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Effectiveness and safety of overnight orthokeratology with Boston XO2 high-permeability lens material: A 24 week follow-up study

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ABSTRACT

Objective: To examine the effectiveness of overnight orthokeratology lenses made with Boston XO2, highly gas-permeable lens material for the temporary correction of myopia.
Methods: Myopic individuals from 9 to 62 years of age were eligible. Participants ≤12 years of age were required to have myopia ≤−4.00 D and astigmatism ≤1.50 D, and for those 13–62 years of age myopia ≤−5.00 D and astigmatism ≤3.00 D. All participants were required to have normal healthy eyes and not be receiving any ocular medications or systemic medications likely to affect the results of visual acuity. Participants wore the lenses for a minimum of 7 h during sleep, and were evaluated on day 1 and weeks 1, 2, 4, 12, and 24. Success was defined as LogMAR ≤ 0.1.
Results: A total of 126 participants (63.5% females) with a mean age of 20.4 ± 11.5 years were recruited. Baseline LogMAR, and vertical and horizontal corneal curvature were 0.8, 7.7 mm, and 7.9 mm, respectively, in both eyes. A consistent decrease in LogMAR was noted from day 1 to week 12. The success rate increased with length of time (from 33.9% to 100% for the right eye and from 35.5% to 100% for the left eye from day 1 to week 24). No severe complications were noted.
Conclusion: Overnight orthokeratology with lenses made of Boston XO2 material are effective and safe for the temporary reduction of myopia.

1. Introduction

Myopia is a common ocular disorder with a prevalence of up to 30% in Western populations [1], and a much higher prevalence (up to 70%) in Asian populations [2,3]. Myopia is associated with vision-threatening conditions including retinal detachment and chorioretinal degeneration [4]. Methods for slowing the progression and correction of myopia include corrective spectacles, contact lenses, atropine and other drugs, and keratorefractive surgeries [5].

Overnight orthokeratology is the use of specially designed gas-permeable rigid contact lenses that are worn during sleep to reshape the front surface of cornea for the purpose of temporary reduction of refractive errors [6,7]. Current overnight orthokeratology lenses use a reverse geometry design that provides more predictable, faster, and greater refractive changes than the lenses used when the technique was first developed in the 1960s [6–8]. Reduction in myopia is thought to be the result of central corneal flattening, thickening of the mid-peripheral cornea, thinning of the central corneal epithelium, and peripheral vision myopic shift [9–14].

Lenses are typically worn during sleep, and can provide acceptable vision during daytime, and reduce the need to wear spectacles or contact lenses. Studies have shown that orthokeratology lenses can temporarily reduce [15–18] and control the progression of myopia [17–19]. Though some studies have indicated that orthokeratology lenses can diminish contrast sensitivity and increase higher-order aberrations [20,21], their use is increasing [6].

Oxygen permeability (Dk/t) is an important attribute of contact lens materials, and a minimum Dk/t is necessary to prevent corneal hypoxia and subsequent damage [22,23]. Study has shown that lens DK/t has an influence on corneal topography and the clinical response to overnight orthokeratology [24,25]. To this end, much research has gone into developing lens materials with higher Dk/t. In a prior study we showed that Hiline overnight orthokeratology lenses using Boston Equalens II material (oprifocon A, Dk 85 as

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measured by ISO/Fatt, Bausch & Lomb, GP lens materials) can safely and effectively reduced myopia in Taiwanese adults and children [26]. Since the time of the prior study, Boston XO2 (hexafocon B) lens material (Polymer Technology Corp., Wilmington, MA, USA) has become available with a higher Dk (Dk 141 as measured by ISO/Fatt) than the Equalens II material [27].

Thus, the purpose of this study was to examine the effectiveness and safety of orthokeratology lenses made from the Boston XO2 material worn overnight for the temporary correction of myopia.

2. Materials and methods

2.1. Participants

This study was approved by the Institutional Review Board and all participants or their legal guardians provided written informed consent.

Myopic individuals from 9 to 62 years of age were eligible for inclusion in the study. Participants ≤12 years of age were required to have myopia ≤−4.00 D and astigmatism ≤1.50 D, and for those 13–62 years of age myopia ≤−5.00 D and astigmatism ≤3.00 D. Subjects were required to have normal, healthy eyes defined as no evidence of active infection involving the conjunctiva, lids, or adnexa (grade 2 or less tarsal conjunctival abnormalities were acceptable); no evidence of structural abnormalities of the lids, conjunctiva, or adnexal tissue; clear cornea with no edema, staining, or opacities as observed with slit-lamp examination; no iritis; no herpes keratitis or other disease that would contraindicate lens wear or decrease the attainability of visual acuity; no use of ocular medications.

