QUALITY OF VISION POST-SHORT TERM OPEN EYE ORTHOKERATOLOGY LENS WEAR

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Aim: To investigate the quality of vision post-short-term open eye orthokeratology (OK) lens wear.

Methods: A total of thirty young adults with myopia between 1.00D to 5.00D wore OK contact lenses for 2 hours in open eye condition in their right eye only. The root-mean-square high order aberrations (RMS-HOA) of the corneal front surface were recorded using Scheimpflug camera. Additionally, unaided visual acuity (VA), objective spherical equivalent refraction (SER), and contrast sensitivity (CS) were recorded using logMAR chart, open field autorefractometer, and CSV-1000 (VectorVision) chart respectively. Data were captured at baseline and post 2 hours of OK lens wear.

Results: Significant improvement in VA and SER of 0.42 ± 0.03log (Mean $\pm$ SEM, $p < 0.0001$) and 0.71 ± 0.06D ($p < 0.0001$) was seen post-OK lens wear respectively. The CS displayed a significant improvement for all spatial frequencies post lens wear. Total RMS values of HOA, RMS spherical aberration (SA; Z12), RMS higher order astigmatism (Z3+Z5) and RMS coma (Z7+Z8) increased by 0.12 ± 0.03µm ($p = 0.001$), 0.15 ± 0.02µm ($p < 0.0001$), 0.07 ± 0.06µm ($p > 0.05$) and 0.08 ± 0.02µm ($p = 0.004$) respectively post lens wear.

Conclusion: Visual acuity and contrast sensitivity demonstrated significant improvement post open eye OK lens wear. However, there was a degradation of visual quality due to an increase in RMS-HOA, SA, and coma post lens wear.

Keywords: Orthokeratology, myopia, high order aberrations, spherical aberration, coma

Orthokeratology (OK) contact lenses are specially designed rigid gas permeable lenses that gently reshape the eye for correction of myopia.[1, 2] Overnight OK has been studied extensively to provide an excellent vision correction option for patients of various age groups.[1, 2] Since the past decade, a renewed interest has been observed in OK lenses among practitioners due to its role in altering peripheral refraction and thus helping in reducing myopia progression among children.[3-5]Although studies have reported significant improvement in visual acuity (VA) post overnight OK lens wear, the same cannot be claimed for quality of vision. Patients have reported side effects like poor night vision, glare and halos especially during the first week of OK lens wear due to an increase in corneal wavefront aberrations.[6]The resultant deterioration in visual quality can lead to dissatisfaction among few patients leading to an increase in dropout cases.Hiraoka*et al.*[7]in their study had reported an increase in higher-order aberrations (HOA) and reduction in contrast sensitivity (CS) post overnight lens wear and suggested to counsel patients before the final dispensing of the lenses.

Most of the studies [1, 2, 5, 7]investigating the effect of OK lenses have been conducted for overnight wear however in clinical practice, OK practitioners generally prefer a short lens trial before finally dispensing the lens for overnight use. In general, the lens fit and corneal curvature changes have only been the most important predictors for a successful OK fit and not much focus has been put on the quality of vision post these in-office lens trials. Apart from lens fit and corneal curvature changes the current study focuses on changes in VA, refraction, as well as the quality of vision to provide the contact lens practitioners with an insight on the expected changes, post-short-term open eye OK lens wear. Further, the present study results will assist the practitioner in identifying patients with an above-average increase of corneal wavefront aberrations post lens wear and who may then require a careful assessment before the final dispensing of the OK lens.

METHODS

Subjects: A total of thirty right eyesof30 young subjects (22 females and 8 males) with a mean age of 21.6 ± 1.8 years (Mean ± SD) were recruited for the study. This research conforms to the Declaration of Helsinki and was approved by the research ethics review board of the institute. Written informed consent was received from all volunteers after all the study procedures were explained and the opportunity provided to ask any questions. None of the participants had a history of any ocular diseases or corneal ectasia and were not previous rigid gas permeable lens wearers or

extended soft lens wearers. Only subjects with refractive error ranging between –1.00DS to –5.00DS and with the rule astigmatism less than 1.50 D were included in the study.

