The Effects of Extended Wear Hydrogel Contact Lenses on Corneal Topography and Contrast Sensitivity

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Abstract

Purpose: To study the effect of hydrogel contact lens extended wear on corneal topography and contrast sensitivity.
Methods: Five daily contact lens wearers (four in Biomedics and one in Acuvue) were changed to an extended wear modality. Slit lamp examination, manifest refraction, Bailey-Lovie visual acuities, Pelli-Robson contrast sensitivities, and corneal topography were performed over a four day period in mesopic and photopic conditions. All data, except baseline and end-study data, was gathered within thirty minutes of waking.
Results: There were no biomicroscopic changes during the study. Four eyes increased in myopia while six eyes decreased or remained the same. There was no statistically significant decrease in Bailey-Lovie VA, high or low contrast, while in extended wear modality. There was a statistically significant decrease in Pelli-Robson contrast sensitivity in mesopic conditions from the beginning of the study to the end of the study (z=0.074), but day to day comparisons proved statistically insignificant. The average of the Corneal Irregularity Measure (CIM) values from the corneal topography showed that corneal irregularity increased over time and approached statistical significance (p=0.091). The average Shape Factor values, also from corneal topography, significantly worsened during the study (p<0.01). Central corneal curvature showed small changes, while selected peripheral points showed large changes ranging from 3.9 diopters of flattening to 6 diopters of steepening. Most changes occurred in the superior cornea.
Conclusions: Extended wear modality of hydrogel contact lenses results in statistically and clinically significant changes in peripheral corneal topography, suggesting that corneal edema may not be a diffuse, but a localized, reaction to decreased oxygen availability. Therefore, the standard tests of evaluating extended wear effects, i.e. VA, slit lamp examination, and possibly contrast sensitivity, may not be sufficient to detect corneal changes secondary to extended wear. Further studies incorporating more test subjects is needed in this area.

Key Words: corneal topography, contrast sensitivity, extended wear hydrogel contact lenses, Pelli-Robson letter sensitivity chart, Bailey-Lovie visual acuity chart

Introduction

It is well known that contact lenses can induce changes to the cornea. These changes are typically referred to as "corneal warpage". Signs and symptoms of corneal warpage include decreased visual acuity, even with spectacles, contact lens intolerance, refraction changes, and keratometry changes[1]. Numerous studies have been done to determine the safety limits of contact lens wear in order to decrease or eliminate corneal warpage. Because extended wear pushes the limits of corneal safety, much research has been put into studying the effects of this modality of lens wear. A concern of extended wear is hypoxia, which commonly leads to corneal swelling. Corneal swelling results in corneal warpage and can leave the cornea susceptible to infections, keratitis, and abrasions[2]. Most agree that VA is not sensitive enough to detect corneal changes induced by extended wear of soft contact lenses[3-5]. Research investigating the effect on contrast sensitivity gives conflicting results. Some find a decrease in contrast sensitivity, while others report no change[6]. Corneal swelling is expected with overnight wear of contact lenses. It is reported that corneal swelling greater than 8% can occur overnight[7]. This, then decreases to less then 6% in open eye conditions, below a level that contrast sensitivity or visual acuity may be useful in detecting corneal changes.

Corneal topography has been proven to be an effective method of determining corneal changes secondary to soft contact lens wear. In fact, corneal changes may be missed without it[8]. Wilson and Kylce reported that 38% of their study group had corneal topography changes secondary to lens wear[8]. Recent corneal topography programs are marketed to be more sensitive to corneal changes than previous programs. However, few of the newer systems have been used in recent studies. With this in mind, the purpose of

this prospective study was to determine if there are changes in corneal topography contrast sensitivity secondary to extended wear of soft contact lenses. The results are interesting. Using a corneal topography system with proven accuracy[9], there seems to be clinically significant changes to the cornea, specifically in the periphery. Although VA showed no statistically significant decrease, and a contrast sensitivity decrease approached significance, topography clearly suggests corneal changes occur in extended wear conditions.

Materials and Methods

Optometry students not currently in extended wear, having no history of ocular infections, corneal epithelial defects, or an allergic response to contact lens wear were eligible for the study. Of the ten eyes analyzed, two eyes were wearing Acuvue (Vistakon, Jacksonville, FL) disposable lenses and eight eyes were wearing disposable Biomedics 55 (Ocular Science/American Hydron, San Francisco, CA). Both lenses are approved for extended wear use. Informed consent was obtained from each patient before beginning the study.

