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Comparing the Optical Properties of Soft Contact Lenses On and Off the Eye

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Abstract

Purpose—The purpose of the current study was to examine the on- and off-eye optical performance of two types of soft contact lenses (hydrogel and silicone hydrogel).

Methods—The monochromatic aberrations ($\lambda = 850$ nm) of contact lenses were measured on-eye using a clinical Shack-Hartmann ocular aberrometer. Additionally, we used an off-eye single-pass contact lens aberrometer ($\lambda = 540$ nm) in which the soft contact lens was placed within a wet cell. Comparison of the lower and higher order aberrations measured with these two methods required compensation for different wavelengths and knowledge of the refractive index of the contact lens materials.

Results—The measured on-eye sphere and spherical aberration values were generally similar to those measured off-eye and those specified by the lens manufacturers for both types of soft contact lenses. However, there were notable differences, especially for high plus-powered lenses, which typically exhibited lower sphere power on the eye than expected from the lens specifications and from the off-eye measured powers, both of which were almost identical. Longitudinal spherical aberration varied with lens power in the hydrogel lenses, as expected from geometrical optics theory. Longitudinal spherical aberration measurements on- and off-eye, however, deviated significantly from that expected of a thin lens with spherical surfaces due to surface asphericities. The difference between on- and off-eye optics can be modeled as a tear lens, or as relative lens thickness changes caused by lens flexure.

Conclusions—The results of the current study reveal that the major difference between the on-eye lens optics and the manufacturers' specifications are not due to lens errors, but due to eye-lens interactions, which could be either lens flexure or a tear lens forming behind the soft contact lens.

Keywords

contact lens; spherical aberration; aspheric; flexure; supplemental power

The paraxial power of a thin lens is proportional to the difference in curvature of its front and back surfaces with a constant of proportionality equal to the difference in refractive index between the lens and surrounding material: $P = (\Delta n) / (1/r_1 - 1/r_2)$. Likewise, a thin conforming soft contact lens (SCL) will change the refracting power of an eye by changing the curvature of the air/eye interface by the difference in curvature of its front and back surfaces. Because of this, the power of a thin SCL in air will approximate its refractive effect on the eye.^{1, 2} These two values may not be identical, however, for a combination of several reasons. First, a SCL may fail to conform to the cornea creating an effective "tear

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lens” between the lens and cornea, as occurs with gas permeable lens fittings.^{1, 3, 4} Second, the lens may change shape and relative thickness while on the eye.⁵ This later scenario is often termed “lens flexure”, and is thought to be the primary source of under-correction by high plus powered SCLs,^{5, 6} with increasingly plus powered lenses losing more power (e.g. 0.50 undercorrection with +5.00D lenses,^{5, 6} and around 1.00 D undercorrection with +10.00 D lenses⁶). It is possible that these two hypotheses can occur simultaneously. The term “supplemental power effect” has been used to describe this scenario, where a lens shape and/or thickness change may occur in combination with an optically powered non-uniform thickness tear layer or “lens”.^{3, 4}

In order to confirm that some on-eye interaction effect (e.g. flexure) is responsible for the observed differences between expected and observed refractive effects of SCLs requires that the optical characteristics of SCLs be measured off-eye. However, the same physical characteristics of SCLs (e.g. edge and center thicknesses of <0.07 mm, elastic modulus as low as 0.4 Mpa for silicone hydrogel lenses, and water content as high as 60+ %) that make them ideal for on-eye comfort and biocompatibility, make them difficult to measure in air. In this case, the SCL will dry out quickly⁷⁻⁹ and deform under their own weight.¹⁰ An alternate strategy is to measure the lenses in a wet cell and scale the observed optical effects by the ratio of refractive index differences.^{1, 11, 12} In water, a SCL is approximately neutrally buoyant, fully hydrated, and surrounded by a uniform refractive index. In order to employ this scaling strategy, however, an accurate estimate of lens refractive index is required.

In addition to designing SCLs with controlled amounts of sphere power, there are now numerous designs that include controlled levels of spherical aberration (SA).¹³⁻¹⁶ Also, the level of SA varies approximately linearly with sphere power in spherically surfaced SCLs^{2, 11} as predicted by geometrical optics.¹⁷ In this study we employ two types of Shack-Hartmann wavefront aberrometers to measure the sphere power and SA of several common SCLs on the eye and in a wet cell. We specifically examine the hypothesis that lenses *with* flexure-induced changes in sphere power will also exhibit changes in higher order aberrations.

METHODS

We employed two Shack-Hartmann wavefront aberrometers (AMO-Wavefront Sciences, Albuquerque, NM) to measure the optics of soft contact lenses on and off of the eye. A COAS-HD clinical aberrometer was used to quantify the monochromatic aberrations of the naked eye, and the eyes wearing various contact lenses. A single-pass ClearWave contact lens aberrometer was used to measure contact lenses off of the eye while the SCLs rested in a saline-filled wet cell.¹¹

Assuming conformity of the lens to the corneal anterior surface, and a uniformly thin tear layer, the change in the eye’s optical path length produced by a soft contact lens when on the eye should be equal to the optical path length of the contact lens in air. This issue is most commonly described in terms of soft contact lens lower order aberration (I.e., power),¹⁸ but the concept holds true for all optical aberrations. Both when in air and when on the eye, the contact lens replaces air in the optical path with the contact lens material. Consequently, lens optical measurements taken in air require no special conversion to the on-eye optical impact of the lens. However, measurements taken in the saline-filled wet cell require conversion to in-air equivalent power, and thus on-eye refractive impact. The expected paraxial power (D) of the contact lens in air, P_{air} , can be determined from the measured power in water, P_{wet} , with knowledge of the lens base curve radius (r_2 , in meters), the refractive index of the lens