Lens selection and fitting: This study used reverse geometry RGP contact lenses from 'Fargo' which are manufactured and distributed by GP Specialist (California, USA). The lenses were made of Paragon HDS material with a Dk value of 100×10^{-11} [$cm^2.mLO_2$]/[sec.mL.mm Hg], the total diameter of 10.6 mm, optic zone diameter of 6 mm, and with a central thickness of 0.24 mm. The lenses were fitted as per the guidelines of the manufacturer that takes into account corneal curvature and refraction of the subject. Slit-lamp fluorescein fitting evaluation was performed for the recommended trial lens to ensure good lens centration/movement with every blink, absence of any air bubbles in the tear reservoir zone, and a clinically acceptable fluorescein fitting pattern. If the manufacturer recommended trial lens fit was not found to be desirable then the next best fit recommended lens was chosen and the fit evaluated.

Clinical measurements: Unaided monocular VA was recorded at baseline and post lens wear using a logMAR chart at 4 meters distance under standard room illumination. The chart was internally illuminated having a luminance value of 120 cd/m^2. It was brought forward at a distance of 2 meters if the subject was unable to read the 1.0 Log letter at a distance of 4 meters. Unaided CS was recorded using the CSV-1000E chart (VectorVision Co., Greenville, Ohio, USA) monocularly under dim room illumination of 3 cd/m^2 at a distance of 1m. The background illumination of the translucent chart using a fluorescent luminance source was calibrated to 85 cd/m^2. The CSV-1000E chart presents vertical sine-wave gratings at four spatial frequencies—3, 6, 12, and 18 cycles per degree (cpd). However, as most of the study subjects were unable to view the chart at the recommended 2.5-meter distance due to the moderate amount of baseline myopia, the measurements were taken from a 1m distance. The spatial frequencies then shift from 3, 6, 12, 18 cpd to 1.125, 2.25, 4.5, and 6.75 cpd respectively as advised by the manufacturer.

The flatter/steeper meridian keratometry values (FlatK/SteepK), corneal cylinder (cyl), central corneal thickness (CCT), corneal front HOA were recorded using Scheimpflug camera Pentacam HR (Oculus; Optikgeräte GmbH, Wetzlar, Germany) for a 6mm pupil size. The quality specification feature of the Pentacam™ ensured the best image was selected for interpretation.Root-mean-square of theZernike's coefficients were obtained using the wavefront aberration analysis software of the

Pentacam for the front surface of the cornea. All wavefront data was recorded as per the Optical Society of America's Standards for Reporting Optical Aberrations. For corneal front HOAs the RMS of total HOAs (3rd to 6th order), RMS higher-order astigmatism (Z3+Z5), RMS coma aberration (Z7+Z8), and RMS spherical aberration (Z12) were used for analysis.

Noncycloplegicobjective spherical equivalent refraction (SER) was recorded monocularly using open field auto-refractometer WAM-5500 (Grand Seiko Co. Ltd, Hiroshima, Japan) at baseline and post lens wear with values recorded in spherical equivalent form. To record SER, the subject was asked to fixate on a 6/60 Snellen target at a distance of 6m under standard room illumination. A total of five readings were taken and averaged for the best accuracy. The values obtained by the auto refractometer were converted from the conventional sphere/cylinder/axis to the spherical equivalent for analysis.

Study protocol: Detailed slit-lamp examination and non-cycloplegic refraction were performed in both eyes to observe overall ocular health and to ensure subjects met the selection criteria. This study was divided into 2 visits; baseline measurements during the first visit included unaided VA, unaided CS, Pentacam readings, and SER values. Post collection of baseline data the recommended trial lens was inserted in the right eye and the lens fit evaluated using slit-lamp (with fluorescein) after 20 minutes of lens settling time. If the selected lens achieved the desirable fit then the lens was removed and the subjects were scheduled for the next day visit post lens removal to avoid any lens after-effects on the cornea. On the second day visit, the lens was inserted in the right eye of the subject for 2 hours period in open eye condition with the left eye acting as the non-lens wearing control. The OK lenses were inserted/removed by a single examiner and all measurements were taken during a similar time of the day to avoid diurnal variations. This was a single centre study and a single examiner took all measurements for each of the instruments. Post 2-hour lens-wear, the lens was removed and all measurements were recorded monocularly in both eyes.

Statistical analysis: Data were analysed using SPSS software v27 (IBM Corp, USA) for comparisons of variables before and after lens wear. The Shapiro-Wilk test was performed to check the normality of data. If the data passed the normality test then the paired t-test was used for analysis. Wilcoxon signed-rank test was used if a normal distribution of data was not seen. A critical *p*-value of 0.05 or less was chosen to denote statistical significance.

