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The Effect of Overnight Contact Lens Corneal Reshaping on Higher-Order Aberrations and Best-Corrected Visual Acuity

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ABSTRACT: *Purpose.* The purpose of this study is to determine the effect of higher-order aberrations after Corneal Refractive Therapy (CRT) on best-corrected visual acuity (BCVA) and the impact of pupil size on BCVA. *Methods.* High-contrast (HC) and low-contrast (LC) Bailey-Lovie BCVA was measured in the morning before and after pupil dilation on 20 myopes (mean spherical equivalent –3.11 D ± 0.96 D) under age 40. BCVA was measured again in the afternoon after dilation. Dilated am and pm aberrations were measured using the Complete Ophthalmic Analysis System (WaveFront Sciences). Patients were fit with CRT lenses in each eye. One month after finalizing the lens fit, BCVA and aberration testing were repeated. Average higher-order RMS error (third to sixth order), spherical aberration, third-, fourth-, fifth-, and sixth-order RMS error were calculated at each visit for a 3-mm and 5-mm pupil. BCVA and aberration data were analyzed using a repeated measures analysis of variance. Linear regression was used to describe the relationship between aberrations and BCVA reductions after CRT. *Results.* Mean refractive error changed by +3.33 D ± 0.96 D. No clinically significant changes were found in HC BCVA post-CRT, whereas LC BCVA reductions of 0.07 logarithm of the minimum angle of resolution (logMAR) (nondilated, $p = 0.002$) and 0.12 logMAR (dilated, $p < 0.001$) were found. No additional decrease in HC BCVA was found after pupil dilation, whereas a mean additional decrease of 0.08 logMAR in LC BCVA was found with dilation post-CRT ($p = 0.013$). Higher-order RMS error increased for both 3-mm and 5-mm pupils ($p < 0.0001$) and remained stable between measurements. Spherical aberration increased for 5-mm pupils after CRT ($p < 0.0001$). For a 5-mm pupil, a 0.1-μm increase in spherical aberration was associated with an additional decrease in LC BCVA after pupil dilation post-CRT of 0.056 logMAR ($R^2 = 0.382$, $p = 0.004$). *Conclusions.* CRT results in reduced low-contrast BCVA as a result of increased higher-order aberrations. Higher-order aberrations appear to be relatively stable after CRT. Spherical aberration appears to drive additional low-contrast BCVA losses as pupil size increases. (Optom Vis Sci 2005;82:490–497)

Key Words: higher-order aberrations, overnight corneal reshaping, best-corrected visual acuity, spherical aberration, corneal refractive therapy, orthokeratology

Overnight orthokeratology is the temporary reduction of myopia achieved by reshaping the cornea using a specially designed rigid gas-permeable (RGP) contact lens that is worn overnight. After wearing their lenses overnight and removing them the next morning, patients should be able to see throughout the day without spectacles or contact lenses. The first mention in the literature of using rigid lenses to intentionally flatten the corneal apex was by Jessen in 1962.[1,2] Recent innovations in contact lens design, computerized custom lathing, and advances in gas-permeable contact lens materials have led to renewed interest in this procedure. The term "accelerated" orthokeratology was first used in 1989 to describe reverse geometry orthokeratology lenses that provide rapid achievement of corneal and refractive changes.[3,4]

In 2002, Corneal Refractive Therapy (CRT; Paragon Vision Sciences, Mesa, AZ) became the first contact lens procedure approved by the U.S. Food and Drug Administration (FDA) for overnight corneal reshaping in the United States. Studies of this modality of myopia correction have found it to be a safe and effective means of correction in adults, adolescents, and children.[5–7] Although this procedure has gained some popularity as an alternative to refractive surgery as a result of its reversibility, its influence on higher-order aberrations (those aberrations that cannot be corrected by a spectacle prescription) has not been fully established.

The overall change in corneal shape in CRT, including central corneal thinning,[8,9] is similar to the general shape changes in patients undergoing photorefractive keratectomy (PRK) and laser *in situ* keratomileusis (LASIK). In general, the central cornea is flattened in these procedures.[9,10] Both PRK and LASIK have been shown to significantly increase higher-order aberrations as a result of these shape changes.[11–13] In these studies, spherical aberration was found to be the predominant aberration induced as pupil size increased. Oliver et al.[13] derived modulation transfer functions for PRK patients based on the corneal profile change and indicated that the calculations suggest a significant loss in visual performance. A study examining visual acuity 1 year after PRK found a mean reduction in high-contrast best-corrected visual acuity (BCVA) of half a line and a mean reduction in low-contrast BCVA of 1½ lines.[14] Greater reductions in BCVA were present with pupil dilation and the introduction of a glare source.

With the recent development of clinical Hartmann-Shack wavefront sensors that are capable of measuring the aberration profile of the human eye, there has been great interest in determining the aberrations induced by current methods of refractive error correction. Quantifying the aberrations induced by a mode of correction is important because of their impact on visual acuity and visual quality. One published study found an increase in higher-order aberrations after CRT, especially spherical aberration.[15] After 1 month of treatment, significant mean increases in higher-order aberrations of 0.0567 μm and 0.4246 μm were reported for both a 3-mm and 6-mm pupil diameter, respectively. Spherical aberration (Z_4^0) was the Zernike coefficient demonstrating the greatest increase for a 6-mm pupil and increased from 0.084 ± 0.16 to 0.39 ± 0.16 μm. This study also found a significant increase in horizontal coma (Z_1^3) for a 6-mm pupil. However, this study did not evaluate the stability of higher-order aberrations after wearing CRT lenses. In addition, the impact of higher-order aberrations on BCVA as a function of pupil size was not measured.

