Contact Lens Discomfort, Vision Correction Preferences, and Accommodative Treatment in Presbyopic and Non-Presbyopic Contact Lens Wearers

Dissertation

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Abstract

Discomfort is the most cited reason for dissatisfaction with and discontinuation of contact lens wear. Most discomfort is attributed to dry eye-type etiologies, but uncomfortable contact lens wearers commonly show few objective signs of dryness, and treatments aimed at eliminating dryness often fail. Uncomfortable contact lens wearers, however, also report symptoms that are similar to binocular vision and accommodative disorders. Research in our laboratory suggested that uncomfortable wearers have an increased incidence of accommodative insufficiency and led us to hypothesize that contact lens discomfort is influenced by symptoms associated with visual discomfort and accommodative fatigue. The projects described in this dissertation sought to better understand how accommodative decline in presbyopes affects comfort and contact lens discontinuation and how alleviation of accommodative demand in non-presbyopes via a multifocal contact lens affects discomfort and satisfaction with contact lens wear.

Presbyopes, a group with known accommodative insufficiency, are also known for being particularly uncomfortable contact lens wearers. Few studies, however, have specifically addressed presbyopic reasons for contact lens discontinuation. The first experiment in this dissertation describes a survey study that aimed to determine why presbyopes discontinued contact lens wear and how factors like vision and comfort influenced dropout. The results

showed that vision and comfort were equal motivators for contact lens dropout. As well, discontinued contact lens wearers had a worse opinion of their vision compared to those still wearing contact lenses.

The second experiment examined the different opinions non-presbyopes and presbyopes have regarding contact lens correction. This survey study found that, overall, non-presbyopes and presbyopes had similar opinions regarding spectacle and contact lens correction. Factors like gender and refractive error did not influence preference for contact lens correction in either age group, suggesting that presbyopes are as motivated to wear contact lenses as non-presbyopes.

The final study, a randomized crossover clinical trial, aimed to determine how a multifocal contact lens affects comfort in a group of otherwise uncomfortable non-presbyopic (30-40 years) contact lens wearers. Subjects wore a single vision and multifocal lens for two weeks each and reported their comfort symptoms after each wear period. Comfort scores improved with both study lenses. Compared to the multifocal, subjects <35 years-old had better comfort with the single vision lens and preferred the single vision lens for most visual distances. Subjects ≥ 35 years-old showed no significant comfort or preference difference between the single vision and multifocal lenses. These results indicate that multifocal contact lens correction may induce discomfort symptoms in younger non-presbyopic contact lens wearers, but those wearers approaching age 40 years may notice no comfort difference in multifocal and single vision designs.

Overall, the studies described in this dissertation suggest that vision, both satisfaction with vision and visual comfort, influences comfort in contact lens wearers. Eye care providers should consider refractive error correction, presbyopic status, and visual fatigue when treating and managing discomfort in contact lens wearers.

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Field of Study

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Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

Dissatisfaction with contact lens wear, no matter what the cause, leads to decreased or discontinued wear patterns. Most contact lens dissatisfaction and dropout is attributed to contact lens discomfort.[1-6] Discomfort, while often appearing as the ubiquitous cause of contact lens dropout, has proven to be difficult to prevent and treat. Discomfort symptoms are most easily attributed to a poor relationship between the lens and the ocular surface and, therefore, dry-eye-type etiologies are usually blamed for contact lens discomfort.[7-16] The severity of objective signs of dryness, however, rarely correlates with the severity of discomfort symptoms in contact lens wearers.[17-19] This mismatch between subjective symptoms and objective signs makes discomfort treatments difficult to determine and oftentimes ineffective.[20] A patient's most common self-treatment, unfortunately, is to decrease or completely discontinue contact lens wear.[3, 4, 21]

While contact lens discomfort symptoms are similar to dry eye symptoms, they also correlate with symptoms of accommodative insufficiency and binocular vision disorders.[22] In fact, research in our laboratory showed that patients with subjective symptoms of dry eye also had a high prevalence of accommodative insufficiency.[22] This finding led to the hypothesis that contact lens discomfort is influenced by not only dryness, but symptoms associated with visual discomfort and eyestrain associated with accommodative fatigue.

Eyestrain or discomfort associated with accommodative insufficiency, fatigue, and presbyopic decline can affect a wide range of contact lens wearers. Young, pre-presbyopic wearers with accommodative deficiencies and/or binocular vision disorders that are exacerbated by contact lens wear may assume their symptoms are caused by dryness and, after failing to treat the true cause of symptoms, abandon contact lens wear. Presbyopes and emerging presbyopes may have discomfort symptoms caused by accommodative strain that are mislabeled as age-associated dryness. If discomfort treatments are focused on the ocular surface and not accommodative fatigue, these wearers may also discontinue contact lens wear after treating the incorrect cause.

Contact lens modalities designed to treat accommodative insufficiency and presbyopic accommodative decline exist, but data suggests that eye care providers utilize and prescribe these modalities at decisively low rates.[23] This low utilization rate is likely due to a variety of factors including assumptions made by eye care providers about dry eye, age, presbyopic preferences, and the quality of presbyopic correction options.[23, 24] If even a portion of an uncomfortable presbyopic contact lens wearer's symptoms are caused by visual discomfort associated with accommodative decline and accommodative treatment is not used to alleviate that discomfort, these patients could be failing in contact lens wear because of misdiagnosed symptoms. The experiments described in this dissertation sought to determine how presbyopia and visual fatigue affect contact lens discomfort and satisfaction with contact lens wear. Before describing the experiments, the next chapters will describe the topics pertinent to them.

Chapter 2: Contact Lens Discomfort

In 2007, the International Dry Eye Workshop (DEWS) stated that dry eye associated with contact lens wear was a subcategory of evaporative dry eye.[25] DEWS did not specify if the contact lens causes dryness or only exacerbates an already existing sub-clinical condition. It is likely that discomfort associated with contact lens wear was assumed to be caused by dryness because dryness is the most commonly reported contact lens discomfort symptom.[4, 5, 7, 11, 17] Approximately 50% of contact lens wearers report some level of dryness symptoms,[26, 27] and it has been reported that, compared to spectacle wearers and emmetropes, contact lens wearers are more likely to report dryness.[28]

On initial evaluation, contact lens discomfort appears to be quite similar to dry eye or, perhaps, an exacerbation of already existing dry eye. Research in recent years, however, has shown that discomfort associated with contact lens wear is different than dry eye symptoms reported in non-contact lens wearers.[6, 7, 9-11, 29, 30] Contact lens discomfort is a condition that is distinct and separate from already existing dry eye.[6, 9, 31, 32] In 2013, the Tear Film and Ocular Surface Society (TFOS) performed an exhaustive review to define contact lens discomfort and determine what treatments and interventions were most effective.[33] Recognizing that contact lens discomfort is a distinct condition, they suggested that terms like "contact lens dry eye" and “contact lens related dry eye” should not be used when referring to discomfort related to contact lens wear.[33]

Symptomology

Uncomfortable contact lens wearers may report a wide range of ocular and visual symptoms. Dryness, irritation, redness, itch, photophobia, and blurry/changeable vision are symptoms reported by uncomfortable wearers.[3, 7, 9-11, 17, 18, 34-36] Regardless of the symptoms, however, contact lens wearers report symptoms that are more intense and frequent at the end of the day.[7, 9, 17, 29, 35, 37] This increase in end-of-day symptom frequency and intensity is what makes uncomfortable contact lens wearers different from general dry eye patients. As well, discomfort symptoms improve with lens removal.[6, 9, 31, 32]

Dryness is the most commonly reported contact lens discomfort symptom,[4, 7, 11, 17] and contact lens wearers, compared to spectacle wearers and emmetropes, are more likely to report dryness.[28] Contact lens discomfort symptomology, however, does not follow general dry eye trends.[26, 27] General dry eye is known to increase with age and female gender,[28, 38, 39] but it has been reported that discomfort symptoms associated with contact lens wear are not associated with gender.[17] As well, Young et al. found no relationship between age and contact lens discomfort.[17] Some have even reported dryness symptoms that decrease with age in contact lens wearers.[9, 13] This trend may be due to more years of contact lens experience in the older population.[13] It could also be argued that this is due to a survivor effect: comfortable wearers maintain wear over the years, while uncomfortable wearers discontinue lens wear earlier in life. Either way, these trends illustrate that contact lens wear is not just an exacerbation of already existing dry eye.

Definition and Etiology

The TFOS defined contact lens discomfort as, "a condition characterized by episodic or persistent adverse ocular sensations related to contact lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and ocular environment which can lead to decreased wearing time and discontinuation of contact lens wear."[6] Investigations studying how contact lens wear affects the ocular surface have aimed to illustrate how a contact lens may induce discomfort. As suggested by DEWS,[25] pre-lens tear film thinning and evaporation caused by tear disruption has been proposed as a cause of symptoms.[14] It has also been proposed that lens wear can disrupt aqueous secretion by the lacrimal gland.[40] Contact lens properties and fitting relationships like wettability,[13, 30, 41, 42] water content,[14] lens material,[14, 42-44] surface properties,[13, 45]and lens movement/centration[13, 42] have been offered as discomfort causes. Some reports have suggested that a contact lens can increase tear osmolarity by disrupting the tear film, causing dryness symptoms as in general dry eye.[14, 30, 46] Eyelid and contact lens interactions, specifically related to Meibomian gland health[47] and lid wiper epitheliopathy,[46, 48] have been suggested to influence discomfort. As well, inflammatory markers in the tear film have been shown to increase in some contact lens wearers.[49-51] Perhaps recognizing the intimidating myriad of apparent physical ocular surface causes of discomfort, McMonnies suggested that psychiatric and psychological conditions like depression and anxiety can reduce the threshold for perception of discomfort symptoms.[52]

Despite all of these proposed etiologies, it is still difficult to determine discomfort cause, clinically, in most patients. The struggle and confusion surrounding determining symptom etiology is primarily due to the poor correlation between subjective symptoms and objective clinical sign severity. In all forms of ocular dryness, it has been reported that signs and symptoms do not correlate.[18, 53] In contact lens wearers, clinical signs that typically indicate dry eye symptoms do not correlate with discomfort. In many of the suggested etiologies mentioned above, weak or inconclusive relationships were found between contact lens discomfort and the investigated etiology.[40, 42, 46, 51]

Treatment

Discomfort treatment plans are typically based on an assessment of the ocular surface, lens fitting relationships, and lens properties.[20] Once dryness and discomfort caused by systemic, environmental, and other ocular surface factors are eliminated,[20] most eye care providers treat discomfort by changing the contact lens or solution.[54] A survey of eye care providers reported that the most common treatments for contact lens related dry eye were refitting into a different lens (47%), refitting into a more frequent replacement schedule (24%), refitting into a different lens material (23%), prescribing topical lubricants (22%), and changing care solutions (15%).[54]

Data supporting various treatment efficacies have been inconclusive. Some studies advocate changing lens material from hydrogel to silicone hydrogel,[15, 55, 56] others promote the reverse strategy,[5] and some suggest no change in discomfort symptoms with either material.[16, 42, 57] Increased lens replacement frequency has been thought to potentially contribute to improved comfort, but results are conflicted about how replacement frequency affects comfort.[37, 58-60] The TFOS concluded that there is "insufficient and unconvincing evidence" supporting material change or increased replacement frequency as effective contact lens discomfort treatments.[20] Similarly, unconvincing evidence exists to support or refute various contact lens solutions or lubricants as effective discomfort treatments.[61-65]

Regardless of the treatment plan chosen, when clinical signs are lacking, it is difficult to assess treatment efficacy objectively. Treatment plans are often based on symptom assessment alone.[18] This had led to heavy reliance on subjective symptom reporting and the subsequent development of surveys that assess and track change in symptoms over time. Specific to contact lens discomfort, the Contact Lens Dry Eye Questionnaire (CLDEQ)[27, 35] and the abbreviated Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)[10] have been used to assess change in contact lens discomfort after various material changes and treatment interventions. These contact lens surveys differ from more general dry eye symptoms surveys[66] because they ask questions specific to contact lens wear.[18, 67, 68] The CLDEQ-8, for example, includes questions about blurry/changeable vision and coping mechanisms (removing lenses and closing eyes).[10] These questions, while not effective in discriminating symptoms in general dry eye, have been shown to be effective in assessing contact lens discomfort.[10, 67]

Contact Lens Discontinuation

Despite a clinician's best attempts at contact lens discomfort treatment, a patient's most common self-treatment for relief of contact lens discomfort is to remove the contact lenses.[9] It has been estimated that 16-34%[1, 3, 4, 69, 70] of contact lens wearers will discontinue lens wear at some point in their lifetime. While discomfort is not the only reason a person ceases lens wear, discomfort and dryness are the most reported reasons for dropout.[3-5, 9, 70, 71]

A patient who discontinues contact lens wear may not do so permanently. Dumbleton et al. reported that 62% of lapsed wearers resumed lens wear at some time.[1] In a group of discontinued contact lens wearers, Pritchard et al. found that almost half had been refitted at least once in an attempt to alleviate discomfort.[3] In fact, 77% of this sample reported resuming contact lens wear after a period of discontinuation.[3] These studies confirm that contact lens wearers are motivated to achieve comfortable wear. The challenge, for researchers and clinicians, is to determine how this goal can be comfortably achieved.

Chapter 3: Ocular and Visual Discomfort

When signs and symptoms of discomfort do not correlate, causative factors are unclear, and treatment strategies are unsuccessful, it is necessary to consider if contact lens discomfort symptoms are triggered by an unconsidered causative factor. While many symptoms of contact lens discomfort (dryness, watering, burning, scratchiness, etc.) suggest a dry-eye-type etiology, other hallmark contact lens discomfort symptoms (eyestrain, fatigue, blurry/changeable vision) do not immediately suggest a dry eye issue.[6, 22] Considering the symptomology of uncomfortable contact lens wearers, one could argue that the general term “asthenopia” more succinctly describes an uncomfortable lens wearer’s experience.

Asthenopia is a word that can be used to describe any discomfort sensation experienced in or around the eyes.[72] In fact, all of the following terms have been used in conjunction with “asthenopia:” ocular pain, headache, photophobia, diplopia, difficulty changing focus at various distances, burning, irritation, blur, dryness, and itch.[72, 73] This list of symptoms describes sensations that result from quite different etiologies and leads one to assume that a complaint of “discomfort” or “asthenopia” cannot conclusively point toward one distinct cause. Perhaps, then, any disorder that is defined using the word “discomfort” will inevitably suffer from an failure to distinguish a distinct etiology.

