Corneal thickness and morphology after orthokeratology of six-month lens wear among young Malay adults

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ABSTRACT

Background: Menicon Z night orthokeratology (OK) lenses was introduced in Malaysia in 2015 and to date there is no report on its effects on the cornea. The objective of this study was to examine short term changes in corneal thickness and morphology of endothelial cells in young Malay adults after wearing Menicon Z night OK lenses.

Methods: Corneal thickness was measured at the central and mid-peripheral locations of 20 participants aged 22.45±1.19 years using Tomey SP-3000 A-scan ultrasonography. Endothelial images of the central and peripheral locations captured using Tomey EM-3000 specular microscope were noted. Corneal thickness, endothelial cell density (ECD), coefficient of variation in cell size (CV), and hexagonality (HEX) at baseline, 24 hours, three months and six months after treatment were noted and analysed using repeated measure analysis of variance.

Results: Central corneal thickness decreased significantly over a three-month period (p=0.001) and stabilised thereafter. There were no significant changes in thickness in all peripheral areas measured (p>0.05), and in ECD, CV and HEX after the six-month period (p>0.05).

Conclusions: The current study showed that significant thinning of central cornea and none at the mid-periphery. OK lens wear with Menicon Z night lenses had no effects on corneal morphology over the six month period.

KEYWORDS:
Orthokeratology, Malays, Endothelium cell density, Pleomorphism, Polymegathism

INTRODUCTION

Orthokeratology (OK) is an optional treatment to correct myopia where a specially designed reverse geometry rigid gas permeable contact lens is placed on the cornea to alter its shape. The corneal curvature is usually flattened, and the myopic power becomes almost zero, enabling the individual to go about without spectacles during the day. The reduction of myopia is accompanied by several changes in corneal structures that include corneal thickness and corneal morphology.

Previous studies have shown that short term wear of OK lens affect corneal thicknesses. Most studies have shown that there was central corneal thinning accompanied by mid peripheral thickening.[1-3] Some studies however only reported central thinning without mid-peripheral corneal thickening.[4,5] Central corneal thinning as results of OK lens has been reported to occur after 24 hours and usually stabilised after one week of lens wear in low-moderate myopia. Light microscopy and electromicroscopy studies in cynomolgus monkeys have shown that central thinning involved compression of the epithelial layer and mid-peripheral thickening in both the epithelium and stromal layers.[6]

Wear of contact lens has long been associated with changes endothelial morphology changes in the cornea.[7,8] Such changes in the long term may affect the functions of the endothelial cells. One of the causes can be chronic hypoxia as results of inadequate oxygen transmission to the endothelium through the material of the contact lens. It is important to ensure that contact lens materials have high oxygen transmissibility so that endothelial function is not affected.

Nowadays contact lens material usually has high oxygen permeability. An example of this is the Menicon Z night lens which has a Dk (oxygen permeability) value 163×10^{-11} (cm^2/sec) [mLO_2/(mL mmHg)]) and the only hyper Dk gas permeable (GP) lens material approved by Food and Drug Administration (USA) for continuous 30 days wear. The OK lens can be worn at night during sleep without producing adverse effects on the eye.[9]

Several studies found no significant changes occurring in the endothelial layer after wearing OK lens for one month to five years.[10-12] A few studies reported using material of Dk value reaching 163×10^{-11}. Since the Menicon Z night lens was only introduced into the Malaysian market in 2015 it is important to find whether it has any impact on the morphology of the endothelial cells.

Only a few studies had reported on the effects of the lens on corneal thickness and endothelium cells; however, none of the study reported on its effect among Malays. Ocular parameters have been shown to be different among different ethnicities, so it is important to document the corneal thickness and endothelial changes as the result of overnight OK lens wear. This is to ensure the safety of the Menicon Z night lens among Malaysians.

Besides the high Dk, lens fitting is also non-traditional because no trial fitting is required to order the lens

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parameters. Lens parameters are generated by EasyFit software supplied by the manufacturer; by putting in topographic and ocular refraction values obtained during clinical examination. It also helps the practitioner to troubleshoot problems faced during fitting.

The objective of this study was to examine short–term changes in corneal thickness and morphology of endothelial cells among young Malay adults after wearing Menicon Z night lens for six months.

MATERIALS AND METHODS

This was a prospective study that examined the effect on the eye of Menicon Z night OK lens. The report here is only on corneal thickness and morphological changes over a six-month period. Measurements were taken at baseline and repeated after 24 hours, one-month, three-month and six-month period.

