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Orthokeratology in road traffic – a pilot study

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Abstract

Purpose. The German regulation on granting persons permission to drive on the road specifies minimum visual requirements for obtaining a driving licence. The aim of this pilot study was to determine orthokeratology-related diurnal variations in visual acuity, contrast vision and twilight vision, as well as glare sensitivity, and to verify compliance with the requirements for obtaining a driving licence.

Material and Methods. Ten orthokeratology lens wearers (26.0 ± 7.1 years) with myopia of −2.43 ± 0.97 D and astigmatism of −0.31 ± 0.41 D were tested twice daily (08:30 a.m. and 20:30 p.m.) with the Binoptometer 4P (Oculus, Wetzlar, Germany). Monocular and binocular visual acuity were tested according to the ISO 8596 and compared with the visual acuity requirements for obtaining a driving licence. In addition, binocular contrast and twilight vision as well as glare sensitivity were tested in both exams. Differences between the morning and evening examinations were determined using the paired t-test or the Wilcoxon signed-rank test (for non-normally distributed data).

Results. There was no statistically significant difference between monocular visual acuity (logMAR) in the morning (right −0.07 ± 0.16; left −0.03 ± 0.15) and evening (right −0.09 ± 0.14; left −0.06 ± 0.17) (p = 0.875; p = 0.353) or binocular visual acuity in the morning (−0.11 ± 0.15) and evening (−0.13 ± 0.13) (p = 0.500). Decimal visual acuity ranged monocularly from 0.63 to 2.00 and binocularly from 0.70 to 2.00. This corresponds to the threshold value of an ophthalmological assessment for visual acuity of the better eye or for a binocular visual acuity of 0.5.
There was no statistically significant difference between the quality of contrast vision in the morning (mean Weber contrast 11.5 ± 3.4 %) and in the evening (15.5 ± 9.3 %) (p = 0.070), and twilight vision and glare sensitivity in the morning (both 0.27 ± 0.09 logCS) and in the evening (both 0.27 ± 0.09 logCS) (p = 1.000).

Conclusion. Visual acuity, contrast sensitivity, twilight vision and glare sensitivity to glare were stable throughout the day in this sample for orthokeratology lens wearers. The requirements of the eye test needed to drive were fulfilled by all but one of the participants in the standard eye test, both in the morning and evening examinations. A more comprehensive eye test was also carried out. This was passed by all test subjects, both in the morning and evening examinations.

Keywords
Orthokeratology, driving licence regulation, ISO 8596, ophthalmological assessment, mesopic vision, sensitivity to glare

Introduction

Orthokeratology (Ortho-k, for short) is a reversible procedure in which the wearing of specially developed rigid gas-permeable contact lenses (RGP lenses) temporarily reshapes the cornea.[1,2] The orthokeratology lenses are worn overnight and allow the user to see well during the day without additional aids such as glasses or contact lenses. Orthokeratology is mainly used for the correction of myopia and low astigmatism.[3] There is currently evidence that orthokeratology is a safe option for the correction of myopia if appropriate lens fitting and strict adherence to lens care and routine examinations takes place.[4-6]

The effect of orthokeratology in reducing myopia and thus improving vision without correction occurs after only one night wearing the lenses. A further significant improvement is then observed within a week and little to no further improvement is observed after a month.[7-10] If the contact lenses are no longer worn, there is a gradual regression of the correction effect. This happens to a lesser extent during the day after the contact lens is removed. In order to still enable good vision throughout the entire day, the manufacturers of contact lenses integrate a compression factor that takes the diurnal regression into account.[11] In various studies, refraction changes in the range of −0.32 to −0.37 D were observed 10 to 14 hours after the contact lenses were removed.[7,9,12] The longer the period of use of the Ortho-k lenses, the longer it seems to take for the cornea to completely return to its original shape.[13]

