

# Empirical Advanced Orthokeratology Through Corneal Topography: The University of Houston Clinical Study

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**Purpose.** Traditionally, orthokeratology has used diagnostic lenses to determine the best fit. The purpose of this study was to determine the efficacy of fitting empirically from corneal topography, without the use of diagnostic lenses. **Methods.** Twenty-nine subjects, 18 to 37 years old, with myopia of 1.00 to 4.00 diopters (D) and astigmatism of no more than 1.50 D, were entered into this 6-month study. Corneal topography, scanning slit topography and corneal thickness (Orbscan), confocal microscopy, ultrasound corneal thickness, aberrometry, and biomicroscopy were used to assess corneal changes. Unaided logMAR high-contrast visual acuity, subjective refraction, and questionnaires were used to monitor vision and symptoms. Follow-up visits were scheduled after 1 day, 1 week, 2 weeks, 1 month, 3 months, and 6 months. **Results.** For 6-month data, unaided logMAR acuity improved from  $0.78 \pm 0.26$  in the right eye and  $0.75 \pm 0.22$  in the left eye to  $0.06 \pm 0.18$  in the right eye and  $0.04 \pm 0.16$  in the left eye. Myopia decreased from  $-2.55 \pm 0.87$  D in the right eye and  $-2.47 \pm 0.89$  D in the left eye to  $+0.45 \pm 0.74$  D in the right eye and  $-0.17 \pm 0.69$  D in the left eye. Shape factor, using corneal topography, increased from  $0.85 \pm 0.13$  in the right eye and  $0.85 \pm 0.15$  in the left eye to  $1.28 \pm 0.32$  in the right eye and  $1.30 \pm 0.29$  in the left eye. Both eyes showed a decrease in lower-order aberrations (i.e., defocus) and an increase in higher-order aberrations (i.e., spherical aberrations and coma). **Conclusions.** Myopia reduction after 1 week was clinically insignificant from the 1-month results, indicating that the full effect is achieved by 1 week. Neither total nor epithelial corneal thickness varied significantly from baseline measurements.

**Key Words:** Confocal microscopy—Corneal topography—Optical aberrations—Optical pachymetry—Reverse geometry.

Orthokeratology is a procedure that uses gas-permeable contact lenses to reshape the cornea to temporarily reduce or modify myopia and astigmatism to achieve a transient improvement in

unaided visual acuity. First described in 1962 by Jessen,<sup>1</sup> the orthokeratology procedure and lens designs have evolved greatly during the last 40 years.<sup>2–39</sup> Lenses were originally made of polymethylmethacrylate and usually fitted flatter than the flat keratometric reading. This concept has limitations with conventional lens designs, especially when the amount of central base curve flattening is significant. Typically, the spherical flat-fitting lens would rock over the cornea and result in induced corneal astigmatism. The solution was to change the base curve gradually with time as the cornea changed. However, this procedure required several months of treatment to achieve only 1 or 2 diopters (D) of myopia reduction. Because of only modest and unpredictable improvements in uncorrected visual acuity, orthokeratology fell into disfavor among most eye care practitioners and was declared not to be a viable option for the correction of myopia in the optometric and ophthalmologic literature.<sup>40–47</sup>

In 1989, Wlodyga and Bryla introduced accelerated orthokeratology, with a report on 15 patients fitted with a new series of reverse-geometry lens designs manufactured by Context, Inc. (Van Nuys, CA), called OK lenses.<sup>48</sup> Keratometry was used to design the lens and monitor corneal changes. The difference between central and peripheral keratometric readings was used to establish the corneal shape factor and to predict the amount of myopia reduction. It may be argued that because of the large mire separation, the keratometer is not the best instrument to use for monitoring orthokeratology results and that the difference between a central and temporal keratometric reading is not truly representative of the corneal shape or shape factor. Nevertheless, during the next 15 years, new technologies in the manufacturing of the lenses and in monitoring their effects on the cornea have revitalized interest in orthokeratology worldwide.<sup>49–65</sup>

Modern contact lenses for overnight orthokeratology are made of enhanced oxygen-permeable materials and have a more complex posterior design. The back surface of newer lens designs may be divided into four or more zones. Each zone influences the lens positioning over the cornea and the resulting visual outcome. The four zones are the optical zone (central), the reverse curve(s) (paracentral), the alignment curve (intermediate), and the peripheral curve (edge lift). Depending on the specific manufacturer, the contact lens has different nomenclature for each zone and different ways of calculating the posterior curvatures of the lens. For

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Accepted March 30, 2007.

DOI: 10.1097/ICL.0b013e318065b0dd

instance, some manufacturers prefer a lens design in which the central optical zone is calculated first, followed by the alignment curve, and finally, the two segments are joined by a return curve of specific geometric shape. Other manufacturers may choose a different approach in which the alignment curve (peripheral segment) is calculated first, followed by the optical zone (central segment), and then, the two segments are joined by the reverse curve patterned after a specific geometric shape. With the aforementioned design, the practitioner sends the keratometric readings and refraction to the laboratory for lens design and fabrication. Lacking information about the asphericity of the individual cornea, the laboratory assumes an average eccentricity, usually 0.5, when manufacturing the lens. In another fitting modality, the practitioner uses a diagnostic set of contact lenses to trial fit the patient. In most cases, the laboratory does not indicate the eccentricity used in their lens design. In yet a third fitting modality, the practitioner uses a corneal topographer to obtain the apical radius of the cornea, the sagittal height at a chord of 9.35 mm, and the eccentricity or shape factor. From this information, a diagnostic lens is chosen for an overnight trial before ordering the lenses. This last fitting modality has an advantage over the previous methods because of the added information about the shape of the cornea, mainly eccentricity or shape factor. The authors prefer to use the term *shape factor* because it differentiates between prolate and oblate elliptical surfaces. For example, if the shape factor is between 0 and 1.0, the shape of the cornea lies on the steeper side of the ellipse (i.e., a prolate shape). If the shape factor is greater than 1.0, the shape of the cornea is on the flat side of the ellipse (i.e., an oblate shape). Because of these innovative designs, lenses may be fitted with base curves significantly flatter than those used in conventional orthokeratology to result in larger and more rapid changes in corneal curvature and thus faster improvements in unaided visual acuity.

Whereas some forms of accelerated orthokeratology typically rely on traditional keratometry,<sup>60,61,66,67</sup> controlled kerato-reformation (CKR) (Eye Research Associates, Inc., Houston, TX), by definition, is based on computer-assisted videokeratography.<sup>68</sup> These instruments produce a comprehensive topographic map of the cornea, which allows the practitioner to more accurately monitor the corneal changes that lenses produce with time. The CKR procedure consists of fitting reverse-geometry, aspheric, gas-permeable contact lenses designed with the aid of the Optivision EH-290 CornealMap (Optivision, Inc. Houston, TX) computerized corneal topographer. The base curve selected depends on the desired amount of myopia reduction, and the corneal shape factor determines the remaining curves.