Participants

Twenty participants, 5 males and 15 females were recruited through advertisements posted around Universiti Teknologi MARA Campus and by personal invitation. The mean age of the participants was 22.45±1.19 years. Sample size was calculated based on previous studies on effects of OK on corneal parameters[13] with α (Type I error) set at 0.05 and power of the study at 80%. The inclusive criteria included age of participants between 18-25 years, first time fitted with OK lens, has low to medium refractive error in the range of -1.00 diopter sphere (DS) to -4.50 DS, astigmatic power of -1.50 diopter cylinder (DC) or less and able to attain visual acuity of 6/6 or better in each eye. Those who wore soft contact lenses were asked to stop wearing their lenses for four weeks prior to baseline measurement.

Participants who had history of systemic and ocular diseases were excluded from the study. as it could affect ocular physiology and contact lens fitting, had lid and anterior segment abnormalities that might contraindicate successful contact lens wear were also excluded.

Instrumentation

Corneal thickness

The Tomey SP-1000 pachymeter (Tomey, Japan) was used in this study to measure corneal and peripheral thickness. It consists of an emitter probe which releases ultrasound wave that travel to the corneal surface to the endothelium layer and reflected back to the transducer. At the speed of sound of 1640 m/s through the cornea and knowing the time taken, the inbuilt system calculated the corneal thickness and displayed on its screen.

Endothelium morphology

Endothelial profile was captured using Tomey EM-3000 specular microscope (Tomey, Japan) without contact with the corneal surface. It uses the same technique that was applied in specular reflection to view the endothelium cells as in slit lamp biomicroscopy. However, this instrument has an innovative system that enable the measurement of endothelial cell count per square millimetre, distribution of the cells in term of range and size as well as percentage of normal hexagon sided cell. A built-in camera enabled photo-documentation to be performed and built-in analysis software to illustrate the endothelial data.

Procedure

Corneal thickness

Participants were seated three meters away from the fixation target. The cornea was desensitized using a drop of 0.5% proparacaine hydrochloride (Alcon). After 30-60 seconds, sensitivity test was performed. Tip of cotton bud was pressed slightly on the inferior peripheral cornea and if no sensation was reported, a measurement was taken. If there was sensation after 60 seconds, another drop of proparacaine hydrochloride was inserted and the procedure repeated. For central corneal thickness (CT) measurement participants were asked to fixate at a marked location on a wall in a straight-ahead position. The probe of the ultrasound pachymeter was held perpendicularly to centre of visual axis and reading was noted once the probe contacted the corneal surface at the desired measurement point. Measurement was taken only when the probe was perpendicularly aligned to the corneal curvature. For peripheral measurements, participants were asked to look at pre-marked targets on the wall at four different locations namely superior, nasal, inferior and temporal positions. All measurements were taken three times and the average noted.

Endothelium morphology

The participants were seated in front of the specular microscope and asked to fixate at the inner fixation target. They were asked to blink and told to hold their blink while the equipment automatically took the image of the endothelium. A single capture generated 15 pictures. An image of most visible and clearest group of cells was selected by the system and analysed. The endothelial data of interest was displayed on the screen and noted.

During the corneal morphology studies, the endothelial cell density (ECD) was usually used as the parameter to measure the of amount of endothelial cell over specific areas, while coefficient of variation (COV) of endothelial cell size was used as measurement of endothelial cell size variation that estimate the degree of endothelial polymegathism, and the percentage of hexagonal cell was used as measurement of endothelial cell shape variation that estimate the amount of endothelial pleomorphism.

RESULTS

Changes in corneal thickness

Central corneal thickness for both eyes showed significant reduction of values from baseline RE: 542.56±36.70µm, left eye (LE): 547.80±32.66µm) to six months of follow-up visit (right eye, RE: 538.19±30.28µm, LE: 547.94±30.05µm). Repeated measure ANOVA test was conducted to compare the effect of OK lens on corneal thickness over the six-month study period. Significant difference was found after three months of wearing OK lens, thereafter CT stabilised until six months of the study period both for the right and left eyes (Figure 1). The peripheral cornea showed an increase in thickness over time, however repeated measure ANOVA showed none of the changes were significant compared to baselines values for both the right and left eyes.

