Vision with Spectacles in Keratoconus

Thesis

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in the Graduate School of The Ohio State University

By
Candace Eva DeCock, B.S.
Graduate Program in Vision Science

The Ohio State University
2009

Thesis Committee:
Karla Zadnik, O.D., Ph.D., Advisor
Gilbert Pierce, O.D., Ph.D
Jeffrey J. Walline, O.D., Ph.D
Copyright by
Candace Eva DeCock
2009
Abstract

Purpose: The vision in keratoconus is most often best corrected with rigid gas permeable lenses, and patients with keratoconus often rely on contact lenses as their primary means to clear vision. In cases of lost contact lenses or anterior segment disease that requires the cessation of contact lens wear, these patients are often left without a viable means of vision correction. The purpose of this study is to determine if “back-up” spectacles could provide adequate vision for keratoconus patients in times of contact lens cessation.

Methods: Eleven participants were prescribed spectacles and completed two examinations in this study. High and low contrast Bailey-Lovie visual acuity was measured with the participants’ habitual contact lenses and manifest refraction was performed at examination one. High and low contrast Bailey-Lovie visual acuity was measured with the spectacles prescribed in the study and a repeat manifest refraction was performed at examination two. Slit lamp biomicroscopy, keratometry, and automated topography using the Atlas topographer was also performed at both examinations. Participants wore their contact lenses from morning to 6:00 p.m. and their spectacles from 6:00 p.m. to bedtime on Day 1 and Days 3-6 of the study. Spectacles only were worn on Day 2 of the study. Participants completed a patient log during the study to record their experiences with glasses wear.
Results: High contrast visual acuity for manifest refraction between examination one and examination two dropped an average of 1.8 ± 4.1 letters both eyes together, dropped by an average of 1.0 ± 4.6 letters for the “worse eyes,” and dropped by an average of 2.4 ± 5.7 letters for the “better eyes.” The average number of hours that the glasses were worn was 6.35 ± 3.80 hours for Days 1 and Days 3-6 of the study and 13.94 ± 4.44 hours for Day 2 of the study. Participants rated that vision in the glasses was slightly worse than vision in the contact lenses on average. The most common subjective visual response reported by the participants was Positive Adaptation.

Conclusions: If proper expectations regarding visual performance are put into place by the eye care practitioner prior to spectacle use, keratoconus patients may be successful with “back-up” spectacles in circumstances that require the cessation of contact lenses.
Dedicated to those who helped me accomplish my goals and
to the upcoming arrival that kicked me when I was tired.
Acknowledgments

I would first like to acknowledge my advisor, Dr. Karla Zadnik, who guided me throughout this process and convinced me that I could finish this project despite some unexpected distractions. Her passion for education and the profession are outstanding and contagious.

I owe thanks to Jeff Rohlff and the staff of The Eyewear Gallery at The OSU College of Optometry for assisting me with all the ordering and dispensing of the glasses used in this study. They made one of the most integral parts of this study easy and achievable.

I owe thanks to the technical support staff at The OSU College of Optometry for helping me with materials for recruitment. I would not have been able to complete a design and concept in the timely fashion that they were able to meet.

I would like to thank my husband, Andrew, for being patient with me and supporting me throughout my entire educational career. Without his help, I would not be able to claim many of the accomplishments I have today.
Vita

December 4, 1982………………………Born – Rolla, North Dakota

May 2005………………………………B.S., Psychology, University of North Dakota

June 2009……………………………..Doctor of Optometry, The Ohio State University

Fields of Study

Major Field: Vision Science
# Table of Contents

Abstract ......................................................................................................................... ii
Dedication ...................................................................................................................... iv
Acknowledgments ......................................................................................................... v
Vita ................................................................................................................................. vi
List of Tables.................................................................................................................... ix
List of Figures................................................................................................................... x

Chapter 1. Introduction ..................................................................................................... 1
  1.1 Epidemiology ............................................................................................................. 2
  1.2 Clinical Features ........................................................................................................ 3
  1.3 Histopathology and Etiology .................................................................................... 5
  1.4 Visual Acuity and Refraction ..................................................................................... 7
  1.5 Contact Lenses .......................................................................................................... 9
  1.6 Personality and Quality of Life ............................................................................... 11

Chapter 2. Methods ......................................................................................................... 14
  2.1 Recruitment .............................................................................................................. 14
  2.2 Study Design ............................................................................................................. 14
  2.3 Visual Acuity ............................................................................................................. 17
  2.4 Manifest Refraction .................................................................................................. 17
  2.5 Spectacles ................................................................................................................ 18

Chapter 3. Results .......................................................................................................... 20
  3.1 The Sample .............................................................................................................. 20
  3.2 Examination 1 and Examination 2 ........................................................................ 21
  3.3 “Worse Eye” and “Better Eye” Comparison ............................................................ 24
  3.4 The “Worse Eye” ..................................................................................................... 25
3.5 The “Better Eye” ........................................................................................................27
3.6 Subjective Results .....................................................................................................29
Chapter 4. Discussion ....................................................................................................33
  4.1 The Sample .............................................................................................................33
  4.2 Binocular Visual Acuity ..........................................................................................34
  4.3 Binocular Comparisons .........................................................................................36
  4.4 “Worse Eye” and “Better Eye” Comparisons ......................................................38
  4.5 Subjective Visual Response ....................................................................................41
  4.6 Limitations ............................................................................................................44
  4.7 Conclusions ............................................................................................................45
References .....................................................................................................................47
Appendix A: Tables and Figures ....................................................................................51
Appendix B: Participant Log ..........................................................................................65
List of Tables

Table 1. Baseline Information........................................................................................................52
Table 2. Examination 1 ................................................................................................................53
Table 3. Examination 2 ................................................................................................................54
Table 4. Binocular Comparisons..................................................................................................55
Table 5. “Worse Eye” Examination 1 ........................................................................................56
Table 6. “Worse Eye” Examination 2 ........................................................................................57
Table 7. “Better Eye” Examination 1 ........................................................................................58
Table 8. “Better Eye” Examination 2 ........................................................................................59
Table 9. “Worse Eye” Comparisons ..........................................................................................60
Table 10. “Better Eye” Comparisons ........................................................................................61
Table 11. Total Subjective Visual Responses Reported ...............................................................62
Table 12. Spectacles vs. Contact Lens Vision ..............................................................................63
List of Figures

Figure 1. “Worse Eye” and “Better Eye” Determination ............................................. 64
Chapter 1

Introduction

Keratoconus is a progressive, asymmetric, non-inflammatory ectasia of the cornea. It is characterized by thinning and steepening of the apical cornea. This ectasia can lead to high amounts of myopia and irregular astigmatism that can cause a decrease in vision and best-corrected spectacle acuity (Rabinowitz 1998).

The vision in keratoconus is typically corrected with rigid gas permeable contact lenses. The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study found that 74% of patients had their vision corrected with contact lenses in both eyes (Zadnik et al. 1998). Some patients, however, cannot tolerate contact lenses for an entire day, thus compromising their vision. The CLEK Study found that 10% of patients were unable to wear their contact lenses for leisure activities, and 18% of patients reported that they could not wear their contact lenses to read at night (Zadnik et al. 1998). Another study found that 69% of keratoconic patients were successful with contact lenses verses 95% of normal patients who were successful with contact lenses (Zhou et al. 2003).

In cases of lost contact lenses or anterior segment disease that requires the cessation of contact lens wear (e.g., a corneal abrasion), these patients are often left without a viable means of vision correction. In a retrospective study that evaluated 38 keratoconic patients and 38 normal patients that received care at a contact lens specialty clinic from January 1999 to December 2000, 36 patients with keratoconus experienced 91
complications during contact lens wear compared to 19 non-keratoconic patients who experienced 29 complications. Complications that are not restricted to keratoconic eyes but that were encountered only by the keratoconic group in the study were: stromal edema, mucus accumulation, neovascularization, soiled lens, lens ejection episodes, lens discomfort, lost lenses, and lens binding (Zhou et al. 2003). Complications with lens wear for keratoconic patients may cause them to cease lens wear periodically. The purpose of this study is to determine if “back-up” spectacles could provide adequate vision for keratoconus patients in times of contact lens cessation.

1.1. Epidemiology

Keratoconus, classically, has its onset at puberty and progresses until the third to fourth decade of life. It is most commonly an isolated condition but may coexist with other disorders including Down syndrome, Leber’s congenital amaurosis, and connective tissue disorders. Atopy, eye rubbing, and hard contact lenses have also been reported to be associated with keratoconus (Rabinowitz 1998). A preliminary part of the CLEK Study cited a patient-reported mean age of keratoconus diagnosis as 27.3 +/- 9.5 years. Nearly 90% reported a diagnosis between the ages of 10 and 39 years (Zadnik et al. 1996). Many (53%) reported a history of atopy (Zadnik et al. 1998).

Keratoconus occurs in all ethnic groups with no male or female preponderance (Rabinowitz 1998). By self-report, CLEK Study participants were 68.5% white, 20% African-American, 8.2% Hispanic, and 3.4% other ethnic categories, which approximated the United States population at the time of enrollment in 1995-96 (Szcotka et al. 2001). Men represented 55.9% of the sample (Zadnik et al. 1998). A positive family history varies between 6-8% (Rabinowitz 198) and 13.5% (Szcotka et al. 2001). Kennedy et al.
(1986) found that the overall average incidence of keratoconus was 2 per 100,000 population annually. The age-specific incidence rates were greatest in the younger groups, and incidence rates did not differ significantly by sex. The overall prevalence rate was 54.5 per 100,000 population.

1.2. Clinical Features

Keratoconus is a condition in which the cornea assumes a conical shape as a result of non-inflammatory thinning of the corneal stroma. This thinning induces irregular astigmatism, myopia, and protrusion (Krachmer 1984). Symptoms are highly variable. Early in the disease, there may be no symptoms. In advanced disease, there is significant distortion of vision accompanied by profound vision loss (Rabinowitz 1998).

Biomicroscopic indicators in moderate or advanced disease may include any one or a combination of the following signs: stromal thinning (most commonly inferiorly or inferotemporally), conical protrusion, an iron line partially or completely surrounding the cone (Fleischer’s ring), and fine vertical lines in the deep stroma and Descemet’s membrane (Vogt’s striae). Accompanying signs might include epithelial nebulae, anterior stromal scars, enlarged/more visible corneal nerves, and increased intensity of the corneal endothelial reflex (Rabinowitz 1998). In the pilot CLEK Study, either Vogt’s striae or Fleischer’s rings was observed in 68% of eyes. Vogt’s striae, a Fleischer’s ring, or corneal scarring was observed in 73% of eyes (Zadnik et al. 1996). In the CLEK Study, 56% of patients had Fleischer’s rings in both eyes and 30% of patients had Vogt’s striae in both eyes. Forty-seven percent of patients entered the study with no corneal scarring in either eye (Zadnik et al. 1998).
External signs include Munson’s sign and Rizzuti’s sign. Munson’s sign is a V-shaped deformation of the lower lid produced by the ectatic cornea in down gaze. Rizzuti’s sign is a sharply focused beam of light near the nasal limbus produced by lateral illumination of the cornea (Rabinowitz 1998). Advanced disease may present with corneal hydrops, which is secondary to an acute break in Descemet’s membrane with the sudden onset of visual loss and pain. Slit-lamp examination of hydrops may reveal injected conjunctiva and a diffuse stromal opacity in the cornea (Rabinowitz 1998).

Keratoconus most often manifests with large between-eye differences. A report from the CLEK Study showed a marked asymmetry between the eyes, both in the absolute sense and when compared with normal, myopic contact-lens wearing patients. Between-eye differences were significant for high- and low-contrast visual acuity, anisometropia, and corneal curvature (Zadnik et al. 2002). Furthermore, there is an association between disease asymmetry and severity. As the disease becomes more severe, more marked asymmetry also occurs. This relation is most robust in measures of keratoconus severity like corneal curvature, refractive error, and corneal scarring (Nichols et al. 2004).

The cornea may appear biomicroscopically normal early in the disease process (Rabinowitz 1998). There may be, however, corneal distortion observed on keratometry, irregular astigmatism, and/or scissoring of the retinoscopic reflex (Krachmer 1984). In the CLEK Study, when corneal curvature was assessed by the base curve radius of the flattest contact lens that vaulted the cornea (the First Definite Apical Clearance Lens, FDACL), the mean corneal curvature was 50.94 ± 5.70 D (Zadnik et al. 1998). The CLEK Study developed a classification system for keratoconus based on corneal
curvature in the steep meridian as follows: mild = <45.00 D, moderate = 45-52 D, advanced = >52 D (Zadnik et al. 1998).

A method for detecting early keratoconus is by measuring anterior corneal topography. Topography systems may be a useful tool in the study of the true incidence and natural progression of subclinical keratoconus as well as documenting subclinical cone progression (Maguire & Lowry 1991).

