USE OF CRT LENSES IN THE REDUCTION OF DRY EYE SYMPTOMS IN SYMPTOMATIC SOFT CONTACT LENS WEARERS

THESIS

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By

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Abstract

Contact lens-related eye dryness is a common complaint leading to discontinuation of contact lens wear within 5 years. This symptom is commonly associated with ocular discomfort, red eyes, eyelid irritation, shortening of wear time, and reduction of expected comfortable wearing duration. Women are affected more than men concerning dryness not associated with contact lenses. Age is the second leading factor in the United States associated with ocular surface irritation related dry eyes.

This study evaluates the effectiveness of Corneal Refractive Therapy contact lenses (Paragon Vision Sciences, Mesa, AZ) in reducing dry eye symptoms associated with soft contact lens wear.

We established a case series of thirteen subjects to investigate the efficacy of Corneal Refractive Therapy contact lenses in reduction of Contact Lens Dry Eye Questionnaire (CLDEQ) scores. All subjects were confirmed to have dry eye symptoms associated with soft contact lens wear via CLDEQ phone interview prior to enrollment (Average value of 2.2 ±0.6, p-value = 0.93). Each subject was asked to wear the Corneal Refractive Therapy contact lenses overnight for one month. Subjects returned for evaluation at two weeks, and one month after the baseline visit to survey their symptoms, and document clinical data.

The primary outcome of this study was a change in CLDEQ Short Form scores from baseline to two weeks and one month after Corneal Refractive Therapy contact lens

wear. The CLDEQ scores improved significantly during each interval between the baseline visit (2.23 ± 0.56), the two week visit (0.67 ± 0.28), and the one month visit (0.38 ± 0.35; ANOVA, p = 0.008). The average bulbar redness was significantly greater at the baseline visit (1.6 ± 0.22) than it was at the one month visit (1.14 ± 0.054; p = 0.006), and it was significantly greater at the two week visit (1.56 ± 0.26) than it was at the one month visit (p = 0.015), but there was not a significant difference between the baseline and two week visit. The average limbal redness was significantly less at the one month visit (1.14 ± 0.05) than at the two week visit (1.54 ± 0.29), but there were no other significant differences. There weren't any differences in tear break up time between the baseline (8.0 ± 2.1 seconds), two week (7.3 ± 0.8 seconds, p = 0.37) or one month visits (8.4 ± 1.5, p = 0.43)Secondary outcome measures in this study were reduction in refractive error that remained stable throughout the day, stable or improved visual acuity, reduction in bulbar and limbal redness, and improvements in tear break up time.

Corneal Refractive Therapy contact lenses could provide an additional management strategy for reducing symptoms associated contact lens-related eye dryness. A randomized controlled clinical trial should be conducted to compare the treatment of contact lens-related dry eye symptoms between Corneal Refractive Therapy contact lens wear and conventional dry eye therapies, such as artificial tears.

Dedication

This document is dedicated to my family.

Acknowledgments

I would like to thank my advisor, Jeffrey J. Walline, OD, PhD for his expert guidance and continued help throughout this entire research. I would like to acknowledge the examination committee for their knowledge, insight, and assistance in completing my thesis.

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Chapter 1: Introduction

Dry eye syndrome (DES) is a multifactorial condition that affects more than 25% of the United States (U.S.) population.[1] Dryness, grittiness, and ocular surface irritation are all common complaints experienced by patients suffering from this condition. According to the Dry Eye Workshop 2007 report, "Dry eye disease is a multifactorial disease consisting of tear irregularity, inflammation, and increased tear osmolarity causing irritation and damage to the ocular surface"[2]. No single diagnostic test can definitively diagnose dry eye, because it is characterized by a multitude of varying signs, which present differently for each individual. Diagnosis and management of dry eyes is difficult. For this reason, most clinicians diagnose the disorder based primarily on symptoms. The most reliable of all clinical tests, based on repeatability studies, are dry eye symptoms questionnaires. The Dry Eye Questionnaire 5-item survey can help practitioners accurately and systematically assess their patients ocular symptoms associated with dry eyes and classify their severity.[3]

Henrik Sjogren was the first to consider dry eyes in a diagnostic manner when he associated the symptoms of ocular surface dryness with dry mouth and arthritis in what is now known as Sjogrens disease, in 1933.[1] The first documentable use of the term "dry eyes" was used by Andrew Roetth in 1950.[1] Many of the first documentations of the disease described it as a reduction of the aqueous phase of the tear film linked with

lacrimal gland inflammation or atrophy.[1] It was not until Holly and Lemp defined all three layers of the tears, that the dry eye definition was redesigned to include disruption of either the lipid, aqueous, or mucin layer.[1] As this disease became more widely studied and documented, more patients began experiencing increased problems associated with external factors. Temperature, humidity, wind exposure, smoking, hormone levels, systemic medications, and systemic inflammation are among the most common secondary factors that exacerbate the symptoms of dry eyes.[1] Dry eyes are commonly associated with poor visual quality, poor comfort, and contact lens discontinuation.

Due to the wide array of primary and secondary risk factors, it becomes very difficult to create a single diagnostic test and treatment.[1] The goal of any clinician is to identify and treat the underlying cause of the disease; however, this is a disease that is rarely caused by one individual factor and requires a complex chronic treatment and management. Patients should be told of their condition and management strategies.

The tear film plays the most important role in maintaining regularity of the ocular surface associated with good ocular health and visual function. Disruption of the tear film results in ocular discomfort, visual impairment, and decreased quality of life .[2] There are three layers to the tears that all play a key role in protecting the ocular surface. The superficial layer that interacts with the air is the lipid layer. This layer is produced by the meibomian glands located along the lid margin. The lipid layer acts as a tear blanket and keeps the underlying layers adhered to the ocular surface and prevents evaporation. Although it is a thinner layer than the aqueous layer, it plays a key role in ocular surface hydration and is the leading cause of dry eye disease worldwide.[4]

The aqueous layer is the bulk layer of the tears with a thickness of 4-6 microns. Secreted by the main and accessory lacrimal glands, this layer contains the majority of the nutrients, oxygen, and defensive enzymes of the tears. This layer causes the second most common form of dry eye and is prevalent in patients that have Sjogrens. This systemic disease causes inflammation of the lacrimal gland and decreases tear production.

The mucin layer is secreted by goblet cells within the conjunctiva and plays a key role in providing an interaction between the corneal and conjunctival epithelium and the tears. The glycocalyx covering the surface of the epithelium interacts with protein molecules in the mucin layer and allows for the aqueous layer to properly adhere to the epithelium. A disturbance in any of these three layers will cause a cascade of improper interactions and a destruction of the tear film. The ocular surface will suffer from desiccation and ultimately suffer damage.

Dry eye affects a wide variety of people, but there are a couple of trends to note. Women have a higher prevalence of ocular surface dryness than men by a nearly 2 to 1 ratio for ages 50 years or older.[1] The United States census reports that between the year 2000 and 2050, the population aged 65-84 years will increase by 100%.[5]As the United States' biggest generation (baby boomers) age, the prevalence of dry eye increases. Interestingly though, the majority of contact lens discontinuation occurs around the average age of 27 years old.[6-8] This is likely due to an increase in the prevalence of contact lens wear in this age group.

The strong correlation between age and the prevalence of dry eye may be due to a decreased functionality of the meibomian glands over time, as well as post-menopausal hormone changes experienced by women.[2] The post-menopausal changes may lead to drying of mucus membranes around the sixth decade of life, and this may also result in burning or grittiness of the ocular surface.[1] Other issues that arise over time include auto-immune inflammatory diseases, which may lead to increased dry eye symptoms, especially when patients are exposed to significant environmental conditions like wind, heat or dust.[2] Even treatments, such as oral contraceptives and/or hormone replacement therapy, also put females at a higher risk of experiencing dry eyes, due to insufficient aqueous production and poor quality tears.

The irritation and psychological weight of dry eyes on an individual can be detrimental to their quality of life. Patients may experience changes in daily vision-related activities such as driving, or reading and they may experience work-related hindrances due to stopping work and instilling lubricating drops.[2] Patients may also experience a change in self-perception and social implications related to having dryness and needing constant lubricating eye drops. In a quality of life study, researchers studied how dry eye syndrome may affect patients' activities of daily living. The patients diagnosed with Dry Eye Syndrome (DES) were three times more likely to complain of problems with driving, watching television, performance at work, computer use, and reading than patients with no dry eye complaints.[9]

Current research recently looked into the wearing of contact lenses and their role in the increased severity and frequency of ocular surface irritation. The main reason for

contact lens dropout is discomfort.[6,7] Approximately half of Americans wearing contact lenses (approximately 17 million people) report having moderate dry eye symptoms.[10] Ocular surface irritation associated with eye dryness is the number one reason patients discontinue wearing their contact lenses. Talking to patients allows the doctor to narrow down the root of the discomfort; dryness discomfort caused by tear film instability. Stability is measured by the even distribution of the tears across the lens surface, without disruption of the tear layer. Disruption of the tears can cause significant detriment to the ocular surface. It has been studied that the introduction of a contact lens to the ocular surface causes significant disruption to the lipid layer, causing increased evaporation and consequently increased discomfort. In a study conducted by Pritchard et al., 12% of contact lens wearers discontinued wearing their contact lenses after five years due to ocular surface irritation associated with dry eye symptoms.[8] In a university based study, researchers reported 24% of patients discontinued lenses permanently, and 26% reported dissatisfaction with their lenses after five years with the main symptoms being dryness and discomfort.[7] The contact lens causes disruption of the tear film leading to exacerbation of evaporation and decreased replenishment of the aqueous layer. This cascade leads to significant symptoms of irritation. Lenses are said to partition the aqueous layer in half. With each blink, the pre-lens tear film layer tends to thin until evaporation causes surface tension to break down and form dry spots. Once surface tension is disrupted, any liquid will dissociate faster and evaporation occurs quicker than normal.