Preliminary retrospective studies conducted by El Hage and Leach<sup>68,69</sup> indicate that perhaps shape factor, as determined by the corneal topographer, would be a better indicator of refractive changes. In their retrospective study of CKR on 51 patients, reverse-geometry lens designs were based on videokeratography and manufactured by Metro Optics, Inc. (Dallas, TX). The amount of myopic reduction ranged from 0.37 to 6.25 D and required from as little as 3 days to as much as 42 weeks to reach a plateau.<sup>68,69</sup>

The purpose of this clinical study was to determine the efficacy and ease of empirically fitted gas-permeable contact lenses, manufactured in Boston Equalens II material (oprifocan A) (Bausch & Lomb, Rochester, NY), for orthokeratology. At the time of this study, the Boston Equalens II material, with a  $D_k$  of  $85 \times 10^{-11}$  ( $\text{cm}^3 \cdot \text{O}_2 \cdot \text{cm})/(\text{sec} \cdot \text{cm}^3 \cdot \text{mm Hg})$  at  $35^\circ\text{C}$ , was marketed with approval by the Food and Drug Administration for daily- and

extended-wear conventional gas-permeable lenses and for daily-wear orthokeratology lens designs. In June 2004, Boston Equalens II material was approved additionally for overnight orthokeratology.

This clinical trial used a different approach for designing and fitting orthokeratology contact lenses, which is based on corneal topography and tear layer thickness. The corneal topographer provided three coordinates ( $x$ ,  $y$ , and  $z$ ) of each point on the cornea and allowed reconstruction of the shape of the cornea and design of the lens from corneal topography information using a built-in software program. Another consideration is the tear layer thickness between the contact lens and the cornea. In normal gas-permeable lens designs, the tear thickness is approximately  $20 \mu\text{m}$  between the cornea and the back surface of the lens. This concept is even more important in fitting reverse-geometry contact lenses in orthokeratology. A change of a few micrometers in the cornea-to-contact lens relationship, for example, in the central segment of the lens, may induce a diopter or more in refractive change. A change of only a few micrometers in the return curve segment or in the alignment segment will affect the centration of the contact lens over the cornea. For instance, to center the contact lens over the patient's cornea, increasing the return curve depth of a few micrometers may be needed to tighten the fit. Alternatively, to loosen the lens, the return curve depth may be decreased. The same applies to the alignment curve. By varying the slope of the alignment curve, it can be brought closer or farther away from the cornea. Bringing the alignment curve closer to the cornea will tighten the fit of the contact lens, and moving the alignment curve away from the cornea will loosen the fit. In this study, the CKR fitting program was integrated with the Focal Points software program (Advanced Medical, SRL, Milan, Italy) to design and manufacture the lenses (Fig. 1).

After designing the orthokeratology lens from the computer nomogram, the lens order is sent to the laboratory electronically. The expected benefit of such an empirical system would be to simplify the overnight therapy process of achieving temporary improvement in unaided visual acuity better than or equal to 20/40 while yielding a clinically acceptable physiologic response. Modern orthokeratology requires, at minimum, to fit the lens according to sagittal height and corneal asphericity, eccentricity or shape factor, and at best based on corneal topography. The traditional notion of fitting contact lenses on the keratometric reading, flatter than the keratometric reading, or steeper than the keratometric reading is not applicable in modern orthokeratology. Corneal topography is generally accepted as the standard of care in orthokeratology for follow-up and assessment of the fitting and positioning of the contact lens over the cornea and the health of the cornea. Along with visual acuity and over-refraction, corneal topography provides the best indication of the efficacy of the procedure.

## MATERIALS AND METHODS

The protocol was approved by the University of Houston College of Optometry Institutional Review Board and the University Committee for the Protection of Human Subjects, in accordance with the Declaration of Helsinki, before the beginning of the study.

Thirty-two subjects were screened, and 29 subjects were entered into the study (11 men and 18 women). Nine subjects withdrew or were discontinued for various reasons. One refused to wear the lenses because of discomfort and they were not dispensed. Two were lost to follow-up; one was unable to be fitted satisfactorily;