1.3. Histopathology and Etiology

Three primary histopathologic features in keratoconus have been described: thinning of the corneal stroma, breaks in Bowman’s layer, and deposition of iron in the basal layers of the corneal epithelium (Rabinowitz 1998). Scroggs and Poira (1992) observed two histopathologic variants based on the appearance of Bowman's layer and the corneal epithelium. "Typical" keratoconus specimens had multiple breaks in Bowman's layer and central epithelial thinning, whereas "atypical" corneas lacked breaks in Bowman's layer and had less thinning of the central epithelium. Although normal epithelial cells can be found in the periphery of keratoconic corneas, the superficial epithelial cells located at the apex of the cone are elongated and arranged in a whorl-like fashion. The apex of the cone also contains highly reflective structures and fold-like changes in the basal cell layer (Somodi et al.1996). Kenney et al. (1997) found fibrotic areas in keratoconic corneas where, due to a lack of Bowman’s layer, the epithelium was in contact with the stroma.

Apoptosis is a genetically programmed, involutional cell death that is present in the development of multicellular organisms. Kim et al. (1999) found increased keratocyte apoptosis in corneas with keratoconus removed at the time of corneal transplantation.
Specifically, keratocyte apoptosis was present in 60% of keratoconus corneas and only 35% of corneas with stromal dystrophy. It was not detected in any of the normal donor corneas. Keratocyte apoptosis may be triggered by cytokines such as interleukin-1, Fas ligand, and bone morphogenic protein released from the epithelium by injury. Chronic corneal epithelial injury such as eye rubbing, poorly fit contact lenses, and atopic disease may release apoptotic cytokines leading to keratocyte apoptosis.

Another theory, the so-called “Cascade Hypothesis,” suggests that keratoconic corneas have underlying defects in their ability to process reactive oxygen species and undergo oxidative damage. This triggers a series of downstream events that lead to corneal thinning. As a result, keratoconic corneas are deficient in at least two or more critical enzymes (ALDH3, superoxide dismutase, and catalase), both of which function to remove reactive oxygen species and reactive aldehydes. Sources of reactive oxygen species include ultraviolet light, mechanical trauma, and atopy/allergies. Therefore, practitioners may be justified in recommending ultraviolet protection and suggesting artificial tears and/or allergy medications to improve ocular comfort (Kenney & Brown 2003).

Genetics may play a role in the etiology of keratoconus. It has been proposed that keratoconus is autosomal dominant with variable penetrance; however, a mouse model for keratoconus is autosomal recessive and androgen dependent (Kenney & Brown 2003). Keratoconus can be familial or sporadic, involving the central cornea or peripheral cornea. These variations suggest that there are multiple gene defects (Kenney & Brown 2003). Environmental factors such as eye rubbing and hard contact lens wear may cause the progression of the disease in genetically susceptible individuals (Rabinowitz 1998).
Presence or absence of family history, however, is not associated with more severe clinical disease (Szczotka et al. 2008).

Xiaohui et al. (2007) conducted a study that compared the relatives of keratoconus patients to normal controls. They found that unaffected keratoconus relatives have higher Central K (central keratometry) values, I-S values (the amount of steepening of the inferior cornea compared with that of the superior cornea), and KISA values (derived from four indices including the Central K value; the I-S value; and the AST index, which quantifies the degree of the regular corneal astigmatism as well as the skewed radial axis index, an expression of irregular astigmatism occurring in keratoconus) as generated by videokeratography. As a whole, relatives of keratoconus patients did not progress at a statistically significant rate compared to normal controls; however, they identified a high risk group of keratoconus relatives (age < 30 years or CK > 47.2 or I-S > 1.2 or KISA > 60) who progressed to keratoconus at a significantly higher rate than the low risk group of keratoconus relatives. They concluded that genetic factors are important in the etiology of keratoconus in younger patients, and contribute to these high risk subjects progressing to keratoconus at a faster rate than others.

1.4. Visual Acuity and Refraction

Clinicians and keratoconus patients have an interest in the rate and degree of visual acuity changes associated with keratoconus. Patients often complain of visual problems and distortion before visual acuity actually decreases. Keratoconic eyes demonstrate abnormal contrast sensitivity, even with good visual acuity (Mannis et al. 1984). A report from the CLEK Study looked at participants with moderate to advanced keratoconus who were followed for seven years. The average seven-year reduction in
low-contrast visual acuity was twice that measured for high-contrast visual acuity. Small shifts in disease severity were more influential on decreasing the visual quality of an eye with better visual acuity compared to an eye with poorer visual acuity. In addition, the study found that several factors at baseline were associated with a subsequent reduction in high- or low-contrast best corrected visual acuity over the seven-year follow-up. These factors included better visual acuity, steeper corneal curvatures (>50.40 D), Vogt’s striae, and race other than non-Hispanic white (Davis et al. 2006).

Zadnik and Mutti (1987) noted variability in visual acuity of keratoconus patients based on position of the cone. A centrally placed cone impinges upon and often covers the visual axis, and the influence of the irregular cornea is marked. Inferiorly displaced cones are below the visual axis and have less effect on visual acuity in keratoconus patients.

A report of the CLEK Study evaluated visual acuity repeatability in keratoconus. The results suggested that visual acuity does not change very much over the time interval tested, a median time interval of 90 days. The sample included a wide range of disease severity. Due to variable vision reported by keratoconus patients, however, visual acuity may not measure the specific aspect of visual function most important to everyday vision in the real world (Gordon et al. 1998).

As keratoconus progresses, marked fluctuations in visual acuity can occur in moderate to advanced disease (Zadnik & Mutti 1987). This makes subjective refraction difficult due to an indefinite endpoint. In contrast, subjective refraction of normal eyes leads to a consistent endpoint and stable visual acuity. As a result, many practitioners avoid refraction in keratoconus patients and instead aim to refine and optimize the
contact lens correction. The pilot CLEK Study found that 58% of keratoconic eyes were able to achieve better than 20/40 visual acuity and 75% reached better than 20/60 visual acuity with manifest refraction. This assessment, however, does not take into account refractive error stability and findings on the inadequacy of visual acuity as a measure of visual function (Zadnik et al. 1996).

A report from the CLEK Study evaluated refraction repeatability in keratoconus. Results showed that repeatability of subjective refraction in keratoconus patients was good but somewhat worse than that found in nondiseased eyes. Only 36% of the repeat measures of sphere power from subjective refraction fell within 0.50 D of each other, compared with more than 90% in studies of normal eyes. For patients who wore contact lenses, 77.2% of repeat subjective refraction measurements were within 2.00 D for sphere power, whereas 89.1% were within 2.00 D for cylinder power (Davis et al. 1998).

1.5. Contact Lenses

Contact lens discomfort is a common problem among keratoconus patients who wear rigid contact lenses. In fact, poor contact lens fit and flatter contact lens fit increased the risk of penetrating keratoplasty (Gordon et al. 2006). A report from the CLEK Study found that there does not appear to be an association between patient-reported rigid contact lens comfort and increasing disease severity. The apical fitting relationship (flat vs. steep) does not appear to be associated with differences in patient-reported comfort. Minimal peripheral clearance, however, may contribute to decreased rigid contact lens comfort in keratoconus, and it is difficult to obtain adequate peripheral clearance on advanced cases of keratoconus (Edrington et al. 2004).
Eighty-eight percent of the rigid contact lens wearers in the CLEK Study were wearing lenses fitted with apical touch (Edrington 1999). Another study found that four of seven eyes fitted flat developed corneal scarring, while none of the seven eyes in the steep fit group developed corneal scarring after 12 months (Korb et al. 1982). Furthermore, only one of 22 eyes fit with apical clearance developed scarring within 12 months (Gundel et al. 1996). In keratoconus, flatter rigid lens fittings appear to provide slightly better visual acuity. Considering the small magnitude of this visual acuity improvement, however, rigid contact lenses should be fit to maximize patient comfort and minimize apical scarring (Zadnik & Mutti 1987).

A report from the CLEK Study determined that an eye that wears a rigid contact lens for keratoconus has a 62% increase in risk of scarring compared with eyes that did not wear rigid lenses. Furthermore, in contrast with the information presented above, the risk of corneal scarring did not increase with flat versus steep rigid contact lens fit (Zadnik et al. 2005).

The information presented above must be considered in the management of keratoconus due to the risk of corneal scarring. Corneal scarring in keratoconus is significantly associated with decreased high- and low-contrast visual acuity (Zadnik et al. 2000). Factors that are associated with the development of corneal scarring include older age, a steeper cornea, contact lens wear, corneal staining, and Fleischer’s ring (Barr et al. 2000). While many of these factors cannot be controlled by an eye care practitioner, contact lens wear and corneal staining potentially can be adjusted. One possible solution could be the use of adequate “back-up” spectacles in the evening and on weekends if viable vision can be established.
1.6. Personality and Quality of Life

A questionnaire, the National Eye Institute-Visual Function Questionnaire (NEI-VFQ), is a vision-related quality of life instrument designed to assess patients’ perception of visual function and quality of life that has been used for a variety of eye conditions. The domains measured include general health and vision, ocular pain, near and distance activities, driving, color vision, and peripheral vision. The relationship between four components of psychological well-being (social functions, mental health, role difficulties, and dependency) and vision can also be evaluated with the NEI-VFQ (Mangione et al. 2001).

The NEI-VFQ was administered to 1166 CLEK Study patients at their first annual follow-up examination. The CLEK cohort scored lower on all scales compared to a reference group of rigid gas-permeable contact lens wearers of similar age who did not have keratoconus. The large differences in the scales that measure visual function and in the Mental Health and Role Difficulties scales indicate that keratoconus patients perceive a loss of function disproportionate to that reflected by clinical measures such as visual acuity. Additionally, this loss of function may lead to a perceived impairment in the ability to perform social duties (Kymes et al. 2004).

In the CLEK sample, visual acuity worse than 20/40 (6% of the sample) and corneal curvature steeper than 52 D (33% of the sample) were associated with lower scores on the Mental Health, Role Difficulties, and Dependency scales. Corneal curvature (steepening greater than 52 D) was strongly associated with measures related to social responsibilities (Mental Health, Role Difficulties, Dependence, and Driving) but not with measures directly related to vision (Near and Distance activities, Color Vision, and
Peripheral Vision). Changes in corneal curvature, even in the absence of decreased visual acuity, may mark a decline in the ability to perform important activities of everyday life (Kymes et al. 2004).

Furthermore, contact lens wearers had significantly higher scores compared with non-contact lens wearers on all NEI-VFQ scales except Distance Activities, Mental Health, and Dependency, indicating overall better function associated with contact lens wear. NEI-VFQ scale scores were significantly lower for Ocular Pain among the keratoconus patients. This increased pain is not likely attributable to rigid contact lens wear alone but is more likely a combination of rigid contact lens wear and the disease (Kymes et al. 2004).

Another personality evaluation of patients with keratoconus found that keratoconus patients are less conforming and more passive-aggressive, paranoid, and hypomanic. They tended to more disorganized patterns of thinking and scored higher on substance abuse indicators. The influence of keratoconus on personality may be a function of the timing and nature of its onset in the context of the patient's psychosocial development. Because keratoconus typically affects young individuals who have had otherwise healthy lives, the medical environment itself may be stressful and uncomfortable (Mannis et al. 1987).

The Millon Behavioral Health Inventory (MBHI), a standardized questionnaire designed for use with physically ill patients to assess factors relevant to their medical care (Millon et al. 1982), was administered to 153 keratoconus patients, and the results were compared with age-matched norms. The results suggested that keratoconus patients are
less respectful of practitioners, uncooperative, and noncompliant with treatment plans (Giedd et al. 2005).

Due to the above personality traits of keratoconus patients, eye care practitioners may have a negative perception regarding the visual performance and outcomes of visual correction including contact lenses and spectacle correction. For this reason, eye care practitioners may aim to solely provide the best visual acuity outcome for their patients with rigid gas-permeable contact lenses without further discussing the option of “back-up” spectacles in cases of ocular emergency or lost lenses.
Chapter 2

Methods

2.1. Recruitment

Participants were recruited from The Ohio State University College of Optometry Clinics database by identifying patients that carried the ICD-9 code for keratoconus, 367.1. These patients were sent a postcard with a brief description of the study and an e-mail address and phone number to contact. Postcards were sent out in alphabetical order of last name in order to avoid discrimination of race, age, or sex. Postcards were not sent out to addresses outside Ohio due to the time requirements of the study, i.e., two visits within 2-4 weeks.

