Purpose: To evaluate corneal changes and ocular aberrations during an orthokeratology test.

Methods: Fourteen myopic patients (26 eyes) underwent an orthokeratology fitting test with the BE contact lens (Ultravision Pty, Ltd, Brisbane, Australia). Best spectacle-corrected visual acuity (BSCVA), uncorrected (UCVA), subjective cycloplegic refraction, biomicroscopy, corneal topography, optical pachymetry, and aberrometry were performed at baseline and one and eight nights orthokeratology. The short-term effect of orthokeratology using corneal topography, tomography, and ocular aberrations was evaluated.

Results: The mean spherical equivalent changed from $-2.24 \pm 0.98$ diopters (D) at baseline to $0.15 \pm 0.76$ D after the eight nights of lens wear ($P = .001$). All patients had an UCVA of $20/30$, $69.2\%$ with $20/20$. Changes in central corneal pachymetry were not observed. There was a statistically significant increase in the temporal corneal thickness from night one, without any difference between nights one and eight ($P > .001$). A significant increase of higher-order root mean square values was observed from baseline ($0.42 \pm 0.16 \mu m$), night one ($0.81 \pm 0.24 \mu m$), and night eight ($1.04 \pm 0.24 \mu m$). Increases in coma ($Z_7 + Z_8$) and spherical aberration ($Z_{12}$) were observed. Positive horizontal ($Z_8$) coma increased in right eyes, and negative horizontal ($Z_8$) coma increased in left eyes ($P < .001$).

Conclusions: Myopia reduction resulting from rapid central corneal flattening and improvement of UCVA occurred after orthokeratology. Higher-order aberrations (HOAs), particularly spherical aberration and coma, increased significantly during the orthokeratology test. An increase of temporal pachymetry and differences in coma direction between the eyes may be related to the subclinical lens decentration temporally.

Orthokeratology, also known as corneal refractive therapy (CRT), was introduced approximately 40 years ago as a method for the temporary reduction of myopia. Orthokeratology is a reversible procedure that uses rigid contact lenses to change the curvature of the cornea to correct refractive errors. Orthokeratology proved to be inefficient and unpredictable within the first two decades of use, losing credibility as a viable option for the correction of myopia. However, the advent of corneal topography coupled with recent advances in the contact lens designs have increased the precision of this technique significantly.

For example, the introduction of reverse-geometry rigid gas-permeable contact lenses with high oxygen transmissibility allows overnight use for greater patient comfort and faster reduction of refractive error.

Reverse-geometry lens wear for myopia alters the prolate corneal shape to make it spherical or mildly oblate, causing a flatter 5- to 6-mm central circular zone and steeper mid-periphery. Several theories have been proposed to explain the mechanism behind orthokeratology. These include changes in the anterior and posterior corneal surface and the induction of spherical aberration ($Z_{12}$). The refractive effect is explained by two different theories. The first theory postulates that changes in the central and paracentral corneal thickness contribute to changes in the anterior corneal surface, causing refractive change. The second theory postulates that anterior and posterior corneal surface modulation results in full-thickness changes in corneal curvature.

Swarbrick and associates found significant central corneal thinning and mid-peripheral thickening in a group of subjects who wore reverse-geometry orthokeratology lenses. From these observations, they concluded that the induced corneal change was the result of the redistribution or remodeling of anterior corneal tissue, rather than an overall bending of the cornea. Alharbi and Swarbrick confirmed these observations in a study on human subjects, and Choo and associates demonstrated these changes in an animal model. Although there is consensus that the central cornea thins, the effect on the mid-periphery is still debated. Furthermore, the response of the back corneal surface after orthokeratology is still controversial. The changes in the corneal surface can be monitored using corneal tomography systems, and the resulting optical changes can be quantified in vivo using aberrometry.
Quantification of the induced wavefront aberrations resulting from any refractive procedure, including orthokeratology, is important because of the impact on visual acuity and visual quality. An increase in ocular and corneal higher-order aberrations (HOAs) has been reported using various reverse-geometry orthokeratology contact lenses.\textsuperscript{15-19} A diminution of low-contrast best-corrected visual acuity (BCVA) resulting from induced HOAs using CRT (Paragon Vision Sciences, Mesa, Arizona, USA) has been reported.\textsuperscript{16} Additionally, the fitting characteristics of orthokeratology lenses have been reported to induce specific types of HOAs.\textsuperscript{18}