There is a constant uphill battle with which many clinicians must contend while trying to keep their patients happy in contact lenses and reduce symptoms of dryness associated with contact lens wear. Nichol's once concluded that the majority of patients experiencing ocular surface irritation associated with dryness, showed signs of early tear break up time and a reduced thickness of the lipid layer of the tear film.[10] However, it is also just as important for the lens to maintain good wettability, in order to not disrupt the tear film.[10] He remarks that there is a possibility that a reduced lipid layer documented in these patients after lens wear, could have been present prior to contact lenses being worn. Therefore, it is important for clinicians to have a tear film layer assessment prior to lenses ever being worn. This will allow assessment of the tear film changes that may occur after contact lenses have been worn.

Contact lens dehydration is a final way that may cause reduction of proper tear chemistry and lead to ocular surface dryness. Releasing wetting agents into the tears with every blink, or hydrophilic agents within the lenses are two ways companies advertise that their particular contact lens will reduce ocular surface irritation and lens discontinuation associated with dryness.

Studies have argued on behalf of both sides that contact lens dehydration causes ocular surface dryness, and a solid conclusion has yet to be made.[10] A study, by Efron and Brennan, found patients wearing low water content lenses maintained better wettability and reported less lens dehydration associated ocular surface dryness.[11] A second study reported patients wearing high water content lenses reported having fewer dry eye problems. Water content refers to the amount of water incorporated into

Hydrogel contact lenses during manufacturing, and was designed to promote oxygen permeability through the lens. Low water content lenses are said to be better for dry eyes because they require less water in their design. When they begin to dry out they absorb fewer tears to regain their water content level. It is thought that high water content contact lenses require more water to be absorbed from the tears to maintain the same water content.

Silicone hydrogel contact lenses were originally developed to supply higher amounts of oxygen through the lens to the cornea. Limited research has been published on ocular surface stability and tear-film changes associated with daily wear silicone hydrogel lenses. A study performed at The University of Medicine in Japan looked into ocular surface changes associated with short-term and long-term senofilcon A silicone hydrogel lens wear.[12] Their results showed no significant differences in ocular surface integrity or tear film regularity after two weeks of wearing senofilcon A silicone hydrogel lenses. Nichols reported findings of pre-lens thinning of the tear film significantly associated with dry eyes and contact lens wear.[10] Nichols and Sinnott concluded that evaporation of the tears and lens dewetting are the two major factors contributing to pre-lens tear film thinning.

In an alternate study performed by Chalmers, 699 silicone hydrogel contact lens wearers were compared to 183 hydrogel contact lens wearers in an analysis of dryness symptoms. No significant difference was found between age or sex in each cohort studied. A larger proportion of silicone hydrogel contact lens patients entered the study with previously reported/documented diagnosis of dry eyes, compared to hydrogel

contact lens wearers.[13] It is unknown whether patients were switched into silicone hydrogel contact lenses due to dryness complaints with hydrogel contact lenses. A report has been issued documenting increased dry eye problems with age in hydrogel contact lens wearers. The study looked into contact lens awareness as well as discomfort and dryness. It was found that a smaller proportion of patients reported awareness of lenses in the silicone hydrogel contact lens group compared to hydrogel contact lens wearers. Contact lens discontinuation was correlated with increased age in the hydrogel contact lens wearing group. There was documentation of greater discontinuation of contact lens wear due to worsening of symptoms at the end of the day by hydrogel contact lens wearers than silicone hydrogel contact lens wearers.[13] Greater than 67% of patients reported that their vision was reduced when their contact lenses were dry.[13] A secondary report by Dr. Richdale concluded that less than 12 hours of wearing lenses was considered unsatisfactory to contact lens wearing patients. Switching these individuals into silicone hydrogel contact lenses significantly increased their comfortable wearing time by more than two hours per day.[14]

According to a recent report published by the Tear Film and Ocular Society (TFOS), more than 50% of contact lens wearers experience contact lens discomfort. They propose that clinicians should use contact lens discomfort to document ocular irritation associated with contact lens wear, instead of using the common phrase "contact lens dry eye."[15] Contact lens wearers present differently for each clinician, but complain of the same overall problems such as dryness, irritation, discomfort, and fatigue.[15] In order to use the term contact lens-related dry eyes, the clinician is proposing the patient has an

underlying diagnosis of dry eyes that becomes exacerbated by contact lens wear. This limits the patients' contact lens discomfort to one underlying problem. TFOS wants clinicians to document contact lens dropout as being related to the umbrella term contact lens discomfort, due to the limited research that pinpoints an exact underlying cause of dropout. There are few in-office techniques that assess ocular comfort in contact lens wearers, with high repeatability and validity.[15] Due to contact lens discomfort being a symptom-related finding, it is acceptable to use symptom surveys to diagnose contact lens discomfort.[15] These surveys provide accuracy and repeatability regarding documentation of frequency and intensity of ocular discomfort related to contact lens wear.[15]

Contact lens discomfort is commonly related to multiple underlying factors such as contact lens material, design, and care of lenses. Up to 90% of contact lens wearers are wearing soft contact lenses, with the majority wearing some form of silicone hydrogel contact lenses.[15] The majority of research has examined the design of soft contact lenses, especially water content, dehydration, oxygen transmissibility, and wettability. No single aforementioned attribute has been documented as the sole cause of contact lens discomfort. Contact lens design effects on-eye movement, tear exchange, and corneal coverage, but direct correlation is hard to pinpoint.[15] Practitioners discuss the importance of proper contact lens wear, care, and replacement. A strong correlation exists between contact lens discomfort and improper wear of lenses, a poor cleaning process, or replacement schedule.[15] However, there is no perfect combination of these factors that fit for every individual. Due to this variability, there is no ideal contact lens replacement

time and wearing schedule for every individual. There is also no perfect combination of contact lens materials and contact lens cleaning solutions that will solve every patient's needs.

The Tear Film and Ocular Society subcommittee reported that there was no significant link between signs of corneal distress such as corneal staining, limbal and bulbar redness, or hypoxia and contact lens discomfort. The study looked into changes in corneal staining, limbal and bulbar redness, and tear break up time (TBUT), and their association with decreased symptoms of ocular surface irritation caused by contact lens-related dry eye.

Most clinicians avoid removing patients from contact lenses if possible, and try a variety of management strategies to keep their patients happy by extending their comfortable wear time throughout the day. One approach that has not been documented in the literature is the use of CRT contact lenses. Orthokeratology lenses were developed for use in 1960.[16] Advances in design and oxygen transmissibility lead to orthokeratology lenses that could be worn during sleep. These lenses allow clear vision throughout the day while allowing the patient to be free of any refractive correction device.[16] CRT contact lenses provide temporary correction of refractive myopia during daytime hours caused by central corneal flattening associated with central epithelial thinning and midperipheral stromal thickening.[16]

Daily wear of soft and gas permeable contact lenses decreases the tear film surface quality, compared to eyes wearing no contact lenses.[17] Therefore, Corneal Refractive Therapy contact lenses may provide relief from dry eye symptoms simply by

allowing for normalization of the tear film, which may, in turn, lead to decreased symptoms associated with ocular surface dryness.

This case series compares dry eye symptoms experienced with soft contact lens wear to dry eye symptoms after one month of CRT contact lens wear. To date, no research has been published regarding dry eye symptom assessment with CRT contact lens wear. This study may provide an alternative treatment option to keep patients in contact lenses while addressing dry eye concerns.

Chapter 2: Methods

Soft contact lens wearers who reported moderate to severe dry eye symptoms were recruited from The Ohio State University College of Optometry soft contact lens wearing subjects in a patient recruitment database.

Institutional Review Board approval was received from the Ohio State University Biomedical Sciences Institutional Review Board on February 5th, 2013. All subjects eligible for participation were required to sign an informed consent form prior to taking part in the study, and all subjects were given a HIPAA privacy document, informing them of confidentiality while being involved in the study.

Participants

Subjects enrolled were between the ages of 18 and 38 years. Subjects older than 38 years of age were eliminated due to the possibility of being susceptible to presbyopic changes and increased susceptibility of dry eye unrelated to contact lens wear. Individuals younger than 18 years of age were excluded due to low frequency of contact lens-related dry eyes.[18] Subjects with spherical component spectacle refractive error between -1.00D sphere and -5.00D sphere and with less than -1.00D cylinder, both measured with non-cycloplegic manifest refraction were included. Each subject was required to be a current soft contact lens wearer and was classified as having dry eye by

the Contact Lens Dry Eye Questionnaire Short Form (CLDEQ). Individuals with significant ocular or systemic health concerns that may affect contact lens wear were excluded. Each individual was required to have best-corrected Snellen visual acuity of 20/20 in each eye.

Equipment and Materials

Following a thorough slit lamp examination, manifest refraction, corneal topography using the Zeiss Atlas Topographer (Carl Zeiss Meditec, Dublin, CA), and best-corrected visual acuity, eligible subjects were fit with Corneal Refractive Therapy contact lenses. A contact lens case and Optifree GP (Alcon Inc, Fort Worth, TX) rigid gas permeable contact lens solution were given to each subject. NEI-RQL and CLDEQ Short Form surveys were used to assess each patient's symptoms related to dryness of the ocular surface.