Each patient was given a new pair of contact lenses to begin the study. The base curve and power matched the habitual contact lenses. In the late afternoon, after several hours of daily wear, the baseline data was gathered for each eye. This included a biomicroscopic evaluation of the contact lens fit, judging centering and movement, and the cornea, looking for edema, striae, microcysts, and sodium fluorescein staining patterns. High and low contrast Bailey-Lovie visual acuities and Pelli-Robson contrast sensitivities, measured at 20 feet, were recorded for low photopic (10 foot candles) and mesopic (2 foot candles) conditions. The manifest refraction was also determined.

Corneal topography tangential maps were obtained on the Humphrey Systems ATLAS with MasterVue Software (model 991, version A8). Throughout the experiment, when obtaining topography measurements, four images were taken for each eye. The image that was judged to have the sharpest focus without irregularity and the least interference from the eyelids was selected for processing. The order of the tests taken and the eye measured first were varied for randomization. All measurements taken throughout the experiment were taken by the same person to avoid measurement error discrepancy between examiners.

The following morning (Day 0 AM), corneal topography was performed within thirty minutes of waking. High and low contrast Bailey-Lovie visual acuities and Pelli-Robson contrast sensitivities were recorded in low photopic and mesopic conditions. The patients were instructed to wear the contact lenses on an extended wear basis for the next three days and two nights. Rewetting drops were given to be used upon waking and as needed throughout the day.

After one full day and night of contact lens wear (Day 1 AM), corneal topography was again performed within 30 minutes of waking and a biomicroscopic exam of the cornea was performed. The lenses were removed for the above tests only, and then reinserted to examine the contact lens movement and centering. High and low contrast Bailey-Lovie visual acuities were obtained in low photopic and mesopic conditions. The patients were instructed to continue extended wear conditions.

After two days and two nights of extended wear conditions (Day 2 AM), corneal topography and Bailey-Lovie visual acuities were performed in the same time and manner as the previous day. Pelli-Robson contrast sensitivities were also completed in

low photopic and mesopic conditions. Patients were instructed to continue contact lens extended wear.

On the evening of Day 2 (after three full days and two nights of extended wear conditions), the final data was obtained. Corneal topography, biomicroscopy of the contact lenses and cornea, NaFl staining, and manifest refraction were performed. High and low contrast Bailey-Lovie visual acuities and Pelli-Robson contrast sensitivities were again performed in low photopic and mesopic conditions. Each patient then completed the patient questionnaires.

Initial and final Pelli-Robsin data were analyzed statistically using Wilcoxon Signed Rank Test and the Student's *t* test for paired observations. Corneal Irregularity Measure (CIM) and Shape Factor values from the corneal topography were also analyzed using the paired *t* test. A p value of <0.05 was considered statistically significant.

Results

When referring to the tables in this section, please note that eyes number 1 through 8 are in Biomedics and 9 through 10 are wearing Acuvue lenses. Eyes number 1and 2 are the first patient, eyes 3 and 4 are the second patient, and so on.

There was no evidence of corneal swelling or fluorescein staining upon slit lamp examination in any of the ten eyes tested. The contact lenses remained centered with minimal movement throughout the testing period. The manifest refraction showed four eyes increased in myopia by less than or equal to 0.50 D, three eyes decreased in myopia by 0.50 D, two eyes decreased by 0.75-1.00 D, and one eye stayed the same.

The Bailey-Lovie visual acuities varied as shown in Table 1. In the low photopic conditions, eight eyes had better vision with the high contrast VAs when comparing the

baseline values to those taken at the end of the study. From Day 0 AM to Day 1 AM, six eyes had decreased acuity. From Day 1 AM to Day 2 AM, six had increased acuity. In low contrast photopic conditions, acuity decreased in four eyes from beginning to the end of the study. From Day 0 AM to Day 1 AM, acuity stayed the same or increased in eight eyes; and from Day 1 AM to Day 2 AM, acuity decreased in five eyes.

In mesopic conditions, high contrast VA decreased in seven eyes from the beginning to the end of the study. From Day 0 AM to Day 2 AM, VA decreased in six eyes. Low contrast VAs resulted in six eyes having decreased acuity from beginning to the end measures, and three eyes having decreased acuity from Day 0 AM to Day 2 AM. Analyzing the above patterns with paired *t* tests proved no statistical significance to a correlation between decreased Bailey-Lovie acuities and extended wear of contact lens wear.