The German regulation on granting persons permission to drive on the road (Fahrerlaubnis-Verordnung - FeV) prescribes a central visual acuity under daylight conditions with or without visual aids of at least 0.7/0.7 in Landolt C vision test to obtain driving licences in the categories A, A1, A2, B, BE, AM, L and T. The test may only be carried out with vision screening instruments, in accordance with DIN 58220, part 6 (road traffic-related visual acuity test).[14,15] For the ophthalmological assessment, the visual acuity of the better eye or the binocular visual acuity must not fall below 0.5 (**Table 1**).[14,16] In addition, the ophthalmological assessment must take into account other visual functions such as visual field, twilight vision or contrast sensitivity, glare sensitivity, diplopia as well as other visual function disorders that may jeopardise safe driving.[14]

For orthokeratology lens wearers, it was also suggested that the eye test should be carried out in the morning and evening and extended to include a test of twilight vision and glare sensitivity.[17]

The aim of this sample study was therefore to determine diurnal variations in visual acuity, contrast sensitivity, twilight vision and glare sensitivity in existing orthokeratology lens wearers, as well as to check compliance with the requirements for fitness to drive.

Material and methods

Subjects

In a monocentric pilot study a total of 10 orthokeratology lens wearers were examined. The age of the 5 female and 5 male subjects was 26.0 ± 7.1 years. The refractive error was SE −2.68 ± 1.10 D with a cylinder power of −0.25 ± 0.33 D in the right eye and SE −2.49 ± 0.97 D with a cylinder power of −0.38 ± 0.33 D in the left eye.

Subjects were excluded from the study if they were pregnant or breastfeeding, had pathological changes in the cornea (such as keratoconus), had eye surgery including refractive surgery, eyelid or corneal surgery, eye injuries or were diabetic. All subjects who participated in the study received an information sheet explaining the study before agreeing to participate by signing it. All procedures received a positive ethical opinion and approval from the Aston University Ethics Committee and were conducted in accordance with the requirements of the Declaration of Helsinki.

Instruments and procedures

The subjects were fitted with DreamLite orthokeratology lenses (Procornea Nederland B.V., Eerbeek, The Netherlands) with a central correction zone of 5.5, 6.0 and 6.6 mm. The contact lenses were worn every night without complications for at least 4 weeks before the measurements. The care products used were those recommended by the manufacturer. Measurements of visual acuity, contrast sensitivity, twilight vision and glare sensitivity were performed in the morning (8:30 a.m.) and in the evening (8:30 p.m.) with the Binoptometer 4P (Oculus, Wetzlar, Germany) after a nightly wearing time of 7.8 ± 1.3 hours. The measurement time in the morning was on average 1.6 ± 1.0 hours after taking off the contact lenses. The average duration of the total measurements per subject was 19.7 ± 2.2 minutes. All measurements were performed by an optometrist on the premises of Avermann Contactlinsen (Dortmund, Germany) in a sequence that was preset by the

Table 1: Visual acuity requirements for driving license categories A, A1, A2, B, BE, AM, L and T according to FeV.[14,16]

	Officially recognised eye test centre	Ophthalmological assessment
Visual acuity requirements for categories A, A1, A2, B, BE, AM, L and T	The eye test is passed when the central visual acuity under daylight conditions with or without visual aids is at least: 0.7 / 0.7	The visual acuity values must not be below: Visual acuity of the better eye or binocular visual acuity: 0.5

Table 2: Monocular and binocular visual acuity (logMAR) at the different times of day.

