



Visual performance after overnight orthokeratology

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Abstract

Purpose: To investigate visual performance after overnight orthokeratology in terms of changes from baseline values, regression of the orthokeratology effect over time, and evaluation of the best-corrected vision after treatment. In particular, to evaluate any residual visual deficits over the duration of a day due to the abnormal corneal topography induced by orthokeratology treatment.

Method: One eye of each of six subjects was fitted with custom designed BE orthokeratology lenses (Capricornia, Brisbane, Australia), with the fellow eye acting as a control. Unaided vision, subjective spherocylindrical refraction, high contrast high luminance visual acuity, low contrast high luminance visual acuity, high contrast low luminance visual acuity and letter contrast sensitivity were measured at baseline and after one night (Day 1) and eight nights (Day 8) of lens wear. Except for baseline, data were collected after overnight lens wear immediately after lens removal, and again 3, 6 and 9 h after lens removal. At each time point throughout the day, the visual performance measures were evaluated with the initial refraction of the day (the 0 h refraction) and also using the optimum subjective refraction at each measurement time. This method was used to evaluate the practical visual performance to be expected after orthokeratology treatment and the residual visual deficits arising from any induced corneal changes after correction of defocus.

Results: As expected, orthokeratology lens wear significantly changed unaided vision and refraction from baseline. However, it did not significantly affect visual acuity in different contrast conditions, or contrast sensitivity. The spherical component of refraction was the only parameter to exhibit regression over each day ($p = 0.021$), with more stability demonstrated on Day 8 than Day 1 ($p = 0.012$). There were no statistically significant changes of best-corrected acuity from baseline in the differing contrast and luminance conditions.

Conclusion: Apart from the predicted improvements in unaided vision and reduction of the myopic refractive error, orthokeratology treatment was not found to significantly change any other aspects of visual acuity and contrast sensitivity. All visual performance measures exhibited stability over a 9-h period. Spherical refractive error changed significantly on Day 1 but became stable after a week of treatment. These results indicate that the corneal topography changes induced by orthokeratology do not induce changes in aberrations that are large enough to significantly diminish visual performance.

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Keywords: Orthokeratology; Visual acuity; Contrast sensitivity; Myopia

The reduction in myopic refractive error during orthokeratology lens wear occurs as a result of changes in the central corneal shape through wear of rigid lenses [1,2], which are designed to place differential pressure over the corneal surface. Modern orthokeratology treatment involves use of reverse geometry lenses (RGL), which when worn overnight, achieve the desired refractive outcome in as little as 7 days [3], and allow the successful patient to be free of spectacles or contact lenses during the day.

The shape of the cornea after orthokeratology is such that unaided visual performance in myopia is improved by the flattening of the apical cornea. The overall topographical change, however, is more complicated than central curvature changes only. The central corneal topography change results in a refractive change, although the contribution of that topography change to refractive change is uncertain. Studies indicate that apical corneal power changes can account for at least 70%, and up to 100%, of the observed refractive change [2,4]. The cornea is the most important refractive structure of the eye, accounting for around two-thirds of the power of the non-accommodating eye [5]. Any lens-induced corneal

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topography changes can lead to changes in corneal aberrations, resulting in decreased visual performance [6].

The efficacy of orthokeratology in reducing myopic refractive error and hence providing improved unaided vision has been shown numerous times [2–4,7–10] with significant improvements from 1 day to 1 week of wear, and little or no further improvement in vision levels from 1 week to 1 month duration of wear [3,7,9,10]. Statistically significant changes in refraction, unaided vision [2], unaided contrast sensitivity [3] and unaided low contrast visual acuity [7,10] occur after only one night of RGL wear. Mountford [11] noted that there was a tendency for refractive change to regress by 0.50–0.75 D over the course of a day, with this regression becoming less and greater stability being achieved over time after 7, 30, and 90 days of treatment. However, other studies have found that no significant regression in unaided vision levels is seen over an 8 h [7] or a 12 h [3] period. Berntsen et al. [12] found that both high and low contrast best-corrected acuity exhibited stability between measurements taken 6 h apart, through dilated pupils. Sorbara et al. [10], however, demonstrated that refractive regression occurred only in the 7–14 h period of post-wear after 10 days of wear, but these measures of vision were not taken in the best-corrected state. It is evident that there is scope for further investigation of the regression of best-corrected visual performance parameters over the course of the day, and the evaluation of any changes in this pattern of regression as the treatment period progresses.