(n_{lens}), the refractive index of the solution (n_{sol}), and center thickness of the lens (meters, d) using Equation 1,

$$P_{air} = (n_{lens} - 1)c_1 + (1 - n_{lens}) \left(\frac{1}{r_2} \right) + \left(\frac{d}{n_{lens}} \right) ((n_{lens} - 1)^2) \left(\frac{1}{r_2} \right) c_1 \quad (1)$$

where c_1 is determined by Equation 2,

$$c_1 = \left[\left[\frac{P_{Wet}}{(n_{lens} - n_{sol}) \left(1 + \left(\frac{d}{n_{lens}} \right) \left(\frac{1}{r_2} \right) (n_{lens} - n_{sol}) \right)} \right] + \left[\frac{\frac{1}{r_2}}{\left(1 + \left(\frac{d}{n_{lens}} \right) \left(\frac{1}{r_2} \right) (n_{lens} - n_{sol}) \right)} \right] \right] \quad (2)$$

and P_{wet} is the measured power of the lens in the wet cell (in diopters).^{19, 20} (For additional details on the derivation of the exact wet-to-in air conversion equation, see Kollbaum 2008.¹¹)

The equation employed to convert wet cell to in air equivalent values for higher order aberration is a simplified version of Equation 1, and is shown in Equation 3,

$$Z_{air} = (Z_{wet}) \left(\frac{n_{lens} - n_{air}}{n_{lens} - n_{solution}} \right) \quad (3)$$

where Z is any given Zernike term or series of terms.^{11, 20, 21} This approximation, which assumes a lens center thickness of zero, ignores the minor effects of wavefront propagation between the two surfaces, which is appropriate given the lens thicknesses of < 0.1 mm and the low levels of higher-order aberrations typically encountered in contact lenses.

In order to calculate the expected on-eye or in-air performance of lenses from data collected in the wet cell (see Equations 1–3), an accurate estimate of the lens refractive index at the ClearWave measurement wavelength of 540 nm is required. However, these refractive index data may not be available for all lenses. ANSI ISO 9342 specifies two wavelengths at which index values can be reported for contact lenses; 546 nm and 587 nm.²² However, many of the instruments commercially available and used by manufacturers to measure refractive index, such as the CLR 12–70 (Index Instruments, Cambridge, UK) and Arias 500/600/700 (Reichert, Depew, NY) report refractive index at 589 nm. Furthermore, there have been reports of difficulties in measuring the index of some silicone hydrogel materials.^{23, 24}

The impact of small errors in refractive index can be seen in an example shown in Figure 1. Using the manufacturer-provided refractive index of 1.426 for the PureVision silicone hydrogel sphere lens to convert wet cell measurements to in-air powers, the data are best fit by a line with a slope of 0.91, indicating too little plus and too little minus power (black line). However, when we alter the refractive index estimate instead to 1.416, the data are well fit by a line with slope = 1.00 (95% CI: 0.99, 1.01) (gray line). Therefore, employing this lower refractive index, the off-eye data more closely agree with the nominally labeled power. This highlights the importance of an accurate estimation of lens refractive index when employing a single-pass, lens only aberrometer like the ClearWave to predict the on-eye or in-air power.

Given the potential inaccuracies in determining refractive index of contact lens materials, and the lack of understanding of what the refractive index of the lens truly is at the time of measurement, if the off-eye data for a given lens appeared to have a power that was a scaled version of the expected power (observed versus expected slope not equal to 1, but a correlation coefficient of >0.99), we assumed that our initial estimate of the refractive index was in error, and we used a revised index estimate that produced a slope closest to 1 (i.e.

95% CI included 1). This adjustment was only required for the two silicone hydrogel lenses evaluated, which indicates that reported refractive index estimates of silicone hydrogel materials are not sufficiently accurate, consistent with reports indicating that they are more difficult to obtain.^{23–24}

The COAS-HD aberrometer uses an infrared (850 nm) super-luminescent diode as the light source, and employs a Shack-Hartmann lenslet array to sample 1541 spots over a 7 mm pupil diameter (spatial resolution at the pupil plane of 158 microns) to measure the lower and higher order aberrations of an eye. We computed the optical impact of the contact lens on the eye using the Dietze and Cox² method where the wavefront error (WFE) of the SCL (WFE_{SCL}) = the $WFE_{(eye\ plus\ SCL)} - WFE_{(eye\ alone)}$. Off-eye measurements of SCLs employed a single pass ClearWave aberrometer in which a collimated 540 nm visible light source and a 101×101 lenslet array with a 10.4 × 10.4 mm field of view, providing a spatial resolution of 104 microns.¹¹

In order to compare the two methods, differences in source wavelength and plane of measurement had to be compensated for. First, the ClearWave aberrometer measures the lens optics using 540 nm wavelength visible light, whereas the COAS aberrometer employs a 840 nm wavelength infrared light. Although expected to cause a very small difference, all COAS aberrometer measured coefficient values were converted to their 540 nm reference equivalent values to match the wavelength used by the ClearWave aberrometer, using a method in which a reduced eye model is constructed by adjusting the length of the Indiana Eye model to make the model emmetropic for the original wavelength. Then, an aberration-free Cartesian oval was perturbed to account for the measured wave aberration. From this the optical path difference between the aberrated wavefront and the Cartesian oval of a field of marginal rays and a central ray were found at 540 nm by changing the refractive index of the model.^{25–27} This approach is described in detail in Ravikumar et al.²⁸