	Morning	Evening	p-value
Right eye visual acuity logMAR	−0.07 ± 0.16	−0.09 ± 0.14	p = 0.875
Left eye visual acuity logMAR	−0.03 ± 0.15	−0.06 ± 0.17	p = 0.353
Binocular visual acuity logMAR	−0.11 ± 0.15	−0.13 ± 0.13	p = 0.500

software of the measuring device and remained the same. First, the central visual acuity under daylight conditions was tested monocularly and binocularly according to DIN 58220 using the Landolt C vision test. Subsequently, contrast sensitivity was tested using the same test in the size of optotype corresponding to a visual acuity of 0.4 in the Weber contrast values 40 %, 20 %, 15 % and 10 %. Patient were allowed a dark adaptation time of at least 10 minutes before the subsequent twilight vision measurement with and without glare. The test was performed on a Landolt ring corresponding to visual acuity 0.1, which was presented in four different contrast levels (1:23; 1:5; 1:2.7; 1:2).

Statistics

The data were tested for normal distribution using the Shapiro-Wilk test and then the appropriate statistical tests were applied. Differences between the two measurement times (morning and evening) were analysed with the paired t-test (for normally distributed data) or the Wilcoxon signed-rank test (for non-normally distributed data). The evaluation of the experimentally collected data was done with SigmaPlot 12 (Systat Software Inc., Chicago, USA).

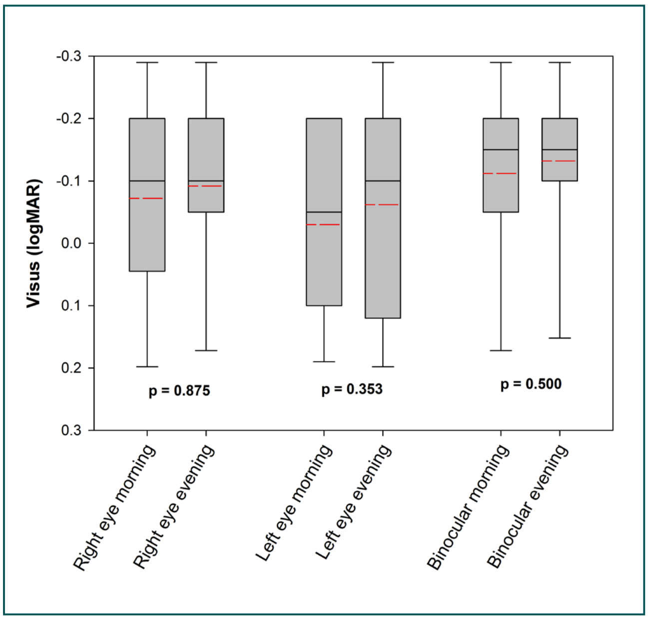

Figure 1: Box plot comparing the visual acuity values (logMAR) at the different times of the day. The black line represents the median and the red dashed line the mean.

Results

Visual acuity

The data for monocular and binocular visual acuity in the morning and evening are summarised in Table 2.

The difference in visual acuity between the two measurement time points was neither statistically significant for the right eye (−0.02 ± 0.15; paired t-test; p = 0.875), nor the left eye (−0.03 ± 0.10; paired t-test; p = 0.353) nor binocular (−0.02 ± 0.08; paired t-test; p = 0.500) (Figure 1).

If the individual visual acuity values of the different test subjects in the morning and in the evening are compared with the requirements of a central visual acuity under daylight conditions of at least 0.7, it can be seen that in the case of one test person, a visual acuity of 0.7 was not achieved in the morning for the right eye (visual acuity level 0.63), but was achieved in the evening. In the left eye, one subject failed to achieve a visual acuity of 0.7 both in the morning and in the evening (visual acuity 0.63). Binocularly, a visual acuity level of at least 0.7 was achieved by all subjects at both times of day (Figure 2).

Contrast sensitivity

There was no statistically significant difference between the quality of contrast sensitivity in the morning (mean Weber contrast 11.5 ± 3.4 %) and in the evening (mean Weber contrast 15.5 ± 9.3 %; Wilcoxon signed-rank test; p = 0.07) (Figure 3).

Comparing the quality of each subject's contrast sensitivity in the morning and evening, there is one outlier where the score deteriorated from 20 % in the morning to 40 % in the evening (Table 3). This was the same subject who had previously failed the visual acuity requirements in the morning and evening.