Furthermore, few studies have been performed which evaluate vision levels under contrast conditions other than high contrast, high luminance visual acuity. Improvement in unaided contrast sensitivity [3] and unaided low contrast acuity [7,10] from baseline values has been demonstrated, but reduction of refractive defocus is the primary reason for these improvements. Berntsen et al. [12] evaluated high and low contrast best-corrected acuity and found little difference between pre- and post-treatment high contrast visual performance. While these authors described an almost full line loss (0.09 log MAR) in low contrast best corrected acuity attributable to orthokeratology treatment, this comparison was made between pre-treatment acuity through undilated pupils and post-treatment acuity through dilated pupils. For the same subjects, comparison of pre- and post-treatment low contrast acuity, both measured through dilated pupils, showed less than one letter difference (0.01 log MAR). Tahhan et al. [9] demonstrated a persistent loss of best-corrected low contrast acuity following orthokeratology over a month, using data averaged from four different lens designs. The question of the true qualitative visual outcome of orthokeratology remains largely unanswered. Whether the abnormal corneal shape induced by orthokeratology induces any more subtle deficits in visual performance, independent of myopic defocus, is not known.

This study, therefore, examines visual performance after one night of wear, as significant changes from baseline will be evident then, and again after seven nights wear, as the majority of orthokeratology change will be noted at this time

[3,7,9,10]. Visual performance will be quantified through the measurement of unaided vision and measurement of visual acuity in differing contrast situations with the starting refractive correction for each day. In this way, the effect of refractive regression on visual performance will be measured. Visual performance will also be measured independent of this refractive regression, through use of the best corrected spherocylindrical refraction to eliminate defocus, which also establishes any residual visual deficits over the course of a day due to corneal topography abnormalities (higher order aberrations).

1. Methods

1.1. Subjects

Six subjects were selected for participation in this study. Subjects met the selection criteria of less than 3.00 D of myopia (equivalent spherical refraction), less than 1.50 D of with-the-rule astigmatism, no against-the-rule or lenticular astigmatism exceeding 0.50 D, no previous rigid gas permeable (RGP) contact lens wear, and no pathology or contraindications to RGP contact lens wear [4,7,13]. The subjects were instructed to cease any soft contact lens wear at least 3 days prior to the beginning of the orthokeratology treatment period, permitting for a 'wash out' period where any corneal irregularity caused by the soft contact lenses could resolve [14].

This study was conducted in accordance with the requirements of the Queensland University of Technology Human Research Ethics Committee. Informed consent was obtained from all subjects before the experimental period commenced.

1.2. Contact lenses

The lenses used in this experiment were BE Orthokeratology custom designed lenses, provided by Capricornia (Brisbane, Australia). Each lens was manufactured in the Boston XO material, which has a nominal Dk of 145 allowing for safe overnight wear [8]. The BE lens design and mechanism of action has been described elsewhere [4,15].

An initial single-wear overnight trial was conducted for each subject before the experimental period began, with 1 week lapsing between this trial fitting and the beginning of data collection to allow any induced effects to regress completely. This was done in accordance with the fitting guide for the BE lens, using the lens design software provided by Capricornia [15]. A custom lens was ordered for each subject for the experimental period.

A satisfactory fit was achieved when the results of the overnight trial exhibited a well-centred treatment zone over the pupil zone. The final lens parameters for the experimental period were determined from the results achieved with the trial lenses [15].

1.3. Vision measurements

A high contrast Bailey–Lovie chart, a low contrast Bailey–Lovie chart ($10 \pm 2\%$ contrast) and a Pelli–Robson letter contrast sensitivity chart were used in data collection. A photometer was used in determination of appropriate luminance levels for the high and low luminance testing conditions, which were set at 260 and 20 lx, respectively, in accordance with the recommendations of Sheedy et al. [16].

