OPTICAL QUALITY AND VISUAL PERFORMANCE ASSOCIATED WITH DAILY SOFT CONTACT LENS WEAR

A thesis presented to the graduate faculty of
New England College of Optometry in partial fulfillment
of the requirements for the degree of Master of Science

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New England College of Optometry, 2012

Abstract

Purpose: Silicone hydrogel soft contact lenses are becoming widely used in clinical practice, so it is important to compare optical aberrations and visual performance between conventional soft hydrogel lenses and silicone hydrogels. Silicone hydrogels improve oxygen transmissibility through the contact lens, so it might be expected that visual performance and optical quality would be better compared to conventional hydrogel lens wear. However, the wetting ability of silicone hydrogel lenses might increase aberrations and reduce visual performance. The purpose of this research project was to compare aberrations and visual performance in daily soft contact lens wearers of both conventional and silicone hydrogel lens types. **Methods:** Aberrations from the whole eye and cornea, as well as corneal thickness, were examined during soft contact lens wear, and during a one-hour period after removal of the contact lenses. Measurements were made on 19 silicone hydrogel lens wearers and 13 conventional lens wearers who had been wearing the lenses at least 4 hours. Average refractions were -3.95 D and -4.91 D for the two lens type groups, respectively. Ocular aberrations were measured with a Wavefront Sciences COAS aberrometer, corneal topography was measured with a Zeiss Humphrey Atlas 995 corneal

topographer, and corneal thickness was measured with an Oculus Pentacam. Visual acuity was assessed at two light levels (12.62 and 200 cd/m^2) with three contrast levels (100%, 25% and 5%) of LogMAR charts. **Results:** Conventional hydrogel wearers had better visual acuity when wearing their contact lenses compared to the silicone hydrogel wearers ($p<0.05$). The two groups of lens wearers did not show differences in acuity with spectacle wear. Silicone hydrogel wearers had a slightly more myopic over-refraction and greater ocular and corneal higher-order RMS aberration with the lenses on the eye than did the conventional hydrogel wearers. Average spherical aberration (SA) was negative for conventional lens wearers and positive for silicone hydrogel wearers. SA of the conventional lenses became more negative with increasing negative lens power ($p=0.0002$) and low contrast acuity improved with greater negative SA ($p=0.043$). These effects were not observed for the silicone hydrogels. After contact lenses were removed, silicone hydrogel lens wearers had significantly greater higher-order ocular RMS aberration than conventional lens wearers. Conventional lens wearers had more change in thickness over one hour than the silicone hydrogel wearers. The difference between central and peripheral corneal thickness was larger in the conventional lens wearers, but this effect was not correlated with SA.

Conclusions: Lower visual acuity observed with the silicone hydrogel lenses on the eye was due to a difference in optical quality of the two lens types. Differences in SA of the two lens types may be related to the difference in over-refractions. The greater negative SA obtained with conventional hydrogels may help to improve low contrast acuity in myopic subjects. The small changes in corneal thickness observed after removal of conventional hydrogels is probably due to corneal de-swelling, but it was not correlated with changes in SA.

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Chapter 1

Introduction

1.1. Optical quality and its relationship to contact lens wear

Measurement of the optical quality of the eye has become more routine in the last decade, due to the availability of wavefront sensing devices, or aberrometers, in both research and clinical settings. The effect of contact lenses on the eye's optical quality had been investigated even before the advent of aberrometers. In the 1970's and 1980's, researchers studied the effects of contact lenses on spherical aberration of the eye. One study reported negligible differences in aberration effects between rigid and soft lenses (Woo and Sivak, 1976) while another noted that visual acuity tended to be better with rigid, or hard, contact lenses than with soft, or hydrogel, lenses (Wechsler, 1978) and that hydrogel lenses would induce significant amounts of spherical aberration that should impair visual function if the pupil were large (El-Nashar and Larke, 1986).

More recently, researchers have studied the effect of contact lenses on the eye's wavefront aberrations. Wavefront aberration measurements with and without contact lenses are equally repeatable (Efron, Efron and Morgan, 2008a). A potential problem with measurement of aberrations of contact lenses is that the within- and between-observer reliability of the wavefront measurement with a contact lens on the eye is slightly lower than it is without the contact lens (Efron et al., 2008a). There may be more sources of variability when the contact lens is on the eye, such as tear film stability, lens flexure, lens decentration and lens movement.

Hong, Himebaugh and Thibos (2001) compared the aberrations and visual performance between soft and rigid contact lenses as well as spectacle correction. Their study showed that rigid contact lenses reduced the overall aberrations of the eye and also provided better visual performance than soft lenses or spectacles. They also found that visual performance with spectacles and soft contact lenses was similar. Hong, et al. (2001) and Lu, Mao, Qu, Xu, and He (2003) found that, although the change in wavefront aberrations with contact lenses vary from eye to eye, soft contact lenses tend to increase the higher-order aberrations overall, whereas rigid contact lenses reduce astigmatism. Jiang, Wang, Yang, Xie and He (2006) investigated wavefront aberrations with soft contact lenses on the eye and found that aberrations varied by the type of lens manufacture, cast-molded vs. spun-cast. Roberts, Athappilly, Tinio, Naikoo and Asbell (2006) compared aberrations in soft contact lens wearers with and without their contact lenses. They found a statistically significant increase in the total higher-order aberrations with regular hydrogel contact lenses when compared to spectacle correction. They also found an increase in the total coma, trefoil and spherical aberrations with contact lenses on the eye but the individual aberration results were not statistically significant when compared to the values obtained without the contact lenses.

A common finding regarding spherical aberration is that eyes exhibit positive spherical aberration without contact lenses, but soft contact lenses reduce the positive spherical aberration (Awwad, Sanchez, Sanchez, McCulley, and Cavanagh, 2008; Lindskoog Pettersson, Jarkö, Alvin, Unsbo and Brautaset, 2008; Berntsen, Merchea, Richdale, Mack and Barr, 2009; Lindskoog Pettersson, Martensson, Salkic, Unsbo and Brautaset, 2011). Some of this effect may be due to the lens power since negatively-powered soft contact lenses reduce

the positive spherical aberration of the eye and can even shift it toward negative spherical aberration (Awwad et al., 2008). The shift toward negative spherical aberration in the Awwad study occurred at a lens power of -4.00 D. Researchers have studied whether custom-designed wavefront aberration correction is worth the effort for the typical eye with normal amounts of wavefront aberrations. They have investigated whether an aspheric design meant to reduce spherical aberration is better than a typical lens design. Efron, Efron and Morgan (2008b) reported no statistically significant difference in aberrations or visual performance with aspheric vs. spherical lens designs. Another study showed that, while the changes in spherical aberration were statistically significant between lens designs, visual quality was not affected by the different amounts of spherical aberration correction (Lindskoog Pettersson et al., 2011).

Studies of soft contact lenses on visual performance may require mesopic and/or low contrast charts to show subtle differences in acuity or sensitivity. A large study of acuity and optical quality indicates that low contrast letter charts and mesopic luminance levels are better than high contrast charts and photopic luminance when investigating effects of the wavefront aberrations induced by aging of the lens cortex (nuclear opalescence) on visual performance (Pesudovs, Marsack, Donnelly, Thibos and Applegate, 2004).

1.2. Corneal swelling during conventional soft contact lens wear

Aberrations of the eye wearing a contact lens could involve effects of both the contact lens optics as well as effects of the contact lens on the corneal optical quality. Conventional

soft contact lens wear causes differential swelling across the cornea, in which the central corneal thickness increases more than the peripheral thickness (Bonanno and Polse, 1985; Holden, McNally, Mertz, and Swarbrick, 1985;Herse, Akakura and Ooi, 1993; Wang, Fonn and Simpson, 2003; Wang, Fonn, Simpson, Sorbara, Kort and Jones, 2003). Differential swelling alters the corneal surface topography and thus should affect the eye's wavefront aberrations. Coletta and Moskowitz (2003) compared wavefront aberrations and contrast sensitivity in non-contact lens wearers, and in soft contact lens wearers shortly after the lenses were removed. They found that soft contact lens wear results in a significant loss of optical quality of the eye immediately after lens removal, and the optical quality deficit is associated with an increase in positive spherical aberration of the eye.

Artal, Guirao, Berrio and Williams (2001) showed that the aberrations of the whole eye, termed the ocular aberrations, are due to a combination of corneal aberrations that arise at the anterior corneal surface and internal aberrations that arise from surfaces inside the eye, such as the posterior corneal and crystalline lens surfaces. In a normal eye, there is more aberration at the anterior cornea than in the whole eye; thus, the internal surfaces of the eye partially compensate for some aberrations that arise at the anterior corneal surface (Artal et al., 2001). The normal compensation of internal aberrations may be altered when a contact lens is placed on the eye. One study noted that a custom aberration-free lens design, when placed on the eye, resulted in measurable aberration, probably because the compensation of the corneal aberrations by the internal optics of the eye was disrupted by the presence of the contact lens (López-Gil, Castejón-Mochón, Benito, Marín, Lo-a-Foe, Marin, Fermigier, Renard, Joyeux, Château and Artal, 2002). A comparison of spherical aberration in the

cornea and whole eye in the soft contact lens wearers in the Coletta and Moskowitz 2003 study suggested that the internal optics of the eye contribute to the increased positive spherical aberration in contact lens wear, because both soft contact lens wearers and non-contact lens wearers had similar amounts of positive spherical aberration at the anterior corneal surface, but the soft contact lens wearers showed more positive spherical aberration than non-wearers in the whole eye. The increase in ocular positive spherical aberration during contact lens wear might have been caused by a loss of the compensation of corneal positive spherical aberration by the internal optics of the eye. Since it is unlikely that there were changes in the crystalline lens surfaces during contact lens wear, the changes in internal aberrations may be caused by topographical changes in corneal thickness due to swelling. Previous studies of corneal swelling after conventional soft contact lens wear (Holden et al. 1985; Bonanno and Polse, 1985) indicate that topographical edema affects the posterior corneal surface shape (Erickson, Comstock, Doughty and Cullen, 1999) and thus edema could alter internal aberrations.

Topographical swelling may disrupt the normal internal compensation of aberrations via changes in the posterior corneal surface shape, but also through changes in the corneal refractive index, or by a combination of these mechanisms. Coletta and Han (2005) simulated the changes in ocular spherical aberration of a schematic eye that arise from corneal swelling and found that changes in the shape of the posterior cornea alone can induce an increase in ocular spherical aberration. They found that most of the change in spherical aberration arises from surface shape rather than thickness or index changes. They also found

that spherical aberration of the eye can change even if corneal swelling does not affect the anterior corneal surface.

The effect of soft contact lens wear on the eye's optical quality is a significant issue because optical quality affects vision under challenging visual conditions such as in low contrast or in dim illumination. In a study by Vaz and Gundel (2003), they state that occasionally patients complain of decreased vision with their contact lenses even though their Snellen VA with contacts may be better than their spectacle VA. Coletta and Moskowitz (2003) showed that the increased positive spherical aberration in soft contact lens wearers was correlated with deficits in mesopic contrast sensitivity. Corneal and ocular aberration measurements can provide a wealth of information about the effects of corneal swelling on visual optics and visual performance.

1.3. Silicone Hydrogel Lenses

Silicone hydrogel soft contact lenses were introduced within the last decade and are aimed at reducing or eliminating the effects of corneal edema, since they allow higher amounts of oxygen to the cornea during contact lens wear (Maldonado-Codina, Morgan Schnider, Efron, 2004). In one study, patients reported significantly fewer problems when wearing high-Dk/t silicone hydrogel lenses compared to their habitual low-Dk/t contact lenses (Dillehay and Miller, 2007). Although the silicone hydrogel lenses improve symptoms related to hypoxia, there have been adverse responses associated with the surface characteristics of silicone hydrogel lenses (Lakkis and Vincent, 2009; Dumbleton, 2002;

Stapleton, Keay, Edwards, Naduvilath, Dart, Brian and Holden, 2008; Dart, Radford, Minassian, Verma and Stapleton, 2008; Efron, Morgan, Hill, Raynor and Tullo, 2005; Santodomingo-Rubido, Wolffsohn and Gilmartin, 2008; Dutta, Cole and Willcox, 2012). Silicone hydrogel lenses are associated with a greater accumulation of mucin balls in subjects wearing the lenses compared to conventional hydrogels (Tan, Keay, Jalbert, Naduvilath, Sweeney and Holden, 2003). Some studies have shown that, compared to conventional hydrogel materials, silicone hydrogel lenses tend to build up more lipid deposits (Cheung, Cho, Chan, Choy and Ng, 2007; Carney, Nash and Sentell,. 2008) and more denatured protein (Luensmann and Jones, 2012). Silicone hydrogels are more hydrophobic than conventional hydrogels and this aspect has been implicated in higher bacterial adhesion to the silicone hydrogel surface (Dutta et al., 2012).

The optical aberrations and visual performance of different brands of silicone hydrogel lenses have been studied (Keir, Simpson and Fonn, 2010). There were some differences in higher-order optical aberrations between brands, specifically in coma and spherical aberration, but there were no significant differences in visual performance or subjective ratings of the lenses across silicone hydrogel brands. This study was performed with new lenses and after only 5 minutes of wear, so changes in lens surface properties that might result from longer duration wear and lens age would not have affected the visual performance results.

With the increasing use of silicone hydrogel contact lenses in clinical practice, it is also important to compare the aberrations and visual performance between conventional hydrogel lenses and silicone hydrogels. It would be expected that silicone hydrogel wearers

should not exhibit effects of corneal swelling on aberrations and visual performance and therefore should have better optical quality and visual performance compared to conventional hydrogel contact lens wearers. However, tear film stability and the wetting ability of silicone hydrogel lenses might increase aberrations and reduce visual performance. There have not been reports that compare optical aberrations and visual performance obtained with silicone hydrogels to those obtained with conventional hydrogel lenses.

1.4. Experimental Aims

The purpose of this research project was to compare aberrations and visual performance in daily soft contact lens wearers of both conventional and silicone hydrogel lens types. Aberrations from the whole eye and cornea, as well as corneal thickness, were examined during soft contact lens wear, and during a one-hour period after removal of the contact lenses. It was expected that the any corneal edema that arose from conventional soft lens wear would recover during the one-hour period after lens removal, since corneal de-swelling after open-eye lens wear may reach a baseline level in a little as 25-30 minutes (Johnson, Boltz and Godio, 1985). In addition to aberrations and corneal thickness, visual performance was compared for the two hydrogel lens types, using low- and high-contrast acuity charts observed at two light levels, low photopic and photopic.

The specific aims of the study were to: 1) Compare the effects of conventional and silicone hydrogel soft contact lenses, while on the eye, on visual acuity, corneal thickness, corneal surface topography and ocular wavefront aberrations after at least 4 hours of lens

wear, and 2) Compare the effects of conventional and silicone hydrogel soft contact lenses on visual performance and corneal properties during the period after contact lens removal.

Chapter 2

Methods and Protocol

2.1. Subjects

These experiments were performed on 32 soft contact lens wearers who had worn daily-wear soft contact lenses for at least 3 months. Subjects were recruited from the students and staff of NECO (Appendix 8.1). Informed consent was obtained from all subjects (Appendix 8.2) and all procedures were approved by the Institutional Review Board of the New England College of Optometry. The total duration of all procedures was approximately 1.5 hours for each subject. Thirteen subjects were wearers of high Dk conventional soft contact lenses (brands Acuvue 2, CibaVision Focus, CooperVision Proclear, Hydrogel Vision Clarity H_2O, and Bausch and Lomb Soflens) and the remaining 19 subjects were wearers of one of the following brands of silicone hydrogel lenses: (Acuvue Advance, Acuvue Oasys, Acuvue TruEye, CibaVision Air Optix, CibaVision Air Optix Night&Day daily wear). For a subject to be included in the study, the particular lens type must have been worn for at least 3 months. Subjects must have worn lenses a minimum of 5 days per week and a minimum of 7 hours per day. The average wearing time for the subjects at testing was 11.6 hours/day, with a minimum of 8 hours and a maximum of 17 hours. The average wearing time for conventional lens wearers was 11.38 hours and 12.84 hours for silicone hydrogel wearers. The difference in the average wearing time between the two groups was not statistically significant ($p>0.05$). The age of the contact lens on the study day

was no more than 30 days old. The average age of the contact lens was 8.92 days for the conventional lens group and 12 days for the silicone hydrogel wearers. The difference in the age of the contact lens for the two groups was not statistically significant ($p>0.05$). All subjects had best corrected visual acuity of at least 20/25 in both eyes, measured during an initial acuity measurement using a high contrast LogMAR acuity chart. The average LogMAR visual acuity measured was -0.006 for conventional lens wearers and 0.025 for silicone hydrogel lens wearers; this difference was not statistically significant ($p>0.05$). The majority of subjects were female (81%) and the average age was 24.96 years +/- 5.64 s.d.

The study had the following exclusion criteria: history or presence of ocular disease or injury, history of cataract or other media opacity, or corneal or other refractive surgery, acuity worse than 20/25 in either eye, and use of rigid gas permeable (RGP), multifocal or extended wear contact lenses during the one-year period prior to the study.

2.2. Study Procedures

The experiments were carried out in Dr. Coletta's lab; the following equipment was used, and all instruments were commercially available and FDA-approved:

- Bailey-Lovie LogMAR High Contrast Visual Acuity Chart
- Precision Vision High and Low Contrast ETDRS Acuity Charts
- Humphrey Atlas 995 Corneal Topography System
- Wavefront Sciences Complete Ophthalmic Analysis System (COAS)
- Oculus Pentacam Rotating Scheimpflug camera
- Marco slit lamp for evaluation of contact lens movement

Subjects were instructed to come in for measurements after at least 4 hours of contact lens wear. Prior to testing, each potential subject was asked to fill out a questionnaire (Appendix 8.3) to establish eligibility based on the inclusion and exclusion criteria. The lens type worn by the subject was determined during this initial questioning. If the subject wore a type of lens, or had a pattern of lens wear, that did not fit the inclusion criteria, they were not allowed to participate in the study. The contents of these records were kept confidential and were used only to evaluate eligibility to participate in the study. At the beginning of the test session, the purpose of the experiment was explained to the subject and s/he was asked to read the consent form. After any questions the subject may have had were satisfactorily answered, the subject was asked to sign the consent form. The following tests/procedures were performed on all subjects.