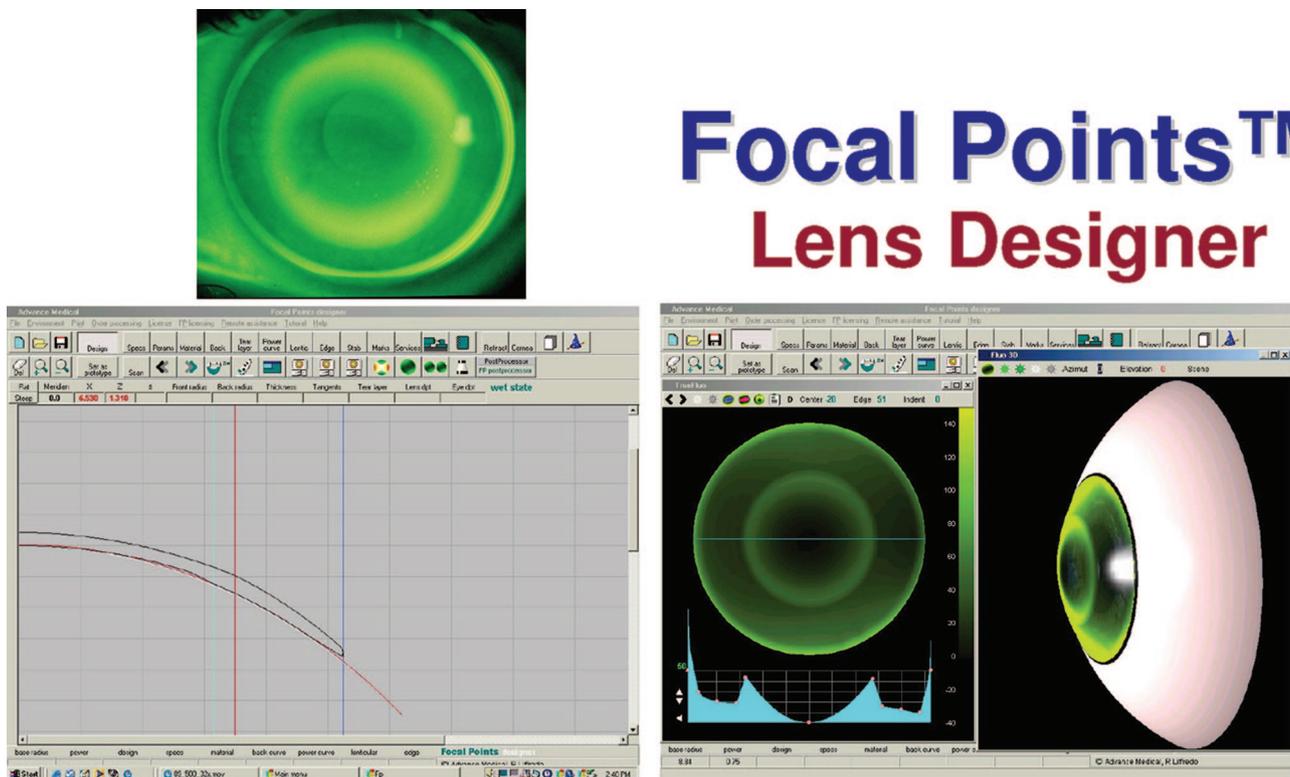


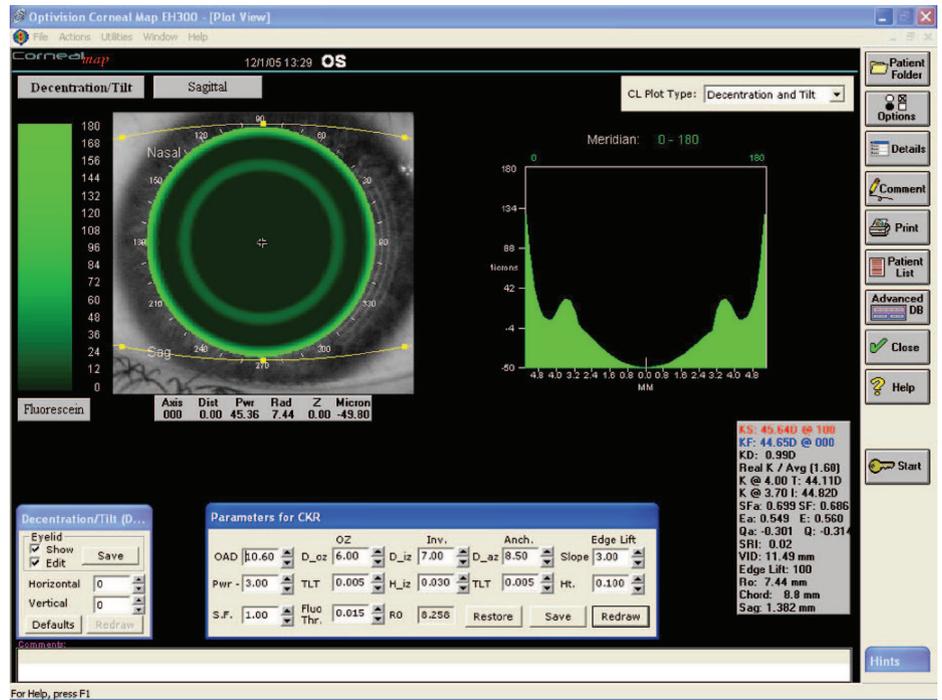
FIG. 1. Focal Points Lens Designer display.

and one did not achieve acceptable unaided visual acuity. The average age of the 20 subjects completing the study was  $26 \pm 3.7$  years (range, 20–32 years). Women accounted for 73% of the cohort, and men accounted for 27%. Each subject was examined at the initial visit to determine eligibility. To be enrolled in the study, subjects were required to have normal ocular and systemic health, myopia between 1.00 and 4.00 D, astigmatism no greater than 1.50 D, and no history of gas-permeable lens wear. The study was explained to the subjects, and they were asked to read and sign a statement of informed consent. Once enrolled, corneal topography measurements were obtained; study lenses were ordered; and the subject was scheduled for a dispensing visit. The design of the lenses was determined directly from corneal topography data and the CKR computerized fitting nomogram using Focal Points, without the use of diagnostic lenses. The values of shape factor, eccentricity, and Q are shown for each cornea and the fitting nomogram (Fig. 2). The CKR nomogram shows the lens characteristics and the fluorescein and tear layer thickness under the contact lens. This program produces an aspheric back surface orthokeratology lens design. Figure 2 shows the CKR fitting nomogram as it appears on the computer monitor. Shown on the left side is the simulated fluorescein pattern (i.e., bull's eye) showing the lens-to-cornea fitting relationship of the designed contact lens. On the right side is the tear layer thickness profile between the contact lens and the anterior corneal surface. The software shows the amount of tear thickness required at the center of the cornea versus the amount required at the junction between the return curve and the alignment curve. The lower left side allows for simulated horizontal and vertical movement of the contact lens over the cornea. Finally, the lower right side of the CKR nomogram display shows the parameters of the designed

contact lens (i.e., the overall diameter [OAD], the optical zone [OZ], the amount of aimed myopia reduction (Pwr), the shape factor of the lens design (SF), the depth and width of the invagination or reverse curve (Inv), the anchorage (Anch) or alignment zone and its slope, and the edge lift. The computer software allows customization of any of these parameters to achieve an optimally fitting lens. For example, by changing the slope of the anchorage zone, the edge lift will increase (loosen) or decrease (tighten) and affect the lens position. Likewise, the location of the alignment curve and the diameter of the lens may be customized to influence the fit. The right side of the nomogram shows the values of the keratometric readings, corneal astigmatism, shape factor, eccentricity, Q (asphericity), central radius of curvature, surface regularity index, visible iris diameter, edge lift, chord, and sagittal height. The asphericity of the cornea is expressed in terms of shape factor ( $\rho$ ), eccentricity ( $e$ ), or asphericity ( $Q$ ), where  $\rho = 1 - e^2$  and  $Q = -e^2$ . After the lenses are designed, the data are electronically sent to the laboratory through the Internet, and the lenses are made.

In addition to the basic eye examination and measurements of corneal topography, confocal microscopy (ConfoScan3; Nidek, Inc., Fremont, CA), Shack–Hartmann aberrometry, ultrasound corneal thickness measurements (CorneaGage Plus; Sonogage, Cleveland, OH), and scanning slit topography and corneal thickness (Orbscan II; Bausch & Lomb, Rochester, NY) data were collected. At the initial dispensing, subjects were asked to wear the lenses overnight, and follow-up visits were scheduled after 1 day, 1 week, 2 weeks, 1 month, 3 months, and 6 months. Corneal topography, subjective refraction, and high-contrast aided and unaided logMAR visual acuity were measured at each office visit. LogMAR visual acuity is a logarithmic transformation of an optotype's size in minutes of arc, which creates a

FIG. 2. Optivision CornealMap CKR lens-fitting nomogram.



geometric progression and simplifies statistical analysis. Each subject was also asked to complete a questionnaire regarding lens comfort and their unaided visual acuity when performing certain tasks. Scanning slit topography and corneal thickness, confocal microscopy, pachymetry, and aberrometry were taken before fitting and then at the 1-month, 3-month, and 6-month follow-up visits.

### RESULTS

All data were analyzed by a mixed-effect repeated-measures analysis of variance. In the mixed-effect model, all the data are used to compute the correlation matrix and standard deviations. Thus, all eyes were used without averaging. SAS Proc Mixed, the computer subroutine, corrects for correlations between eyes and

unnecessary gains in power caused by repeated measures over time. To correct for significance owing to multiple comparisons, the Tukey–Kramer correction was applied in all calculations.

### Visual Acuity

Baseline visual acuity values were compared to each subsequent visit. When compared to baseline, the *t* value for each visit showed a significant change ( $P < 0.0001$ ). Over the seven time points at which vision without correction was assessed, there was a significant difference ( $F = 59.99, P < 0.0001$ ). An initial improvement in unaided high-contrast logMAR visual acuity was noted after the first night of lens wear, and most subjects reported functional vision for most of the day. The peak of visual acuity improvement was reached at the end of the first week (Fig. 3).