RESULTS

During the 2-hour open eye lens wear period none of our subjects reported any major discomfort.

Unaided VA and central refraction: Baseline unaided visual acuity of the test eyes was 0.94 ± 0.05 log (Mean $\pm$ SEM) that improved to 0.52 ± 0.07 log ($p < 0.0001$, Wilcoxon signed-rank test) after 2 hours of OK lens wear and was found to be significant. Table 1 displays changes in VA post-OK lens removal. The baseline SER values recorded of the test eyes were -2.93 ± 0.24D that reduced to -2.22 ± 0.24D ($p < 0.0001$, paired t-test) post 2 hours lens wear. The baseline control eye unaided visual acuity and SER were 0.82 ± 0.05 log and -2.52 ± 0.22D respectively but did not report any significant changes post the 2 hour period.

Table 1: Changes from baseline (Mean ± SEM) for unaided VA, central refraction, FlatK, SteepK, corneal cylinder, and central corneal thickness post 2 hours lens wear.The *p* values are in comparison with the baseline visit and (*) denotes not significant.

Parameters	Changes from baseline	p-value
Unaided VA change	0.42 ± 0.03 log	$p < 0.0001$
Spherical equivalent refraction change (SER)	-0.71 ± 0.06 D	$p < 0.0001$
FlatK change	0.72 ± 0.07 D	$p < 0.0001$
SteepK change	0.66 ± 0.08 D	$p < 0.0001$

Corneal cylinder change	**0.01 ± 0.05 D**	**p > 0.05 ***
Central corneal thickness change	**6.77 ± 0.77 μm**	**p < 0.0001**

Contrast sensitivity: The unaided CS displayed an improvement for all spatial frequencies post lens wear (Wilcoxon signed rank test). The 1.125cpd, 2.25cpd, 4.5cpd and 6.75cpd spatial frequencies improved by mean 0.25 ± 0.03 cpd (mean ± SEM, $p < 0.0001$), 0.30 ± 0.04 cpd ($p < 0.0001$), 0.18 ± 0.02 cpd ($p < 0.0001$) and 0.19 ± 0.03 cpd ($p < 0.0001$) respectively post lens wear. The greatest improvement was observed at 2.25 cpd as seen in Figure 1. No significant difference was seen in the control eye readings post the 2- hour period.