2.2.1. Visual acuity with SCLs on eye: Visual acuity in both eyes was first tested at a distance of 10 feet using a 100% contrast logMAR letter chart (Bailey-Lovie) while the subject wore contact lenses. The LogMAR chart provides acuity as the logarithm of the minimum angle of resolution (MAR) in min arc. For example, the letter stroke width on the 20/20 line is 1 min arc so the logMAR value for 20/20 acuity would be 0.0; acuity of 20/40 would have a letter stroke width of 2 min arc or logMAR value of 0.3. If the subject satisfied the inclusion criterion of having at least 20/25 acuity in both eyes (logMAR of 0.1), the following measurements were then made on the right eye.

2.2.2. Slit lamp evaluation of lens movement on the eye: Contact lens fit was evaluated by observing movement of the lens on the right eye for straight ahead gaze after a blink.

Lens fit was evaluated by pressing on the lower lid and moving the lens upward (push-up test). A fit was considered acceptable in this study if it had 360 degrees corneal coverage in all gaze positions, good comfort, and movement of 0.20 mm to 0.25 mm with blink. We did not find any subjects with an unacceptable fit.



Fig 2.1a: 100 % contrast chart



Fig 2.1b: 25 % contrast chart



Fig 2.1c: 5 % contrast chart

Fig. 2.1: Charts used to test visual acuity at two illumination levels.

2.2.3. Visual acuity at various contrasts with contact lenses on eye: The subject was seated 10 feet from a back-illuminated acuity chart holder. The laboratory lights were extinguished and the subject dark adapted for 10 minutes. The left eye was patched and a Wratten 1.2 log neutral density (ND) filter was placed in front of the right eye. The subject viewed a back-illuminated 100% contrast ETDRS chart (Precision Vision), as shown in Fig. 2.1a, through the filter. The display luminance with the 1.2 ND filter in place was 12.62 cd/m^2. Acuity for the right eye was measured starting from the top line of the chart. Visual acuity for the 1.2 ND filter condition was then recorded for a 25% contrast chart and a 5% contrast chart, depicted in Figs. 2.1b and 2.1c, respectively. The

1.2 ND filter was removed and acuity was recorded again for the three different contrast charts. The chart illumination without the filter (0.0 ND condition) was 200 cd/m^2.

2.2.4. Measurements of corneal thickness, aberrations and topography with soft contact lenses in place:

a) The cornea+lens thickness profile was measured with an Oculus Pentacam rotating Scheimpflug camera. This device has software designed for biometry of the anterior segment. A series of cross-sectional images of the cornea were taken along 25 meridians to generate a three-dimensional reconstruction of the cornea and anterior chamber. The method yields a topography map of the posterior cornea as well as a topographic corneal thickness map. This method was superior to ultrasound pachymetry for these experiments because the device does not touch the eye and therefore does not affect either the measurements of corneal thickness or any subsequent measurements of aberrations. Optical measurements of corneal thickness are consistent with ultrasound pachymetry (Barkana, Gerber, Elbaz, Schwartz, Ken-Dror, Avni, Zadok, 2005; Lackner, Schmidinger, Pieh, Funovics, Skorpik, 2005; Al-Mezaine, Al-Amro, Kangave, Sadaawy, Wehaib, Al-Obeidan, 2008), even in cases of corneal edema (Bechmann, Thiel, Neubauer, Ullrich, Ludwig, Kenyon and Ulbig, 2001). Three readings were taken and the thickness measurements for various positions on each map were averaged. Thickness measurements were taken from the reconstructed corneal thickness map at the

cornea center, the thinnest point on the cornea, and at 1, 2 and 3 mm eccentricity from the corneal center along the superior, nasal, inferior and temporal meridians.

b) Wavefront aberrations of the eye, using the Wavefront Sciences COAS aberrometer, which uses the Shack-Hartmann technique. Measurements were made in darkness to maximize pupil diameter. Whole-eye, or ocular, aberrations up to seventh Zernike order were determined from the COAS measurements for the soft contact lens on-eye condition. Five readings were taken and the Zernike coefficients were averaged from the five readings.

c) Anterior corneal topography using the Zeiss Humphrey 995 topographer. Typically four maps were recorded and checked for completeness; if a map had missing sectors due to inadequate tear film coverage, additional maps were recorded until there were four complete maps. The COAS whole-eye aberration data are referenced to the pupil center, as recommended by the ANSI standard (ANSI, 2010), so we also computed the corneal aberrations at the pupil center in order to compare whole-eye (ocular) and corneal aberration data at the same reference point. To do this, the raw topographer images were first analyzed using custom Matlab software to determine the offset of the pupil center from the center of the topographer rings. The topography data were then exported and analyzed using VolCT software (Sarver Associates, Version 7.3), using the shifts of the pupil center from the topography map center, to compute anterior corneal surface wavefront aberrations for the soft contact lens on-eye condition referenced to the

pupil center.

2.2.5. Measurements of corneal thickness, aberrations and topography immediately after removal of the soft contact lens: The contact lenses were removed from each eye; solutions and lens cases were provided for each subject. All measures listed above were repeated on the right eye. Pentacam measures were performed first, followed by COAS, then by corneal topography. Measurements were made as quickly as possible, and were completed within 12 minutes after lens removal.

2.2.6. Subjective refraction with spectacle correction after soft contact lens removal: A subjective refraction was then performed, using the Bailey-Lovie high contrast LogMAR chart, with the subject's spectacle correction and/or with trial lens refinement. This spectacle correction was then used for subsequent visual acuity measurements with the Precision Vision high and low contrast charts.

2.2.7. Measurements of corneal thickness, aberrations and topography at 20 minutes after lens removal: All procedures in step 2.2.5 were repeated again 20 minutes after contact lens removal, beginning with Pentacam, then COAS and finally corneal topography.

2.2.8. Visual acuity at various contrasts and illuminations with spectacle correction: Following the second set of COAS, Pentacam and corneal topography measures after lens removal (thus about 30 minutes after contact lens removal), the subject was dark adapted for 10 minutes. Visual acuity for both high and low contrast acuity charts were measured

using the best spectacle correction, again with the 1.2 ND filter and then without the filter. These acuity measurements were completed in about 10 minutes after the dark adaptation period.

2.2.9. Measurements of corneal thickness, aberrations and topography one hour after lens removal: All procedures in step 2.2.5 were repeated again starting one hour after contact lens removal, beginning with Pentacam, then COAS and finally corneal topography.

In summary, there was one set of corneal thickness, aberration and topography measures taken with the contact lenses in place, and there were three sets of these measures taken during the period after contact lens removal. This period of de-swelling, covering a total period of just over 60 minutes after lens removal, should have allowed 15% corneal swelling to return to baseline according to published results (Johnson, et al. 1985). In addition, acuity for the high- and low-contrast Precision Vision charts was measured at two light levels, both with contact lenses in place and then with spectacle correction, the latter being performed about 40 minutes after contact lens removal.

These measurements allowed an examination of the topography of the cornea during contact lens wear and during the one-hour period after lens removal, and how it may be related to any changes in corneal and whole-eye aberrations. The soft contact lens thickness profile was estimated from the difference between the Pentacam 'cornea+lens' thickness profile and the first Pentacam measurement without the soft contact lens. Comparison of

aberrations with and without the lens provided an assessment of the soft contact lens' effect on the eye's anterior surface aberrations, and ocular aberrations.

Conventional hydrogel contact lens wear should have resulted in topographical swelling and we expected this effect to be minimal in the silicone hydrogel wearers. To assess changes in corneal thickness that may have occurred over time after contact lens removal, the corneal thickness in various locations in the Pentacam images were compared in sequential images. Any changes in aberrations over time during the de-swelling phase were compared to changes in corneal thickness.

Finally, the visual acuity was compared with and without contact lenses. The lens-on-eye data provided a comparison of visual performance between the two types of lenses, and the spectacle-corrected data after lens removal provided a comparison of performance during the de-swelling phase.

2.3. Data Analysis

Means, t-tests, correlation and linear regression were used to analyze results. T-tests and/or ANOVA were performed to examine whether the means for conventional vs. silicone hydrogel lens wearers differed for the following conditions:

- Mean visual acuity at each acuity condition (light level and chart contrast), with contacts in place, and with spectacles in place after contact lenses were removed.
- Mean pupil diameter in the COAS measurements for all four conditions (with contact lens on the eye and during the three measures after lens removal).

- Mean COAS refraction with the contact lens on the eye (over-refraction) and the average COAS refractions from the three measurements after lens removal.
- Root mean square (RMS) aberration in Zernike orders from the 3rd through the 7th order and mean spherical aberration (c_4^0) in the cornea (from topography) and in the whole eye (from COAS) with contacts in place.
- RMS aberration in Zernike orders from the 3rd through the 7th order and mean spherical aberration (c_4^0) in the cornea and whole eye immediately after lens removal, and for each subsequent time interval.
- Difference in whole-eye and corneal aberration due to the presence of the contact lens for the spherical aberration (c_4^0) coefficient.
- Internal spherical aberration coefficient (c_4^0) after contact lens removal.
- Mean corneal thickness in the center of the cornea for each time interval after lens removal.
- Mean corneal thickness in each of the peripheral corneal locations for each time interval after lens removal.

In addition, the following correlations and linear regressions were performed:

- In each lens type group, correlation and linear regression of the low-contrast visual acuity deficit (amount by which VA with 5% contrast chart is worse than 100% contrast chart) with spherical aberration in the whole eye.
- In each lens type group, correlation and linear regression of spherical aberration contributed by the contact lens with lens power (refraction).

- In each lens type group, correlation and linear regression of spherical aberration with the difference in central vs. average peripheral corneal thickness at 3 mm after lens removal.

Chapter 3

Visual Performance with Conventional and Silicone Hydrogel Lenses

3.1. Visual performance with contact lenses on the eye

Average LogMAR visual acuity results for the three contrast level acuity charts are shown in Fig. 3.1 for the contact lens on-eye condition. Data for the conventional lens wearers are shown as green circles, and data for silicone hydrogel wearers are shown as pink diamonds. The results indicate that conventional lens wearers had better acuity than silicone hydrogel wearers at all contrasts and at both illumination levels.

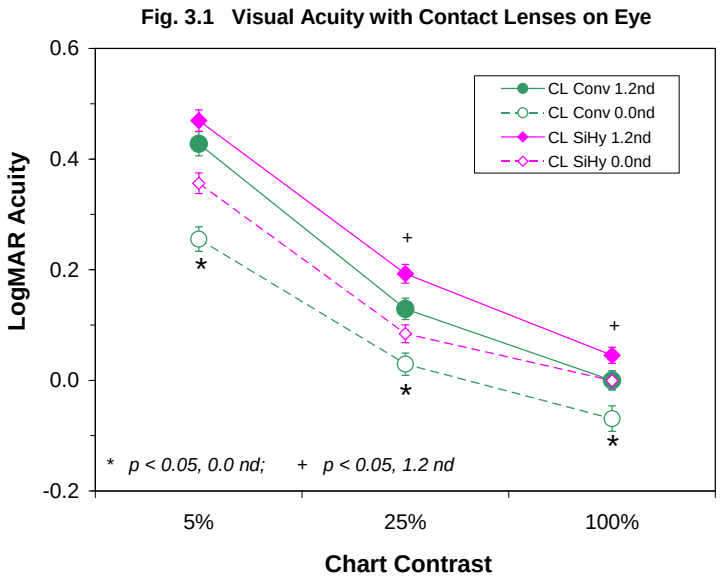


Fig. 3.1: Average LogMAR acuity plotted as a function of chart contrast for conventional lens wearers (green circles) and silicone hydrogel lens wearers (pink diamonds). Data for the low illumination level (1.2 log neutral density filter) are shown as filled symbols and data at the high illumination level (0.0 log neutral density filter) are shown as open symbols. Error bars are +/- 1 s.e.m.

Acuity of the silicone hydrogel lens wearers for the 100% contrast chart at the higher light level (0.0 n.d., open symbols) was the same as that for the conventional lens wearers at the lower illumination level (1.2 n.d., filled symbols). Differences between the lens types were significant for all contrast levels at the high illumination level ($p=0.008$ at 5%, $p=0.041$ at 25% and $p=0.018$ at 100% in t-tests), and at the 25% and 100% contrast levels at the low illumination level ($p=0.020$ and $p=0.034$, respectively, in t-tests). The reason for the difference in visual performance between the two lens groups may be related to aberrations of the lenses on the eye, as discussed in Chapter 4.

3.2. Visual performance after removal of contact lenses

Average spherical equivalent COAS refractions for the conventional soft lens users, taken from the three measurements during the period after contact lens removal, ranged from +3.50 D to -9.00 D with a mean of -4.91 D +/-3.54 D. Spherical equivalent COAS refractions for the silicone hydrogel users, averaged from the three measurements following contact lens removal, ranged from -1.67 D to -8.75 D with a mean of -3.95 D +/- 1.92 D. Although the average spherical equivalent refraction was more myopic in the conventional lens wear group, there was no significant difference in mean refraction between the two groups of lens wearers (t-test; $p=0.19$).

Average LogMAR acuity with spectacles, measured at about 30 minutes after contact lens removal, is shown in Fig. 3.2 for the two lens type groups. These data are the raw values obtained and have not been corrected for the minifiying effect of minus spectacle

wear. Unlike the performance with contact lenses on the eye, visual acuity of the two lens groups was essentially the same with spectacle lenses. Conventional lens wearers (green symbols) had slightly better acuity than silicone hydrogel wearers at the lower illumination level, and at the highest contrast at the high illumination level, but these differences did not reach statistical significance at any chart contrast level.

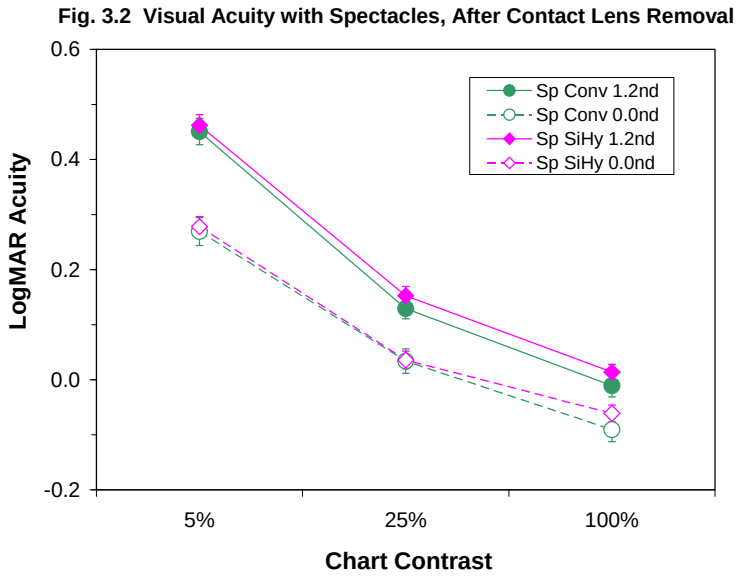


Fig. 3.2: Average LogMAR acuity plotted as a function of chart contrast for conventional lens wearers (green circles) and silicone hydrogel lens wearers (pink diamonds) during the period after contact lens removal. Subjects wore best spectacle correction. Data for the low illumination level (1.2 log neutral density filter) are shown as filled symbols and data at the high illumination level (0.0 log neutral density filter) are shown as open symbols. Error bars are +/- 1 s.e.m.

3.3. Comparison of visual performance with spectacles and contact lenses

Visual acuity measured with contact lenses and with best spectacle correction is compared for the conventional lens wearers in Fig. 3.3a and the silicone hydrogel lens wearers in Fig. 3.3b. Conventional lens wearers showed similar visual acuity at all contrasts

and at both light levels with either type of correction, and no condition had a statistically significant difference in acuity in a paired t-test ($p>0.05$). Silicone hydrogel lens wearers, on the other hand, had significantly worse acuity with their contact lenses (blue symbols) compared to spectacle wear (red symbols) at the high light level at all three contrast levels, as shown in Fig. 3.3b ($p=0.006$ at 5%, $p=0.031$ at 25% and $p=0.002$ at 100% in paired t-tests). This effect is also apparent at the lower illumination level for 25% and 100% contrast charts, but these differences did not reach significance.

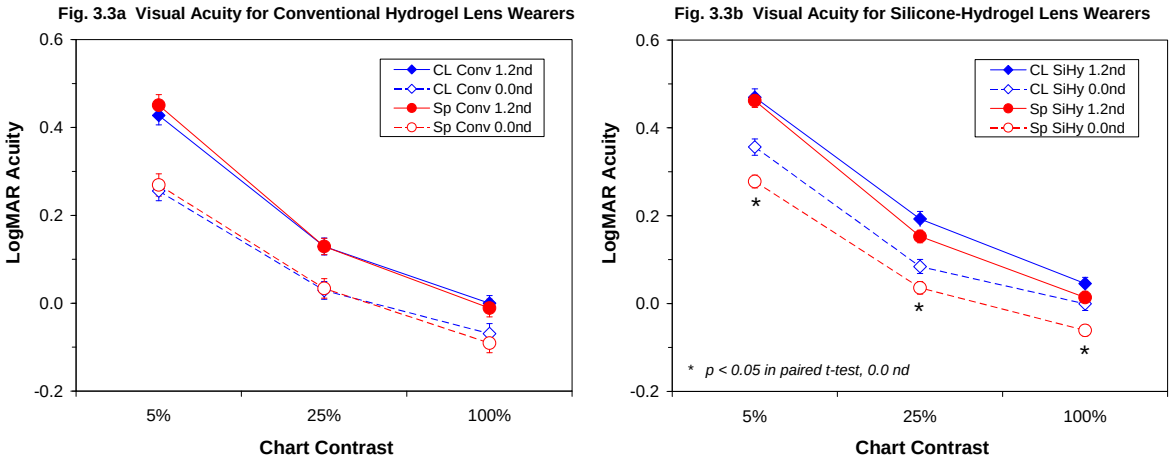


Fig. 3.3: Average LogMAR acuity plotted as a function of chart contrast for conventional lens wearers (a) and silicone hydrogel wearers (b). Blue diamond symbols are for the contact lens on the eye and red circle symbols are for best spectacle correction during the period after contact lens removal. Data for the low illumination level (1.2 log neutral density filter) are shown as filled symbols and data at the high illumination level (0.0 log neutral density filter) are shown as open symbols. Error bars are +/- 1 s.e.m.

3.4. Visual performance for spherical lens wearers only

The silicone hydrogel group had more toric lens wearers than the conventional lens group (five vs. two, respectively) so it is possible that toric lenses contributed to the worse

visual acuity in the silicone hydrogel group with the contact lenses on the eye (Figs. 3.1 and 3.3b). When the data were analyzed with toric lens wearers excluded, silicone hydrogel wearers still had worse visual acuity than conventional lens wearers for most conditions (Fig 3.4), although only the 5% contrast level at 0.0 ND was significant (p=0.019 in t-test).