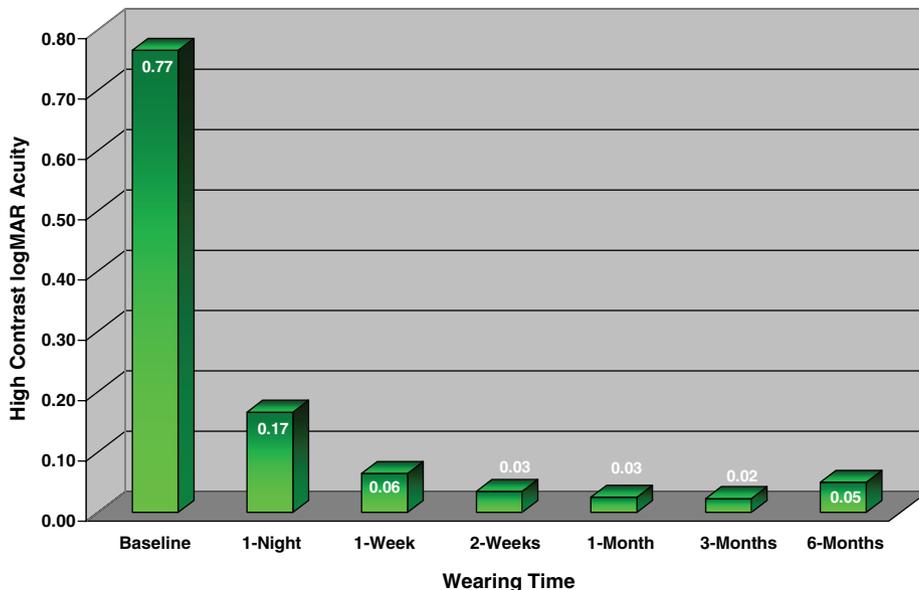


FIG. 3. Uncorrected visual acuity for 20 subjects wearing CKR lenses for overnight orthokeratology during a 6-month period.

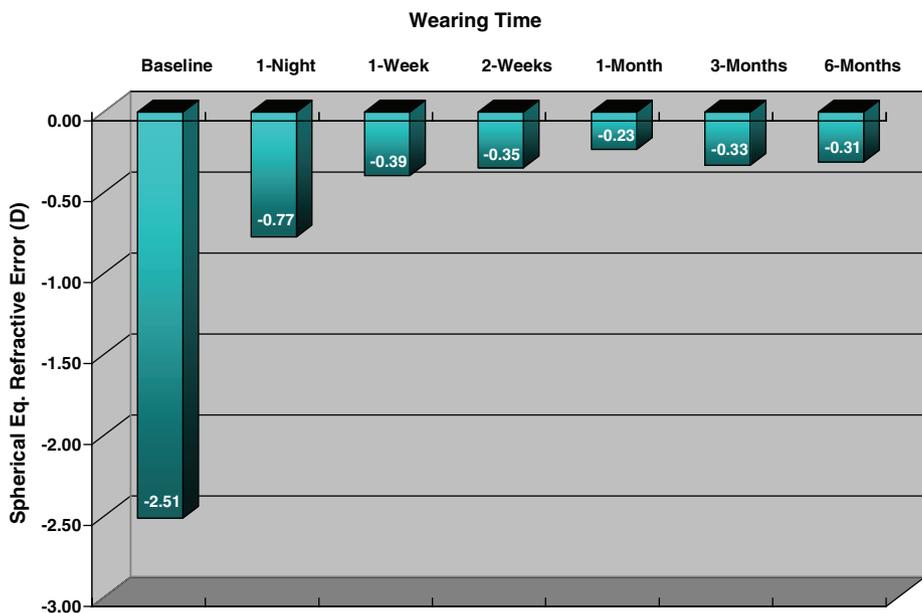


FIG. 4. Myopia reduction for 20 subjects wearing CKR lenses for overnight orthokeratology during a 6-month period.

**Refractive Error**

Subjects achieved a 66% to 80% reduction in refractive error (Fig. 4). Baseline spherical values were compared to each subsequent visit. When compared to baseline, the *t* value for each visit showed a significant change ( $P < 0.0001$ ). Dioptric spherical power changed significantly over time ( $F = 36.30, P < 0.0001$ ) from  $-2.51$  D to  $-0.31$  D after 180 days. On the first overnight follow-up visit, the mean was  $-0.77$  D and  $-0.35$  D by day 14. The change in refractive error as a function of the baseline refractive error is shown in Figure 5.

**Keratometry**

Keratometry in the horizontal axis did not change clinically or statistically over time, and follow-up visits did not differ from baseline values. However, vertical keratometry was statistically significant over time ( $F = 5.33, P = 0.002$ ), but comparisons from baseline showed small, clinically insignificant changes.

**Corneal Topography**

Corneal topography was shown to change significantly over time ( $F = 21.21, P < 0.0001$ ) and, when compared to baseline, was significant at each subsequent visit, after correcting for multiple comparisons. The shape factor showed a significant change ( $F = 13.78, P = 0.0003$ ), with the average shape factor increasing in proportion to the change in refractive error from a prolate to oblate ellipsoidal shape (Fig. 6). When the shape factor increased by 0.1 units, the spherical equivalent decreased by  $0.8153 \pm 0.1412$ . Also, when the shape factor increased by 0.1 units, the logMAR results improved by  $7.58 \pm 2.04$  letters, or a gain greater than one line of vision on the Bailey–Lovie Chart.

**Higher-Order Aberrations**

Higher-order aberrations were determined by using an in house Shack–Hartmann aberrometer. Measurements were taken in total

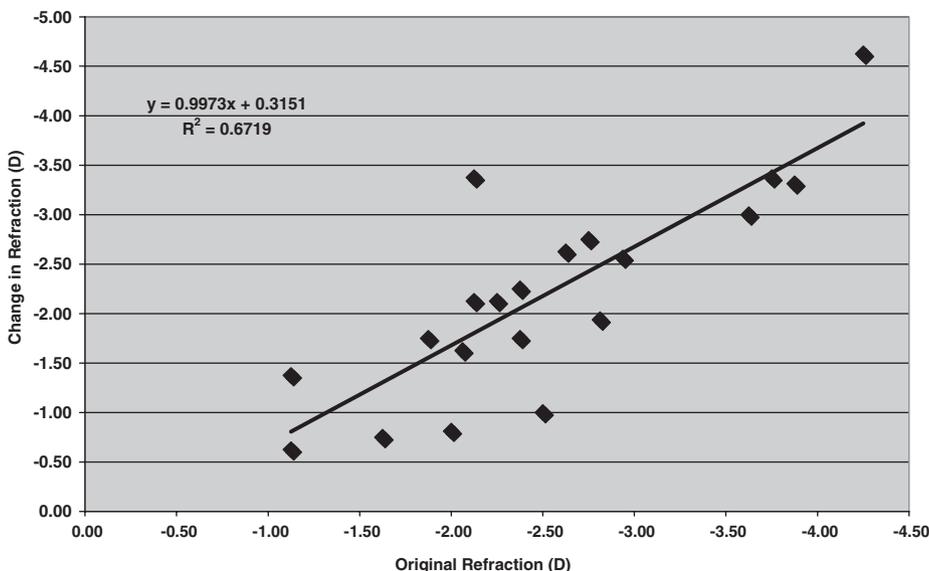
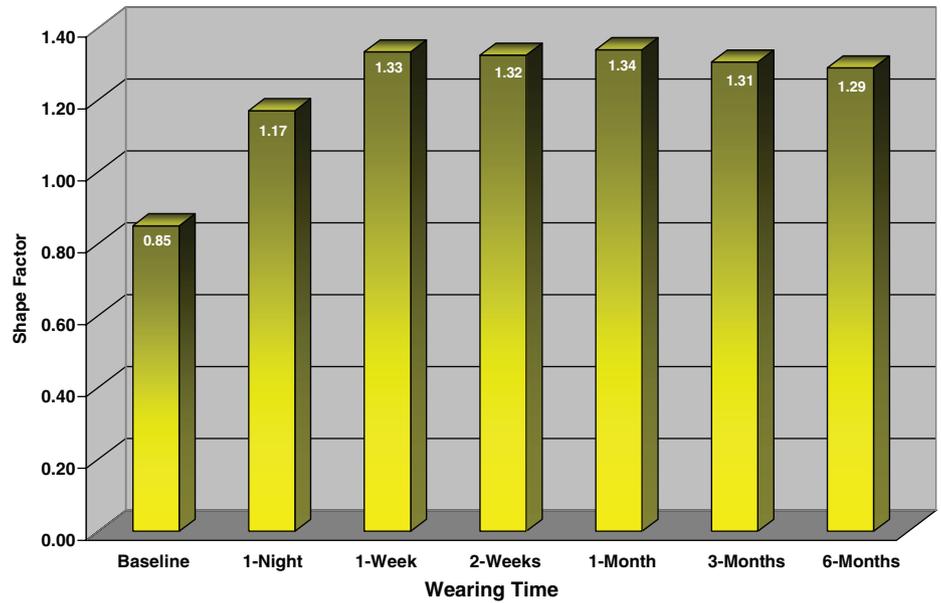