Most previous examinations of overnight corneal reshaping have used uncorrected visual acuity and nondilated manifest refractions to measure how successfully the procedure reduces myopia. Although these outcomes are vital to understanding the effectiveness of the procedure, it does not address its impact on best potential vision. In addition, visual acuity measurements through habitual photopic pupil sizes fail to describe the impact of the procedure on vision when the pupil dilates, such as under mesopic and scotopic conditions.

By measuring BCVA through both a nondilated and dilated pupil, it is possible to eliminate residual lower-order aberrations allowing us to clinically measure the impact of induced higher-order aberrations on BCVA as pupil size increases. One study thus far has reported that high-contrast BCVA at both high and low illumination was not significantly reduced after 1 month of overnight corneal reshaping. However, low-contrast BCVA was significantly reduced by two letters under high illumination and by five letters under low illumination.[16] The greater reduction in low-contrast BCVA under low illumination suggests that increased higher-order aberrations play a role in the additional acuity reduction.

Studies of the retention and regression of orthokeratology with time have found that the amount of myopic regression appeared to stabilize between −0.25 D and −0.75 D during the day after 90 days of treatment.[17,18] This suggests that subjective visual fluctuation[16] could be a combination of myopic regression during the day, induced higher-order aberration instability, and the impact of higher-order aberrations as pupil size increases. Nichols et al. in 2000[19] reported that the majority of corneal and refractive change occurred within the first 7 days of overnight orthokeratology and leveled off by 30 days. In a study by Soni et al. in 2003[8] evaluating visual and corneal changes after overnight orthokeratology, they found that all corneal and visual changes had reached a maximum level and remained relatively stable throughout the day by the end of 1 week of wear. Therefore, we hypothesize that higher-order aberrations reach a level of stability similar to that of prefit stability after 1 month of lens wear and that subjective fluctuation is a combination of both myopic regression and the impact of induced higher-order aberrations on BCVA as a function of pupil size. The ultimate goal of this study was to determine whether subjectively reported visual fluctuation after CRT is the result of myopic regression throughout the day, the instability of induced higher-order aberrations, the impact of higher-order aberrations as pupil size increases, or a combination of these factors.

METHODS

Subjects

Twenty healthy myopic patients between 21 and 37 years of age (mean ± standard deviation = 27 ± 5) were fit with Paragon CRT lenses (manufactured in Paragon HDS 100 material) in each eye. Of the subjects, five (25%) were male and 15 (75%) were female. To be eligible for the study, all subjects were between the ages of 18 and 39 and were free of ocular disease. In each eye, subjects had –1.00 D to –6.00 D of myopia, had no more than –1.25 D of astigmatism, were correctable to 20/20, and had flat keratometry readings of >41.00 D. The average initial refractive M value (spherical equivalent) was –3.11 D ± 0.96 D and ranged from –1.00 D to –5.50 D. The study protocol was approved by the Institutional Review Board at The Ohio State University and followed the tenets of the Declaration of Helsinki. Patients were provided the informed consent document and were required to review and sign this form before beginning any testing. A total of 24 patients were consented and examined; however, only 20 patients met the eligibility criteria.

Study Design

One month was chosen as the study length as a result of general agreement in the literature that the corneal reshaping effect is stable by this time.[8,17,19] Morning and afternoon visits separated by at least 6 hours were performed at baseline at which the aberrations of each dilated eye were measured. Patients were then fit in CRT lenses in each eye following the manufacturer's fitting guide. The lens fit was considered finalized after 1 week of successful overnight wear in the same CRT lens parameters. One month after finalizing the lens fit, the aberrations of each dilated eye were again measured in the morning and afternoon.

Wavefront measurements were made using the previously validated Wavefront Sciences Complete Ophthalmic Analysis System

(COAS) G200 (Albuquerque, NM) following the manufacturer's recommended protocol.[20] At each visit, eight dilated measurements (1% tropicamide and 2.5% phenylephrine) were made per eye within 1 minute and the average of each Zernike coefficient (third through sixth order) was determined. All Zernike coefficients were reported using Optical Society of America (OSA) standards.[21] The average Zernike coefficients at each visit were used to calculate root mean squared (RMS) error for total higher-order aberrations (third through sixth order), higher-order aberrations excluding spherical aberration (Z_4^0) and secondary spherical aberration (Z_6^0), third order only, fourth order only, fifth order only, and sixth order only. The average Zernike coefficient for spherical aberration (Z_4^0) was also included in subsequent analyses. All values were calculated for both a 3-mm and 5-mm pupil diameter. The maximum pupil diameter of 5 mm was determined by evaluating each Hartmann-Shack spot image and finding the one with the smallest analyzable image diameter as determined by the COAS.