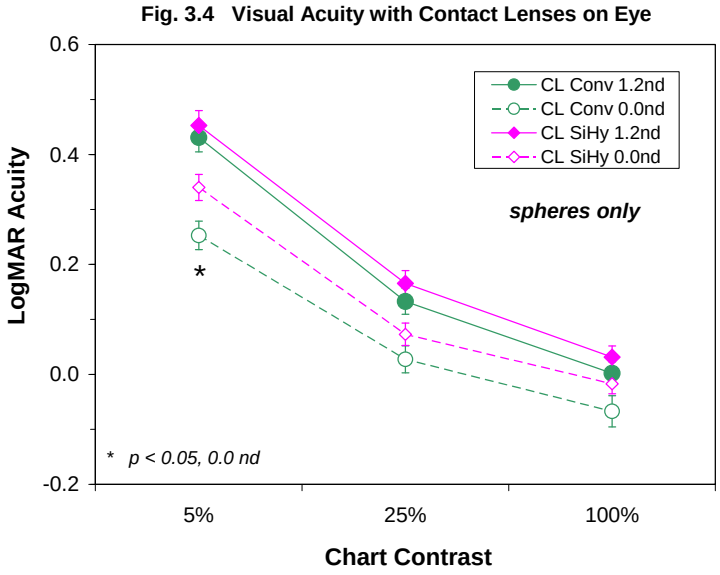


Fig. 3.4: Average LogMAR acuity plotted as a function of chart contrast for conventional lens wearers (green circles) and silicone hydrogel lens wearers (pink diamonds) with toric lens wearers excluded (spherical lens wearers only). Data for the low illumination level (1.2 log neutral density filter) are shown as filled symbols and data at the high illumination level (0.0 log neutral density filter) are shown as open symbols. Error bars are +/- 1 s.e.m.

Fig. 3.5 compares the contact lens vs. spectacle wear conditions for the silicone hydrogel wearers with spherical lenses. Again, as observed in the entire group of silicone hydrogel wearers, acuity with contact lenses was worse compared to spectacle correction. This difference was significant at all contrast levels at the high illumination level (p=0.005 at

5%, p=0.012 at 25% and p=0.0006 at 100% in paired t-tests). Thus, the acuity deficit observed in the silicone hydrogel wearers for the contact lens-on-eye condition is not due merely to the presence of the toric lens wearers in that group.

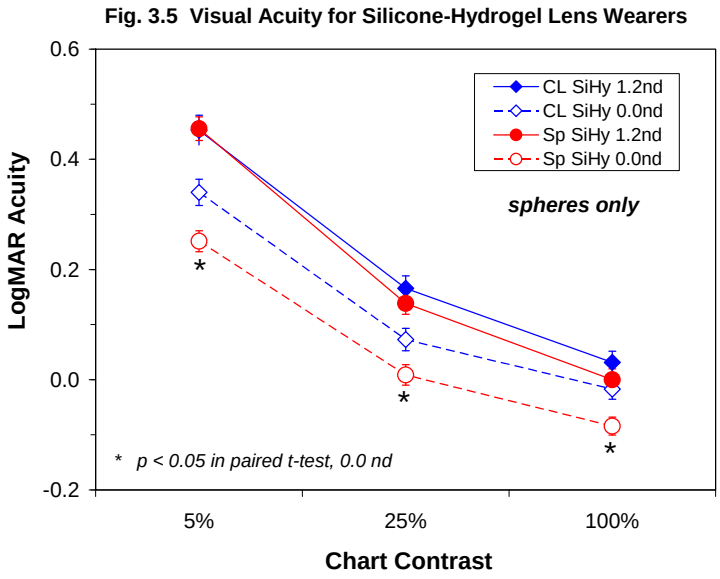


Fig. 3.5: Average LogMAR acuity plotted as a function of chart contrast for silicone hydrogel wearers with toric lens wearers excluded. Blue diamond symbols are with the contact lens on the eye and red circle symbols are for best spectacle correction during the period after contact lens removal. Data for the low illumination level (1.2 log neutral density filter) are shown as filled symbols and data at the high illumination level (0.0 log neutral density filter) are shown as open symbols. Error bars are +/- 1 s.e.m.

3.5. Low contrast acuity deficit with lenses on the eye

Differences in lens design, *i.e.*, how the lens power changes across the lens, could also affect wavefront aberrations when the lens is on the eye which in turn could affect visual performance. In theory, conventional lens wear should have resulted in more corneal swelling than silicone hydrogel lens wear and prior experiments indicated that swelling

should have induced more spherical aberration in the eye (Coletta and Moskowitz, 2003). The increased spherical aberration in contact lens wearers in that study was correlated with the refractive error of the eye, which is consistent with the dependence of corneal swelling on contact lens power (Erickson et al., 1999). In addition, deficits in contrast sensitivity at a middle spatial frequency of 4 cyc/deg were correlated with the amount of spherical aberration (Coletta and Moskowitz, 2003).

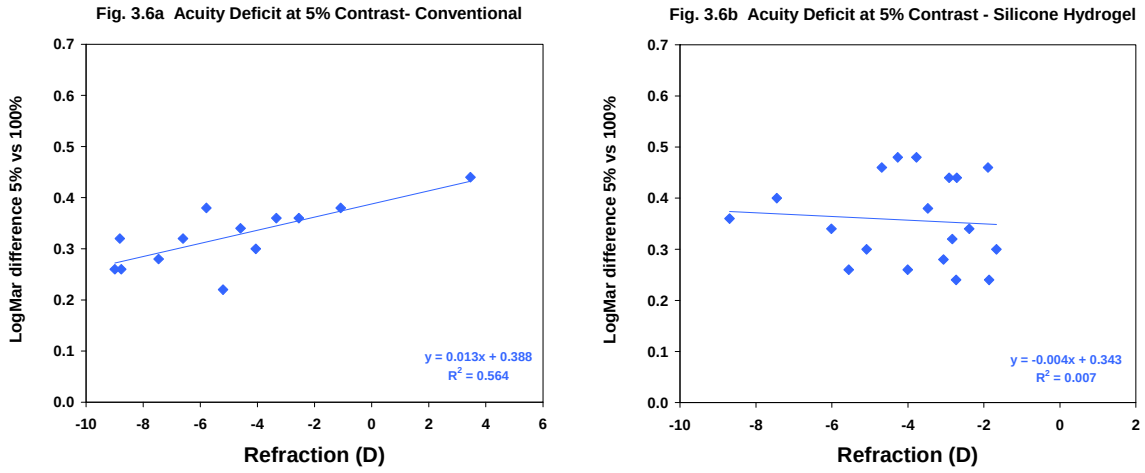


Fig. 3.6: Difference in 5% LogMAR acuity from 100% LogMAR acuity, plotted as a function of the subject's spherical equivalent refractive error for conventional hydrogel lenses (a) and silicone hydrogel lenses (b). Data are for the high illumination level.

In this study, contrast sensitivity was not measured directly at low to middle spatial frequencies; however a loss of contrast sensitivity that affects lower spatial frequencies more than the high spatial frequency cut-off (acuity) of the contrast sensitivity function can be inferred by comparing the 5% and 100% contrast acuities. The deficit in acuity at low contrast, relative to high contrast acuity, is shown in Fig. 3.6 for the condition when the

contact lenses were worn. This analysis was performed for the high illumination level, since a greater difference in performance between contact lens types was observed at the high illumination level. The data were obtained by subtracting the 100% LogMAR acuity from the 5% LogMAR acuity, yielding the deficit in acuity for the low contrast chart, which is plotted against the subject's spherical equivalent refractive error.

The results show a strong correlation of the low contrast acuity deficit with refraction in the conventional lens wearers ($p=0.003$) but not in the silicone hydrogel wearers. The low contrast acuity deficit became smaller as the refraction became more negative. Even when the hyperope was excluded from the conventional wear group, this correlation was still significant ($R^2 = 0.356$; $p=0.04$). As cited above, corneal swelling depends on lens power, so the correlation of the low contrast acuity deficit with refraction could be related to spherical aberration induced by corneal swelling, or it could be due to the spherical aberration characteristics of the conventional lens itself. The low contrast acuity deficits for the conventional lens wearers did not show the same correlation with refraction after the contact lenses were removed ($R^2 = 0.111$; $p=0.26$), implying that the effect observed in Fig. 3.6 is related to the aberrations of the conventional hydrogel lens itself rather than to corneal swelling. The contribution of the contact lens aberrations to the ocular aberrations will be presented in Chapter 4.

Chapter 4

Ocular and corneal wavefront aberrations with conventional and silicone hydrogel lenses

4.1. Ocular aberrations

Ocular or whole-eye aberrations were measured with the COAS aberrometer and expressed as Zernike coefficients in micrometers (μms or microns) from the 2nd to 7th order for a wavelength of 550nm. The 2nd order aberrations include the sphere and cylinder component of the refraction, while the 3rd through 7th order are termed the higher-order aberrations. The Optical Society naming convention for Zernike coefficients was used in this study (ANSI 2010). Ocular aberrations were measured under four conditions as described in Chapter 2: with the contact lens on the eye, immediately after lens removal, 20 minutes after lens removal, and one hour after lens removal. Five measurements were obtained for each condition and the Zernike coefficients were averaged.

4.1.1. Ocular aberrations and pupil diameter

The average pupil diameter for all subjects during the COAS measurements was 5.87, 5.92, 5.93 and 6.13 mm for the four measurement conditions, respectively. There was no significant difference in pupil diameter among the four conditions (single factor ANOVA; $p>0.05$), nor was there a significant difference in pupil diameter between the conventional vs.

silicone hydrogel wearers. The mean pupil diameter for all four conditions was 5.98 mm +/- 1.01 s.d. for conventional wearers and 5.95 mm +/- 0.95 s.d. for silicone hydrogel wearers; $p > 0.05$ in t-test. The smallest average pupil diameter for all four conditions among subjects was 3.47 mm and the largest was 7.22 mm; these were both silicone hydrogel wearers. There was not a significant correlation of pupil diameter with the COAS refraction in this study ($p>0.05$).

To examine how the higher-order aberrations would change with varying pupil diameter, the COAS aberrations were computed for 3, 4, 5, and 6 mm pupil diameters. All 32 subjects had pupils large enough to analyze aberration coefficients at a pupil diameter of 3 mm, 31 had large enough pupils to analyze at 4 mm, 27 had large enough pupils to analyze at 5 mm, and 24 subjects had pupils large enough to analyze at 6 mm. The root-mean-square (RMS) aberration in each Zernike order (3^{rd} through 7^{th}) was computed for each eye by taking the square root of the sum of the squares of the individual Zernike coefficients in each order. The mean RMS aberration in each order, as well as the mean of the single spherical aberration (c_4^0) Zernike coefficient, was computed for each contact lens type and compared. These means were obtained for all subjects who could be measured at a given pupil diameter and for just the group of 24 subjects that had 6 mm pupil diameters. Spherical equivalent refractions were obtained from the 2^{nd} order coefficients and expressed in Diopters; the refractions were compared for both the contact lens on-eye condition and for each of the time intervals after contact lens removal.

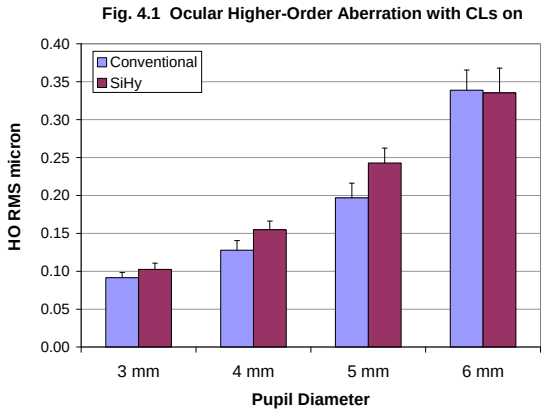


Fig. 4.1: Average ocular higher-order RMS aberration in μms with contact lenses on the eye, for four pupil diameters. Conventional refers to the conventional hydrogel lens type and SiHy refers to the silicone hydrogel lens type. Error bars are 1 s.e.m.

4.1.2. Ocular higher-order aberrations with contact lenses on the eye

The ocular (whole-eye) higher-order aberrations from 3rd through 7th order are compared at various pupil diameters for the two types of contact lenses in Fig. 4.1. For the 3, 4 and 5 mm pupil diameters, subjects with silicone hydrogel lenses showed greater aberrations with the lenses on the eye than did the conventional lens wearers. These differences did not quite reach significance ($p>0.05$) in one-tailed t-tests, although several conditions approached significance ($p=0.07$ for 4 mm pupil; $p=0.065$ for 5 mm pupil).

Fig. 4.2 compares the RMS aberration in each Zernike order for the two lens types, at each pupil diameter from 3 to 6 mm. At the 3, 4 and 5 mm diameters, silicone hydrogel wearers exhibit more aberration in each Zernike order than conventional lens wearers. The differences in aberration between contact lens types did not reach significance in t-tests. For the 6 mm pupil diameter (Fig. 4.2d), conventional wearers had greater aberration than

silicone hydrogel wearers in all Zernike orders except the 4th order, at which the silicone hydrogel wearers had greater aberration. When the same analyses were performed with only the 24 subjects who had 6 mm diameter pupils, the results were the same: silicone–hydrogel wearers had greater aberrations in all orders for 3, 4 and 5 mm pupils but not at the 6 mm diameter, and again, no condition reached statistical significance.

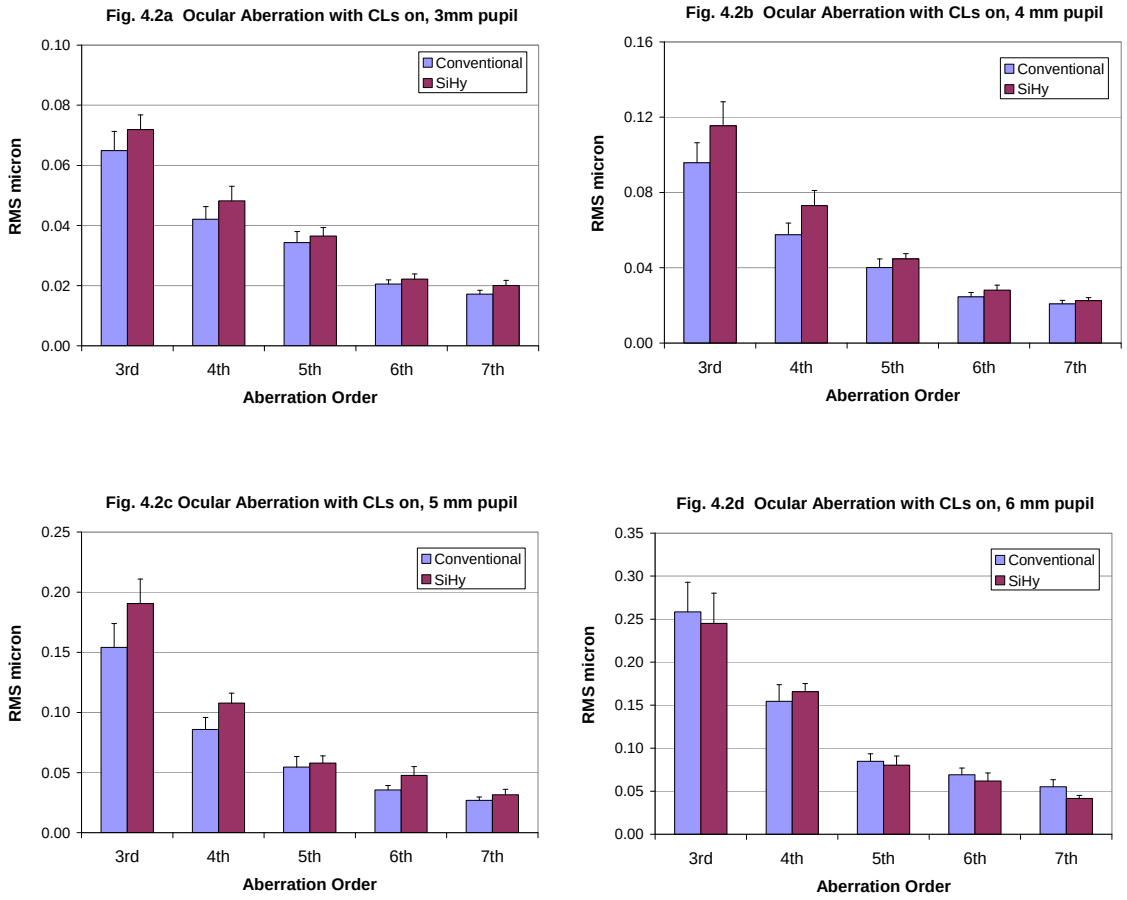


Fig. 4.2: Average ocular aberrations in the third through seventh Zernike orders with contact lenses on the eye, for pupil diameters of (a) 3 mm, (b) 4 mm, (c) 5 mm, and (d) 6 mm. Error bars are 1 s.e.m.

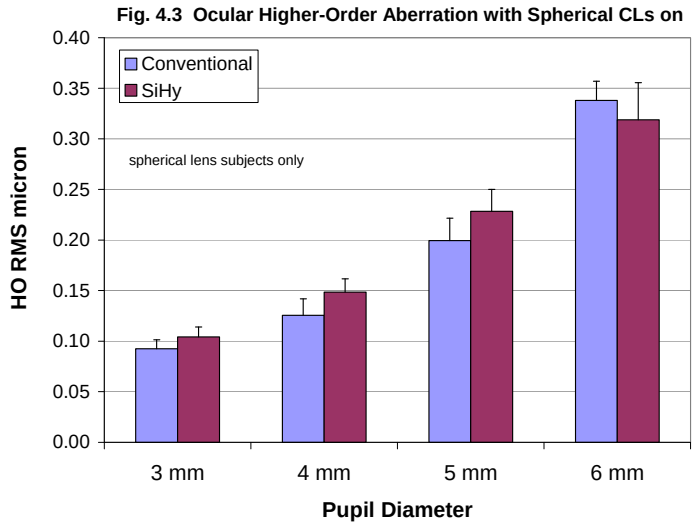


Fig. 4.3: Average ocular higher-order aberrations for subjects with spherical lenses only. Aberrations were measured with the contact lenses on the eye and are shown for pupil diameters from 3 to 6 mm. Error bars are 1 s.e.m.