FIG. 5. Change in refractive error as a function of original refractive error.

**FIG. 6.** Changes in corneal topography shape factor ( $1 - e^2$ ) for 20 subjects wearing CKR lenses for overnight orthokeratology during a 6-month period.



darkness without pupil dilation, and the Zernike polynomials were calculated for a 4-mm pupil diameter (Fig. 7). As expected, there was a decrease in lower-order aberrations, primarily defocus, and an increase in higher-order aberrations, primarily coma and spherical aberration. These results were not unexpected and are similar to those found after refractive surgery. As with refractive error, defocus and higher-order aberrations did not change after the 1-month visit (Fig. 8).

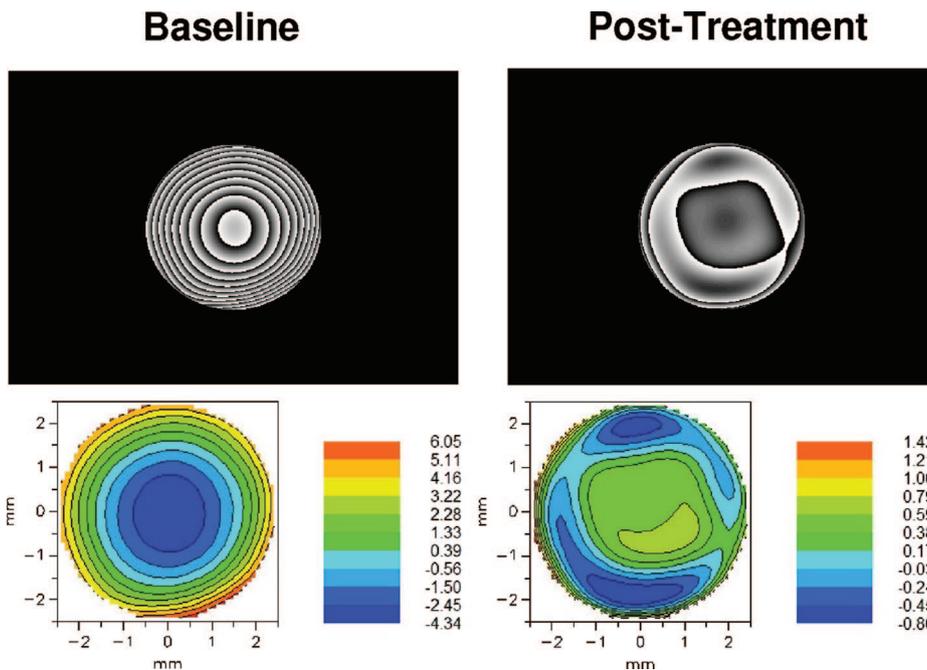
**Confocal Microscopy**

The Nidek ConfoScan3 confocal microscope is a noninvasive instrument that images the cornea. It is a commonly used instrument in highly specialized corneal practices for the express purpose of diagnosis, especially of diseases of the cornea. Each cornea is imaged in nearly 60 seconds with 350 images gathered

throughout the entire corneal thickness at 5- $\mu$ m intervals. The confocal microscopy images showed that there does not appear to be any significant structural changes secondary to orthokeratology (Fig. 9).

**Corneal Thickness**

Corneal thickness measurements were taken with three different instruments: the ConfoScan3, the CorneaGage Plus, and the Orbscan II. The CorneaGage Plus, according to the manufacturer, can measure total and epithelial corneal thickness, whereas the Orbscan II is capable of providing a profile of total corneal thickness across the corneal surface. The ConfoScan3 instrument is not generally used for obtaining corneal thickness measurements, but was said to have that capability.



**FIG. 7.** Change in wavefront before and after CKR treatment.

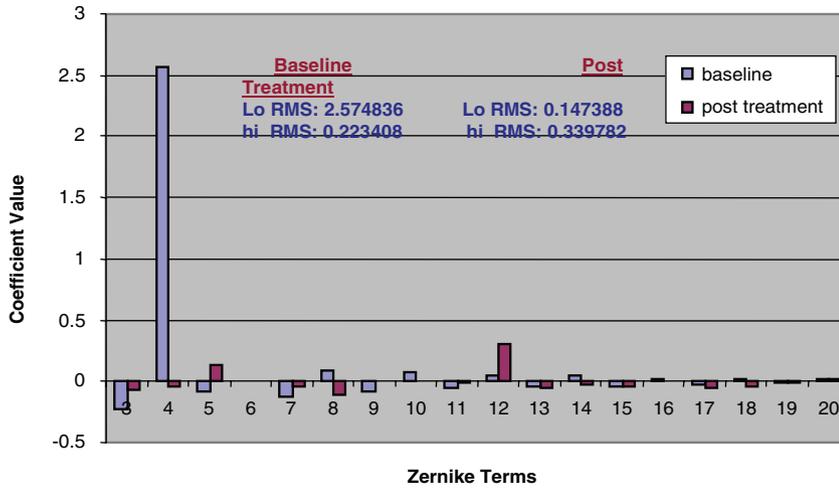


FIG. 8. Zernike coefficients before and after CKR treatment.