Study Design

All subjects were pre-screened over the telephone by the primary examiner for eligibility. "Yes" responses to the following questions were required prior to scheduling of the baseline examination:

1) Is the subject between 18 and 38 years of age?

2) Is the subject a current soft contact lens wearer?

3) Does the subject have confirmed dry eyes according to the CLDEQ?

Due to the limited literature on contact lens relief and corneal refractive therapy, this study was designed to be a case series with no control group in order to collect preliminary data on the efficacy of corneal refractive therapy in its attempts to relieve dry eye symptoms.

Each participant completed an NEI-RQL survey in order to document quality of life associated with soft contact lens wear, and a general ocular health assessment was performed to assess if the eyes were in good health for contact lens wear.

Visual acuity was measured using the logMAR ETDRS chart at a distance of four meters from the subject. Subjects were instructed to begin at the top of the chart with both eyes open wearing their habitual correction, and read every letter on every line until they missed three or more letters on a given line. The total number of letters correct was documented.

Each individual had a non-cycloplegic manifest refraction performed to document the overall refractive error, with documented best-corrected visual acuity using logMAR ETDRS chart at 4 meters. The endpoint of non-cycloplegic manifest refraction was maximum-plus-to-maximum-visual acuity and binocular blur balance. Corneal Topography (Carl Zeiss Meditec, Dublin, CA) was measured on each individual to document simulated keratometry values in each of the major meridians for each eye. One picture was taken for each eye at each exam.

Slit lamp examination was performed to assess anterior segment health, along with bulbar redness and limbal redness using the CCLRU grading system. Fluorescein was instilled using Bio-Glo and a drop of non-preserved saline in order to record tear

break up time, which was recorded to the nearest second. Corneal staining type, depth, and extent recorded using the CCLRU grading system estimated to the nearest 0.1.

The CRT contact lenses were fit according to the manufacturer's instructions. In short, an initial contact lens was determined by entering the flat keratometry reading and desired spherical refractive error reduction in a slide rule. The corresponding contact lens was pulled from the Paragon CRT fitting set and put on each eye of the subject with a single drop of proparacaine 0.5% ophthalmic solution (anesthetic) in place prior to lens instillation. Successful fit, according to proper centration, edge lift, treatment zone diameter, and bulls-eye fluorescein pattern behind the lens was confirmed using the fitting guide insert from the Paragon CRT fitting set. Upon determination of successful fitting of contact lenses in both eyes, the patient was educated on proper contact lens wear and care. Each contact lens pulled at this visit was documented. A spherical over-refraction was performed with a phoropter over the final lenses on each eye. The subjects were then scheduled for the one-day follow-up visit in order to determine proper lens fitting after one night of sleeping in the lenses for a minimum of 6 to 8 hours.

At the one day visit, the subjects arrived in the morning wearing the contact lenses. No anesthetic was used at this visit during lens wear. LogMAR binocular visual acuity was documented while wearing the lenses, using the same protocol as the baseline visit. A spherical over-refraction was performed with maximum-plus-to-maximum-visual acuity endpoint. Lenses were assessed for centration, edge lift, and treatment zone diameter. The contact lenses were removed and corneal staining type, depth, and extent as well as bulbar and limbal redness, were assessed using the CCLRU grading system.

Manifest refraction with maximum-plus-to-maximum-visual acuity endpoint was performed to document the current prescription for the subject. Corneal Topographic simulated keratometry values were recorded for each major meridian for each eye.

At the two week visit and one month visit, the subjects arrived in the afternoon not wearing any contact lenses. Protocols at these visits were identical to the baseline visit, and included the following. LogMAR visual acuity was documented with both eyes open while not wearing the contact lenses. Both the CLDEQ and NEI-RQL questionnaires were completed. Manifest refraction with maximum-plus-to-maximum-visual acuity endpoint was performed to document the current prescription for each eye. Topographic simulated keratometry values were documented for each eye. Topographic images were also used to assess centration and even distribution of the treatment zone. Corneal staining type, depth, and extent, as well as bulbar and limbal redness were documented using the CCLRU grading scale. The contact lenses were modified at this visit, if needed, to improve fit. The final base curve, return zone diameter, and landing zone angles were documented.

Subjects were educated that the study was finished and they were free to continue wearing the lenses if they choose. The patients kept the lenses free of charge and each patient was given a prescription for replacement lenses that they could order if necessary.

Data Entry

Data were entered twice into an excel database and maintained on a computer that was password encrypted. Comparisons were documented between the two spreadsheets

and corrections were made. The final data set was corrected and reviewed prior to final analysis.

The primary outcome of this study was the evaluation of dry eye symptom relief after wearing Corneal Refractive Therapy contact lenses for one month. Symptoms were scored based on each subject's response to the CLDEQ and NEI-RQL surveys taken at the baseline, two weeks, and one month visits. Thirteen subjects were recruited for this study, and eight subjects were analyzed, accounting for dropout.

Chapter 3: Results

We began our study by screening twenty-four subjects by telephone. Eleven subjects did not participate in the study due to ineligibility. Of those eleven, eight subjects had refractive error outside the range of the parameters in this study, and three subjects were not able to participate due to scheduling conflicts and time constraints. Thirteen subjects were entered into the one month study, and 8 (61.5%) subjects finished the entire study. Of those that did not finish the study, three subjects could not adapt to the visual changes associated with the transition to no refractive error. One subject dropped out after the baseline visit due to feeling unsure about the thought of her cornea being reshaped. One subject dropped out due to being a medical student, and being involved in surgical procedures during the time of the study and could not afford having potential visual struggles. No subjects discontinued the study due to new or continued dry eye complaints.

Of the thirteen enrolled in this study, seven subjects (54%) were male and six subjects (46%) were female. None of the subjects were Hispanic or Latino and all subjects were white. The average (± standard deviation) age for subjects was 26.1 ± 2.3 years.

Of the thirteen subjects, eight completed the one month study. Comparison of subjects who completed and those that did not found no significant differences (Table 3.1).

	Completed	Not completed	p-value
TBUT OD	8.0 ± 2.1	6.8 ± 2.3	0.43
TBUT OS	8.0 ± 2.1	7.2 ± 2.1	0.59
Bulbar Redness OD	1.6 ± 0.2	2.0 ± 0.4	0.11
Bulbar Redness OS	1.6 ± 0.2	2.0 ± 0.4	0.11
Limbal Redness OD	1.5 ± 0.3	1.4 ± 0.5	0.94
Limbal Redness OS	1.5 ± 0.3	1.4 ± 0.5	0.94
Steep keratometry OD	44.20 ± 1.69	43.99 ± 1.18	0.83
Steep keratometry OS	44.55 ± 0 .17	43.95 ± 0.94	0.51
Flat keratometry OD	43.50 ± 1.52	43.25 ± 1.66	0.81
Flat keratometry OS	43.97 ± 1.75	43.05 ± 1.33	0.37
M OD	-3.33 ± 0.36	-3.75 ± 1.33	0.55
M OS	-3.30 ± 0.42	-3.53 ± 1.39	0.74
J0 OD	0.13 ± 0.10	0.00 ± 0.00	**0.01**
J0 OS	0.00 ±0 .11	0.03 ± 0.06	0.046
J45 OD	0.15 ± 0.00	0.00 ± 0.00	**0.01**
J45 OS	0.01 ± 0.00	0.00 ± 0.00	0.046
logMAR	-0.09 ± 0.06	-0.13 ± 0.06	0.38
Age	25.8 ± 2.6	26.4 ± 2.3	0.70

Table 3.1: Comparison of demographics information and ocular characteristics between those that completed the study and those that did not. Values found to be significant are highlighted in bold print (independent sample t-test with Bonferroni correction for multiple comparisons; the p-value must be less than 0.01 for refractive error, slit lamp signs, and keratometry readings).

A second comparison of subjects who completed and those that did not found no significant difference between the two groups regarding NEI-RQL subcategory survey scores (Table 3.2). Therefore the analysis of those that completed the study can act as representation of the entire group as a whole.

	Completed	Not-completed	p-value
CLDEQ	2.2 ± 0.6	2.3 ± 1.1	0.93
Clarity of Vision	55.9 ± 19.6	57.9 ± 26.9	0.89
Expectations	15.0 ± 22.4	5.0 ± 11.2	0.40
Near Vision	95.0 ± 7.5	80.0 ± 19.2	0.14
Far Vision	87.0 ± 5.3	81.7 ± 13.2	0.43
Diurnal Fluctuations	59.2 ± 17.0	57.5 ± 26.7	0.91
Activity Limitations	90.0 ± 12.9	63.8 ± 33.8	0.14
Glare	62.5 ± 21.7	70.0 ± 25.9	0.63
Symptoms	51.4 ± 9.7	59.3 ± 11.8	0.28
Dependence on Correction	56.7 ± 22.4	48.4 ± 29.1	0.63
Worry	52.5 ± 22.4	40 ± 10.5	0.29
Suboptimal Correction	72.5 ± 16.3	77.5 ± 25.6	0.72
Appearance	38.7 ± 23.3	49.3 ± 40.5	0.62
Satisfaction	60.0 ± 14.1	60.0 ± 0.0	1.00

Table 3.2: Comparison of NEI-RQL survey responses between those that completed and those that did not complete the study (independent sample t-test with Bonferroni correction for multiple comparisons; the p-value must be less than 0.004).

Baseline data were gathered at an initial examination, after individuals were defined as eligible via phone interview. Follow-up visits were scheduled one day, two weeks, and one month after the first night of contact lens wear. Subjects were examined within seven days of the expected follow-up date.