Second, the ClearWave instrument is designed to provide a detailed description of the lens optics relative to the contact lens back vertex, whereas the COAS aberrometer, quantifies the eye/lens optics at the entrance pupil plane. We corrected for the wavefront propagation distance between the pupil plane and lens back vertex, assuming this distance to be 3 mm (based on the estimated difference between the cornea and entrance pupil plane). The method employed was identical to that commonly used in the clinical setting to “vertex” a spectacle prescription to a contact lens prescription, (Equation 4), where F_{pp} is the power of the lens at the pupil plane and F_{BV} is the power of the lens at the lens back vertex.

$$F_{BV} = \frac{1}{\left(\frac{1}{F_{PP}} - 0.003\right)} \quad (4)$$

As the higher-order Zernike coefficients are typically small (e.g. <<1 micron), and the difference in distance between these two measurement planes is also small (e.g. 3 mm), this propagation effect was ignored in our analysis of higher order aberrations. Additionally, we have previously shown experimentally that axial misalignments of higher-order aberrometry measurements of this magnitude to have little impact.²⁹

Paraxial sphere powers were obtained by first converting the Zernike coefficients into the power vector components J_0 , M , and J_{45} .³⁰ We found the paraxial spherical equivalent, M , by Equation 5³¹, which effectively sums the r^2 components of both C_2^0 and C_4^0 .³⁰

$$M = \frac{-4\sqrt{3}C_2^0 + 12\sqrt{5}C_4^0}{r^2} \quad (5)$$

Astigmatism (first order) was included in the determination of the final clinical paraxial sphere power, using the methods of Thibos et al.³⁰ Zernike spherical aberration was converted to the clinically relevant units of peak-to-valley longitudinal spherical aberration (LSA) at the pupil margin by Equation 6,

$$LSA = \frac{24C_4^0\sqrt{5}}{r^2} \quad (6)$$

where LSA is the longitudinal spherical aberration in diopters, C_4^0 is the OSA normalized Zernike spherical aberration coefficient value in microns, and r^2 is the pupil radius in mm squared.¹¹ For the current study, the analysis radius was always 3mm.

Both eyes of the subject were pharmacologically dilated with 1% tropicamide and 2.5% phenylephrine to ensure a large pupil size and help minimize accommodation. Repeated instillations of both medications occurred halfway through the two-hour testing period to ensure a sustained effect. All lenses were fit according to the manufacturer's fitting guides, and allowed to stabilize for 15 minutes following insertion prior to taking a measurement. To minimize the effect of any local tear film changes, blink-induced lens movements, and any residual accommodation five repeated measurements were taken, and the Zernike coefficients over a 6mm analysis diameter corresponding to each single measurement were averaged to represent the result for that "trial". Each individual acquisition was taken immediately following the investigator-observed (through the instrument alignment camera) approximate stabilization of the lens on the eye following a blink (i.e., 1–2 seconds following a blink). Subjects wore lenses of different types in the two eyes during testing (e.g. a series of lenses ranging from high minus to high plus power ACUVUE 2 lenses on the right eye and a series of lenses ranging from high minus to high plus power Frequency 55 sphere on the left eye). Not all lens type-power combinations were tested on all eyes/subjects, and several combinations were tested on many eyes. The range of over-correction provided by the Badal refraction system inherent to the COAS instrument to measure and compensate for the sphere power of the eye limited the contact lens power testing range possible, so the lens testing range for each eye was tailored to that eye based on each its baseline sphere equivalent refraction. Lens type-power combinations and testing order was randomized for each eye of each subject. Naked eye data were collected at the beginning and end of each lens measurement session and the Zernike coefficients averaged to yield a baseline level of eye alone aberration to use in the analysis.

The parameters of the contact lenses (as reported by the manufacturers in the respective product inserts) used in the series of experiments described below, are shown in table 1. In the current study, we refer to the powers reported on the lens labels (as determined by the manufacturers) as the "Expected Power".

The optical effects of lens flexure are minimized when the refracting medium at the anterior surface closely matches that at the posterior surface (e.g., if lens deformations are mirrored on the front and back surface, their optical impact will approximate zero when $n_1=n_2$),¹¹ as is the case in the ClearWave, where the contact lens is sitting entirely in a wet cell. Previously, comparisons of rigid and soft CLs measured with the ClearWave found flexure effects within the saline-filled cell to be quite small (<0.1 D LSA for lenses ± 10 D).¹¹ On the eye, however, any flexure effects at the front surface of the lens will only be partially

cancelled at the posterior surface because of the difference in refractive index of the tears and air. Additionally, with any lens flexures a corresponding tear lens could be formed (e.g. as in GP lens).^{1, 12}

A range of dioptric powers (e.g. -12.00 to $+8.00$ in 1.00 D steps) for several different types of spherical hydrogel lenses [Focus Dailies (Foc) (ALCON Vision Care, Duluth, GA), ACUVUE 2 (AV2) (Vistakon, Jacksonville, FL), Frequency 55 (F55S) (CooperVision, Fairport, NY)] and spherical silicone hydrogel lenses [Air Optix Night and Day (ND) (ALCON Vision Care, Duluth, GA), PureVision (PV) (Bausch + Lomb, Rochester, NY)] lenses were measured in the ClearWave and using the on-eye method on 30 eyes of 15 subjects over a 6mm analysis diameter (for both instruments). In all, 104 different lens type/power combinations were evaluated. Each subject wore an average of 6 lenses on each eye. The paraxial sphere and LSA powers obtained (calculated using Equations 5 and 6 above, respectively) using these two methods were compared. This study followed the Declaration of Helsinki conventions and was approved by the Indiana University Institutional Review Board. Subjects were informed of the study purpose, procedures, and consequences, and written consent was obtained.