The total central corneal thickness was measured with the Orbscan II, ConfoScan 3, and CorneaGage Plus (Fig. 10). The Orbscan II did not detect any significant thickness change over time, nor did it detect differences from baseline and subsequent visits. Total central corneal thickness was unchanged with this instrument. The confocal total

central corneal thickness data are similar to those of the Orbscan II and did not show any thickness change over time, nor did the Orbscan II detect differences from baseline and subsequent visits. Total central corneal thickness was also unchanged with this instrument. The CorneaGage Plus total central corneal thickness did not show thick-

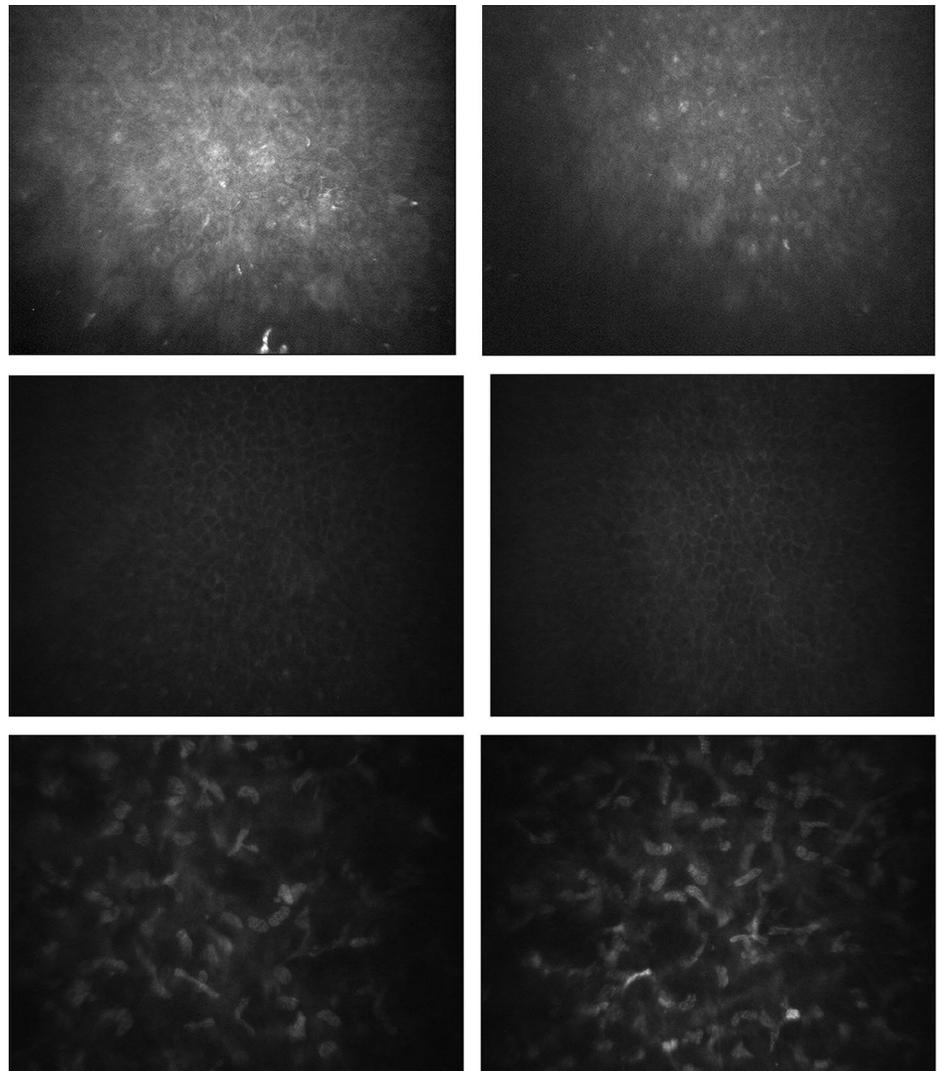
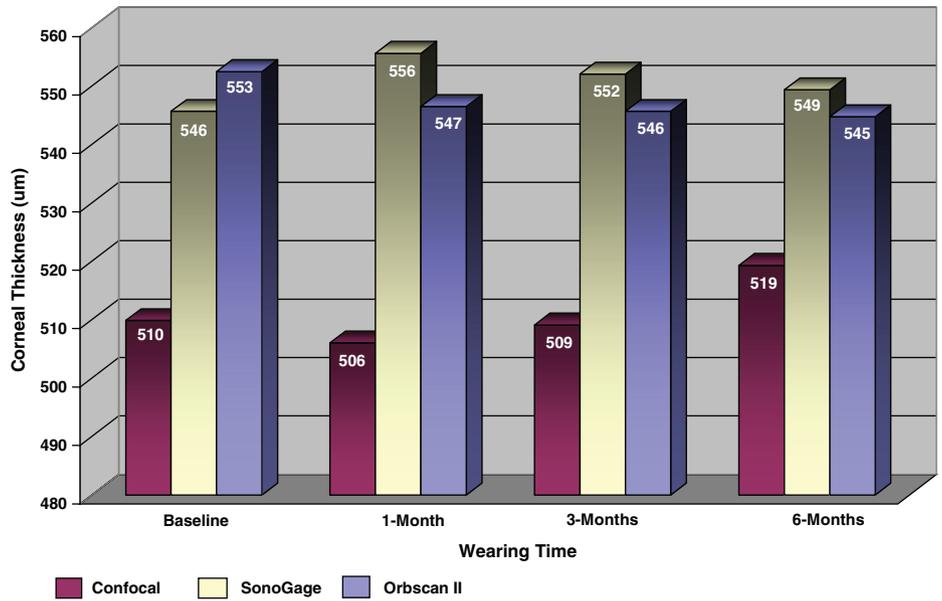


FIG. 9. Confocal microscopy of the corneal epithelium, anterior basal lamina, and anterior stroma before and after CKR treatment.

**FIG. 10.** Total central corneal thickness before and after CKR treatment, as measured with the ConfoScan 3, CorneaGage Plus, and Orbscan II.

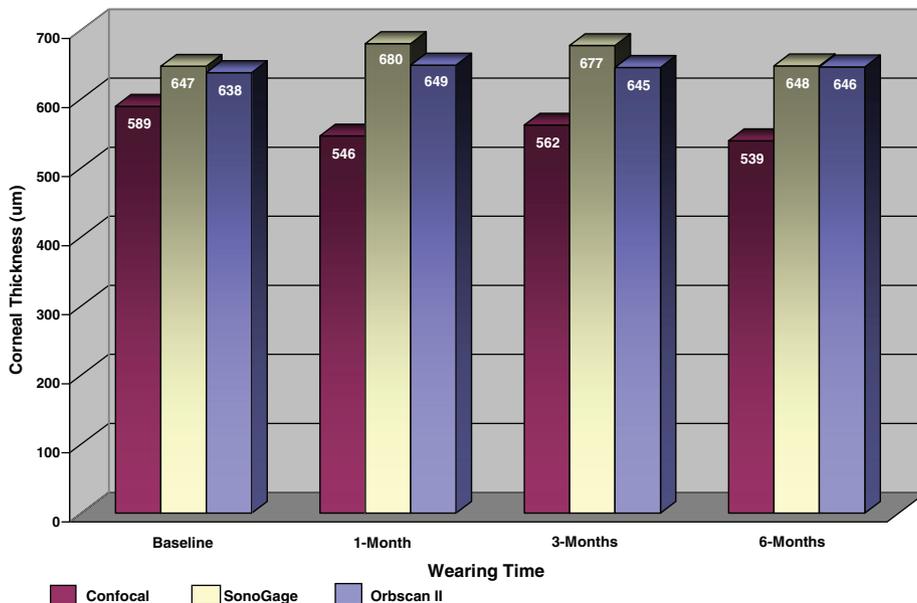


ness change over time, nor did it detect differences from baseline and subsequent visits. Total central corneal thickness was unchanged with this instrument.