The silicone hydrogel group had more toric lens wearers than the conventional lens group (five vs. two, respectively) so it is possible that toric lenses contributed to the greater on-eye aberrations in the silicone hydrogel group. However when toric wearers were excluded, the silicone hydrogel wearers still had greater higher-order aberrations than conventional lens wearers at the 3-mm to 5-mm pupil diameters (Fig 4.3). Removing the toric lens wearers resulted in a relative reduction in 3rd order aberration in the silicone hydrogel wearers at pupil diameters from 3 to 5 mm, but the silicone hydrogel wearers still have greater aberrations than conventional wearers at these pupil diameters. At the 6 mm pupil diameter, silicone hydrogel wearers had greater aberration than conventional wearers only in the 4th order, as was observed for the entire group in Fig. 4.2d. Thus, the increased aberration observed in the silicone hydrogel wearers for the lens-on-eye condition is not due merely to the presence of more toric lens wearers in that group.

4.1.3. Ocular higher-order aberrations after contact lens removal

Higher-order aberrations measured immediately after removal of the contact lens are shown for both types of contact lens at four pupil diameters in Fig. 4.4. For each pupil diameter, silicone hydrogel lens wearers had significantly greater higher-order RMS than did the conventional lens wearers (p=0.045 for 3 mm pupil; p=0.039 for 4 mm pupil; p=0.009 for 5 mm pupil and p=0.032 for 6 mm pupil in t-tests). When only the 24 subjects with 6 mm pupils were included in the analysis, results were still significant for the 4, 5 and 6 mm pupil diameters.

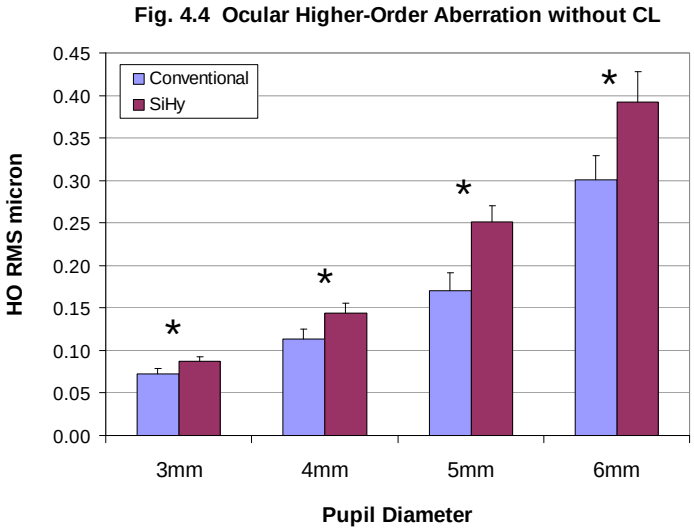
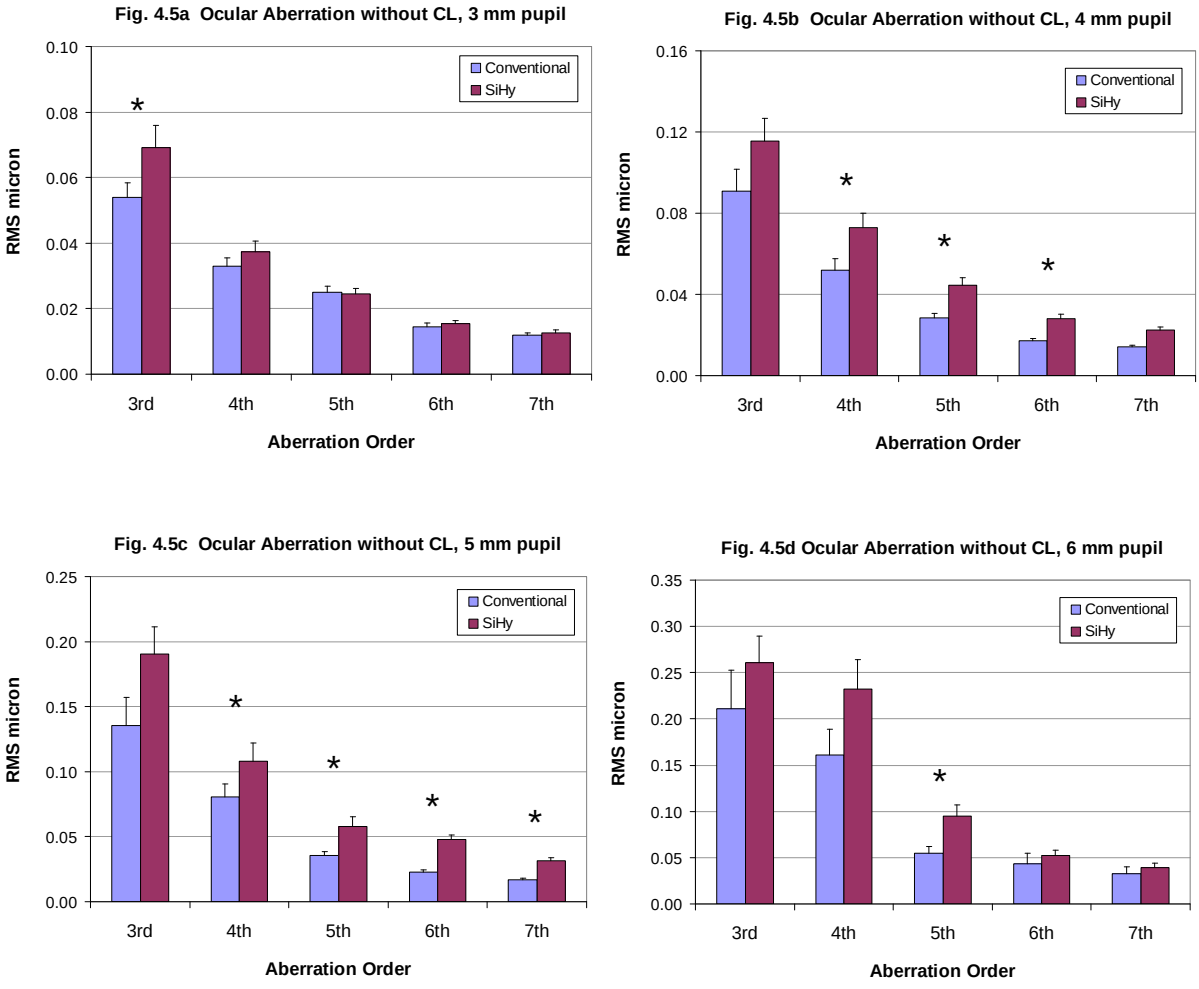


Fig. 4.4: Average ocular higher-order aberration for the period immediately after removal of the contact lenses. Aberrations are shown for pupil diameters from 3 to 6 mm. Error bars are 1 s.e.m. Asterisks indicate conditions with p<0.05 on t-tests.

The results for the individual aberration orders are shown for this same time period in Fig. 4.5 for 3 mm through 6 mm pupil diameters. With the 3 mm pupil diameter, only the 3rd order aberration was significantly greater in the silicone hydrogel wearers (p=0.038; Fig.

4.5a). The silicone hydrogel wearers had significantly greater aberrations in the 4th, 5th and 6th order with the 4 mm pupil diameter (p=0.039, p=0.016 and p=0.041, respectively in Fig. 4.5b) and in the 4th through 7th orders with the 5 mm pupil diameter (p=0.004, p=0.006, p=0.003 and p=0.007, respectively Fig. 4.5c). Aberration in the silicone hydrogel wearers was significantly greater only in the 5th order for the 6 mm pupil diameter data (p=0.005 in Fig. 4.5d).



Figs. 4.5: Average ocular aberration in each Zernike order during the period immediately after removal of the contact lenses. Aberrations are shown for pupil diameters from 3 to 6 mm in panels (a) to (d), respectively. Error bars are 1 s.e.m. Asterisks indicate conditions with p<0.05 on t-tests.

When these results were analyzed for only the 24 subjects with large pupils, the results for were essentially the same: significantly greater aberrations in the silicone hydrogel wearers in the 4^{th}, 5^{th}, and 6^{th} orders for the 4mm pupil and 4^{th} through 7^{th} order for the 5 mm pupil; however, the difference in 3^{rd} order aberration between the two lens types became non-significant ($p=0.13$) for the 3 mm pupil diameter.

The higher-order RMS aberration measured at 20 minutes and 1 hour after contact lens removal were similar to those measured immediately after lens removal, for each pupil diameter. This was also true for the aberration values in the single orders with a 6 mm pupil diameter. A single-factor ANOVA on the higher-order RMS data for the three measurements after lens removal (immediately after removal, 20 minutes after removal and 1 hour after removal) showed there was no significant effect of time for any pupil diameter, and for each lens type ($p>0.05$).

4.1.4. Ocular spherical aberration with contact lenses on the eye

Fourth-order spherical aberration is designated as the c_4^0 coefficient in the OSA Zernike terminology. Fig. 4.6 plots the c_4^0 coefficient for four pupil diameters in the conventional and silicone hydrogel lens wearers while the lenses were on the eye. Aberration magnitude increased with increasing pupil diameter as expected. Conventional lens wearers, on average, had negative spherical aberration while silicone hydrogel wearers had positive spherical aberration. The difference in spherical aberration between lens types was significant for the 5 mm pupil diameter ($p=0.01$ in t-test, one-tailed). Positive spherical

aberration results in marginal rays, at the edge of the pupil, focusing in front of paraxial rays. Positive spherical aberration would effectively create myopic defocus for larger pupil diameters, which could be related to the reduced visual performance observed in the silicone hydrogel wearers, described in Chapter 3.

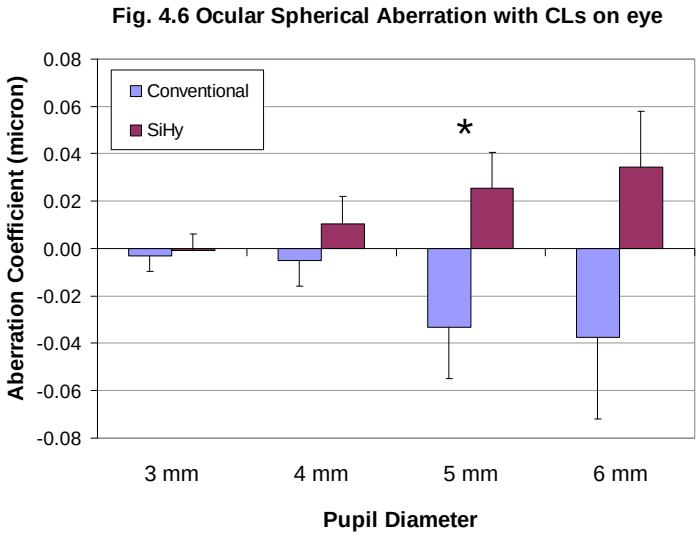


Fig. 4.6: Average ocular spherical aberration coefficient c_4^0 for subjects with lenses on the eye. Aberrations are shown for pupil diameters from 3 to 6 mm. Error bars are 1 s.e.m.

4.1.5. Refractions with the contact lens on the eye

The average over-refraction in the COAS measurements at the subject's natural pupil size, expressed as the spherical equivalent in diopters, was -0.17 D for the conventional lens wearers and -0.58 D for the silicone hydrogel wearers. This difference was significant in a t-test ($p=0.015$) and indicates that the silicone hydrogel wearers were more myopic with their lenses on than the conventional wearers. The difference in over-refraction was not due to the presence of having more toric lens wearers in the silicone hydrogel group, since excluding

toric lens wearers from both groups resulted in mean over-refractions of -0.22 D for the conventional lens wearers vs. -0.62 D for the silicone hydrogel wearers (p=0.04 in t-test).

An explanation for this difference is that the COAS over-refraction may have been affected by the type of spherical aberration of the eye when the contact lenses were in place. Positive spherical aberration observed in the silicone hydrogel group (Fig. 4.6) could have biased the COAS refraction toward a more myopic endpoint due to the more myopic focus position of the marginal rays. The COAS aberrometer allows one to select the 'Seidel sphere' option in calculating the refraction – this option adds in the 4th order spherical aberration term to the 2nd order coefficients. With positive spherical aberration added to the 2nd order coefficients, the refraction shifts to a more hyperopic or less myopic position. In this case, the Seidel sphere option was not selected; if it had been, the over-refractions of the silicone hydrogel wearers would have shifted to a less myopic position, so the difference in over-refractions in the two contact lens groups is likely due to the differing signs of their spherical aberration coefficients.

To verify that spherical aberration could affect the over-refraction, the spherical equivalent over-refraction was calculated for a 4 mm pupil from the Zernike 2nd order defocus coefficient and the 4th order spherical aberration coefficient, using the following equation (Iskander, et al., 2007):

$$M = \frac{-4\sqrt{3}}{r^2} c_2^0 + \frac{12\sqrt{5}}{r^2} c_4^0$$

where M is the spherical equivalent refraction, r is the pupil radius and the c terms are the Zernike coefficients. The mean spherical equivalent over-refraction became -0.27 D for the

conventional lens wearers and -0.41 D for the silicone-hydrogel wearers. Thus, the addition of the spherical aberration term shifted the refraction to a more myopic position for the conventional lens wearers and to a less myopic position for the silicone hydrogel lens wearers. This difference in over-refraction was not significant in a t-test ($p>0.05$).

4.1.6. Ocular spherical aberration after contact lens removal

The fourth-order spherical aberration coefficient (c_4^0) is shown in Fig. 4.7 for each pupil diameter and lens type during the period immediately after lens removal. Unlike the situation observed for the contact lens on the eye (Fig. 4.6), all subjects now have positive ocular spherical aberration without their contact lenses. As expected, spherical aberration increases with pupil diameter. Figs. 4.7b and 4.7c show the spherical aberration coefficient for the conditions at 20 minutes after lens removal and at 60 minutes after lens removal, respectively. Results for spherical aberration are similar for each time period and there was no significant effect of time on the spherical aberration coefficient (single-factor ANOVA, $p>0.05$). Contrary to the expectation that conventional lenses cause more swelling, and hence, should result in more positive spherical aberration of the eye than silicone hydrogel lenses, the spherical aberration coefficient tends to be more positive in the silicone hydrogel wearers. However, the difference in ocular spherical aberration between the two lens types was not significant for any pupil diameter ($p>0.05$ in t-tests).

Fig. 4.7a Spherical Aberration immediately after CL removal

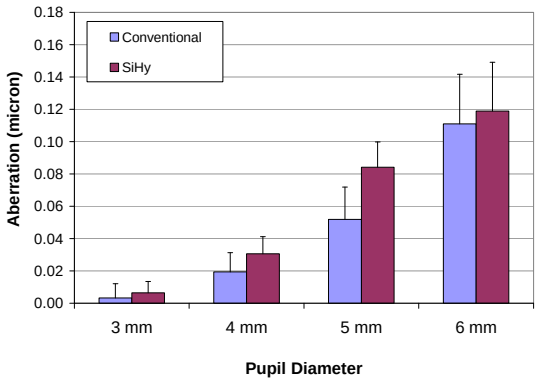


Fig. 4.7b Spherical Aberration 20 min after CL removal

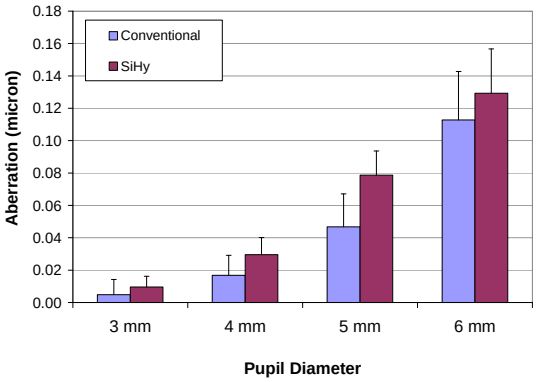
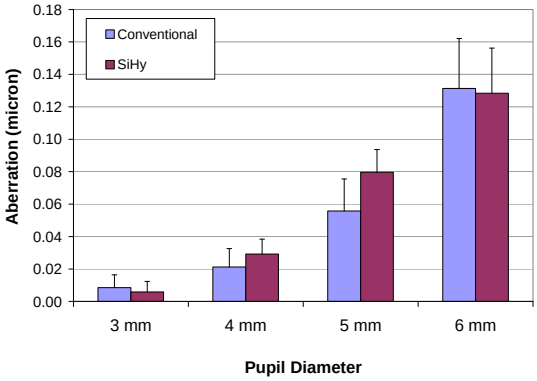


Fig. 4.7c Spherical Aberration 60 min after CL removal



Figs. 4.7: Ocular spherical aberration coefficient (c_4^0) averaged for each lens type and shown as a function of pupil diameter for each of the time intervals measured after contact lens removal; (a) immediately after lens removal; (b) 20 minutes after lens removal; (c) 60 minutes after lens removal. Error bars are 1 s.e.m.

4.1.7. Contribution of the contact lens to ocular spherical aberration

The contact lenses must have contributed negative spherical aberration to the eye, since subjects had positive spherical aberration after lens removal (Figs. 4.7a-c) while spherical aberration was either less positive or even negative for the lens-on-eye condition (Fig. 4.6). Fig. 4.8 shows the amount of spherical aberration contributed by the contact lens

for each pupil diameter from 3 mm to 6 mm. These coefficients were calculated by subtracting the c_4^0 spherical aberration coefficient obtained during the period immediately after lens removal from the c_4^0 coefficient obtained in the lens-on-eye condition. This value represents the contribution of the lens itself to the spherical aberration of the eye. Both conventional and silicone hydrogel lenses produced negative spherical aberration. The conventional lenses tended to induce a greater amount of negative spherical aberration compared to the silicone hydrogel lenses, although this difference was not significant. It has been reported that negative-powered contact lenses induce negative spherical aberration in proportion to the amount of negative power (Awwad et al., 2008).

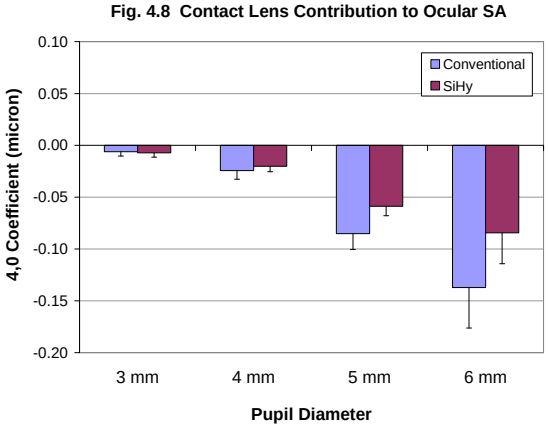


Fig. 4.8: Spherical aberration coefficient (c_4^0) contributed by the contact lens itself. Data were obtained by subtracting the ocular c_4^0 coefficient obtained immediately after lens removal from the ocular c_4^0 coefficient obtained with the lens on the eye. This difference is averaged for each lens type and is shown as a function of pupil diameter. Error bars are 1 s.e.m.