Monocular nondilated high- and low-contrast BCVA was measured at the morning visits and dilated high- and low-contrast BCVA was measured at both the morning and afternoon visits. All visual acuity measurements were measured through a phoropter. Bailey-Lovie visual acuity charts (high contrast = 100% and low contrast = 10% Michaelson contrast) were read under photopic conditions (chart illumination = 75–110 cd/m^2) following the protocol established by the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study and reported in logMAR.[22] Best correction for each visual acuity measure was determined by a standardized manifest refraction performed by the same clinician.[23] All refractive data were converted to vector notation (M, J_0, J_{45}) for the purpose of analysis.[24]

Data Analysis

All statistical analyses were performed using SAS version 8.02 software. So that data collected on both eyes could be properly used, eye (OD or OS) was included as a factor in each repeated-measures analysis of variance to account for the covariance between eyes. If no significant interaction with the eye factor was found, the data for right and left eyes were averaged for any necessary posthoc analyses. If a significant interaction with eyes was present, post hoc comparisons were performed separately for right and left eyes. Post hoc t-test comparisons were performed using the method described by Tukey and the appropriate mean square error from the analysis of variance. Statistical significance for all repeated-measures analyses of variance was set at $p < 0.05$.

Other than eye (OD or OS), the other potential factors included in each repeated-measures analysis of variance when appropriate were visit (baseline or 1 month post-CRT), time (am or pm) and condition (nondilated or dilated pupil). Repeated-measures analyses of variance were used to determine if significant changes existed in the nondilated manifest refractive data collected at the baseline and 1 month am visits as well as the dilated manifest refractive data collected at the am and pm visits at both baseline and 1 month. All analyses of logMAR visual acuity data were performed for both high- and low-contrast BCVA. A repeated-measures analysis of variance was performed to examine differences in dilated BCVA at the am and pm visits at both baseline and 1 month as well as to determine whether significant differences in BCVA were present between the baseline and 1-month am measurements when measured through a nondilated and dilated pupil.

All RMS error analyses were performed for both a 3-mm and 5-mm pupil diameter. Repeated-measures analyses of variance were performed to examine differences in RMS error and spherical aberration (Z_4^0) at the am and pm visits at baseline and 1 month. For all 5-mm pupil Zernike coefficients other than spherical aberration (Z_4^0), additional paired t-tests were used to determine if changes existed between baseline and post-CRT values with significance set at $p < 0.01$.

Pearson correlation coefficients were calculated to examine the relationship between the am change in both higher-order RMS error and spherical aberration (Z_4^0) for a 5-mm pupil diameter and the change from baseline to 1 month in the difference between dilated and non-dilated low-contrast BCVA measured at the am visit (i.e., the change in BCVA as pupil size increases). If no significant eye effect was noted in the repeated-measures analysis of variance performed for each calculated aberration value, right and left eye data were averaged for the correlation analyses. Pearson correlation coefficients were also calculated to assess the strength of the relationship between the change in both higher-order RMS error and spherical aberration (Z_4^0) for a 5-mm pupil and changes in dilated low-contrast BCVA as well as initially treated refractive M. A Bonferroni correction was used to adjust the p value necessary to be considered statistically significant to $p < 0.008$. If a correlation was deemed to be clinically significant, a linear regression analysis was conducted to obtain parameter estimates to further describe the relationship.

RESULTS

In all of the following results, unless specifically stated otherwise, no significant interaction between eyes was found in each repeated-measures analysis of variance performed.

Refractive Error

No significant changes in the astigmatism terms J_0 ($p = 0.72$) or J_{45} ($p = 0.14$) were present when examining the am nondilated manifest refractions. There was a significant reduction in M (i.e., a decrease in myopia) 1 month post-CRT of +3.33D ± 0.96 D ($p < 0.001$).

Dilated manifest refractions were performed at the am and pm visits at both baseline and 1 month. After CRT, there were no significant changes in either the amount of J_0 ($p = 0.81$) or the stability of J_0 throughout the day ($p = 0.98$). There were also no significant changes in either the amount of J_{45} ($p = 0.85$) or the stability of J_{45} throughout the day ($p = 0.54$). There was a significant reduction in myopia after CRT; however, the amount of myopia reduction depended on the time of day the refraction was done ($p = 0.007$). A significant positive change in M was found for both the am (+3.20 ± 0.86 D, $p < 0.001$) and pm (+3.04 ± 0.78 D, $p < 0.001$) dilated manifest refractions 1 month post-CRT. However, although refractive M was stable between the am and pm visits before CRT ($p = 0.41$), a significant increase in myopia of −0.20 D ± 0.27 D was found from the am to pm visit 1 month post-CRT ($p < 0.001$).

Best-Corrected Visual Acuity

Nondilated BCVA was measured at both the baseline and 1-month post-CRT am visits. No change was found in nondilated high-contrast BCVA after CRT (p = 0.32). A statistically significant decrease in nondilated low-contrast BCVA of 0.07 ± 0.02 logMAR was measured after CRT (p = 0.002), a loss of nearly four letters.

Dilated BCVA was measured at the baseline and 1-month post-CRT am and pm visits (Fig. 1). There was no significant difference between am and pm high-contrast BCVA measurements before or after CRT (p = 0.25). Although a significant decrease in dilated high-contrast BCVA of 0.02 logMAR was found post-CRT (p = 0.033), this change corresponds to a single letter loss in acuity and may not be clinically meaningful.

When examining dilated low-contrast BCVA, a marginally significant improvement of 0.03 logMAR was found between am and pm measurements (p = 0.049). However, although the visit-by-time interaction term is marginally below significance (p = 0.052), further analysis of these data show that no mean change in dilated low-contrast BCVA was present at baseline and that an improvement of 0.06 logMAR (three letters) was present from am to pm 1-month post-CRT (Table 1). Of greater statistical and clinical significance is that, regardless of time of day, CRT resulted in a reduction in low-contrast BCVA of more than one line (0.12 logMAR, $p < 0.001$).