RESULTS

Paraxial Sphere Power

The first part of this study compared the measured sphere power to the manufacturer's specified sphere power for spherical soft contact lenses ranging in power from -12.00 diopters to $+8.00$ diopters. We present these data in observed vs. expected plots (Figure 2a–c), and of course, if the measured sphere power equals the observed, data should be well fit by a straight line with slope of 1.00 and intercept of 0.00. We also quantify any discrepancies between the observed and expected values using a Bland-Altman type of plot,³² in which the differences between observed and expected are plotted as a function of the expected (Figure 2d–f). This type of plot provides insight into any systematic errors (mean slope and intercept of the difference data) as well as evidence of non-systematic errors (95% confidence interval for best fitting line).

The off-eye ClearWave measured (observed) versus manufacturer labeled (expected) lens paraxial sphere power for a series of ALCON Vision Care Focus Dailies sphere lenses is shown in Figure 2a. The best-fit line of this data approximates the $y=x$ line with a slope of 1.01, which is not significantly different than 1 (95% CI: 0.99, 1.02), and intercept of -0.03 , which is not significantly different than 0 (95% CI: -0.10 , 0.04). These results indicate that the manufacturer lens specifications accurately represent the SCL power in air, as shown previously.¹¹ The paraxial sphere results of the on-eye measurement method are best fit with a line with a slope of 0.95 and intercept of -0.34 , which are significantly different than 1 (95% CI: 0.94, 0.96) and 0 (95% CI: -0.38 , -0.26), respectively. For negative lens powers the data fall close to the $y=x$ line, but on-eye positive lens powers are less than expected. Similar off- and on-eye data are shown for two other hydrogel spherical lenses, (Vistakon ACUVUE 2 shown in Figure 2b and CooperVision Frequency 55 sphere shown in Figure 2c). In both cases, the off-eye measurements are as predicted by the manufacturer, whereas the on-eye measurements, show reduced plus power with increasing positive lens powers.

These subtle deviations in the on-eye paraxial sphere power from that expected can be seen more clearly in Figures 2d–f, which plot the difference between the observed and expected powers on the y-axis against the expected lens power on the x-axis. In this graphical format, negative values indicate that the observed values were less positive or more negative than expected. The solid line marks the regression of the data and indicates the pattern of systematic errors, the solid ellipse the 95% confidence estimate of the mean (plus sign), and

the dashed ellipse the 95% confidence interval of the data. The slope of the off-eye Focus Dailies data (Figure 2d) approximates the $y=0$ line ($m = 0.01$, 95% CI: $-0.01, 0.02$; $b = -0.03$, 95% CI: $-0.10, 0.04$), indicating the off-eye results show no systematic difference from expected. In this case the 95% CI of the difference scores spans about $\pm 0.25D$ indicating significant between lens variability, which is significantly higher than the $\pm 0.10D$ test-retest measurement variability of lenses previously found¹¹. When on the eye, negative-powered Focus Dailies lenses have effective lens powers close to expected, however, positive powered lenses are significantly under-powered, becoming between 0.50 and 1.00 D under-powered at +6.00 D labeled power. This negative slope seen in these on-eye data ($m = -0.05$, 95% CI: $-0.06, -0.04$) has an x-intercept at about $-5.00D$, indicating that both low powered negative lenses and positive powered lenses generally are more negative or less positive than expected ($b = -0.32$, 95% CI: $-0.38, -0.26$). These differences are probably clinically insignificant, except for the highly positive lenses.

The results for the ACUVUE 2 (Figure 2e) and Frequency 55 (Figure 2f) lens show similar trends. Off of the eye, neither of the slopes were significantly different from 0, indicating no trend in the difference from expected as a function of lens power. However, the Frequency 55 lenses had an intercept that was very slightly, but significantly greater than 0 ($b = 0.08$, 95% CI: $0.01, 0.14$) indicating the measured lenses typically were of higher plus/less minus power than expected. On the eye, the ACUVUE 2 lens again demonstrated trends similar to the Focus Dailies lens (slopes and intercepts significantly different from 0) with both low powered negative lenses and higher positive powered lenses generally having more negative or less positive than expected. However, the Frequency 55 lenses were more variable on the eye, and more negative/less positive power was found across the full power range of lenses (mean observed – predicted power = $-0.33 D$). As off-eye measurements for the Frequency 55 were not more variable than other lenses, yet the on-eye measurements were, the observed variability reflects between-subjects variability in how the lenses combine optically with these eyes.

Importance of Precise Knowledge of Contact Lens Refractive Index

Utilizing the same graphical approaches as Figure 2, Figure 3 shows the observed versus expected (Figure 3a and 3b) results for the silicone hydrogel PureVision and Air Optix Night and Day lenses, respectively. As expected from our index optimization of these lenses, for both lenses the slopes of the off-eye observed versus expected data were not significantly different from 1. Additionally, the intercepts did not differ significantly from 0. The on-eye data for the PureVision lens show reduced plus power with increasing positive lens powers (Figure 3a). The positive and negative powered Night and Day lenses (Figure 3b) appear quite similar to the expected and to the off-eye data. The difference (observed-expected) plots (Figure 3c and 3d) show that, when on the eye, the PureVision lenses tended to have less minus and less plus power than observed off-eye ($m = -0.10$, 95% CI: $-0.14, -0.06$) with on-eye effective lens power of the high plus and high minus lenses differing by $>0.50D$ from expected. The observed-expected on-eye data for the Night and Day lenses did not show this pattern, but interestingly, the wet-cell measurement of these lenses revealed a small but consistent minus bias of about $-0.20D$.

