it does not affect the fluorescein assessment underneath the lens. Typically, an optimised fitting lens is stable, centres well on the cornea moves upon blinking and re-centres quickly. The non-optimum fitting lens may be classified as either steep or flat. Steep-fitting lenses may have good centration but may be displaced inferiorly with minimal lens movement upon blinking. It has a small treatment zone, a wider tear reservoir zone and a narrow edge lift. A flat-fitting lens has reverse characteristics.

Evaluation of OK lenses using a slit lamp alone is not enough to ensure successful fitting. A topographical map assessment is also needed to aid examiners in making the correct decision regarding fitting. The map describes the corneal surface relative to the optical axis and gives a general view of the corneal contour. The topography of fluorescein underneath a well-fitting OK lens shows the typical 'bull eye appearance' which indicates the correct sagittal depth and centration. A steep-fitting OK lens will show a 'central island pattern' indicative well-centred lens but with higher sagittal depth and inadequate corneal clearance. A 'smiley pattern' indicates a flat-fitting lens with decentred lens and excessive corneal clearance. Lens parameters need to be adjusted if the fitting is not optimum. Having dispensed the lens, a topography assessment needs to be made to assess corneal changes on the following morning after overnight lens wear. This is repeated after one week and results after three weeks of overnight lens wear will indicate whether the lens fit is satisfactory (Cho *et al.*, 2012).

Procedure

Interested participants were given appointments for an initial vision examination and those who met the criteria were enrolled in the study. Successful participants were given the subject information sheets and consent forms to sign before the study. Baseline measurements included visual acuity, objective and subjective refraction without cycloplegia, and corneal curvature measurements using a topographer. By inputting parameters of ocular refraction and corneal topography into the Easyfit software, it automatically calculates the adequate OK lens to start with and assesses whether the potential patient will be successful with OK lens wear. Two topography measurements were taken on two different days to ensure the reliability of lens parameters. Only then are the lenses ordered from the manufacturer. During delivery, lens fitting was analysed and participants were taught the use and maintenance of their OK lenses following the guidelines of rigid lens fitting in clinical optometry.

The same measurements were repeated after one day, one week, three months and six months. Every visit was scheduled in the morning after three to four hours of waking. All participants were university students and occasionally for

those who have classes in the morning, the follow-up visits shifted to lunchtime.

Aftercare consultations related to contact lens wear were asked and noted during the follow-up sessions regarding vision changes, lens sensation upon insertion (pain and stingy), handling and insertion method used. Changes were made accordingly. The Easyfit software also helps in troubleshooting to improve lens fitting.

The data was analysed 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 ($p > 0.05$). Data were normally distributed; therefore, repeated-measures analysis of variance (ANOVA) with $p \leq 0.05$ was used to examine the visual-parameter changes from the baseline to the six months study period. Post hoc analysis (Bonferroni) was used to find significance during each follow-up visit. Correlation and regression tests were used to find an association between spherical equivalent refractive (SER) changes with visual acuity and corneal curvature.

Results and Discussion

Altogether 24 participants met the inclusion criteria and were recruited for the study. However, only 20 participants completed the six months study period. Those who discontinued were due to poor vision (1), unsuccessful OK lens wear (1) and unable to attend delivery sessions (2). The demography data is depicted in Table 1.

The mean change in refraction during the six months is shown in Figure 1. The refractive error for both eyes was significantly reduced after six months (ANOVA, $p = 0.001$). Both eyes showed a similar trend in mean changes over the six months. Refractive error change was significant only after the first night of OK lens wear.

The effect of OK treatment on low myopia is well-known and is effective in reducing low myopic power to near zero (Cho *et al.,* 2005; Mohd-Ali *et al.,* 2014; Swarbrick, 2015; Liong *et al*., 2015). In this study, the mean change of SER at a 24-hour follow-up visit was significantly different from baseline, thereafter, SER stabilised for six months of the study period.