Fig.No.1 Unaided contrast sensitivity in Log units at baseline and post 2 hours lens wear. Error bars represent the standard error of the mean. The X-axis denotes different spatial frequencies of the CSV-1000E chart and the Y-axis denotes contrast sensitivity in log units. Data labels marked with (*) denotes statistically significant difference ($p < 0.05$) observed as compared with the baseline values.
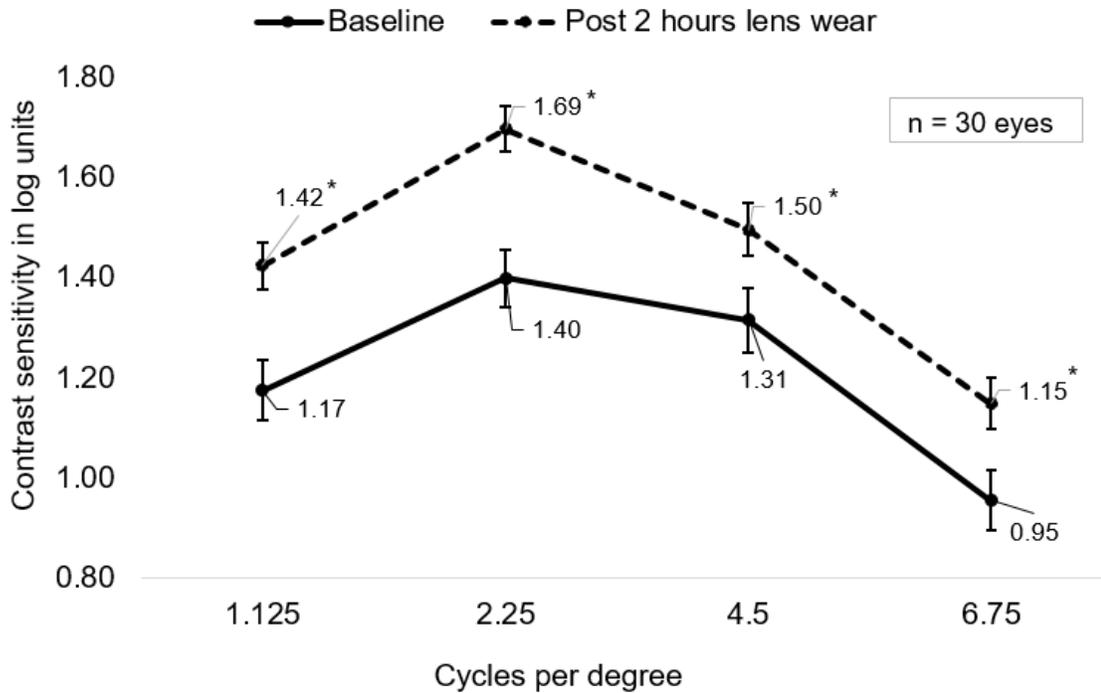
Corneal topography and central corneal thickness: Both the FlatK and SteepK readings demonstrated flattening of central corneal curvature post lens wear. Baseline FlatK and SteepK reading were 43.38 ± 0.28D (Mean $\pm$ SEM) and 44.34 ± 0.27D respectively that reduced to 42.66 ± 0.30D ($p < 0.0001$, paired t-test) and 43.68 ± 0.29D ($p < 0.0001$) respectively post 2 hours lens wear. The measured corneal cylinder at baseline was -1.02 ± 0.09D that displayed a slight increase of -1.03 ± 0.08D post lens wear but was found to be not significant ($p > 0.05$). The rapid effects of the OK lens were seen on CCT post lens wear with baseline CCT of 525.53 ± 6.06 µm significantly reduced to 518.77 ± 5.79 µm ($p < 0.0001$, paired t-test). The changes in corneal K and CCT post-OK lens wear are summarised in Table 1. No significant changes were seen in non-lens wearing control eye for corneal K and CCT post the 2 hour period.

Corneal wave-front high order aberrations: Total RMS-HOA and RMS Coma data were not normally distributed (Shapiro-Wilk) and hence the (non-parametric) Wilcoxon signed-rank test was performed. A paired t-test was performed for comparing normally distributed data of other HOA parameters. Total RMS-HOA, RMS SA (Z12), RMS higher-order astigmatism (Z3+Z5) and RMS coma (Z7+Z8) increased by $0.12 \pm 0.03\mu m$ (Mean $\pm$ SEM, $p = 0.001$), $0.15 \pm 0.02\mu m$ ($p < 0.0001$), $0.07 \pm 0.06\mu m$ ($p > 0.05$) and $0.08 \pm 0.02\mu m$ ($p = 0.004$) respectively post lens wear. Except for higher-order astigmatism, the present study reported a significant increase in corneal front surface HOA post 2 hours lens wear as seen in Figure 2. Again minimal non-significant changes were reported in the control eye during the study period.