Longitudinal Spherical Aberration

Generally, spherically surfaced negative lenses generate negative spherical aberration, while spherically surfaced positive lenses generate positive spherical aberration in direct proportion to their sphere power.¹⁷ Mahajan¹⁷ described a nonlinear equation (Equation 7) to calculate the expected spherical aberration of a thin lens (a_s) (in microns at the edge of the pupil of radius (r)) based on the front (R_1) and back surface (R_2) radii, pupil radius in m (r), and refractive index (n) of the lens material.

$$a_s = -\frac{r^4 10^6}{32n(n-1)f^3} \left[\frac{n^3}{n-1} + (3n+2)(n-1)p^2 + \frac{n+2}{n-1}q^2 + 4(n+1)pq \right] \quad (7)$$

Redistributing this equation to eliminate unknown terms, assuming a position factor (p) of -1 for a distant object, and substituting in a shape factor (q) = (R₂+R₁)/(R₂-R₁), and 1/f' = (n-1)(R₂-R₁)/R₁R₂), we arrive at Equation 8.

$$a_s = -\frac{r^4 10^6 (n-1)^2 (R_2 - R_1)^3}{32nR_1^3 R_2^3} \left[\frac{n^3}{n-1} + (3n+2)(n-1) + \frac{n+2}{n-1} \left(\frac{R_2 + R_1}{R_2 - R_1} \right)^2 - \frac{4(n+1)(R_2 + R_1)}{R_2 - R_1} \right] \quad (8)$$

This result (LSA at pupil margin) is then divided by -6*sqrt(5) to get the Z₄⁰ coefficient, which can be converted to LSA in Diopters utilizing Equation 6. Using this equation, n of 1.39 and R₂ of 8.7mm, we predict 0.0259 microns of C₄⁰ per diopter of power for a distant target.

This theoretical expectation of Mahajan was confirmed by Dietze and Cox² who used ray tracing to evaluate the expected spherical aberration of SofLens 66 lenses (Bausch + Lomb) as a function of lens power. They also utilized an on-eye technique to measure the spherical aberration of these same lenses on the eye. In general, their modeled and on-eye results were quite close (slopes of best-fitting straight lines of 0.0277 and 0.0267 microns Zernike SA/D power and intercepts of 0.0088 and 0.0363 microns, for the modeled and on-eye results, respectively). However, as evidenced by the intercept differences in the best-fitting regression lines, they observed slightly more positive SA in the on-eye case than predicted by ray tracing.

A direct comparison between the theoretical prediction of Mahajan¹⁷ (calculated based on the manufacturer-reported refractive index and base curve) and our on- and off-eye experimental results for a series of Focus Dailies lenses is plotted in Figure 4. The Mahajan¹⁷ predictions have been converted from microns to a more clinically relevant unit of measured longitudinal spherical aberration (LSA) (dioptric difference between the focus of a paraxial and a marginal ray at a radius of 3mm, see Equation 6). In this case, the Mahajan prediction for an unflexed lens (solid line in Figure 4) is 0.155 D of LSA per D of spherical power. We also include a second prediction from Mahajan with slightly different parameters, with a flexed base curve radius (R₂=7.3mm), which generates more SA (slope = 0.18 D of LSA per D of power, dot-dashed line in Figure 4). This result shows how sensitive SA is to lens base curve. Both the on- and off-eye measures of LSA were generally close to the predictions of Mahajan¹⁷ in the maximum flexure case which used the steeper base curve radius, but were always greater than the minimum flexure prediction of Mahajan in which the manufacturer specified lens base curve radius was used. These measured results were similar to the results reported by Dietze and Cox,² who found slopes of 0.17 and 0.16 D of LSA per D of sphere, respectively, with the SofLens 66 lens.

Similar trends in LSA are shown for the ACUVUE 2 (Figure 5a) and Frequency 55 (Figure 5b) lenses, both revealing similar on- and off-eye levels of SA that do not follow the minimum flexure predictions of Mahajan (solid lines), but generally follow the predictions of Mahajan if the base curve were maximally flexed (dot-dashed lines). In all cases the prediction was based on the parameters for each specific lens type (linear fits to off-eye data each have slopes of 0.20 D of LSA per D of sphere). A somewhat different pattern of LSA is seen with the PureVision (Figure 5c) and Night and Day (Figure 5d) silicone hydrogel lenses. The approximately linear relationship between LSA and sphere power is only seen in

the off-eye LSA data of the PureVision lenses (Figure 5c), the observed on-eye LSA with higher-powered negative lenses deviates significantly from this pattern indicating some significant on-eye flexure, specifically a flattening of the lens radius, or tear lens. Interestingly, the negative powered Night and Day silicone hydrogel lenses (Figure 5d) follow the trend observed with the hydrogel lenses and that expected from geometrical optics. In the positive powered Night and Day lenses, however, LSA is generally unaffected by sphere power both on and off-eye, indicating a potential asphericity inherent or designed into these lenses.