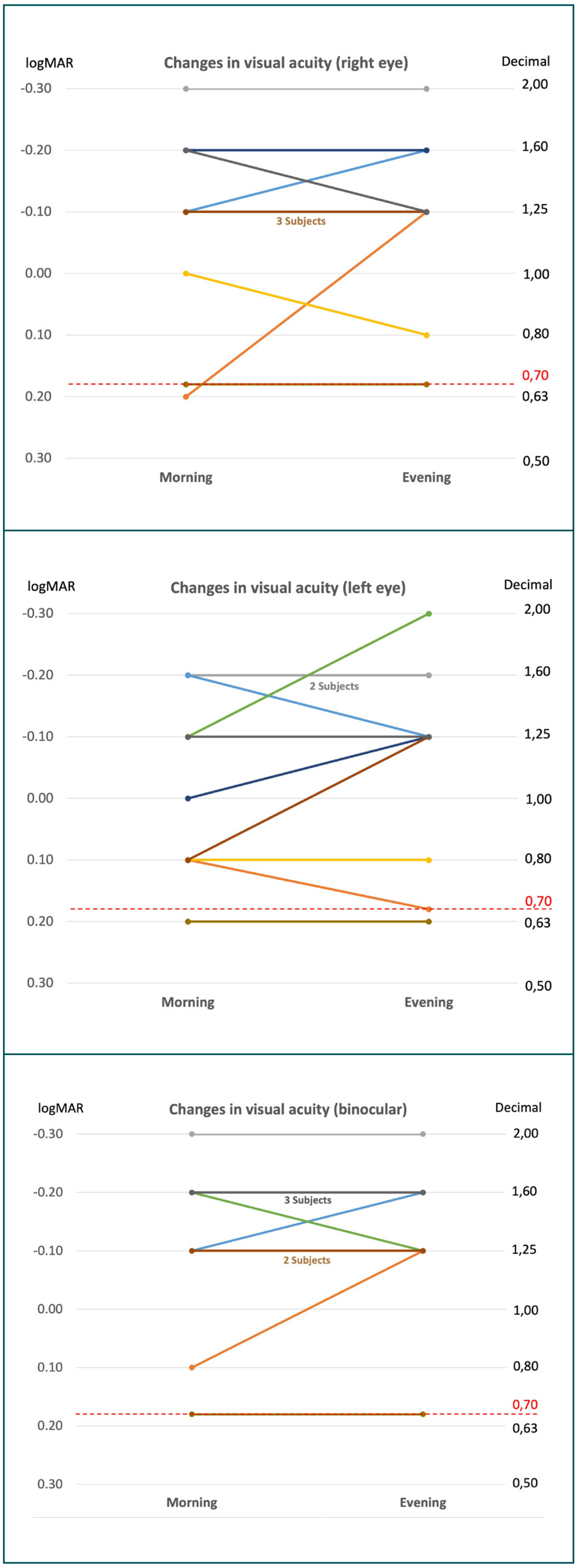

Figure 2: Before-and-after plots comparing individual changes in achieved visual acuity levels (logMAR) in the morning and evening.

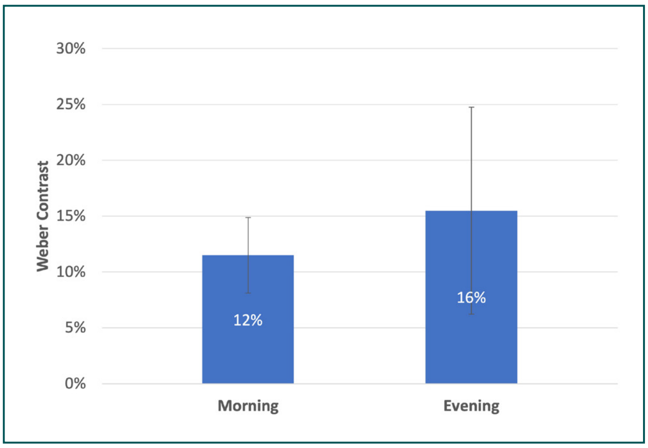

Figure 3: Bar chart comparing the detected Weber contrasts at the different times of day.