Fig.No.2 Root-mean-square of corneal front high order aberrations at baseline and post 2 hours lens wear for a 6mm pupil diameter. Error bars represent the standard error of the mean. The X-axis denotes different types of corneal high-order aberrations and Y-axis denotes aberration values in µm units. Data labels marked with (*) denotes statistically significant difference ($p < 0.05$) observed as compared with the baseline values.
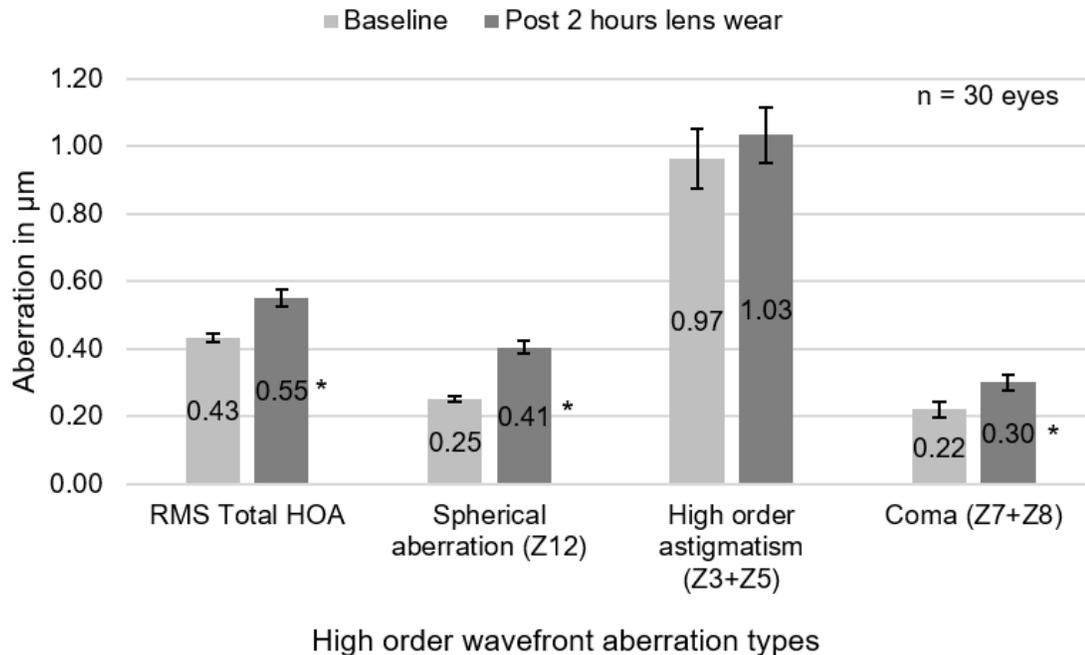
DISCUSSION

Analysing HOAs is of particular importance as it helps in understanding changes in optical quality of eye post corneal remodeling after OK lens wear. Earlier studies[15-17] have reported an increase in corneal HOAs post overnight OK lens wear thereby affecting final visual outcome and hence it becomes of particular importance to identify subjects with an above-average response to HOAs during in-office lens trials.

Corneal changes: The FlatK and SteepK responded rapidly to open eye OK lens wear with a change of 0.72 ± 0.07D (Mean $\pm$ SEM, $p < 0.0001$) and 0.66 ± 0.08D ($p < 0.0001$) respectively from baseline and thus suggests that OK lenses lead to flattening of both meridians. Previous studies[15-17]have reported that an increase in wavefront aberrations is mainly attributed to flattening of the central cornea and the steepening of the mid-peripheral cornea. Sridharan and Swarbrick [8] although in agreement with this study reported slightly more central corneal flattening with just 1 hour of lens wear. The minor corneal K differences in both study values can be attributed to the usage of different designs of lenses in both studies. The present study used Fargo OK lenses (GP Specialist, USA) while the above-mentioned study used a larger 11mm diameter BE UltraVision lenses (Brisbane, Australia). Cho et al. [10]in their study of comparing various OK lens designs had postulated that comparatively Fargo lenses had a lesser aggressive optic zone design for myopic reduction as compared to other popular OK lens brands and can thus be the possible explanation for the relatively lesser changes in K values observed in this study post-OK lens wear. This particular reduced compression effect design of Fargo lenses also led to an extended 2-hour lens wear trial in the present study with these lenses versus the one hour approach used in previous literature [8, 9] with other lens brands. The corneal cylinder did not alter significantly post lens wear in this study and is in agreement with previous literature.[8]

This study further reported a reduction in CCT of 6.77 ± 0.77 µm ($p < 0.0001$) post 2 hours lens wear. The results concur with a similar study performed by Jayakumar and Swarbrick [9] who had reported a significant central epithelial thinning post 1 hour of open eye OK lens wear among young adults. The changes in CCT are mainly due to tear film forces acting under the OK lens leading to the rapid thinning of the central corneal epithelium.[9, 13]

Refractive error: This study observed a significant reduction in SER of -0.71 ± 0.06D ($p < 0.0001$) with just 2 hours of open eye OK lens wear. Liam *et al.*[11] had recorded an almost 50% higher reduction in SER than the present study results post 1 night of lens wear, but it was expected as the study was conducted for an overnight period. Along with the SER change observed in this study a similar corneal FlatK change of 0.72 ± 0.07D was also recorded post 2 hours lens wear. This suggests that most of the change in SER occurring post OK lens wear is mostly due to central corneal flattening. The complete elimination of the central refraction was not the aim of this study and hence the residual central refraction has not been discussed. The control eye did not report any significant changes in SER post 2 hours in the present study and thus it can be concluded that the repeatability of the WAM-5500 auto-refractometer instrument is excellent for central refraction. This is in agreement with previous literature where WAM-5500 auto-refractometer gave good repeatable values for central SER.[12]