Recognizing that asthenopic symptoms can be caused by countless conditions, Sheedy et al. set out to develop an asthenopia classification system.[73] Various asthenopic symptoms were induced by exposing subjects to different ocular environments (astigmatic viewing, dry eyes, flare, flickering lights, changing accommodative targets, etc.) while they read.[73] Subjects read until their ocular comfort was "barely tolerable" and then rated the severity of their asthenopic symptoms.[73] Symptoms were significantly related to their inducing conditions, and these relationships were statistically stronger when symptoms were classified into one of two groups: external and internal symptom factors.[73] External factor symptoms were common to dry eye (burning, redness, dryness, etc.) and internal factor symptoms were associated with symptoms induced my accommodative and vergence demands (eyestrain, eye fatigue, headaches, etc.).[73]

The Sheedy investigation shows that symptoms of eye discomfort can be caused by a disruption of the ocular surface (ocular discomfort) or a strain of the visual system (visual discomfort).[73] While these two groups of symptoms originate from different causes, they may be difficult for a patient and/or clinician to differentiate or separate from one another. Aakre et al. examined symptoms of asthenopia associated with computer use and found that asthenopia associated with computer use could have ocular and visual causes.[74] Prolonged screen viewing can lead to decreased blink rate and tear film disruption, causing ocular discomfort. Long periods of near work, however, can cause visual discomfort associated with accommodative fatigue and eyestrain. Adults in this study completed a survey about ocular symptoms (dryness, burning, etc.) and visual symptoms (blur, eyestrain, etc.) during computer use.[74] Symptoms of visual and ocular discomfort were positively correlated, suggesting that subjects were unable to differentiate the two groups of symptoms from one another.[74]

Considering Sheedy's asthenopia classification system,[73] it is reasonable to assume that visual discomfort can be caused by binocular vision issues and/or accommodative fatigue. Recent studies have illustrated relationships between visual discomfort and accommodative lag. Measuring accommodative response with an autorefractor and using the Conlon Visual Discomfort Survey[75] to assess symptoms, Chase et al. reported that accommodative lag and symptoms of visual discomfort are positively correlated.[69] Tosha et al. recruited groups with high and low visual discomfort and also observed accommodative lag.[76] While the low discomfort group showed a normal accommodative response, the high visual discomfort group had significantly higher amount of accommodative lag.[76] The higher discomfort group also had accommodative lag that increased over time, while the low discomfort group exerted a stable accommodative response.[76] These findings support the idea that visual discomfort symptoms are influenced by accommodative fatigue and/or insufficiency.

In the investigations described above,[69, 76] the Conlon Visual Discomfort Survey[75] was used to evaluate severity of visual discomfort symptoms. This survey was developed to measure symptoms associated with visual discomfort and/or Meares-Irlen Syndrome.[75] Patients reporting visual perceptual distortions and asthenopia, often times associated with near work, have been described as having Meares-Irlen syndrome.[77] It is thought that Meares-Irlen Syndrome, which is associated with dyslexia,[78] is caused by a hyperexcitability of the visual cortex.[79] Treatment strategies for Meares-Irlen patients focus on colored filters and tinted lenses for alleviation of perceptual and discomfort symptoms,[80-82] but investigations have suggested that some patients diagnosed with Meares-Irlen Syndrome actually have symptoms caused by ocular motor issues like vergence and accommodative abnormalities.[79, 83, 84] While the Conlon Visual Discomfort Survey is a validated and reliable tool to assess visual discomfort, the symptoms assessed on the survey are common to both dry eye and binocular vision etiologies. Ocular symptoms like watering, dryness, grittiness redness are assessed alongside visual symptoms like blurred vision, double vision, and skipping lines.[75] This survey, therefore, could be assessing discomfort symptoms associated with dry eye and binocular vision and accommodative anomalies.

Symptom overlap between ocular and visual etiologies is also seen on other commonly used symptom surveys. The Ocular Surface Disease Index (OSDI) is a validated symptom survey used regularly in clinic and research to assess severity and change in dry eye symptoms.[66] The Convergence Insufficiency Symptom Survey (CISS), similarly, is a validated survey used to assess severity and change in symptoms of convergence insufficiency, the most prevalent binocular vision disorder, in children and adults.[85, 86] While these two surveys assess symptoms of disorders with apparently different etiologies, they share questions that are remarkably similar. Table 1 compares similar survey questions on the OSDI and CISS. Recognizing the commonalities between the two surveys, we administered the OSDI and CISS to a group of adults that had been recruited for a larger dry eye study.[22] We found that the symptom scores of the two surveys were, indeed, significantly correlated (Figure 1).[22]

Table 1: *Similar Symptom Questions on the Ocular Surface Disease Index (OSDI) and Convergence Insufficiency Symptom Survey (CISS)*

OSDI Item	CISS Item
Have you experienced *painful or sore eyes* during the last week?	Do your *eyes feel tired* when reading or doing close work? Do your eyes feel *uncomfortable* when reading or doing close work? Do you have *headaches* when reading or doing close work? Do your eyes ever *hurt* when reading or doing close work? Do your eyes ever feel *sore* when reading or doing close work?
Have you experienced *blurred vision* during the last week? Have you experienced *poor vision* during the last week?	Do you notice the words *blurring or coming in and out of focus* when reading or doing close work?
Have problems with your eyes limited you in performing *reading* during the last week? Have problems with your eyes limited you in *working with a computer or bank machine* during the last week?	Every question on the CISS refers to symptoms while *reading* or *doing close work*.

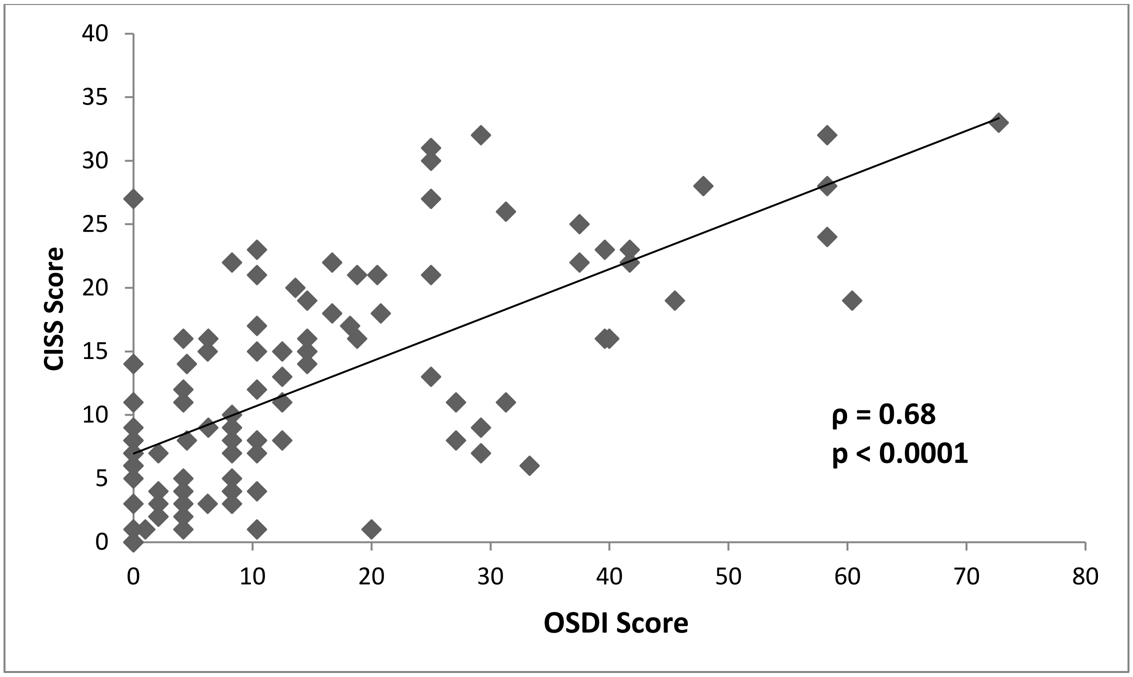

Figure 1: *Scatterplot of the Correlation Between Ocular Surface Disease Index (OSDI) and Convergence Insufficiency Symptom Survey (CISS) Scores* ($\rho = 0.68$, $p < 0.001$)

The studies described in this chapter indicate that ocular discomfort symptoms (those associated with ocular surface abnormalities) and visual discomfort symptoms (those associated with accommodative and vergence functions), while arising from different etiologies, are easily grouped into a single cluster of symptoms. Failure to separate reported symptoms and treat them according to their unique etiology will, of course, result in failed treatments and remaining symptoms of discomfort. Most discomfort treatments focus on the ocular surface,[54] yet most contact lens wearers resort to self-treating their discomfort symptoms with discontinuation of lens wear.[3, 4, 20] It is reasonable, therefore, to hypothesize that symptoms of contact lens discomfort are not caused by an ocular surface issue, but perhaps an internal, binocular vision and/or accommodative cause.

Chapter 4: Optical Etiology and Evidence of Visual Contact Lens Discomfort

Because the term "discomfort" is able to lend itself to so many etiologies, we must consider causes other than ocular surface disruption and dryness when evaluating and treating contact lens discomfort. Symptoms of discomfort can mimic dry eye symptoms, but uncomfortable contact lens wearers also report symptoms that are consistently reported in patients with accommodative and binocular vision disorders.[22] Uncomfortable contact lens wearers and patients with accommodative and binocular vision disorders both report symptoms of ocular discomfort, sore eyes, tired eyes, and blurry/changeable vision.[7, 10, 30, 87-89] Importantly, the described symptoms in both groups are noted to be more intense and frequent at the end of the day.[7, 9, 10, 85] As discussed in the Chapter 2, the symptom feature that sets uncomfortable contact lens wearers apart from general dry eye patients is this increased symptom frequency and intensity at the end of the day. While no distinct dryness etiology has been proposed to explain how contact lenses cause discomfort, an optical etiology can explain how a contact lens introduces increased accommodative and convergence demands and, therefore, induces visual discomfort symptoms in certain wearers.

Basic optical principles show that people with myopic refractive errors must exert more convergence and accommodation when they are corrected with contact lenses compared to spectacles.[90] The opposite effect (increased convergence and accommodative demand while corrected with spectacles versus contact lenses) is seen in hyperopes.[91] Myopic spectacle lenses produce a base-in effect when looking at near, resulting in a decreased convergence demand.[90] Myopic contact lenses eliminate this base-in effect, so a greater convergence effort is required when a myope looks at a near target when wearing contact lenses compared to spectacles.[92]

An increased accommodative demand is also experienced when myopes are corrected with contact lenses. The effective power of a myopic lens increases as it gets closer to the corneal plane. If this effective power increase is not adjusted for when determining the contact lens power, myopic subjects will have to exert more accommodation, compared to spectacle correction, to maintain a clear image at both distance and near.[90] Similar to convergence, the opposite accommodative effect is seen in hyperopes.[90] This change in accommodative demand is significant. Hermann et al. suggested that, "It is possible to precipitate the state of presbyopia by placing a middle-aged myope in contact lenses. Conversely, it is theoretically possible to forestall the state of presbyopia in a hyperope by successfully placing them in contact lenses."[91]

Recognizing the optical demand changes induced by contact lenses, early investigations sought to prove these optical theories. These studies measured vergence and accommodation in myopic[91] and hyperopic[93] eyes and showed that less vergence and accommodation was exerted by contact-lens-corrected hyperopes, while more convergence and accommodation was used in contact-lens-corrected myopes.[91] These initial studies, however, employed methods that may have influenced the accommodative response unintentionally,[91, 93] so more recent investigations have continued to better observe how accommodation and vergence change with different correction types.[92, 94, 95]

In 2006, Hunt et al. tested the theory that myopes converge and accommodate more in contact lenses.[92] As suggested by optical theory, myopes in this study exerted more accommodation and convergence with contact lens correction while hyperopes exhibited less.[92] In a study that examined refractive and binocular vision changes in myopic children wearing spectacles and contact lenses, Fulk et al. reported that near heterophoria changed approximately 4.5 prism diopters in the exophoric direction when corrected with contact lenses.[94] Jimenez et al. also compared accommodative and vergence responses in myopic contact lens and spectacle wear.[95] In this study, higher accommodative lag and more esophoric near phoria was observed in contact lens-corrected myopes.[95] Recognizing the interaction and coupled nature of accommodation and convergence,[96, 97] this result is somewhat unexpected.

We performed a study to determine if uncomfortable myopic contact lens wearers displayed signs of dry eye or accommodative/binocular vision disorders. The purpose of the study was to determine if uncomfortable contact lens wearers had an abnormally high prevalence of binocular vision and/or accommodative disorders. Subjects were tested for dry eye and binocular vision and accommodative abnormalities while wearing their contact lenses. Approximately half (48%) of the sample had significant signs of dry eye, but the same proportion (48%) had signs of a binocular vision and/or accommodative disorders.[22] This prevalence was higher than previously reported binocular vision/accommodative disorder prevalences.[22, 98, 99]

Importantly, insufficient accommodation was quite common in this sample.[22] Accommodative lag ≥ +1.00 D was observed in 48% of the sample. Previous reports of non-contact lens wearers, for comparison, have reported accommodative insufficiency prevalences of 6-9%.[98, 99] It could be suggested, therefore, that the high prevalence of accommodative insufficiency in our sample was caused, at least in part, by the increased accommodative demands induced by myopic contact lens wear. Considering the symptom similarity of contact lens discomfort and binocular vision/accommodative disorders, it can be hypothesized that discomfort associated with contact lens wear may be related to accommodative fatigue and discomfort.

Chapter 5: Presbyopia and Presbyopic Contact Lenses

If contact lens discomfort is, in part, caused by visual discomfort associated with accommodative insufficiency and fatigue, it may be possible to treat this accommodative discomfort with contact lens modalities that aid in accommodation. At this time, the majority of contact lens modalities and adaptations aimed at accommodative assistance are prescribed for presbyopic contact lens wearers.

Presbyopia is the natural, age-related decline in accommodative amplitude.[100] Accommodation, best described by Helmholtz[101] and Fincham,[102, 103] occurs when the crystalline lens changes shape. When the eye is not accommodating, the ciliary muscle is relaxed, causing lens zonules to pull on the lens capsule, resulting in a relative flattening of the front and back lens surfaces. When accommodation is initiated, the ciliary muscle contracts, relaxing zonular tension. This release in zonular tension causes the lens to become more spherical with both the front and back surface steepening and effectively increasing the dioptric power of the eye.[101-103] The mechanism of presbyopia, while varying theories exist,[104, 105] is primarily due to physiological changes in the crystalline lens with age.[24, 106-110] The lens and lens capsule lose elasticity and become thicker over time and are unable to change shape.[4, 24, 100, 107, 108, 110]

This gradual presbyopic loss of accommodative amplitude actually begins in childhood, but symptoms of presbyopia (near blur, fatigue when reading, trouble maintaining focus, etc.) typically present between the ages of 40 and 45 years.[100, 111] The "onset" of presbyopia, objectively, has been described as the point when a person's subjective amplitude of accommodation falls below 3 diopters.[112-115] Although the symptoms of presbyopia often seem to emerge quite suddenly, the progression of decreased accommodative amplitude is linear throughout life.[113] It has been estimated that the accommodative amplitude approaches zero around the ages of 50 and 55 years.[112-114, 116, 117] Notably, presbyopic changes have very little variation between individuals despite differences in gender, lifestyle, and overall health.[115]

Various visual correction options exist for presbyopes. Spectacle wearers can adopt a bifocal spectacle that contains distance and near correction within the same lens. Contact lens wearers can utilize several strategies and have multiple options to address their near vision demands. Most simply, a contact lens wearer can remain in their distance-corrected contact lenses and simply use over-spectacles, powered for their near vision needs, when looking at close targets. Contact lens-specific correction options include monovision or bifocal/multifocal options.

