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Clinical performance of an orthokeratology lens fitted with the aid of a computer software in Chinese children

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ABSTRACT

Purpose: To report the clinical performance of the orthokeratology (ortho-k) lens fitted with computer assisted system after 1-month of lens wear, in a group of children undergoing ortho-k treatment in a 2-year randomized myopic control study.

Method: Children aged 6–11 years old were fitted with the ortho-k lenses using computerized fitting. The initial myopia was 4.00–0.50 D and the initial refractive astigmatism was within 1.25 D. Lens performance, in terms of centration, myopic reduction, vision, ocular health status and lens binding incidence, was evaluated at one night, one week and one month after lens wear. Only data from the right eye was presented.

Results: The initial spherical equivalent refraction (SER) for the 51 subjects was -2.29 ± 0.81 D. The first fit success rate was 90%. The reduction of SER after one night and one week aftercare visit were 57% and 81%, respectively. At the one month visit, the mean reduction in SER was 89% with unaided logMAR visual acuity of 0.03 ± 0.11. Mild central corneal staining was found in 9–20% of the subjects at the aftercare visits. The incidences of lens binding at one night, one week and one month aftercare visits were 17%, 39% and 30%, respectively.

Conclusions: Computer assisted system for Menicon Z Night lens fitting gave a high first fit success rate. Menicon Z Night lens was effective in myopic reduction and provided stable vision after one week of lens wear. Ocular health of the subjects after lens wear was generally unremarkable.

1. Introduction

Overnight orthokeratology (ortho-k) has been shown to have potential in slowing eyeball elongation in children with low to moderate myopia [1–3]. The use of ortho-k on children is increasing [4] in places with high prevalence of myopia such as Hong Kong [5]. The efficacy of overnight ortho-k on myopic reduction has been well studied and it has been proven to be effective in improving unaided visual acuity in both children and adults [6–11].

Like conventional rigid lens fitting, ortho-k fitting may require a diagnostic set provided by the manufacturer. Since the fitting of ortho-k requires information of the peripheral profile of the cornea, parameter other than the back optics zone radius and lens diameter, such as the sagittal depth, is also required for a successful ortho-k fitting. With the numerous possible combinations of lens parameters involved, many trial lenses are needed and this may pose a problem of storage. Chair time is also increased if a number of attempts are required to achieve the optimal fitting. As computerized fitting approach is becoming more popular, it is necessary to evaluate the clinical performance of ortho-k fitted using this fitting method.

Some contact lens manufacturers have put a lot of effort to simplify ortho-k lens fitting by importing corneal profile information into the computer software to reduce the dependency of the diagnostic lens kit. Tahhan et al. [12] compared the efficacy of four brands of reverse-geometry lenses and Maldonado-Codina et al. [13] compared the clinical performance of a brand of ortho-k lenses fitted empirically and with another brand which employed a trial set. Tahhan et al. [12] reported that all four brands of lenses performed similarly in myopic reduction while Maldonado-Codina et al. [13] concluded that lenses fitted by trial set system were more effective in myopic reduction. El Hage et al. [10] studied the efficacy of ortho-k lenses ordered empirically using corneal topographical data and concluded that myopic reduction could be achieved by one week of lens wear. In these studies, the attention was only on myopic reduction and ocular health after lens wear.

This paper presents the 1-month data of children who are undergoing ortho-k treatment in a 2-year randomized myopic control study (Retardation of Myopia in Orthokeratology (ROMIO) study). The aim of this paper was to report the clinical performance of

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Table 1
Entry criteria.

Inclusion	
Age	6–11 years
Refractive errors (cycloplegic autorefraction)	
Myopia	0.50–4.00 D
Astigmatism	Within 1.25 D
Anisometropia	Not more than 1.50 D in myopia or astigmatism
Best corrected visual acuity (LogMAR)	Not worse than 0.10
Exclusion	
Abnormal ocular and general health	
History of rigid contact lens wear	
History of myopic control therapy i.e. progressive add spectacles	

the ortho-k lens fitted with computer assisted system, in terms of centration, myopic reduction, vision, ocular health status and lens binding incidence.

2. Methods

Fifty-one subjects were randomly assigned to ortho-k group and fitted with ortho-k lenses in the ROMIO study. The entry criteria of the study are shown in Table 1. Data collected at each visit included non-cycloplegic subjective refraction, ocular health, and unaided visual acuity (UVA) (Computerized LCD LogMAR acuity chart). Topographic data (Medmont E300 topographer (Medmont Pty Ltd., Australia)), manifest refractive errors and horizontal visible iris diameter were imported into the computer installed with the Easyfit software (NKL Contactlenzen, Netherlands). Lens parameters for the optimum Menicon Z Night (NKL Contactlenzen, Netherlands) of Menicon Z material (Menicon Co. Ltd., Nagoya, Japan) was determined by the Easyfit software. The lens design of Menicon Z Night lens is described in Table 2.