When examining the difference between nondilated and dilated am high-contrast BCVA measurements, there was a significant decrease after pupil dilation ($p < 0.001$) regardless of CRT treatment (p = 0.38). On average, high-contrast BCVA decreased from −0.11 ± 0.05 to −0.07 ± 0.05 logMAR after dilation, an average decrease in acuity of two letters (0.04 ± 0.05 logMAR, $p < 0.001$). Thus, CRT does not appear to impact high-contrast visual acuity changes related to increases in pupil size.

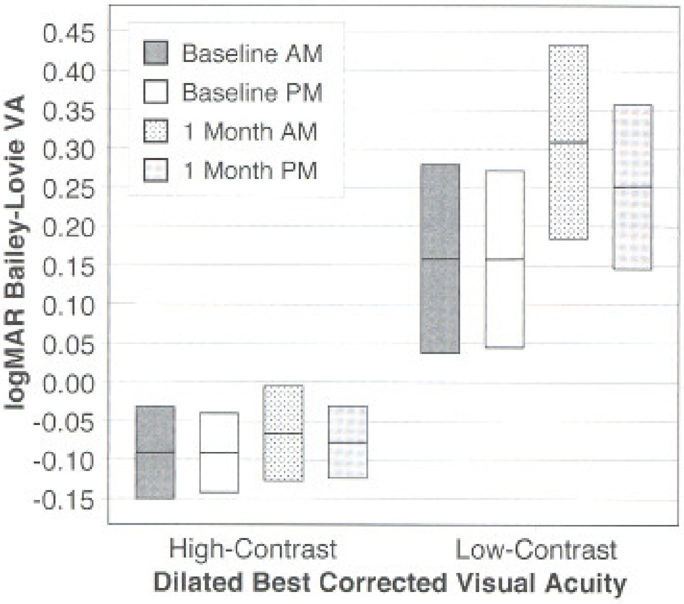

FIGURE 1.

Dilated high- and low-contrast Bailey-Lovie BCVA (mean ± standard deviation) measurements at the am and pm visits at both baseline and 1 month post-CRT are shown. A clinically significant reduction in low-contrast BCVA was noted after CRT of 0.12 logMAR (six letters; $p < 0.001$). A marginally significant improvement (p = 0.049) in low-contrast BCVA from the am to the pm visit was found. Although CRT did not statistically appear to impact this improvement (p = 0.052), no mean change in low-contrast BCVA was present at baseline, whereas a 0.06-logMAR (three-letter) improvement was present from am to pm 1 month post-CRT.

The reduction in low-contrast BCVA after dilating the pupil was significantly impacted by CRT (p = 0.013). The average decrease in low-contrast BCVA increased from 0.11 ± 0.09 logMAR ($p < 0.001$) to 0.19 ± 0.12 logMAR ($p < 0.001$) post-CRT representing an additional four-letter loss after CRT when pupil size increases. The difference between dilated and nondilated BCVA was significantly different between right and left eyes (p = 0.022); however, the difference in acuity between eyes was not significantly related to the comparison of BCVA at the baseline visit and the 1-month post-CRT visit (p = 0.27). In other words, regardless of the eye considered, an additional decrease in low-contrast BCVA was present post-CRT after pupil dilation in both right (0.06 logMAR, three letters) and left eyes (0.10 logMAR, five letters).

Aberrations for a 3-mm Pupil Diameter

The average RMS error values at each of the baseline and 1-month post-CRT visits are listed in Table 2.

For a 3-mm pupil, significant increases in higher-order RMS error were found for all calculated outcomes after CRT except the spherical aberration term (Table 3). After excluding spherical aberration (Z_4^0) and secondary spherical aberration (Z_6^0) from the higher-order RMS calculation, little reduction in the change in RMS error after CRT is observed (Table 3). Aberration measurements had the same level of stability from am to pm at both baseline and post-CRT with the exception of fifth-order and sixth-order RMS error. Although no difference was found between am and pm measurements for fifth-order (p = 0.89) and sixth-order (p = 0.51) RMS error at baseline, both showed a slight decrease from am to pm at 1 month (−0.003 µm; p = 0.008 and −0.001 µm; p = 0.033, respectively). The small post-CRT am to pm changes for both fifth- and sixth-order RMS error, although having statistical significance, may not be clinically significant. When included with the other higher-order aberration terms, the fifth- and sixth-order terms do not result in a statistically significant impact on higher-order RMS (third to sixth order) stability after CRT (p = 0.12).

Aberrations for a 5-mm Pupil Diameter

For a 5-mm pupil, statistically significant increases in higher-order RMS error were present for all calculated outcomes after CRT (Table 3). Aberration measurements were stable from am to pm at both baseline and post-CRT with the exception of spherical aberration. Although a significant difference was not found in spherical aberration (Z_4^0) between am and pm measurements at baseline (p = 0.60), a significant increase from am to pm was found post-CRT (0.025 µm; p = 0.0082). Spherical aberration increased on average by up to 0.186 µm post-CRT ($p < 0.0001$). When examining the 5-mm pupil Zernike coefficients (Fig. 2),

TABLE 1.