The amount of spherical aberration contributed by the contact lens with a 4 mm pupil is plotted against the subject's spherical equivalent refraction, and thus lens power, in Fig. 4.9. The trends show that spherical aberration becomes more negative as lens power

becomes more negative. This effect was significant for the conventional lenses, which included a hyperopic subject (p=0.0002); even when the hyperopic subject was excluded, the trend for conventional lenses was still significant (R^2=0.488; p=0.01). The trend was not so apparent in the silicone hydrogel group, although the data point at the highest myopic refraction may be an outlier. Spherical aberration should be affected by the lens design, *i.e.*, how the lens curvature changes across the lens surface, and this could differ for conventional and silicone hydrogel lenses.

Fig. 4.9 Contact Lens Spherical Aberration vs. Power

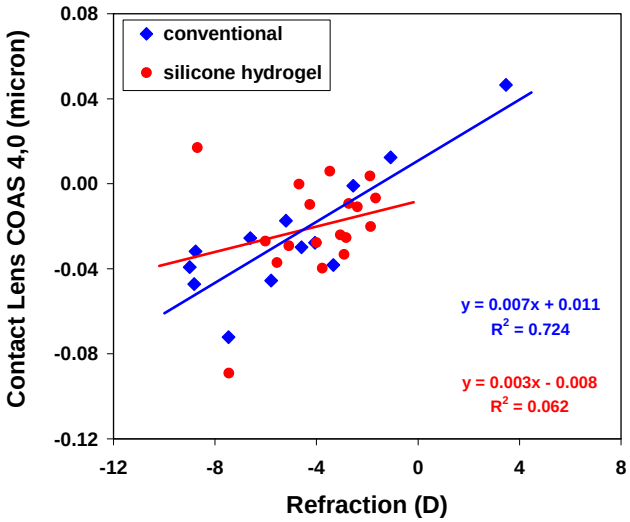


Fig. 4.9: Spherical aberration coefficient (c_4^0) contributed by the contact lens itself, plotted against the subject's spherical equivalent refraction in Diopters. Data were obtained as in Fig. 4.8, and are for a 4 mm pupil diameter. Blue diamond symbols are for the conventional lens wearers and red open circle symbols are for the silicone hydrogel wearers. Solid lines are linear regressions fit to the data.

As shown in Chapter 3, there was a correlation in the conventional lens wearers between the low contrast acuity deficit obtained with the lens on the eye and the refraction, or lens power. The relationship in Fig. 4.9 between negative spherical aberration and

refraction implies that the greater negative spherical aberration in higher minus contact lenses may improve low contrast acuity. The log deficit in low contrast acuity, obtained with contact lenses on the eye, is plotted against the spherical aberration coefficient contributed by the contact lens in Fig. 4.10. The acuity deficits are the same as those plotted in Fig. 3.6 and were taken by subtracting the 100% logMAR value from the 5% contrast logMAR acuity at the high illumination level. In the conventional lens wear group, there is a significant correlation between the low contrast acuity deficit and the contact lens spherical aberration ($p=0.043$), while this trend is not observed in the silicone hydrogel wearers. The results imply that the negative spherical aberration of conventional hydrogel lenses depends on lens power and may help to improve low contrast acuity in myopic subjects.

Fig. 4.10 Low Contrast Acuity Deficit vs. CL 4,0

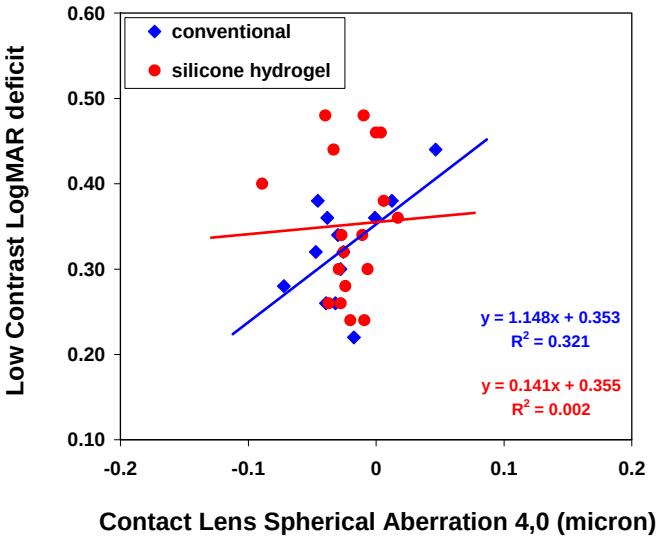


Fig. 4.10: Low contrast acuity deficit in log units, plotted as a function of the spherical aberration coefficient (c_4^0) in μms contributed by the contact lens itself. The acuity deficit was obtained by taking the difference in 5% LogMAR acuity from 100% LogMAR acuity at the high illumination level; data are plotted for conventional hydrogel lens wearers (blue diamonds) and silicone hydrogel lens wearers (red open circles). Spherical aberration coefficients are those from Fig. 4.9 and are for a 4 mm pupil diameter. Solid lines are linear regressions fit to the data.

4.2. Corneal anterior surface aberrations

Wavefront aberrations were derived from the corneal topography maps using VolCT version 7.3 software (Sarver Associates). The COAS aberrations are referenced to the pupil center; thus aberrations derived from the corneal topography maps were referenced to the pupil center rather than to the topography map center so that they could be directly compared to the ocular aberrations. In order to reference corneal aberrations to the pupil center, the position of the pupil center was first determined relative to the topographer ring center in each map. To do this, the raw topographer *.bmp* ring image and the topography data *.mva* file were obtained from each map, using the 'Photokeratoscope' and the 'External Interface' menus in the Humphrey MasterVue software, respectively. These files were analyzed with custom Matlab software (Mathworks, Natick, MA) to locate the pupil edge in the topography image. The centroid of the pupil edge was used as the position of the pupil center. The Matlab image analysis software also determined the position of the ring center (topography map center) and calculated the distance in mm in the x- and y-directions of the pupil center relative to the ring center. As shown in Fig. 4.11, each map had an x- and y- offset for the pupil center relative to the ring center, and the software also determined the diameter of the pupil in the horizontal and vertical directions.

The pupil offset values determined for each topography map were used in the VolCT program under the 'Edit Details' menu to shift the Zernike coefficients calculated for the map to the pupil center. Zernike coefficients were determined up to the 7^{th} order for the corneal data for a wavelength of 550 nm, and at two pupil diameters, 4 mm and 6 mm. These coefficient values represent the aberrations that would be contributed by the front surface of

the cornea (or contact lens, if the images were taken with the lens on the eye) over the designated pupil diameter. It was possible to calculate front-surface aberrations out to a pupil diameter of 6 mm even if the subject had pupils smaller than 6 mm in the topographer image, since the topography data extends beyond the pupil area. Subjects had four topography maps for each condition, and the coefficients derived from each of the four maps were then averaged.

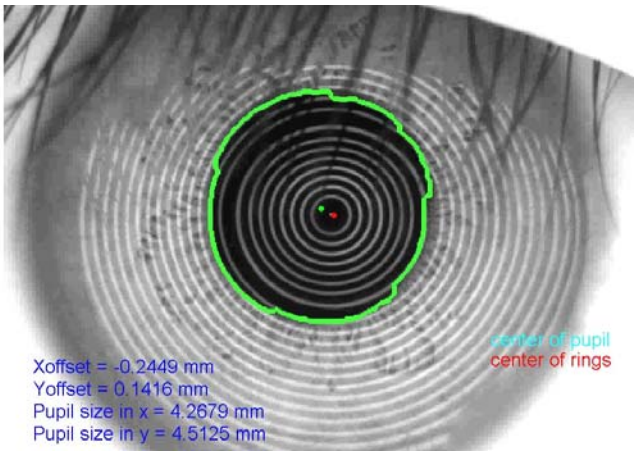


Fig. 4.11: Analysis of a raw topographer ring image, using Matlab custom software. The green circle is the edge of the pupil and the green dot indicates the pupil center; the red dot indicates the ring center. The x- and y- direction distances of the pupil center are given relative to the ring center in mm units.

It is customary to use an index of 1.3375 to convert the corneal radius of curvature measured by a keratometer or topographer to Diopters of corneal power (Bennett and Rabbets, 2nd edition, p. 468). This index is lower than the actual corneal index of 1.376 because the keratometer reading is meant to represent the overall power of the cornea, not just the power of the anterior surface. The posterior surface of the cornea is negatively powered, so the overall corneal power is lower than the power that would be contributed by

the anterior surface alone. The 'keratometer' index value is derived from the total corneal power and assumes that the posterior corneal surface has a radius of curvature of 7.7 mm, or a power of about -5 Diopters, assuming the indices of the Gullstrand Schematic Eye (Bennett and Rabbetts, 2nd edition). In this study, however, aberrations derived from the corneal topography measures were calculated for the anterior surface only. For the condition when the contact lens was in place on the eye, anterior surface aberrations were computed using the index of refraction of the contact lens material. This index varied from 1.38 to 1.43, according to the lens brand and type. Refractive indices for the various contact lens types are summarized in Table 4.1. For the conditions after contact lens removal, the refractive index of the cornea (1.376) was used to calculate the anterior surface aberrations. Thus the 'corneal' aberrations derived here represent the contribution of the contact lens or corneal anterior surface alone and make no assumption about the shape of the posterior surface of the cornea.

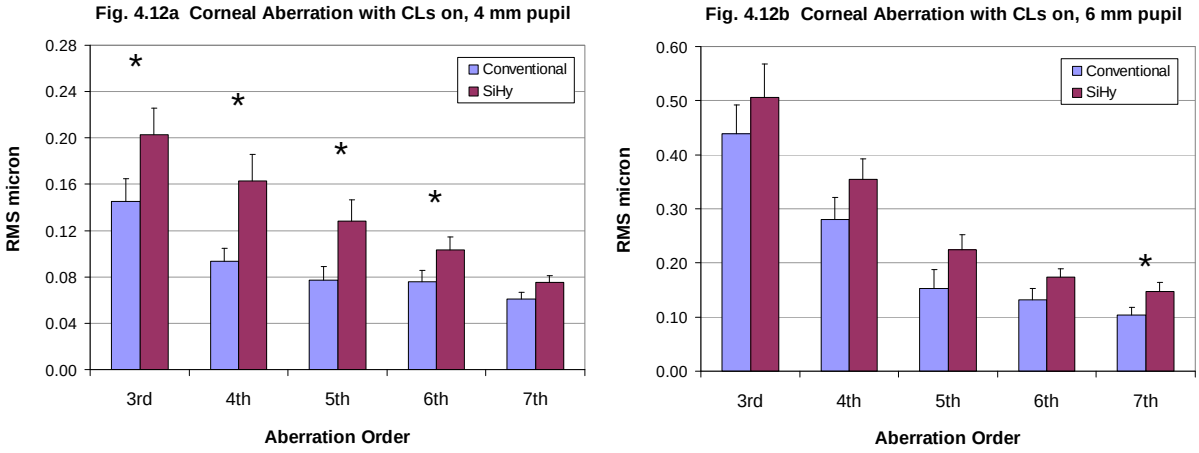
Conventional Brand	Refractive index
Acuvue 2	1.400
Bausch & Lomb Soflens	1.404
Ciba Vision Focus	1.380
CooperVision Proclear	1.387
Hydrogel Vision Clarity H2O	1.414

Silicone Hydrogel Brand	Refractive index
Acuvue Advance	1.410
Acuvue Oasys	1.420
Acuvue TruEye	1.410
Ciba Vision Air Optix	1.420
Ciba Vision Air Optix Night & Day	1.430

Table 4.1. Contact lens refractive indices by type of lens and brand.

4.2.1. Anterior surface aberrations with and without contact lenses on the eye

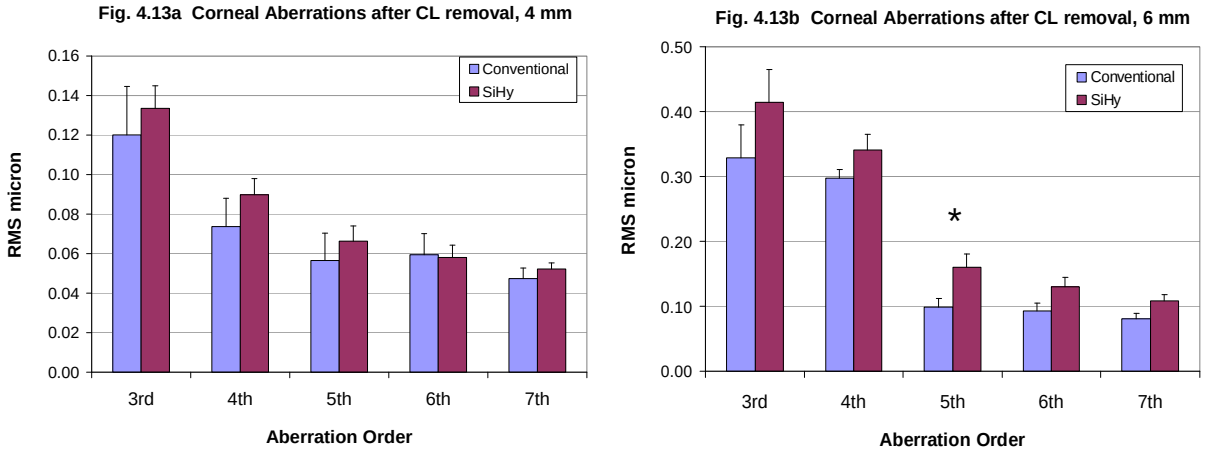
Silicone hydrogel wearers had greater front-surface higher-order aberrations, in the combined 3rd through 7th orders, than conventional lens wearers for both 4 mm and 6 mm pupil sizes. The difference in higher-order aberrations between the two groups was significant for the 4 mm pupil diameter ($p = 0.012$ in t-test).



Figs. 4.12: Anterior surface aberrations contributed by the contact lens in corneal topography images. Higher-order aberrations are shown in each of the 3rd through 7th Zernike orders expressed as RMS in μms, for each lens type group at the 4 mm pupil diameter (a) and 6 mm pupil diameter (b). Error bars are 1 s.e.m.

Anterior surface aberrations in each of the Zernike higher orders are shown for the two contact lens groups for a 4 mm pupil in Fig. 4.12a and for a 6 mm pupil in Fig. 4.12b. Silicone hydrogel wearers have greater corneal aberrations with the lens on the eye than conventional wearers at all Zernike orders, and this effect was significant for all orders except the 7th with the 4 mm pupil ($p=0.04$ for 3rd order; $p=0.006$ for 4th order; $p=0.012$ for 5th order; $p =0.041$ for 6th order in Fig. 4.12a) and in the 7th order with the 6 mm pupil

(p=0.03 in Fig. 4.12b). These aberrations represent the wavefront error determined from the anterior surface of the contact lens while the lens is in place on the eye. The difference in corneal aberrations for the two contact lens groups was relatively greater for the 4 mm pupil than for the 6 mm pupil. This effect implies that aberrations change more rapidly in the silicone hydrogel lenses as a function of distance from the pupil center, which may reflect a difference in the optical design of the silicone hydrogel lenses compared to the conventional lenses.



Figs. 4.13: Average higher-order anterior corneal surface aberrations immediately after contact lens removal, derived from corneal topography images. Higher-order aberrations are shown in each of the 3rd through 7th Zernike orders expressed as RMS in μms, for each lens type group at the 4 mm pupil diameter (a) and 6 mm pupil diameter (b). Error bars are 1 s.e.m.

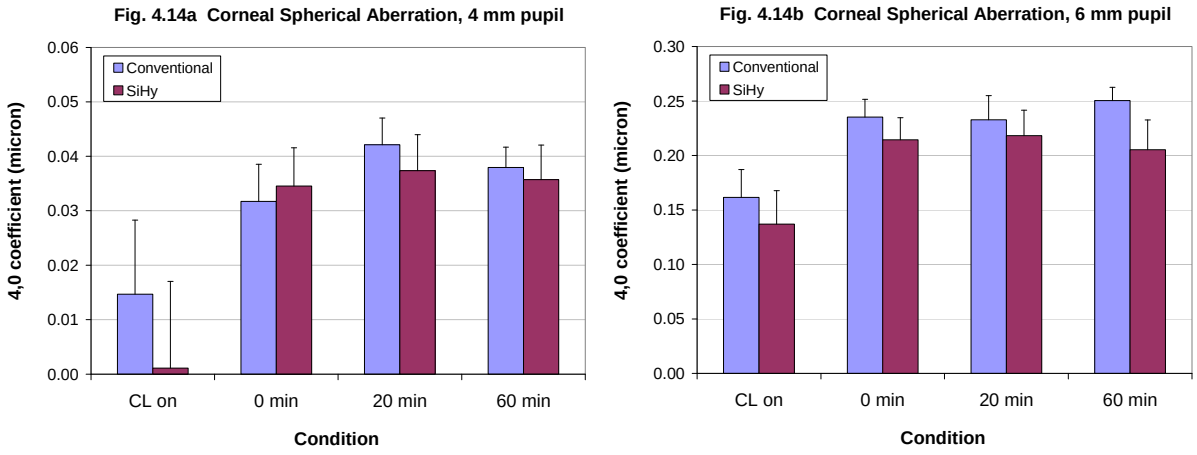
Aberrations derived from the corneal front surface during the time period immediately after contact lens removal are shown in Fig. 4.13a for a 4mm pupil and Fig. 4.13b for a 6 mm pupil. Generally, aberrations without the contact lens are lower than with the contact lens in place. The only exception is that fourth order RMS was lower for

conventional lenses with the contact lens on the eye than without the lens for the 6 mm pupil diameter. After the contact lenses were removed, silicone hydrogel wearers have greater corneal aberrations in nearly all of the Zernike orders compared to conventional lens wearers, although this difference was not significant for the 4 mm pupil, and it was significant only in the 5^{th} order for the 6 mm pupil diameter.