1.4. Experimental protocol

Each subject was delivered their lens on the day of the first night's wear, and instructed in care and maintenance and insertion and removal. Baseline measurements were taken, and the subjects instructed to wear the lens each night for at least 8 h, removing the lens each morning, with the exception of the mornings of testing days. Testing days took place after the first night of wear (described here as 'Day 1' measurements) and after eight nights of wear ('Day 8').

The following visual performance measures were evaluated on both the treatment eye and the control eye at 0, 3, 6 and 9 h after lens removal:

- Unaided vision (high contrast chart in high luminance).
- Subjective refraction.
- High contrast visual acuity in high luminance conditions (HCHL).
- Low contrast visual acuity in high luminance conditions (LCHL).
- High contrast visual acuity in low luminance conditions (HCLL).
- Letter contrast sensitivity using the Pelli–Robson letter contrast sensitivity chart, under the high luminance conditions.

All vision and visual acuity measures were undertaken through a phoropter, using the Bailey–Lovie distance visual acuity chart and recorded in log MAR, where each correct letter was scored as 0.02, affording for a more accurate measure of acuity than the Snellen chart [17]. Letter contrast sensitivity was scored in accordance with the recommendations of Pelli et al. [18]. All tests were performed at a distance of 4.8 m.

At each time point, these visual performance measures were evaluated using the subjective sphero-cylindrical refraction obtained at time = 0 h, and then again using the current, best corrected refraction. This allowed for both quantification of the regression of the visual performance over the course of the day, and elimination of defocus such that any finer deficits in visual performance due to corneal shape irregularities (higher order aberrations) could be determined.

Learning effects and examiner bias were minimised by the use of three different chart configurations and three

examiners. All subjects were tested an equal number of times by each examiner, and each examiner encouraged the subject to read each letter chart until reaching their threshold. Measurements were performed first on the treatment eye, with the '0 h refraction' measures occurring before the 'best corrected' measures, and finally on the control eye. These procedures were adopted to minimise learning effects within each test period.

1.5. Analysis

All visual performance measurements were statistically analysed using two-way repeated measures analyses of variance; the factors were time (4 levels) and day (2 levels). A significance level of $p = 0.05$ was adopted and p -values of less than 0.10 were also noted.

Although six subjects participated in the experiment, one subject experienced marked lens decentration on the final night of wear, which resulted in highly abnormal topography and reduced visual acuity measurements throughout that day. This subject's data were excluded from subsequent analysis.

The measurements of the cylindrical component of the subjective refraction have been omitted from the analysis due to their lack of significance. Although three subjects had a prefit cylindrical component of -0.25 DC, this cylinder was only present in two cases on Day 1 and in only 1 case at one time point on Day 8.

2. Results

2.1. Changes in visual performance from baseline

Table 1 shows the baseline values and statistical significance of changes from baseline in spherical refraction and vision measures immediately after lens removal at Days 1 and 8 of lens wear. Unaided vision and spherical refractive error were significantly improved from baseline levels. Best-corrected low contrast high luminance visual acuity on Day 1 was worse than baseline levels and the difference approached statistical significance ($p = 0.09$). No other best-corrected visual acuity measurements changed significantly from their baseline values.

2.2. Changes in visual performance during each testing day

The mean and standard deviation for unaided vision and spherical refractive error measures performed through the morning 0 h refraction are shown in Figs. 1 and 2, respectively. Both unaided vision and spherical refractive error were notably more stable on day eight, as indicated by the smaller magnitude of regression, and smaller standard deviations seen in the Day 8 data.

Table 1

Baseline findings and statistical significance levels (*p*-values) for comparison between best corrected baseline data (pre-orthokeratology) and best corrected visual performance at the beginning of each testing day, after orthokeratology has commenced.