Changes in dilated low-contrast BCVA (logMAR) over time of day (am or pm) and visit (baseline or 1-month post-CRT) demonstrating a reduction of six letters after CRT and a borderline significant but weak improvement in BCVA from am to pm 1-month post-CRT

Dilated best-corrected low-contrast VA	Baseline (BL)	1 month post-CRT (1M)	Change (1M-BL)	Average 1M-BL change
AM	0.16 ± 0.12	0.31 ± 0.12	0.15 ± 0.16	0.12 ± 0.15
PM	0.16 ± 0.11	0.25 ± 0.11	0.09 ± 0.14	($p < 0.001$)
Change (PM–AM)	0.00 ± 0.09	−0.06 ± 0.12		
Average PM–AM change	−0.03 ± 0.11 ($p = 0.049$)		Visit * time interaction ($p = 0.052$)	

BCVA, best-corrected visual acuity; CRT, Corneal Refractive Therapy; VA, visual acuity.

TABLE 2.

Average wavefront error at the am and pm visits at both baseline and 1-month post-CRT

		3-mm pupil				5-mm pupil			
Average OD and OS (microns)	Time	Baseline		1 Month post-CRT		Baseline		1 Month post-CRT	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Higher-Order RMS	AM	0.053	0.02	0.088	0.04	0.147	0.04	0.330	0.12
	PM	0.052	0.01	0.077	0.03	0.157	0.05	0.334	0.12
Higher-Order RMS Without Z_4^0 & Z_6^0	AM	0.049	0.02	0.081	0.04	0.133	0.04	0.231	0.08
	PM	0.049	0.01	0.074	0.03	0.143	0.05	0.224	0.09
Spherical aberration (Z_4^0)	AM	0.012	0.01	0.018	0.03	0.045	0.04	0.202	0.14
	PM	0.009	0.01	0.007	0.02	0.041	0.05	0.227	0.12
Third-order RMS	AM	0.040	0.02	0.069	0.04	0.115	0.04	0.193	0.08
	PM	0.040	0.01	0.065	0.03	0.124	0.05	0.190	0.09
Fourth-order RMS	AM	0.027	0.01	0.042	0.02	0.077	0.03	0.233	0.12
	PM	0.024	0.01	0.031	0.01	0.080	0.03	0.245	0.11
Fifth-order RMS	AM	0.015	0.01	0.021	0.01	0.030	0.01	0.069	0.04
	PM	0.015	0.01	0.018	0.01	0.028	0.01	0.061	0.03
Sixth-order RMS	AM	0.010	0.00	0.014	0.01	0.024	0.01	0.059	0.03
	PM	0.011	0.00	0.013	0.00	0.024	0.01	0.055	0.02

CRT, Corneal Refractive Therapy; SD, standard deviation; RMS, root mean squared.

spherical aberration (Z_4^0) is the Zernike coefficient with the greatest impact on the increase in higher-order aberrations. The only other individual Zernike coefficient with a statistically significant increase 1 month post-CRT was secondary spherical aberration (Z_6^0), which increased by 0.0406 ± 0.0302 μm ($p < 0.001$). After excluding spherical aberration (Z_4^0) and secondary spherical aberration (Z_6^0) from the higher-order RMS calculation, a large reduction in the change in RMS error after CRT is observed (Table 3).

Linear Regression Analyses

Linear regression analysis was performed on the two Pearson correlation coefficients significant after Bonferroni correction ($p < 0.008$). For a 5-mm pupil, every 0.1-μm increase in spherical aberration (Z_4^0) after CRT accounts for an additional 0.056-logMAR reduction in low-contrast BCVA after pupil dilation, again suggesting that spherical aberration is a significant driving force in the additional reduction in low-contrast BCVA as pupil size increases after CRT ($R^2 = 0.382$, $p = 0.004$). For a 5-mm pupil, every 0.1-μm increase in higher-order RMS error resulting from CRT is associated with an additional reduction in dilated low-contrast BCVA of 0.076 logMAR ($R^2 = 0.343$, $p = 0.007$).

Central Corneal Staining

The percentage of eyes with any detectable corneal staining in the central corneal area was determined at each visit. At baseline, 2.5% of eyes exhibited central staining at the am visit and 2.5% exhibited central staining at the pm visit. One month post-CRT, 27.5% of eyes exhibited central staining at the am visit and 10% of eyes exhibited central staining at the pm visit.

DISCUSSION

With the recent FDA approval of multiple contact lenses for overnight corneal reshaping, it is important to understand fully the impact of this procedure on visual acuity and visual quality. Only one previously published study examined the impact of corneal reshaping on higher-order aberrations.[15] Although this study showed an overall increase in higher-order aberrations, the impact of these aberrations on BCVA was not studied. Understanding the stability of these aberrations is also necessary to determine whether they play a role in subjective visual fluctuation. In addition to the stability of higher-order aberrations, factors that could impact subjective vision include myopic regression throughout the day and

TABLE 3.