Visual acuity: Reduction in corneal K, CCT, and SER post lens wear also improved unaided logMAR VA significantly. Post 2 hours lens wear VA improved by 0.42 ± 0.03 log ($p < 0.0001$) as compared to baseline. Previous authors[8, 9] reported slightly better improvement in VA as compared to the present study results after 1-hour open eye lens wear using BE UltraVision OK lenses (Australia). Both the study authors reported a slightly higher corneal K flattening with the BE (UltraVision) OK lenses versus the Fargo lenses used in the present study and thus can be the reason for improved VA. The current study also observed a relationship between reduction in SER with improvement in unaided VA post 2 hours lens wear. Based on the assumption that every 1 line improvement in logMAR VA occurs with 0.25D of refraction change [14] the SER change of -0.71 ± 0.06D related well with VA change 0.42 ± 0.03 log post 2 hours lens wear. The slight discrepancies in their relationship can be postulated to the non-significant changes in with-the-rule astigmatism in the central cornea post-OK lens wear.[8]

Contrast sensitivity: The CS in this study also demonstrated good improvement for all spatial frequencies post lens wear. This can be attributed to the significant reduction in SER and improvement in VA observed post lens wear. This is in contrast to study results reported by Santolaria*etal.*[18]who had reported a degradation in CS for all spatial frequencies post 1 night of lens wear. This implies that CS gets degraded with a longer duration of lens wear. Although in the

present study variation in spatial frequency in the control eye of few subjects was observed post 2 hours, the comparison of mean results displayed non-significance.

Corneal wavefront aberrations: A significant improvement in VA and CS post lens wear was observed however, there was a substantial increase in corneal wavefront aberrations that degrade the visual quality. This study reported an increase in total corneal RMS-HOA and RMS higher-order astigmatism (Z3 + Z5) post lens wear, however, changes in the latter were found to be not significant. This is in contrast to the results observed by Lian*et al.*[11]where they had reported significant changes in RMS higher-order astigmatism post 1 night of OK lens wear.

The SA in this study displayed the highest change among all wavefront aberrations of 0.15 ± 0.02 µm ($p < 0.0001$) post lens wear and contributed most to the increased total HOA reported. The current study findings are in agreement with Lian*et al.*[11]findings where they had reported a similar higher change for SA post overnight lens wear. Zhang *et al.*[19] observed that SA comprises a major portion of total HOAs and plays an important role in the final retinal image quality. Poor image quality due to an increase in SA and total HOA values has been linked to myopia progression among children.[19] The present study reported 10 out of 30 eyes with above-average increased response to SA with the highest change reported being 0.36 µm post 2 hours lens wear. Hence, monitoring SA values becomes more important especially during prescribing OK lenses to young children for myopia control. This study also found a significant increase of 0.08 ± 0.02 µm ($p = 0.004$) of RMS coma post lens wear and is of particular importance as they are mostly observed due to a decentered lens.[15-17]Post 2 hours lens wear the highest reported coma value was 0.38 µm in this study, however, with fluorescein slit lamp examination the lens fit looked acceptable. Further observations revealed that although few subjects recorded excellent 0.0 log VA post lens wear they continued to display an increase in HOA. This suggests that apart from improvement in VA and SER, HOAs need to be monitored post lens wear. Subjects displaying an above-average increase in HOAs will then probably require an altered lens design or counseling before the final dispensing of the lens.

One minor drawback of the study was not recording changes in low contrast VA and comparing its changes with high contrast acuity post lens wear. A study by Berntsen *et al.*[15]observed a reduction in low contrast acuity post overnight OK lens wear due to an increase in SA. Further for better

understanding, studies can also be carried out on short-term OK lens effects with different brands of OK lenses and their effects on VA and quality of vision in predicting a successful fit.

CONCLUSION

This study observed significant improvement in visual acuity and contrast sensitivity with just 2 hours of open eye OK lens wear. Rapid central corneal flattening change was observed for both corneal meridians. However, there was a degradation in the quality of vision due to an increase in RMS-HOA, SA, and coma post lens wear.

Conflict of Interest Disclosure

The authors declare that they have no competing interests.

Funding Sources Disclosure

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