Endothelial changes

The endothelial component changes over the six months period is shown in Table I. Repeated measure ANOVA was conducted to examine the effect of the OK lens on endothelial

Table I : Mean changes of endothelial components for right eye (RE) and left eye (LE)

ECD (cells/mm^2)	Baseline	One month	Three months	Six months	p-value
RE	2875.88 ±172.11	2900.00 ±231.31	2826.44 ±225.32	2851.81 ±263.07	0.16
LE	2851.75 ±230.41	2884.50 ±180.05	2884.50 ±164.89	2884.50 ±240.28	0.60
CV					
RE	37.81±5.27	37.88±6.59	38.19±5.48	36.81±4.22	0.74
LE	38.06±6.49	37.94±7.16	38.94±7.22	38.25±6.27	0.82
HEX (%)					
RE	54.19±6.39	54.25±5.72	54.75±7.53	56.00±5.40	0.65
LE	55.25±7.44	54.81±8.26	53.94±11.78	55.38±9.44	0.92

p>0.05 for all values for the six month period

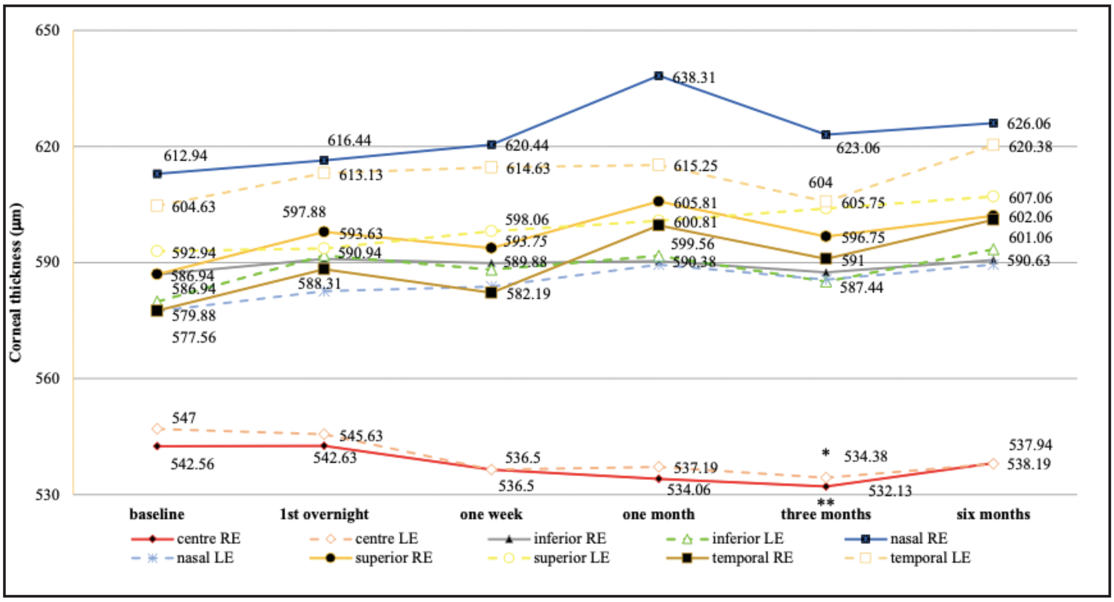

Fig. 1: Changes of mean corneal thickness profile.

*,**p<0.05 for central right eye(RE) and left eye (LE)

profile of each eye of the participants after six months of the study period. There was no significant changes in the mean density of endothelial cell (ECD) (baseline RE: 2875.88±172.11cells/mm^2, six month's RE: 2851.81±263.07cells/mm^2, baseline LE: 2851.75±230.04cells/mm^2, six month's LE: 2853.19±240.28cells/mm^2). The same results were obtained for coefficient of variation (CV) which showed minimal changes but not significant (baseline RE: 37.81±5.27, six month's visit RE: 36.81±4.22, baseline LE: 38.06±6.49, six month's visit LE: 38.25±6.27). The mean of percentage of cell's hexagonality (HEX) for both eyes from baseline to six month of the study period also was not significant (baseline RE: 54.19±6.39%, six month's visit RE: 56.00±5.40%, baseline LE: 55.25±7.44%, six month's visit LE: 55.38±9.44%).

DISCUSSION

Corneal thickness after OK treatment

Our results showed significant thinning of the central corneal thickness in both eyes from baseline until six months follow-up. Central corneal thicknesses were significantly reduced after three months of OK treatment and no further reduction was seen in subsequent visits for both eyes. There appear to be thickening of the mid-peripheral cornea after six months of OK lens wear, but the changes were not significant.

The thinning of central corneal thickness seen in this study is in agreement with many previous studies.[1-3] However some studies also showed only central thinning with no significant changes in the mid periphery areas as found in this study.[4,5] Transmission electron microscopy study in primates showed central corneal thinning and mid-peripheral thickening occurred as results of wearing OK lens.[6] The thickened areas seemed to correspond with the mid-peripheral tear reservoir created under the steeper secondary curve of the OK lens.