Monovision Contact Lenses

Monovision is a presbyopic correction strategy that corrects one eye for distance vision and the other eye for a specific near distance, inducing anisometropia.[118] When looking at distance, the brain effectively suppresses the near-corrected eye, and vice versa. In theory, this suppression results in binocular acuity that matches the better seeing eye for a particular visual task.[119] For the majority of patients, the "dominant" eye is corrected for distance while the "non-dominant" eye is corrected for near vision.[118]

Monovision is preferred by some prescribers because it provides crisp vision at each corrected distance.[120] There is a perception that this presbyopic modality is simpler and requires less fitting time.[121] As well, unlike multifocal corrections, monovision is not dependent on pupil size or precise centration. The anisometropia induced by this correction type, however, reduces stereoacuity, especially with high add powers.[34, 122-125] Because of this depth perception reduction, monovision is prohibited in certain professions like pilots, professional drivers, and competition sports.[118] Additionally, the two corrected distances typically provide clear images, but visual targets in between those two distances may result in reduced acuity.

Multifocal Contact Lenses

The term "multifocal" contact lens refers to a large range of optical contact lens designs used to treat presbyopic vision.[115, 121] Multifocals are most easily divided into translating and simultaneous image designs. Translating lenses have defined near and distance zones that are fitted to center over the pupil during distance and near viewing. Translating designs are currently only utilized in gas permeable lens materials.[121] Simultaneous image lenses may include lenses with concentric, diffractive, aspheric, or extended depth of focus designs.[126, 127] Simultaneous image multifocals, in general, position distance and near powers over the pupil at the same time. The optical zone that centers over the pupil contains multiple powers that correspond to a range of near and far distances.[115] The lens simultaneously focuses multiple images on the retina and the patient attends to the clearest images based on the visual task.[126] In monovision correction, a patient experiences binocular image degradation and suppresses one eye to alleviate blur. With simultaneous image designs, image degradation occurs monocularly and a patient suppresses the worse image in each eye individually.[128] The intraocular suppression required with simultaneous image designs allows better depth perception and binocularity, theoretically, compared to the interocular suppression required in monovision.

Multifocal contact lenses utilizing simultaneous image optics include diffractive, concentric, aspheric, and extended depth of focus designs.[115, 127] Concentric designs have small annular zones that contain distance and near power.[129] Diffractive designs focus distance images by refraction of light and near images by diffraction.[130] Diffractive designs are not currently commercially available and concentric designs only exist in older, less utilized options.[128] This discussion, therefore, will focus on aspheric simultaneous image multifocal designs which encompass the majority of the soft contact lens market and were utilized in the third study described in this dissertation. Extended depth of focus designs, which utilize relatively new technology, will be discussed after aspheric designs.

The most common simultaneous multifocals available commercially today use aspheric designs. Instead of having near or distance “zones” like a translating or concentric multifocal design, aspheric designs use spherical aberration to increase the depth of focus and “pseudo-accommodate” for the lacking true accommodation in presbyopes.[131-134] When focused at distance and not accommodating, an eye typically has positive spherical aberrations. As the eye accommodates, spherical aberrations become more negative.[131, 135, 136] Aspheric multifocals are designed with center near or center distance power orientations. Center near designs add negative spherical aberrations and center distance designs add positive spherical aberrations to the center of the lens.[133, 134] The change in aberrations results in a power profile that gradually changes from near to distance power or vice versa.[134] This increased depth of focus, therefore, introduces simultaneous distance and near images on the retina.[137]

Center-near designs are most common commercially. Because of miotic pupil changes that occur when accommodation is stimulated[138] and the age-related decrease in pupil size,[139] maximal near vision is achieved when the near correction is located in the middle of the optical zone. Center-distance designs have been suggested to be optimal for early presbyopes and/or presbyopes with high distance vision demands. As well, center distance designs are utilized to prevent progression of myopia in children.[140, 141] Because of this reliance on pupil interaction, centration of the lens and the relationship between the optic zone size and the pupil size are important for a successful visual outcome with aspheric designs.[115, 121, 142] Spherical aberrations can degrade the image on the retina, but this image degradation is thought to be compensated for by the increased depth of focus introduced by the lens design.[143, 144] This image degradation has been reported to cause blur, decreased contrast sensitivity, and glare.[34, 123, 145-149]

Extended depth-of-focus designs use relatively new technology that also manipulates the magnitude and sign of higher order spherical aberrations to increase depth of focus.[127, 150] While traditional aspheric designs have a monotonic, gradually changing power over the pupil, extended depth of focus designs utilize multiple higher order aberration terms to produce a "non-monotonic, non-aspheric, aperiodic, non-diffractive, refractive power profile across the optic zone diameter."[127, 150] The advantage, theoretically, is that these designs will improve presbyopic near and intermediate vision without compromising distance vision as much as previous aspheric designs.[127, 150] These designs are novel to the contact lens market and are being evaluated as options for presbyopic correction and myopia control in pediatric populations.[151-153] At the time of the experiments described in this dissertation, extended depth of focus designs were not readily available commercially.

Comparison of Monovision and Multifocal Contact Lenses

Because single vision, non-multifocal contact lens options were the first commercially available, monovision was the first non-spectacle strategy used to correct presbyopia in contact lens wearers. The introduction of multifocal options has changed how eye care providers treat the visual needs of presbyopic contact lens wearers. Studies using various multifocal designs have compared multifocals to monovision to determine which modality works best. Recognizing the limitations of each correction type, studies comparing monovision to simultaneous image multifocals typically examine visual acuity at distance and near, contrast sensitivity, stereoacuity, glare sensitivity, and patient preferences.[154]

A 2003 investigation refit existing monovision wearers into a multifocal.[155] High-contrast visual acuity was the same for monovision and multifocals at all distances and stereoacuity was better with the multifocal.[155] Subjective ratings for various distances and tasks were better for the multifocal.[155] Richdale et al. also found that high-contrast visual acuity was no different for either correction and stereoacuity is improved with multifocals.[34] An impressive 76% of wearers preferred the multifocal to monovision in this trial.[34] Other trials have similarly reported better stereopsis[123, 148, 156, 157] with multifocals compared to monovision. Visual acuity assessment appears mixed between the two corrections with some studies reporting reduced vision with multifocals only in low-light and/or low-contrast environments,[34, 122, 158] while others suggest objective visual assessment is better with monovision at all distances.[123, 148, 155] A recent study by Almutairi et al. reported that early presbyopes corrected with monovision frequently accommodated with the distance-corrected eye, leaving the near eye with myopic defocus and reduced acuity at near.[159]

The most important factor when assessing the success of any presbyopic contact lens modality is subjective response. A patient's opinion and satisfaction with their correction is the factor that will determine if they remain in that particular correction. When considering subjective assessments of multifocal and monovision contact lenses designs, it appears that patients prefer simultaneous vision multifocals to monovision. In the studies mentioned above, 51-76% of patients preferred multifocals to monovision.[34, 148] Subjective ratings of a multifocal were higher for most tasks[34, 53, 122, 148, 155] and especially for changing focus.[122, 148] These findings show that objective visual assessments of presbyopic contact lens options may not be as valuable as subjective responses.

Multifocal Contact Lenses: Effect on Accommodation

Simultaneous vision multifocal contact lenses have been evaluated, primarily, for use in two major groups: presbyopes and myopic children. In presbyopes, the increased depth of focus provided by the lens allows for corrected near vision in the absence of sufficient accommodation. In myopic children, the peripheral myopic defocus induced by center distance aspheric multifocal designs slows progression of myopia.[141, 160] Unlike complete presbyopes who wear multifocal contact lenses and do not have functional accommodation, myopic children wearing multifocals for myopia control still have the ability to accommodate. Research, therefore, has been done to determine how multifocal contact lenses influence accommodation in non-presbyopes. These topics are of acute interest when considering prescribing multifocal contact lenses for children because their eyes and binocular vision systems are still developing. As well, understanding how a multifocal contact lens affects ocular functions will allow better understanding of how it influences myopia progression.

Because blur stimulates accommodation,[96, 97] one could assume that, when corrected with an aspheric lens that increases depth of focus and provides a clear near image, accommodation would decrease. It is known that accommodative effort decreases when positive power is used for a near task,[161-164] but the literature reports conflicting results on how the spherical aberrations induced by aspheric multifocal contact lenses affect accommodative response in children and adult non-presbyopes. The majority of studies have concluded that aspheric multifocals cause no significant change in accommodative effort[137, 165, 166] or, at best, a small reduction.[167-169] One notable exception to this generalization, is Tarrant et al., who suggested that aspheric multifocals induced accommodative lead in myopic subjects that were otherwise lagging.[170]

The Optometry Research Group in Valencia, Spain has performed several studies to determine how aspheric multifocals affect accommodation and has concluded, primarily, that multifocals do not significantly reduce accommodative effort in young adults.[137, 165, 166] In two similarly designed studies, Ruiz-Alocer et al. and Madrid-Costa et al. compared accommodation in young adults corrected with single vision and center-near multifocal aspheric contact lenses. In both investigations, accommodative effort with a multifocal lens was not significantly different from accommodation when corrected with a single vision lens.[137, 165] Montes-Mico et al. evaluated accommodation with multifocals in presbyopes and non-presbyopes and also reported that multifocals did not affect accommodative function in non-presbyopes.[166] Recognizing that accommodation is driven by blur, the authors speculated that the multifocals did not provide a clear enough image at near to relax the accommodative system.[137, 165, 166] As well, the measurements were taken before the subjects had time to adapt to the lenses, so it is possible that they accommodated in the multifocal because their accommodative system had not yet learned that it could relax and still achieve a clear image.[137, 165, 166]

Kang et al. examined accommodation in young adults wearing multifocal contact lenses over a two week period.[169] This group reported accommodative lag that increased significantly for the lens with a +1.50 D add, but not for the +3.00 D add. Overall, however, they concluded that any differences in accommodation were clinically small and not significant.[169] Gong et al. measured accommodation with single vision and multifocal contact lenses in children (10-15 years old) and reported that accommodative lag increased significantly with the multifocal contact lens compared to single vision.[168] Interestingly, Gong et al. also reported increased exophoria at near with multifocal correction.[168] Recognizing that convergence and accommodation are linked,[96, 97] the finding of decreased accommodation and increased near exophoria suggests that the multifocal, in this case, relaxed the accommodative and vergence systems in response to a clear near image.

In a recent study, Altoaimi et al. measured accommodation monocularly and binocularly with single vision and multifocal contact lenses. This group reported reduced accommodative responses with multifocals.[167] When comparing binocular accommodation to monocular viewing, they showed that more accommodation was exerted when subjects were viewing targets binocularly. This supports the idea of linked convergence and accommodation.[96, 97] When monocularly viewing, accommodation is not stimulated by convergence, so subjects were able to relax their accommodation more fully. In binocular conditions, convergence drives accommodation, and accommodative response was higher compared to monocular conditions.[167] Altoaimi et al. suggested that this convergence-driven accommodation may prevent young, non-presbyopic subjects from taking full advantage of the near add in a multifocal contact lens.[167]

The conflicting results related to accommodative response in non-presbyopes wearing aspheric multifocals may be due to several factors. First, the inherent optics of the aspheric multifocal make accurate refractive measurements difficult to achieve.[166, 167] The changing power profiles on the lens make it challenging, regardless of measurement type, to assess true refractive state, especially with center-near designs.[167] As mentioned above, most investigations examining accommodation with multifocals take measurements after little to no adaptation time.[137, 165, 166, 168] Though it has been reported that objective accommodative responses do not change after up to two weeks of adaptation,[169, 171] subjective acceptance of multifocals is commonly seen clinically, so it is possible that some accommodative adaptation occurs. Finally, most of the previously mentioned studies had very small sample sizes.[137, 165-167] A sample was so limited in size that one author suggested that, "it would be inappropriate to assert that the sample means are representative of the broader population.[167]" More research in this area is needed to truly understand how a multifocal contact lens affects accommodation in non-presbyopes.

Presbyopic Prescribing Patterns

Despite the many options a contact lens wearer has to correct presbyopia, presbyopic contact lens options have yet to be fully embraced by eye care providers.[129] With the development of new designs, materials, and lens options in recent years, however, it appears that presbyopic contact lens options, especially multifocals, are showing an increase in utilization and prescribing.[32, 172, 173] Still, these modalities are prescribed at disappointingly low rates. In a large international survey of, the majority of presbyopes (63%) were fitted in non-presbyopic contact lens designs.[23] This suggests that the majority of presbyopic contact lens wearers rely on wearing spectacles over their contact lenses in order to perform near visual tasks.

The low prescription rate of presbyopic modalities is likely multifaceted. Some aversion to initiating presbyopic contact lens fits may relate directly to an eye care provider's business concerns. The perception that presbyopic contact lens corrections take longer to fit and cost more in-office time may dissuade doctor's from trialing these modalities.[121] As well, fearing the possibility that a patient fails with the suggested modality, a doctor may worry that a patient will lose confidence in her/him.[129] The perceived disadvantages of multifocals and monovision likely dissuade providers from initiating a presbyopic contact lens fit, especially on discerning patients. Finally, some presbyopic contact lens prescribing avoidance may be due to inadequate knowledge of product availability and/or lack of fitting skills among eye care providers.[129]

Chapter 6: Summary of Studies

The first two studies described in this dissertation sought to better understand opinions and visual correction preferences of presbyopic contact lens wearers who have known accommodative insufficiency. While studies exist that ask doctors what they prefer to prescribe for their presbyopic contact lens wearers,[23] few ask patients directly what their opinions and preferences are when it comes to visual correction.[174] Better understanding the experiences this group has had with contact lenses and what visual correction modalities they prefer will aid eye care providers in prescribing contact lenses and treating discomfort in this group that is known for discontinuing lens wear.