A number of orthokeratology lens are commercially available; one such lens, the Mountford lens (BE lens), purportedly differs from other orthokeratology lens designs. The BE lenses are designed from the periphery in, commencing with the tangent periphery, an outer curve that depends largely on the measured value of corneal eccentricity, rather than starting with base curve selection. Furthermore, the refractive changes are brought about by the manipulation of squeeze film forces generated by differing pressure gradients beneath the lens.\textsuperscript{20} The BE trial lens parameters are calculated using corneal topography and a computer program provided by the manufacturer. To date, there are no peer-reviewed publications reporting ocular wavefront analysis with the BE lens.

The current study analyzed the efficacy and corneal changes induced by overnight orthokeratology fitting test using the BE lens design. Given the lack of wavefront data and the apparently differing mechanism of action, it is important to determine whether the BE lens induces similar or different wavefront aberrations compared with those reported for other orthokeratology lenses. We believe that wavefront analysis aids in understanding the underlying short-term biomechanical and optical response of the eye after orthokeratology and allows for further refinements in lens design.

**METHODS**

- **SUBJECTS:** This was a prospective study of 26 eyes of 14 myopic patients (seven women and seven men) who underwent overnight orthokeratology fitting tests with the BE lens. This study was conducted at the Contact Lens Sector of the Vision Institute of the Federal University of São Paulo/Universidade Paulista School of Medicine (UNIFESP/EPM). The inclusion criteria for this study included myopia up to $-4.50$ diopters (D) with or without against-the-rule astigmatism of up to $-0.75$ D and with-the-rule astigmatism of up to $-1.50$ D. Any patient with ophthalmic disease or who had undergone previous ocular surgery was excluded from this study. Soft contact lenses had to be removed for one month before the beginning of the study. There were no rigid contact lens wearers participating in this study.

- **ORTHOKERATOLOGY CONTACT LENS FITTING PROCEDURE:** Patients were fitted with the BE standard contact lenses for testing (UltraVision Pty, Ltd., Brisbane, Australia), Boston XO material (DK = $100 \times 10^{-11}$ $[\text{cm}^2/\text{s}] [\text{ml O}_2/\text{ml} \times \text{mm Hg, ISO/Fatt}];$ Bausch & Lomb, Rochester, New York, USA), manufactured by Mediphacos, a Brazilian enterprise (Mediphacos Ltda, Belo Horizonte, Brazil). The BE Retainer is designed using topographical data only. Each retainer is individually designed specific to the patient’s corneal topography. The BE lens is designed to control the fluid forces in the tear layer to allow controlled and predictable corneal shape and refractive change.

   All but two subjects were fitted with the BE orthokeratology contact lenses in both eyes. All patients underwent a baseline examination and follow-up examinations after one and eight nights after orthokeratology. All examinations included the measurement of best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), subjective cycloplegic refraction, biomicroscopy, corneal topography and tomography (including optical corneal pachymetry and posterior corneal surface mapping), and ocular aberrometry.

   These lenses have a similar design to reverse geometry lenses (Figure 1): posterior central curve, reverse curve,
tangential curve, and peripheral curve. The parameters include a 11-mm chord diameter, 6.0- to 6.5-mm optical zone, 0.02- to 0.24-mm center thickness, and 7.70- to 9.35-mm base curve with proprietary secondary and peripheral curves. The BE lens was fitted using a trial set and a scientifically validated predictive computer program version 1.1.3 (BE Enterprises Studio, Vancouver, Canada) that relates corneal shape to refractive change. The BE trial lens were fitted according to the manufacturer’s recommended fitting procedure described by Mountford, which includes the determination of baseline refractive error, average apical radius (R0), sagittal height or corneal elevation (sag), horizontal visible iris diameter (HVID), and interpretation of the post-fit corneal topography.\(^7\) The elevation data of R0 and sag were determined over a chord length of 9.35 mm as directed for BE lenses. These data were entered into the BE Enterprises computer program to identify the trial lens base curve.

Subjects were instructed to wear the lenses overnight during sleep and to return the next morning within one hour of waking with the lenses in situ. If the first overnight trial was unsuccessful, a second trial was performed after a minimum of 72 hours. If an unacceptable topographic map showing small or centered treatment zone was present after the eighth night of wear, the lens parameters were changed and another fitting test was performed after two weeks of discontinuing lens wear. The criteria to define a successful overnight trial were the following: presence of bull’s-eye corneal topography pattern on the first and eighth nights, tendency to a bull’s-eye pattern on the first night, and absence of keratitis or other complications that could affect the corneal response.

