

## Changes in Refraction and Contrast Sensitivity Following Short Term Orthokeratology Treatment in High Myopic School Children: A Pilot Study

(Perubahan Refraksi dan Sensitiviti Kontras selepas Rawatan Ortokeratologi Jangka Pendek dalam Kalangan Kanak-kanak Sekolah Miop Tinggi: Suatu Kajian Awal)

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### ABSTRACT

*It is well established the efficacy of orthokeratology (OK) treatment in improving refraction and visual acuity (VA) of low myopic subjects. However, limited data is available on high myopes. The purpose of this study was to investigate the changes of refraction, VA and contrast sensitivity (CS) over time in high myopic school children after 1 week of overnight OK treatment. A total of 19 high myopic school children were fitted with OK lenses. Mean refraction at baseline was  $-6.29 \pm 1.25$  DS. Refraction was conducted using cross cylinder method and LogMAR chart. CS was evaluated using Pelli-Robson and FACT charts. All measurements were taken at baseline, 1, 2, 3 and 7 days after overnight OK. Data was analyzed using repeated measures of ANOVA. The results showed that refraction and CS were significantly improved throughout the study period ( $p < 0.05$ ). Significant changes in all parameters were noted after the first overnight treatment. Mean refraction and unaided VA after 7 nights of treatment was  $-0.64 \pm 1.17$  DS and  $0.08 \pm 0.29$ , respectively. The results from Pelli-Robson and FACT charts showed improvement comparable to aided baseline values ( $p > 0.05$ ). This study concludes that overnight OK reduces refraction but does not compromise VA and CS in high myopic children within the study period. Further studies are needed to determine the long term impact of OK treatment on visual functions in a larger sample of high myopic children.*

*Keywords: Contrast sensitivity; orthokeratology; refraction; visual acuity*

### ABSTRAK

*Keberkesanan rawatan ortokeratologi (OK) dalam menurunkan nilai refraksi dan meningkatkan akuiti visual (VA) dalam kalangan subjek miop telah diketahui umum. Walau bagaimanapun data tentang keberkesanan teknik ini dalam kalangan subjek miop tinggi agak terhad. Penyelidikan ini bertujuan untuk mengkaji perubahan nilai refraksi, VA dan sensitiviti kontras dalam kalangan kanak-kanak sekolah miop tinggi selepas 1 minggu rawatan OK. Seramai 19 orang kanak-kanak sekolah miop tinggi telah dipasangkan dengan kanta OK. Purata nilai refraksi sebelum rawatan adalah  $-6.29 \pm 1.25$  DS. Nilai refraksi diukur menggunakan teknik silinder silang dan carta LogMAR. Sensitiviti kontras (CS) diukur menggunakan carta Pelli-Robson dan FACT. Semua bacaan diambil sewaktu sebelum pemakaian kanta, 1, 2, 3 dan 7 hari selepas rawatan OK. Analisis data dilakukan menggunakan ANOVA. Keputusan kajian menunjukkan penurunan nilai refraksi dan peningkatan nilai CS yang signifikan di sepanjang waktu kajian ( $p < 0.05$ ). Perubahan signifikan pada semua parameter yang diukur dikesan selepas malam pertama rawatan. Purata refraksi dan VA tanpa pembetulan selepas 7 malam adalah  $-0.64 \pm 1.17$  DS dan  $0.08 \pm 0.29$ . Keputusan daripada carta Pelli-Robson dan FACT menunjukkan peningkatan setanding dengan nilai sewaktu pemakaian kaca mata ( $p > 0.05$ ). Kajian ini menyimpulkan bahawa rawatan jangka pendek OK menurunkan nilai refraksi tanpa menjejaskan nilai VA dan CS dalam kalangan subjek miop tinggi. Kajian jangka masa panjang diperlukan untuk memastikan kesan pemakaian kanta OK ke atas fungsi penglihatan kanak-kanak miop tinggi dengan saiz sampel yang lebih besar.*

*Kata kunci: Akuiti visual; ortokeratologi; refraksi; sensitiviti kontras*

### INTRODUCTION

Orthokeratology (OK), also known as corneal reshaping or corneal refractive therapy is a clinical technique that uses programmed application of reverse geometry rigid gas permeable (RGP) contact lenses to reshape the cornea to temporarily reduce refractive errors (Swarbrick 2006). The most common clinical application of OK is for the reduction of myopia through corneal flattening. Reverse geometry RGP contact lens is fitted with a base curve flatter than the

central corneal curvature producing corneal flattening and thus reducing myopia. This technique has been widely accepted as one of the alternative options to wearing glasses or contact lens especially for school children.