The final experiment aimed to determine how multifocal contact lens correction affects symptoms of discomfort in a non-presbyopic population. As mentioned above, symptoms of contact lens discomfort are remarkably similar to symptoms of accommodative fatigue.[22] It was hypothesized that, in uncomfortable contact lens wearers who have no significant signs of dry eye or general binocular vision disorders, accommodative assistance in the form of multifocal contact lens may affect their comfort and overall satisfaction with contact lens wear. For all described experiments, approval was obtained from the Ohio State University (OSU) Institutional Review Board (IRB) and the tenants of the declaration of Helsinki were followed.

Chapter 7: A Survey of Presbyopic Contact Lens Wearers in a University Setting

Introduction and Rationale

Rates of contact lens discontinuation tend to increase with age,[1, 3, 4] and presbyopia has been suggested to be a reason for patients both ceasing and struggling to resume contact lens wear.[5] Presbyopic contact lens wearers face comfort and vision challenges that non-presbyopes may not. Frequency of symptoms and signs of general, non-contact lens associated dry eye tend to increase with age.[38, 175] This well-accepted knowledge of increased dryness with age may dissuade patients or doctors from pursuing contact lens wear, despite evidence that contact lenses have little effect on the ocular surface environment.[176]

Discomfort is commonly cited as the primary reason for contact lens discontinuation.[1, 3-5] Despite attempts to combat contact lens dropout through development of improved materials and more frequent replacement options, contact lens discontinuation rates have not varied significantly over the last two decades.[1] Although discomfort is the most common reason for contact lens discontinuation, poor vision quality has also been found to contribute to contact lens dissatisfaction.[1, 3-5] When Young et al. re-fitted lapsed contact lens wearers into a different contact lens, vision issues, not discomfort were the primary reason for discontinuation.[5] It may be important, therefore, to consider both comfort and vision satisfaction when assessing contact lens discontinuation.

Presbyopic contact lens wearers must adopt new vision correction modalities to maintain a range of vision across various distances. Monovision and multifocal options are available, but only about one third of presbyopic contact lens wearers utilizes a presbyopic contact lens design.[172, 177, 178] This observation may be due to the visual compromise associated with presbyopic contact lenses. Considering these visual compromises, it is not surprising that the majority of presbyopic contact lens wearers remain in single vision corrections while using over-spectacles for near tasks.[23]

In a review of the literature at the time of the following experiment, no study had investigated the opinions and contact lens discontinuation rates of presbyopic contact lens wearers exclusively. What symptoms cause this group to stop wearing contact lenses? Is their contact lens frustration related more to discomfort symptoms, unsatisfactory vision, or a combination of both factors? This study aimed to better define the perceptions and opinions of presbyopic contact lens wearers and identify reasons some may discontinue contact lens wear. The results and conclusions of this study were published in *Optometry and Vision Science* in 2016 and adapted to fit this dissertation.[179]

Methods

A database search of the Ohio State University College of Optometry Contact Lens Services was performed to identify presbyopic patients (age 40 years and older) who had an eye exam within the last four years. Name and home address information was obtained, and surveys were mailed to these patients via the United States Postal Services. Because the College of Optometry had only recently implemented the collection of patient email information during the search period, postal mail was determined to be the best way to reach this population.

Each envelope contained a cover letter describing the purpose of the study, a survey, and a prepaid postage and addressed envelope for the subject to mail the survey back to investigators. The cover letter explained that each subject's participation was voluntary and no linked identifiers would be used to connect an individual subject to his or her responses. If the subject chose to participate, he or she mailed the completed survey in the provided reply envelope.

The survey was designed to assess opinions and satisfaction with current or past contact lens wear. Questions on the survey addressed age, gender, age of contact lens wear initiation, current contact lens material (soft versus gas permeable), and design (monovision versus multifocal), opinions on comfort and visual quality at various distances, and if the subject had permanently discontinued contact lens wear.

Statistical analysis was performed using SPSS version 22 (IBM). Results were summarized in frequencies, means, and standard deviations. Chi-square tests were performed when comparing groups of categorical variables, and t-tests were used when comparing categorical variables to continuous variables. Binary logistic regression was performed to determine what factors, if any, influenced a subject's tendency to discontinue contact lens wear. As well, binary logistic regression was performed to determine if, controlling for age, gender, start of contact lens wear, and contact lens material, discontinued contact lens wearers had different opinions of vision than current contact lens wearers. To investigate any relationship between age of beginning contact lens wear and discontinuation, the sample was divided into two groups: subjects who began contact lens wear before presbyopia (before age 40 years)[122, 145, 147, 180] and subjects who began contact lens wear after age 40 years. Discontinuation rates and reasons for discontinuation were examined in these groups. As well, a t-test was performed to determine if years of contact lens wear (age of initial contact lens fitting subtracted from age) and discontinuation were related. The level of statistical significance used to make conclusions in this study was $p < 0.05$.

Results

Surveys were mailed to 2,400 patients. The postal service returned 121 surveys due to incorrect addresses. A total of 513 surveys were returned to investigators (23% response rate). Fourteen returned surveys were not analyzed because the patient indicated they had never worn contact lenses and three surveys were not analyzed because the subjects reported ages less than 40 years. Therefore, 496 surveys were analyzed.

Demographic data (age, gender, lens material/modality, etc.) is summarized in Table 2. Permanent discontinuation of contact lens wear was reported by 15% of subjects. Univariate analysis showed no significant association between contact lens discontinuation and age, gender, age of beginning contact lens wear, or contact lens material/modality (Table 2). As well, no significant relationship was observed between age and gender ($t = 1.2$, $p = 0.2$) or age of starting contact lens wear and gender ($t = 0.9$, $p = 0.4$). A larger proportion ($X^2 = 5.2$, $p = 0.02$) of females (73%) wore soft lenses compared to males (63%). Binary logistic regression was performed to determine if, controlling for other factors, certain patient characteristics were related to contact lens discontinuation. Age ($p = 0.7$, Odds ratio [OR] = 1.0, 95% confidence interval [CI] = 0.96 to 1.0), gender ($p = 0.2$, OR = 0.7, 95% CI = 0.3 to 1.2), age of beginning contact lens wear ($p = 0.3$, OR = 1.0, 95% CI = 0.97 to 1.0), and lens material ($p = 0.1$, OR = 1.8, 95% CI = 0.9 to 3.6), when analyzed together, were not found to be predictors of contact lens discontinuation.

Discontinued wearers were asked to describe their primary reason for ceasing contact lens wear. Subjects could choose from the following options: discomfort, poor vision, cost, or convenience. There was no significant difference between the proportion of subjects who reported “poor vision” compared to “discomfort” as the primary reason for discontinuation (Table 3, $X^2 = 0.2$, $p = 0.7$). The proportion of subjects who reported “poor vision” as their primary reason for discontinuation was significantly greater than those who reported “convenience” ($X^2 = 6.5$, $p = 0.01$) and “cost” ($X^2 = 28.6$, $p < 0.0001$). Table 3 displays reasons for discontinuation for the entire sample and for subjects who began contact lens wear before and after onset of presbyopia. Years of contact lens wear (age of initial contact lens fitting subtracted from current age) was not related to discontinuation ($t = -0.9$, $p = 0.5$).

Table 2: *Demographic Data and Associations with Contact Lens Discontinuation*

Factor	Presence in Population		Associated with Contact Lens Discontinuation? *
Age (mean, years) (n = 493)	57 ± 9 (40 to 92)		No ($t = 0.4$, $p = 0.7$)
Female (n = 495)	68%		No ($X^2 = 1.8$, $p = 0.2$)
Age of Beginning Contact Lens Wear (mean, years) (n = 468)	24 ± 13 (1.5 to 72)		No ($t = 1.6$, $p = 0.1$)
Lens Material (n = 487)	Soft	70%	No ($X^2 = 2.7$, $p = 0.1$)
	Gas Permeable (GP)	30%	
Lens Design (n = 494)	Monovision (21%) Multifocal (35%) or Both (4%)	60%	*Monovision*: No ($X^2 = 1.2$, $p = 0.3$) *Multifocal*: No ($X^2 = 0.1$, $p = 0.8$)
	Non-Presbyopic Contact Lens	40%	

*Permanent contact lens discontinuation was reported by 15% of the sample

Table 3: *Contact Lens Discontinuation for the Entire Sample and Subjects Beginning Wear Before and After the Onset of Presbyopia*

Primary Reason for Contact Lens Discontinuation	**Entire Sample (n = 494)**	**Began Contact Lens Wear before Age 40 Years (n = 390)***	**Began Contact Lens Wear at Age 40 Years or After (n = 73)**
Poor Vision	38%	40%	44%
Discomfort	35%	38%	22%
Convenience	21%	17%	22%
Cost	6%	4%	11%
Percentage reporting poor vision different from discomfort?	No ($X^2 = 0.2$, $p = 0.7$)	No ($X^2 = 0.05$, $p = 0.8$)	No ($X^2 = 1.3$, $p = 0.2$) Fisher's Exact $p = 0.6$
Discontinuation Rate	15%	13%	19%

Figure 2 shows the percentage of subjects who reported various symptoms in the overall subject population and in the current and discontinued wearer groups. Figure 3 displays subject opinions of their contact lens corrected vision. If subjects had discontinued contact lens wear, they were asked to rank their vision as it was when they were wearing their contact lenses. Figures 4, 5, and 6 display the opinions discontinued and current contact lens wearers had of their distance, intermediate, and near vision, respectively. As described in the figures, discontinued contact lens wearers had a worse overall opinion of their distance (Figure 4), intermediate (Figure 5), and near vision (Figure 6) with contact lenses compared to the opinions expressed by current contact lens wearers.

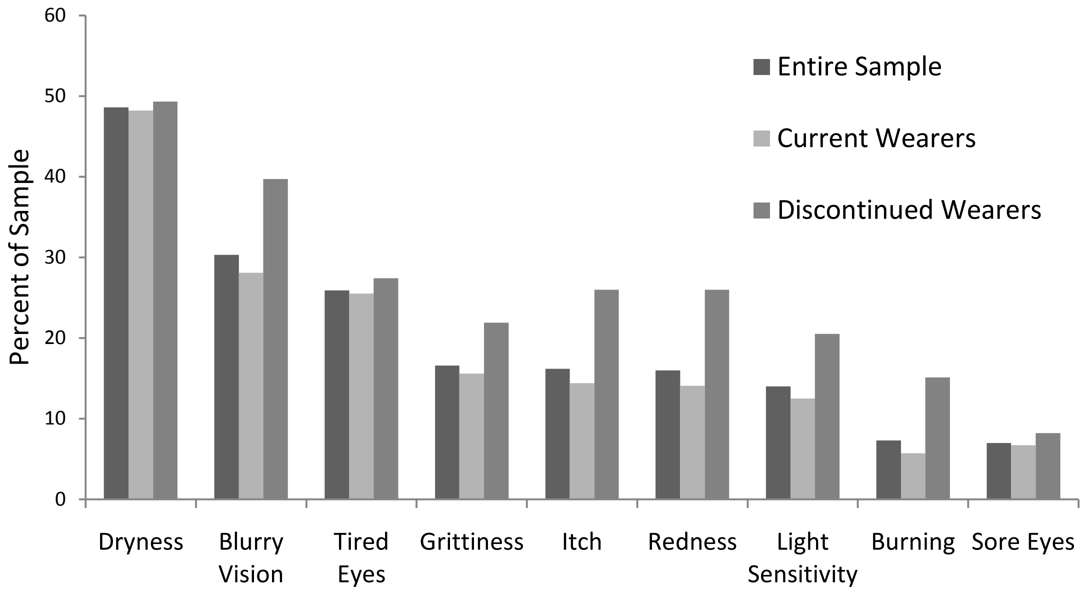

Figure 2: *Symptoms Associated with Contact Lens Wear*

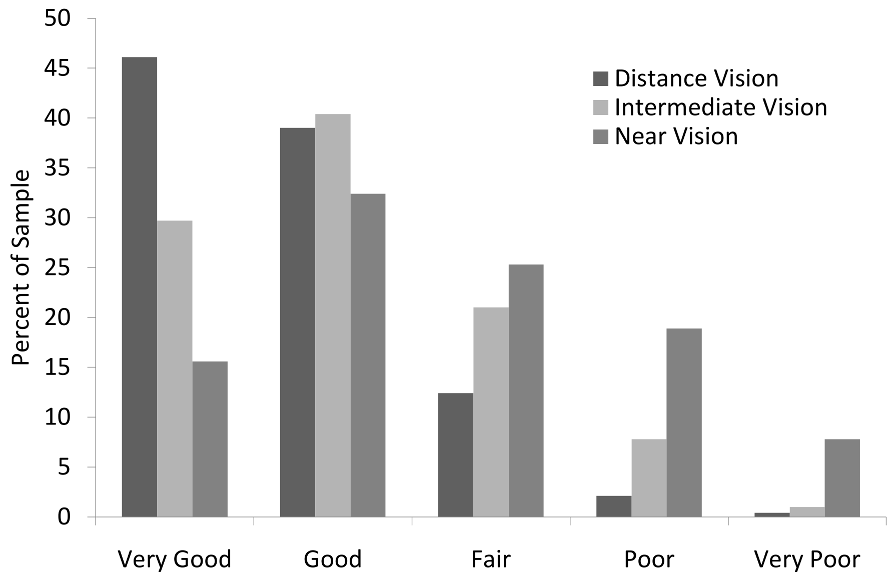

Figure 3: *Opinion of Vision with Contact Lenses for Entire Sample*

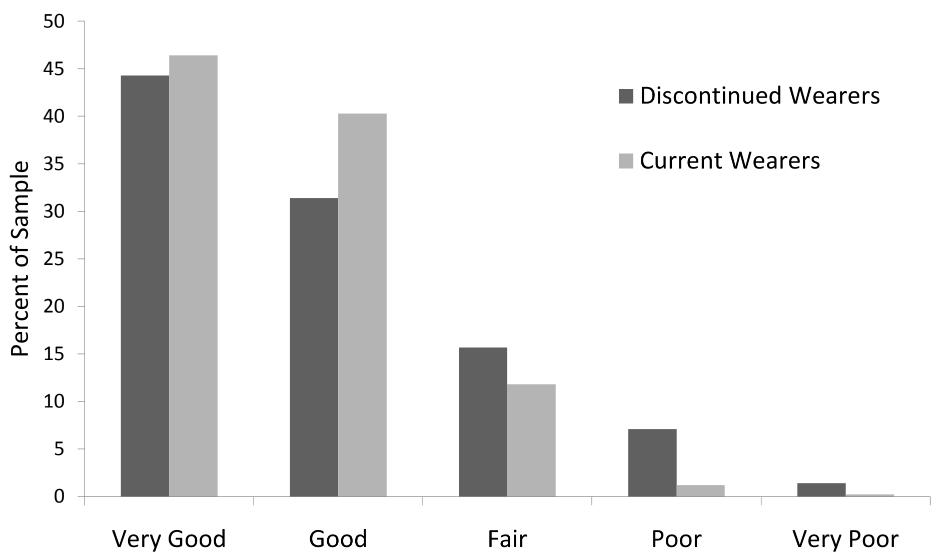

Figure 4: *Opinion of Distance Vision in Discontinued and Current Contact Lens Wearers*. Discontinued wearers had a worse opinion of their distance vision than current wearers, ($p = 0.03$, OR = 0.7, 95% CI = 0.5 to 1.0) controlling for age, gender, age of beginning contact lens wear, and contact lens material.