All study subjects were instructed to take appropriate care of the lenses, including regular disinfection and deproteinization using Unique Ph (Alcon Laboratories, Inc, Forth Worth, Texas, USA). Compliance with the maintenance and disinfection protocol was confirmed and reiterated at all follow-up visits.

At all follow-up visits, biomicroscopy was used to evaluate fit of the lenses, to assess the anterior segment, and to monitor the effects of lens wear. Sodium fluorescein patterns and alignment were evaluated with the lens in situ. Criteria for an acceptable symmetric fit were a smiling face with a fake central island, a frowning face, and central divots.

The bull’s-eye pattern indicates ideal apical clearance between the BE lens and cornea that results in a large consistent spherical treatment zone. Ideally, this treatment zone should match the photopic pupil diameter. This treatment zone appears as a deep blue pool centered over the corneal apex on axial curvature difference maps. All patients in this study obtained a bull’s-eye topographic pattern. In the cases that did not achieve the bull’s-eye pattern initially, the base curve of the trial lens was altered as recommended by the fitting software. A retrial was performed only after the cornea achieved normal curvature.

All patients were classified as good candidates for the orthokeratology fitting test based on the following relationship: therapy target – BE retainer potential (indicated by adjustment value < −1.00 D or any positive value).

Corneal tomography was performed using the Orbscan IIz (Bausch & Lomb, Rochester, New York, USA). One map was obtained at baseline and after the first and eighth overnight orthokeratology fitting test. The Orbscan IIz provides anterior and posterior corneal elevation maps and optical pachymetry based on Scheimpflug slit-scanning technology.

The numerical values of the highest and lowest points corresponding to the posterior float map were recorded, in addition to the nasal, central, and temporal pachymetry. Average nasal and temporal pachymetry values were calculated between 5 to 7 mm from the corneal center, corresponding to the corneal mid-periphery.

Aberrometry. Ocular aberrometry was performed to gain an understanding of the optical effects of the change in corneal shape induced by orthokeratology. Ocular aberra-
Measurements were obtained approximately 30 minutes after instillation of one drop of 1% tropicamide. All measurements were performed by an experienced examiner (I.G.S.) who ensured the patients’ line of sight was coaxial to the optical axis and fixation target of the aberrometer. The subjects were instructed to blink once and remain still, and five images were acquired after stabilization of the tear film as seen on the sensor spot pattern (generally within two seconds after blinking).

Data from the five maps were averaged automatically and subsequently were analyzed for changes between baseline and the first and eighth nights after orthokeratology. Total aberrations (total RMS), HOAs (HOA RMS), lower-order aberrations (defocus-Z4 and astigmatism-Z3/H11001 Z5), coma RMS (Z7/H11001 Z8), and spherical aberration RMS (Z12) values were analyzed. Horizontal (Z8) and vertical (Z7) coma values were analyzed separately for right and left eyes.

Statistical Analysis. Data were analyzed for each patient’s eye independently using Microsoft Excel 2000 version 9.0.2720 (Microsoft Corp, Redmond, Washington, USA). Spherical equivalent (SE) was analyzed using the Student t test. A P value less than .001 was considered statistically significant.

TABLE 1. Mean and Pattern Deviation of the Measurements of Apical Radius, Sagittal Height, Eccentricity, and Keratometry from the Medmont Corneal Topographer in 26 Eyes That Underwent Orthokeratology

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Night 1</th>
<th>Night 8</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R0 (mm)</td>
<td>7.82 ± 0.25</td>
<td>8.00 ± 0.25</td>
<td>8.20 ± 0.24</td>
<td>.001*</td>
</tr>
<tr>
<td>Sag (mm)</td>
<td>1.50 ± 0.05</td>
<td>1.50 ± 0.05</td>
<td>1.50 ± 0.05</td>
<td>.279</td>
</tr>
<tr>
<td>e (mm)</td>
<td>0.69 ± 0.17</td>
<td>0.46 ± 0.24</td>
<td>0.30 ± 0.21</td>
<td>.001*</td>
</tr>
<tr>
<td>steep K (D)</td>
<td>44.17 ± 1.11</td>
<td>43.18 ± 1.11</td>
<td>42.28 ± 1.08</td>
<td>.001*</td>
</tr>
<tr>
<td>flat K (D)</td>
<td>43.01 ± 1.21</td>
<td>42.06 ± 1.08</td>
<td>41.44 ± 1.18</td>
<td>.001*</td>
</tr>
</tbody>
</table>

D = diopters; e = corneal eccentricity; flat K = flat keratometry; R0 = apical curvature radius; Sag = corneal sagittal height; steep K = steep keratometry.