Potential participants were screened over the telephone or by e-mail to ensure that they met entry criteria. In order to be included in the study, participants had to be current rigid gas permeable contact lens wearers. They also had to be at least 18 years old by their initial visit. Exclusion criteria included a corneal transplant in either eye or non-keratoconic ocular disease in both eyes including cataract, intraocular lens implant, macular disease, or optic nerve disease other than glaucoma. Pregnant women were not included in the study due to the variable vision that may be caused by pregnancy. Participants that met entry criteria were scheduled for an initial visit.

2.2. Study Design
Participants in this study had two examinations. The first examination was scheduled at a convenient time for the participant. If the participant qualified for the study, as discussed below, participants chose a spectacle frame from The Ohio State University Eyewear Gallery to be used in the study. Participants were notified by phone when the finished spectacles came in from the manufacturer. Spectacles were either picked up by or mailed to the participant. After receiving the spectacles, participants scheduled an appointment for their second examination. The second examination occurred on the seventh day of spectacle use. Participants were told to wear their contact lenses from morning to 6:00 p.m. and their spectacles in the evening from 6:00 p.m. to bed time on Day 1 and Days 3-6 of the study. They were told to wear spectacles only on Day 2 of the study. Participants came to the second examination on Day 7 of the study wearing their spectacles. The second examination was performed on a Saturday, Day 7 of the study. Therefore, Day 1 of the study started on a Saturday. Day 2 of the study was a Sunday so that the spectacles prescribed in the study could be worn for that entire day. Days 3-6 of the study represent Monday through Friday.

At the first examination, informed consent was obtained from each subject as approved by the Biomedical Sciences Institutional Review Board at The Ohio State University. Participants were assigned a random study identification number. The examiner then obtained basic demographic information including gender, race, and date of birth and a short patient history including contact lens and spectacle use, contact lens comfort, and leisure and work activities (see Appendix). Visual acuities were recorded monocularly and binocularly with the participants’ habitual contact lens correction. Contact lenses were then removed, and a manifest refraction was performed. Participants
had to be correctable to 20/40 or better in at least one eye in order to be included in the study. Slit lamp biomicroscopy, manual keratometry, and corneal topography using an Atlas topographer were performed. Participants were then allowed to choose a frame from The Ohio State University Eyewear Gallery to use for spectacles. At the end of the first examination, participants were given a participant log (see Appendix) to fill out during the week of spectacle use to log their experiences with spectacles versus contact lenses.

The participant log required the participants to record what time their habitual contact lenses came off in the evening and what time they went to bed for day 1 and days 3-7 of the study. For day 2 of the study, the participants were not to wear their contact lenses and wear the glasses prescribed in the study only. Therefore, for day 2, the participants recorded the time they woke up in the morning and the time they went to bed.

The participant log also required each participant to record visual experiences they had with their glasses for each day of the study. These experiences could include the ways the eyes felt with glasses wear, tasks that were more or less difficult with the glasses as compared to contact lens wear, or any other experience that was or was not expected with glasses wear. The visual experiences were recorded on the participant log in the participants’ own words.

The participant log also required each participant to compare their vision in their contact lenses to their vision in the prescribed glasses. The comparison was based on a 1-5 point scale. The participants had to decide if the vision in their glasses was: 1=Much
worse than with contact lenses, 2=Slightly worse than with contact lenses, 3=The same as with contact lenses, 4=Slightly better than with contact lenses, 5=Much better than with contact lenses.

Participants wore their study-prescribed spectacles to the second examination. Another short history involving contact lens and spectacle use during the study was obtained. Visual acuities were measured both monocularly and binocularly while the patient wore the spectacles from the study. A manifest refraction was performed as well as slit lamp biomicroscopy, manual keratometry, and corneal topography using an Atlas topographer. The patient log was collected from the participants. Tables 1-12 attached summarize the data collected at each examination.

2.3. Visual Acuity

Visual acuity was measured using Bailey-Lovie high and low contrast charts (Bailey & Lovie 1976) at a distance of 6 meters. Near acuities were taken at 40 centimeters using a near Snellen acuity chart. At the first examination, high and low contrast distance visual acuities were measured with the participants’ habitual contact lenses monocularly for the right and left eyes and binocularly. Near visual acuities were also measured monocularly and binocularly with contact lenses and additional reading correction if required by the patient. Distance and near visual acuities were measured in the same fashion at the second examination using the spectacles from the study. Four participants required an add power in the spectacles to aid in near vision.

2.4. Manifest Refraction
Manifest refraction was performed following contact lens removal at the first examination. First, retinoscopy was performed with the patient behind the phoropter. If possible, the manifest refraction was performed using the phoropter. In certain cases, trial frame refraction had to be performed when the lens power limits of the phoropter were exceeded. Auxiliary cylinder correction was not used in this study. A distance Snellen acuity chart was used during measurement of the manifest refraction. All manifest refractions were demonstrated in a trial frame to determine the final spectacle prescription that was used to order the spectacles used in the study. Final recorded visual acuities were measured with the Bailey-Lovie high contrast chart monocularly and binocularly using the trial frame demonstration (Zadnik et al. 1998).

2.5. Spectacles

The participants were allowed to choose a frame to use for spectacles with guidance from the examiner. Participants were encouraged to choose a frame with a full eyewire and a small eye size. In many cases, the resulting lenses had thick edges and could be quite heavy. The full eyewire was meant to aid in support of the lens and the small eye size was to minimize the edge thickness.

Impact-resistant, polycarbonate lenses were ordered with an anti-reflective coating. The anti-reflective coating minimized glare and reflections that could have confounded the visual experience of the participant. A few cases required the use of a bifocal lens. Flat top-28 lenses were used for these participants. A progressive additional lens was not used due to the induced peripheral astigmatic aberration that can be induced...
by the corridor. The spectacles were paid for by the Fry Fund at The Ohio State University College of Optometry.
Chapter 3

Results

3.1. The Sample

Seventeen participants signed consent forms to be enrolled in the study. One of the seventeen participants was not eligible for the study because he did not meet the visual acuity requirement. Five of the seventeen participants were lost to follow-up. One of these lost subjects had changed her phone number by the time of her follow-up visit. One of the subjects who was lost to follow-up had difficulty adjusting to the glasses and was not interested in completing the study. The reasons for the other losses to follow-up are unknown. Eleven subjects completed the study. Table 1 contains the baseline data for each participant that completed the study. Tables 2 and 3 contain the information from examination one and examination two for the participants who completed the study.

Eleven participants completed the first and second examinations and were dispensed spectacles. The mean age of this sample was $42.4 \pm 13.1$ years (mean ± standard deviation) with a range of 26 years to 61 years. Ten were male (91%). The reported mean age of first rigid contact lens wear was $28.9 \pm 6.3$ years with a range of 17 to 37 years. The reported average contact lens wear per day was $10.20 \pm 5.44$ hours, and the average spectacle lens wear per day was $7.95 \pm 7.34$ hours.
One of the 11 participants underwent radial keratotomy in both eyes prior to his diagnosis of keratoconus. Due to his surgical history, he is clearly an outlier in terms of refraction and keratometry, so his data have been excluded from further analysis.

3.2. Examination 1 and Examination 2

Tables 2 and 3 contain the data from examination one and examination two. Visual acuity measurements are reported as the number of letters read correctly. For examination one, entering visual acuities were taken with the participants’ habitual contact lenses. The mean numbers of letters read correctly for high contrast distance visual acuity (Dist VA) were 41.1 ± 10.7 letters for the right eye, 39.5 ± 5.0 letters for the left eye, and 45.2 ± 5.3 letters for both eyes together. This converts to a Snellen equivalent of approximately 20/25+1 for the right eye, 20/25 for the left eye, and 20/20 for both eyes together. The mean number of letters read correctly for low contrast distance visual acuity (Low VA) were 29.5 ± 12.1 letters for the right eye, 26.9 ± 9.2 letters for the left eye, and 34.2 ± 9.9 letters for both eyes together. Manifest refraction visual acuity (MR VA) was measured through lenses in a trial frame using the high contrast visual acuity chart. This manifest refraction was used to manufacture the glasses used in the study. The numbers of letters read correctly were 37.5 ± 14.6 for the right eye, 32.0 ± 11.8 for the left eye, and 40.8 ± 5.7 for both eyes together. This converts to a Snellen equivalent of approximately 20/32+2 for the right eye, 20/40+2 for the left eye, and 20/25+1 for both eyes together.

For examination two, entering visual acuities were taken with the spectacles prescribed in the study. The mean numbers of letters read correctly for high contrast
distance visual acuity (Dist VA) were 34.8 ± 13.6 letters for the right eye, 31.2 ± 13.0 letters for the left eye, and 39.7 ± 9.0 letters for both eyes together. This converts to a Snellen equivalent of approximately 20/32 for the right eye, 20/40+2 for the left eye, and 20/25 for both eyes together. The number of letters read correctly for low contrast visual acuity (Low VA) were 23.6 ± 11.7 for the right eye, 16.7 ± 11.9 for the left eye, and 26.8 ± 12.0 for both eyes together. Manifest refraction visual acuity (MR VA) was measured through a trial frame using the high contrast chart. The number of letters read correctly were 35.3 ± 13.5 for the right eye, 30.7 ± 12.3 for the left eye, and 39.0 ± 6.6 for both eyes together. This converts to a Snellen equivalent of approximately 20/32 for the right eye, 20/40+1 for the left eye, and 20/25-1 for both eyes together.

For examination one, the mean steep keratometric reading was 47.40 ± 6.00 diopters (D) for the right eye with a range of 43.37 D to 63.12 D. The mean steep keratometric reading for the left eye was 49.10 ± 1.50 D for the left eye with a range of 46.25 D to 50.87 D. For examination two, the mean steep keratometric reading for the right eye was 48.90 ± 7.20 D with a range of 43.37 D to 67.12 D. The mean steep keratometric reading for the left eye was 51.20 ± 5.80 D with a range of 45.50 D to 62.12 D. For some participants, keratometry values could not be determined by the Atlas topographer and, therefore, were not included in the above means and ranges. These missing values can be found in Tables 2 and 3.

For examination one, four values are missing for the left eye and one value is missing for the right eye. For examination two, two values are missing for the left eye and one value is missing for the right eye. Due to these missing data, the means stated
above may be less steep than the true keratometric readings of the participants in the samples because the true corneal topography was too steep and/or irregular to be calculated by the Atlas topographer. In addition, the standard deviation could also be larger if these data were available.

The mean keratometric reading for examination two may be falsely steeper than the mean keratometric reading for examination one for the left eye. Two values could be calculated at examination two that were not determined at examination one. The additional values caused the mean value to be steeper for examination two.

Table 4 contains data that compare the performance of both eyes together. The first comparisons made are between examination one and examination two. The high contrast distance visual acuity (Dist VA1 vs. Dist VA2) decreased by an average of 5.7 ± 6.7 letters (p=0.02, Wilcoxon signed rank test). The low contrast visual acuity (Low VA1 vs. Low VA2) decreased by an average of 7.4 ± 9.7 letters (p = 0.038, Wilcoxon Signed Rank Test). These comparisons are made between examination one with habitual contact lenses and examination two with the spectacles prescribed in the study. This represents a drop of about one line in high contrast Bailey-Lovie acuity and 1.5 lines in low contrast Bailey-Lovie acuity. The manifest refraction high contrast visual acuity (MR VA1 vs. MR VA2) dropped an average of 1.8 ± 4.1 letters between examination one and examination two and does not represent a statistically significant change (p = 0.16).

Another comparison was made between the manifest refraction high contrast visual acuity from the first examination (MR VA1) and the high contrast distance visual acuity from the second examination (Dist VA2). This comparison was made because the
MR VA1 was used to make the glasses that were used to obtain the Dist VA2. The visual acuity decreased by an average of $1.1 \pm 5.9$ letters with a range of five letters better to 12 letters worse. This does not represent a statistically significant change ($p = 0.86$).

A final comparison was made between the high contrast visual acuity from the second examination (Dist VA2) and the manifest refraction high contrast visual acuity from the second examination (MR VA2). This comparison was made to determine if the spectacle prescription remained stable from the glasses made in the study to a second manifest refraction. The visual acuity dropped an average of $0.7 \pm 2.7$ letters with a range from 4 letters better to 5 letters worse. This does not represent a statistically significant change ($p = 0.38$).

3.3. “Worse Eye” and “Better Eye” Comparison

Keratoconus is typically a bilateral but asymmetric corneal disease. Therefore, the participants’ eyes were split into a group of “worse eyes” and a group of “better eyes.” Figure 1 outlines how the “worse eye” was determined. The first factor examined to determine the “worse eye” versus “better eye” was visual acuity because visual performance is a main outcome of this study. It can be argued that a clinically significant difference is considered to be one line of visual acuity. For this study, this represents a difference of 5 letters or more between the two eyes on the Bailey-Lovie visual acuity chart. In examination one, if one eye read $\geq 5$ letters more than the other eye on the high contrast visual acuity chart with habitual contact lenses, that eye was considered to be the “better eye.” The other eye, therefore, was labeled the “worse eye.” This assumes that the
participants’ habitual contact lenses provide the best corrected visual acuity at study entry.