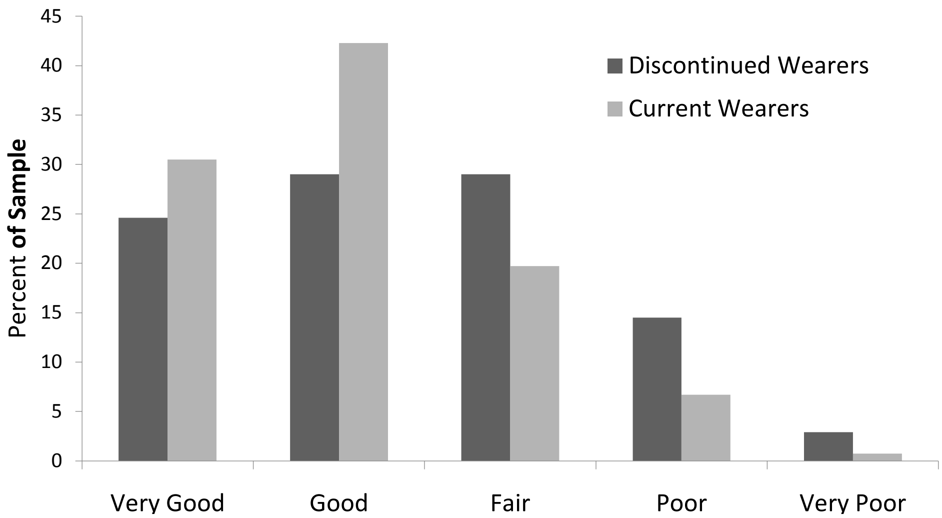

Figure 5: *Opinion of Intermediate Distance Vision in Discontinued and Current Contact Lens Wearers*. Discontinued contact lens wearers had a worse opinion of their intermediate distance vision than current contact lens wearers (p = 0.01, OR = 0.7, 95% CI = 0.5 to 0.9), controlling for age, gender, age of beginning contact lens wear, and contact lens material.

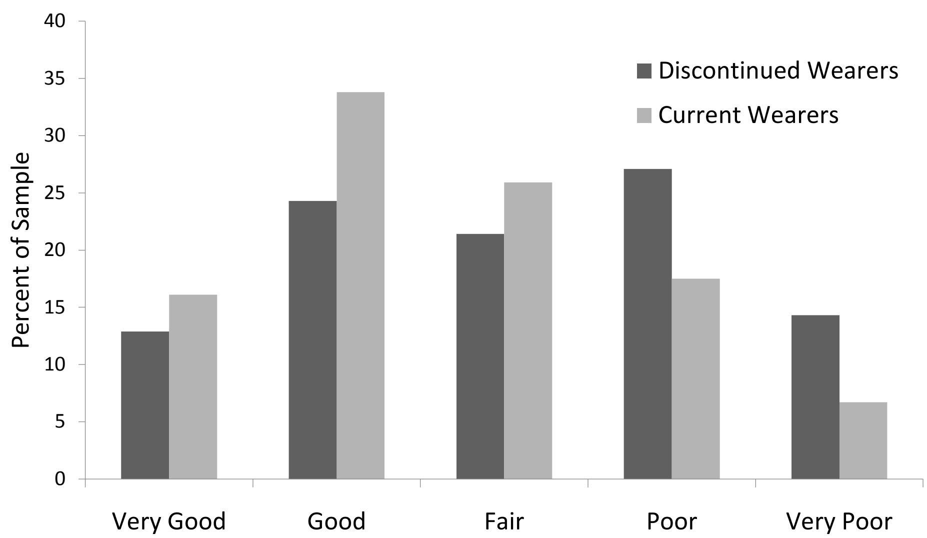

Figure 6: *Opinion of Near Vision in Discontinued and Current Contact Lens Wearers*. Discontinued wearers had a worse opinion of their near vision than current wearers (p = 0.002, OR = 0.7, 95% CI = 0.5 to 0.9), controlling for age, gender, age of beginning contact lens wear, and contact lens material.

Discussion

This presbyopic sample reported poor vision as commonly as discomfort as the main motivation for contact lens discontinuation. This result differs from previous studies that surveyed patients of all ages and reported dryness and discomfort as the primary reason for contact lens dropout.[1, 3, 5, 174] Supporting this finding, when assessing the relationship between vision and contact lens dropout rates, discontinued wearers had a worse overall opinion of their distance, near, and intermediate vision compared to current contact lens wearers.

Because it is possible that subjects who began contact lens wear after presbyopia might be more or less likely to discontinue contact lens wear than long-term wearers, we also compared those two groups. When we evaluated those two groups separately, their reasons for discontinuation were not significantly different than the overall sample. Similarly, years of contact lens wear was not associated with tendency to stop wearing lenses. In our sample, the group of subjects who had started contact lens wear after presbyopia onset and had also ceased lens wear was small (n = 14), making statistical comparisons less reliable.

Univariate and multivariate analysis showed that age, gender, age of beginning contact lens wear, and contact lens material did not have a significant impact on contact lens discontinuation. The lack of relationship between these variables and contact lens discontinuation is contrary to previous reports of younger contact lens wearing populations. In the previous reports, current age and later age of starting contact lens wear have been shown to be predictors of contact lens dropout.[1, 3, 4] Similarly, male gender has been suggested as a contact lens dropout predictor.[3] The major difference between our sample and the previously cited studies is the older and narrower age range of the sample. Our mean age of approximately 57 years was much higher than the mean sample ages reports in the previous studies (29 to 42 years).[1, 4, 5] The fact that the majority of our subjects were female was similar to the ratio of male to female presbyopic contact lens wearers reported by Morgan et al.[23] The lack of association between age, gender, and contact lens wear starting age in our sample suggests that, as patients progress through presbyopia, other factors may contribute to contact lens satisfaction.

The percentages of subjects reporting discomfort versus poor vision as the primary reason for dropout in our study were not significantly different. It is important to note that previous surveys evaluating contact lens dropout have not reported this similarity. Pritchard et al. reported discomfort, dryness, and red eyes as the three primary reasons for dropout,[3] whereas Dumbleton et al. cited discomfort and dryness.[1] Similarly, Richdale et al. ordered dryness, discomfort, and grittiness as the most reported discontinuation reasons.[4] Although Pritchard et al. did not report mean age[3], the two previously mentioned studies had samples with mean ages around 30 years.[1, 4] Samples with this mean age are not expected to be experiencing presbyopic symptoms. Therefore, the differences in symptom reporting between this study and previous survey studies could be attributed to presbyopia.

Young et al. surveyed an older group of contact lens wearers (mean age 42 years) and reported, similarly to previous studies, that discomfort was the primary reason for contact lens dropout.[5] In addition, poor vision was the second most reported discontinuation reason.[5] Compared to the previously mentioned investigations, Young et al.[5] was the only study to report vision-related complaints as a secondary discontinuation reason, but it also contained a sample with a mean age more than 10 years older than the other survey studies.[1, 4] It should be mentioned that the difference between discomfort (51%) and poor vision (13%) was large.[5]

As with any anonymous survey study, limitations are encountered due to the possibility of subject misreporting. In my clinical experience, patients commonly utilize mixed presbyopic contact lens designs and may wear a combination of multifocal and monovision designs. These design combinations may have led to confusion in patient reporting. For instance, 4% of subjects reported wearing both monovision and multifocal corrections. Because of this potential confusion, no conclusions were drawn based on contact lens design data.

The contact lens clinic surveyed in this study examines a wide variety of contact lens wearers. It is likely that respondents to the survey may have been wearing specialty contact lenses to treat conditions like keratoconus, ocular surface disease, and postsurgical correction. One could argue that these patients are less likely to discontinue contact lens wear than patients who can be corrected with options other than contact lenses. If our sample had not included specialty contact lens wearers, it is possible that we may have found a higher dropout rate. Due to the anonymous nature of this study, however, we were unable to identify which subjects wore more advanced lens designs.

Presbyopic age, in this study, was defined as 40 years and older. Studies examining presbyopia and presbyopic contact lenses commonly include 40-year-old subjects.[122, 145, 147, 180] Still, early presbyopic patients, at or near 40-years-old, may not yet be experiencing difficulty with near vision due to the insidious onset of presbyopia.[122] It is possible that young presbyopes in our study were not experiencing visual strain or discomfort due to presbyopic advancement.

The 23% response rate reported in this study seems slightly lower than response rates reported by similar survey-based contact lens studies.[3, 181, 182] In two separate studies, Dumbleton et al. mailed or emailed surveys to eye care providers.[181, 182] They requested the eye care providers administer the surveys to qualifying patients and send the completed surveys back to investigators. These studies reported 27-30% response rates.[181, 182] The administration pattern of these studies, however, was different than our anonymous mailing method. In contact lens survey more similar in methods to this study, surveys were mailed to patients and responses were received anonymously.[3] A 33% response rate was reported.[3]

In conclusion, the results of this survey show that presbyopes are a unique group of contact lens wearers with distinct visual demands compared to non-presbyopic patients. When attempting to maintain contact lens wear in dissatisfied patients, doctors should consider not only impressions of comfort, but also opinions of vision quality at all distances. Comfort and visual quality seem to be equally important contributors to presbyopic contact lens dropout.

Chapter 8: Presbyopic and Non-Presbyopic Contact Lens Opinions and Vision Correction Preferences

Introduction and Rationale

As discussed in previous chapters, survey studies exist that query eye care practitioners about their prescribing habits and opinions of various contact lens designs,[23, 172, 178, 183] but few studies ask patients what visual corrections they prefer. Presbyopes are known to be a difficult group to initiate and maintain satisfactory contact lens wear. Visual correction at all distances becomes more complex with presbyopia and symptoms of dryness and discomfort tend to increase with age.[175] This combination of factors may contribute to the tendency of contact lens wearer to discontinue lens wear as they grow older,[1, 4] but preconceptions of eye care providers may influence the relatively low number of presbyopic contact lens prescriptions worldwide.[23] Morgan et al. suggested that the low utilization of presbyopic contact lens designs was likely due to a lack of fitting skills/clinical knowledge by contact lens fitters and a general preconception that visual compromises introduced by presbyopic designs are too great. Despite these potential preconceptions, recent data suggest that presbyopic (multifocal or monovision) contact lens wearers actually wear their lenses more frequently than more traditional lens modalities like single vision spherical and toric lenses.[2]

How do presbyopic patients differ from their non-presbyopic counterparts in opinions of vision correction preference? This survey study aimed to determine the vision correction preferences (spectacles versus contact lenses) of non-presbyopes and presbyopes and how refractive error and gender are related to these preferences. This study was published in *Contact Lens and Anterior Eye* in 2017 and has been adapted to fit this dissertation.[174]

Methods

For this prospective cross-sectional study, participants were recruited at the Center of Science and Industry (COSI) Life Labs in Columbus, Ohio. COSI, a science museum, is a unique setting to recruit study subjects from the general population. All subjects provided written informed consent. COSI visitors that reported habitually wearing some form of refractive correction (contact lenses or spectacles) for distance, near, and/or full-time correction and met all inclusion criteria (Table 4) were asked to answer questions about their refractive error correction and demographic information on an iPad. Data were collected and analyzed using Research Electronic Data Capture (REDCap) tools hosted at OSU.[184]

Subjects who reported wearing spectacles as their primary vision correction were asked if they had previously tried contact lenses and, if so, why they discontinued contact lens wear. Subjects who reported contact lenses as their primary vision correction were asked if they had ever discontinued lens wear for a significant (≥ 1 month) amount of time and, if so, why they temporarily discontinued and resumed contact lens wear. All contact lens wearers and spectacle wearers who reported a history of contact lens wear were asked what their preferred form of vision correction would be (spectacles or contact lenses), assuming they could achieve good comfort and vision. Spectacle wearers with no history of contact lens wear were not asked this question because they had no contact lens experience on which to base their preference. After completing the survey, subjects were asked to remove their habitual vision correction and autorefraction was performed on both eyes using a Grand Seiko autorefractor while the subject viewed a distance target positioned at approximately 20 meters. Autorefraction data for both eyes were recorded in each subject's REDCap record.

Table 4: *Spectacle and Contact Lens Wearer Inclusion Criteria*

Inclusion Criteria
Age ≥ 18 years Distance visual acuity 20/30 or better in both eyes (*with habitual correction on a Bailey-Lovey logMAR chart*) Current spectacle or contact lens wearer No history of ocular surgery or the following ocular conditions: *Glaucoma* *Macular degeneration* *Retinal detachment* *Keratoconus or corneal disease*

Statistical analysis was performed using SPSS Version 24 (IBM). The level of significance used to make conclusions in the study was $p < 0.05$. Spherical equivalent (SE) values for each eye were calculated and averaged to produce a mean SE for each subject. A mean binocular magnitude of astigmatism was determined for each subject. Cylinder and axis components of refractive error were converted to power vectors (J0 and J45, as described by Thibos et al.[185] and Raasch et al.[186]) and a mean binocular value was produced for both vectors on all subjects. Anisometropia values were calculated and reported as the absolute value of the difference in SE between the two eyes in each subjects. Chi-square tests were used to compare groups of categorical variables, and t-tests were performed when comparing means of continuous variables to categorical groups. Multivariate binary logistic regression was used to determine if gender, SE, J0, J45, or anisometropia varied between age groups (non-presbyopes and presbyopes) and vision correction groups (spectacle and contact lens wearers).

Results

Data from 304 subjects were collected. The mean age of the entire sample was 37.1 ± 14.4 years (range 18 to 76 years), 59.2% (n = 180) of the sample was female, and 38.2% (n = 116) of subjects were in the presbyopic age range (≥ 40 years). When asked to identify their primary vision correction (spectacles or contact lenses), 78.0% (n = 237) of the sample reported wearing spectacles for the majority of their vision correction needs. The proportion of presbyopes was higher ($p = 0.006$, $X^2 = 7.4$) in the spectacle group (42.2% presbyopic, 100/237) compared to the contact lens wearing group (23.9% presbyopic, 16/67).