Table 1: Demographic data of participants (n=20) at baseline visit

Demographic Data			
Gender	Male	Female	Total
	5	15	20
Age (years) (mean ± SD)	22.73 ± 1.19	22.42 ± 1.22	22.45 ± 1.19
Baseline parameter			
Biometric parameter		Right eye (mean ± SD)	Left eye (mean ± SD)
Unaided VA (log MAR)		1.06 ± 0.22	1.04 ± 0.23
Spherical equivalent refraction (D)		-2.84 ± 0.87	-2.89 ± 0.94
Dioptric cylindrical (D)		-0.30 ± 0.33	-0.34 ± 0.30
Steep corneal curvature-Ks (D)		44.13 ± 1.38	44.08 ± 1.34
Flat corneal curvature-Kf (D)		43.20 ± 1.42	43.08 ± 1.44

Data presented as mean ± standard deviation
VA=visual acuity, log MAR=log minimum angle of resolution, D=Dioptre

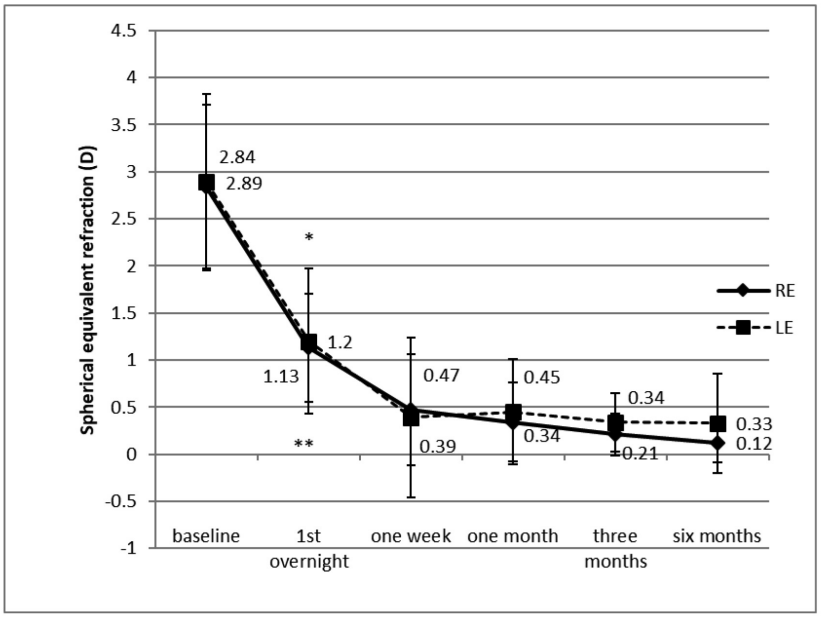

Figure 1: Changes in spherical equivalent refraction (SER) for right and left eyes. Error bar indicates standard deviation
*,** indicate significance $p < 0.05$ for both right (RE) and left eyes (LE), which stabilised after one night of OK lens wear

Myopia reduced from -2.84 ± 0.87 to -0.12 ± 0.21 D for the right eye and from -2.89 ± 0.94 D to -0.33 ± 0.53 D for the left eye consecutively after six months of OK treatment. The greatest change was seen after one night of lens wear.

Our findings are similar to those of Chan *et al.* (2012) that used the same Menicon Z night lenses and modality, although their participants comprised school children aged 6-11 years old. Lipson (2008) studied changes in SER between two different age groups, < 12 years old and > 12 years old and found no significant differences between them after 15 months of OK lens treatment. In our study, SER stabilised after one day of OK treatment and continued until six months of the study period. This also concurred with many previously reported studies using different brands of OK lenses (Cho *et al.,* 2012; Liong *et al*., 2015; Khan *et al*., 2017). Indeed, Santodomingo-Rubido *et al*. (2017) reported the stability of their participants' myopia treated with OK lenses monitored over seven years.

Figure 2 shows changes in unaided vision for each eye for each visit during the six months. Statistically, significant improvements were seen relative to baseline in all participants during the six-month OK lens wear (ANOVA, p = 0.0001). The greatest change relative to baseline occurred after the first overnight OK lens wear and stabilised soon after. No more significant change occurred between subsequent visits (p >0.05).

The pattern seen in refractive changes was also reflected in changes in unaided visual acuity. VA changes were found to be clinically significant for both eyes at 24 hours follow-up visits compared to baseline. The unaided visual acuity improved from 1.06 ± 0.22 log MAR for the RE and 1.04 ± 0.23 log MAR for the LE at baseline to log MAR 0.01 ± 0.05 (RE) and 0.03 ± 0.14 (LE) after six months of wearing the OK lenses. The greatest change also occurred after one night of lens wear. This means that participants attained good vision after one night