Knowledge of the actual intended level of LSA within a lens design is not readily available (e.g. cannot read off of the packaging as with sphere power) and generally not specified for typical spherical lens designs. Therefore, it is generally not possible to compare our observed measures of lens LSA to those intended by the manufacturer. We were, however, fortunate to obtain the manufacturer designed and expected level of LSA for the Focus Dailies lens design (ALCON Vision Care, technical communication). The observed versus expected LSA for the series of Focus Dailies sphere lenses is shown in Figure 6. The regression line fit to the off-eye data (Figure 6a, black line) approximates the $y=x$ line with a slope of 1.00, with a slightly positive y-intercept (intercept=0.14D, 0.02; 95% CI: 0.27). The on-eye measured LSA (gray symbols and line) of the lenses appear close to the expected values for minus lenses (minus lenses predict minus LSA), but there is a negative bias over most of the power range resulting in a slope and intercept that differ significantly from 1 and 0, respectively (slope: 0.77; 95% CI: 0.66, 0.87, intercept: -0.31; 95% CI: -0.46, -0.17). The difference between these two data sets indicates a significant change in lens optics when on the eye.

Again, these subtle differences in LSA from expected can be seen more easily in plotting the differences from the expected (y-axis) against the expected lens power (Figure 6b). As previously, in this graphical format negative values indicate that the observed values were lower than expected. The solid line marks the regression of the data, the solid ellipse the 95% confidence estimate of the mean (plus sign), and the dashed ellipse the 95% confidence interval of the data. In this example, the off-eye data (black circles) approximate a line with a slope not significantly different from 0 (-0.00; 95% CI: -0.02, 0.02), but y-intercept significantly different from 0 (0.15; 95% CI: 0.03, 0.27). The on-eye data (gray squares) reflect a slope (-0.06; 95% CI: -0.08, -0.03) and intercept (-0.31; 95% CI: -0.46, -0.17), significantly different from 0.

DISCUSSION

This study has employed two methods for assessing the optical performance of soft contact lenses, one in a saline-filled wet cell and one with the lens on the eye. Both approaches generate accurate and precise measurements of lower and higher order monochromatic aberrations,^{29,33,11} and we used both to compare the on- and off-eye aberrations of defocus and spherical aberration observed over a wide dioptric range of three hydrogel and two silicone hydrogel contact lenses. The wet cell provides neutral buoyancy and stable hydration, and thus largely avoids the mechanical forces and hydration fluctuations that might be present when on the eye. Differences between the two datasets, therefore, provide a direct experimental method for separating lens-specific (e.g. manufacturing process) from on-eye flexure and/or tear lens contributions to the optical imperfections of soft contact lenses. In order to make these comparisons, however, accurate refractive index data are required to convert in-water measurements to expected in air and thus on-eye performance. Our observations indicate that the specified refractive index of silicone hydrogel lenses may not be precisely correct. For example, in order for the off-eye data to match the on-eye performance, the effective refractive index estimate at 540 nm had to be modified from

1.426 to 1.416 for PureVision and Night and Day lenses. These minor alterations in the refractive indices of silicone hydrogel lenses were all within error estimates previously reported,^{23, 24} which may also be significantly affected by minor temperature changes (e.g. wet cell solution temperature was typically around 78 degrees Fahrenheit, while corneal temperatures may typically approach upwards of 95 degrees Fahrenheit).¹ The refractive index values obtained for the hydrogel lenses provided off-eye power measures that were indistinguishable from the manufacturer's reported powers, indicating that these refractive index estimates (see Table 1) were correct.

Measuring the optical properties of soft contact lenses on the eye does not require knowledge of refractive index. However, the on-eye optics of SCLs include two additional components. First, any failure of the SCL posterior surface to conform to the cornea will generate a "tear lens" between the two, which increases the optical path length (OPL) or product of the physical distance and the refractive index of the medium. In the case of a tear layer filling the space between the posterior contact lens and anterior cornea, the OPL would be increased by an amount that varies across the diameter of the lens. This change in OPL can introduce changes in power and higher order aberrations. Alternatively, the very process of conforming can alter the relative thickness of a SCL, called "lens flexure". Similarly, in this second case, these regional changes in OPL within the lens can also change the power and higher order aberrations. Conformation and failure to conform are known to influence the optical effects of SCLs. Indeed, there is a long history of studies attributing unexpected refractive effects of gas permeable^{1,12} and soft contact^{3-6, 34-53} lenses to their failure to conform to the anterior corneal surface and/or lens flexure. Our measurement methodology generated similar differences between observed and expected sphere power as some of the earlier studies. Figure 7 plots the difference data from two hydrogel lenses (circles, black line) of the current study and best-fit lines representing data from the previous results of Holden et al.,⁶ Weissman,⁵¹ the equal percentage change hypothesis,⁴¹ equal change hypothesis,³ and Plainis and Charman.⁵

Based on the hypothesis that the soft contact lens completely conforms to the corneal surface the optical effect of the contact lens on the eye can be determined as the difference between the optics of the eye wearing the contact lens and the eye alone^{1, 2} in which case subtracting the off-eye or expected power of the contact lens from this total would yield 0. However, the current study found that this is not always the case, and that there are residual or supplemental optical effects due to a combination of on-eye lens thickness or shape changes and/or the creation of an optically powered tear layer between the contact lens and cornea (Figure 8).