Changes in higher-order root mean squared (RMS) wavefront error and spherical aberration (1 month post-CRT – baseline) for both a 3-mm and 5-mm pupil diameter are shown for those outcomes that were stable from am to pm both before and after Corneal Refractive Therapy (CRT)[a]

	3-mm pupil			5-mm pupil		
Outcome (in microns)	Change ± SD (post–pre)	p Value	Factor change (post/pre)	Change ± SD (post–pre)	p Value	Factor Change (post/pre)
HO RMS (third to sixth)	0.030 ± 0.02	< 0.0001	1.57	0.180 ± 0.09	< 0.0001	2.18
HO RMS w/o Z_4^0 & Z_6^0	0.029 ± 0.02	< 0.0001	1.58	0.090 ± 0.05	< 0.0001	1.65
Spherical Ab (Z_4^0)	0.002 ± 0.02	0.63	1.19	CRT caused aberration instability (p = 0.024)		
Third-order RMS	0.027 ± 0.03	0.0002	1.68	0.072 ± 0.06	< 0.0001	1.60
Fourth-order RMS	0.011 ± 0.01	0.0004	1.43	0.161 ± 0.11	< 0.0001	3.04
Fifth-order RMS	CRT caused aberration instability (p = 0.039)			0.036 ± 0.03	< 0.0001	2.24
Sixth-order RMS	CRT caused aberration instability (p = 0.049)			0.033 ± 0.02	< 0.0001	2.38

[a] The only aberration outcome that did not significantly increase after CRT was spherical aberration calculated for a 3-mm pupil diameter; however, spherical aberration did significantly increase for a 5-mm pupil diameter. Although all aberrations were stable from am to pm at baseline, CRT resulted in significant changes from am to pm 1 month post-CRT in fifth- order and sixth-order RMS error for a 3-mm pupil diameter and for spherical aberration for a 5-mm pupil diameter.

SD, standard deviation; HO, higher-order.

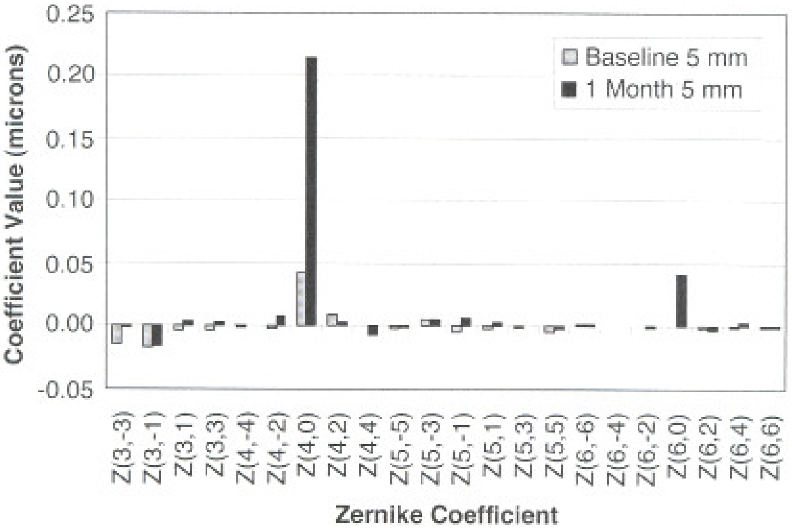

FIGURE 2.

Average Zernike coefficient values at baseline and 1 month post-CRT for a 5-mm pupil diameter. Spherical aberration (Z_4^0) and secondary spherical aberration (Z_6^0) are the aberrations that showed the greatest change. Spherical aberration appears to be the major aberration driving the increase in higher-order aberrations after CRT.

fluctuations in optical quality secondary to pupil size changes[25] after increased levels of higher-order aberrations are induced by CRT.

As a side note, although all analyses discussed here included both right and left eyes using the proper statistical methods, the same results are found when examining BCVA, higher-order aberrations, and manifest refractive data if the analyses are repeated using only right eyes.

Higher-Order Aberration Changes

As expected, total higher-order aberrations significantly increased for both 3-mm and 5-mm pupil diameters after CRT confirming previous study findings.[15] Furthermore, spherical aberration appears to be the most influenced aberration contributing to the increase in higher-order RMS error as pupil size increases. For a 3-mm pupil, spherical aberration does not seem to play a large role in the increase in higher-order aberrations, which was expected because spherical aberration does little to impact optical quality in the center of an optical system. However, once pupil size increases to 5 mm, spherical aberration (Z_4^0) and secondary spherical aberration (Z_6^0) are the predominant aberrations resulting in the increase in RMS error. Spherical aberration (Z_4^0) significantly increased from approximately 0.043 μm to 0.215 μm, a finding consistent with that of Joslin et al. in 2003.[15] Unlike their study, no significant increase was found in horizontal coma (Z_3^1), which may have resulted from lens decentration in their study.

Higher-order aberrations for a 3-mm pupil appear to maintain a similar level of stability 1 month post-CRT. Although separate analyses of fifth-order and sixth-order aberrations revealed a statistically significant change from am to pm post-CRT for a 3-mm pupil, these changes were on the order of 0.003 μm and 0.001 μm, respectively. When compared with the total higher-order RMS change of 0.030 μm, these small changes do not appear to be clinically significant. Because no significant am to pm changes were found post-CRT in any of the other RMS values, it appears that higher-order aberrations for a 3-mm pupil are just as stable post-CRT as they were before CRT.

Higher-order aberrations for a 5-mm pupil also appear to maintain a similar level of stability 1 month post-CRT. With the exception of spherical aberration (Z_4^0), all calculated RMS values exhibited the same level of stability before and after CRT. Perhaps of greatest clinical significance is the post-CRT fluctuation of spherical aberration (Z_4^0). Although no fluctuation was measured at baseline, a significant increase of 0.025 μm was noted from am to pm post-CRT. Because spherical aberration appears to be the driving force behind the increase in higher-order aberrations for a 5-mm pupil, an increase in Z_4^0 throughout the day could result in fluctuations in vision if the patient has habitually large pupils. However, it should be noted that total higher-order RMS error, which includes spherical aberration, did not demonstrate a statistically significant change from am to pm at either baseline or 1 month post-CRT.