Night 1 denotes pachymetry after the first night of lens wear.

Night 8 denotes pachymetry after the eight night of lens wear.

*Denotes statistical significance.

TABLE 2. Mean and Pattern Deviation of the Measurements in Millimeters of Higher and Lower Elevation Points of the Posterior Float Map from Orbscan Itz Corneal Tomography in 26 Eyes That Underwent Orthokeratology

<table>
<thead>
<tr>
<th>Posterior Float</th>
<th>Baseline</th>
<th>Night 1</th>
<th>Night 8</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher elevation point</td>
<td>0.03 ± 0.01</td>
<td>0.03 ± 0.01</td>
<td>0.03 ± 0.01</td>
<td>.576</td>
</tr>
<tr>
<td>Lower elevation point</td>
<td>−0.05 ± 0.01</td>
<td>−0.04 ± 0.01</td>
<td>−0.05 ± 0.01</td>
<td>.235</td>
</tr>
</tbody>
</table>

Night 1 denotes pachymetry after the first night of lens wear.

Night 8 denotes pachymetry after the eight night of lens wear.

RESULTS

The mean age of the patients was 31.0 ± 8.43 years (range, 14 to 52 years). Before orthokeratology, 30.7% of the patients had an UCVA between 20/200 and 20/400, 42.2% between 20/150 and 20/100, and 26.9% between 20/60 and 20/40. At the end of the night eight of BE lens wear, 100% of patients had an UCVA equal to or better...
than 20/30, of which 69.2% saw 20/20 or better. The mean UCVA changed from +0.90 ± 0.31 logarithm of minimum angle of resolution units (20/160 Snellen) at baseline examination to +0.04 ± 0.09 logarithm of minimum angle of resolution units (20/20 Snellen) after orthokeratology. The BSCVA at baseline was 20/15 in 38.46% of the patients, 20/20 in 57.69% of the patients, and 20/25 in 3.84% of the patients. After the orthokeratology fitting test, the BSCVA was 20/15 in 23.00% of the patients, 20/20 in 65.38% of the patients, and 20/25 in 11.50% of the patients.

The mean baseline SE ranged from −1.00 to −4.25 D. The SE changed from −2.24 ± 0.98 D at baseline to 0.15 ± 0.76 D after orthokeratology (P < .001). There were statistically significant changes from baseline to night one and night eight in R0, steep k, flat k, and e (P = .001; Table 1). There was no statistically significant change in back surface elevation in the highest point (P = .576) or the lowest point (P = .235; Table 2).

Significant changes in central and nasal pachymetry between baseline and night one, baseline and night eight, and between night one and night eight were not observed. There was a 13.58-μm increase in temporal corneal thickness from baseline to the first night, and no differences between the first and eighth nights (P = 1.000; Table 3).

The mean total RMS decreased from 3.90 ± 1.22 μm at the baseline examination to 3.32 ± 1.22 μm after night one to 2.63 ± 1.20 μm after night eight. There was a statistically significant increase of HOA RMS from 0.42 ± 0.16 μm at the baseline examination to 0.81 ± 0.24 μm after night one (P = .006) to 1.04 ± 0.24 μm after night eight (P = .004). Figure 2 plots the increase of coma (Z7+Z8) from baseline through the follow-up period. Orthokeratology induced positive spherical aberration in all eyes. Figure 3 plots the increase of spherical aberration (Z12) from baseline through the follow-up period.

Analysis of the right and left eyes separately shows a distinct pattern for horizontal coma [Z8] (Figure 4). Horizontal coma increased in a positive direction in right eyes and in a negative direction in left eyes (P < .001; Figure 4). Figures 5 and 6 represent the Zernike plot of the right and left eyes, respectively. There was no statistically significant difference in vertical coma (Z7) between eyes. Two patients experienced central corneal erosion (Grade 4 staining) on night one after (non-recommended) extended overnight and daily use (12 hours). The patients were instructed to discontinue lens wear until the epithelium healed completely and the orthokeratology lens was refitted after one week.