If a difference of 5 letters or more did not exist between the eyes with high contrast visual acuity, the second factor considered was low contrast visual acuity with the habitual contact lenses. As with high contrast visual acuity, a clinically significant change was considered to be 5 or more letters difference between the two eyes. The eye that read $\geq 5$ letters more than the other eye on the low contrast visual acuity chart was considered to be the “better eye” and the fellow eye the “worse eye.” This second factor was only considered if the difference between high contrast visual acuity did not meet the difference requirement between the eyes (i.e., five or more letters).

When a difference of 5 letters or more did not exist between the eyes for low contrast visual acuity, then the steep keratometric measurement was considered. The eye with the steeper keratometric reading as measured at examination one with the Atlas topographer was considered to be the “worse eye” and the fellow eye the “better eye.”

Tables 5 and 6 contain the data for the participants’ “worse eye” for examination one and examination two. Tables 7 and 8 contain the data for the participants’ “better eye” for examination one and examination two.

3.4. The “Worse Eye”

For the “worse eye,” the mean number of letters read correctly for high contrast distance visual acuity (Dist VA) was 36.1 ± 7.8 letters and for low contrast distance visual acuity (Low VA) was 22.3 ± 10.2 letters for examination one with habitual contact
lenses. This converts to an approximate Snellen equivalent of 20/32+1 and 20/63+2 respectively. The mean number of letters read correctly following manifest refraction (MR VA) through a trial frame was 28.9 ± 15.7 letters, an approximate Snellen equivalent of 20/40-1.

For the “worse eye,” the mean number of letters read correctly for Dist VA was 27.5 ± 15.2 letters and for Low VA was 15.8 ± 9.8 letters for examination two with the glasses prescribed in the study. This converts to an approximate Snellen equivalent of 20/40-2 and 20/80+1 respectively. The mean number of letters read correctly for MR VA was 27.9 ± 14.9 letters, an approximate Snellen equivalent of 20/40-2.

The average spherical equivalent based on the manifest refraction was -6.70 ± 6.00 D at examination one and -6.90 ± 6.20 D at examination two for the “worse eye.” The average steeper keratometric reading was 50.50 ± 5.60 D at examination one and 50.50 ± 6.00 D at examination two for the “worse eye.” For certain participants, the Atlas topographer was unable to determine a keratometry value. This missing data can be found in tables 5 and 6.

For examination one, three keratometric values are missing. As described above, this may cause a mean value that is artificially less steep than the true mean value. For examination two, the same three keratometric values are missing. Therefore, comparison between examination one and examination two should not be affected by the missing data.

Table 9 contains data that compare the performance of the participants’ “worse eyes.” The high contrast distance visual acuity (Dist VA1 vs. Dist VA2) decreased by an
average of 8.6 ± 12.5 letters, and the low contrast visual acuity (Low VA1 vs. Low VA2) decreased by an average of 6.5 ± 8.4 letters between examination one with habitual contact lenses and examination two with the spectacles prescribed in the study. This represents a visual acuity decline of about two lines and 1.5 lines respectively. The manifest refraction high contrast visual acuity (MR VA1 vs. MR VA2) decreased by an average of 1.0 ± 4.6 letters between examination one and examination two.

A comparison was made between the manifest refraction high contrast visual acuity from the first examination (MR VA1) and the high contrast distance visual acuity of the second examination (Dist VA2). The visual acuity decreased by an average of 1.4 ± 7.6 letters with a range of 8 letters better to 16 letters worse. Another comparison was made between the high contrast visual acuity from the second examination (Dist VA2) and the manifest refraction high contrast visual acuity from the second examination (MR VA2). The visual acuity improved by an average of 0.4 ± 4.9 letters with a range of 11 letters better to 6 letters worse.

The spherical equivalent changed by an average of -0.20 ± 0.70 D from examination one to examination two which represents a slight myopic change. The steeper keratometric value remained relatively stable with an average change of 0.07 ± 2.00 D.

3.5. The “Better Eye”

For the “better eye,” the mean number of letters read correctly for high contrast distance visual acuity (Dist VA) was 44.5 ± 6.3 letters. The mean number of letters read correctly for low contrast distance visual acuity (Low VA) was 34.1 ± 7.3 letters for
examination one with the habitually worn contact lenses. This converts to an approximate Snellen equivalent of 20/20 and 20/32-1 respectively. The mean number of letters read correctly following manifest refraction (MR VA) through a trial frame was 40.6 ± 6.6 letters, an approximate Snellen equivalent of 20/25.

For the “better eye,” the mean number of letters read correctly for Dist VA was 38.5 ± 7.8 letters and for Low VA was 24.5 ± 12.9 letters for examination two with the glasses prescribed in the study. This converts to an approximate Snellen equivalent of 20/25-1 and 20/50 respectively. The mean number of letters read correctly for MR VA was 38.2 ± 8.1 letters, an approximate Snellen equivalent of 20/25-2.

The average spherical equivalent based on the manifest refraction was -6.80 ± 6.40 D at examination one and -6.50 ± 5.90 D at examination two for the “better eye.” The average steeper keratometric reading was 46.30 ± 1.90 D at examination one and 50.00 ± 7.10 D at examination two for the “better eye.” For certain participants, the Atlas topographer was unable to determine a keratometry value. This missing data can be found in Tables 7 and 8.

For examination one, two keratometric values are missing for the “better eye.” As described previously, this may cause the mean value to be less steep than the true keratometric value mean of the sample. For examination two, no keratometric values are missing. As a result, the difference in mean values between examination one and examination two may be larger than the true comparison.

Table 10 contains data that compare the performance of the participants’ “better eyes.” The high contrast distance visual acuity (Dist VA1 vs. Dist VA2) decreased by an
average of 6.0 ± 7.8 letters and the low contrast visual acuity (Low VA1 vs. Low VA2) decreased by an average of 9.6 ± 8.5 letters between examination one with habitual contact lenses and examination two with the spectacles prescribed in the study. This represents a visual acuity decline of about one line and two lines respectively. The manifest refraction high contrast visual acuity (MR VA1 vs. MR VA2) decreased by an average of 2.4 ± 5.7 letters between examination one and examination two.

The manifest refraction high contrast visual acuity from the first examination (MR VA1) and the high contrast distance visual acuity of the second examination (Dist VA2) were compared. The visual acuity decreased by an average of 2.1 ± 6.1 letters with a range from 6 letters better to 11 letters worse. Another comparison was made between the high contrast visual acuity from the second examination (Dist VA2) and the manifest refraction high contrast visual acuity from the second examination (MR VA2). The visual acuity dropped by an average of 0.3 ± 3.5 letters with a range of 4 letters of improvement to 7 letters of worsening.

The spherical equivalent changed by an average of 0.37 ± 1.0 D from examination one to examination two. The steepest keratometry value became steeper with an average change of 0.50 ± 1.40 D.

3.6. Subjective Results

Each participant was asked to fill out a participant log form for each of the seven days of the study as described in methods. The log form included the time of contact lens wear each day, a comparison of contact lens versus glasses visual performance, and a subjective response from each participant for every day involving their visual experiences.
with glasses use. Table 11 contains the information from the patient log. Because these results are based on subjective visual responses rather than objective visual measures, all 11 participants are included in the following data.

As described in the methods section, each participant was instructed to wear his or her contact lenses during the day and his or her glasses from 6:00 p.m. to bedtime on days 1 and days 3-7 of the study. The average number of hours that the glasses were worn was 6.35 ± 3.80 hours. They were instructed to wear the glasses only on day 2 of the study for a full day from morning to bedtime. The average number of hours that the glasses were worn on day 2 was 13.94 ± 4.44 hours. The average number of hours of glasses wear for each day of the study can be found in Table 11.

For each day of the study, the participants were asked to compare their vision with contact lenses to their vision with glasses prescribed in the study. The data were reported on a 1-5 point scale. The participants had to decide if the vision in their glasses was: 1=Much worse than with contact lenses, 2=Slightly worse than with contact lenses, 3=The same as with contact lenses, 4=Slightly better than with contact lenses, 5=Much better than with contact lenses. The average response for all 7 days of the study was 1.9. The responses for each participant and average response for each day of the study can be found in Table 12.

In order to interpret the subjective responses provided by the participants, 12 categories of common responses were extrapolated from the subjective responses. The total number of responses for all eleven participants for each day can be found in Table
11. For example, blur was subjectively reported a total of 13 times for days 1-7 of the study among the eleven participants.

Incidents of blur were recorded for subjective responses that involved the word blur specifically or for a complaint that involved a decrease in acuity or clarity of distance vision. Incident of tilt/slant was recorded for subjective responses that involved the words tilt or slant specifically or for complaints of angled walls and corners. Incidents of driving problems were recorded for subjective responses that related to driving problems specifically including difficulty reading road signs and experiencing haloes and other disturbances around lights. Incidents of mobility problems were recorded for responses that involved difficulty walking and moving around obstacles. Incidents of reading/near vision problems were recorded for responses that involved difficulty with reading, computer work, and any other near activity. The words dizzy and depth perception had to be used specifically for these two incidents to be recorded.

Incidents of ocular comfort were divided into positive (+) and negative (-) responses. Incidents of positive ocular comfort were recorded for responses that involved a decrease in the feeling of dryness and contact-lens related discomfort or for responses that involved a feeling of rested eyes. Incidents of negative ocular comfort were recorded for responses that involved physical discomfort from the weight and use of glasses.

Incidents of glasses adaptation were also divided into positive (+) and negative (-) responses. Incidents of positive adaptation were recorded for responses that involved an improvement in vision after wearing the glasses for a period of time or for comments of good vision with the glasses. Incidents of negative adaption were recorded for responses
that involved a decrease in vision after wearing the glasses or for comments of poor vision with no improvement.

Incidents of other visual disturbance were recorded for responses that could not be included in the above subjective responses. Examples of other visual disturbances include eyestrain and headache, undefined distortion, and experiencing a “fishbowl effect” when wearing the glasses.
Chapter 4

Discussion

4.1. The Sample

The sample of keratoconus patients in this study does not reflect the gender profile that is typically reported for keratoconus. Keratoconus typically occurs in all ethnic groups with no male or female preponderance (Rabinowitz 1998). A vast majority of participants enrolled in this study were male. An analysis of the CLEK Study determined that women had worse visual acuity than men for monocular and binocular high-contrast distance entrance acuity. In addition, women more frequently reported itching, burning, redness, and dryness than men (Fink et al. 2005).

Females are more likely to report experiencing restrictions on their physical capabilities. Furthermore, those who perceive themselves as more susceptible to illness are consequently more likely to be self-derogating, vulnerable to distress, externally oriented and report a greater number of symptoms (David JL 1995). Due to personal views on their health, as described above, women may have been more reluctant to participate in a study that required them to wear glasses.

Advanced disease is associated with a greater likelihood of Vogt’s striae, Fleischer’s ring, corneal scarring, (Zadnik et al. 1996), steeper corneal curvature, and more toric corneas (Zadnik et al. 1998). In the CLEK Study, the presence of typical
clinical measures that are indicative of more severe disease severity were associated with more rapid deterioration of vision (Davis et al. 2006). Corneal scarring in keratoconus is associated with worse high and low contrast visual acuity (Zadnik et al. 2000). No difference in disease severity as measured by first definite apical clearance lens (FDACL), keratometry, or scarring has been determined between men and women (Fink et al. 2005). Visual performance for both genders, therefore, should be similar. The bias toward male participants should not interfere with the ability to generalize the results to both genders.

The completion rate of this study was low with only 69% (11/16) of participants who were prescribed glasses completing the study. Keratoconus patients may be less respectful of practitioners, uncooperative, and noncompliant with treatment plans (Giedd 2005). One of the participants that was lost to follow-up admitted to having difficulty adjusting to the glasses and was unwilling to complete the study.

4.2. Binocular Visual Acuity

Entering visual acuities for examination one were taken with the participants’ habitual contact lenses. The contact lens-corrected visual acuity was very good with an average high contrast binocular visual acuity of approximately 45 letters (Snellen equivalent of 20/20) and low contrast binocular visual acuity of approximately 34 letters (Snellen equivalent of 20/32). Of the 11 participants who completed the study, 10 (91%) had entrance visual acuities of 20/40 or better in both eyes. This is significantly better than reported by the CLEK Study, which found that 63% of the CLEK sample had entrance visual acuity of 20/40 or better in both eyes (Zadnik et al. 1998). This indicates
that the 11 participants who completed this study may have better visual performance than the general population of keratoconus patients.