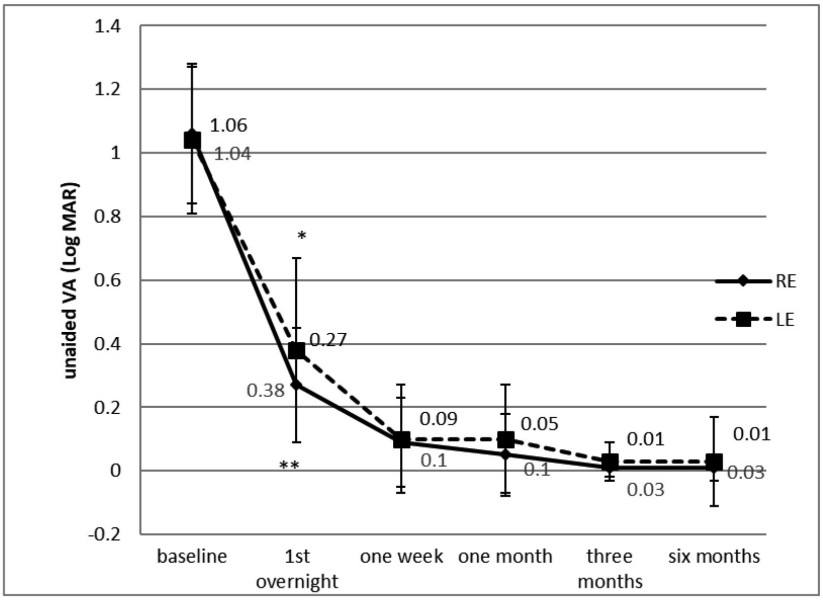

Figure 2: Changes (mean) in unaided visual acuity (VA) for both eyes for all visits. Error bar indicates standard deviation

*,** indicate significance p <0.05 for both right (RE) and left eyes (LE), which stabilised after one night of lens wear

of lens wear and can go around without their spectacle during the day. To our knowledge, this is the first reported study on Menicon Z night lenses among young Malay adults.

A study conducted by Chan *et al*. (2012) in Hong Kong using Menicon Z night lenses also produced the same results, although their study was carried out among children 6-11 years old and their participants consisted of Chinese ethnicity. Different brands of OK lenses fitted using conventional fitting methods and trial lenses also produced the same results among school children aged 7-17 years old, as shown in a prospective study by Liong *et al.* (2015), who used Global OK lenses. Their participants also consisted mainly of Chinese ethnicity. It is interesting to note that although Liong *et al.* participants consisted of low to moderate myopes with initial power -3.9 ± 1.01 D and using a different brand of lenses, the results attained are similar to ours, whereby cornea stabilisation was achieved after one night of OK lens wear.

There was a strong negative correlation between SER and unaided VA during the six months study period (Figure 3), which was statistically significant (correlation coefficient, r=-0.349, n=102, p <0.000). Results from the right eye only are shown for illustration.

Figures 4 and 5 showed a reduction in corneal power along the steepest and flattest meridians for both RE and LE after a different period of OK lens wear. In both eyes, the Sim K along the steepest and flattest meridians flattened significantly over time compared to the baseline (ANOVA, p=0.001). For both eyes, corneal curvature along the steeper and flatter meridians changed significantly after one night of lens wear and stabilised for the rest of the study period.

Reduction in SER among myopes who underwent OK treatment has been attributed partly to changes in corneal curvature achieved using the reverse geometry lens design. The lens has a flatter curve in the central area relative to the peripheral areas. The central curve resulted in significant flattening of corneal curvature along the vertical and horizontal meridians of the cornea. This was found in our study, whereby corneal curvature changed from 44.13 ± 1.38 D

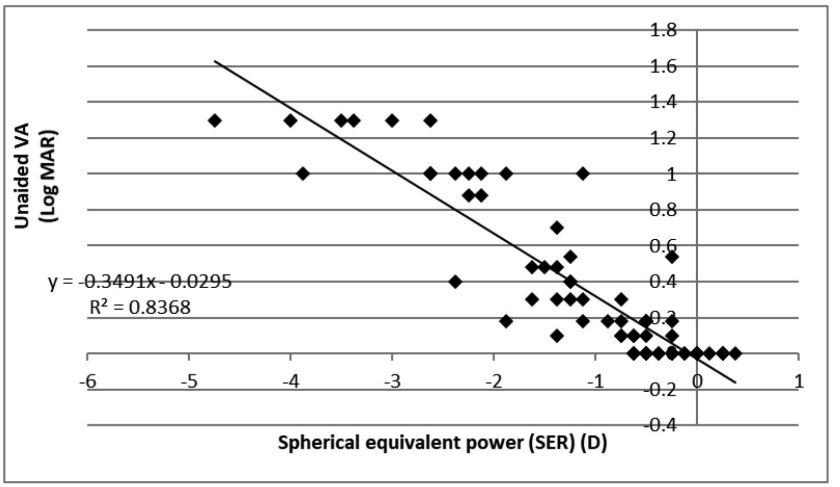

Figure 3: Relationship between spherical equivalent power (SER) and unaided visual acuity during the six-month overnight OK lens wear