The primary outcome of this study was the evaluation of dry eye symptom relief at the end of the one month wearing of corneal refractive therapy contact lenses. Symptoms were scored based on each subject's response to the CLDEQ and NEI-RQL surveys taken at the baseline, two week, and one month visits. Figure 3.1 shows the average (± standard deviation) CLDEQ scores reported at each visit. The CLDEQ scores improved significantly between each visit (p-value = 0.008).

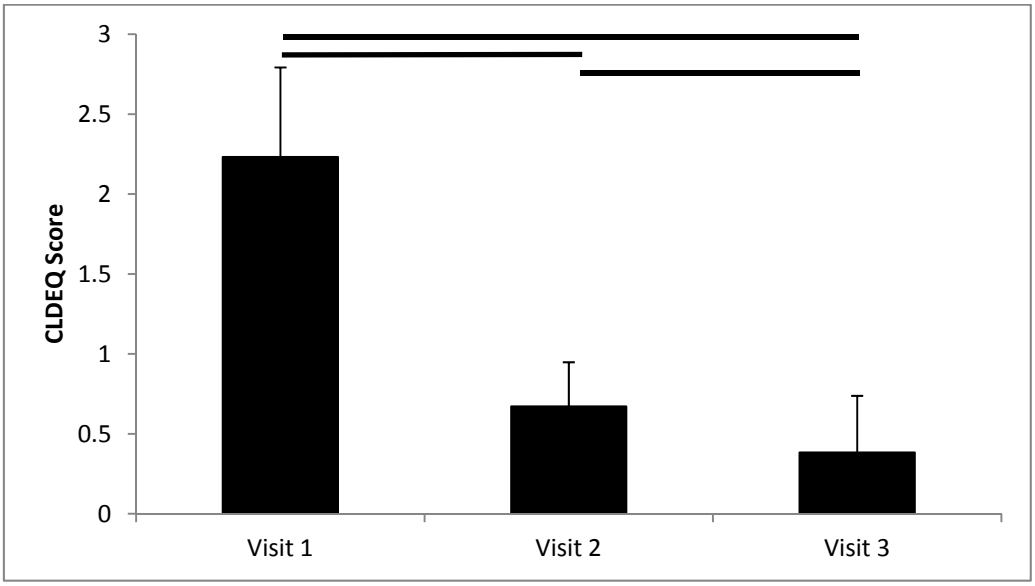

Figure 3.1: Average CLDEQ score at each visit. Horizontal bars indicate CLDEQ scores that are significantly different from one another. Vertical lines indicate standard deviation of the CLDEQ score.

No significant differences were found between the right and left eyes for any of the variables assessed.

Figure 3.2 shows that the bulbar redness was less at the one month visit than the baseline visit ($p=0.006$) and two weeks ($p=0.015$) for both eyes, but there wasn't a significant difference between the baseline and two week visits.

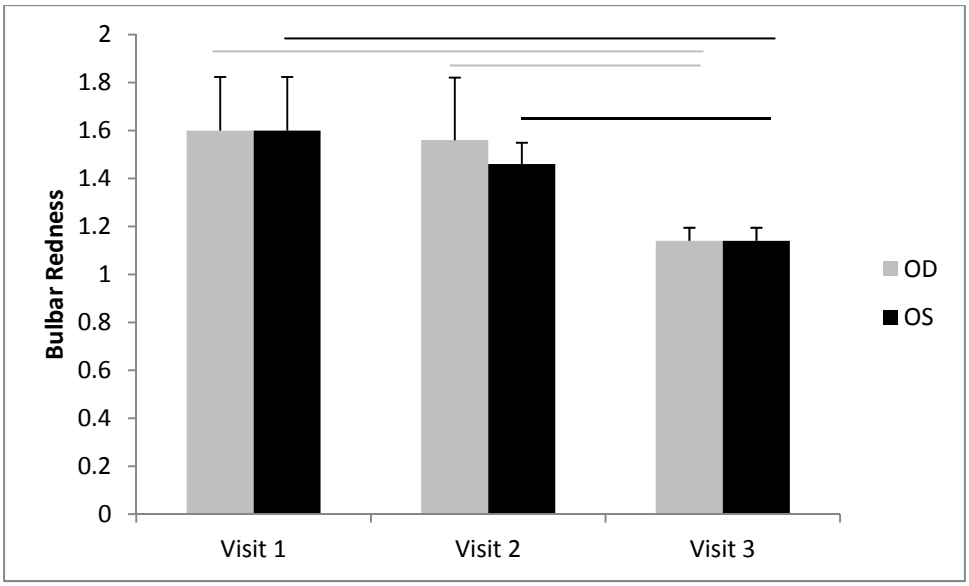

Figure 3.2: Average bulbar redness of the right and left eyes at each visit. Horizontal bars indicate bulbar redness values that are significantly different. Vertical lines indicate standard deviation.

Limbal redness was also less at the one month visit than the two week visit ($p=0.025$), but there was no difference between baseline and the one month visit (Figure 3.3).

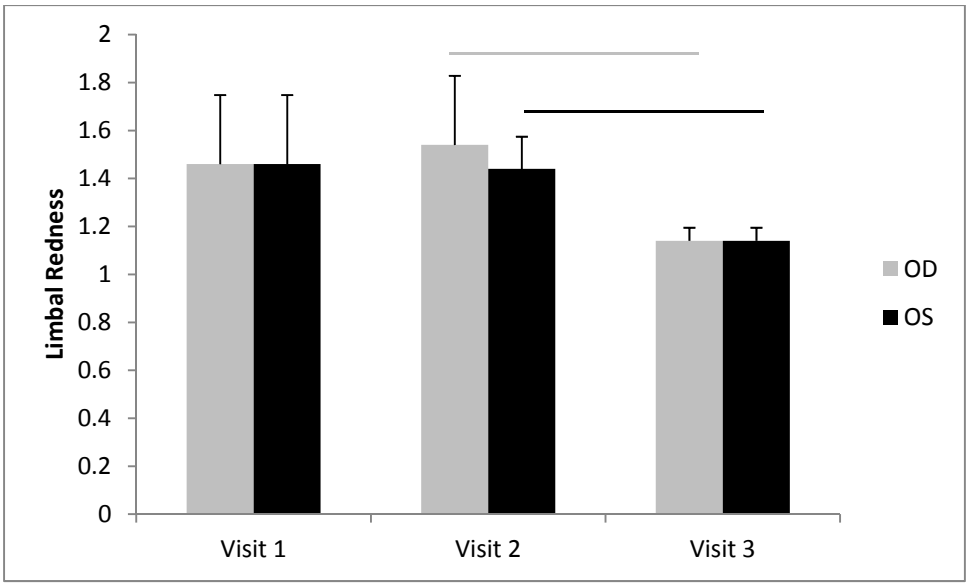

Figure 3.3: Average limbal redness OD and OS at each visit. Horizontal bars indicate limbal redness values that are significantly different. Vertical lines indicate standard deviations.

The average tear break up time (TBUT) was approximately eight seconds and it did not change over time (Figure 3.4).

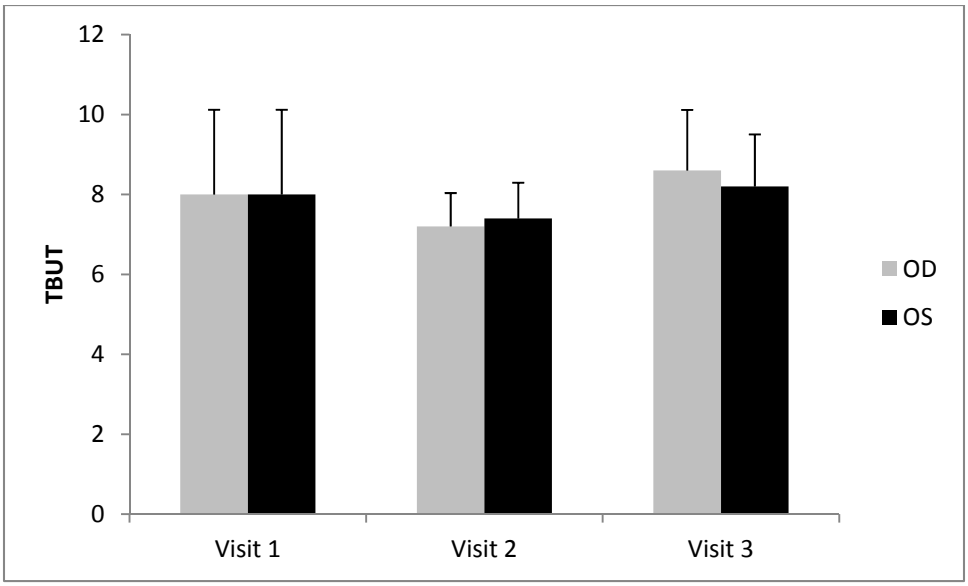

Figure 3.4: Average tear break up time (TBUT) in the right and left eyes at each visit. Vertical lines indicate standard deviations.

Figure 3.5 depicts the two scales of the NEI-RQL that exhibited significant differences between visits. Patients experienced a significant improvement in Symptoms between visit 1 and visit 3 ($p<0.001$). Appearance showed significant improvement between visit 1 and 3 ($p=0.006$), and visit 1 and 2 ($p=0.043$). No significant difference was found for Satisfaction, Far Vision, and Glare between all visits. Scales presented in the figure were chosen due to pertinence in the study. It was important to document that distance subjective vision did not change from the start of the study to the end.