Table 5 shows a comparison of age, gender, and refractive error in non-presbyopes versus presbyopes and spectacle wearers versus contact lens wearers in the entire sample.

Independent t-tests, Chi-square testing, and binary logistic regression were performed to determine if there were differences between the two age groups and vision correction groups. Table 6 shows a comparison of age groups (non-presbyopes versus presbyopes) in each of the spectacle and contact lens wearing vision correction groups. Independent t-test, Chi-square testing, and binary logistic regression were performed to determine if differences occurred between the two age groups within each vision correction group. Subjects who reported wearing spectacles as their primary vision correction were asked if they had ever tried wearing contact lenses. Table 7 shows a comparison of the age, gender, and refractive error of non-presbyopic and presbyopic spectacle wearers that reported trying contact lenses in the past.

Spectacle wearers were asked if they had ever tried contact lens wear and, if so, what vision correction they would prefer if they could achieve good vision and comfort. Contact lens wearers were asked if they had ever discontinued contact lens wear for a significant amount of amount of time (≥ 1 month). The results of these three questions, compared between non-presbyopic and presbyopic subjects are displayed in Figure 7. The percentage of spectacle wearers that would prefer contact lens correction was significantly different than zero in the entire sample ($t = 36.5$, $p < 0.0001$), non-presbyopes ($t = 27.4$, $p < 0.0001$), and presbyopes ($t = 24.5$, $p < 0.0001$).

All spectacle wearers who reported wearing contact lenses in the past were asked to choose the primary reason for discontinuing contact lens wear. Figure 8 shows the reasons reported by the entire sample, non-presbyopes, and presbyopes. Contact lens wearers who reported a period of lens discontinuation were also asked to report the primary reason for this discontinuation (Figure 9). This group of contact lens wearers was also asked to report the primary reason they chose to resume contact lens wear (Figure 10).

Table 5: *Comparison of Non-Presbyopes (< 40 years) Versus Presbyopes (≥ 40 years) and Spectacles Wearers Versus Contact Lens Wearers in the Entire Sample*. Statistically significant results (p < 0.05) are bolded.

	Non-Presbyopes (n = 188, 61.8%)	*Presbyopes (n = 116, 38.2%)*	*Difference between age groups?*		*Spectacle Wearers (n = 237, 88.0%)*	*Contact Lens Wearers (n = 67, 22.0%)*	*Difference between vision correction groups?*	
			Univariate Analysis	*Multivariate Analysis*			*Univariate Analysis*	*Multivariate Analysis*
Mean Age (years) (range)	27.6 ± 6.3 (18 to 39)	52.5 ± 9.4 (40 to 76)	**t = -27.7 p = 0.006**	-	38.3 ± 14.7 (18 to 76)	32.7 ± 12.2 (18 to 74)	**t = 2.9 p = 0.005**	-
Gender (% female)	59.0% (111/188)	59.5% (69/116)	X^2 = 0.006 p = 0.9	OR = 1.1 95% CI: 0.7 to 1.7 p = 0.8	54.9% (130/237)	74.6% (50/67)	**X^2 = 8.5 p = 0.004**	**OR = 2.5, 95% CI: 1.3 to 4.8 p = 0.004**
Refractive Error								
Mean Spherical Equivalent (SE)	-3.67 ± 3.13 (-13.30 to 3.87)	-2.51 ± 4.14 (-17.56 to 6.62)	**t = -2.8 p = 0.006**	**OR = 1.1 95% CI: 1.0 to 1.2 p = 0.02**	-2.68 ± 3.43 (-15.24 to 6.62)	-5.16 ± 3.48 (-17.56 to 3.28)	**t = 5.2 p <0.0001**	**OR = 0.8 95% CI: 0.7 to 0.9 p <0.0001**
Mean Astigmatism(D)	0.81 ± 0.74 (0 to 4.81)	0.81 ± 0.48 (0 to 2.56)	t = 0.03 p = 1.0	**-**	0.85 ± 0.69 (0 to 4.81)	0.68 ± 0.46 (0 to 2.00)	t = -1.9 p = 0.07	**-**
Mean Astigmatism: J0 (D)	0.16 ± 0.68 (-2.21 to 3.50)	-0.9 ± 0.55 (-1.64 to 1.67)	**t = 3.4 p = 0.001**	**OR = 0.5 95% CI: 0.3 to 0.8 p = 0.004**	0.6 ± 0.68 (-2.22 to 3.50)	0.09 ± 0.51 (-0.86 to 1.46)	t = -0.4 p = 0.7	OR = 0.9 95% CI 0.6 to 1.5 p = 0.7
Mean Astigmatism: J45 (D)	-0.03 ± 0.36 (-1.26 to 1.96)	-0.04 ± 0.36 (-0.91 to 1.53)	t = 0.3 p = 0.7	OR = 1.3 95% CI: 0.6 to 2.6 p = 0.5	-0.04 ± 0.38 (-1.26 to 1.96)	-0.03 ± 0.23 (-0.56 to 0.50)	t = -0.07 p = 0.9	OR = 0.8 95% CI 0.3 to 1.8 p = 0.5
Anisometropia (based on SE)	0.58 ± 0.68 (0 to 4.87)	0.44 ± 0.39 (0 to 2.19)	t = 1.9 p = 0.053	OR = 0.7 95% CI: 0.4 to 1.0 p = 0.07	0.52 ± 0.54 (0 to 4.75)	0.53 ± 0.72 (0 to 4.87)	t = -0.1 p = 0.9	OR = 1.0, 95% CI 0.6 to 1.6 p = 0.9

Table 6: *Comparison of Non-Presbyopic (< 40 years) and Presbyopic (≥ 40 years) Spectacle and Contact Lens Wearers in the Entire Sample*. Significant results ($p < 0.05$) are bolded.

	Spectacle Wearers (n = 237)				*Contact Lens Wearers (n = 67)*			
	Non-Presbyopes (n = 137, 57.8%)	Presbyopes (n = 100, 42.2%)	*Difference between age groups?*		*Non-Presbyopes (n = 51, 76.1%)*	*Presbyopes (n = 16, 23.9%)*	*Difference between age groups?*	
			Univariate Analysis	*Multivariate Analysis*			*Univariate Analysis*	*Multivariate Analysis*
Mean Age (years) (range)	27.7 ± 6.3 (18 to 39)	52.9 ± 9.4 (40 to 76)	**t = -24.6 p = 0.001**	-	27.2 ± 6.4 (18 to 39)	50.3 ± 9.0 (40 to 74)	**t = -11.3 p < 0.01**	-
Gender (% female)	54.0% (74/137)	56.0% (56/100)	X^2 = 0.09 p = 0.8	OR = 1.1 95% CI: 0.6 to 1.8 p = 0.8	72.5% (37/51)	81.3% (13/16)	X^2 = 0.5 p = 0.5	OR = 1.5 95% CI: 0.3 to 6.5 p = 0.6
Refractive Error								
Mean Spherical Equivalent (SE)	-3.19 ± 3.10 (-13.30 to 3.87)	-1.99 ± 3.74 (-15.24 to 6.62)	**t = -2.7 p = 0.008**	**OR = 1.1 95% CI: 1.0 to 1.2 p = 0.03**	-4.98 ± 2.81 (-12.19 to 0.22)	-5.74 ± 5.15 (-17.56 to 3.28)	t = 0.8 p = 0.5	OR = 1.0 95% CI: 0.8 to 1.1 p = 0.6
Mean Astigmatism Magnitude (D)	0.86 ± 0.81 (0 to 4.81)	0.83 ± 0.50 (0 to 2.56)	t = -0.3 p = 0.7	**-**	0.67 ± 0.48 (0 to 2.00)	0.71 ± 0.39 (0 to 1.69)	t = 0.3 p = 0.8	-
Mean Astigmatism: J0 (D)	0.18 ± 0.73 (-2.21 to 3.50)	-0.11 ± 0.55 (-1.64 to 1.67)	**t = 3.3 p = 0.001**	**OR = 0.5 95% CI: 0.3 to 0.8 p = 0.007**	0.12 ± 0.52 (-0.77 to 1.45)	0.02 ± 0.51 (-0.86 to 1.14)	t = 0.6 p = 0.5	OR = 0.7 95% CI: 0.2 to 2.3 p = 0.5
Mean Astigmatism: J45 (D)	-0.02 ± 0.39 (-1.26 to 1.96)	-0.06 ± 0.37 (-0.91 to 1.53)	t = 0.7 p = 0.5	OR = 1.2 95% CI: 0.5 to 2.5 p = 0.7	-0.05 ± 0.22 (-0.58 to 0.37)	0.03 ± 0.25 (-0.34 to 0.50)	t = -1.3 p = 0.2	OR = 4.5 95% CI: 0.3 to 66.1 p = 0.3
Anisometropia (based on SE)	0.57 ± 0.62 (0 to 4.75)	0.46 ± 0.40 (0 to 2.19)	t = 1.6 p = 0.1	OR = 0.7 95% CI: 0.4 to 1.2 p = 0.2	0.58 ± 0.81 (0 to 4.87)	0.35 ± 0.28 (0 to 1.13)	t = 1.2 p = 0.3	OR = 0.4 95% CI: 0.09 to 1.7 p = 0.2

Table 7: *Comparison of Non-Presbyopic (< 40 years) and Presbyopic (≥ 40 years) Spectacle Wearers who Reported Permanently Discontinuing Contact Lens Wear* (n = 123). Statistically significant results (p < 0.05) are bolded.

	Non-Presbyopes (n = 76, 61.8%)	*Presbyopes (n = 47, 38.2%)*	*Difference between age groups?*	
			Univariate Analysis	*Multivariate Analysis*
Mean Age (years) (range)	28.0 ± 6.2 (18 to 39)	53.5 ± 9.4 (40 to 72)	**t = -18.2 p < 0.01**	-
Gender (% female)	57.9% (44/76)	61.7% (29/47)	X^2 = 0.2 p = 0.7	OR = 1.0 95% CI: 0.5 to 2.2 p = 1.0
Preferred vision correction	56.6% (43/76) contact lenses	68.1% (32/47) contact lenses	X^2 = 1.6 p = 0.2	OR = 0.2 95% CI: 0.2 to 1.1 p = 0.1
Refractive Error				
Mean Spherical Equivalent (SE)	-4.32 ± 2.95 (-13.30 to 3.87)	-3.51 ± 3.54 (-11.90 to 4.00)	t = -1.4 p = 0.2	OR = 1.1 95% CI: 1.0 to 1.2 p = 0.2
Mean Astigmatism Magnitude (D)	0.67 ± 0.58 (0 to 3.00)	0.98 ± 0.52 (0.13 to 2.56)	**t = 3.0 p = 0.004**	-
Mean Astigmatism: J0 (D)	0.09 ± 0.49 (-1.63 to 1.75)	-0.06 ± 0.68 (-1.64 to 1.67)	t = 1.4 p = 0.2	OR = 0.8 95% CI: 0.4 to 1.6 p = 0.4
Mean Astigmatism: J45 (D)	0.00061 ± 0.37 (-1.07 to 1.96)	-0.11 ± 0.39 (-0.91 to 0.97)	t = 1.5 p= 0.1	OR = 0.4 95% CI: 0.1 to 1.4 p = 0.2
Anisometropia (based on SE)	0.55 ± 0.57 (0 to 2.88)	0.53 ± 0.45 (0 to 2.19)	t = 0.2 p = 0.9	OR = 1.0 95% CI: 0.5 to 2.1 p = 0.1

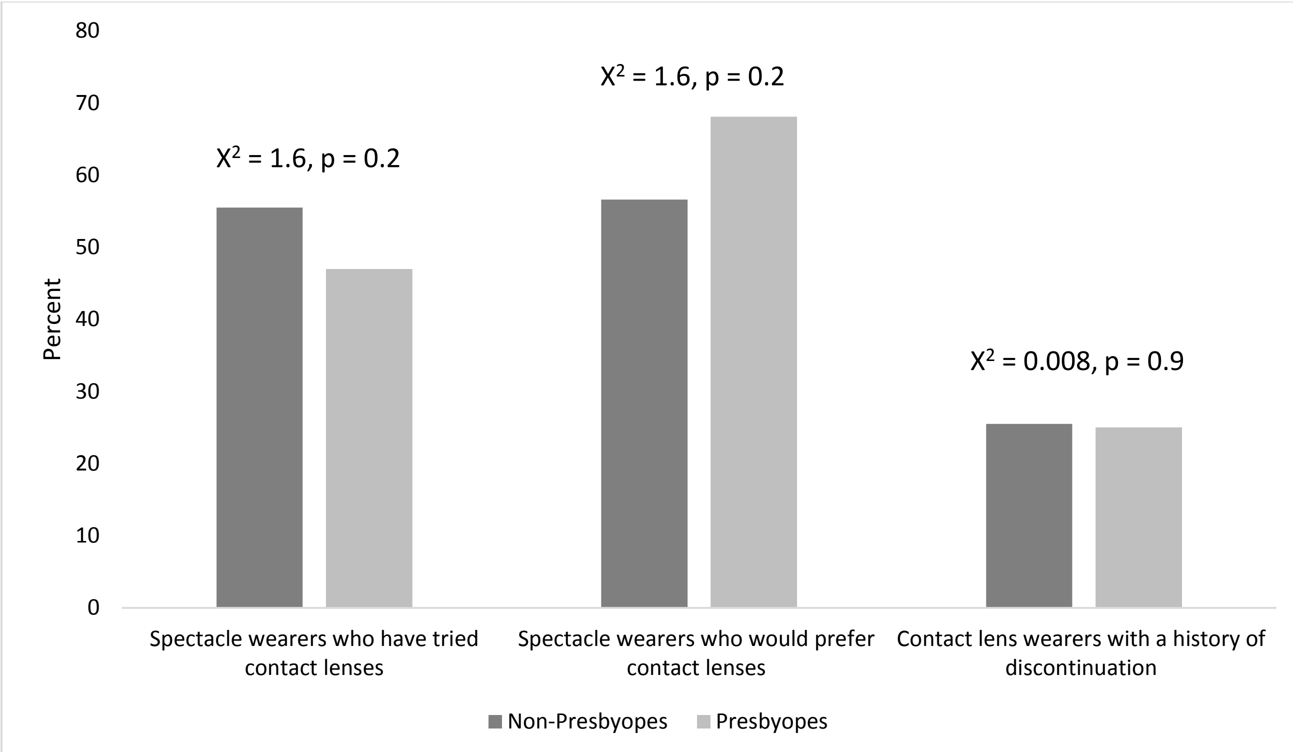

Figure 7: *Comparison of Non-Presbyopic (< 40 years) and Presbyopic (≥ 40 years) Experience with and Preference of Spectacles and Contact Lenses*. There was no difference between the percentage of presbyopes and non-presbyopes that had tried contact lenses ($X^2 = 1.6$, $p = 0.2$). Of spectacles wearers with a history of contact lens wear, there was no difference between the percentage of presbyopes and non-presbyopes that would prefer contact lenses ($X^2 = 1.6$, $p = 0.2$). For subjects who wore contact lenses as their primary vision correction, there was no difference between the percentage of presbyopes and non-presbyopic contact lens wearers with a history of discontinuation ($X^2 = 0.008$, $p = 0.9$).