	Baseline value	Day 1	Baseline—Day 1	Day 8	Baseline—Day 8
		Day 1 value	(<i>p</i> -value)	Day 8 value	(<i>p</i> -value)
Unaided vision	0.75 ± 0.27 (log MAR)	0.24 ± 0.31 (log MAR)	0.006**	-0.09 ± 0.07 (log MAR)	0.004**
Sphere	-2.10 ± 0.89 DS	-0.95 ± 0.98 DS	0.002**	+0.25 ± 0.25 DS	0.002**
Cylinder	-0.15 ± 0.14 DC	-0.05 ± 0.11 DC	0.18	-0.05 ± 0.11 DC	0.18
High contrast high luminance acuity	-0.11 ± 0.02 (log MAR)	-0.08 ± 0.06 (log MAR)	0.31	-0.14 ± 0.04 (log MAR)	0.24
Low contrast high luminance acuity	0.09 ± 0.03 (log MAR)	0.17 ± 0.10 (log MAR)	0.09 [†]	0.15 ± 0.15 (log MAR)	0.47
High contrast low luminance acuity	0.03 ± 0.04 (log MAR)	0.05 ± 0.03 (log MAR)	0.39	0.03 ± 0.08 (log MAR)	1.00
Letter contrast sensitivity	1.75 ± 0.06	1.73 ± 0.08	0.18	1.72 ± 0.06	0.47

[†] Statistical significance < 0.10.

** Statistical significance < 0.05.

Statistically significant spherical refractive error changes were found over the time course of each day ($p = 0.01$) and between the 2 measurement days ($p = 0.02$), by two-way analysis of variance. Unaided vision regression over each day also approached statistical significance ($p = 0.06$).

Results of the visual performance testing including visual acuity under the differing contrast and luminance situations are depicted in Figs. 3 and 4. When the morning 0 h refraction was used to measure visual performance (Fig. 3), a regression in the acuity measures was apparent on each day, with the magnitude of regression being less on the eighth day than on the first day. This trend, however, was not statistically significant for any of the visual performance measures. The only visual performance measure that approached a significant regression over the course of each

day was high contrast low luminance visual acuity ($p = 0.07$).

The best corrected visual acuity measures (Fig. 4) showed no significant deterioration over the course of either Day 1 or Day 8. Only low contrast high luminance best corrected visual acuity approached a significant change over the course of a day ($p = 0.09$). The levels of statistical significance calculated for each visual performance measure are given in Table 2.

2.3. The control eye

Data were also collected at each time point for the fellow control eye of all subjects. There was no significant variation in these data over the time course of each day or between the 2 days.