The Pelli-Robson contrast sensitivity measures are summarized in Table 2. Seven eyes had equal or increased contrast sensitivity in low photopic conditions from the beginning to the end of the study. From day 0 AM to day 2 AM, contrast sensitivity remained the same or increased in nine eyes. In mesopic conditions, six eyes had equal or increased contrast sensitivity from baseline to the end of the study. From day 0 AM to day 2 AM, nine eyes had equal acuities. Wilcoxin's Signed Rank Test comparison of the data from Baseline PM to Day 2 PM in mesopic conditions was the only data that proved to approach statistical significance with a *z* value of 0.074. All other comparisons proved to be statistically insignificant.

The CIM values from the corneal topography are in Table 3. Although the individual eyes in our study did not show any consistent regularity or irregularity, the

average CIM values from all of the eyes combined are outside normal limits and worsened throughout the experiment. In other words, the irregularity increased over time. A paired *t* test performed on these numbers found that the irregularity approaches statistical significance with a *p* value of 0.091. The individual Shape Factor values were all within normal limits and are listed in Table 4. However, the average values showed a sudden decrease after one full day and night of extended wear conditions. A paired *t* test showed this decrease over time to be statistically significant with a *p* value of <0.01. Paired *t* tests were also used to compare acuities and contrast sensitivities to the Shape Factor and showed no significant relationship between the shape change and VA or contrast sensitivity.

Minor curvature changes occurred in the central cornea from day to day as shown in Table 5. In most eyes, the dioptric change was less than +/- 0.50 diopters. Peripheral curvature, Table 6, showed the most change and location varied with each eye. The peripheral points that showed the greatest amount of dioptic difference over the time specified were analyzed. Most of the changes occurred in the superior cornea and ranged from 3.9 diopters of flattening to 6 diopters of steepening.

The questionnaires filled out at the end of the study varied in responses. In comparison to their regular, daily wear schedule, the greatest complaint with extended wear modality was morning and evening discomfort. Every patient stated their comfort was compromised, sometimes greatly, in extended wear. Half of the patients reported morning blur as well. All patients stated they had to use artificial tears at least once upon awakening and sometimes additionally throughout the day and evening hours. However, in spite of the discomfort, all reported overall good vision by midday. There were no

patients who experienced increasing glare, ghost images, or impairments in night driving vision.

Discussion

While slit lamp detection of edema is one of the classic indicators of oxygen deficiency in the cornea, it has little predictive value for the individual patient in a clinician's office[10]. At corneal edema levels of approximately 6 or 7 percent, striae can be observed at the level of the posterior stroma and Descemet's membrane[11]. However, a cornea may be enduring chronic hypoxia, and the clinician is unable to detect it. This is because the cornea may swell by greater than 8 percent[7] during closed eye wear, but return to less than 6 percent, below the threshold for striae, within the time period before the slit lamp examination. For example, etafilcon A (the material Acuvue lenses are made of) causes 8.4 +/- 3.3% overnight swelling[12]. Taking the 3.3% variance into account, our 10 eyes may have been below the clinical value for detecting striae upon, or soon after, awakening. Perhaps we may have seen more incidence of striae with a larger sample size or if we had seen the patients immediately, instead of within a half hour of awakening.

It has been reported that soft contact lens wear has been associated with an initial early flattening followed by a modest degree of steepening and secondary myopia[13]. Of the 10 eyes tested, only 4 increased in myopia from the beginning to the end of the study. Five eyes actually decreased and one eye stayed the same. Such a wide variety of responses shows that the degree of corneal steepening or flattening varies with each individual and between eyes.

The Bailey-Lovie visual acuity chart is a standardized chart in which the only significant variable is a change in letter size. The clinical method of scoring for the test uses logMAR units, giving equal additional credit for each letter read correctly. Giving credit for every letter read provides more sensitivity for the detection of changes in acuity[14]. Looking at Table 1 and the result of the paired *t* test on the data, it shows there is no statistical or clinical significance to a correlation between Bailey-Lovie acuities and extended wear modality of contact lens wear. This agrees with previous studies reporting that VA measures are too insensitive to detect corneal changes[3-5]. However, Table 1 does show the individual variations. The large standard deviations in all comparisons prove that VA changes are unpredictable.

Pelli-Robson charts measure contrast sensitivity with letters rather than gratings that decrease in contrast but not in size. This test was chosen as a result of the proven reliability of the contrast sensitivity measurements given[14]. The large standard deviations in Table 2 illustrate the variability in the pattern of contrast sensitivity loss or gain with extended wear. The only value that approaches statistical significance is the decrease in sensitivity from Baseline PM to Day 2 PM. Perhaps enough swelling had occurred from the beginning to the end of the study to reach measurable values since Pelli-Robson is only capable of detecting edema greater than 9%[14]. Edema caused by hydrophilic lenses may be at levels too subtle for Pelli-Robson contrast sensitivity and visual acuity testing to detect, especially in the open-eye environment. This is also the possibility of a learning curve with contrast sensitivity since our subjects were educated optometry students.