Table 3: Comparison of the contrast levels achieved in the morning and evening.

Subject	Morning	Evening
1	10%	10%
2	15%	20%
3	10%	10%
4	10%	15%
5	10%	10%
6	10%	15%
7	10%	10%
8	10%	10%
9	10%	15%
10	20%	40%

Twilight vision and glare sensitivity

The values for twilight vision and glare sensitivity to glare were converted into logarithmic units (logCS) for the statistical evaluation.[18] For both twilight vision and glare sensitivity, there was no statistically significant difference between the contrast levels achieved when measured in the morning (0.27 ± 0.09 logCS) and in the evening (0.27 ± 0.09 logCS; Wilcoxon signed-rank test; $p = 1.000$).

At the individual measurement results here, all test subjects except for one outlier achieved the contrast level 1:2. Here, too, the outlier was the test subject already mentioned with regards to the visual acuity test and contrast sensitivity test (Figure 4).

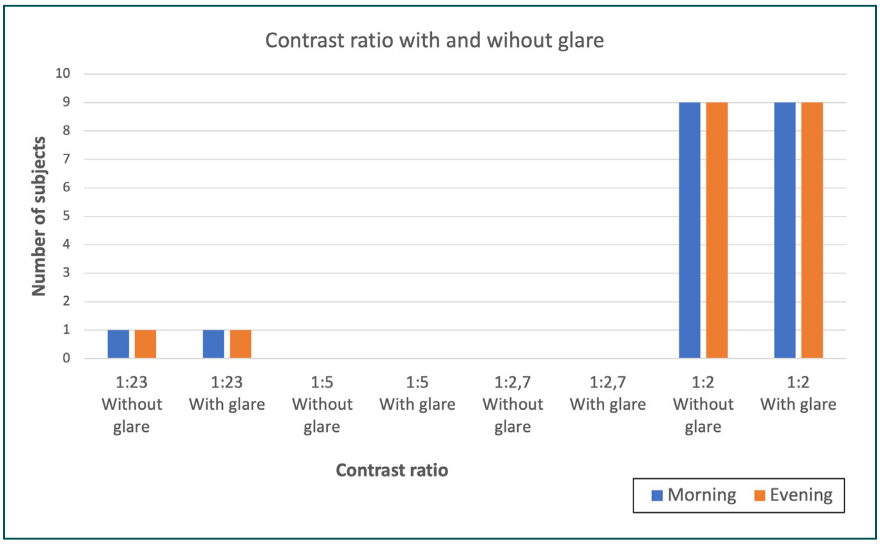

Figure 4: Bar chart comparing the contrast ratios achieved with and without glare in the morning and evening.

Discussion

The evaluation of the small sample in this pilot study shows that, with two exceptions, all test subjects passed the eye test with the requirement of a central visual acuity under daylight conditions of at least 0.7/0.7, both in the morning and in the evening. Comparing these two exceptions with the requirements of an ophthalmological driving fitness assessment for categories A, A1, A2, B, BE, AM, L and T (visual acuity of the better eye or binocular visual acuity: 0.5), these requirements would have been met by all participants.[16] Although the visual requirements for driving are not uniform across European countries, the requirements for central visual acuity under daylight conditions are met in most countries.[19]

Orthokeratology contact lens wear does not appear to result in a statistically significant difference in visual acuity between morning and evening measurements. Interestingly, there were subjects in the sample who showed an increase in visual acuity in the evening. There was also an increase in measured central visual acuity in the evening in the sample as a whole, but this was not statistically significant. In order to clarify whether the measured changes in the visual acuity of a test subject can be attributed to orthokeratology wear or whether these are individual fluctuations, visual acuity measurements would have to be made at the same times of day before fitting orthokeratology contact lenses. In previous studies, diurnal refractive changes between 0.07 and 0.37 D were found with orthokeratology wear.[7,20] In future studies, it would be helpful to determine the subjective or objective refractive change at the same time as the visual acuity measurements throughout the day.