The efficacy of OK in reducing low myopia and hence improving refractive error and visual acuity (VA) has been shown by many researchers (Nichols et al. 2000; Soni et al. 2002), but there are limited evidences in the literature about visual function changes in high

myopic eyes undergoing overnight OK treatment. Contrast sensitivity is a fundamental feature of vision that can provide information about visual function that cannot be obtained by the standard VA measurement. Tahhan et al. (2003) demonstrated a persistent loss of low contrast best corrected acuity after one month of OK treatment using data averaged from four different lens designs. The authors attributed the loss to the limitation of the overall size of the treatment zone from the four lens designs. Berntsen et al. (2005) evaluated the high and low contrast best corrected acuity in low myopic patients undergoing OK treatment for 1 month and found no significant difference between pre and post treatment high contrast acuity. The authors also described a full line loss of low contrast best corrected acuity, which they attributed to OK treatment. The comparison however, was made through undilated pupil at pre-treatment and through dilated pupil post-treatment. When comparison of low contrast best corrected acuity was made through dilated pupil between pre and post treatment, less than one letter difference was detected.

Hiraoka et al. (2007) evaluated the relationships between changes in contrast sensitivity function (CSF) and high order aberration in subjects undergoing overnight OK treatment for 3 months and showed overall reduction in low frequency CSF. The authors attributed the reduction to increase high order aberrations induced by OK lens wear. In another study, Stillitano et al. (2008) monitored the changes in ocular wavefront aberrations and CS during a 12 month follow up of overnight OK treatment in 26 eyes. The results showed significant increment in high order aberrations but no statistically significant reduction in contrast sensitivity in both photopic or mesopic conditions.

The purpose of this study was to evaluate changes in refraction and CS after 1 week of overnight OK treatment in high myopic school children. It is important for practitioners to understand the visual changes that occur during the initial phase of the treatment so that proper management can be provided. Given the growing interest in OK treatment and number of high myopic school children in Malaysia (Chung et al. 1996; Goh et al. 2005), it is crucial for us to investigate and understand the impact of OK treatment on refraction and CS in school children in this country. The results may help to improve the present ophthalmic management of high myopic children in this region.

#### MATERIALS AND METHODS

This is a prospective cohort study design looking at pre and post orthokeratology treatment in high myopic school children. A total of 19 subjects were included in this study. Subjects were selected based on the following inclusion criteria; age between 7 and 17 years old, spherical equivalent refraction between -4.00 and -6.00 dioptres (D), refractive astigmatism up to -1.50D, best corrected visual acuity of 6/6 or better, no systemic disease and no experience with OK prior to enrolling to this study. The research protocol was approved by the institutional

ethical review board (UKM 1.5.3.5/244/NN-175-2009) and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from the parents or legal guardians of each subject before participation and possible consequences of the study had been fully explained. All subjects in this study were fitted with reverse geometry lenses (Optimum, Contamac Ltd, Essex, UK) following the guidelines provided by the manufacturer. The overnight OK lens was made of OPTIMUM Extra (Roflufocon D) material with oxygen permeability of  $100 \times 10^{-11}(\text{cm}^2/\text{s})$  ( $\text{mL O}_2/(\text{mL} \times \text{mm Hg})$ ).

All subjects were required to wear their lenses every night during the study period and remove them at least 2 h before coming to the clinic in the morning. Corneal topography was performed using corneal topographer (Tomey TMs4, Japan) and corneal integrity was examined using slit lamp biomicroscopy (Topcon SL-7F, Japan). Non cycloplegic refraction was performed using cross cylinder method and LogMAR chart. The CS values were measured using Pelli Robson chart at 1 m and FACT chart at 3 m under room illumination of  $240\text{cd}/\text{m}^2$ . Pelli Robson chart consists of letters of equal size arranged in 16 groups of three. The contrast of the first three letters is 100%. The contrast of each subsequent triplets are reduced by a factor of 0.707 (0.15 log unit). Thus, the contrast of the last triplet is around 0.56%. Subjects were asked to identify correctly the last letter seen and the results were recorded. FACT chart is a sine wave grating chart that consists of 5 different spatial frequencies (1.5, 3, 6, 12 and 18 cycles/degree) and nine levels of contrast. The subjects were asked to determine the last grating seen and the orientation of the grating. The results were plotted in a CS curve.