Contact lens solutions were provided to the subjects to ensure that all subjects used the same solutions and were compliant with the replacement schedule. Subjects were instructed not to switch to other solutions unless advised by the practitioners. Proper procedures in lens handling were taught before the delivery of the lenses. At the delivery visit, fluorescein pattern of each lens on the eye was examined and the lens was not dispensed if the fluorescein pattern was deemed unacceptable. Lenses with excessive central clearance, inadequate edge lift or inadequate bearing at the alignment curve were regarded as unacceptable fit.

The subjects were required to wear the lenses every night for at least 6 h. They were examined in the mornings after the first night of lens wear (1-overnight visit), one week (1-week visit) and one month (1-month visit) after lens wear. The subjects were required to attend the 1-overnight visit without removing their lenses, within 2 h after awakening. At the subsequent visits, they were required to remove their lenses before attending. Refraction, corneal topography, visual acuity and external ocular health assessment were performed at each of these visits. At the 1-overnight aftercare, if corneal topography revealed a decentered treatment zone, the subject would be instructed to continue lens wear only if the fluorescein pattern of the decentered lens was acceptable and the corneal condition was unremarkable. Refit was indicated if both centration and the fluorescein pattern were not acceptable and or if the centration worsened at the 1-week visit. The lens performance was reviewed at the 1-month visit and refit was indicated only if lens decentration persisted or if the cornea under-responded (i.e. residual myopia was more than half a dioptre or UVA was worse than 0.20 (1-month visit)).

Table 2
Lens design of Menicon Z Night lens.

Fitting philosophy	Jessen factor (+0.50 D)
Fitting method	Computer assisted system – Easyfit software
Material	Menizon Z
Dk	163×10^{-11}
Design	Spherical lens
BOZR (mm)	7.20–9.50 (in 0.05 mm step)
Lens diameter (mm)	10.20/10.60/11.00
Tangential angle (°)	50–65 (in 1° step)
Sagittal depth (mm)	0.50–0.99 (in 0.01 mm step)
Fenestration	Three, located in the reverse curve, 120° apart

Table 3
Grading scale of lens binding.

Grade	Definition
0	No binding observed. Lens moving freely
1	Lens bound and loosens up spontaneously after ≤5 forced blinks
2	Lens bound and loosens up after one episode of pressure on the upper lid, then repeated on the lower lid and ≤5 forced blinks
3	As Grade 2, but two pressure pushes on the lids and ≤5 forced blinks
4	As Grade 2, but with three pressure pushes and ≤5 forced blinks

Subjects were required to cease lens wear in case of adverse general or ocular condition (e.g. fever or significant central corneal staining), the former monitored by parents, and the latter determined by the practitioner. Resumption of lens wear was indicated only after the adverse condition had subsided. Medical referral was indicated if the subject presented with significant or/persistent ocular problems (e.g. >Grade 3 corneal staining).

The level of severity of corneal staining was graded using the Efron scale [14]. Incidence of lens binding was graded by the subjects themselves, except at the 1-overnight visit which was evaluated by the practitioner (as the subjects were required to wear the lenses to this visit). The subjects were told to grade from Grade 0 to Grade 4 (Table 3). Incidences of corneal indentation ring and dimple veiling were determined by the practitioners at each visit. Data of the both eyes were measured but only results from the right eyes are reported in this paper.

2.1. Statistical analysis

The distributions of the SER at all visits were not statistically different from normal (Kolmogorov–Smirnov tests, $P > 0.05$). Repeated measures analysis of variance (ANOVA), followed by paired *t*-tests with Bonferroni corrections for multiple comparisons, where appropriate, were used to evaluate the effect of ortho-k on myopic reduction after wearing the lenses for one night, one week, and one month.

3. Results

3.1. Centration

Forty-six subjects (90%) had good lens centration at the 1-overnight visit, giving a first fit success rate of 90% (Fig. 1). Five subjects had laterally displaced treatment zone at the 1-overnight visit and refits were performed for these subjects at this or subsequent visits. However, their data were excluded from the following analyses.

3.2. SER reduction and vision

The SER and UVA of each visit are shown in Tables 4 and 5. The baseline mean ± standard deviation (SD) SER was −2.29 ± 0.81 D.