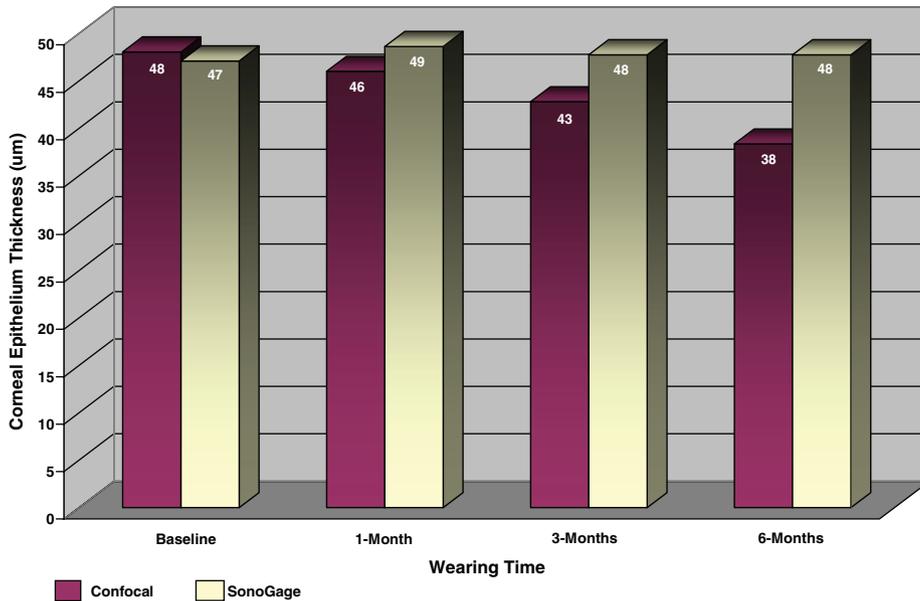
Total inferior corneal thickness was also measured with each instrument (Fig. 11). The Orbscan total inferior corneal thickness did not show thickness change over time, nor did it detect differences from baseline and subsequent visits. Inferior corneal thickness was unchanged with this instrument. The confocal total inferior corneal thickness showed a barely significant inferior thickness change over time, but did not detect differences from baseline and subsequent visits. Values changed by as much as 50  $\mu\text{m}$ , but the change was random over time and did not show a consistent trend. The CorneaGage Plus showed a significant inferior thickness change over time ( $F = 7.92, P < 0.0001$ ), but detected differences from baseline only at the 3-month visit. Values changed by as much as 28  $\mu\text{m}$ , but the change appeared to be random over time and did not show a consistent trend.

When measuring central epithelial thickness, the ConfoScan3 showed a barely significant epithelial thickness change over time by 10  $\mu\text{m}$  and detected a difference from baseline only at the 6-month visit (Fig. 12). There seemed to be a decreasing trend, but it probably was not clinically significant given test-retest variability. The central epithelial thickness with the CorneaGage Plus showed a significant epithelial thickness change over time ( $F = 7.69, P < .0001$ ) by only 1  $\mu\text{m}$  and detected a difference from baseline only at the 1-month visit.

The inferior epithelial thickness with the ConfoScan3 failed to show a significant epithelial thickness change over time, with just 5  $\mu\text{m}$  in variability, and did not detect a difference from baseline and any subsequent visit. The inferior epithelial thickness with the CorneaGage Plus also failed to show a significant epithelial thickness change over time, with less than 1  $\mu\text{m}$  in variability, and did not detect a difference from baseline and any subsequent visit. (Fig. 13).



**FIG. 11.** Peripheral total corneal thickness before and after CKR treatment, as measured with the ConfoScan 3, CorneaGage Plus, and Orbscan II approximately 4.0 mm inferior to the geometric center of the cornea.



**FIG. 12.** Central corneal epithelial thickness before and after CKR treatment, as measured with the ConfoScan 3 and CorneaGage Plus.

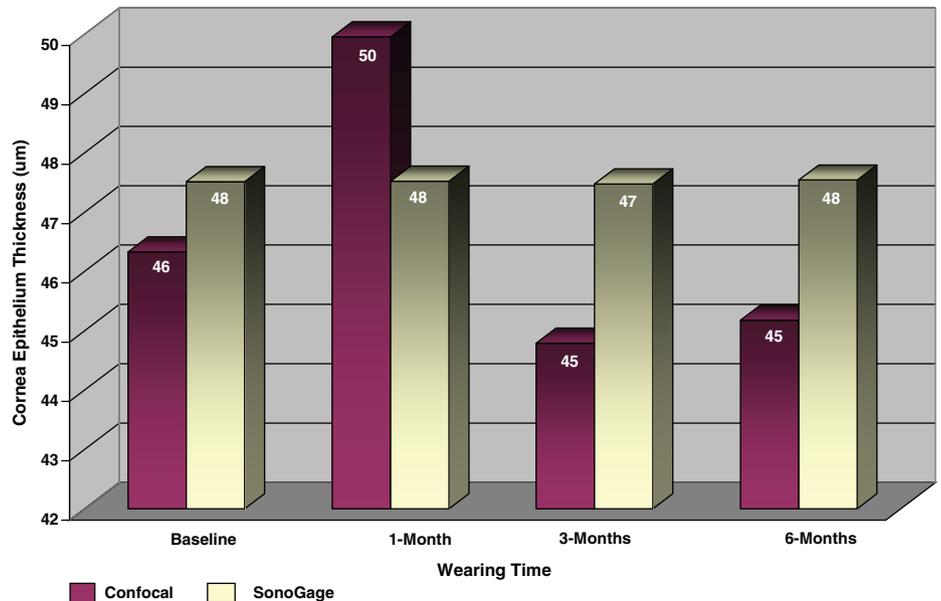
**Subjective Comfort**

Subjects were asked to rate the overall comfort of the lenses on a scale of 0 to 10, with 0 being not tolerable and 10 being unable to feel. Comfort is a subjective estimate, and in this study, there was no control lens. Thus, there could be a bias toward patients giving information to please the investigators (i.e., the halo effect). However, there was a large change ( $F = 75.01, P < 0.0001$ ) in perception of comfort over time, from a mean comfort rating of 2.73 at the initial dispensing visit to 7.30 at the 6-month visit (Fig. 14).

**DISCUSSION**

The mechanism of orthokeratology is not clear. Is it corneal bending? Is it epithelial cell migration? Is it epithelial cell compression? Is it posterior corneal changes, or is it a combination of all of the above? Current evidence supports changes in corneal epithelial thickness as the means by which a refractive error is

reduced. Certainly, the effects of contact lenses on the corneal epithelium have been well documented. Holden et al.<sup>70</sup> showed that a bound silicone elastomer lens resulted in the covered corneal epithelium becoming thinner while the adjacent, uncovered epithelium became thicker. Carkeet et al.<sup>63</sup> measured and compared central and peripheral corneal thickness in spectacle wearers, standard gas-permeable lens wearers, and orthokeratology lens wearers. They did not find any significant difference between the different treatment groups. Iskeleli et al.<sup>71</sup> found a steady decrease in corneal thickness of 17  $\mu\text{m}$  in response to orthokeratology during a 6-month period in 29 subjects. Swarbrick et al.,<sup>64</sup> using the Payor–Holden optical micropachometer, measured the difference in the total and stromal corneal thickness to obtain epithelial corneal thickness at eight locations across the horizontal corneal meridian on six subjects. For each corneal location, they took three measurements. They were the first to show a decrease in total and epithelial ( $7.1 \pm 7.1 \mu\text{m}$ ) central corneal thickness and an increase



**FIG. 13.** Peripheral corneal epithelial thickness before and after CKR treatment, as measured with the ConfoScan 3 and CorneaGage Plus approximately 4.0 mm inferior to the geometric center of the cornea.