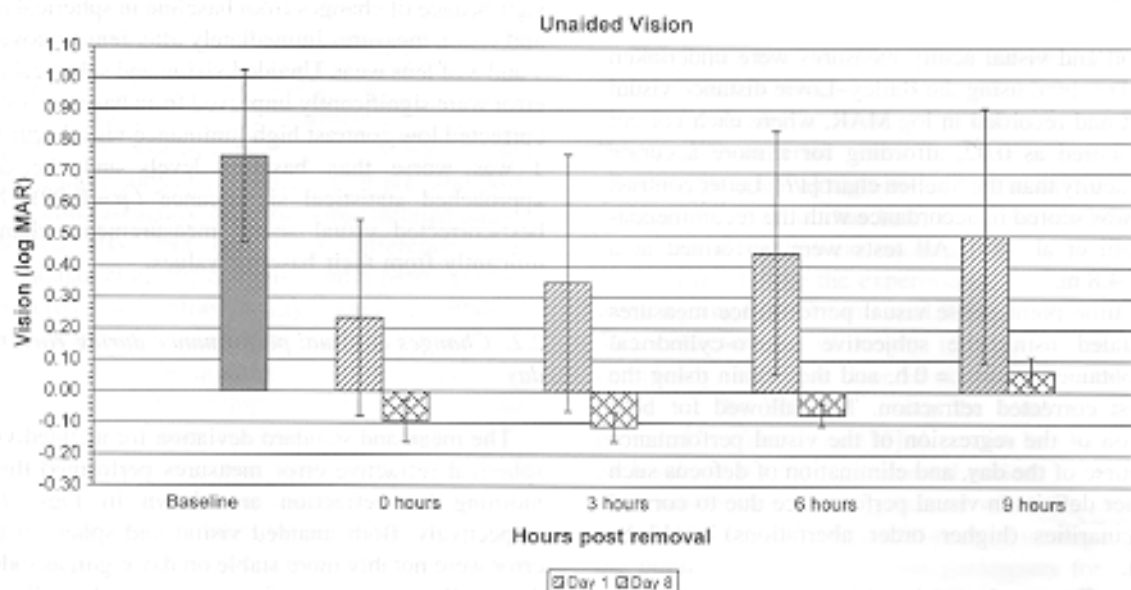


Fig. 1. Unaided vision measurements (high contrast high luminance) at baseline and during testing on Days 1 and 8.

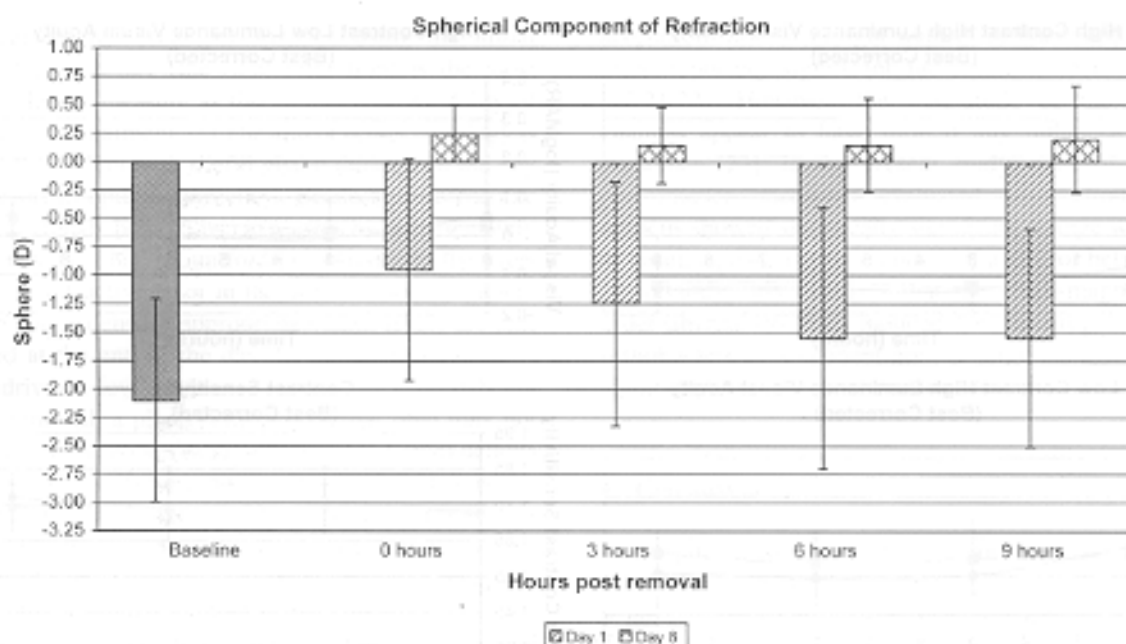


Fig. 2. Spherical refractive error measurements at baseline and during testing on Days 1 and 8.

3. Discussion

It is well established [2–4,7–11] that unaided vision and spherical refractive error will change significantly after orthokeratology treatment, and this is supported by the results of this study. It is however interesting to note that no

other vision measurements, as determined at the start of each testing day, were significantly different from their baseline (pre-orthokeratology) values. Comparison of the baseline values to any other experimental point throughout the day may have yielded significant results, but these would then include the confounding factor of refractive regression