Exclusion criteria were disease that may affect the eye or be exacerbated by wearing contact lens; allergy to ingredients in the study lens care solutions; pregnant, lactating, or not using a reliable contraceptive; serious systemic disease; participation in another trial within 4 weeks of entering this study; prior intraocular or corneal surgery; Schirmer's test (without anesthetic) results <5 mm/5 min; endothelial cell count <2000 cells/mm^2; use of systemic medications that may significantly affect vision or healing within 2 weeks before entering the study; prior use of rigid contact lenses or use of soft contact lenses within 4 weeks before entering the study.

2.2. Lens design and fitting

Participants received a 24-week trial of overnight orthokeratology reverse geometry rigid contact lenses. The contact lenses were designed and manufactured by the Hiline Optical Company (Taipei, Taiwan) with Boston XO2 (hexafocon B) lens material. The diameters of the lenses were 10.0 mm and 10.6 mm, and the contact lens base-curve radius (BCR) was determined using a proprietary algorithm that was similar to: BCR (in diopter) = apical radius in diopter + corneal eccentricity + 0.75 diopter of adjusted value. Participants were asked to wear the lenses every night for at least 7 h of closed eye wear, and to record insertion and removal times.

2.3. Evaluation and outcome measures

Participants received a comprehensive ophthalmological examination at the screening visit (visit 1), and then lenses were dispensed at a subsequent visit (visit 2). Participants were then seen on day 1 and weeks 1, 2, 4, 12, and 24 (visits 3–8, respectively) for evaluation. The day 1 visit was performed in the morning, and all other visits in the afternoon. At each visit uncorrected visual acuity (UCVA) was measured with a standardized tumbling E acuity chart placed 6 m from the patient. The total number of correct responses were recorded, and converted to LogMAR. Autorefraction and autokeratometry were performed at each visit using a Nikon Autorefractor/Autokeratometer (Tokyo, Japan). Corneal topography was measured at each visit using an Orbscan II instrument (Orbtek, Salt Lake City, UT). Corneal thickness values were averaged centrally over a circular area 3 mm in diameter by the instrument. The peripheral thickness values were located 5 mm from the center in the superior, inferior, nasal, and temporal quadrants. Slit-lamp biomicroscopy was performed at each visit, and the conjunctiva and cornea were evaluated for injection, edema, neovascularization, and peripheral staining with fluorescein.

The primary outcome was the success rate of vision correction, defined as LogMAR ≤ 0.1. Secondary success outcomes were clinically significant ocular health issues as determined with biomicroscopy.

2.4. Statistical analyses

Categorical variables were presented as number and percentage, while continuous variables were presented as mean and standard deviation. Data were analyzed for both eyes from each subject for follow-up visits 3–8. All statistical analyses were performed with IBM SPSS statistical software version 22 for Windows (IBM Corp., New York, USA).

3. Results

3.1. Study participants

A total of 126 participants (63.5% females) with a mean age of 20.4 ± 11.5 years were recruited at the screening visit. Regardless of right or left eye, LogMAR and vertical and horizontal corneal curvature were 0.8, 7.7 mm, and 7.9 mm, respectively. The mean sphere of the right and left eye were −3.3 D and −3.0 D, respectively, and the mean cylinder for the right and left eye were −0.5 and −0.7, respectively (Table 1).

Eleven subjects were lost to follow-up during visits 3–8. Two participants provided data for only one eye (one left and one right

Table 1
Participant characteristics (N = 126).

Age	20.4 ± 11.5
Sex	
Male	46 (36.5)
Female	80 (63.5)
LogMAR	
Right eye	0.8 ± 0.3
Left eye	0.8 ± 0.3
Vertical corneal curvature (mm)	
Right eye	7.7 ± 0.3
Left eye	7.7 ± 0.3
Horizontal corneal curvature (mm)	
Right eye	7.9 ± 0.3
Left eye	7.9 ± 0.3
Sphere	
Right eye	−3.3 ± 1.3
Left eye	−3.0 ± 1.2
Cylinder	
Right eye	−0.5 ± 0.6
Left eye	−0.7 ± 0.7

Data presented as mean ± standard deviation, except for sex which is presented as number (percentage).