The non-significant changes found in the mid peripheral areas could be due to newer design of lenses and high transmissibility (Dk/L) found in the Menicon Z night lenses. The material has a higher Dk/L value compared to the ones used by Cheah et al.[6] Furthermore it has fenestrations located at the mid-peripheral areas that might contribute to the non-significant changes in the peripheral areas. Cho, Collins, & Sawano, described the different forces acting on the cornea induced by tears in between the OK lens and the corneal surface.[14] The main forces are lid force which lead to central compression of the cornea and the squeeze film force which is dependent on the pressure induced by tears under the reverse zone area. Combination of these forces results in tangential stress at different regions of the cornea that lead to changes in the corneal surface to become spherical in shape at the centre and prolate shape at the periphery. This partly explained mechanism of central thinning and peripheral thickening of corneal thickness in OK lens wear.

In Menicon Z Night design, the fenestration points are precisely located at tangent periphery areas that are in the reverse zone area. These will cause the tear film forces to be reduced and as such will have less effect on peripheral corneal changes. This fenestration point can be a possible explanation for insignificant peripheral corneal thickening found in this study compared to the majority of the studies that used the non-fenestrated OK lenses.[14]

The time in which significant changes in corneal thickness occurred was also different between different studies, varying from one day to one month of OK lens wear in most low-moderate myopes. Liong et al., study showed that cornea with higher myopic power need more time to stabilise compared to lower myopic power.[2] The time difference in which significant changes occurred between studies has been attributed to different optical instruments being used (optical verses ultrasonic pachymeter), different lens designs and brands, inter observer differences, close and open eye conditions whilst wearing the OK lens.[1] When measuring the desired retinal points for instance, the oblique incidence of the probe to the cornea can overestimate corneal thickness. Effect of topical anaesthetic instilled to desensitise the cornea may also affect speed of ultrasound through the various corneal layers.[15] However, Parafita et al., showed that central and peripheral corneal thickness measured using ultrasonic pachymeter were reproducible.[16]

Endothelial changes

This study showed there were no significant changes in the endothelial components after wearing the Menicon Z Night lens after six months. The ECD, CV and HEX values at the baseline remain unchanged relative to the six-month's visits study period. It appears that the Menicon Z night lenses do not alter the morphology of the endothelial cells within six months of the study period.

Nieto-Bona et al. reported different findings after one year of post-OK treatment compared to our finding. They found a significant increase of the CV among young adult aged 18-30 years old with no changes on the ECD and HEX. Their study used material that had oxygen permeability of [100x10^{-11} (cm^2/s) (mLO_2/mL mmHg)] while we used material that have higher oxygen permeability [163x10^{-11} (cm^2/s) (mLO2/mL mmHg)].[17] The lower level of oxygen permeability could be a reason that caused the morphological changes in their long-term OK treatment.

In young OK lens wearers 6-12 years old, Cheung & Cho discovered a significant reduction of the ECD, HEX and CV at the central endothelial layer after two years under OK treatment.[18] However, they also found a greater reduction of the ECD, which was significant, seen in their control group compared to their OK lens group. They used Menicon Z night OK lens and it is well known that this lens has the highest oxygen permeability, theoretically unlikely to cause the morphological changes for overnight treatment. They acknowledged the significant reduction of the central ECD seen in their study was a natural process of aging and was not related to the mechanical stress induced by the OK lens. Yunliang et al.,[19] also recognised that the reduction of ECD occurred in the healthy young corneas who did not wear any contact lenses.

The sagittal height of the OK lens could also play a role in changes in the morphology of the endothelium layer. A lens with too low sagittal height can cause mechanical irritation to the corneal layers.[20] A correct sagittal height will yield a well fit OK lens to prevent vaulting off the central corneal apex and also to prevent excessive bearing in the alignment zone.[21] The morphology of the endothelial layer in this study remained unchanged after wearing Menicon Z Night lens for six months. Menicon Z night lens series has a wide range of sagittal height available from 0.50 to 0.90 mm with 0.01 mm step that was determined using the EasyFit software. The software generates the optimum and suitable sagittal height for each lens to achieve the maximum reduction of myopia on the eye while maintaining the health and functionality of the corneal cells. This may imply that the high oxygen transmissibility and the variable sagittal height of Menicon Z Night have less or no impact on the cornea layers especially to the endothelium layer.

This study was carried out among young Malay adults from a local university with a mean age of 22.45±1.19 years, therefore the results cannot be generalised to the Malaysian population. This is considered as a limitation of the study.

CONCLUSION

In summary, our results sowed significant changes in central cornea but not at the mid-peripheral regions. The endothelial cells were also not affected in the sixth month's period of wearing the Menicon Z Night lens. The initial results may imply that young Malay adults may safely wear the OK lens as an alternative for myopic treatment, however long-term study is warranted.

ETHICAL APPROVAL

The study was approved by the Human Ethical committee of University (REC 286/16) and followed the tenets of Declaration of Helsinki.

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