Corneal Irregularity Measurement (CIM) is a statistical measure that uses topographic data from the pupil area and compares it to the best fit corneal surface found. It determines the regularity, or lack of, the corneal surface used for vision[15]. Since corneal distortion is said to result from lens induced hypoxia[16], it is not surprising that the average CIM values show increase in irregularity over the course of the study. A p value of 0.091, although it only approaches statistical significance, is important to note. Because of the small sample size, this irregularity becomes clinically relevant. Again, the large standard deviation shows patient variability.

The Shape Factor normally ranges from 0, a spherical shape, to 0.3, a slightly aspheric shape[7]. Corneas with shape factors greater than 0.50 exhibit greater than normal peripheral flattening[7]. The corneas in our study showed statistically significant steepening as contact lens wearing time increased ($p<0.01$). The results of Pelli-Robson contrast sensitivity and Bailey-Lovie visual acuity testing indicate no relationship between this corneal steepening and a decrease in acuity or contrast sensitivity. This lack of significance makes sense because the central corneal curvature did not change significantly and the shape factor is off the line of sight. The peripheral curvature changes in all ten eyes support the theory that lenses with acceptable central Dk/l still may not have an acceptable transmissibility because of the increased lens thickness in the mid-pheriphery[16]. The quadrant of greatest change is superior, likely due to the combined effects of the lids and the decreased oxygen transmissibility of the lens in that location.

The overall response in the questionnaires stated the participants' vision was good throughout the time in extended wear. Only half stated their vision was compromised in

the morning upon awakening, when the amount of edema is greatest[17] and may be significant enough to blur vision. An important consideration with this finding is what the vision may be like for morning driving, especially if it is still dark. The area of largest concern to these patients was the comfort. Most participants stated the need to use artificial tears twice as often as they had to with daily wear lenses.

The results of this study indicate that corneal topography measurements changed in statistically and clinically significant amounts with extended wear modality. However, in spite of these changes, no large decrease in contrast sensitivity or visual acuity was measured. The results of all testing show extreme patient variability, even in the eyes of the same person. There is no way to predict how an individual will react to extended wear. Although not widely used in hydrogel lens practice management today[16], the benefits of using corneal mapping to monitor for hypoxia-induced corneal changes are illustrated in this study. It was the only test showing the results of the hypoxic environment. Further study in this area would be beneficial. These topographic changes occurred after only three days and two nights extended wear. What would the effects be after lenses have been worn for a week, or even a month on an extended wear basis? All ten eyes in this study showed topography changes so a larger sample size may prove to be even more significant. The question is then raised...at what point do these alterations in corneal curvature become clinically significant? The long term effects of corneal edema are not known, but a long term hypoxic environment can only cause harm.

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Eye	Low photopic-high contrast			Low photopic-low contrast		
	AM 0-1	AM 1-2	PM	AM 0-1	AM 1-2	PM
1	9.18	-7.48	6.06	0.00	-1.06	0.00
2	5.05	1.92	5.05	0.00	2.15	9.09
3	1.01	-1.00	-4.81	5.62	1.06	-2.11
4	-2.00	-1.02	-1.98	1.09	-5.38	-10.53
5	4.00	0.96	1.90	-7.45	5.75	-1.06
6	-1.96	0.00	10.00	-7.45	1.15	4.35
7	-3.00	2.06	2.04	0.00	1.15	3.49
8	-5.10	6.45	3.09	7.23	-1.12	-6.45
9	-1.01	7.14	6.06	3.19	-4.12	8.14
10	-5.77	7.14	1.01	1.08	-1.06	8.05
Average	0.04	1.62	2.84	0.33	-0.15	1.30
Std dev	4.76	4.52	4.26	4.79	3.17	6.55

Eye	Mesopic-high contrast		Mesopic-low contrast	
	AM 0-2	PM	AM 0-2	PM
1	-5.38	4.71	1.30	5.48
2	1.08	4.65	0.00	0.00
3	2.27	-1.14	5.80	-6.76
4	2.38	-5.68	-4.29	-13.70
5	-1.11	-2.22	6.15	11.86
6	-1.10	2.25	6.49	4.11
7	-3.53	-9.78	2.94	-7.35
8	-2.38	-11.49	-10.96	-4.48
9	0.00	-5.62	0.00	-16.00
10	-1.11	-4.49	-1.33	-9.33
Average	-0.89	-2.88	0.61	-3.62
Std dev	2.47	5.62	5.38	8.87

Table 1: Bailey-Lovie visual acuities
Positive numbers indicate an increase in acuity over the time period indicated. Negative numbers indicate a decrease. AM measurement comparisons are between Day 0, 1, and 2. PM figures compare Baseline PM to Day 2 PM measurements. The standard deviation computations indicate a wide range of variability between eyes and acuity.