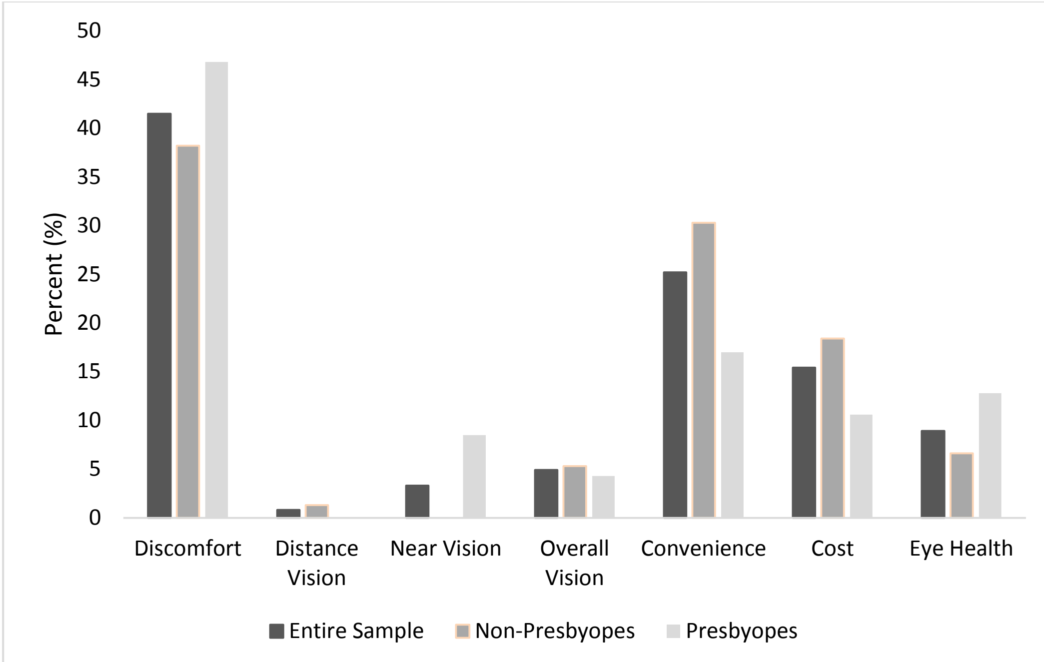

Figure 8: *Reason for Contact Lens Discontinuation in Spectacles Wearers who Reported Previous Contact Lens Wear* (n = 123). There was no difference in the proportion of presbyopes (≥ 40 years) and non-presbyopes (<40 years) who reported discomfort as their primary reason for discontinuation (X^2= 0.9, p = 0.3).

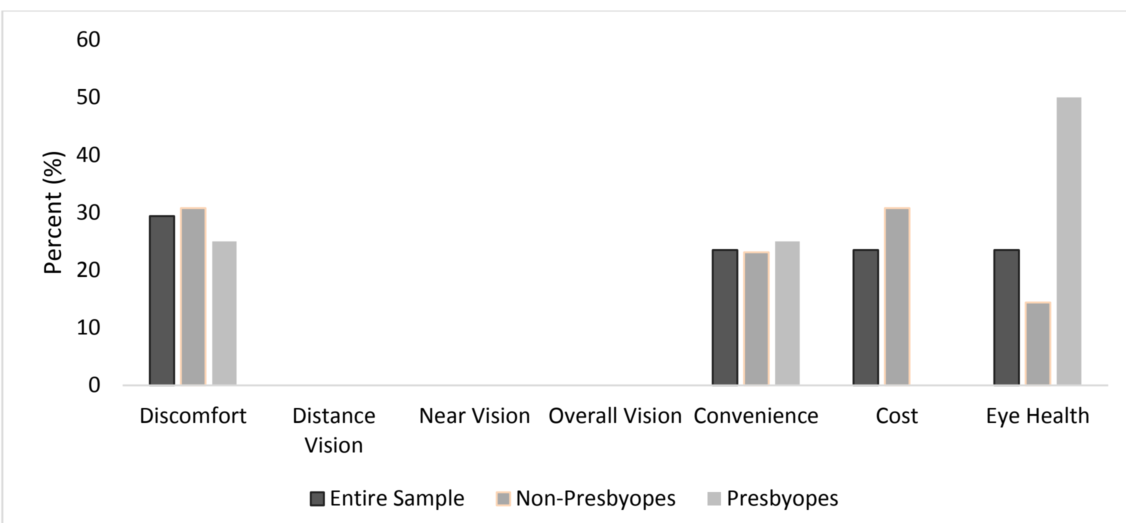

Figure 9: *Temporary Contact Lens Discontinuation Reasons in Contact Lens Wearers* - in the entire sample (n = 17), non-presbyopes (<40 years)(n = 13), and presbyopes (≥ 40 years)(n = 4)

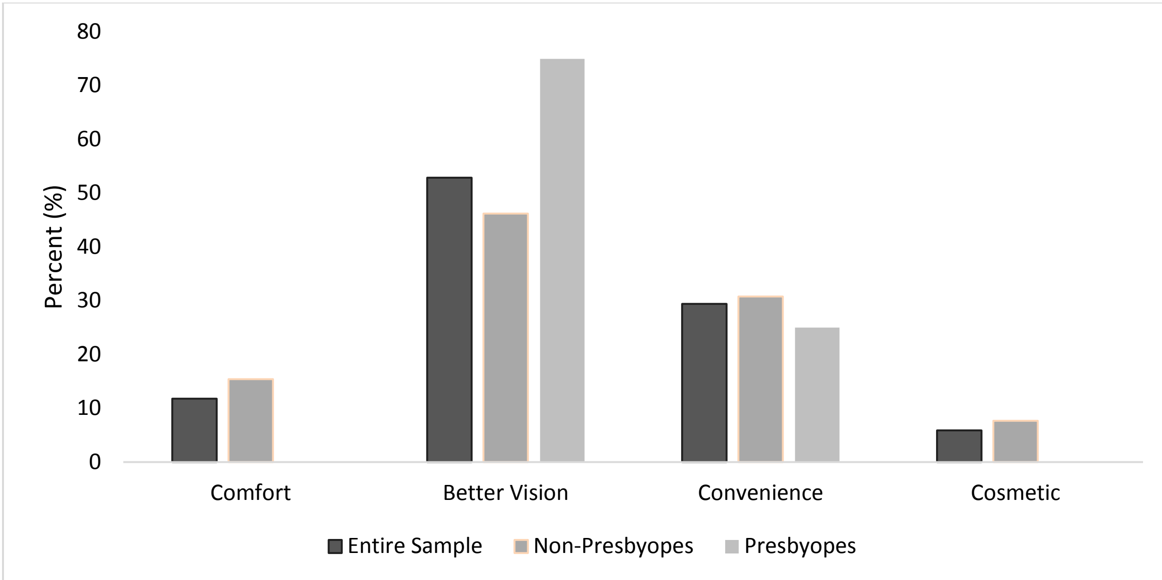

Figure 10: *Reasons for Resuming Contact Lens Wear* - in habitual wearers who reported a period of discontinuation in the entire sample (n = 17), non-presbyopes (<40 years)(n = 13), and presbyopes (≥ 40 years)(n = 4)

Discussion

In this sample, non-presbyopic and presbyopic subjects reported similar experiences with and opinions of contact lenses. The proportion of spectacle wearing presbyopes that had tried contact lenses in the past and that would prefer to wear contact lenses, if their vision and comfort needs could be met, was not different when compared to non-presbyopes. As well, the proportion of contact lens wearers who had a history of a discontinuation period, was the same between age groups (Figure 7). Spectacle-wearing presbyopes preferred contact lenses as often as non-presbyopes (Figure 7), demonstrating that presbyopic spectacle wearers have a meaningful interest in contact lens wear. In both age groups and in the overall sample, more than half of the spectacle wearers reported a preference for contact lenses. The majority of spectacle wearers, therefore, do not prefer their spectacles. This finding should encourage eye care providers to discuss contact lens options with all spectacle wearers, regardless of age group, since this group of patients has an obvious interest in contact lens wear.

In the overall sample and in spectacle wearers, presbyopes were significantly less myopic than the non-presbyopes (Tables 5 and 6). This finding was likely a result of hyperopic refractive error shifts that occur with physiological changes in the anatomical lens with age.[187] As well, the sample contained presbyopes who wore spectacles for reading only and were, therefore, emmetropic. Further, non-cycloplegic refractive error was measured, which may have contributed to the fact that non-presbyopes were more myopic. When comparing presbyopes to non-presbyopes, magnitude of astigmatism was not different in the spectacle or contact lens wearing groups (Table 6). Vector analysis of astigmatism showed that J0 was different (more against-the-rule) for presbyopes in the entire sample (Table 5) and in spectacle wearers (Table 6). This finding, combined with the fact that magnitude of astigmatism was not different between age groups, supports evidence that astigmatism shifts to against-the-rule with age,[188] and suggests that astigmatism was not different between groups. In spectacle wearers who reported permanently discontinuing contact lens wear, the magnitude of astigmatism was higher in presbyopes (Table 7). The mean astigmatism difference observed between non-presbyopes and presbyopes in this group, however, was approximately 0.30 diopters, which may not be clinically meaningful. Aside from the differences discussed above there were not meaningful differences in refractive error when comparing presbyopic and non-presbyopic contact lens and spectacles wearers.

Contact lens wearers, in the entire sample, were more likely to be younger, female, and more myopic (Table 5). This age and gender trend has been reported in previous studies.[1, 4, 173] While females were the predominant gender in both contact lens age groups, there was no significant difference in the proportion of women contact lens wearers in presbyopes and non-presbyopes (Table 6). A 2011 survey that reported contact lens fitting patterns of eye care providers found that the proportion of women fitted in contact lenses was greater in presbyopes compared to non-presbyopes.[23] This large, international survey, however, defined presbyopic age as ≥ 45 years, while our study used a ≥ 40 years criterion.[23] When this ≥ 40 years threshold criterion was applied to this study's sample, no meaningful difference in the proportion of women was still found in the newly defined presbyopic group (n = 13, 76.9% female) compared to the non-presbyopic group of contact lens wearers (n = 54, 74.1% female). This result suggests that, despite previously reported fitting trends,[23] presbyopic women are as motivated to pursue and possible maintain contact lens wear as non-presbyopic contact lens wearers. In spectacle wearers, there was also no significant gender difference in presbyopes and non-presbyopes.

As reported by previous studies,[1, 4, 5] discomfort was the primary reason for permanent discontinuation, regardless of age group (Figure 8). Vision quality (distance, near, overall) was not a substantial factor in discontinuation. This finding may suggest that optical and vision correction quality in the current contact lens market is superior to technology related to comfort. Conversely, it is also possible to speculate that "discomfort" symptoms could be attributed to both ocular or external discomfort (dryness, irritation, etc.) as suggested by Sheedy, et al.[73]

Approximately one quarter of the contact lens wearing subjects reported experiencing a period of contact lens discontinuation. This proportion was not significantly different in non-presbyopic and presbyopic contact lens wearers. While discomfort was the primary reason for discontinuation in spectacle wearers who reported permanent contact lens discontinuation (Figure 8), current contact lens wearers had more variable reasons for temporary discontinuation (Figure 9). In the entire contact lens wearing group, there was no substantial difference between discomfort, convenience, cost, and eye health for discontinuation. Vision (near, distance, or overall) was not reported as a reason for temporary discontinuation (Figure 9). Presbyopes did seem to report eye health as a discontinuation reason more than non-presbyopes, but the sample size was very small (n = 4 presbyopes, n = 13 non-presbyopes), so these results may not represent the true population.

The reasons for contact lens discontinuation, continuation, and vision correction preference, when considered across the various groups in this sample allow us to make several important observations. Discomfort was the primary reason for permanent contact lens discontinuation in spectacle wearers, regardless of age group. A small percentage (<10%) of spectacle wearers cited vision as their primary reason for discontinuation (Figure 8). When considering temporary discontinuation in current contact lens wearers, however, the primary reason for stopping lens wear was not as clear. While the groups were too small to reliably statistically analyze in Figures 9 and 10, a visual comparison of temporary discontinuation reasons (Figure 9) shows that aside from eye health reasons for presbyopes, no single discontinuation reason stands out as the primary reason reported for the entire sample, or for the non-presbyopic and presbyopic groups. While vision quality (near, distance, and overall) was never cited as a reason for temporary discontinuation, “better vision” was the main reason for resuming contact lens wear, and this reason may be higher in presbyopes compared to non-presbyopes. Considering the tendency of practitioners to assume that presbyopic contact lens wearers have worse vision in their contacts compared to their spectacles,[23] this finding is particularly notable.

The results reflected in Figures 8-10 show that discomfort was the primary reason for permanent discontinuation in this sample. These results vary from discontinuation reasons reported in the study described in the previous chapter. This difference may be due to the fact that the discontinuation question was different in the two studies. In the previous study, subjects could choose discomfort, vision, convenience, or cost as discontinuation reasons. For this study, however, the discontinuation reasons were expanded to include near, intermediate, and distance vision and eye health. Even if we combined all visual distances, it does not appear that vision was a primary reason for discontinuation in this sample. That, however, cannot be concluded decisively since the questions were different.

Discomfort should be addressed early in the fitting process to encourage long-term successful contact lens wear, and research should continue to address treatments for contact lens discomfort. Improved visual quality with contact lens correction compared to spectacles can motivate temporary contact lens dropouts to resume contact lens wear, regardless of presbyopic status. This finding may be especially important to eye care providers who assume that presbyopic patients dislike the vision with their contact lenses.

In conclusion, this study found that spectacle and contact lens wearers have similar opinions about contact lenses, regardless of if they are presbyopic or not. Spectacle wearers, in fact, would prefer to wear contact lenses if they could achieve good vision and comfort. While females were more likely to wear contact lenses, there was no gender difference amongst presbyopic and non-presbyopic contact lens wearers, suggesting that males and females are equally motivated to initiate and maintain contact lens war, even as they progress into presbyopia. Presbyopes of all refractive errors, even those near emmetropia, prefer contact lens correction, when good vision and comfort can be achieved. Discomfort is the main factor contributing to contact lens discontinuation in all age groups, but the possibility of improved vision may be a primary motivator that causes a person to resume contact lens wear. When considering vision correction options, eye care providers should not assume that presbyopic status, refractive error, or gender are factors that preclude a patient from being interested and/or successful in contact lens wear.

