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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).

eye), and one subject had missing UCVA values for visit 4. As a result, the number of participants included at visits 3–8 were 125, 122, 121, 119, 117, and 115, respectively, and the number of eyes studied were 248, 242, 240, 236, 232, and 228, respectively.

3.2. Vision correction success rate

The vision correction success rate (LogMAR ≤ 0.1) at each of the follow-up visits is shown in Table 2. The success rate increased with length of time after beginning treatment (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). Specifically, the success rates were lower than 80% before week 4, and reached 100% at week 24 for both eyes.

3.3. Time trends of LogMAR, corneal curvature, sphere, and cylinder

The mean LogMAR at baseline (right eye, 0.77 ± 0.28; left eye, 0.76 ± 0.27) was higher than at any of the follow-up visits. A significant decrease in LogMAR was noted from day 1 to week 24 (p-value for time trend <0.001 for both eyes); there was a sharp decrease from day 1 to week 4, after which LogMAR remained stable. A slight flattening in both vertical and horizontal corneal curvature were noted from the screening visit to week 4; however, no changes were noted after week 4. Horizontal corneal curvature, but not vertical curvature, flattening from day 1 to week 24 (horizontal curvature: $p < 0.001$ for right eye and $p = 0.001$ for left eye; vertical curvature: $p = 0.148$ for right eye and $p = 0.162$ for left eye). Significant improvement of sphere were found in both eyes (p-value for time trend <0.001 for both eyes), and sphere reached a plateau at week 4 (Table 3).

3.4. Safety evaluation

Grading of injection, edema, neovascularization, and peripheral staining with fluorescein was based on the Cornea and Contact Lens Research Unit (CCLRU) grading scale. At the screening visit, there were three participants (2.4%) with signs of very slight conjunctival injection without texture by palpebral conjunctival observation. No other problems were noted in any participant at baseline. On day 1, one participant (0.8%) was found to have slight conjunctival injection without texture on both eyes by palpebral conjunctival observation. Another participant had conjunctival hyperemia of the left eye at week 4. Corneal staining was noted in 24 right eyes (very slight, 22 eyes; slight, 2 eyes) and 32 left eyes (very slight, 27 eyes; slight, 5 eyes) during follow-up visits. The rate of very slight corneal staining of right eye was >3% after week 4, and the rate of the left eye ranged from 2.5% to 6.1% during the follow-up (Table 4).

Table 2
Treatment success rates.

	Right eye	Left eye
Day 1		
n	124	124
Success	42 (33.9%)	44 (35.5%)
Week 1		
n	120[a]	120[a]
Success	78 (65.0%)	78 (65.0%)
Week 2		
n	120	120
Success	87 (72.5%)	88 (73.3%)
Week 4[a]		
n	118	118
Success	102 (86.4%)	98 (83.1%)
Week 12		
n	116	116
Success	115 (99.1%)	115 (99.1%)
Week 24		
n	114	114
Success	114 (100%)	114 (100%)

Success defined as LogMAR ≤ 0.1.
[a] There was one missing UCVA value at week 4.

4. Discussion

The results of this study showed that overnight orthokeratology with lenses made of Boston XO2 material resulted in a success rate of 100% for the reduction of myopia (defined as LogMAR ≤ 0.1) at 24 weeks of treatment with minimal complications or corneal staining.

Interest and use of overnight orthokeratology has increased markedly over the past decade as a result of advances in the measurement of corneal topography, development and manufacturing techniques of reverse geometry lens designs, and lens materials with higher Dk/t which provide a greater safety profile for overnight wear [23]. Overnight orthokeratology is generally considered safe [6], though recently concerns have been raised about the occurrence of microbial keratitis [28]. The technique has been shown to slow axial elongation and myopia, though in most studies the follow-up duration has been 2 years or less [9,14,29]. In a study with a follow-up length of 5 years, Hiraoka et al. [17] compared the results of overnight orthokeratology with spectacles in 43 subjects who completed all follow-up visits (22 orthokeratology, 21 spectacles). The increase in axial length during the 5-year study period was 0.99 ± 0.47 and 1.41 ± 0.68 mm in the orthokeratology and spectacle groups, respectively ($p = 0.0236$). Annual increases in axial length were significantly different between the groups in the first, second, and third years, but not in the fourth and fifth years. Additionally, there were no severe complications associated with the orthokeratology lenses.