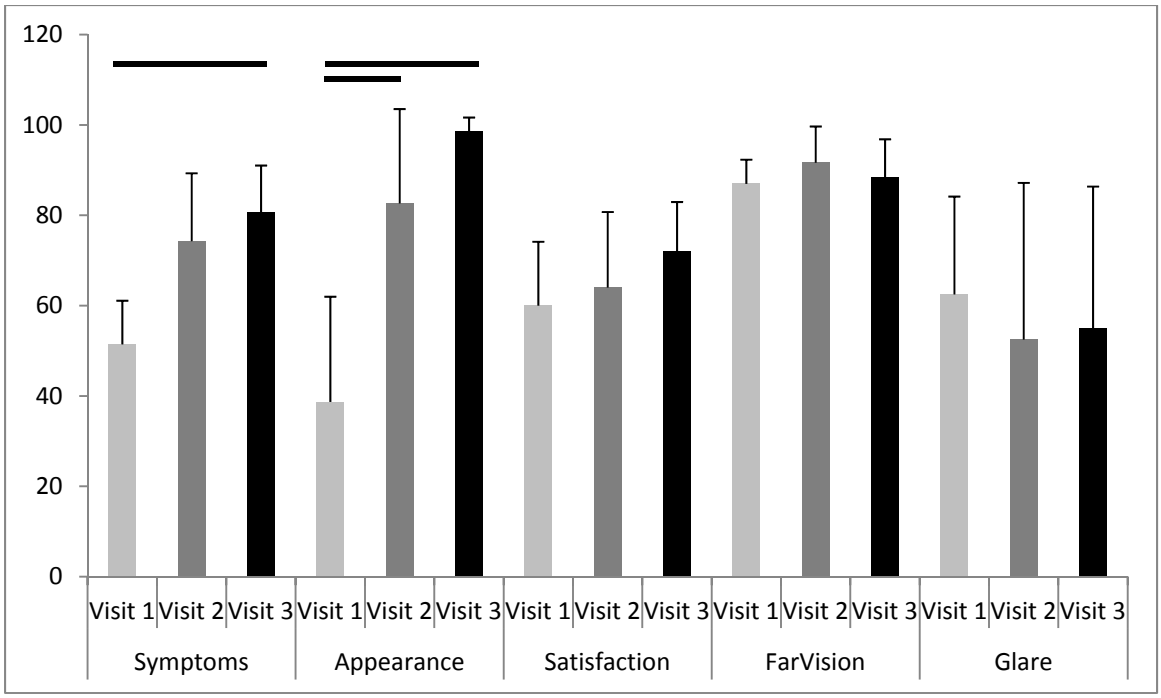

Figure 3.5: Average NEI-RQL scales regarding symptoms, appearance, and satisfaction at each visit. Horizontal bars indicate values that are significantly different. Vertical lines indicate standard deviations.

Table 3.3 depicts the average (±standard deviation) NEI-RQL scale scores for each visit.

NEI-RQL Scale	Visit	Mean
Clarity of Vision	1	55.9 ± 19.6
	2	42.9 ± 16.3
	3	50.0 ± 15.8
Expectations	1	15 ± 22.4
	2	20 ± 20.9
	3	35.0 ± 22.4
Near Vision	1	95 ± 7.5
	2	87.1 ± 9.9
	3	98.3 ± 3.7
Far Vision	1	87.0 ± 5.3
	2	91.7 ± 8.0
	3	88.3 ± 8.5
Diurnal Fluctuations	1	59.2 ± 17.0
	2	52.5 ± 22.2
	3	58.4 ± 8.8
Activity Limitations	1	90.0 ± 12.9
	2	98.8 ± 2.8
	3	95 ± 11.2
Glare	1	62.5 ± 21.7
	2	52.5 ± 34.7
	3	55 ± 31.4
Symptoms	1	51.4 ± 9.7
	2	74.3 ± 15.0
	3	80.7 ± 10.3
Dependence on Correction	1	56.7 ± 22.4
	2	85.0 ± 14.9
	3	98.3 ± 3.7
Worry	1	52.5 ± 22.4
	2	47.5 ± 22.4
	3	50 ± 29.3
Suboptimal Correction	1	72.5 ± 16.3
	2	67.5 ± 14.3
	3	65 ± 32.4
Appearance	1	38.7 ± 23.3
	2	82.7 ± 20.9
	3	98.7 ± 3.0
Satisfaction	1	60 ± 14.1
	2	64.0 ± 16.7
	3	72.0 ± 11.0

Table 3.3: Average (± standard deviation) NEI-RQL scale scores by visit.

Figure 3.6 depicts the average steep simulated keratometry values at each visit. Steep keratometry values were steeper at visit 1 than visit 2 (p=0.012), and visit 3 (p=0.008).

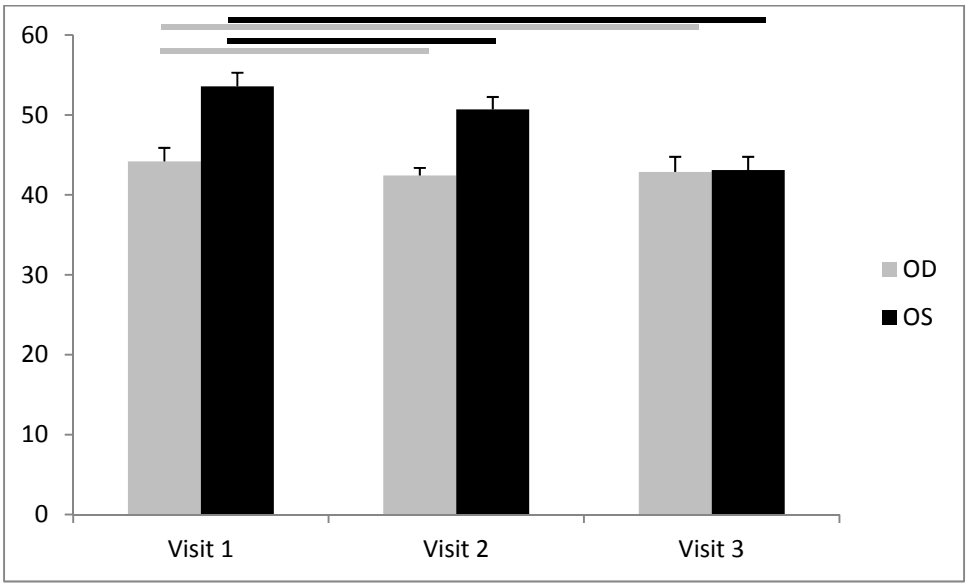

Figure 3.6: Average Steep keratometry values at each visit. Horizontal bars indicate values that are significantly different. Vertical lines indicate standard deviations.

The flat keratometry values were also flatter at visit 2 and 3, than the values at baseline (Figure 3.7).

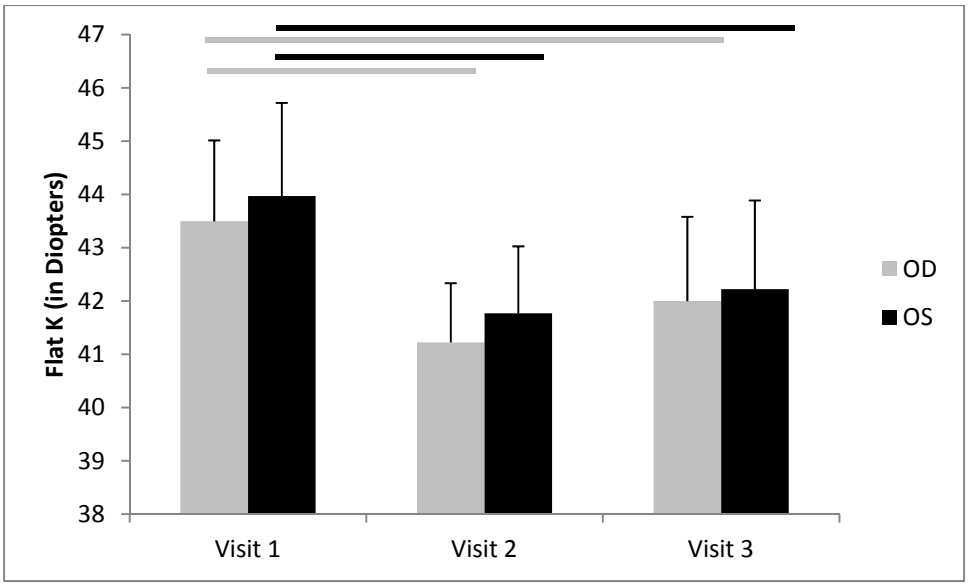

Figure 3.7: Average Flat keratometry values at each visit. Horizontal bars indicate values that are significantly different. Vertical lines indicate standard deviations.

No significant difference in binocular distance visual acuity was noted between baseline visit, and visit 2 and 3. Baseline visual acuity was taken in the subject's best correction, and visits 2 and 3 were uncorrected vision results after overnight wear of Corneal Refractive Therapy contact lenses.