Possible explanations for the small aberration fluctuations that were only noted after CRT include superficial punctate staining or tear film instability. Tear film instability can result in small changes in higher-order aberrations and image quality.[26,27] Thus, because the percentage of eyes with central corneal staining 1 month post-CRT was greater at the am visit than at the pm visit, this could account for the small higher-order aberration fluctuations that were measured. These results should be repeated to verify the findings, especially the significant increase from am to pm in spherical aberration post-CRT. Overall, higher-order aberrations appear to exhibit a similar level of stability before and after CRT at the time points we tested. To provide a more complete description of aberration stability throughout the day, this study would need to be repeated with more frequent measurements over a longer timespan within a single day.

Having shown that higher-order aberrations have the same relative level of stability before and after CRT, myopic regression may account for visual fluctuation when pupil size is held constant. However, to completely describe the potential causes of visual fluctuation, the impact of increased pupil size, and thus higher-order aberrations, on BCVA must be considered.

Best-Corrected Visual Acuity Changes

As pupil size increases, such as under mesopic and scotopic conditions, higher-order aberrations play a greater role in visual acuity. Our finding that nondilated high-contrast BCVA measured under photopic conditions does not change after CRT is consistent with two recent studies.[15,16] However, we did find a significant decrease in nondilated low-contrast BCVA of 0.07 logMAR post-CRT, a loss of between three and four letters. This finding is similar to the results reported by Tahhan et al. in 2003[16] who found a significant decrease of approximately two letters when testing photopic nondilated low-contrast BCVA after 1 month of treatment.

Dilated BCVA has not been reported previously in the literature. High-contrast BCVA measured through a dilated pupil significantly decreased by approximately one letter post-CRT. Although this loss is not clinically significant, a roughly six-letter loss in dilated low-contrast BCVA was present after CRT. Because lower-order aberrations were corrected by the manifest refraction, it can be presumed that the visual reduction was the result of the increase in higher-order aberrations. Because the majority of central staining present at the am visit was typically resolved before the pm dilated BCVA measurement was taken, increased higher-order aberrations resulting from the change in corneal shape can be differentiated from aberrations induced by corneal staining.

A nearly significant interaction between time of day and visit (pre- or post-CRT) was present ($p = 0.052$) for dilated low-contrast BCVA as well as a marginally significant improvement in visual acuity from am to pm at both baseline and 1 month post-CRT ($p = 0.049$). This suggests that patients may have learned the charts or were becoming more experienced with visual acuity testing. However, evaluation of Table 1 shows that although no mean difference between am and pm measurements of dilated low-contrast BCVA was present at baseline, a slight improvement in BCVA was present from am to pm after CRT. Because aberrations have been shown to be relatively stable, this again suggests that corneal staining or tear film disturbances may have played a role in the additional am reduction in acuity measured after CRT. Although it is possible that corneal edema could also potentially contribute to this additional reduction, we have no assessment of corneal edema in these patients. However, regardless of staining, tear film, or edema, a significant reduction was observed in dilated low-contrast BCVA that was statistically associated with the increase in higher-order aberrations after CRT.

The reduction in low-contrast BCVA secondary to pupil dilation also demonstrates the impact of higher-order aberrations. Low-contrast BCVA decreased on average by 0.11 logMAR with pupil dilation before CRT and 0.19 logMAR with dilation after CRT, an additional four-letter loss ($p < 0.001$). Linear regression analysis of spherical aberration, which has already been shown to be the major Zernike term accounting for the increase in higher-order RMS error, appears to account for the majority of additional acuity loss with pupil dilation after CRT. This result suggests that spherical aberration is the most significant driving force behind losses in visual acuity after CRT.

One limitation of this study is that nondilated and dilated pupil sizes were not measured. Although we recognize that the regression analyses do not completely describe the association between CRT induced aberrations and BCVA reductions as a function of pupil size, we feel that they do demonstrate the major role of spherical aberration in driving reductions in low-contrast BCVA as the pupil area increases.

Another potential limitation of this study design is that dilated photopic high- and low-contrast BCVA was used to describe the impact of higher-order aberrations on BCVA as pupil size increases rather than actually measuring under mesopic or scotopic conditions. An evaluation of photopic and mesopic visual acuity found that mesopic visual acuity is more sensitive to optical degradation than photopic visual acuity.[28] Thus, we feel that if mesopic measurements had been used, the reduction in visual acuity measured would be similar or potentially even worse than the photopic visual acuity reductions reported in this study. Tahhan et al.[16] measured high- and low-contrast BCVA using both high and low illumination and found results similar to ours. The six-letter reduction in dilated photopic low-contrast BCVA we found is supported by the five-letter reduction they found in low-contrast low-illumination BCVA. Overall, the results presented here appear to clearly describe the impact that higher-order aberrations, especially spherical aberration, have on BCVA when the pupil dilates.