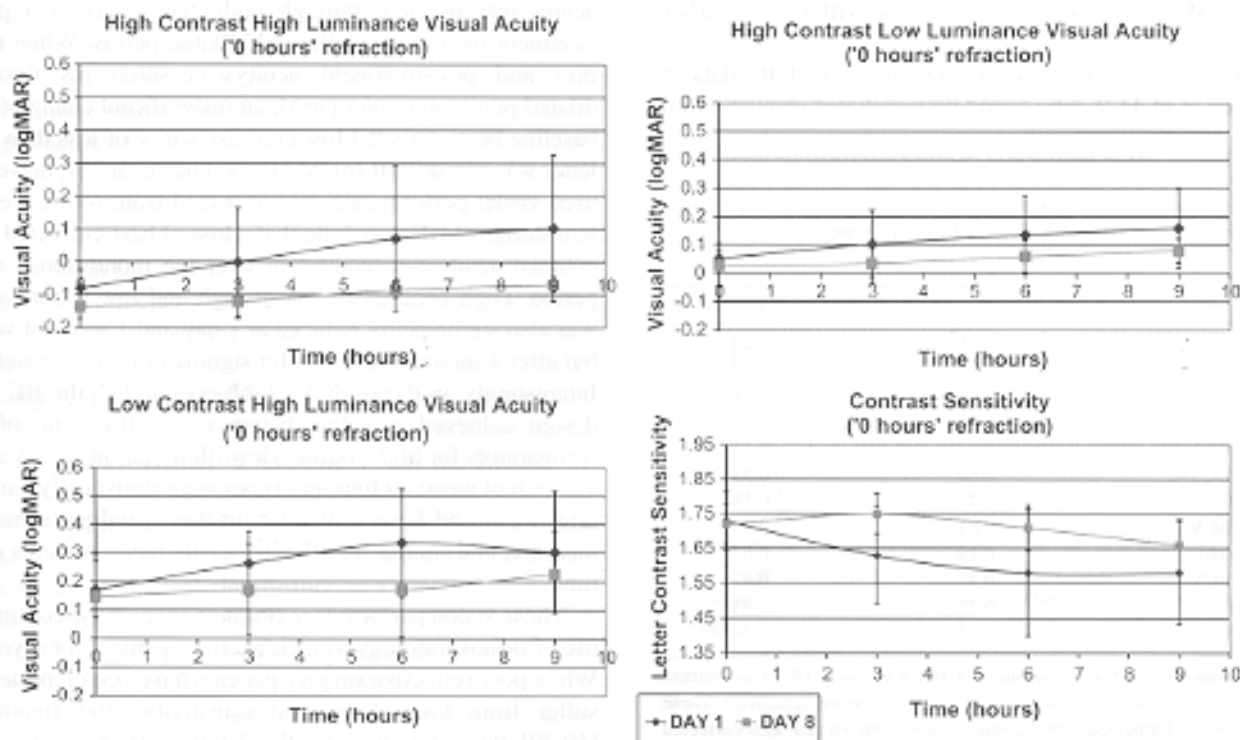


Fig. 3. Visual acuity measurements (log MAR) under different contrast and luminance conditions, and letter contrast sensitivity, as a function of time, all measured using the 0h refraction.