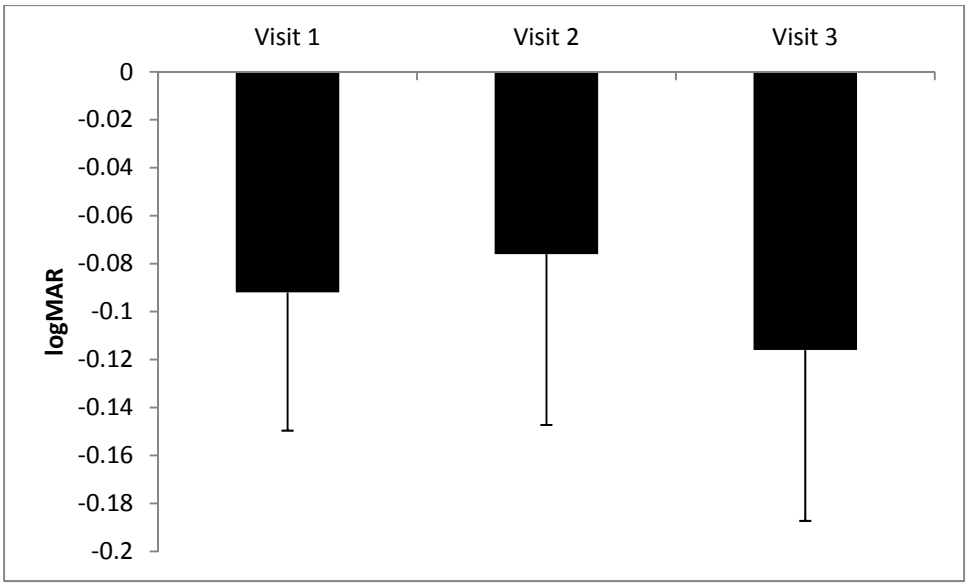

Figure 3.8: Average logMAR acuity at each visit. Vertical lines indicate standard deviations.

Spherical equivalent refractive error decreased from the baseline visit to visit 2 and 3 (Figure 3.9). The majority of refractive correction was seen within the first two weeks of overnight wear of Corneal Refractive Therapy contact lenses.

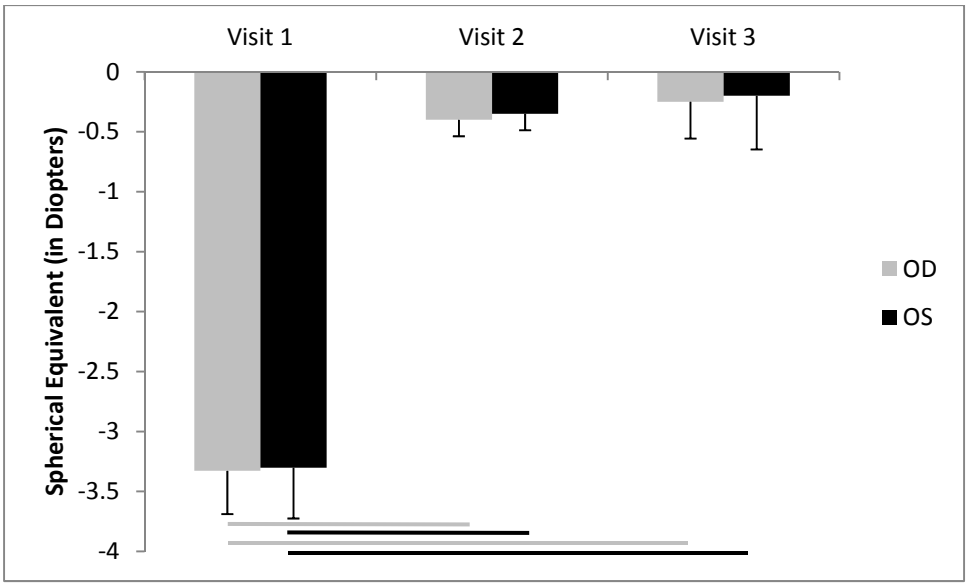

Figure 3.9: Average spherical equivalent values at each visit. Horizontal bars indicate values that are significantly different. Vertical lines indicate standard deviations.

Astigmatic refractive error was seen to diminish to minimal values by visit 2 and kept stable at visit 3, compared to the baseline visit. The values recorded for visits 2 and 3 are values of zero (Figure 3.10 and Figure 3.11).

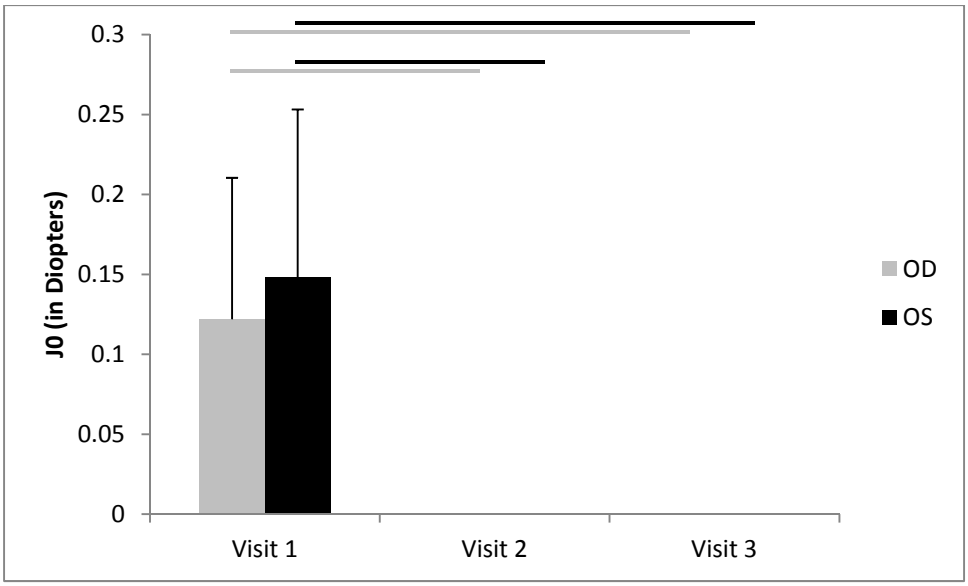

Figure 3.10: Average J0 values at each visit. Horizontal bars indicate values that are significantly different. Vertical lines indicate standard deviations.

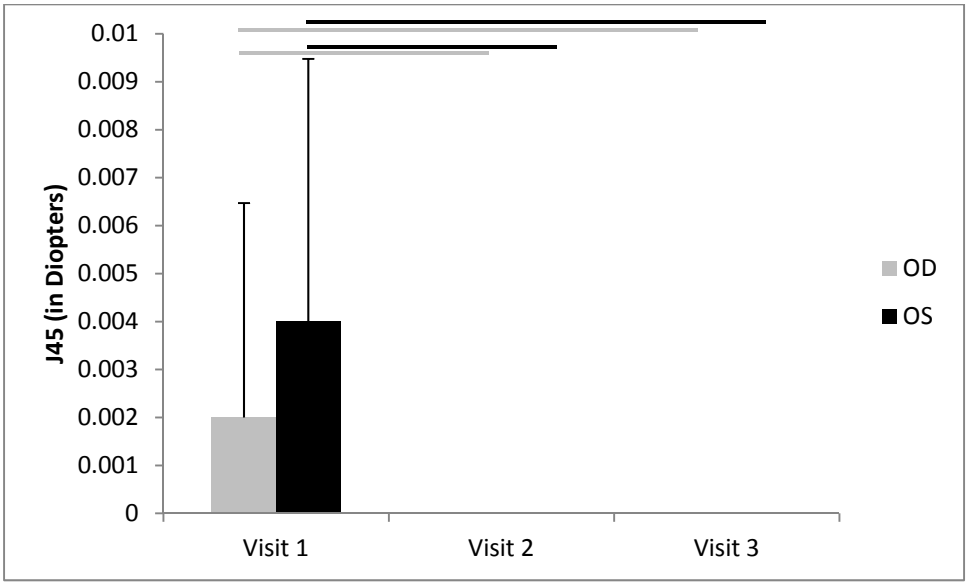

Figure 3.11: Average J45 values at each visit. Horizontal bars indicate values that are significantly different. Vertical lines indicate standard deviations.

Our study revealed no significant difference in Contact Lens Dry Eye Questionnaire scores between genders (p=0.11) (Table 3.4). However, the female sub-population showed a trend towards having higher CLDEQ symptoms scores than men. Clarity of Vision between genders showed significant difference (p=0.03) (Table 3.4). No significant difference was found regarding the remaining NEI-RQL scales when comparing gender responses at the baseline visit.

	Males	Females	p-value
CLDEQ	1.7 ± 0.8	2.6 ± 0.7	0.11
Clarity of Vision	74.5 ± 20.4	45.2 ± 15.1	**0.03**
Expectations	0.0 ± 0.0	16.7 ± 20.4	0.15
Near Vision	89.6 ± 20.9	86.1 ± 13.6	0.76
Far Vision	87.9 ± 9.4	81.9 ± 10.3	0.38
Diurnal Fluctuations	68.8 ± 31.6	51.5 ± 7.8	0.22
Activity Limitations	82.8 ± 34.4	72.9 ± 25.2	0.61
Glare	59.4 ± 27.7	70.8 ± 20.4	0.47
Symptoms	58.0 ± 14.4	53.6 ± 9.0	0.56
Dependence on Correction	56.3 ± 26.7	50.0 ± 25.8	0.72
Worry	50.0 ± 20.4	43.8 ± 17.2	0.62
Suboptimal Correction	75.0 ± 28.9	75.0 ± 15.8	1.00
Appearance	46.7 ± 32.7	42.2 ± 33.9	0.84
Satisfaction	65.0 ± 10.0	56.7 ± 8.2	0.19

Table 3.4: Gender comparisons regarding CLDEQ scores, and NEI-RQL scales.

Chapter 4: Discussion

Summary of Results

Subjects on average showed statistically significant improvement in their CLDEQ Short Form scores at each visit compared to baseline. Subjects consistently vocalized the feeling of "freedom from [their] contact lenses," and the relief of irritation associated with end-of-day eye dryness while previously wearing their soft contact lenses. Our data suggest there is potential benefit in Corneal Refractive Therapy contact lenses regarding relief of dry eye symptoms.