The Dk/t is an important attribute of contact lens materials, and early study showed that a minimum Dk/t of 87 is required to limit corneal edema to levels that occur naturally during sleep (4%) [30]. Subsequent physiological data have indicated that a minimum DK/t of 125 is required to prevent corneal edema with the eyes closed [31,32]. Furthermore, lens DK/t has been shown to affect the clinical response to overnight orthokeratology. Lum and Swarbrick [24] compared the outcomes of Boston EO and XO lenses having a nominal Dk/t of 58 and 100 ISO Fatt, respectively, and reported that after 2 weeks of overnight lens wear changes from baseline with the EO lenses were significantly less than with the XO for visual acuity (-0.72 ± 0.37 vs. -0.83 ± 0.41; $p = 0.012$), refraction ($+2.19 \pm 0.73$ D vs. $+2.74 \pm 0.70$ D; $p = 0.004$), r_o (0.34 ± 0.08 mm vs. 0.46 ± 0.11 mm; $p = 0.001$), and Q (0.26 ± 0.08 vs. 0.36 ± 0.08; $p = 0.001$). After the first night, change in central stromal thickness was greater with the EO compared with XO lenses (27 ± 36 μm vs. 10 ± 31 μm; $p = 0.05$), but overnight edema was reduced after 2 weeks for both lens materials (8 ± 25 μm vs. -1 ± 33 μm; $p > 0.05$). Other study has shown that lenses made with the Boston XO material effectively and safely reduce myopia [33].

Our prior study [26] used Hiline overnight orthokeratology lens made of Boston Equalens II (oprifocon A) material, with a Dk of 85 (ISO/Fatt). Sixty four participants (128 eyes) completed the study, and at week 40 (final evaluation) all subjects had ≥20/40 Snellen UCVA, with the most significant change in VA occurring between day 1 and 7 of treatment. This current study used the same Hiline overnight orthokeratology lens design, but were made of the Boston XO2 (hexafocon B) material which has a Dk of 141 (ISO/Fatt). Similar results were seen in the current study, with all subjects meeting the predefined criteria of success (LogMAR ≤ 0.1)

Table 3
LogMAR, corneal curvature, sphere, and cylinder at screening and during follow-up.