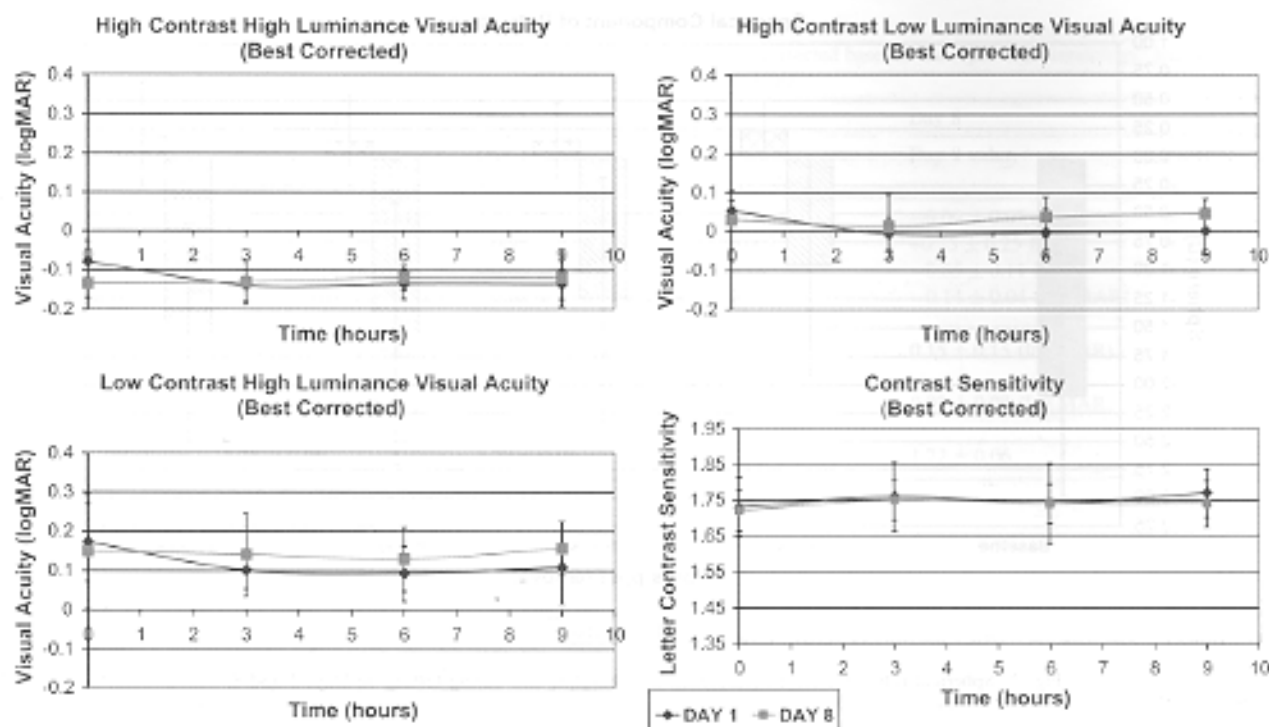


Fig. 4. Visual acuity measurements (log MAR) under different contrast and luminance conditions, and letter contrast sensitivity, as a function of time, all measured using the 'best corrected' subjective spherocylindrical refraction at each time point.

within the analysis. Likewise, previous findings of improvement in unaided contrast sensitivity [3] and unaided low contrast acuity [7,10] from baseline levels cannot be compared to the data found here, due to the presence of defocus during vision measurements within the earlier studies.

These findings are in general agreement with the data of Berntsen et al. [12], who found no significant changes from

baseline in best-corrected high contrast acuity. While those authors claimed that an almost full line loss (0.09 log MAR) in low contrast best corrected acuity occurred after orthokeratology treatment, they compared a pre-treatment acuity measurement through undilated pupils to a post-treatment measurement through dilated pupils. When both pre- and post-treatment acuity measurements through dilated pupils were compared, an insignificant change from baseline best corrected low contrast acuity of less than one letter was noted (0.01 log MAR). Tahhan et al. [9], however, used visual performance data averaged from four different lens designs to demonstrate that a loss of best-corrected low contrast acuity was consistent over the month-long study period. High contrast BCVA at high and low illumination was also significantly reduced at 1 day and 1 week of wear, but after 1 month, did not differ significantly from baseline. Interestingly, in the study by Tahhan et al. [9], the BE lens design achieved one line better vision than one of its comparators for high contrast, low illumination BCVA after 1 month of wear; all four lens types were statistically similar after 1 day and 1 week of wear for this visual performance measure, and similar for all other acuity measurements over time.

These vision performance findings support the continued use of orthokeratology as a viable management for myopia. While post-refractive surgery patients have been reported to suffer from loss of contrast sensitivity after treatment [19,20], this study indicates that letter contrast sensitivity is relatively unaffected by the corneal changes resulting from orthokeratology lens wear.

Table 2

Levels of significance for repeated measures analyses of variance for all visual performance data, with factors of day and time.

	p-Values	
	Day	Time of day
Vision	0.06*	0.20
Sphere	0.01**	0.02**
Cylinder	0.09*	0.38
Axis	0.32	0.54
HCHL (0 h)	0.12	0.31
HCHL (BCVA)	0.80	0.55
LCHL (0 h)	0.43	0.58
LCHL (BCVA)	0.61	0.09*
HCLL (0 h)	0.29	0.07*
HCLL (BCVA)	0.37	0.47
CS (0 h)	0.22	0.33
CS (BCVA)	0.73	0.30

HCHL, high contrast high luminance; LCHL, low contrast high luminance; HCLL, high contrast low luminance; CS, letter contrast sensitivity. These conditions are duplicated with measurement of both 0 h and 'best corrected (BCVA)' refractions in each case.