4.2.2. Effect of the contact lens on corneal spherical aberration

In general, the silicone hydrogel wearers tended to have greater wavefront aberrations with contacts on the eye than conventional hydrogel wearers, in both the corneal and in the whole eye measurements. However the spherical aberration coefficient, c_4^0, derived from the corneal topography data, tends to be higher in the conventional hydrogel wearers, both with lenses on the eye and after the lenses were removed. Spherical aberration coefficients derived from the corneal topography data are shown in Fig. 4.14, for the conditions with the lens on the eye and for each of the time periods measured after contact lenses were removed. There is more positive spherical aberration contributed by the anterior corneal surface after the contact lenses are removed than when the contact lenses are worn. This indicates that the contact lenses contribute negative spherical aberration to the cornea when they are on the eye. With the contact lens on the eye, spherical aberration of the anterior surface is still positive for both lens types but conventional lens wearers had more positive spherical aberration than silicone hydrogel lens wearers. This is more evident at the 4 mm pupil diameter, but the differences between lens types in spherical aberration were not significant for any condition.

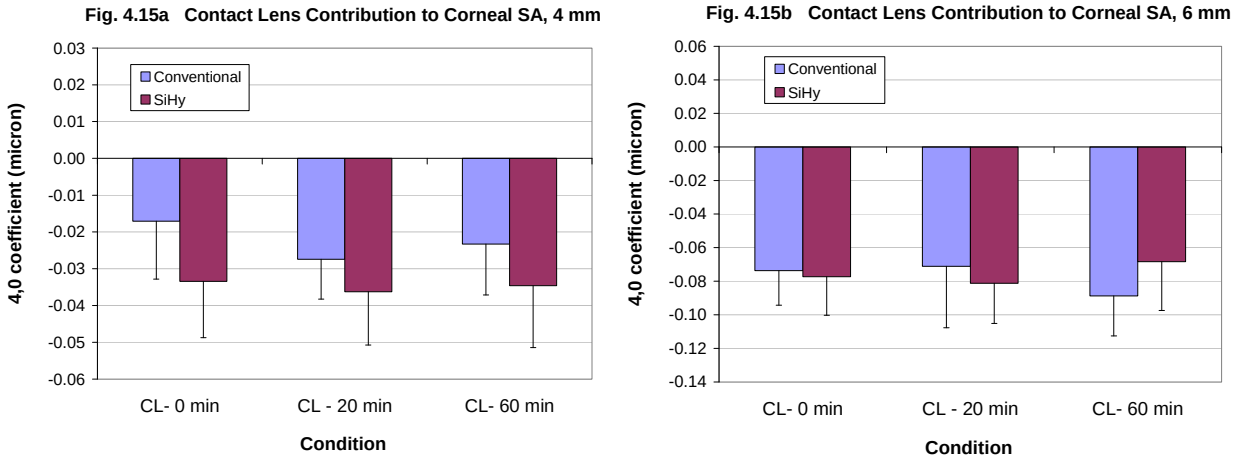
The effect of the contact lens on the spherical aberration of the corneal surface is shown for each of the time intervals in Fig. 4.15. These data were taken as the difference in the spherical aberration coefficient between the contact lens on-eye condition and the condition after lens removal. This more easily demonstrates that the contact lenses contribute negative spherical aberration to the anterior surface of the eye when they are worn. This is generally consistent with the results in Fig. 4.8, which shows the negative spherical aberration contributed by the contact lens to the ocular aberrations.



Figs. 4.14: Spherical aberration coefficient (c_4^0) derived from the corneal topography data, with contact lenses on the eye and at different time intervals after removal of the contact lenses. Aberration coefficients are expressed in μms, and shown for each lens type group at the 4 mm pupil diameter (a) and 6 mm pupil diameter (b). Error bars are 1 s.e.m.

There were no significant differences in spherical aberration contributed by the two types of lenses to the corneal surface. The COAS whole eye aberration data in Figs. 4.6 and 4.8 indicated that the conventional lenses had more negative spherical aberration than silicone hydrogel lenses but this effect is not observed in the corneal data. This discrepancy

could be due to differences in the tear lens behind the contact lens, since the COAS data with the lens on the eye would include effects of the tear lens between the contact lens and the cornea, while the topography data only include the contribution from the anterior lens surface.



Figs. 4.15: Spherical aberration coefficient (c_4^0) contributed by the contact lens derived from the corneal topography data, for each time interval after removal of the contact lenses. Aberration coefficients are expressed in μms, and shown for each lens type group at the 4 mm pupil diameter (a) and 6 mm pupil diameter (b). Error bars are 1 s.e.m.

4.3. Internal aberration before and after contact lens removal

Inspection of the ocular aberrations (Fig. 4.5) and the corneal aberrations (Fig. 4.13) after the contact lenses were removed confirms the reported finding that aberrations of the whole eye are less than aberrations contributed from the cornea alone (Artal et al., 2001). This effect is caused by internal compensation of the corneal aberrations, mainly by the

optics of the crystalline lens and perhaps by a contribution of the posterior corneal surface. Corneal swelling during conventional contact lens wear may result in changes to the posterior corneal surface, which can alter the internal aberrations.

Internal spherical aberration, derived by subtracting the 4 mm pupil corneal spherical aberration from the 4 mm pupil ocular spherical aberration, was averaged for each lens group and shown for each measurement condition in Fig. 4.16. Subjects tend to have a small amount of negative internal spherical aberration, which is slightly greater in magnitude in the conventional lens wearers. However, the differences between lens types for the internal spherical aberration are not significant for any of the four measurement conditions. There also was no significant correlation between the amount of internal spherical aberration and the lens power (subject's refraction) for any of the four conditions.

Fig. 4.16 Internal Spherical Aberration, 4 mm

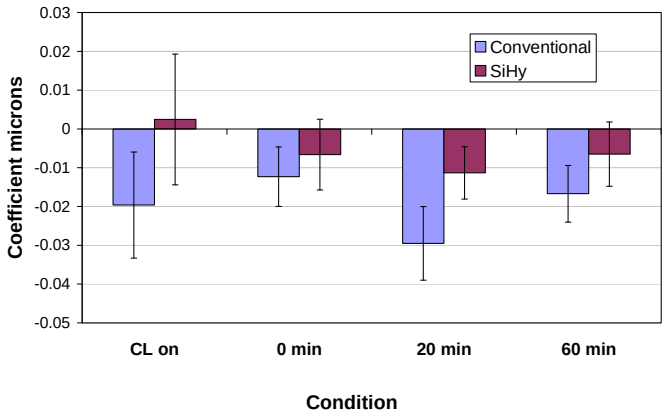


Fig. 4.16. Average internal spherical aberration coefficient for each measurement condition, taken by subtracting the corneal from the ocular spherical aberration coefficient. Error bars are +/- 1 s.e.m.

Internal aberration coefficients were derived for all the Zernike polynomials by subtracting the corneal from the respective ocular aberration coefficient for each subject and then calculating each subject's RMS value in the Zernike orders. The overall internal aberrations for a 4 mm pupil were greater when the contact lens was worn (Fig. 4.17a) compared to the condition immediately after contact lens removal (Fig. 4.17b). This was true for both types of lenses. The data indicate, though, that the silicone hydrogel wearers have significantly more internal higher-order aberration in the 4th through 7th orders when the contact lenses are on the eye, compared to the conventional hydrogel wearers (p=0.044 for 4th order, p=0.028 for 5th order, p=0.006 for 6th order, and p=0.023 for 7th order; p=0.038 for HO aberration). When the lenses were removed, internal aberrations decreased and there were no differences between the lens types.

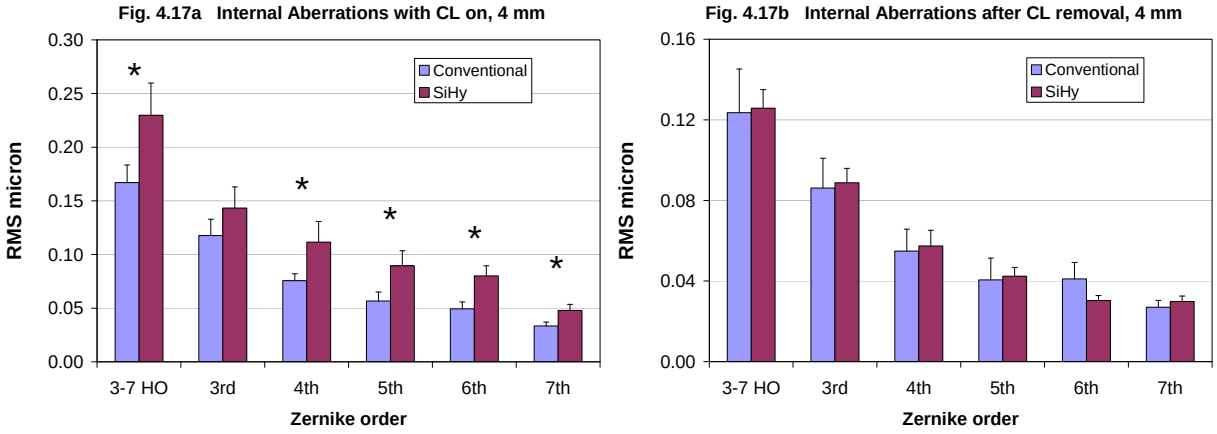


Fig. 4.17. Average higher-order internal aberrations in the 3rd through 7th orders combined (left columns) and in each Zernike order, for the 4 mm pupil diameter and for both lens types. Internal coefficients were derived by subtracting the corneal from the ocular aberration coefficients for each subject and then calculating each subject's RMS value. Panel (a) is when the contact lens is on the eye and panel (b) is for the period immediately after lens removal. Error bars are 1 s.e.m.

Chapter 5

Corneal Thickness in Conventional and Silicone-Hydrogel Lens Wearers

5.1 Central corneal thickness with and without contact lenses on the eye

Fig 5.1a shows the central corneal thickness with the contact lenses on the eye for conventional and silicone hydrogel wearers. With lenses on the eye the average central corneal thickness for conventional wearers was 599 μms and for silicone hydrogel wearers was 591 μms. The difference between the central thicknesses for the two types of contact lenses was not statistically significant ($p>0.05$). This Fig. also shows, in the right hand columns, the corneal thickness at the thinnest point with lenses on the eye for conventional and silicone hydrogel lens wearers. As with the central corneal thickness, we can see that the corneal thickness is higher for conventional lens wearers as compared to silicone hydrogel wearers. The average thinnest local point for conventional contact lens wearers was 597 μms and for silicone hydrogel wearers it was 587 μms. There is no statistically significant difference ($p>0.05$) between the two types of lens wearers.

When the contact lenses were removed, the central and thinnest corneal points were reduced in thickness by about 39 μms for both contact lens types (Fig. 5.1b). Thus the central thicknesses of the two contact lens types were comparable, according to the Pentacam measurements, although silicone hydrogel lenses are supposed to be thicker than conventional lenses. Figs. 5.1a and 5.1b show that the thickness of the cornea in the

conventional contact lens wearers is higher than that for silicone hydrogel lens wearers. As our subjects had to wear the contact lenses for a minimum of 4 hours prior to the study, the increased thickness in the conventional wearers could be due to the swelling of the cornea during conventional lens wear.

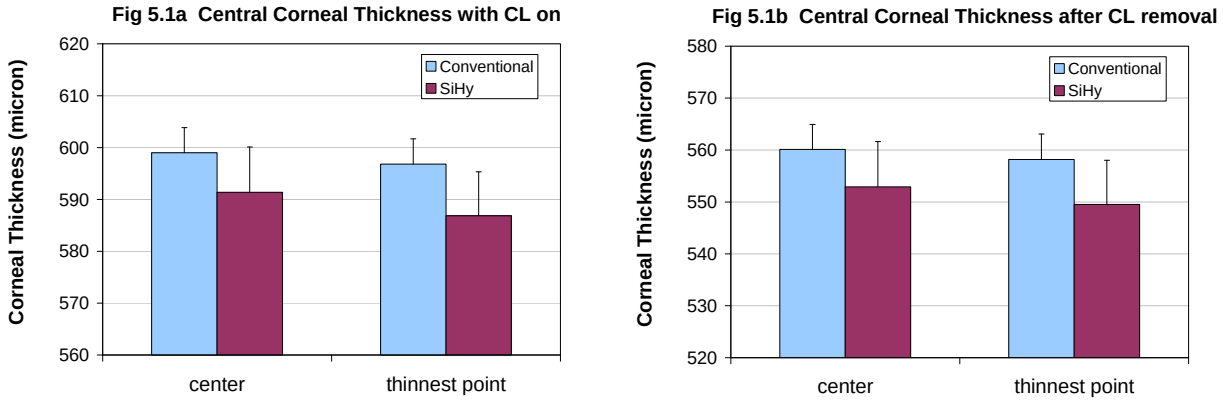


Fig. 5.1: Average central corneal thickness (left hand columns) and thickness of the cornea at the thinnest point (right hand columns) for both types of contact lenses, (a) with contact lenses on the eye and (b) immediately after removal of the contact lenses. Error bars are 1 s.e.m.

5.2 Contact lens thickness profiles

The contact lens thickness can be estimated from the difference between the Pentacam thickness measurement with the contact lens on the eye minus the measurement immediately after lens removal. These values for all of the measured locations are shown in Fig. 5.2. The contact lens thickness values derived from the measurements at the central cornea and at the thinnest corneal location are shown in the two left hand columns. The remaining columns show the derived lens thickness for each of the peripheral corneal measurements. The central thicknesses of the two contact lens types were comparable, as

stated above, but the conventional lenses tend to be thicker in the periphery than the silicone hydrogels. This may be due to the fact that the conventional lens wearers were on average more myopic than the silicone hydrogel wearers and thus the more minus conventional lenses would have thicker peripheral profiles.

Fig 5.2 Contact Lens Thickness Profiles

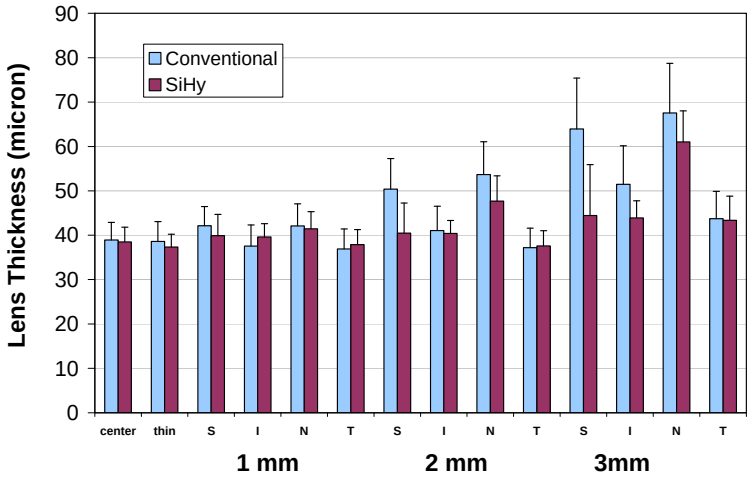


Fig. 5.2: Average contact lens thickness for each lens type at each of the corneal measurement locations. These values were taken as the difference of the Pentacam measurement with the contact lens on the eye minus the corneal thickness measurement immediately after contact lens removal. Data are shown for the central cornea, thinnest location, and peripheral locations at 1 mm distance, 2 mm distance and 3 mm distance from the corneal center in each meridian (s=superior; i=inferior; n=nasal; t=temporal). Error bars are 1 s.e.m.

The average contact lens center thickness measured in this study was 39 μms for conventional hydrogel lenses and 38 μms for silicone hydrogel lenses. These center thickness measurements are thinner than the corresponding values specified by the manufacturers, as shown in Table 5.1. This discrepancy could be due to the variation in lens power in our study lenses, or to the resolution and accuracy of the Pentacam thickness

values. To our knowledge, measurement of contact lens thickness with a Pentacam has not been reported, although it agrees well with ultrasound pachymetry for measurements of central corneal thickness (Lackner et al., 2005; Barkana et al., 2005; Al-Mezaine et al., 2008). Contact lens thickness estimates could also be affected by the quality of the tear film over the contact lens while taking Pentacam measurements.

Conventional Brand	**Center thickness (microns)**
Acuvue 2	84
Bausch & Lomb Soflens	50 to 75
Ciba Vision Focus	100
Cooper Vision Proclear	35 to 65
Hydrogel Vision Clarity H2O	85
Silicone Hydrogel Brand	**Center thickness (microns)**
Acuvue Advance	70
Acuvue Oasys	70
Acuvue TruEye	85
Ciba Vision Air Optix	80
Ciba Vision Air Optix Night & Day	80

Table 5.1: Center thickness of the various brands of contact lenses, as provided by the manufacturers. All values are for a -3.00D lens except B&L Soflens and Cooper Vision Proclear which just specify the ranges that vary with power.

5.3 Peripheral corneal thickness after contact lens removal

Fig 5.3 shows the thickness profile of the superior, inferior, nasal and temporal locations 1 mm (Fig. 5.3a), 2 mm (Fig. 5.3b) and 3 mm (Fig. 5.3c) from the center of the cornea during the period immediately after contact lens removal. As expected, the corneal thickness increases towards the more peripheral locations of the cornea. For both types of contact lenses, the cornea is thickest in the superior and nasal regions as compared to the

inferior and temporal regions. For all the measurements of the corneal thickness, the conventional lens wearers had greater corneal thickness when compared to the silicone hydrogel wearers. The difference in the thickness between the 2 types of contact lens wearers however is not statistically significant at any of the corneal locations.