Symptoms vs. Signs

Subjects experienced significant improvements in their dry eye symptoms based on their responses to the CLDEQ Short Form, with the majority of their relief of symptoms occurring between the baseline visit and the two week visit. The lasting benefit of their relief remained stable throughout the remainder of the study. Little research has been published regarding dry eye relief involved with Corneal Refractive Therapy contact lenses. It can be assumed the reduction in their dry eye symptoms is correlated with the removal of soft contact lens wear during the day. Soft contact lenses have been

shown to cause disruption in the tear film, and can lead to significant contact lens-related discomfort.[10,15,19]

NEI-RQL scale scores regarding Symptoms and Appearance are the only variables that showed significant statistical improvements from the baseline visit to the one month visit. Previous studies assessing NEI-RQL responses among myopes corrected by spectacles or contacts and emmetropes found a similar improvement in appearance.[20] A similar study in Spain compared orthokeratology contact lens wearers to spectacle wearing children, assessing their compared responses regarding quality of life. They conclude there was significant improvement in appearance, expectations, and vision related quality of life measures in kids wearing orthokeratology contact lenses compared to spectacle wearing children.[21] These data suggest that Corneal Refractive Therapy contact lenses relieve dry eye symptoms. They also provide good self-appearance feelings for each subject, because they know they will not need to resort to glasses full time.

Anterior segment evaluation showed significant improvements in average bulbar and limbal redness from baseline visit to the one month visit. Drying of the ocular surface will lead to irritation, inflammation, and redness of the eyes. It was statistically and clinically significant to see improvements in bulbar and limbal redness in our subjects throughout the one month study. This suggests there was significant reduction in ocular surface irritation, and/or inflammation associated with ocular surface dryness caused by previous soft contact lens wearing.

There was no significant change in tear break up time at each visit throughout the one month study. We expected to see improvements in tear break up time throughout the one month study similar to standard therapy with lubricating tear drops. The study's short duration may not have allowed for enough time for the tear film to regain its full normalized state. Alternate studies regarding lubricating eye drops found a significant improvement in tear break up time, and Schirmers test in subjects given lubricating eye drops for 30 days, compared to placebo drops. [22-24]

Solomon et al concluded in 1996 that daily disposable soft contact lens wearers reported better end-of-day comfort, vision, and reduced dryness compared to 2 week and one month replacement contact lens wearers.[25] Our study looked to further improve end-of-day discomfort associated with daily or replacement soft contact lens wear, by removing contact lens wear during the day and providing ocular correction with Corneal Refractive Therapy contact lenses worn overnight. Our method of management provides an additional avenue clinicians can take in order to make their patients happy, reduce ocular discomfort related to end-of-day dryness, and keep their patients in contact lenses. Our study showed improvements in ocular surface signs associated with contact lens-related eye dryness. Inferences can be made to assume our improvements are similar to subjects who switched to daily disposable soft contact lenses in the previous study by Solomon et al. However, due to differences in methodology and data collection, we cannot directly compare our success with the success of their study. By reducing mechanical irritation experienced by deposit build up on any modality of soft contact lenses, we provide an advantageous method of dry eye management while keeping

patients in contact lenses. Our methodology may provide a more trouble-free method of wearing contact lenses and reducing dry eye symptoms.

Effects of Overnight Orthokeratology

With the help of the reverse geometry designed Corneal Refractive Therapy contact lenses, our study subjects were able to achieve clear vision within the first two weeks of overnight wear. Similar findings are reported in numerous studies exhibiting effects that occur immediately after putting the lenses on for the first time, and lasting effects that stabilize around 7 to 10 days.[16,26] On average, our subjects' spherical equivalent refractive error significantly reduced between the baseline visit and the two week visit. Similar significant reduction in astigmatic refractive error was seen between the baseline visit and the one month visit. Previous studies report an average of two weeks for reduction of refractive error.[27,28]

After initial adaptation, visual acuity remains stable throughout the process of corneal reshaping.[16] Our subject's visual acuity remained stable throughout the one month study, and no significant difference was found in logMAR visual acuity at each visit. It is beneficial to know there was no significant decline in visual acuity throughout each subject's transition period while wearing Corneal Refractive Therapy.

Both the flat and steep keratometry values were significantly flattened at the two week and one month visit, compared to the baseline visit.[28] Graphical topography provided visual representation of central corneal flattening, with mid-peripheral steepening to be expected from these lenses being worn overnight.

Demographics and Gender Differences

The average age of the subjects in the study was 26.1 ± 2.3 years. This compares with the current literature that documents the majority of contact lens dropout, due to ocular discomfort associated with dryness, occurs near the age of 27 years.[6] It can be concluded that our sample population is representative of the entire population who suffers from contact lens-related eye dryness.

No significant difference was found between males and females regarding CLDEQ scores at the baseline visit. However, the female sub-population trended towards reporting worse CLDEQ symptom scores than men (2.6 ± 0.7, and 1.7 ± 0.8 respectively). Clarity of Vision, a scale of the NEI-RQL, was the only variable that showed a significant difference between males and females at the baseline visit. Previous studies show women are more symptomatic regarding contact lens-related dry eyes[1,5], but our data do not show a statistical difference in symptom results between the two genders.

Limitations

The dropout rate of five subjects out of thirteen can pose clinical relevance when fitting this lens. It is relevant to know some subjects could not adapt to the visual demands of this lens during the first two weeks of the transition. Subjects reported noticing halos or shadows around objects and lights, and were not happy with their vision. This can be of clinical significance when prescribing Corneal Refractive Therapy contact lenses as a means of vision correction. Patients may become uncomfortable with

their vision at night, and potentially feel unsafe while driving, if their doctor does not mention these transition changes. Clinicians should be aware of these adaptation changes and educate their patients on them. With proper instructions and education, patients may become more comfortable with the visual changes and continue wearing the contact lenses until full transition effects are achieved. We hope to provide interest in this field of study for future larger studies. Due to some unforeseen circumstances five out of thirteen subjects resigned from the study prior to completion. Orthokeratology can present its own limitations due to limited range of refractive correction for myopia and astigmatism. Many patients will complain of glare at night caused by halos around lights when the pupil dilates larger than the treatment zone.

Future Research and Improvement

Our study could be improved by comparing two clinicians' data collected for each visit. Examiner differences could potential change current results of the study. An average of each examiner's clinical evaluation of CCLRU scores, tear break up time, and bulbar and limbal redness could prove to more accurately document the true grading scale. Taking an average of the examiner's findings could help reduce human error of one examiner's judgment on clinical findings. Further improvements could be made by incorporating objective clinical testing including tear lab samples, phenol red thread testing, and Schirmer's testing. These additional tests can provide more information regarding the tear film quality aside from tear break up time evaluation.

Future research should perform our study on a larger scale to assess further correlation between overnight Corneal Refractive Therapy wearing and reduction in dry eye symptoms. Our current research data had adequate power for our primary outcome; therefore our statistics regarding CLDEQ scores were truly significant.

A final research study could be performed analyzing the efficacy of our management of dry eyes related to contact lens wear in comparison to standard-of-care methods. Artificial tears have been shown to consistently increase tear break up time and relieve dry eye symptoms. A randomized controlled clinical trial could be performed assessing CLDEQ scores, in which a control group is given artificial tears for dry eye management while wearing soft contact lenses and the study group is switched into Corneal Refractive Therapy contact lenses. In order to determine our study is acceptable as an additional method of contact lens-related dry eye management, we need to confirm that our treatment efficacy is comparable to the standard-of-care.

Chapter 5: Conclusion

Our study showed significant improvements in CLDEQ scores, regarding a reduction of dry eye symptoms over time. Clinical signs of bulbar and limbal redness were shown to improve throughout the one month study. Tear break up time was the only clinical finding that did not show a significant change over time.

We can conclude that transitioning soft contact lens wearers into Corneal Refractive Therapy contact lenses can provide beneficial improvement in symptoms associated with contact lens-related eye dryness.

A randomized controlled clinical trial is necessary in assessing the efficacy of our current method of dry eye management regarding improvements in CLDEQ scores compared to conventional standard-of-care methods, in which a control group is given artificial tears for dry eye management while wearing soft contact lenses and the study group is switched into Corneal Refractive Therapy contact lenses

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Appendix A: CLDEQ Short Form

1. DRYNESS:

a. During a typical day in the past week, **how often** did your eyes feel dry while wearing your contact lenses?

1 Never **(SKIP TO QUESTION 2)**
2 Infrequently
3 Occasionally
4 Frequently
5 Constantly

When your eyes felt dry, **how intense** was the feeling of dryness...

b. Within the first two hours of putting in your lenses?

Not at All Intense				Very Intense
1	2	3	4	5

c. In the middle of the day?

Not at All Intense				Very Intense
1	2	3	4	5

d. At the end of the day?

Not at All Intense				Very Intense
1	2	3	4	5

2. LIGHT SENSITIVITY:

a. During a typical day in the past week, **how often** did your eyes feel unusually sensitive to bright lights while wearing your contact lenses?

1 Never **(SKIP TO QUESTION 3)**
2 Infrequently
3 Occasionally
4 Frequently
5 Constantly

On average, **how intense** was this light sensitivity while wearing your contact lenses?

b. Within the first two hours of putting in your lenses?

Not at All Intense				Very Intense
1	2	3	4	5

c. In the middle of the day?

Not at All Intense				Very Intense
1	2	3	4	5

d. At the end of the day?