* Statistical significance <0.10.

** Statistical significance <0.05.

Measurement of visual performance using the initial refraction for each day (the '0h' refraction) is the most clinically relevant measure as this is the usual modality of orthokeratology treatment. [1] The aim of orthokeratology is to provide the patient with useful vision throughout the day without resort to optical correction. Because the refractive error has previously been shown to regress by approximately 0.30 D over a day [11], Mountford [11] advocates the over-correction of refractive error in the orthokeratology patient by this amount to ensure appropriate vision levels are still maintained at the end of the day. If, however, a patient is likely to drive in low luminance conditions several hours after lens removal, a plano refraction at that time may not adequately provide good visual performance if other deficits are present. The results here indicate that no such deficits are present, either as a change from baseline measures or as a factor of daily regression, although it should be noted that the design of this study involved detailed vision measurements on only a limited number of patients.

Few previous studies have evaluated changes in visual performance after 1 day and 1 week of orthokeratology wear. Two studies found no statistical regression of unaided vision, unaided low contrast vision [7] or unaided contrast sensitivity [3] over the time course of either testing day. Bertsen et al. [12] found no regression of high and low contrast best corrected acuity over a 6 h testing period after 1 month of wear. Sorbara et al. [10], however, showed that refractive regression of unaided high and low contrast acuity still occurred after 10 days, between 7 and 14 h post-lens removal.

The refractive and vision measurements in this study relate to the first 8 days of lens wear only. Previous studies have shown a tendency for refractive and vision outcomes to become more stable over time [11] with the limit of these changes achieved after approximately 1 week of treatment, and stability of these changes illustrated by the lack of statistical regression [3,7,9,12]. Visual performance through use of the initial daily refraction was demonstrated here to be more stable on Day 8 than on Day 1, owing to more constant levels of uncorrected vision and spherical refractive error. While the analysis of the data suggests that each visual performance measure regressed less on Day 8 than on Day 1, the only experimental measure which was statistically significant as a function of day was the spherical refractive error ($p = 0.01$). This is in agreement with the findings of Tahhan et al. [9], who found significant improvement in subjective spherical refraction and unaided vision from 1 day to 1 week of wear. The unaided vision data found here did approach statistical significance as a function of day of measurement (Day 1 versus Day 8) ($p = 0.06$).

Use of the best corrected acuity measurements at each time point was intended to ascertain any finer visual deficits which may be present due to any abnormal topography induced by orthokeratology treatment, while removing defocus from the manifest aberrations of the eye. A number of studies have now reported on corneal higher order

aberrations after overnight wear of orthokeratology lenses, often reporting significant increases in aberration levels [12,21,22]. However, the magnitude of the aberration changes appear to have little if any influence on visual outcomes [23]. In the present study, none of the visual performance measures evaluated with elimination of defocus showed statistically significant change with respect to baseline, over the time course of a day, or between days. Importantly, this confirms that the small-magnitude high order aberrations from induced corneal irregularities after orthokeratology treatment are not large enough to cause a significant loss of visual performance.

4. Conclusion

Despite significant changes in corneal topography induced by orthokeratology treatment, visual performance is not affected by this topography change to the extent that a visual deficit is evident. Orthokeratology lens wearers should suffer no loss of best-corrected levels of high and low contrast visual acuity and letter contrast sensitivity after orthokeratology treatment. The only statistically significant changes found here were a reduction in myopic refractive error and an improvement in unaided vision. The stability of the refractive error change appears to improve with time, when comparing the results at Days 1 and 8. The change in corneal topography produced by orthokeratology, therefore, does not appear to significantly influence the visual performance of the eye.

Conflict of interest

John Mountford is a clinical consultant to BE Enterprises, developer of the BE Orthokeratology lens, and has a financial interest in the BE Orthokeratology fitting system. There are no other conflicts of interest.

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