Manifest refraction visual acuity was measured through a trial frame with a high contrast Bailey-Lovie visual acuity chart at examination one. The average binocular visual acuity measured was approximately 41 letters (Snellen equivalent of 20/25). In addition, 16 out of 17 participants (94%) who underwent examination one were able to achieve a visual acuity of 20/40 or better in at least one eye with the manifest refraction and were prescribed glasses. Of the 34 total eyes tested in examination one, 21 eyes were able to achieve a visual acuity of 20/40 or better (62%). This is slightly better than previous reports that found 58% of keratoconic eyes were able to achieve better than 20/40 visual acuity (Zadnik et al. 1996). Unfortunately, only 11 of the 16 participants (69%) who were prescribed glasses completed the study.

Two participants, Participant 2 and Participant 11, were “monocular” following the manifest refraction at examination one. “Monocular” participants were not able to read any letters on the Bailey-Lovie visual acuity chart at 6 meters with one eye. Both of these participants were able to achieve recordable visual acuities on the Bailey-Lovie chart at 6 meters in their contact lenses. One small study of 10 subjects found that monocular visual impairment affects binocular performance for reaching and grasping to an extent that it becomes worse than the performance of the good eye alone (Pardhan 2005). Incidentally, these two participants both complained of depth perception problems subjectively and comprise three of the eight total visual responses in Table 11. Furthermore, this study required these participants to switch between contact lenses that
provided seemingly binocular vision to monocular vision in spectacles that may precipitate monocular visual impairment. Surprisingly, both participants reported positive adaptation with spectacle use.

4.3. Binocular Comparisons

A comparison was made between the habitual contact lens-corrected binocular high and low contrast visual acuity from examination one and the binocular high and low contrast visual acuity with the prescribed glasses from examination two. The visual acuity decreased by an average of 5.7 ± 6.7 high contrast letters and 7.4 ± 9.7 low contrast letters with the spectacle correction relative to the habitually worn contact lenses. It could be argued that a clinically significant change is considered to be one line on a visual acuity chart. In the case of this study, a clinically significant change is five letters, the number of letters that make up one line on the Bailey-Lovie high contrast and low contrast visual acuity charts. Therefore, a clinically significant change was observed in both high contrast and low contrast visual acuity when the habitual contact lens correction and the prescribed glasses correction were compared.

Gordon et al. (1998) analyzed visual acuity repeatability in keratoconus using a random sample from CLEK participants in which 75% of the subjects wore rigid contact lenses. The mean absolute difference for high contrast binocular visual acuity was 3.24 ± 3.1 letters and for low contrast binocular visual acuity was 4.71 ± 4.1 letters between baseline and repeat visits. As expected, the difference in visual acuity in this study is higher when comparing habitual contact lenses to the prescribed glasses correction.
The manifest refraction that was performed in examination one was used to manufacture the glasses that were used in the study. Therefore, a comparison was made that compared the binocular manifest refraction visual acuity from examination one to the binocular entering distance visual acuity for examination two. The mean binocular visual acuity remained relatively stable with a decrease of approximately one letter with a wide range of visual acuity change that can be found in Table 4. This is similar to the mean difference of 0.38 ± 10.9 letters in a report that evaluated repeated subjective refraction (Davis et al. 1998).

Two participants, participants 4 and 5, experienced the largest increase in visual acuity of 5 letters when comparing the binocular manifest refraction visual acuity from examination one to the binocular entering distance visual acuity for examination two. Their years of diagnosis were 1985 and 1999. One participant, participant 10, experienced the largest decline in visual acuity of 12 letters. His year of diagnosis was 1984. Longevity of the disease, therefore, was fairly comparable between the participants who were diagnosed in 1985 and 1984. Keratoconus is a progressive disease but may progress or arrest at any age (Rabinowitz 1998). A retrospective study of videokeratography data found that the yearly rate of change was significant for the spherical component and high order irregular astigmatism (Oshika 2002). Furthermore, the progression of keratoconus is associated with deterioration of visual acuity, which is in turn significantly correlated with increases in corneal higher order irregularity (Suzuki 2007). Interestingly, the two participants that experienced an increase in visual acuity were primarily glasses wearers, while the participant with the largest decline in visual acuity relied on contact lenses as his primary means of vision based on self-reported
contact lens and spectacle wear found in Table 1. Additionally, the manifest refraction resulted in a much more myopic prescription for participant 10, and participant 10’s low contrast visual acuity in the spectacles was much worse compared to participants 4 and 5.

A follow-up manifest refraction was performed at examination two to assess the stability of the manifest refraction performed at examination one. Therefore, the binocular manifest visual acuity from examination two was compared to the entering binocular visual acuity of examination two that was measured with the glasses from the study. A comparison of average binocular visual acuity resulted in relatively stable visual acuity with a mean decrease of approximately one visual acuity letter.

4.4. “Worse Eye” and “Better Eye” Comparison

A common clinical feature of keratoconus includes large between-eye differences in disease symmetry and severity. As the disease becomes more severe, more marked asymmetry in the disease occurs. These differences may manifest in corneal curvature, refractive error, and corneal scarring (Nichols 2004). Visual performance, therefore, is also markedly different between the two eyes of a keratoconic patient. As a result, a keratoconic with disease asymmetry may rely on the less affected eye for most daily visual demands. For this reason, the data in this study have been divided into “worse eye” and “better eye” subsections.

Average manifest refraction visual acuity was approximately 29 letters (Snellen equivalent of 20/40). Of the ten “worse eyes” analyzed in this study, only two eyes (20%) were not correctable to 20/40 or better. The remaining eight participants were able to be corrected to 20/40 or better following manifest refraction of their “worse eyes” at
examination one. The CLEK Study found that 63% of “worse eye” entrance acuities were 20/40 or better (Zadnik et al. 1998).

For examination two, average entering high contrast visual acuity was approximately 28 letters (Snellen equivalent of 20/40), and low contrast visual acuity was approximately 16 letters (Snellen equivalent of 20/80) with the glasses prescribed in the study. The average visual acuity for manifest refraction was approximately 28 letters (Snellen equivalent of 20/40). Of the ten “worse eyes,” two eyes (20%) were not correctable to 20/40 or better on the follow-up manifest refraction, the same two eyes that were not correctable to 20/40 or better at examination one.

Average manifest refraction visual acuity was approximately 41 letters (Snellen equivalent of 20/25). Of the ten “better eyes,” 100% of them were correctable to 20/40 or better as was required by the study criteria. For examination two, average entering high contrast visual acuity was approximately 39 letters (Snellen equivalent of 20/25) and low contrast visual acuity was approximately 25 letters (Snellen equivalent of 20/50).

Of the ten “better eyes,” one eye (10%) of participant 11 was not correctable to 20/40 or better on the follow-up examination. His visual acuity dropped by eight letters from examination one to examination two. The change in acuity for this participant is significantly higher than the mean difference found in a previous report of 0.38 ± 10.9 letters (Davis et al. 1998) although it does fall within the standard deviation. One possible explanation for this decrease in visual acuity may be that, due to decreased contact lens wear, the cornea was allowed to conform to its more natural and irregular state.
The average spherical equivalent as determined by manifest refraction at was -6.70 ± 6.00 D at examination one and -6.90 ± 6.20 D at examination two resulting in a mean difference of -0.20 ± 0.70 D for the “worse eye.” For the “better eye,” the average spherical equivalent was very similar with -6.82 ± 6.40 D for examination one and -6.45 ± 5.90 D for examination two resulting in a mean difference of 0.37 ± 1.0 D. Davis et al. (1998) found a slightly higher spherical equivalent of -7.58 ± 5.59 D at baseline and -7.99 ± 5.93 D at the repeat visit indicating a mean difference of -0.41 ± 2.81 D. The repeatability of manifest refraction found in this study resulted in a similar change with less variability.

The average steeper keratometric reading at examination one for the “worse eye,” was 50.50 ± 5.60 D at examination one and 50.50 ± 6.00 D at examination two. This corresponds to moderate disease severity (Zadnik et al. 1998).

The average steeper keratometric reading for examination one for the “better eye,” was 46.30 ± 1.90 D at examination one and 50.00 ± 7.10 D at examination two. This also corresponds to moderate disease severity (Zadnik et al. 1998). The difference between examination one and examination two may be exaggerated due to missing data as explained in the results section. Eighty-eight percent of patients in the CLEK Study who wore rigid contact lenses at study enrollment had been fitted with or were wearing flat lenses (Edrington et al. 1999). While the fluorescein pattern of the contact lens fit was not evaluated in this study, decreasing contact lens wear may have induced the steepening in keratometric readings. Flatter lenses have been thought to “mold” the keratoconic cornea, exerting pressure on the apex of the cornea and regularizing its shape.
and providing better vision, while steep lenses that vault the cone allow the eye to conform to its most distorted shape and degrade vision through the presence of irregular astigmatism (Zadnik & Mutti 1987). While corneal curvature may have been affected with decreased contact lens wear, visual acuity repeatability was not significantly affected in this study.

4.5. Subjective Visual Response

Clinically, visual acuity in patients with keratoconus fluctuates markedly regardless of lens type or base curve relation to corneal curvature (Zadnik & Mutti 1987). While visual acuity appeared to remain relatively stable between the examination one manifest refraction and the examination two manifest refraction, other factors in keratoconus may affect visual performance. A reduction in contrast sensitivity function before a measurable decrease in visual acuity in eyes with keratoconus has been reported (Mannis et al. 1984). Small shifts in disease are more influential on the visual quality of an eye with better visual acuity compared to an eye with poorer visual acuity (Davis et al. 2006). Zadnik and Mutti demonstrated that centrally placed cones have a greater negative impact on visual acuity compared to inferiorly displaced cones (Zadnik & Mutti 1987.) Irregular corneas like those in keratoconus produce “ghosting” and/or monocular diplopia (Camp et al. 1990).

For the reasons described above, the participants’ common subjective responses have been interpreted into 12 categories that can be found in Table 11. Surprisingly, the most common response for this study was Positive Adaptation. Participants commented on having clear vision through the glasses and/or were able to adapt to the vision through
the glasses within their period of wear. Positive Adaptation was a much more common response with 35 total subjective responses when compared to 7 total Negative Adaptation responses (comments of worsening vision through the glasses or poor vision without improvement). Eye care practitioners, therefore, should be encouraged to offer the option of “back-up” spectacles to their keratoconus patients if proper expectations are put into place involving adaptation to the glasses.

The common response of Positive Adaptation may be due to a form of self-selection. Participants in this study may have enrolled because they felt that glasses would help or could provide adequate vision. The entry criteria in the study required that the participants be able to see 20/40 or better in one eye in spectacles. The vision in the participants in this study, therefore, may be better than the general population of keratoconus patients.

Another comparison that was interpreted from the subjective responses was Positive Ocular Comfort (responses that involved a decrease in the feeling of dryness and contact-lens related discomfort or for responses that involved a feeling of rested eyes) and Negative Ocular Comfort (responses that involved physical discomfort from the weight and use of glasses). Positive Ocular Comfort was a much more common response with 11 total responses when compared to 4 total responses of Negative Ocular Comfort. Therefore, eye care practitioners should be motivated to provide “back-up” spectacles to patients that complain of poor comfort with their contact lenses or dry eyes to provide periodic relief, especially at the end of the day.
Participants in this study were asked to wear their glasses for several hours on a daily basis. A majority of the participants were able to comply with this requirement within a reasonable time frame as can be seen in the average hours of glasses wear in Table 11. This may not be the case if “back-up” spectacles were to be used by the general population of keratoconus patients. Therefore, if eye care practitioners are considering prescribing “back-up” spectacles for keratoconus patients, proper expectations involving adaptation and possible visual experiences should be emphasized.

This study identified common visual experiences reported by keratoconus patients while using “back-up” spectacles. Some common subjective visual responses that may affect “back-up” spectacle adaptation found in this study include Reading/Near Vision Problems, Blur, Depth Perception Problems, Mobility Problems, Dizziness, perception of Tilt/Slant, and Driving Problems. Explanations of these categories can be found in the results section. This study, therefore, provides eye care practitioners with education tools for adaptation when attempting to prescribe “back-up” spectacles. Eye care practitioners should be encouraged by the results of this study due to the most common subjective response of Positive Adaptation and the subjective response of Positive Ocular Comfort.

Additionally, when participants were asked to compare their vision in contact lenses to vision in glasses, as can be seen in Table 12, there is a slight average increase in the response as the week progressed. This suggests that vision in the glasses may have improved as the week of glasses wear progressed. As to be expected, the average response for vision in glasses for all seven days of the study was 1.88 which represents a response of Slightly Worse than Contact Lenses. Eye care practitioners may use this
information to education their patients and to provide proper expectations when comparing vision in glasses to vision in contact lenses.