Not at All Intense				Very Intense
1	2	3	4	5

3. DO YOU THINK YOU HAVE DRY EYES WHILE WEARING YOUR CONTACT LENSES?

1 Yes
2 No
3 Unsure

Appendix B: NEI-RQL

1. If you had perfect vision without glasses, contact lenses, or any other type of vision correction, how different would your life be?
   - No difference ..... □1
   - Small difference for the better ..... □2
   - Large difference for the better ..... □3
   - I have this already ..... □4

2. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, fixing things around the house, sewing, using hand tools, or working with a computer?
   - No difficulty at all ..... □1
   - A little difficulty ..... □2
   - Moderate difficulty ..... □3
   - A lot of difficulty ..... □4
   - Never try to do these activities because of vision ..... □5
   - Never do these activities for other reasons ..... □6

3. How much difficulty do you have seeing because of changes in the clarity of your vision over the course of the day?
   - Don't have changes in the clarity of my vision ..... □1
   - No difficulty at all ..... □2
   - A little difficulty ..... □3
   - Moderate difficulty ..... □4
   - A lot of difficulty ..... □5

4. How much difficulty do you have judging distances, like walking downstairs or parking a car?
   - No difficulty at all ..... □1
   - A little difficulty ..... □2
   - Moderate difficulty ..... □3
   - A lot of difficulty ..... □4

5. How much difficulty do you have seeing things off to the side, like cars coming out of driveways or side streets or people coming out of doorways?

No difficulty at all ..... □1
A little difficulty ..... □2
Moderate difficulty ..... □3
A lot of difficulty ..... □4

6. How much difficulty do you have getting used to the dark when you move from a lighted area into a dark place, like walking into a dark movie theater?

No difficulty at all ..... □1
A little difficulty ..... □2
Moderate difficulty ..... □3
A lot of difficulty ..... □4

7. How much difficulty do you have reading ordinary print in newspapers?

No difficulty at all ..... □1
A little difficulty ..... □2
Moderate difficulty ..... □3
A lot of difficulty ..... □4
Never try to do this because of vision ..... □5

8. How much difficulty do you have reading the small print in a telephone book, on a medicine bottle, or on legal forms?

No difficulty at all ..... □1
A little difficulty ..... □2
Moderate difficulty ..... □3
A lot of difficulty ..... □4
Never try to do this because of vision ..... □5

9. How much difficulty do you have driving at night?

No difficulty at all ..... □1
A little difficulty ..... □2
Moderate difficulty ..... □3
A lot of difficulty ..... □4
Never drive at night because of vision ..... □5
Never do this for other reasons ..... □6

10. How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic?

No difficulty at all ..... □1
A little difficulty ..... □2
Moderate difficulty ..... □3
A lot of difficulty ..... □4
Never drive in these conditions because of vision ..... □5
Never do this for other reasons ..... □6

11. Because of your eyesight, how much difficulty do you have with your daily activities?
    - No difficulty at all ..... □1
    - A little difficulty ..... □2
    - Moderate difficulty ..... □3
    - A lot of difficulty ..... □4

12. Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like hiking, swimming, aerobics, team sports, or jogging)?
    - No difficulty at all ..... □1
    - A little difficulty ..... □2
    - Moderate difficulty ..... □3
    - A lot of difficulty ..... □4
    - Never try to do these activities because of vision ..... □5
    - Never do these activities for other reasons ..... □6

13. Do you need to wear glasses or bi-focal lenses or use a magnifier when you are reading something brief, like directions, a menu, or a recipe?
    - Yes, all of the time ..... □1
    - Yes, some of the time ..... □2
    - No ..... □3

14. Do you need to wear glasses or bi-focal lenses or use a magnifier when you are reading something long, like a book, a magazine article, or the newspaper?
    - Yes, all of the time ..... □1
    - Yes, some of the time ..... □2
    - No ..... □3

15. When driving at night, do you need to wear glasses or contacts?
    - Yes, all of the time ..... □1
    - Yes, some of the time ..... □2
    - No ..... □3
    - Don't drive at night because of vision ..... □4
    - Don't drive at night for other reasons ..... □5

16. At dusk, when it is just starting to get dark, do you need to wear glasses or contacts for driving?
    - Yes, all of the time ..... □1
    - Yes, some of the time ..... □2
    - No ..... □3
    - Don't drive at dusk because of vision ..... □4
    - Don't drive at dusk for other reasons ..... □5

17. How often when you are around bright lights at night do you see starbursts or halos that bother you or make it difficult to see?
    - All of the time ..... □1
    - Most of the time ..... □2
    - Some of the time ..... □3
    - A little of the time ..... □4
    - None of the time ..... □5

18. How often do you experience pain or discomfort in and around your eyes (for example, burning, itching, or aching)?
    - All of the time ..... □1
    - Most of the time ..... □2
    - Some of the time ..... □3
    - A little of the time ..... □4
    - None of the time ..... □5

19. How much does dryness in your eyes bother you?
    - Don't have dryness ..... □1
    - Not at all ..... □2
    - Very little ..... □3
    - Moderately ..... □4
    - Quite a bit ..... □5
    - A lot ..... □6

20. How often are you bothered by changes in the clarity of your vision over the course of the day?
    - Never ..... □1
    - Rarely ..... □2
    - Occasionally ..... □3
    - Sometimes ..... □4
    - All of the time ..... □5

21. How often do you worry about your eyesight or vision?
    - Never ..... □1
    - Rarely ..... □2
    - Occasionally ..... □3
    - Sometimes ..... □4
    - All of the time ..... □5

22. How often do you notice or think about your eyesight or vision?

Never ..... □1
Rarely ..... □2
Occasionally ..... □3
Sometimes ..... □4
All of the time ..... □5

23. At this time, how clear is your vision using the correction you normally use, including glasses, contact lenses, a magnifier, surgery, or nothing at all?

Perfectly clear ..... □1
Pretty clear ..... □2
Somewhat clear ..... □3
Not clear at all ..... □4

24. How much pain or discomfort do you have in and around your eyes (for example, burning, itching, or aching)?

None ..... □1
Mild ..... □2
Moderate ..... □3
Severe ..... □4
Very severe ..... □5

25. How often do you have headaches that you think are related to your vision or vision correction?

Never ..... □1
Rarely ..... □2
Occasionally ..... □3
Sometimes ..... □4
All of the time ..... □5

26. How satisfied are you with the glasses, contact lenses, magnifier, or other type of correction (including surgery) you have?

Completely satisfied ..... □1
Very satisfied ..... □2
Somewhat satisfied ..... □3
Somewhat dissatisfied ..... □4
Very dissatisfied ..... □5
Completely dissatisfied ..... □6

27. In terms of your appearance, how satisfied are you with the glasses, contact lenses, magnifier, or other type of correction (including surgery) you have?
    - Completely satisfied ..... □1
    - Very satisfied ..... □2
    - Somewhat satisfied ..... □3
    - Somewhat dissatisfied ..... □4
    - Very dissatisfied..... □5
    - Completely dissatisfied ..... □6

28. If you had perfect vision without glasses, contacts, or any other type of vision correction, how much do you think your life would change?
    - No change ..... □1
    - Small change for the better ..... □2
    - Large change for the better ..... □3
    - I have this already ..... □4

29. In terms of your appearance, is the type of vision correction you have now the best you have ever had?
    - Yes ..... □1
    - No..... □2

30. In terms of your appearance, is there a type of vision correction that is better than what you have now?
    - Yes ..... □1
    - No..... □2

31. How often did you use a type of correction or treatment that was uncomfortable in the last 4 weeks because it made you look better?
    - All of the time ..... □1
    - Most of the time ..... □2
    - Some of the time ..... □3
    - A little of the time ..... □4
    - None of the time ..... □5

32. How often did you use a type of correction that did not correct your vision as well as another correction would have in the last 4 weeks because it made you look better?
    - All of the time ..... □1
    - Most of the time ..... □2
    - Some of the time ..... □3
    - A little of the time ..... □4
    - None of the time ..... □5

33. Because of your vision, do you take part less than you would like in active sports or other outdoor activities (like hiking, swimming, aerobics, team sports, or jogging)?

Yes. ..... □1
No..... □2

34. Are there any recreational or sports activities that you don't do because of your eyesight or the type of vision correction you have?

Yes, many ..... □1
Yes, a few..... □2
No..... □3

35. Are there daily activities that you would like to do, but don't do because of your vision or the type of vision correction you have?

Yes, many ..... □1
Yes, a few..... □2
No ..... □3

Have you experienced any of the following problems in the last 4 weeks? If yes, how bothersome has it been? Please respond for problems in either or both eyes.

36. Tearing?

a.		If yes, how bothersome has it been? **b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2
		A little ..... □3
		Not at all..... □4

37. Distorted vision?

a.		If yes, how bothersome has it been? **b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2
		A little ..... □3
		Not at all..... □4

38. Glare?

a.		If yes, how bothersome has it been? **b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2
		A little ..... □3
		Not at all..... □4

39. Blurry vision with your eyesight or the type of vision correction you use?

a.		If yes, how bothersome has it been? **b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2

A little ..... □3
Not at all..... □4

If yes, how bothersome has it been?

40. Trouble seeing?

a.		**b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2
		A little ..... □3
		Not at all..... □4

Have you experienced any of the following problems in the last 4 weeks? If yes, how bothersome has it been? Please respond for problems in either or both eyes.

If yes, how bothersome has it been?

41. Itching in or around your eyes?

a.		**b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2
		A little ..... □3
		Not at all..... □4

If yes, how bothersome has it been?

42. Soreness or tiredness in your eyes?

a.		**b.**
Yes .....□1	→	Very..... □1
No.....□2		Somewhat..... □2
		A little ..... □3
		Not at all..... □4