If we make the simplifying assumption that the on-/off-eye differences are due entirely to the formation of a tear layer, we can divide the WF differences observed on-eye from those observed off-eye by the difference between the index of refraction of air and that of tears to estimate the change in thickness of the this tear film across the pupil (Dt) (Equation 9).

$$Dt = - \left(\frac{WF_{eye+CL} - WF_{eye} - WF_{CL}}{n_{tear} - n_{air}} \right) \quad (9)$$

Equation 9 could also be used to determine lens thickness changes caused by lens flexure by substituting the index of refraction of the lens (n_{lens}) instead of that of the tears (n_{tear}) (e.g. optical path length changed by adding more lens material for light to pass through). This analysis is shown schematically in the top row of Figure 8, which shows sample data from ACUVUE 2 lenses, with corresponding sample wavefronts shown in the bottom row for each component of the numerator of Equation 9 in the bottom row. The current analysis

presents results assuming the differences in optical path length are entirely due to tears, but these differences could also be due to lens flexure thickness changes, in which case they are merely approximately 83% ($n_{\text{tear}}/n_{\text{lens}}$) lower than what we report below.

Previous measures of post-contact lens tear film thickness have ranged from a minimum of 2.3⁵⁴ to around 4.5⁵⁵ to a maximum of 11.5⁵⁶ microns, but have been restricted to one location on the cornea, and to one or two low minus lens powers. We provide an estimate for tear thickness across the entire central 6mm of the cornea, for a range of lens powers. For low-powered lenses, the current results are quite similar to the results of Nichols.⁵⁴ Because the WFE method for estimating tear lens thickness (Figure 8) only documents changes in tear lens thickness it will not include any uniform thickness component of the tear lens and thus methods that measure the actual tear lens thickness (e.g. OCT, interferometry) would always report a thicker tear lens than what we observe. Since optical imaging is unaffected by any constant (piston) term (at the visible and infrared wavelengths used in the current study),⁵⁷ it is typically ignored when computing image quality.

In reality, this difference between on- and off-eye lens measurements will also contain the impact of any on-eye lens decentrations as well as these tear lens and lens flexure optical differences. For example, Guirao⁵⁸ predicts the induction of prism and coma from the decentration of lenses containing sphere and spherical aberration. Presumably, on-eye flexures and/or tear lenses could be asymmetric in nature and therefore, accordingly contain levels of prism and coma. However, in the current analysis we make the assumption that any extra coma introduced when the SCL is on the eye is a result of lens decentrations, and thus we did not include these in our calculations of lens flexure/tear lens.¹¹

The top row in Figure 9 shows the results of employing Equation 9 to quantify the thickness (in microns) of the tear layer under the entire lens surface necessary to fully account for the differences observed on- and off-eye for a +1, +4, and +8 D Vistakon ACUVUE 2 lens. As predicted by the very similar on- and off-eye performance of low-powered plus lenses, low-powered lenses generate virtually no tear lens, whereas higher-plus lenses have a very thin central tear thickness, but an increasingly thick periphery. This is the classic negative powered “tear lens” encountered with gas permeable lens fitting.¹ For example, a +1 D lens has a maximum tear thickness under the entire lens surface of only 2.32 microns (mean $\pm$ std = 0.89 $\pm$ 0.14), whereas a +8 D lens has a max tear thickness of 15.91 microns (mean $\pm$ std=12.15 $\pm$ 1.17). It is plausible that the thicker high plus power lenses will act more like a rigid gas permeable contact lens conforming less to the cornea. Therefore, in these high plus lenses, it is likely that the differences between on and off-eye performance with these lenses are due to a tear lens. Alternatively, because negative power SCLs can have very thin centers (e.g. 50–60 microns), it is likely that they conform well to the cornea² and on-/off-eye differences reflect lens flexure not a tear lens.

The differences between on- and off-eye wavefront error data observed in the current study may in fact not be just a tear or lens thickness change, but a combination of tear lens and lens flexure, which has been referred to as a “supplemental power effect”.⁴

The reduced plus power of the soft contact lens on the eye predicts a reduction in positive spherical aberration. Also, since the lens is, presumably, conforming to some unknown combination of the cornea and tears, there is added potential for changes in spherical aberration as well as changes in lens paraxial power. Indeed, our on-eye measurements of spherical aberration fail to mirror those of the same lenses in the wet cell indicating that the lens-eye interaction can alter spherical aberration as well as spherical power. This issue becomes significant when we consider that many modern lenses are designed to introduce controlled levels of spherical aberration, such as aspheric lenses (e.g. CooperVision

Biofinity, Bausch + Lomb PureVision), multifocal lenses (e.g. Bausch + Lomb PureVision Multifocal, ALCON Vision Care AirOptix Multifocal), or custom aberration-correcting lenses.

It is important to note that the calculations of flexure effects reported here may contain variability from several sources. Off-eye measurements show that variability (e.g. Figure 2d, black symbols) of roughly $\pm 0.25D$ exists due to either the off-eye measurement or manufacturing process. This amount of variability is significantly higher than the test-retest variability previously reported¹¹, so is believed to be largely due to manufacturing. The more variable on-eye results (e.g., Figure 2f, gray symbols) clearly identify that lenses will conform differently on different eyes, resulting in a slightly different amount of flexure-induced optical change depending on the eye on which the lens is placed. However, when evaluating these trends across the sample population (as a function of lens power), the current results approximate previous reports in the literature utilizing different techniques.^{5,6}

CONCLUSIONS

The results of the current study indicate that if lens refractive index is known precisely, off-eye measures of lens power and spherical aberration are mostly as expected, but on-eye measurements indicate lenses often have less power and spherical aberration. These optical differences can be accounted for by on-eye changes in lens flexure resulting in local lens thickness and/or post-lens tear thickness changes. In order to achieve predictable and optimized performance with a lens design, knowledge of the optical impact of how the soft contact lens conforms to the eye may be essential.