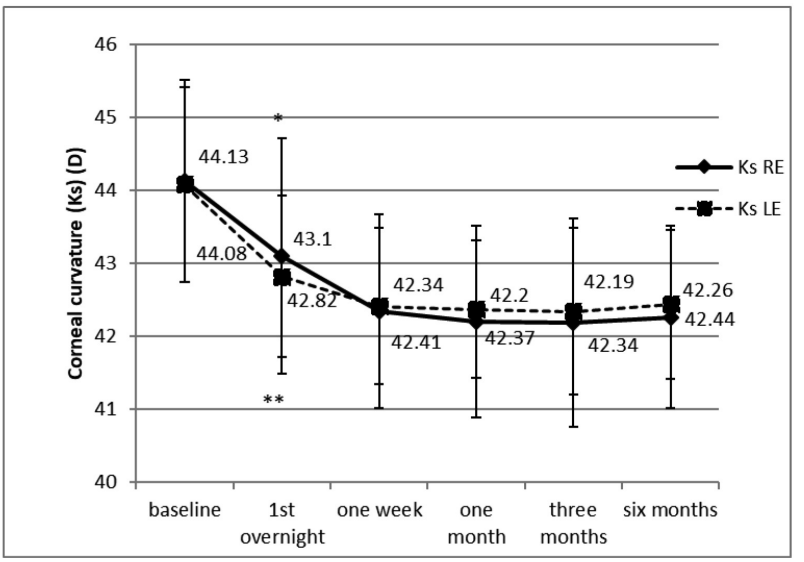

Figure 4: Simulated mean steep keratometer reading (Ks) for right (RE) and left eyes (LE) over time. *,** $p < 0.05$ for RE and LE

to 42.26 ± 1.25 D along the vertical meridian and from 43.20 ± 1.42 D to 41.24 ± 1.43 D in the horizontal meridian of the right eye over the six months. The same pattern was seen for the left eye. Corneal curvature stabilised after one night after lens wear and no more significant changes were noted afterwards.

This study also showed a significant negative correlation between SER and corneal curvature (mean keratometry reading for vertical and horizontal meridian) for both the right and left eyes. For illustration, only results for the right eye are shown in Figure 6 (correlation coefficient, r=-0.548, n=102, p <0.000).

The strict inclusion criteria that included low refractive error and low astigmatism probably contributed to the successful outcome. The results reaffirm what has been reported by

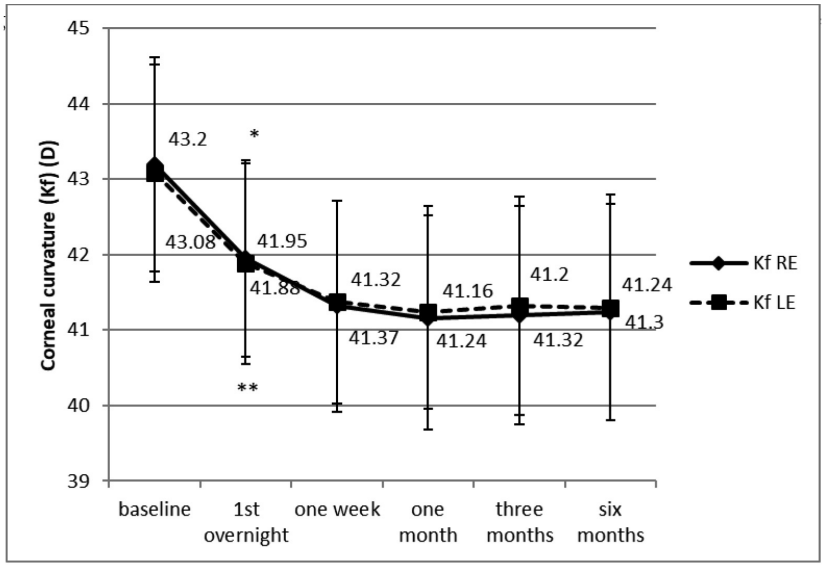

Figure 5: Simulated mean flat keratometer reading (Kf) for right (RE) and left eyes (LE) over time. *,** $p < 0.05$ for RE and LE