Contrast sensitivity dropped about 1.5 lines of low contrast visual acuity when habitual contact lenses were compared to glasses prescribed in the study. Keratoconic eyes demonstrate abnormal contrast sensitivity, even with good visual acuity (Mannis et al. 1984). A study evaluating the repeatability of visual acuity found that low contrast monocular visual acuity was the most variable type of acuity analyzed (Gordon et al. 1998). Decreased contrast sensitivity in glasses, therefore, may be a factor that influences visual performance and should be considered by eye care practitioners.

The use of “back-up” spectacles could reduce the amount of daily contact lens wear. A report from the CLEK Study determined that an eye that wears a rigid contact lens for keratoconus has a 62% increase in risk of scarring compared with eyes that did not wear rigid lenses (Zadnik et al. 2005). Factors that are associated with the development of corneal scarring include older age, a steeper cornea, contact lens wear, corneal staining, and Fleischer’s ring (Barr et al. 2000). By decreasing the wear time of contact lenses with the use of “back-up” spectacles, two of these factors, contact lens wear and corneal staining, may be reduced and corneal health may be promoted.

4.6. Limitations

One limitation of this study is the small sample size and poor completion rate of the study. The small sample size does not permit statistical hypothesis testing. The poor completion rate brings into question the visual performance through the glasses for participants that chose not to complete the study.
Secondly, four participants (36%) claimed to use glasses more than contact lenses on a daily basis. These participants may have had an advantage in adjusting to the glasses. The CLEK Study found that most patients’ vision was corrected with contact lenses in both eyes (74%); of these, 64% also used glasses in some capacity. Glasses were used alone in 16.1% (Zadnik et al. 1998).

Another limitation to this study involves the interpretation of the subjective responses. Because participants explained their visual experience in the spectacles in their own words, variability in responses was possible and objectivity could have been affected. In order to optimize the objectivity of the subjective response interpretation, the 12 categories of subjective visual responses were created prior to analysis of the subjective responses and applied to all participants in the same way as described in the results section.

4.7. Conclusions

The participants that completed this study gave the impression of being motivated to achieve acceptable vision in glasses. This may not be the case with all keratoconus patients. Eye care practitioners must evaluate their patients accordingly and assess their expectations with all forms of visual correction. This study does not claim that visual correction through spectacles is equivalent to that through contact lenses. It has demonstrated that high and low contrast visual acuity is decreased through spectacles versus contact lenses. The results of this study did suggest, however, that if the proper expectations regarding visual performance are put into place prior to spectacle use,
keratoconus patients may be successful with “back-up” spectacles in circumstances that require the cessation of contact lens wear.
References


Appendix A: Tables and Figures
### Table 1. Baseline Information

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Gender</th>
<th>Race</th>
<th>Year of Diagnosis</th>
<th>Age 1&lt;sup&gt;st&lt;/sup&gt; rigid CL Use/Day (hours)</th>
<th>Range of CL Use/Day (hours)</th>
<th>Range of Spec Use/Day (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26</td>
<td>F</td>
<td>Caucasian</td>
<td>2007</td>
<td>25 12.5-16</td>
<td></td>
<td>0-4†</td>
</tr>
<tr>
<td>2</td>
<td>44</td>
<td>M</td>
<td>Caucasian</td>
<td>1996</td>
<td>32 12.5-16</td>
<td></td>
<td>0-4†</td>
</tr>
<tr>
<td>3</td>
<td>33</td>
<td>M</td>
<td>African American</td>
<td>2005</td>
<td>32 0-4</td>
<td></td>
<td>8.5-12†</td>
</tr>
<tr>
<td>4</td>
<td>51</td>
<td>M</td>
<td>African American</td>
<td>1985</td>
<td>26 4.5-8</td>
<td></td>
<td>20.5-24†</td>
</tr>
<tr>
<td>5</td>
<td>46</td>
<td>M</td>
<td>Caucasian</td>
<td>1999</td>
<td>37 0-4</td>
<td></td>
<td>12.5-16†</td>
</tr>
<tr>
<td>6</td>
<td>52</td>
<td>M</td>
<td>Caucasian</td>
<td>1983</td>
<td>28 8.5-12</td>
<td></td>
<td>4.5-8†</td>
</tr>
<tr>
<td>7</td>
<td>29</td>
<td>M</td>
<td>Caucasian</td>
<td>2002</td>
<td>25 8.5-12</td>
<td></td>
<td>0-4†</td>
</tr>
<tr>
<td>8</td>
<td>26</td>
<td>M</td>
<td>Caucasian</td>
<td>2004</td>
<td>24 12.5-16</td>
<td></td>
<td>0-4†</td>
</tr>
<tr>
<td>9</td>
<td>37</td>
<td>M</td>
<td>Caucasian</td>
<td>N/A</td>
<td>36 4.5-8</td>
<td></td>
<td>16.5-20†</td>
</tr>
<tr>
<td>10</td>
<td>61</td>
<td>M</td>
<td>Caucasian</td>
<td>1984</td>
<td>36 16.5-20</td>
<td></td>
<td>4.5-8*</td>
</tr>
<tr>
<td>11</td>
<td>61</td>
<td>M</td>
<td>Caucasian</td>
<td>1964</td>
<td>17 12.5-16</td>
<td></td>
<td>0-4*</td>
</tr>
</tbody>
</table>

* Glasses used over CLs †Glasses used without CLs
Table 2. Examination 1

<table>
<thead>
<tr>
<th>Subject</th>
<th>Letters Correct Dist VA*</th>
<th>Letters Correct Low VA*</th>
<th>Manifest Refraction</th>
<th>Letters Correct MR VA</th>
<th>Simulated Keratometry× (Diopters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>51 OD 47 OS 49 OU</td>
<td>38 OD 35 OS 39 OU</td>
<td>-7.00 -8.00 x 058</td>
<td>43 OD 38 OS 38 OU</td>
<td>46.87/41.75 @ 042 OD 49.75/42.12 @ 146 OS</td>
</tr>
<tr>
<td>2</td>
<td>52 OD 35 OS 48 OU</td>
<td>39 OD 13 OS 38 OU</td>
<td>-8.50 sph OD -10.00 -4.00 x 140 OS Add +1.75</td>
<td>49 OD 0 OS 45 OU</td>
<td>43.37/43.00 @ 090 OD No K values OS</td>
</tr>
<tr>
<td>3</td>
<td>36 OD 41 OS 39 OU</td>
<td>15 OD 21 OS 11 OU</td>
<td>+1.00 -4.75 x 078 OD +0.50 -6.00 x 011 OS</td>
<td>35 OD 41 OS 39 OU</td>
<td>63.12/52.87 @ 148 OD No K values OS</td>
</tr>
<tr>
<td>4</td>
<td>33 OD 36 OS 37 OU</td>
<td>33 OD 30 OS 31 OU</td>
<td>-3.25 -1.50 x 049 OD -0.75 -3.00 x 091 OS Add +2.50</td>
<td>32 OD 34 OS 33 OU</td>
<td>46.87/46.00 @ 046 OD 49.00/50.25 @ 100 OS</td>
</tr>
<tr>
<td>5</td>
<td>49 OD 35 OS 49 OU</td>
<td>42 OD 19 OS 44 OU</td>
<td>-4.50 -1.00 x 074 OD -2.00 -4.00 x 075 OS Add +2.50</td>
<td>46 OD 32 OS 45 OU</td>
<td>44.37/43.62 @ 076 OD 48.12/48.00 @ 180 OS</td>
</tr>
<tr>
<td>6</td>
<td>42 OD 38 OS 49 OU</td>
<td>38 OD 35 OS 42 OU</td>
<td>PI -2.75 x 065 OD +1.25 -3.25 x 115 OS Add +2.50</td>
<td>48 OD 33 OS 48 OU</td>
<td>45.75/44.12 @ 074 OD 50.87/44.50 @ 146 OS</td>
</tr>
<tr>
<td>7</td>
<td>49 OD 35 OS 49 OU</td>
<td>33 OD 19 OS 39 OU</td>
<td>-2.00 -1.75 x 140 OD -2.75 -4.00 x 119 OS Add +2.50</td>
<td>44 OD 39 OS 43 OU</td>
<td>47.50/43.62 @ 006 OD 48.84/45.00 @ 162 OS</td>
</tr>
<tr>
<td>8</td>
<td>47 OD 49 OS 51 OU</td>
<td>23 OD 43 OS 39 OU</td>
<td>-3.00 -1.25 x 135 OD -2.50 -0.50 x 073 OS</td>
<td>33 OD 39 OS 43 OU</td>
<td>43.62/40.87 @ 088 OD 46.25/44.62 @ 080 OS</td>
</tr>
<tr>
<td>9</td>
<td>46 OD 40 OS 48 OU</td>
<td>40 OD 30 OS 37 OU</td>
<td>-6.50 -2.50 x 115 OD +5.00 -6.00 x 095 OS</td>
<td>45 OD 34 OS 45 OU</td>
<td>35.87/34.75 @ 032 OD No K values OS</td>
</tr>
<tr>
<td>10</td>
<td>33 OD 39 OS 41 OU</td>
<td>30 OD 29 OS 34 OU</td>
<td>-8.25 -1.75 x 015 OD -7.00 -0.50 x 125 OS Add +2.25</td>
<td>45 OD 32 OS 44 OU</td>
<td>49.12/47.50 @ 068 OD 49.37/46.12 @ 118 OS</td>
</tr>
<tr>
<td>11</td>
<td>19 OD 40 OS 40 OU</td>
<td>4 OD 25 OS 25 OU</td>
<td>-20.00 sph OD -20.00 -6.00 x 114 OS</td>
<td>0 OD 32 OS 30 OU</td>
<td>No K values OD No K values OS</td>
</tr>
<tr>
<td>Subject</td>
<td>Letters Correct Dist VA*</td>
<td>Letters Correct Low VA*</td>
<td>Manifest Refraction</td>
<td>Letters Correct MR VA*</td>
<td>Simulated Keratometry*</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------</td>
<td>-------------------------</td>
<td>---------------------</td>
<td>------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>1</td>
<td>32 OD 33 OS 35 OU</td>
<td>25 OD 15 OS 26 OU</td>
<td>-5.50 -8.25 x 058 OD -6.00 -9.00 x 123 OS</td>
<td>33 OD 30 OS 34 OU</td>
<td>47.87/41.75 @ 052 OD 49.75/41.62 @ 142 OS</td>
</tr>
<tr>
<td>2</td>
<td>43 OD 0 OS 44 OU</td>
<td>24 OD 0 OS 27 OU</td>
<td>-7.50 -0.75 x 060 OD -10.25 -4.25 x 140 OS</td>
<td>43 OD 0 OS 43 OU</td>
<td>43.37/42.12 @ 056 OD No K values OS</td>
</tr>
<tr>
<td>3</td>
<td>43 OD 42 OS 39 OU</td>
<td>22 OD 18 OS 20 OU</td>
<td>+0.75 -5.00 x 078 OD +0.75 -6.00 x 110 OS</td>
<td>37 OD 35 OS 38 OU</td>
<td>67.12/48.62 @ 030 OD 62.12/52.87 @ 140 OS</td>
</tr>
<tr>
<td>4</td>
<td>37 OD 38 OS 38 OU</td>
<td>30 OD 30 OS 31 OU</td>
<td>-3.25 -1.00 x 031 OD -1.50 -2.75 x 095 OS</td>
<td>38 OD 38 OS 39 OU</td>
<td>50.62/48.50 @ 026 OD 46.87/46.25 @ 034 OS</td>
</tr>
<tr>
<td>5</td>
<td>45 OD 36 OS 50 OU</td>
<td>42 OD 23 OS 43 OU</td>
<td>-5.00 sph OD -1.50 -4.00 x 074 OS</td>
<td>49 OD 36 OS 45 OU</td>
<td>44.12/43.62 @ 078 OD 48.37/46.62 @ 180 OS</td>
</tr>
<tr>
<td>6</td>
<td>42 OD 37 OS 47 OU</td>
<td>35 OD 23 OS 33 OU</td>
<td>+0.25 -2.25 x 065 OD +1.75 -4.00 x 125 OS</td>
<td>44 OD 33 OS 45 OU</td>
<td>45.62/44.12 @ 070 OD 50.12/44.37 @ 148 OS</td>
</tr>
<tr>
<td>7</td>
<td>45 OD 27 OS 45 OU</td>
<td>27 OD 14 OS 28 OU</td>
<td>-1.50 -1.50 x 135 OD -2.50 -2.75 x 120 OS</td>
<td>43 OD 38 OS 43 OU</td>
<td>48.25/43.62 @ 006 OD 48.75/44.62 @ 158 OS</td>
</tr>
<tr>
<td>8</td>
<td>32 OD 45 OS 47 OU</td>
<td>13 OD 36 OS 40 OU</td>
<td>-2.50 -1.50 x 075 OD -2.75 -1.50 x 075 OS</td>
<td>32 OD 45 OS 44 OU</td>
<td>44.50/41.12 @ 076 OD 45.50/45.50 @ 090</td>
</tr>
<tr>
<td>9</td>
<td>48 OD 27 OS 50 OU</td>
<td>40 OD 16 OS 40 OU</td>
<td>+6.75 -2.75 x 115 OD +2.00 -3.75 x 032 OS</td>
<td>45 OD 18 OS 45 OU</td>
<td>34.50/33.37 @ 116 OD No K values OS</td>
</tr>
<tr>
<td>10</td>
<td>29 OD 33 OS 32 OU</td>
<td>18 OD 8 OS 20 OU</td>
<td>-9.75 -1.75 x 157 OD -8.50 -0.50 x 030 OS</td>
<td>35 OD 28 OS 35 OU</td>
<td>48.75/47.25 @ 052 OD 49.00/45.75 @ 120 OS</td>
</tr>
<tr>
<td>11</td>
<td>0 OD 21 OS 20 OU</td>
<td>0 OD 0 OS</td>
<td>-20.00 sph OD -18.00 -6.00 x 110 OS</td>
<td>0 OD 24 OS 24 OU</td>
<td>No K values OD 60.12/57.00 @ 130 OS</td>
</tr>
</tbody>
</table>