	Right eye	Left eye
Screening		
LogMAR	0.77 ± 0.28 (0.15, 1.00)	0.76 ± 0.27 (0.05, 1.00)
Vertical corneal curvature	7.65 ± 0.26 (7.01, 8.22)	7.65 ± 0.26 (7.03, 8.28)
Horizontal corneal curvature	7.87 ± 0.26 (7.11, 8.48)	7.88 ± 0.26 (7.12, 8.47)
Sphere	−3.30 ± 1.30 (−6.75, 1.00)	−3.04 ± 1.22 (−6.25, −0.50)
Cylinder	−0.49 ± 0.61 (−2.50, 0)	−0.67 ± 0.71 (−3.50, 0)
Day 1		
LogMAR	0.35 ± 0.33 (−0.08, 1.00)	0.33 ± 0.33 (-0.08, 1.00)
Vertical corneal curvature	7.78 ± 0.25 (7.13, 8.35)	7.76 ± 0.26 (7.17, 8.41)
Horizontal corneal curvature	8.04 ± 0.26 (7.26, 8.68)	8.05 ± 0.26 (7.31, 8.73)
Sphere	−2.32 ± 1.25 (−5.50, 0.25)	−2.27 ± 1.26 (−6.50, 0)
Cylinder	−1.11 ± 0.90 (−4.25, 0)	−1.35 ± 1.10 (−5.00, 0)
Week 1		
LogMAR	0.16 ± 0.25 (−0.08, 1.00)	0.15 ± 0.24 (−0.08, 1.00)
Vertical corneal curvature	7.88 ± 0.26 (7.20, 8.45)	7.85 ± 0.27 (7.03, 8.44)
Horizontal corneal curvature	8.12 ± 0.26 (7.46, 8.77)	8.12 ± 0.27 (7.45, 8.77)
Sphere	−1.78 ± 1.27 (−5.75, 0.50)	−1.79 ± 1.34 (−5.75, 0.50)
Cylinder	−1.11 ± 0.90 (−4.25, 0)	−1.34 ± 1.22 (−7.00, 0)
Week 2		
LogMAR	0.11 ± 0.21 (−0.18, 1.00)	0.11 ± 0.21 (−0.08, 1.00)
Vertical corneal curvature	7.90 ± 0.26 (7.30, 8.46)	7.88 ± 0.28 (7.27, 8.53)
Horizontal corneal curvature	8.15 ± 0.28 (7.46, 8.89)	8.15 ± 0.31 (7.48, 9.10)
Sphere	−1.71 ± 1.23 (−5.50, 0.50)	−1.61 ± 1.35(−4.75, 1.00)
Cylinder	−1.17 ± 1.11 (−8.00, 0)	−1.36 ± 1.21 (−8.25, 0.50)
Week 4		
LogMAR	0.06 ± 0.19 (−0.18, 1.00)	0.07 ± 0.16 (−0.08, 1.00)
Vertical corneal curvature	7.93 ± 0.27 (7.18, 8.64)	7.89 ± 0.28 (7.13, 8.48)
Horizontal corneal curvature	8.18 ± 0.28 (7.50, 8.97)	8.17 ± 0.28 (7.47, 8.96)
Sphere	−1.46 ± 1.16 (−5.25, 0.50)	−1.50 ± 1.19 (−4.75, 0.75)
Cylinder	−1.18 ± 1.09 (−7.25, 0.75)	−1.40 ± 1.21 (−8.50, 0.50)
Week 12		
LogMAR	−0.01 ± 0.06 (−0.08, 0.15)	−0.00 ± 0.07 (−0.18, 0.15)
Vertical corneal curvature	7.93 ± 0.29 (7.06, 8.50)	7.90 ± 0.29 (7.00, 8.46)
Horizontal corneal curvature	8.18 ± 0.27 (7.45, 8.86)	8.18 ± 0.29 (7.51, 8.86)
Sphere	−1.50 ± 1.26 (−6.50, 0.50)	−1.54 ± 1.31 (−6.25, 0.50)
Cylinder	−1.40 ± 1.47 (−9.75, 0)	−1.45 ± 1.15 (−4.75, 0)
Week 24		
LogMAR	−0.01 ± 0.07 (−0.18, 0.10)	0.00 ± 0.06 (−0.18, 0.10)
Vertical corneal curvature	7.90 ± 0.29 (7.16, 8.68)	7.88 ± 0.28 (7.04, 8.45)
Horizontal corneal curvature	8.17 ± 0.31 (7.21, 9.04)	8.15 ± 0.30 (7.36, 8.93)
Sphere	−1.48 ± 1.36 (−9.00, 0.50)	−1.54 ± 1.07 (−5.00, 0.75)
Cylinder	−1.36 ± 0.98 (−4.00, 0)	−1.40 ± 1.17 (−6.50, 0)
Test for time trend from Day 1 to Week 24[a]		
LogMAR	<0.001	<0.001
Vertical corneal curvature	0.148	0.162
Horizontal corneal curvature	<0.001	0.001
Sphere	<0.001	<0.001
Cylinder	0.011	0.494

Data are presented as mean ± standard deviation; the range of data was shown in the parenthesis.
[a] *p*-values for time trend are shown.

Table 4
Distribution of corneal staining during follow-up.

Visit	Right eye		Left eye	
	Very slight	Slight	Very slight	Slight
Day 1	2 (1.8%)	0 (0%)	4 (3.2%)	3 (2.4%)
Week 1	2 (1.7%)	0 (0%)	5 (4.2%)	1 (0.8%)
Week 2	3 (2.5%)	1 (0.8%)	4 (3.3%)	0 (0%)
Week 4	6 (5.1%)	1 (0.8%)	3 (2.5%)	1 (0.8%)
Week 12	4 (3.4%)	0 (0%)	4 (3.4%)	0 (0%)
Week 24	5 (4.4%)	0 (0%)	7 (6.1%)	0 (0%)

by 28 weeks. However, lenses made with XO2 material were associated with a marked reduction in corneal staining as compared with the Equalens II material (14.0% vs. 19.2%, respectively) at week 24. In addition, no cases of bulbar or palpebral conjunctiva inflammation were associated with the XO2 lenses, as compared with 6.8% (bulbar) and 12.4% (palpebral) with the Equalens II material.

The primary limitation of this study is the lack of long-term follow-up. Though the results clearly show that overnight orthokeratology with Boston XO2 lens material can safely and effectively reduce myopia, long-term follow-up studies to evaluate

parameters such as corneal contour, thickness, and cell density are necessary to confirm the safety and effectiveness of the technique.

In summary, overnight orthokeratology with lenses made of Boston XO2 material is effective and safe for the temporary reduction of myopia. When comparing with the Equalens II material, the newer XO2 as lens material is able to achieve improved ocular health with significant reduction of cornea staining and conjunctiva inflammation. Future long-term study of lenses made with this higher DK/t XO2 material is recommended for better understanding of its impact on human eyes.

Conflict of interest

None.

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