In conclusion, CRT results in an increase in higher-order aberrations with spherical aberration being the greatest contributor to this increase. Higher-order aberrations appear to reach a level of stability throughout the day that is similar to their pretreatment level of stability. Low-contrast BCVA is decreased after CRT for both nondilated and dilated pupils and can be attributed in part to the measured increase in higher-order aberrations. As the pupil dilates, CRT results in an additional reduction in low-contrast BCVA resulting from the increase in higher-order aberrations, mainly spherical aberration. Subjective visual fluctuation is most likely a result of both myopic regression throughout the day and the impact of higher-order aberrations on low-contrast visual acuity under mesopic and scotopic conditions in which the pupil dilates.

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REFERENCES

1. Jessen GN. Orthofocus techniques. Contacto 1962;6:200–4.
2. Jessen GN. Contact lenses as a therapeutic device. Am J Optom Arch Am Acad Optom 1964;41:429–35.
3. Winkler TD, Kame RT. Orthokeratology Handbook. Boston: Butterworth-Heinemann; 1995.
4. Wlodyga RJ, Bryla C. Corneal molding: the easy way. Contact Lens Spectrum 1989;4:58–65.
5. Rah MJ, Jackson JM, Jones LA, Marsden HJ, Bailey MD, Barr JT. Overnight orthokeratology: preliminary results of the Lenses and Overnight Orthokeratology (LOOK) study. Optom Vis Sci 2002;79: 598–605.
6. Walline JJ, Rah MJ, Jones LA. The Children's Overnight Orthokeratology Investigation (COOKI) pilot study. Optom Vis Sci 2004;81: 407–13.
7. Fan L, Jun J, Jia Q, Wangqing J, Xinjie M, Yi S. Clinical study of orthokeratology in young myopic adolescents. ICLC 1999;26: 113–6.
8. Soni PS, Nguyen TT, Bonanno JA. Overnight orthokeratology: visual and corneal changes. Eye Contact Lens 2003;29:137–45.
9. Swarbrick HA, Wong G, O'Leary DJ. Corneal response to orthokeratology. Optom Vis Sci 1998;75:791–9.
10. Sridharan R, Swarbrick H. Corneal response to short-term orthokeratology lens wear. Optom Vis Sci 2003;80:200–6.
11. Oshika T, Klyce SD, Applegate RA, Howland HC, El Danasoury MA. Comparison of corneal wavefront aberrations after photorefractive keratectomy and laser in situ keratomileusis. Am J Ophthalmol 1999;127:1–7.
12. Miller JM, Anwaruddin R, Straub J, Schwiegerling J. Higher order aberrations in normal, dilated, intraocular lens, and laser in situ keratomileusis corneas. J Refract Surg 2002;18:S579–83.
13. Oliver KM, Hemenger RP, Corbett MC, O'Brart DP, Verma S, Marshall J, Tomlinson A. Corneal optical aberrations induced by photorefractive keratectomy. J Refract Surg 1997;13:246–54.
14. Verdon W, Bullimore MA, Maloney RK. Visual performance after photorefractive keratectomy. A prospective study. Arch Ophthalmol 1996;114:1465–72.
15. Joslin CE, Wu SM, McMahon TT, Shahidi M. Higher-order wavefront aberrations in corneal refractive therapy. Optom Vis Sci 2003; 80:805–11.
16. Tahhan N, Du Toit R, Papas E, Chung H, La Hood D, Holden AB. Comparison of reverse-geometry lens designs for overnight orthokeratology. Optom Vis Sci 2003;80:796–804.
17. Mountford J. Retention and regression of orthokeratology with time. ICLC 1998;25:59–64.
18. Jackson JM. Power vector analysis of refractive error changes in overnight orthokeratology [MS thesis]. Columbus, OH: The Ohio State University; 2001.
19. Nichols JJ, Marsich MM, Nguyen M, Barr JT, Bullimore MA. Overnight orthokeratology. Optom Vis Sci 2000;77:252–9.
20. Cheng X, Himebaugh NL, Kollbaum PS, Thibos LN, Bradley A. Validation of a clinical Shack-Hartmann aberrometer. Optom Vis Sci 2003;80:587–95.
21. Thibos LN, Applegate RA, Schwiegerling JT, Webb R. Standards for reporting the optical aberrations of eyes. J Refract Surg 2002;18: S652–60.
22. Gordon MO, Schechtman KB, Davis LJ, McMahon TT, Schornack J, Zadnik K. The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Group. Visual acuity repeatability in keratoconus: impact on sample size. Optom Vis Sci 1998;75:249–57.
23. Davis LJ, Schechtman KB, Begley CG, Shin JA, Zadnik K. The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Group. Repeatability of refraction and corrected visual acuity in keratoconus. Optom Vis Sci 1998;75:887–96.
24. Thibos LN, Wheeler W, Horner D. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Sci 1997;74:367–75.
25. Liang J, Williams DR. Aberrations and retinal image quality of the normal human eye. J Opt Soc Am (A) 1997;14:2873–83.
26. Koh S, Maeda N, Kuroda T, Hori Y, Watanabe H, Fujikado T, Tano Y, Hirohara Y, Mihashi T. Effect of tear film break-up on higher-order aberrations measured with wavefront sensor. Am J Ophthalmol 2002;134:115–7.
27. Tutt R, Bradley A, Begley C, Thibos LN. Optical and visual impact of tear break-up in human eyes. Invest Ophthalmol Vis Sci 2000;41: 4117–23.
28. Pesudovs K, Marsack JD, Donnelly WJ, Thibos LN, Applegate RA. Measuring visual acuity - high or low luminance, and high or low contrast? Invest Ophthalmol Vis Sci 2004;45:E-abstract 2769.

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