Eye	Low photopic		Mesopic	
	AM	PM	AM	PM
1	19.35	9.68	0.00	0.00
2	9.68	8.82	0.00	0.00
3	0.00	-17.65	0.00	-13.64
4	0.00	-19.35	0.00	-13.64
5	9.68	0.00	0.00	0.00
6	-8.82	9.68	-12.00	13.64
7	0.00	0.00	0.00	-13.64
8	0.00	-8.82	0.00	0.00
9	0.00	0.00	0.00	-27.27
10	0.00	0.00	0.00	0.00
Average	2.99	-1.76	-1.20	-5.45
Std dev	7.82	10.53	3.79	11.50

Table 2: Pelli-Robson contrast sensitivity
Positive numerals indicate an increase in contrast sensitivity, while negative digits indicate a decrease. AM values compare Day 0 AM to Day 2 AM. PM measurements are a comparison of Baseline PM to Day 2 PM.

Eye	Base PM	D2 PM	Percent Change over time
1	0.51	0.48	-5.88
2	0.53	0.45	-15.09
3	0.46	0.46	0.00
4	0.52	0.68	30.77
5	0.57	0.55	-3.51
6	0.64	0.85	32.81
7	0.62	0.79	27.42
8	0.58	1.00	72.41
9	0.54	0.56	3.70
10	0.44	0.49	11.36
Average	0.54	0.63	16.64
Std dev	0.06	0.19	25.96

Table 3: Corneal Irregularity Measure (CIM)
CIM values range from .35 to .50 in normal shaped corneas.
A value of 1.0 or higher indicates an abnormally shaped cornea.

Eye	Base PM	Day 2 PM	Percent Change over time
1	0.20	0.18	-10.00
2	0.20	0.18	-10.00
3	0.19	0.15	-21.05
4	0.23	0.22	-4.35
5	0.22	0.12	-45.45
6	0.24	0.15	-37.50
7	0.14	0.16	14.29
8	0.12	0.09	-25.00
9	0.24	0.10	-58.33
10	0.26	0.14	-46.15
Average	0.20	0.15	-26.96
Std dev	0.04	0.04	22.52

Table 4: Shape Factor
Notice the decreasing trend in the numbers from Base PM to Day 2 PM, indicating a peripheral corneal steepening.

Eye	AM 0-1	AM 1-2	PM
1	0.20	0.20	0.40
2	0.20	-0.10	0.20
3	0.00	0.10	-0.20
4	-0.40	0.10	-0.50
5	0.20	-0.50	-0.20
6	0.00	0.10	-0.60
7	-0.50	-0.10	-0.40
8	-0.50	0.20	0.00
9	0.00	-0.30	0.00
10	0.10	0.10	0.10
Average	-0.07	-0.02	-0.12
Std dev	0.29	0.23	0.32

Table 5: Central corneal curvature (in diopters)
Positive numbers indicate steepening. Negative numbers indicate flattening.

Eye	Day 0 to Day 1 AM (Diopter change)	Location	Day 1 to Day 2 AM (Diopter change)	Location	Baseline to Day 2 PM (Diopter change)	Location
1	1	3.5mm S	1.5	3.25mm S	1.5	3.6mm T, I & N
2	1.4	3.5mm SN	1.4	3.5mm S	2.5	3.5mm S
3	1.1	2.75mm N	1.9	3.7mm S	-1.7	4.0mm S
4	2.7	3.3mm S	1	3.0mm ST	5.1	3.0mm S
5	1.6	1.87mm S	1.4	4.0mm I	1	2.2mm S
6	1.8	3.18mm S	1	3.44mm IT	1.7	2.37mm SN
7	2.7	3.0mm N	-2.9	3.0mm N	-3.2	4.0mm T
8	1.2	3.0mm S	3.5	4.1mm S	3	3.0mm S
9	6	2.5mm S	2	4.86mm I	4.5	3.75mm S
10	2.5	5.0mm IT	1.7	4.0mm T	5.1	3.8mm S

Table 6: Peripheral corneal topography values
Location from center of cornea: S=superior, I=inferior, N=nasal, T=temperal

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