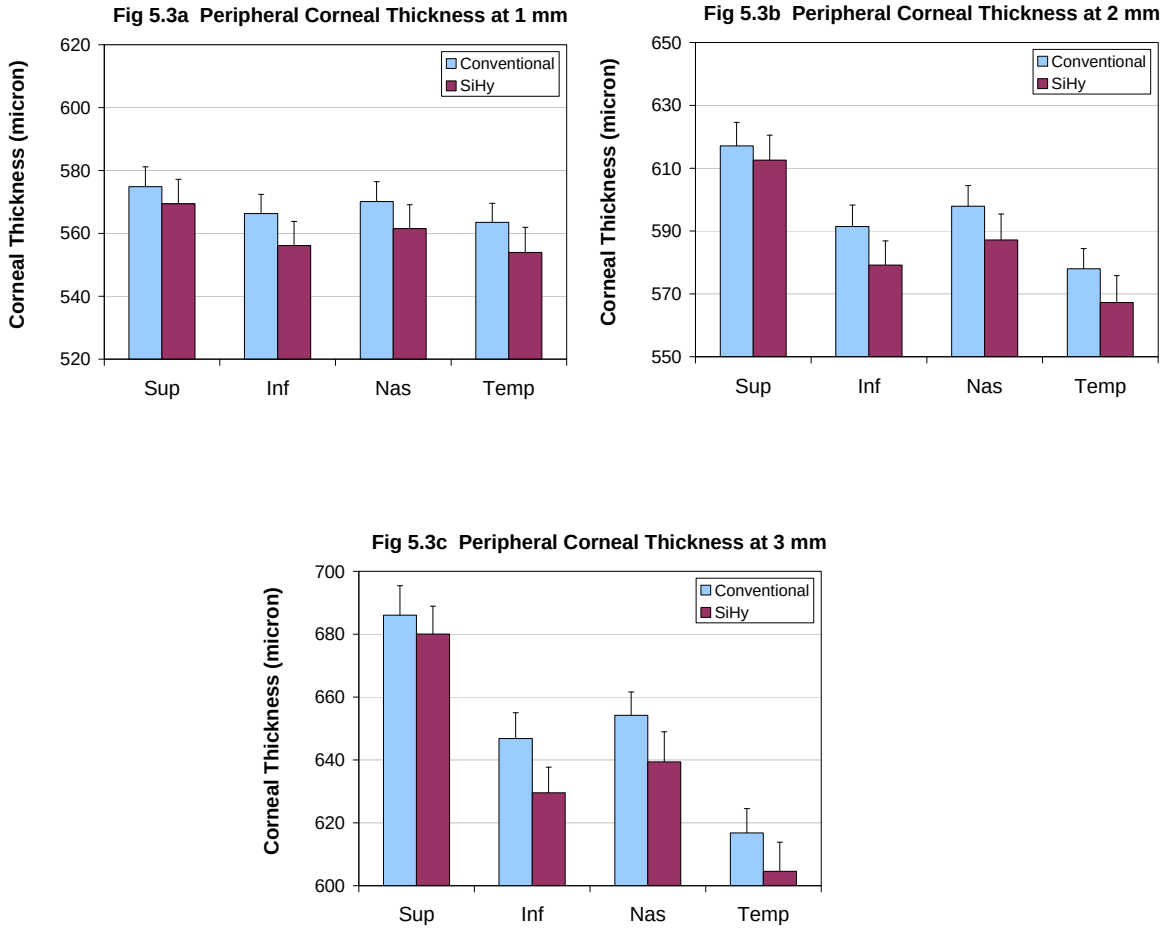


Fig. 5.3: Average peripheral corneal thickness for both types of contact lenses, immediately after removal of the contact lenses, in four meridians at (a) 1 mm distance, (b) at 2 mm distance and (c) at 3 mm distance from the corneal center. Each thickness scale on the y-axis covers 100 μms. Error bars are 1 s.e.m.

5.4 Changes in corneal thickness during the period after removal of contact lenses

5.4.1 Central corneal thickness

Fig 5.4 shows the central corneal thickness in conventional and silicone hydrogel lens wearers after contact lens removal at three time intervals – immediately after CL removal, 20 minutes after CL removal and 60 minutes after CL removal. Fig. 5.4a shows the central corneal thickness while Fig. 5.4b shows the change in the thinnest corneal location. For conventional lens wearers the average central thickness for each of the time intervals after contact lens removal were 560 μms immediately after contact lens removal, 557 μms 20 minutes after contact lens removal and 557 μms 1 hour contact lens removal. For silicone hydrogel wearers, the average corneal thickness was 553 μms immediately after contact lens removal, 553 μms 20 minutes after contact lens removal and 551 μms 1 hour contact lens removal. For all of the conditions shown in the graph, the cornea thickness was greater in conventional lens wearers than in silicone hydrogel wearers. However, the difference between the corneal thicknesses for the two types of contact lens was not statistically significant for any of the conditions.

Fig 5.4b shows the thinnest point for each of the conditions for the conventional and silicone hydrogel lens wearers. As with the central corneal thickness we can see that the corneal thickness is thicker for conventional lens wearers as compared to silicone hydrogel wearers. For all the conditions there is no statistically significant difference ($p>0.05$) between the two types of lens wearers. However in both plots of Fig. 5.4, the conventional lens wearers show some thinning of the cornea between the first measurement and the second

measurement after lens removal. This effect is not observed in the silicone hydrogel wear group. This effect suggests there may be some minor de-swelling of the cornea over this short time period.

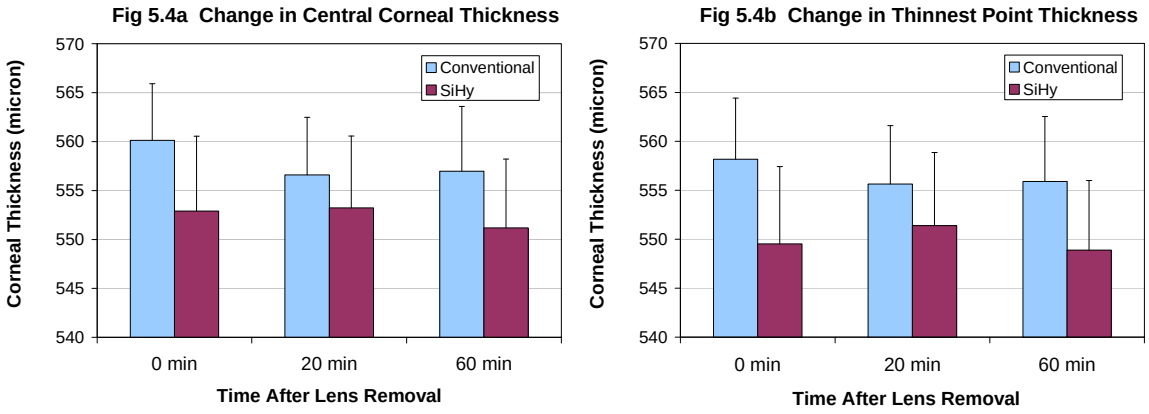
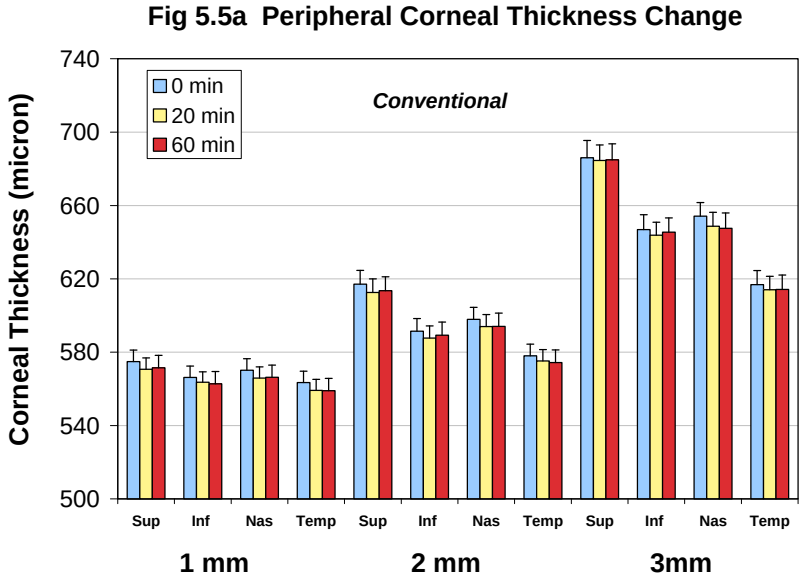


Fig. 5.4: Average central corneal thickness (a) and thickness of the cornea at the thinnest point (b) for both types of contact lenses, at different times after removal of the contact lenses. Error bars are 1 s.e.m.

5.4.2 Peripheral corneal thickness after contact lens removal

Corneal thickness profiles of peripheral locations for conventional and silicone hydrogel wearers are shown in Fig. 5.5. Thickness increases towards the periphery, as expected. There was not a statistically significant difference in the thickness at any of the locations between the two lens types. The conventional lens wearers showed more change over the period of 1 hour at the different time intervals as compared to silicone hydrogel wearers. The change over time in conventional lens wearers could be related to the de-swelling of the cornea.



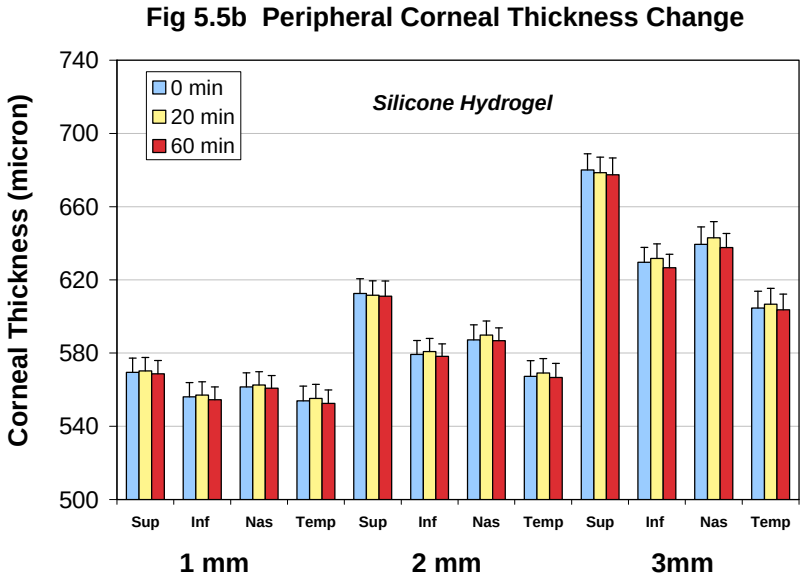


Fig. 5.5: Average peripheral corneal thickness during the period after removal of the contact lenses in four meridians, and at 1 mm distance, 2 mm distance and 3 mm distance from the corneal center for (a) conventional lenses and (b) silicone hydrogel lenses. Error bars are 1 s.e.m.

Fig. 5.6 shows more clearly the changes in corneal thickness over the one hour period after contact lens removal. The thickness recorded at 60 minutes was subtracted from the

thickness recorded immediately after lens removal, and this difference in plotted in Fig. 5.6 for the center thickness, thinnest location and each of the peripheral locations at 1, 2 and 3 mm from the corneal center. A positive value indicates de-swelling or thinning of the cornea over the one hour period after lens removal.

Fig. 5.6 Difference in Corneal Thickness Immediately vs. 60 min After CL Removal

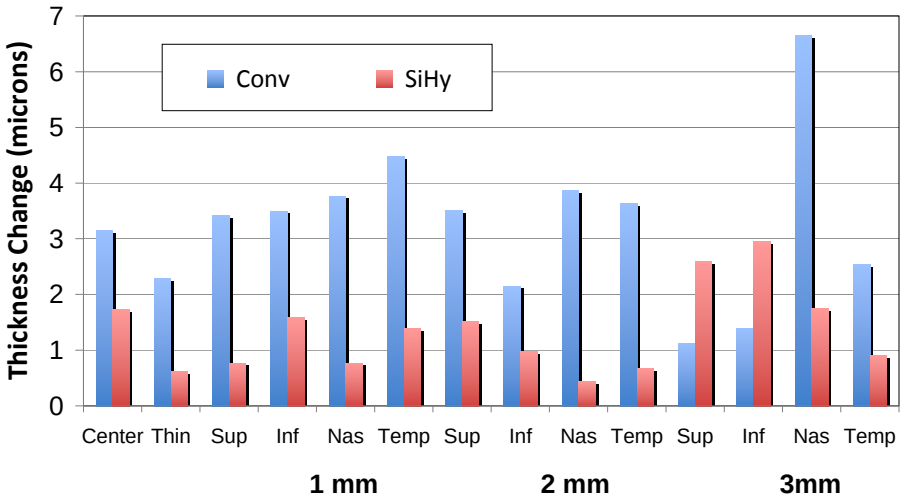


Fig. 5.6: Change in corneal thickness during the period after removal of the contact lenses in the center, thinnest point, and in the periphery in four meridians at 1 mm distance, 2 mm distance and 3 mm distance from the corneal center, for conventional lenses (blue) and silicone hydrogel lenses (red). Change in corneal thickness is expressed as the difference of the thickness measured immediately after lens removal minus the thickness measured at one hour.

The conventional lens wearers show more change in corneal thickness over the one hour period than the silicone hydrogel wearers, suggesting that the cornea is de-swelling over this time period in the conventional wearers. For the conventional lens wearers, de-swelling tends to occur more uniformly across the four meridians at the 1 mm eccentricity than in

more peripheral locations. In the far nasal periphery, the conventional wearers showed a large change in corneal thickness over time while there were only small changes in the superior and inferior meridians.

5.5 Difference in corneal thickness between center and periphery

Corneal swelling can be topographical, in that different regions of the cornea can swell more than others; typically the center swells more than the periphery (Holden et al., 1985; Herse et al., 1993; Erickson et al., 1999). This can result in a change in the internal spherical aberration (Coletta and Han, 2005) since topographical swelling affects the posterior corneal shape (Erickson et al., 1999). To investigate the possibility that conventional lens wearers might exhibit topographical swelling, we subtracted corneal central thickness from the peripheral thickness at 3 mm eccentricity. A smaller relative difference between the center and peripheral thickness could indicate central topographical swelling. Fig 5.7 shows the difference in the corneal thickness between the center and 3 mm peripheral locations with the contact lens on eye (Fig 5.7a), immediately after lens removal (Fig 5.7b), 20 minutes after lens removal (Fig 5.7c) and 60 minutes after lens removal (Fig 5.7d). For all the time intervals, both the silicone hydrogel lenses and the conventional lenses showed greater difference between the center and peripheral locations for the superior location followed by the nasal location. The conventional lens wearers generally showed a greater relative difference in thickness at most meridian locations compared to the silicone hydrogel wearers, indicating that the peripheral cornea was relatively thicker in the conventional lens wearers. This difference between the two contact lens types was

significant for the inferior location with contact lens on the eye (p=0.035), immediately after contact lens removal (p=0.02) and at 60 minutes after lens removal (p=0.04).

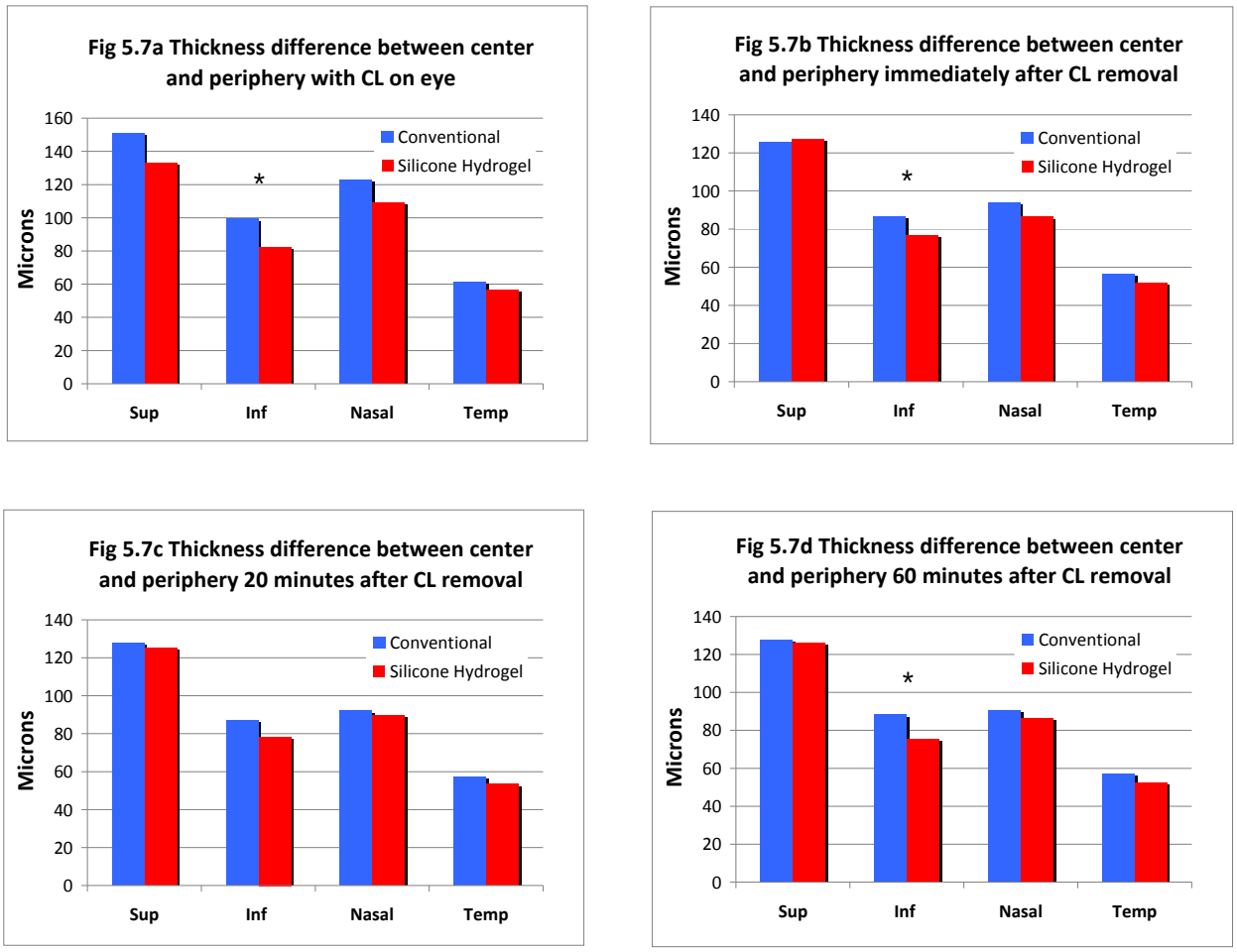


Fig. 5.7: Difference in corneal thickness from the center to 3 mm in the periphery with (a) the contact lens on the eye, (b) immediately after removal of the contact lenses, (c) 20 minutes after lens removal and (d) one hour after lens removal, in four meridians. Average values for conventional lenses (blue) and silicone hydrogel lenses (red).

Since there were significant differences in the relative peripheral thickness in the inferior cornea between the lens wear groups, we compared the thickness differences in the inferior meridian to the amount of internal spherical aberration. The correlations between these values were not significant for any time period or lens type, although the one-hour data did show a moderate correlation of 0.476 in the conventional lens wearers ($p=0.10$). In summary, there could be evidence of differential swelling in these subjects, but the data did not fit the expected direction that central thickness should have been relatively greater in the conventional lens wearers. Instead the silicone hydrogel wearers had relatively greater central corneal thickness, at least relative to the peripheral thickness at 3 mm eccentricity.