**DISCUSSION**

A number of studies have reported the effectiveness of modern orthokeratology using a variety of different designs of reverse-geometry lenses. The results of our
FIGURE 4. Graph showing the change in horizontal coma for right and left eyes during the orthokeratology fitting test (n = 26 eyes; P < .001).

FIGURE 5. (Top) Baseline and (Bottom) post-orthokeratology Zernike plot of a right eye showing the increase of coma in the positive direction.
study show that the reduction in myopia by central corneal flattening and related improvement of UCVA occurred rapidly during orthokeratology fitting test with the BE lens. However, there were also associated changes in lower-order aberrations and HOAs and corneal thickness.

The refractive outcomes from this study concur with those of Alharbi and Swarbrick,12 who reported a mean refractive change in SE of 2.63 D and improvement in the mean UCVA from 20/130 at baseline examination to 20/15 after orthokeratology in 18 eyes using the BE lens. We found a change of 2.39 D with an improvement in UCVA from 20/160 at baseline examination to 20/20 after orthokeratology.

The corneal topography changes seen in our study support the work of others9,10,22 that elliptical form reorganization causes the refractive changes during overnight orthokeratology. For example, the reduction in R0, keratometry, and eccentricity all indicate that the cornea became flatter after orthokeratology (Table 1). Just one night of overnight orthokeratology lens wear induced significant changes in corneal curvature, myopia correction, and UCVA. These results support previous conclusions23,25 that the corneal remodeling occurs very early during orthokeratology.

However, our findings contradict those of Owens and associates, who reported significant flattening of the posterior corneal surface.14 In all cases, we found no changes in posterior corneal curvature after orthokeratology. This difference may be the result of the methods used to measure posterior curvature changes between studies. We used a tomography system that directly measures the posterior cornea, whereas Owens and associates used an indirect method based on the subjective measurement of arc length using Purkinje images.14 Based on our findings, it seems that the posterior cornea is not modified during the initial period of overnight orthokeratology with the BE lens. There is increasing clinical evidence that the effect of orthokeratology is achieved by the sudden remodeling of the anterior layers,12 rather than changes in corneal thickness. Some have theorized that localized differences in the tear film thickness under the contact lenses cause positive and negative pressure gradients that reduce corneal thickness and flatten it centrally, yet thicken the corneal mid-periphery.12 In our short-term

**FIGURE 6.** (Top) Baseline and (Bottom) post-orthokeratology Zernike plot of a left eye showing the increase of coma in the negative direction.
Ocular wavefront analysis is necessary for future design, development, and improvement in fitting techniques for orthokeratology lenses. We believe that different lens design can induce different combinations of HOAs. Thus, it is important to determine how this method of corneal reshaping and orthokeratology lens models can be refined to maximize visual performance.

The two cases of adverse corneal erosion observed during this short-term trial healed without sequelae. There have been a number of reports of more serious corneal complications, such as Acanthamoeba and Pseudomonas infection, that warrant longer-term and larger-scale studies to assess this risk.

In summary, myopia reduction with rapid central flattening and improvement of the UCVA was obtained in the short-term with the BE overnight orthokeratology lens. An increase in HOAs was observed, particularly spherical aberration (Z12) and coma (Z7+Z8). There was also an increase in the temporal thickness, induction of positive horizontal coma (Z8) in the right eyes and negative in the left eyes, and temporal flattening of the cornea likely related subclinical decentration area.

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**THE AUTHORS INDICATE NO FINANCIAL SUPPORT OR FINANCIAL CONFLICT OF INTEREST. INVOLVED IN DESIGN OF STUDY (I.G.S., C.L., A.L.H.L.); conduct of study and collection (I.G.S., E.M., M.M.L.); management (C.L., A.L.H.L.); analysis (I.G.S., P.S.); and interpretation of the data and preparation, review, or approval of the manuscript (I.G.S., M.R.C., P.S., C.L., A.L.H.L.). The research protocol was**
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2. Pearson R. The concept of orthokeratology in which corneal lenses are fitted in order to temporarily reduce or eliminate a refractive error. Cont Lens Anterior Eye 2000;23:67.