All measurements were taken 3 times on each eye and binocularly at baseline (with glasses) and 1, 2, 3 and 7 days after overnight OK treatment (without correction). However, the data presented in this report were from the right eye only. Measurements at follow up visits were compared to baseline results. Normality of data was tested using Shapiro-Wilk test ( $p > 0.05$ ) prior to statistical analysis. Repeated measure analysis of variance (ANOVA) was used to compare the changes between baseline and different wearing periods for parametric data whereas the Friedman test was used for the non-parametric data.

#### RESULTS

A total of 19 Chinese school children (10 males, 9 females) were involved in this study. Mean age of subjects was  $13.09 \pm 4.06$  years with age range from 7 to 17 years old. Mean refraction (in spherical equivalent) and VA at baseline was  $-6.14 \pm 1.68\text{DS}$  and  $-0.08 \pm 0.04$ , respectively (Table 1). The OK lens significantly improved the refraction ( $p < 0.001$ ) and VA ( $p < 0.05$ ) values throughout the study period. Mean refraction and unaided VA after 7 nights of treatment was  $-0.64 \pm 1.17\text{DS}$  and  $0.08 \pm 0.29$ , respectively.

The results from Pelli-Robson chart showed improvement of CS comparable to baseline values after 1 week of overnight OK treatment. Mean CS with Pelli-

TABLE 1. Demographic data of subjects

Parameters	Values (Mean±SD)
Mean age	13.09 ± 4.06
Gender	10 males, 9 females
Mean refraction (sphere)	-6.14 ± 1.68DS
Mean visual acuity (VA) in Log MAR	-0.08 ± 0.04

Robson chart at baseline was  $1.64 \pm 0.06$  and after seven nights of treatment was  $1.61 \pm 0.13$ . Statistical analysis indicate insignificant difference between the two measurements ( $p > 0.001$ ).

Mean CS from FACT charts at different spatial frequencies at baseline were as follow: 1.5 cyl/deg:  $1.79 \pm 0.15$ ; 3 cyl/deg:  $1.80 \pm 0.42$ ; 6 cyl/deg:  $1.93 \pm 0.19$ ; 12 cyl/deg:  $1.65 \pm 0.29$ ; 18 cyl/deg:  $1.22 \pm 0.39$ . Mean CS after 7 nights of treatment were as follow: 1.5 cyl/deg:  $1.76 \pm 0.21$ ; 3 cyl/deg:  $1.73 \pm 0.47$ ; 6 cyl/deg:  $1.68 \pm 0.51$ ; 12 cyl/deg:  $1.38 \pm 0.49$ ; 18cyl/deg:  $0.97 \pm 0.59$ . No significant difference was noted in all the measurements ( $p > 0.05$ ). The summary of results are shown in Table 2. Changes in all parameters measured are shown in Figures 1-4.

#### DISCUSSION

The goal of OK treatment is to provide patient with good quality unaided vision during day time through programmed application of specifically design rigid gas permeable contact lenses. As a result, cornea is flattened and temporary correction of myopia is achieved. To evaluate quality of vision accurately, CS measurement is needed as it can provide information about visual function that cannot be disclosed by standard visual acuity measurement. It is well known that subjects undergoing refractive surgery experience glare disabilities and night vision disturbances even though their VA is excellent (Stevens et al. 2002). This study evaluates changes of refraction and CS in high myopic school children undergoing OK treatment for 1 week.

The results of the present study showed that refraction, VA and CS improved significantly after 1 week of OK treatment. The results concurred with several earlier works that showed significant reduction in myopic refractive error and improvement of high contrast VA and CS after 1 week of OK treatment (Berntsein et al. 2005; Stillitano et al. 2008). However, to the best of our knowledge this is the first study that demonstrates changes of refraction, VA and CS in high myopic subjects. Immediate effects induced by OK lens were found after the first night of treatment where refraction was reduced to more than half of baseline values hence improving the VA and CS. Earlier studies have shown similar effects induced by one night OK lens treatment in low myopic subjects (Johnson et al. 2007; Sorbara et al. 2005). Sorbara et al. (2005) showed a decrease in refraction from  $-3.00 \pm 1.03$  DS at baseline to  $-1.70 \pm 0.53$  DS after the first night wear. Johnson et al. (2007) demonstrated a change of refraction from  $-2.10 \pm 0.89$  to  $-0.95 \pm 0.98$  DS after 1 night of OK treatment.