Chapter 6

Summary

6.1 Vision and aberrations with contact lenses on the eye

In this study, silicone hydrogel wearers had worse visual acuity when wearing their contact lenses compared to the conventional hydrogel wearers. The two groups of lens wearers did not show differences in acuity with spectacle wear, indicating that the relative loss of visual acuity with the silicone hydrogel lenses on the eye is due to a difference in optical quality of the two contact lens types. The lower visual acuity observed for the silicone hydrogel wearers was only significant for the condition when acuity was measured in a darkened room, when the pupil diameter was probably large and aberrations could exert a larger effect on visual performance. The initial entrance acuities, measured with the Bailey-Lovie chart in a brightly lit room, were lower in the silicone hydrogel wearers compared to the conventional wearers but not by a significant amount. Thus, when the pupil is small in bright illumination, the difference in optical quality of the silicone hydrogel lenses may not be noticeable to the subject.

Whole eye aberrations were greater in the silicone hydrogel wearers when contact lenses were on the eye, although not significantly. However, silicone hydrogel lenses contributed significantly greater aberrations than conventional hydrogels in the anterior surface measurements (Fig. 4.12a). The increase in aberrations of the anterior surface of the contact lens could be a contributing factor to the reduced visual acuity with silicone hydrogel lenses on the eye. The positive spherical aberration observed in the silicone hydrogel

wearers when the lenses were on the eye may have also contributed to the worse visual acuity of the silicone hydrogel wearers. Other studies have shown that higher-order aberrations of contact lenses can vary by brand and type of manufacture (Jiang et al., 2006). Keir et al. (2011) showed that the spherical aberration of the CibaVision Night and Day contact lens does not vary with lens power in the same fashion as other brands of silicone hydrogels. Rather than having negative spherical aberration increase with negative lens power, the spherical aberration of the Night and Day lenses appear to be compensated in high minus lenses by a change in the lens design. This might have resulted in our group of silicone hydrogel wearers having relatively more positive spherical aberration than the conventional lens wearers. Negative spherical aberration increased with increasing negative power of the conventional lenses (Fig. 4.9) and this was associated with relatively smaller deficits in low contrast acuity relative to the high contrast acuity (Fig. 4.10). The spherical aberration contributed by the contact lens thus could affect visual performance, particularly at low contrast levels.

The internal aberration coefficients represent the aberrations contributed to the whole eye aberrations by optical surfaces behind the anterior surface. The increased internal aberrations measured with the contact lens on the eye (Fig. 4.17a) indicate that silicone hydrogel lenses also contribute significantly more aberrations at their posterior surface and/or at the tear lens behind the contact lens, compared to conventional hydrogel lenses. This might be related to tear film quality or the wettability of the silicone hydrogel lenses or to other aspects of these lens materials such as lipid deposition.

Optical quality can be affected by tear film integrity and this aspect is probably different for the silicone hydrogel and conventional hydrogel lenses. Liu et al (2010) assessed silicone hydrogel lens wearers for changes in visual performance and optical quality associated with tear break up during blink suppression. Their study showed that optical metrics of tear quality and retinal image quality are associated with the decline in vision that occurs with tear break up. Tear film quality has been reported to be degraded for silicone hydrogel lenses (Sengor et al., 2011; Dogru et al., 2011), since the silicone hydrogel lens material is more hydrophobic compared to conventional hydrogel lens materials (Dutta et al., 2012).

6.2 Vision and aberrations after contact lens removal

Silicone hydrogel lens wearers had greater wavefront aberrations than conventional lens wearers after removal of the contact lens. This was evident in both the ocular wavefront aberrations (Figs. 4.4 and 4.5), which were significantly greater in the silicone hydrogel wearers, and in the corneal surface aberrations (Fig. 4.13). These results suggest that the tear film quality of silicone hydrogel wearers is affected even after removal of the lens. Perhaps lens wear with the silicone hydrogel disrupts normal tear film quality, compared to conventional hydrogel wear, at least during the interval immediately after lens removal. Another factor could be that silicone hydrogel lens wear causes more change in the corneal surface shape that introduces more aberrations. The silicone hydrogel lenses have a higher modulus than the conventional lenses, meaning they are stiffer and thus could affect corneal

shape to a greater extent compared to a conventional hydrogel lens that may drape more on the eye.

Even though the optical quality of the silicone hydrogel wearers was worse after lens removal than the conventional lens wearers, this did not have a great influence on visual acuity since the spectacle-corrected acuity was not significantly different in the two lens wear groups (Fig. 3.2). There was, though, a slightly worse acuity with spectacle correction in the silicone hydrogel lens wear group and this effect might be related to the greater aberrations recorded in these subjects after lens removal.

6.3 Corneal thickness before and after contact lens removal

The corneal thickness for conventional lens wearers was higher than that for silicone hydrogel wearers. This was true with the contact lens on the eye as well as after contact lens removal at all time intervals in the 1-hour period after contact lens removal. This could be due to the swelling of the cornea caused by the lower oxygen permeability of conventional contact lenses. Conventional contact lens wearers showed a greater change in corneal thickness over the 1 hour time period after removal of contact lenses (Fig. 5.6). This also suggests that the swelling of the cornea reduced after removal of the lens. Silicone hydrogel lens wearers did not have much of a change in corneal thickness after removal of the contact lens. This is consistent with the fact that silicone hydrogel lenses cause lesser corneal swelling due to higher oxygen permeability (Stapleton et al. 2006)

The expectation of this study was that conventional lens wearers would exhibit corneal swelling and more positive spherical aberration after lens removal than the silicone hydrogel wearers (Coletta and Moskowitz, 2003). While corneal thickness was greater in the conventional lens wear group, this was not associated with increased positive spherical aberration in the whole-eye measurements (Fig. 4.7). The corneal surface did show slightly increased positive spherical aberration in the conventional wear group after contact lens removal (Fig. 4.14) although this effect was not significant. It may be that the newer generation of higher Dk/t conventional lenses causes only minimal swelling that does not have much effect on the aberrations, while lenses of an older design that were used in the 2003 study may have resulted in more swelling that degraded optical quality.

6.4 Limitations of the study

Pupil sizes were not recorded during the acuity measurements and this might be considered a limitation since increased pupil diameter could have resulted in greater effects of aberration on visual performance. However, the COAS pupil diameters, which were also measured in a dark room, were not different between the groups of lens wearers. Subjective over-refractions were measured only with spectacle correction and not with contact lenses on the eye. Over-refractions were measured with the COAS aberrometer, and showed that the silicone hydrogel wearers had a more myopic over-refraction as compared to conventional hydrogel wearers. It would have been helpful to have the subjective over-refractions with the contact lenses on the eye in order to know if the subjects would have accepted the additional myopic corrections over their contact lenses. However, as noted above, the entrance acuities

measured with the Bailey-Lovie charts were not significantly different between the two groups of contact lens wearers.

In this study, we had a small number of subjects in each lens wear group and the number of subjects in each group was not equal. Toric lens wearers were included in the study along with spherical contact lens wearers, although when we analyzed the data without the toric lens wearers, we did not find any statistically significant difference in the results. We also had mixed lens designs in each group. It would have been preferable to use one brand of contact lenses and compare the conventional and silicone hydrogel lenses of that particular brand to minimize effects of factors such as lens design. Perhaps then factors due to lens design, such as aberrations, could be separated from effects due to lens material, such as surface wetting or tear film quality.

We had a higher number of daily disposable lens wearers in the conventional lens group as compared to the silicone hydrogel group and also the age of the lens was older for silicone hydrogel lens wearers; however lens age was within the recommended wearing schedule. Although the difference between the ages of the lens was not statistically significant between the conventional hydrogel and silicone hydrogel lens wearers, this may have had an effect on the results. In a future study, it would be preferable to fit subjects with a new contact lens and take measurements when the lenses have been worn for an equal number of days for the two types of lens materials.

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Chapter 8. Appendix

Appendix 8.1

To: College Students, Faculty & Staff
From: Nancy Coletta, O.D., Ph.D., Sneha Kataria, OD2012
Re: Volunteers for Research Study

We are recruiting up to 40 volunteers to participate in a study of optical quality during daily wear of soft contact lenses. We are comparing results in two groups of subjects: those who wear conventional soft contact lenses and those who wear silicone hydrogel lenses.

Subjects who wear conventional soft contact lenses should have lenses with greater than 50% water content (minimum Dk of 16). When you tell us the brand of your lenses, we will determine if it qualifies. Subjects who wear silicone hydrogel lenses should be wearing one of the following brands: O_2Optix, Night&Day, Acuvue Advance, Acuvue Oasys or PureVision.

All lenses must not be worn as extended wear. The particular lens type must have been worn for at least 3 months. Subjects must wear lenses a minimum of 5 days per week and a minimum of 7 hours per day. The age of the contact lens on the day of testing must be no more than 3 months. All subjects must have best-corrected visual acuity of at least 20/25 in both eyes.

On the day of testing, you should have been wearing the lenses at least 4 hours. We plan to measure visual acuity, corneal thickness, corneal shape and optical quality of the eye. All of these tests are non-invasive and will be performed using conventional devices. We estimate that the total duration of the testing will be approximately 2 hours.

Subjects with the following characteristics will not be able to participate in the study:

- history of ocular disease or injury
- history of cataract or other media opacity, or corneal or other refractive surgery
- best-corrected acuity worse than 20/25 in either eye
- use of RGP, multifocal or extended wear contact lenses during the one-year period prior to the study

Your participation in this study will contribute to our understanding of how corneal swelling during soft contact lens daily wear relates to the optical quality of the eye. You will be given $25 within two weeks of completion of the study, in appreciation for your effort.

If you wish to participate, or if you have any questions, please contact Dr. Nancy Coletta by e-mail (colettan@neco.edu) or by phone (617-266-2030).

Please provide the following information:

- name, phone number and/or e-mail address
- age and approximate refractive error
- brand of contact lens worn (we will determine if your lenses are eligible)

- best days and times for your appointment

The above information will be maintained in confidence. The testing will be done in Dr. Coletta's lab in the basement of 424 Beacon St. We will schedule the appointment at your convenience.

Thanks for your help,
Nancy J. Coletta, O.D., Ph.D.
Sneha Kataria, OD2012

Appendix 8.2 (next page)

THE NEW ENGLAND COLLEGE OF OPTOMETRY
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Fax: 617.587.5551

STATEMENT OF INFORMED CONSENT

Corneal swelling associated with daily soft contact lens wear:
Its relation to optical quality and posterior corneal shape

Overview

You are being asked to participate in a research project to study the effect of soft contact lens daily wear on corneal shape and optical quality. The following tests will be performed: visual acuity using a high contrast letter chart, corneal shape, corneal thickness and optical quality of the eye. All of these tests are non-invasive and the devices used are commercially available clinical instruments. The testing will take place at New England College of Optometry and is expected to take approximately 2 hours in one session.

There will be up to 40 subjects. Half of the subjects will be wearers of conventional soft contact lenses with greater than 50% water content (minimum Dk of 16) and half of the subjects will be wearers of one of the following brands of silicon hydrogel lenses: O_2Optix, Night&Day, Acuvue Advance, Acuvue Oasys or PureVision. The particular lens type must have been worn for at least 3 months. Subjects must wear lenses a minimum of 5 days per week and a minimum of 7 hours per day. The age of the contact lens must be no more than 3 months. All subjects must have best corrected visual acuity of at least 20/25 in both eyes.

Subjects with the following characteristics will not be able to participate in the study:

- history of ocular disease or injury
- history of cataract or other media opacity, or corneal or other refractive surgery
- acuity worse than 20/25 in either eye
- use of RGP, multifocal or extended wear contact lenses during the one-year period prior to the study

Description of Tests & Procedures

The same tests and procedures will be performed on all subjects after at least 4 hours of lens wear.

Visual acuity: You will be asked to a read a high-contrast letter chart with the right eye while wearing your contact lenses. To qualify for participation in the study, subjects must have 20/25 or better acuity in the each eye. However the following measurements will be made on the right eye only.

Anterior corneal shape, or corneal topography:
You will be seated at a chinrest and forehead restraint in front of the corneal topography device and asked to fixate a red fixation light in the center of a concentric ring pattern. Several pictures will be taken of your eye, from which the surface curvature of your anterior cornea will be derived.

Corneal thickness, contact lens thickness profile and posterior corneal shape:
You will be seated at a chinrest and forehead restraint in front of a rotating camera device (Pentacam) and asked to fixate the center of a blue light. Several pictures will be taken of your eye; the corneal thickness, contact lens thickness and posterior corneal shape will be derived from these images.

Optical quality of the eye (aberrometry):
The optical quality of your eye will be measured using an instrument that records images of light passing through the eye. You will be seated at a chinrest and forehead restraint in front of the device and asked to fixate a ring target. Several pictures will be taken of your eye, from which the optical quality of the entire eye will be determined.

The last three procedures will be repeated immediately after removal of your contact lenses and then repeated three times over a period of one hour at increments of about 15 minutes.

Possible Discomforts or Risks
This study presents no foreseeable discomforts or risks. If any information is developed that might influence your willingness to participate, you will be informed.

Benefits
Your participation in this study will contribute to our understanding of the effect of contact lens wear on corneal shape. There are no direct benefits to you from participating in this study. You will be given $25 within two weeks of completion of the study, in appreciation for your effort and to help defray transportation costs.

Confidentiality
Your medical records will be kept as confidential as possible within the limitations of state and federal law.

If you decide to be a subject in this study, both demographic and technical information about you will be collected. Demographic information will include, but will not be limited to such things as, your name, date of birth, address, gender, ethnicity, etc. Technical information will include elements of your personal health history and results of all the tests and measurements related to the study. This information is collected in order to determine whether you are eligible to be a subject in the study; that is, to meet the inclusion/exclusion criteria and, if so, to allow the study investigators to gather the data from you that is necessary to support the study's purpose. The results from all of the subjects in the study can then be analyzed to develop the study's conclusion.

All study-related information will remain confidential with the study investigators or administrative staff. However, any regulatory authority or the Institutional Review Board may inspect the investigator's records pertaining to you as a subject. But they too should maintain confidentiality.

The results of the study may be used in health care education or in scientific publications. Neither your name nor any information that specifically could identify you will be used in any such presentation or publication.

Personal Health Information
Your personal health information (PHI), as related to this study, is described in the "Confidentiality" section above. If you sign this informed consent form, it grants permission to use your PHI as

specifically discussed. This permission does not have an expiration date, but you can cancel it at any time by writing to the principal investigator(s) at the address below.

If you cancel your permission to use your PHI after you have started the study but before your study participation would normally be concluded, you will not be allowed to continue in the study and the investigators will stop collecting data. However, they retain the right to use the information they have already collected to evaluate the study's results.

Privacy Practices and Your Rights

Health care providers are required by law to keep private any health information that identifies people. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or inspect all of the health information generated or collected about you during this study includes the study doctor(s), the study staff, the Institution, any study Sponsor (or the authorized agents of the sponsor), the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies, and the Institutional Review Board. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be redisclosed, at which point your health information may no longer be protected by federal privacy regulations.

You may ask the study investigator to see a copy of your PHI related to the study. You may also request the study investigator to correct any information that you feel is incorrect. However, you may have to wait until the end of the study to see your records so that the study can be organized and conducted scientifically.

You must be given notice of your investigator's privacy policies. The Confidentiality, Personal Health Information, and Privacy Practices and Your Rights sections of this form fulfill this requirement.

Unless you authorize the use and disclosure of your personal health information, you cannot participate in this research study. If you refuse to give your authorization, your medical care will not be affected.

Voluntary Participation/Withdrawal from the Study

Participation in this study is voluntary and you may withdraw at any time. Refusal to participate or withdrawal from the study will not involve any penalty or loss of benefits to which you are otherwise entitled, including your status at NECO. We will disclose to you in a timely manner any significant new findings that may influence your willingness to participate in the study. The investigators or the Institutional Review Board may terminate your participation in the study (with or without your consent) if it is believed to be in your best interest.

Questions

Any questions you may have about this study or about your rights as a study participant may be directed to the investigator, Dr. Nancy J. Coletta (617-587-5681). This study presents minimal risks. In the unlikely event of injury resulting from your participation in this study, contact Dr. Coletta at 617-587-5681. If she is not available, or in an emergency, call the New England Eye Institute at 617-262-2020, or go to the emergency room of a hospital. You and/or your healthcare insurance are responsible for payment for this treatment.

You may also contact Dr. Paul White (617-266-2030 ext. 5251), Chairman of the Institutional Review Board of the New England College of Optometry, 424 Beacon Street, Boston MA 02115.

Voluntary Consent

I have read this consent form and I understand it. Any questions concerning this study have been answered to my satisfaction and I have been offered a copy of this consent form. By signing this form, I voluntarily agree to participate in this study.

I understand the potential risks and benefits involved in this study and that I may withdraw at any time without penalty. I understand that I must notify the study investigator immediately (617-587-5681) if I notice any medical problems that may be related to my participation in the study. I also understand that my participation in the study may be terminated at any time if the investigators or the Institutional Review Board feel that it in my best interest.

I understand that the study records may be inspected by the Institutional Review Board of the New England College of Optometry.

_____

Subject's Name (PRINT)

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

_____ _____

Signature of Investigator or Designee Date

Appendix 8.3

Name _____ DOB _____ Gender ____ M ____ F

Eye History:

1. Do you have any current or past eye pathology? ____ yes ____ no

If yes, please describe:

_____

_____

_____

2. Have you had any eye surgery (including refractive surgery)? ____ yes ____ no

If yes, please describe:

_____

_____

_____

3. Have you had any eye injuries? ____ yes ____ no

If yes, please describe:

_____

_____

_____

4. When was your most recent eye exam? _____

Contact Lens Wear:

5. What type of lenses do you wear?

____ daily wear ____ extended wear*

____ single vision ____ multifocal* ____toric

*If you wear extended wear or multifocal lenses, you may not participate in the study. (Monovision is OK.)

(continued next page)

6. How long have you worn the type of lenses you are currently wearing?
_____months or _____ years

7. Did you wear a different type of lenses prior to your current lenses? ____ yes ____ no

If yes, what type of lenses did you previously wear? _____
For how long? _____

8. What is the brand of lenses you are wearing today?_____

9. How old is the lens you are wearing today?_____

10. How many days per week do you typically wear your lenses? ____ days

11. How many hours per day do you typically wear your lenses? ____ hours

12. Have you had any problems with your lenses? ____ yes ____ no

If yes, please describe:
_____

_____

_____