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Figure 1. Observed versus expected paraxial power measured using the off-eye technique where the raw data were converted from wet to in-air equivalence using the manufacturer reported refractive index of 1.426 (black solid line), and also an iteratively optimized hypothesized index of refraction of 1.416 (gray solid line).

Figure 2.

The observed (measured) versus expected (manufacturer labeled) paraxial sphere powers of ALCON Vision Care Focus Dailies (a.), Vistakon ACUVUE 2 (b.), and CooperVision Frequency 55 (c.) lenses using the, the ‘off’ eye method (black circular symbols) in which the lens was measured within the wet cell and the “on” eye method (gray square symbols) in which the aberration of the lens was found by subtracting the naked eye from the eye+lens aberration (gray square symbols). The corresponding dioptric difference between the observed and expected lens powers (Diopters), for the off- (black circular symbols) and on-eye (gray square symbols) plotted as a function of expected lens power (D) for the ALCON Vision Care Focus Dailies (a.), Vistakon ACUVUE 2 (b.), and CooperVision Frequency 55 (c.) lenses. The solid line notes the robust linear regression for each data series, while the solid ellipse represents the 95% confidence limits of the mean (+), and the dashed ellipse represents the 95% probability range of the data.

Figure 3.

The observed (measured) versus expected (manufacturer labeled) paraxial sphere powers of Bausch + Lomb PureVision (a.), and ALCON Vision Care AirOptix Night and Day (b.) spherical lenses using the, the off-eye method (black circular symbols) in which the lens was measured within the wet cell and the on-eye method (gray square symbols) in which the aberration of the lens was found by subtracting the naked eye from the eye+lens aberration (gray square symbols). The dioptric difference between the observed and expected lens powers (D, Observed-Expected), for the off- (black circular symbols) and on-eye (gray square symbols) plotted as a function of expected lens power (D) for these lenses are shown in (c.) and (d.), respectively. The solid line notes the robust linear regression for each data

series, while the solid ellipse represents the 95% confidence limits of the mean ('+'), and the dashed ellipse represents the 95% probability range of the data.

Figure 4.

The longitudinal spherical aberration (LSA, D) of a series of ALCON Vision Care Focus Dailies lenses as a function of their labeled lens power using the on-eye (gray squares) and off-eye (black circles) technique. These results are compared to the lens specific results predicted by Mahajan (black solid line)¹⁷ assuming the lens retains its specified base curve radius and assuming the back base curve radius flexes maximally to meet a relatively steeper cornea of 7.3 mm (black dot-dashed line).

Figure 5.

The longitudinal spherical aberration (LSA, D) of a series of (a.) Vistakon ACUVUE 2, (b.) CooperVision Frequency 55, (c.) Bausch + Lomb PureVision, and (d.) ALCON Vision Care AirOptix Night and Day spherical lenses, as a function of their labeled lens power using the on-eye (gray squares) and off-eye (black circles) technique. These results are compared to the lens specific results predicted by Mahajan (black solid line)¹⁷ assuming the lens retains its specified base curve radius and assuming the back base curve radius flexes maximally to meet a relatively steeper cornea of 7.3 mm (black dot-dashed line), utilizing the refractive index and reported base curve radius of each lens type.

Figure 6.

(a.) The observed (measured) versus expected LSA (D) of Focus Dailies lenses using the, the off-eye method (black circular symbols) and on-eye method (gray square symbols). The expected results were provided by the lens manufacturer (ALCON Vision Care, technical communication). (b.) The dioptric difference between the observed and expected LSA (D, Observed-Expected), for the off- (black circular symbols) and on-eye (gray square symbols) plotted as a function of expected lens power (D) for the Focus Dailies lenses. The solid line notes the robust linear regression for each data series, while the solid ellipse represents the 95% confidence limits of the mean ('+'), and the dashed ellipse represents the 95%

probability range of the data. The expected results were provided by the lens manufacturer (ALCON Vision Care, technical communication).

Figure 7.

The difference in paraxial sphere power between that measured on the eye and expected for a series of thin ((mean $\pm$ std) 0.11 ± 0.018 mm) (Vistakon ACUVUE 2 and ALCON Vision Care Focus Dailies) spherical lenses compared to the previous results of Holden et al,⁶ Weissman,⁵¹ the equal percentage change hypothesis,⁴¹ equal change hypothesis,³ and Plainis and Charman.⁵

Figure 8.

A revised model of the soft contact lens on the eye that no longer assumes the difference between the eye plus lens optics and the eye alone optics equals the in-air optics of the lens, but rather includes on-eye flexure effects, such as a post-lens tear layer or localized lens shape or thickness changes. The optical impact of these changes can be calculated as the difference between the lens optics of the lens measured on the eye (eye+lens minus eye alone) and off of the eye.

Figure 9. Calculated thickness (microns) of the difference between the off- and on-eye contact lens optics assuming these differences are generated by a tear layer between the lens and cornea for a +1, +4, and +8 D Vistakon ACUVUE 2 lenses.

Table 1

Contact lenses used in the current study, and their respective material, water content, refractive index, and base curve (as reported by the lens manufacturers within their respective product inserts).

Lens Type	Material	Nominal water content (%)	Nominal refractive index	BCR (mm)
ACUVUE 2	Etafilcon A	58	1.4051	8.7
Focus Dailies sphere	Nefilcon A	69	1.383	8.6
AirOptix Night and Day sphere	Lotrafilcon A	24	1.430	8.6
Frequency 55 sphere	Methafilcon A	55	1.420	8.7
PureVision sphere	Balafilcon A	36	1.426	8.6