By the end of 1 week study, more than 90% of the subjects were within 0.50 D of ametropia. We believed that patient selection (low cylindrical values) and the material of OK lens (high Dk) used in this experiment contributed to the success of the treatment. High cylindrical values and low Dk of lens materials have been shown to contribute to visual degradation in OK lens wearers (Hiraoka et al 2004; Lum & Swarbrick 2011). Lum and Swarbrick (2011) compared the clinical effects of 2 OK lenses of different materials and the results showed greater change of refraction and VA in higher Dk material lenses. Hiraoka et al. (2004) recruited 39 subjects with high astigmatism to be fitted with OK lenses and found significant increase in astigmatism after 3 months of OK lens wear. The authors attributed the increment to the OK lens design and fitting.

The post treatment VA and CS at 1 week were comparable to baseline values measured with spectacle correction. These findings are in general agreement with Johnson et al. (2007) who showed no significant change in VA when compared to baseline results after 1 week of overnight OK treatment in low myopic subjects. Berntsen et al. (2005) also found similar results in best corrected high contrast acuity of low myopic patients undergoing OK treatment for 1 month.

The results of the present study support continued use of OK as a viable management of myopia in school children. However, longitudinal impact of OK treatment in high myopic children is not well understood. Further longitudinal studies with larger sample size were needed to confirm these findings. As majority of OK patients in Malaysia are young school children whose visual development is incomplete, proper ophthalmic management needs to be considered by practitioners when fitting these lenses. Quality and stability of vision needs to be measured carefully during follow up visits to ensure no deprivation in the visual development.

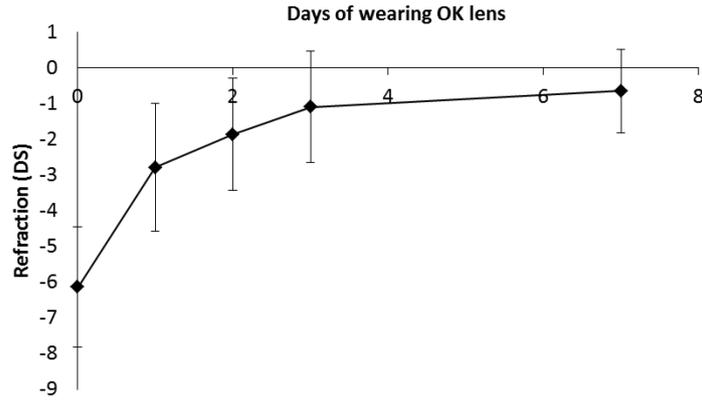
#### CONCLUSION

In conclusion, this study shows that short term OK treatment does not compromise VA and CS in high myopic school children. The findings also serve as a reminder to OK practitioners in Malaysia to be vigilant in their practices especially when dealing with children. Further studies are needed to evaluate the long term impact of OK on refraction and CS in larger sample of high myopic school children.