The Weber contrast measured under photopic conditions in the evening did not differ statistically significantly from the contrast measured in the morning. In the driving licence vision test for the driving licence categories A, A1, A2, B, BE, AM, L and T, a test of contrast sensitivity is not stipulated (FeV, Annex 6, par. 1.1). If the driving licence vision test is not passed, the ophthalmologist must also check for twilight vision or contrast sensitivity and glare sensitivity (FeV, Annex 6, par. 1.2 and 1.3). There is currently no fixed threshold value for the test of photopic contrast sensitivity. According to Wilhelm et al.[21] the recognition of Landolt rings of visual acuity 0.4 with a Weber contrast of 15 % is suggested as a threshold value.

In contrast, there are specifications for the measurement of twilight vision and glare sensitivity from the German Society of Ophthalmology (Deutsche Ophthalmologische Gesellschaft, DOG) and the German Association of Ophthalmologists (Berufsverband der Augenärzte, BVA).[16] For categories A, A1, B, BE, M, L, S and T, a contrast level of at least 1:23 applies here, which must be achieved with and without glare during an ophthalmological driving fitness assessment. This contrast level was achieved by all study participants both in the morning and in the evening. Nine out of ten study participants even achieved a contrast ratio of 1:2, which means that the requirements for driving licence categories C, C1, CE, C1E, D, D1, DE, D1E and taxi drivers were also met.

In a multicentre study, Uthoff et al.[22] showed that 73.9 % of Ortho-k users were fit to drive at 7.55 ± 4.81 hours after having removed the contact lenses according to the driving licence regulation (visual acuity under daylight conditions of at least 0.7/0.7). If the recommendations of the DOG (visual acuity of the better eye or binocular visual acuity: 0.5) were applied, including twilight vision and glare sensitivity, 95.7 % of Ortho-k users were suitable for driving a motor vehicle in categories A, A1, B, BE, M, L, S and T at the time of measurement.[22] In a non-controlled test series, a stable visual acuity was shown between the measurement in the morning, one to two hours after removing the orthokeratology contact lenses, and a second measurement ten to eleven hours later.[23] Several studies were able to prove that the visual acuity under daylight conditions of Ortho-k users remains stable during the course of the day usually already after one week, and at the latest four weeks after fitting.[8-10,3,20,24,25]

This small sample has limitations: Due to the small number of subjects, the statistical power for some evaluations is below the target of at least 80 %. The interpretation of the result of this sample should therefore be taken with caution and the significance should not be overestimated. The number of cases is too low, which means that there is less chance of detecting a real and meaningful effect in the study population. In addition, the chosen study design does not allow for the control of confounding variables and does not allow for a comparison with the baseline situation before Ortho-k application. Accordingly, the amount of myopia to be corrected, the topography of the cornea and the parameters of the contact lens may have an influence on the topographic zones after orthokeratology.[26] Nevertheless, the findings are consistent with previously published results on visual acuity under daylight conditions, mesopic vision and sensitivity to glare at a time of day,[22] and provide valuable additional information on the diurnal course of these visual functions.

Conclusion

In this small sample, no statistically significant diurnal difference in visual acuity, contrast sensitivity, twilight vision and glare sensitivity was found in existing orthokeratology lens wearers. One of the participants did not meet the visual acuity requirements of the simple driving licence vision test in one eye at both measurement time points, although it is not known what visual acuity was previously achieved with glasses or contact lenses using the same measurement procedure. Further prospective controlled studies with a larger number of subjects as well as a diurnal comparison with spectacle wearers or wearers of non-orthokeratology contact lenses are required.

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