*Bailey-Lovie Acuity with Glasses  ×From Atlas Topographer
Table 4. Binocular Comparisons

<table>
<thead>
<tr>
<th>Subject</th>
<th>Exam 1 vs Exam 2</th>
<th>Exam 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Letters Correct (^a) Dist VA 1 vs Dist VA 2</td>
<td>Letters Correct (^a) Low VA 1 vs Low VA 2</td>
</tr>
<tr>
<td>1</td>
<td>-14</td>
<td>-13</td>
</tr>
<tr>
<td>2</td>
<td>-4</td>
<td>-11</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>+9</td>
</tr>
<tr>
<td>4</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>+1</td>
<td>-1</td>
</tr>
<tr>
<td>6</td>
<td>-2</td>
<td>-9</td>
</tr>
<tr>
<td>7</td>
<td>-4</td>
<td>-11</td>
</tr>
<tr>
<td>8</td>
<td>-4</td>
<td>+1</td>
</tr>
<tr>
<td>10</td>
<td>-9</td>
<td>-14</td>
</tr>
<tr>
<td>11</td>
<td>-20</td>
<td>-25</td>
</tr>
<tr>
<td>p-value</td>
<td>0.020(*)</td>
<td>0.038(*)</td>
</tr>
</tbody>
</table>

\(^a\) - indicates a decrease in letters read (visual acuity), + indicates an increase in letters read (visual acuity)

\(*\) Indicates statistical significance (p<0.05) via Wilcoxon Signed Ranks Test
<table>
<thead>
<tr>
<th>Subject</th>
<th>Letters Correct Dist VA*</th>
<th>Letters Correct Low VA*</th>
<th>Manifest Refraction</th>
<th>Spherical Equivalent (Diopters)</th>
<th>Letters Correct MR VA*</th>
<th>Simulated Keratometry× (Diopters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 OS</td>
<td>47</td>
<td>35</td>
<td>-6.50 -6.00 x 130</td>
<td>-9.50</td>
<td>38</td>
<td>49.75/42.12 @ 146</td>
</tr>
<tr>
<td>2 OS</td>
<td>35</td>
<td>13</td>
<td>-10.00 -4.00 x 140</td>
<td>-12.00</td>
<td>0</td>
<td>No K values</td>
</tr>
<tr>
<td>3 OD</td>
<td>36</td>
<td>15</td>
<td>+1.00 -4.75 x 078</td>
<td>-1.375</td>
<td>35</td>
<td>63.12/52.87 @ 148</td>
</tr>
<tr>
<td>4 OS</td>
<td>36</td>
<td>30</td>
<td>-0.75 -3.00 x 091</td>
<td>-2.25</td>
<td>34</td>
<td>49.00/50.25 @ 100</td>
</tr>
<tr>
<td>5 OS</td>
<td>35</td>
<td>19</td>
<td>-2.00 -4.00 x 075</td>
<td>-4.00</td>
<td>32</td>
<td>48.12/48.00 @ 180</td>
</tr>
<tr>
<td>6 OS</td>
<td>38</td>
<td>35</td>
<td>+1.25 -3.25 x 115</td>
<td>-0.375</td>
<td>33</td>
<td>50.87/44.50 @ 146</td>
</tr>
<tr>
<td>7 OS</td>
<td>35</td>
<td>19</td>
<td>-2.75 -4.00 x 119</td>
<td>-4.75</td>
<td>39</td>
<td>48.84/45.00 @ 162</td>
</tr>
<tr>
<td>8 OD</td>
<td>47</td>
<td>23</td>
<td>-3.00 -1.25 x 135</td>
<td>-3.625</td>
<td>33</td>
<td>43.62/40.87 @ 088</td>
</tr>
<tr>
<td>9 OS</td>
<td>40</td>
<td>30</td>
<td>+5.00 -6.00 x 095</td>
<td>+2.00</td>
<td>34</td>
<td>No K values</td>
</tr>
<tr>
<td>10 OD</td>
<td>33</td>
<td>30</td>
<td>-8.25 -1.75 x 015</td>
<td>-9.125</td>
<td>45</td>
<td>49.12/47.50 @ 068</td>
</tr>
<tr>
<td>11 OD</td>
<td>19</td>
<td>4</td>
<td>-20.00 sph</td>
<td>-20.00</td>
<td>0</td>
<td>No K values</td>
</tr>
</tbody>
</table>

* Bailey-Lovie Acuity with Contact Lenses  ×From Atlas Topographer
Table 6. “Worse Eye” Examination 2

<table>
<thead>
<tr>
<th>Subject</th>
<th>Letters Correct Dist VA*</th>
<th>Letters Correct Low VA*</th>
<th>Manifest Refraction</th>
<th>Spherical Equivalent (Diopters)</th>
<th>Letters Correct MR VA*</th>
<th>Simulated Keratometry× (Diopters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 OS</td>
<td>33</td>
<td>15</td>
<td>-6.00 -9.00 x 123</td>
<td>-10.50</td>
<td>30</td>
<td>49.75/41.62 @ 142</td>
</tr>
<tr>
<td>2 OS</td>
<td>0</td>
<td>0</td>
<td>-10.25 -4.25 x 140</td>
<td>-12.375</td>
<td>0</td>
<td>No K values</td>
</tr>
<tr>
<td>3 OD</td>
<td>43</td>
<td>22</td>
<td>+0.75 -5.00 x 078</td>
<td>-1.75</td>
<td>37</td>
<td>67.12/48.62 @ 030</td>
</tr>
<tr>
<td>4 OS</td>
<td>38</td>
<td>30</td>
<td>-1.50 -2.75 x 095</td>
<td>-2.875</td>
<td>38</td>
<td>46.87/46.25 @ 034</td>
</tr>
<tr>
<td>5 OS</td>
<td>36</td>
<td>23</td>
<td>-1.50 -4.00 x 074</td>
<td>-3.50</td>
<td>36</td>
<td>48.37/46.62 @ 180</td>
</tr>
<tr>
<td>6 OS</td>
<td>37</td>
<td>23</td>
<td>+1.75 -4.00 x 125</td>
<td>-0.25</td>
<td>33</td>
<td>50.12/44.37 @ 148</td>
</tr>
<tr>
<td>7 OS</td>
<td>27</td>
<td>14</td>
<td>-2.50 -2.75 x 120</td>
<td>-3.875</td>
<td>38</td>
<td>48.75/44.62 @ 158</td>
</tr>
<tr>
<td>8 OD</td>
<td>32</td>
<td>13</td>
<td>-2.50 -1.50 x 075</td>
<td>-3.25</td>
<td>32</td>
<td>44.50/41.12 @ 076</td>
</tr>
<tr>
<td>9 OS</td>
<td>27</td>
<td>16</td>
<td>+2.00 -3.75 x 032</td>
<td>+0.125</td>
<td>18</td>
<td>No K values</td>
</tr>
<tr>
<td>10 OD</td>
<td>29</td>
<td>18</td>
<td>-9.75 -1.75 x 157</td>
<td>-10.625</td>
<td>35</td>
<td>48.75/47.25 @ 052</td>
</tr>
<tr>
<td>11 OD</td>
<td>0</td>
<td>0</td>
<td>-20.00 sph</td>
<td>-20.00</td>
<td>0</td>
<td>No K values</td>
</tr>
</tbody>
</table>

*Bailey-Lovie Acuity with Glasses  †Near Snellen Acuity with Glasses  ×From Atlas Topographer
<table>
<thead>
<tr>
<th>Subject</th>
<th>Letters Correct Dist VA*</th>
<th>Letters Correct Low VA*</th>
<th>Manifest Refraction</th>
<th>Spherical Equivalent (Diopters)</th>
<th>Letters Correct MR VA*</th>
<th>Simulated Keratometry× (Diopters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 OD</td>
<td>51</td>
<td>38</td>
<td>-7.00 -8.00 x 058</td>
<td>-11.00</td>
<td>43</td>
<td>46.87/41.75 @ 042</td>
</tr>
<tr>
<td>2 OD</td>
<td>52</td>
<td>39</td>
<td>-8.50 sph</td>
<td>-8.50</td>
<td>49</td>
<td>43.37/43.00 @ 090</td>
</tr>
<tr>
<td>3 OS</td>
<td>41</td>
<td>21</td>
<td>+0.50 -6.00 x 011</td>
<td>-2.50</td>
<td>41</td>
<td>No K values</td>
</tr>
<tr>
<td>4 OD</td>
<td>33</td>
<td>33</td>
<td>-3.25 -1.50 x 049</td>
<td>-4.00</td>
<td>32</td>
<td>46.87/46.00 @ 046</td>
</tr>
<tr>
<td>5 OD</td>
<td>49</td>
<td>42</td>
<td>-4.50 -1.00 x 074</td>
<td>-5.00</td>
<td>46</td>
<td>44.37/43.62 @ 076</td>
</tr>
<tr>
<td>6 OD</td>
<td>42</td>
<td>38</td>
<td>Pl -2.75 x 065</td>
<td>-1.375</td>
<td>48</td>
<td>45.75/44.12 @ 074</td>
</tr>
<tr>
<td>7 OD</td>
<td>49</td>
<td>33</td>
<td>-2.00 -1.75 x 140</td>
<td>-2.875</td>
<td>44</td>
<td>47.50/43.62 @ 006</td>
</tr>
<tr>
<td>8 OS</td>
<td>49</td>
<td>43</td>
<td>-2.50 -0.50 x 073</td>
<td>-2.75</td>
<td>39</td>
<td>46.25/44.62 @ 080</td>
</tr>
<tr>
<td>9 OD</td>
<td>46</td>
<td>40</td>
<td>+6.50 -2.50 x 115</td>
<td>+5.25</td>
<td>45</td>
<td>35.87/34.75 @ 032</td>
</tr>
<tr>
<td>10 OS</td>
<td>39</td>
<td>29</td>
<td>-7.00 -0.50 x 125</td>
<td>-7.25</td>
<td>32</td>
<td>49.37/46.12 @ 118</td>
</tr>
<tr>
<td>11 OS</td>
<td>40</td>
<td>25</td>
<td>-20.00 -6.00 x 114</td>
<td>-23.00</td>
<td>32</td>
<td>No K values</td>
</tr>
</tbody>
</table>

* Bailey-Lovie Acuity with Contact Lenses  ×From Atlas Topographer
### Table 8. “Better Eye” Examination 2