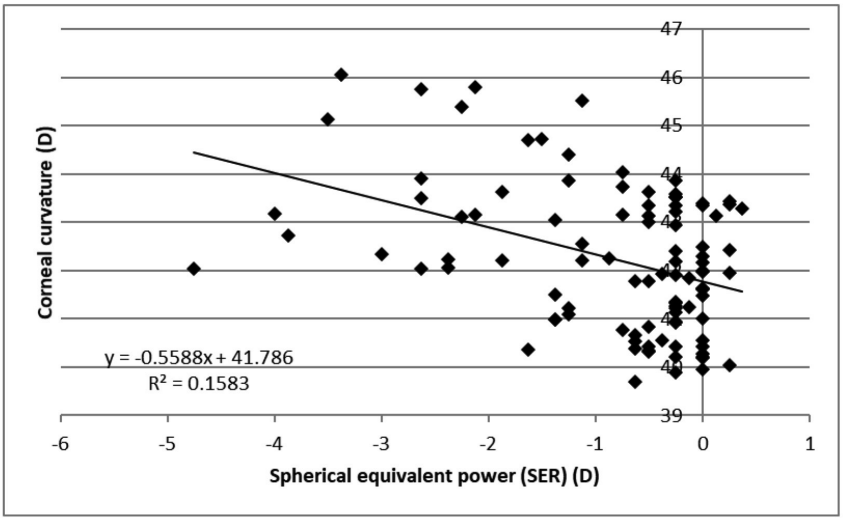

Figure 6: Relationship between spherical equivalent power and corneal curvature during the six-month overnight OK lens wear

previous studies on OK treatment among low myopes (Soni *et al*., 2003; Cho *et al*., 2005; Liong *et al.,* 2015; Khan *et al.,* 2016). It appears that ethnicity and brands of OK lenses do not affect the outcome provided they are fitted well in line with the manufacturer's recommendation. Some of the unique features found in the Menicon Z lenses such as fenestration (Cho *et al.,* 2012) may also contribute to the ease of fitting and adaptation to the OK lens by participants. Moderate myopia with relatively flatter corneal curvature has also been cited to be less rigid (Lim *et al*., 2008) and this may also contribute to the successful outcome after one night of wearing an OK lens.

This study did not show any change in toricity for six months. The findings agree with the majority of previously reported studies on corneal toricity (Sridharan & Swabrick, 2003; Kang *et al*., 2007; Chou *et al*., 2013; Liong *et al*., 2015). The OK lens flattened the horizontal and vertical meridians almost equally; thus, toricity was not significantly altered for the six months study period. Wang *et al*. (2005) reported an astigmatic increase in their moderate myopic participants partly due to different inclusion criteria and the nature of astigmatism being investigated.

The limitation of the study included not having a control group. However, like most previous studies, it was presumed that eye growth is stabilised in young adults and the short-term duration of the study may not affect ageing. Conversion from the Snellen unit to the Log MAR unit in measuring the VA is considered a limitation in this study. This is due to the limited number and access to the Log MAR chart within the facility. A similar conversion has been reported by Khan *et al*. (2016) in their OK study. Future work may examine the long-term effects of OK lens wear on corneal curvature and its effect on other ocular parameters.

Conclusion

In summary, the Menicon Z-Night lens fitted with the aid of software in this study reduced myopia up to -4.00 D to almost Plano among young Malay adults, enabling them to go about without spectacles during the day. The change was accompanied by a decreased corneal curvature and improved visual acuity. These findings are useful to eye care providers who have the option to correct myopia using OK lenses, especially those who want to be free of their spectacles. Future work may include the OK effect on visual and corneal parameters in a longitudinal study that can provide more data for managing myopia.

Since high myopia poses risks that may lead to blindness, it must be detected early by eye care providers and allied health professionals, parents, and people who work within the communities such as doctors, teachers and social workers. The communities need to be educated and informed of the debilitating effects of myopia if it is not treated and OK offers alternative treatment for myopia correction. If myopia is diagnosed and treated early with OK lenses, especially in children, the myopic power can be kept low (<3.00D) until the individual reaches adulthood, when myopia usually stabilises. The community can play a part by referring individuals suspected of having myopia to the respective eye care providers for further management.

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