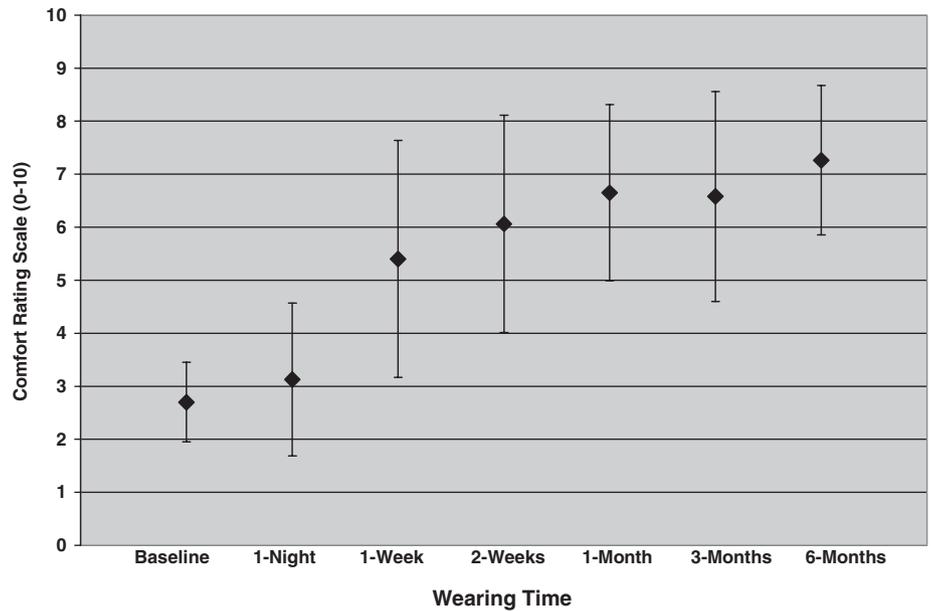


FIG. 14. Subjective comfort rating of the CKR lenses over time.

in midperipheral corneal thickness ( $13.0 \pm 11.1 \mu\text{m}$ ) after 1 month of treatment. Fan et al.<sup>72</sup> measured the corneal thickness of 54 subjects (age range, 11–15 years) with myopia between  $-1.25$  and  $-10.75$  D and astigmatism up to  $-3.00$  D. They did not find any statistically significant difference in total corneal thickness after 6 months when using A-scan ultrasonography. Nichols et al.<sup>73</sup> found a reduction in total corneal thickness with the Orbscan II instrument on 10 subjects during a 60-day treatment period. Chow<sup>74</sup> measured corneal thickness on 593 subjects by using an ultrasound pachometer and found an average reduction in corneal thickness of  $34.8 \pm 19.0 \mu\text{m}$ . Mitsui et al.,<sup>75</sup> measuring the corneal thickness on 60 subjects by using the Orbscan II, found an increase in central corneal thickness of  $18 \mu\text{m}$  and an increase at the periphery of  $22 \mu\text{m}$ . Wang et al.,<sup>76</sup> using an optical coherence tomography system, measured the effect of Corneal Refractive Therapy contact lenses (Paragon Vision Sciences, Inc., Meza, AZ) on corneal thickness, as compared to a control group wearing regular gas-permeable lenses. They found a central epithelial thinning of  $5.1\% \pm 4.9\%$  and midperipheral thickening of  $1.9\%$  on the temporal side and  $2.4\%$  on the nasal side of the cornea. There was no change in the control group wearing standard gas-permeable lenses. Although the percentage of standard deviation is almost equal to the percentage of the corneal thinning, the change was found to be statistically significant ( $P=0.005$ ). In reviewing the findings of the aforementioned authors (Table 1), five groups of researchers found a decrease in corneal thickness; two groups did not find any change; and one group found an increase in corneal thickness with orthok-

eratology treatment. Perhaps the variation in the results reflects the inherent physical limitations of the instrument used to measure corneal thickness. It would be expected that confocal microscopy is a more appropriate method in measuring the total corneal thickness, including the epithelial layer. However, the accuracy of measuring corneal thickness may vary among different confocal microscopes.<sup>77</sup> Perhaps the difference in instrumentation could explain why no statistically significant reduction in epithelial or total corneal thickness was found in the current study. Also, the Sonogage ultrasound pachometer did not show any significant variation in the epithelium measurements or total corneal thickness measurements. The scanning slit optical pachymeter (i.e., Orbscan II) likewise did not show any statistically significant reduction in total corneal thickness. In summary, confocal microscopy, ultrasound pachymetry, and optical pachymetry did not show any statistically significant changes in corneal thickness.

Corneal topography showed a shift from a prolate to oblate ellipsoidal shape and showed a good correlation with changes in refractive error. As shown in Figures 4 and 6, as myopia decreased over time, shape factor increased. Aberrometry showed a decrease in defocus and an increase in higher-order aberrations (i.e., third- and fourth-order aberrations). This result was not unexpected and is similar to results found after myopic refractive surgery. Recently, Joslin et al.<sup>78</sup> also found an increase in spherical aberration and coma after orthokeratology. The increase in spherical aberration is attributed to the change of the corneal shape from a prolate to an oblate shape. The increase in coma could be the result of slight decentration of the treatment zone. Most subjects had functional vision after the first night of lens wear.

TABLE 1. Corneal Thickness Measurements in Orthokeratology Patients From Eight Investigators

Authors	Increase	Decrease	No change
Carkeet et al. <sup>63</sup>			+
Iskeleli et al. <sup>71</sup>		+	
Swarbrick et al. <sup>64</sup>		+	
Fan et al. <sup>72</sup>			+
Nichols et al. <sup>73</sup>		+	
Mitsui et al. <sup>75</sup>	+		
Chow <sup>74</sup>		+	
Wang et al. <sup>76</sup>		+	

CONCLUSION

The CKR empirical lens design is an effective and safe method for temporarily reducing myopia and improving unaided visual acuity. The amount of myopia reduction found at the 1-week visit was clinically insignificant from the 1-month results, indicating that the full effect is achieved after 1 week. There is an increase in higher-order aberrations, primarily coma and spherical aberration (i.e., third and

fourth order of Zernike polynomial), with a decrease in lower-order aberration, primarily defocus (second-order aberration).

Changes in total and epithelial corneal thickness measurements using different instrumentation are contrary to the results of many other researchers.<sup>79,80</sup> Epithelial and total corneal thickness measurements showed variations as a function of the instrumentation used and the time of measurements. For instance, the Orbscan II system showed central corneal thickness results different from the CorneaGage Plus and ConfoScan3. The ConfoScan 3 results showed a small decrease in central corneal epithelial thickness and a slight increase in peripheral epithelial thickness noted at the 3-month visit (Figs. 12 and 13). However, the large variance in the data prevents any conclusive statements regarding epithelial thickness. The ConfoScan 3 showed a greater level of variability in epithelial thickness measurements, whereas the CorneaGage Plus did not. Data are similar for each instrument used in assessments of corneal thickness. In view of these results, no clear differences in total or epithelial corneal thickness were noted over time.

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