<table>
<thead>
<tr>
<th>Subject</th>
<th>Letters Correct Dist VA*</th>
<th>Letters Correct Low VA*</th>
<th>Manifest Refraction</th>
<th>Spherical Equivalent (Diopters)</th>
<th>Letters Correct MR VA*</th>
<th>Simulated Keratometry× Diopters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 OD</td>
<td>32</td>
<td>25</td>
<td>-5.50 -8.25 x 058</td>
<td>-9.265</td>
<td>33</td>
<td>47.87/41.75 @ 052</td>
</tr>
<tr>
<td>2 OD</td>
<td>43</td>
<td>24</td>
<td>-7.50 -0.75 x 060</td>
<td>-7.875</td>
<td>43</td>
<td>43.37/42.12 @ 056</td>
</tr>
<tr>
<td>3 OS</td>
<td>42</td>
<td>18</td>
<td>+0.75 -6.00 x 110</td>
<td>-2.25</td>
<td>35</td>
<td>62.12/52.87 @ 140</td>
</tr>
<tr>
<td>4 OD</td>
<td>37</td>
<td>30</td>
<td>-3.25 -1.00 x 031</td>
<td>-3.75</td>
<td>38</td>
<td>50.62/48.50 @ 026</td>
</tr>
<tr>
<td>5 OD</td>
<td>45</td>
<td>42</td>
<td>-5.00 sph</td>
<td>-5.00</td>
<td>49</td>
<td>44.12/43.62 @ 078</td>
</tr>
<tr>
<td>6 OD</td>
<td>42</td>
<td>35</td>
<td>+0.25 -2.25 x 065</td>
<td>-0.875</td>
<td>44</td>
<td>45.62/44.12 @ 070</td>
</tr>
<tr>
<td>7 OD</td>
<td>45</td>
<td>27</td>
<td>-1.50 -1.50 x 135</td>
<td>-2.25</td>
<td>43</td>
<td>48.25/43.62 @ 006</td>
</tr>
<tr>
<td>8 OS</td>
<td>45</td>
<td>36</td>
<td>-2.75 -1.50 x 075</td>
<td>-3.50</td>
<td>45</td>
<td>45.50/45.50 @ 090</td>
</tr>
<tr>
<td>9 OD</td>
<td>48</td>
<td>40</td>
<td>+6.75 -2.75 x 115</td>
<td>+5.375</td>
<td>45</td>
<td>34.50/33.37 @ 116</td>
</tr>
<tr>
<td>10 OS</td>
<td>33</td>
<td>8</td>
<td>-8.50 -0.50 x 030</td>
<td>-8.75</td>
<td>28</td>
<td>49.00/45.75 @ 120</td>
</tr>
<tr>
<td>11 OS</td>
<td>21</td>
<td>0</td>
<td>-18.00 -6.00 x 110</td>
<td>-21.00</td>
<td>24</td>
<td>60.12/57.00 @ 130</td>
</tr>
</tbody>
</table>

*Bailey-Lovie Acuity with Glasses  ×From Atlas Topographer
Table 9. “Worse Eye” Comparisons

<table>
<thead>
<tr>
<th>Subject</th>
<th>Letters Correct (^a) Dist VA 1 vs Dist VA 2</th>
<th>Letters Correct (^a) Low VA 1 vs Low VA 2</th>
<th>Axis Change (^b) (Degrees)</th>
<th>Spherical Equivalent 1 vs Spherical Equivalent 2 (^c)</th>
<th>Letters Correct (^a) MR VA 1 vs MR VA 2</th>
<th>Steep K 1 vs Steep K 2 (^d) (Diopeters)</th>
<th>MR VA 1 vs Dist VA 2 (^a)</th>
<th>Dist VA 2 vs MR VA 2 (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 OS</td>
<td>-14</td>
<td>-20</td>
<td>+7</td>
<td>+0.5</td>
<td>-8</td>
<td>0</td>
<td>-5</td>
<td>-3</td>
</tr>
<tr>
<td>2 OS</td>
<td>-35</td>
<td>-13</td>
<td>0</td>
<td>-0.375</td>
<td>0</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3 OD</td>
<td>+7</td>
<td>+7</td>
<td>0</td>
<td>-0.375</td>
<td>+2</td>
<td>+4</td>
<td>8</td>
<td>-6</td>
</tr>
<tr>
<td>4 OS</td>
<td>+2</td>
<td>0</td>
<td>-4</td>
<td>-0.625</td>
<td>+4</td>
<td>-3.38</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>5 OS</td>
<td>+1</td>
<td>+4</td>
<td>+1</td>
<td>+0.5</td>
<td>+4</td>
<td>+0.25</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>6 OS</td>
<td>-1</td>
<td>-12</td>
<td>-10</td>
<td>+0.125</td>
<td>0</td>
<td>-0.75</td>
<td>4</td>
<td>-4</td>
</tr>
<tr>
<td>7 OS</td>
<td>-8</td>
<td>-5</td>
<td>-1</td>
<td>+0.875</td>
<td>-1</td>
<td>-0.09</td>
<td>-12</td>
<td>+11</td>
</tr>
<tr>
<td>8 OD</td>
<td>-15</td>
<td>-10</td>
<td>+60</td>
<td>+0.375</td>
<td>-1</td>
<td>+0.88</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>10 OD</td>
<td>-4</td>
<td>-12</td>
<td>-142</td>
<td>-1.5</td>
<td>-10</td>
<td>-0.37</td>
<td>-16</td>
<td>+6</td>
</tr>
<tr>
<td>11 OD</td>
<td>-19</td>
<td>-4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

a) \(-\) indicates a decrease in letters read (visual acuity), \(+\) indicates an increase in letters read (visual acuity)
b) \(-\) indicates a shift toward 180 degrees, \(+\) indicates a shift toward 0 degrees
c) \(-\) indicates a myopic shift, \(+\) indicates a hyperopic shift
d) \(-\) indicates a flatter keratometry reading, \(+\) indicates a steeper keratometry reading
Table 10. “Better Eye” Comparisons

<table>
<thead>
<tr>
<th>Subject</th>
<th>Exam 1 vs Exam 2</th>
<th>Exam 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Letters Correct ( ^a ) Dist VA 1 vs Dist VA 2</td>
<td>Letters Correct (^a) Low VA 1 vs Low VA 2</td>
</tr>
<tr>
<td>1 OD</td>
<td>-19</td>
<td>-13</td>
</tr>
<tr>
<td>2 OD</td>
<td>-9</td>
<td>-15</td>
</tr>
<tr>
<td>3 OS</td>
<td>+1</td>
<td>-3</td>
</tr>
<tr>
<td>4 OD</td>
<td>+4</td>
<td>-3</td>
</tr>
<tr>
<td>5 OD</td>
<td>-4</td>
<td>0</td>
</tr>
<tr>
<td>6 OD</td>
<td>0</td>
<td>-3</td>
</tr>
<tr>
<td>7 OD</td>
<td>-4</td>
<td>-6</td>
</tr>
<tr>
<td>8 OS</td>
<td>-4</td>
<td>-7</td>
</tr>
<tr>
<td>10 OS</td>
<td>-6</td>
<td>-21</td>
</tr>
<tr>
<td>11 OS</td>
<td>-19</td>
<td>-25</td>
</tr>
</tbody>
</table>

a) - indicates a decrease in letters read (visual acuity), + indicates an increase in letters read (visual acuity)
b) - indicates a shift toward 180 degrees, + indicates a shift toward 0 degrees
c) - indicates a myopic shift, + indicates a hyperopic shift
d) - indicates a flatter keratometry reading, + indicates a steeper keratometry reading
Table 11. Total Subjective Visual Responses Reported

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
<th>Total Days 1-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blur</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>Tilt/Slant</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Driving Problems</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Ocular Comfort (+)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Ocular Comfort (-)</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Adaptation (+)</td>
<td>4</td>
<td>6</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>35</td>
</tr>
<tr>
<td>Adaptation (-)</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Mobility Problems</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Dizzy</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Reading/Near Vision</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Depth Perception Problems</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Other Visual Disturbance</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
</tbody>
</table>

Average ± Stdev hours of wear time reported*  

<p>| | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.52 ±</td>
<td>13.93 ±</td>
<td>6.81 ±</td>
<td>6.02 ±</td>
<td>6.26 ±</td>
<td>6.45 ±</td>
<td>6.02 ±</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.72</td>
<td>4.44</td>
<td>3.55</td>
<td>2.77</td>
<td>3.99</td>
<td>4.34</td>
<td>4.01</td>
<td></td>
</tr>
</tbody>
</table>

*rounded to nearest quarter hour
Table 12. Glasses vs. Contact Lens Vision

<table>
<thead>
<tr>
<th>Subject</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
<th>Average Response for all 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1.29</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2.00</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2.00</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2.86</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>2.14</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2.00</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1.43</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1.71</td>
</tr>
<tr>
<td>9</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>2.57</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1.71</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1.00</td>
</tr>
<tr>
<td>Average Response</td>
<td>1.73</td>
<td>1.82</td>
<td>1.82</td>
<td>1.82</td>
<td>1.82</td>
<td>2.09</td>
<td>2.09</td>
<td>1.88</td>
</tr>
</tbody>
</table>
Figure 1. “Worse Eye” and “Better Eye” Determination

1. High Contrast Visual Acuity Difference of at Least One Line (≥ 5 letters) with Habitual Contact Lenses

   - Yes
   - "Better Eye" measured ≥ 5 letters better than "Worse Eye"

   - NO

2. Low Contrast Visual Acuity Difference of at Least One Line (≥ 5 letters) with Habitual Contact Lenses

   - Yes
   - "Better Eye" measured ≥ 5 letters better than "Worse Eye"

   - NO

3. Eye with the Steeper Keratometric Reading as Measured at Examination One

   - "Worse Eye"
Appendix B: Participant Log
Vision with Spectacles in Keratoconus
Participant Log and Instructions

Saturday – Wear glasses form 6:00 p.m. to bedtime.
Date:_______________________

Record time took contact lenses off:_______________
Record time went to bed:_______________

Experience with my glasses
on:__________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
___________________________________________________

Complete at bedtime:
Today, my vision in my glasses was:
☐ Much worse than with my contact lenses
☐ Slightly worse than with my contact lenses
☐ The same as with my contact lenses
☐ Slightly better than with my contact lenses
☐ Much better than with my contact lenses

Sunday – Wear glasses all day, do not use contact lenses.
Date:_______________________

Record time woke up this morning:_______________
Record time went to bed:_______________

Experience with my glasses
on:__________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
___________________________________________________

Complete at bedtime:
Today, my vision in my glasses was:
☐ Much worse than with my contact lenses
☐ Slightly worse than with my contact lenses
☐ The same as with my contact lenses
☐ Slightly better than with my contact lenses
☐ Much better than with my contact lenses
Vision with Spectacles in Keratoconus
Participant Log and Instructions

**Monday** – Wear glasses from 6:00 p.m. to bedtime.

**Date:** _____________________

Record time took contact lenses off: ______________
Record time went to bed: ______________

Experience with my glasses on: ______________________________________________________
_______________________________________________________________________________
_______________________________________________________________________________
_______________________________________________________________________________
_______________________________________________________

Complete at bedtime:

Today, my vision in my glasses was:

☐ Much worse than with my contact lenses
☐ Slightly worse than with my contact lenses
☐ The same as with my contact lenses
☐ Slightly better than with my contact lenses
☐ Much better than with my contact lenses

**Tuesday** – Wear glasses from 6:00 p.m. to bedtime.

**Date:** _____________________

Record time took contact lenses off: ______________
Record time went to bed: ______________

Experience with my glasses on: ______________________________________________________
_______________________________________________________________________________
_______________________________________________________________________________
_______________________________________________________________________________
_______________________________________________________

Complete at bedtime:

Today, my vision in my glasses was:

☐ Much worse than with my contact lenses
☐ Slightly worse than with my contact lenses
☐ The same as with my contact lenses
☐ Slightly better than with my contact lenses
☐ Much better than with my contact lenses
Vision with Spectacles in Keratoconus
Participant Log and Instructions

**Wednesday** – Wear glasses from 6:00 p.m. to bedtime.

**Date:**

Record time took contact lenses off: 

Record time went to bed:

Experience with my glasses

on:

Complete at bedtime:

Today, my vision in my glasses was:

- [ ] Much worse than with my contact lenses
- [ ] Slightly worse than with my contact lenses
- [ ] The same as with my contact lenses
- [ ] Slightly better than with my contact lenses
- [ ] Much better than with my contact lenses

**Thursday** – Wear glasses from 6:00 p.m. to bedtime.

**Date:**

Record time took contact lenses off: 

Record time went to bed:

Experience with my glasses

on:

Complete at bedtime:

Today, my vision in my glasses was:

- [ ] Much worse than with my contact lenses
- [ ] Slightly worse than with my contact lenses
- [ ] The same as with my contact lenses
- [ ] Slightly better than with my contact lenses
- [ ] Much better than with my contact lenses
Vision with Spectacles in Keratoconus
Participant Log and Instructions

Friday – Wear glasses form 6:00 p.m. to bedtime.

Date:____________________

Record time took contact lenses off:____________________
Record time went to bed:____________________

Experience with my glasses
on:________________________________________________________________
________________________________________
________________________________________
_____________________________________________________________________
___________________________________________________

Complete at bedtime:

Today, my vision in my glasses was:
□ Much worse than with my contact lenses
□ Slightly worse than with my contact lenses
□ The same as with my contact lenses
□ Slightly better than with my contact lenses
□ Much better than with my contact lenses

Saturday – Day of examination. Please wear glasses to exam.

Date:____________________

Record time took contact lenses off:____________________
Record time went to bed:____________________

Experience with my glasses
on:________________________________________________________________
________________________________________
________________________________________
_____________________________________________________________________
___________________________________________________

Complete at bedtime:

Today, my vision in my glasses was:
□ Much worse than with my contact lenses
□ Slightly worse than with my contact lenses
□ The same as with my contact lenses
□ Slightly better than with my contact lenses
□ Much better than with my contact lenses