TABLE 2. Summary of measurements

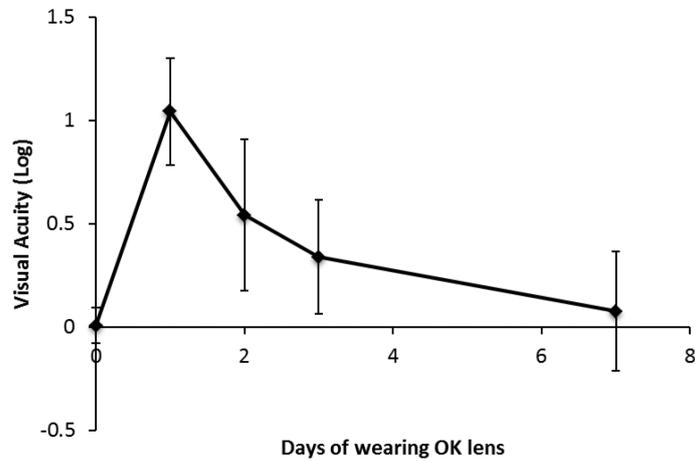
Measurement (Mean±SD)	Baseline (Aided) (n=19)	Day 1 (n=19)	Day 2 (n=19)	Day 3 (n=19)	Day 7 (n=19)	Statistical analysis significant value
Refraction (DS)	-6.14 ± 1.68	-2.79 ± 1.79	-1.86 ± 1.57	-1.09 ± 1.57	-0.64 ± 1.17	ANOVA $p < 0.001$
VA	0.008 ± 0.09	1.04 ± 0.21	0.54 ± 0.37	0.34 ± 0.28	0.08 ± 0.29	ANOVA $p < 0.05$
CS using Pelli Robson chart	1.64 ± 0.06	1.05 ± 0.27	1.38 ± 0.13	1.41 ± 0.18	1.61 ± 0.13	ANOVA $p > 0.001$
CS using FACT chart at 1.5cyc/deg	1.79 ± 0.15	1.37 ± 0.44	1.57 ± 0.28	1.59 ± 0.29	1.76 ± 0.22	Mann-Whitney $p > 0.05$
CS using FACT chart at 3 cyc/deg	1.80 ± 0.423	1.20 ± 0.58	1.43 ± 0.61	1.62 ± 0.49	1.73 ± 0.47	Mann-Whitney $p > 0.05$
CS using FACT chart at 6 cyc/deg	1.93 ± 0.19	1.02 ± 0.67	1.35 ± 0.59	1.52 ± 0.61	1.68 ± 0.51	Mann-Whitney $p > 0.05$
CS using FACT chart at 12 cyc/deg	1.65 ± 0.29	0.65 ± 0.53	0.94 ± 0.64	1.15 ± 0.68	1.38 ± 0.49	Mann-Whitney $p > 0.05$
CS using FACT chart at 18 cyc/deg	1.22 ± 0.39	0.32 ± 0.39	0.52 ± 0.57	0.93 ± 0.65	0.97 ± 0.59	Mann-Whitney $p > 0.05$

Result are presented as mean±SD



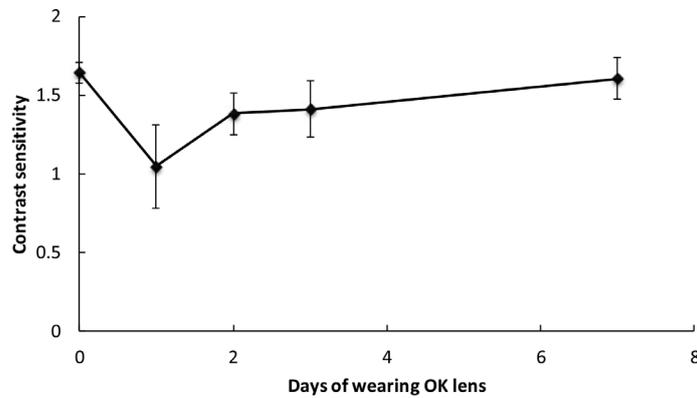
Results are presented in mean±SD

FIGURE 1. Changes in refraction (DS) during 1 week of overnight OK treatment



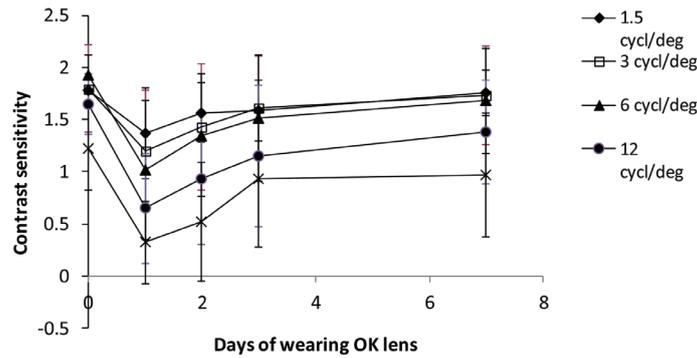
Results are presented in mean±SD

FIGURE 2. Changes in visual acuity (VA) during 1 week of overnight OK treatment



Results are presented in mean±SD

FIGURE 3. Changes in contrast sensitivity (Pelli-Robson chart) during 1 week of overnight OK treatment



Results are presented in mean $\pm$ SD

FIGURE 4. Changes in contrast sensitivity (FACT chart) during 1 week of overnight OK treatment

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