Chapter 9: Accommodative Relief for Uncomfortable Non-Presbyopes

Introduction and Rationale

Discomfort is the primary reason for contact lens dropout, but attempts to combat discomfort are often unsuccessful and result in discontinued contact lens wear.[33] When treatments focused on the ocular surface do not sufficiently alleviate contact lens discomfort, it is necessary to consider other factors that contribute to comfort. As discussed in Chapter 1, symptoms of contact lens discomfort are similar to symptoms associated with binocular vision and accommodative disorders.[22] Because myopes accommodate and converge more when corrected with contact lenses compared to spectacles,[90, 95] it is reasonable to hypothesize that myopic contact lens wearers with symptoms of discomfort, but no signs of significant ocular dryness, could be experiencing symptoms related to accommodative and/or convergence fatigue that they do not experience when corrected with spectacles.

If any portion of contact lens discomfort is being caused by accommodative and/or vergence fatigue, could a contact lens that alleviates this stress improve comfort? While contact lens corrections do not exist that compensate for vergence insufficiency or fatigue, aspheric multifocal contact lenses address blurred near vision by introducing spherical aberrations and increasing depth of focus.[131, 137, 189] As discussed in Chapter 5, research has been performed to determine how aspheric multifocal contact lenses affect accommodative responses in non-presbyopes. While some studies reported no significant change in accommodation when non-presbyopes were corrected with a multifocal contact lens,[137, 165, 166] others have demonstrated that accommodative effort may decrease with multifocal contact lenses in non-presbyopes.[167-169] The differences in conclusions may be, in part, due to error involved in measuring accommodation over the varied power profile of a multifocal contact lens.[166, 167] Due to the difficulty measuring accommodation through a multifocal lens, assessing symptoms of visual discomfort may be an optimal way to determine if visual fatigue symptoms are alleviated with a multifocal contact lens. By introducing a clear near image, it is possible that a multifocal contact lens could provide relief from accommodative fatigue and its associated symptoms. At the time of the study described below, no studies had investigated how multifocal contact lenses influence perception of comfort.

This study, the final experiment described in this dissertation, aimed to determine how contact lens comfort differs with single vision and multifocal contact lenses in myopic non-presbyopes. We hypothesized that myopic non-presbyopes with contact lens discomfort could experience symptom relief from aspheric multifocal contact lens correction. Recognizing the increased accommodative demands associated with magnitude of myopic contact lens correction and the natural decrease in accommodative amplitude that occurs with age, we also hypothesized that older subjects and those with increased magnitude of myopia may have improved comfort with multifocal contact lens correction.

Methods

For this randomized, subject-masked crossover clinical trial, uncomfortable non-presbyopic (30-40 years) myopic soft contact lens wearers were recruited. Threshold for significant discomfort was determined with the CLDEQ-8. Each subject received a single vision (Bausch + Lomb ULTRA®) and a multifocal contact lens (Bausch + Lomb ULTRA® for Presbyopia) to wear for two weeks each. ULTRA® for Presbyopia is a center near aspheric multifocal design. Subjects were masked and randomly assigned to the first lens and then crossed over to the remaining lens for the second two week period. Figure 11 displays a flow chart of study procedures. The study was registered at clinicaltrials.gov (NCT03544216).

Soft contact lens wearers with symptoms of discomfort were recruited using advertisements mailed and emailed to the Ohio State University faculty, staff, and communities throughout Columbus, Ohio. Interested subjects contacted investigators by email and/or phone. Subjects who reported a history of ocular surgery, strabismus/patching, or were currently using any type of ocular medication were excluded. Because this trial is testing the performance of a multifocal, each enrolled subject was required to report use of a digital device (smart phone, tablet, computer, etc.) for at least three hours per day to ensure adequate near viewing time was achieved. The CLDEQ-8, a survey validated to reflect change in opinion of contact lenses,[10, 190] was administered over the phone before scheduling the first study visit to ensure each subject had clinically significant discomfort symptoms. Subjects who achieved a score ≥ 12[190] and who met all inclusion criteria mentioned above were scheduled for a baseline visit. Table 8 lists complete inclusion criteria.

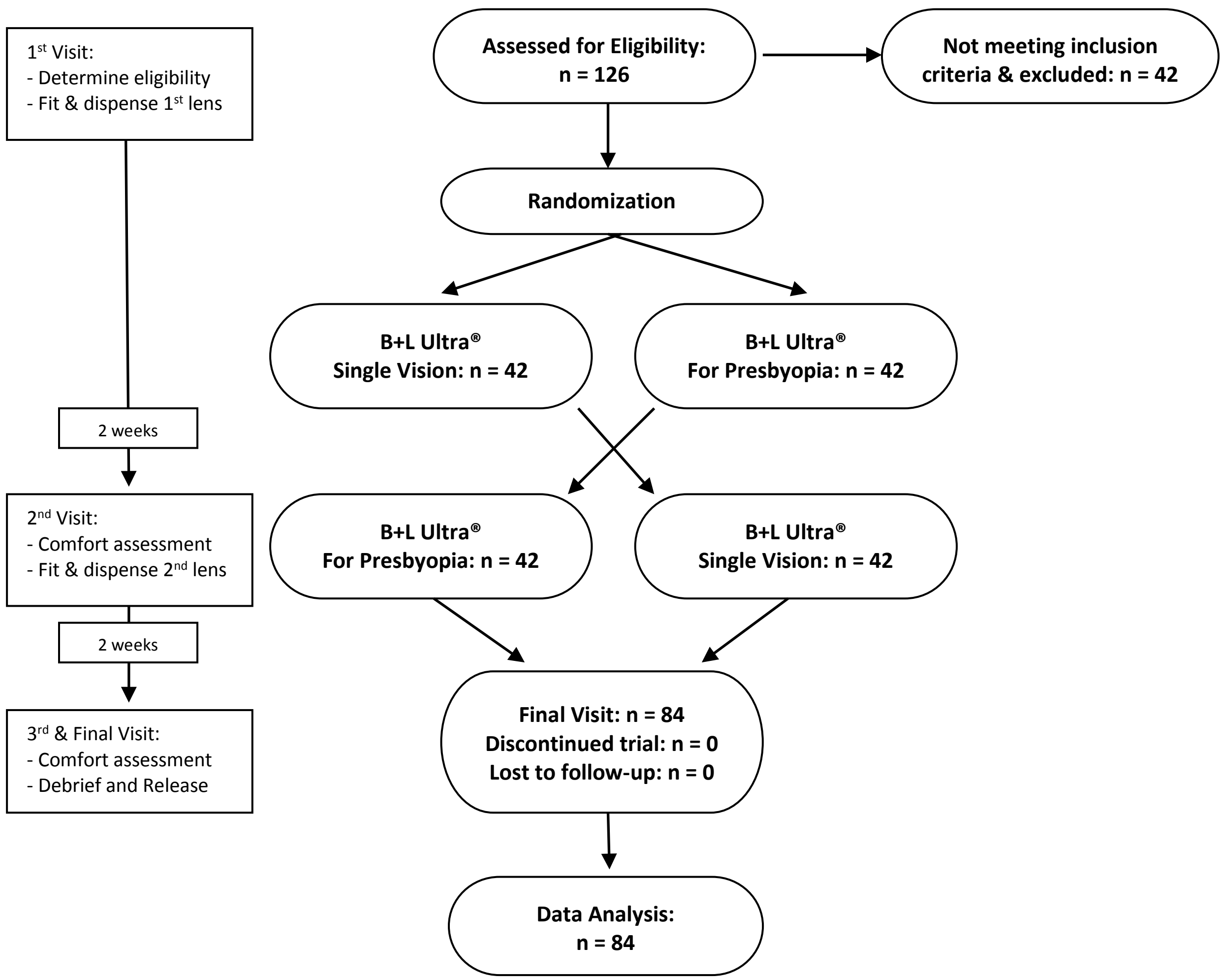

Figure 11: *Flow Chart of Randomized Crossover Clinical Trial Procedures*

Table 8: *Inclusion Criteria for Randomized Crossover Clinical Trial*

Personal Characteristics	Dry Eye Status	Binocular Vision Status
Soft, single vision contact lens wearer Visual acuity of 20/25 or better in each eye with habitual correction Myopic OU (-0.75 D or more myopic on autorefraction) Spherical OU (-0.75 D or less astigmatism on autorefraction) CLDEQ-8 score ≥ 12 points[190] No ocular surgery history No current ocular medication use Not currently using any type of reading aid (bifocals, multifocal contact lens, reading glasses, etc.) Reports cumulative digital device (smart phone, tablet, computer) of at least 3 hours per day	≤ Grade 1 ocular surface staining[191] Schirmer score ≥ 7 mm[192] Tear break-up time (TBUT) ≥ 7 seconds[192]	≤ 4 prism diopters eso or exophoria at distance and near (via Modified Thoringon)[193] Near point of convergence ≤ 6 cm[193] No history of strabismus, patching

Baseline Examination

At the baseline visit, inclusion criteria were confirmed (Table 8). Visual acuity was measured with each subject's habitual contact lens correction at distance (6 meters) using a high-contrast, Bailey-Lovie logMAR chart. Any subject who could not read the 20/25 line or better in each eye while wearing their habitual contact lenses was excluded.

Because symptoms of contact lens discomfort are similar to symptoms of binocular vision disorders,[22] the Convergence Insufficiency Symptom Survey (CISS), a survey validated to assess symptoms of convergence insufficiency,[85] was also administered. While the CISS has not been validated to specifically assess comfort, many CISS questions are similar to CLDEQ-8 questions and relate to asthenopia and ocular discomfort. The CISS, therefore, was administered in order to be a secondary measure of comfort throughout the study.

The main outcome measure in this study was contact lens discomfort, so the presence of any disorder with symptoms similar to contact lens discomfort would confound study results. Therefore, subjects with significant signs of dry eye and/or binocular vision disorders were excluded. Binocular vision testing included heterophoria testing at near and distance and near point of convergence (NPC). All testing was performed with the subject's habitual contact lens correction. Heterophoria testing was performed using the Modified Thorington method at distance (6 meters) and near (40 cm) because this particular method has been shown to be the most repeatable.[194] Subjects who had an esophoria or exophoria greater than four prism diopters at distance or near were excluded.[193] NPC was evaluated binocularly using the push-up technique and an accommodative (20/30) target on a fixation stick. NPC was repeated three times to determine a mean NPC. Subjects with a mean NPC greater than 6 cm were excluded from the study.[193]

After binocular vision testing, subjects removed their habitual contact lenses in order to determine objective refractive error and perform dry eye tests. Objective refractive error in each eye was measured using a Grand Seiko autorefractor while the patient viewed a distant (approximately 6 meters) viewing target. Because this study's hypothesis is based on the fact that myopes have to accommodate and converge more when corrected with contact lenses, only myopic subjects were included. Subjects who had spherical refractive error > -0.75 diopters in either eye, as measured by the autorefractor, were excluded. The multifocal contact lenses used in this study are not available in astigmatic powers, so any patient with more than 0.75 diopters of astigmatism in either eye, as measured by the autorefractor, was also excluded.

Tear break up time (TBUT), ocular surface staining, and Schirmer testing were performed to determine if a subject had significant signs of dry eye. A fluorescein sodium strip was used to instill fluorescein into the inferior palpebral conjunctiva of the right eye and measure TBUT. Each subject was positioned in a slit lamp and, after several blinks, asked to hold their blink for as long as possible. During this time, the tear film was observed with cobalt blue light and a yellow barrier filter and timed to when the first apparent tear break was recorded. TBUT was measured three times to obtain a mean value. Subjects with mean TBUT less than 7 seconds were excluded from the study.[192] Ocular surface staining was assessed according to the Oxford grading scale and any subject with ocular surface staining in the right eye (conjunctival or corneal) greater than grade 1 was excluded.[191] Schirmer test, which measures tear flow and volume, was measured without anesthetic using a Schirmer filter paper inserted in the inferior temporal conjunctival sac for five minutes. Subjects who had a Schirmer score less than 7 mm were excluded from the study.[192]

After all inclusion criteria were confirmed, subjects were enrolled and randomized to receive either the single vision or multifocal lens first. Randomization to treatment group was achieved using a random number generator to determine the order of allocation. Subjects were masked to which lens type they received during either period. Subjective manifest refraction was performed in both eyes to determine refractive error and contact lens powers. For the single vision and multifocal lens, the initial trial lens power was based on their vertexed spherical equivalent manifest refractive error. For the multifocal, a “Low Add” power was used in both eyes. Lenses were allowed to settle on the eyes for several minutes and vision was assessed. Over-refraction was performed to determine if adding/removing power at distance and/or near would improve subjective vision. Any preferred over-refraction was then demonstrated in office. The powers preferred by the patient were dispensed at the end of the visit. Lens fit was assessed using a slit lamp to ensure proper centration, movement, and corneal coverage in both eyes.

Subjects were instructed to wear the lenses as they would their habitual lenses. No minimum or maximum wear time was required, but subjects were asked to estimate their average wear time at each follow-up visit. Biotrue® solution and a new, clean contact lens case was dispensed to each patient. Subjects were instructed not to sleep in the contact lenses and to clean and soak the lenses each night with Biotrue® solution.

Second Visit and Crossover

After wearing the first dispensed lens pair for at least two weeks (but no longer than three), subjects returned for their second visit. The CLDEQ-8 and CISS were administered and subjects were asked to report their answers based on the first dispensed pair of lenses. For subjects that had been wearing the single vision lens, accommodative function (lead/lag) was measured using a Grand Seiko autorefractor. While viewing binocularly, accommodative responses (accommodative lead/lag) were measured in the right eye while the subject focused on an accommodative target at two and four diopters. We chose to analyze accommodative function after adaptation to the single vision lens only. Aspheric multifocal contact lenses create different refractive states across the pupil, and center near aspheric multifocals, like the one used in this study, have been reported to be particularly challenging to measure refractive state through.[166, 167] We did not analyze accommodative status with the habitual lenses, because, if the subjects were not appropriately corrected with those lenses, they may have been under- or over-accommodating for some time. Measuring accommodative lead/lag over the single vision contact lenses ensured that each subject's refractive error was optimally corrected (i.e. measurements were not influenced by over/under correction) and that autorefractor measurements were not affected by the optics of the multifocal lens.

Anterior segment assessment was performed in both eyes to assure no adverse ocular health events had occurred since the first visit. The subject discarded their first pair of study lenses, and the remaining study lens pair (single vision or multifocal, depending on what the patient wore first) was fitted according to the manifest refraction from the baseline visit. Vision and fit assessment were performed as described in the baseline visit and subjects were given identical contact lens wear and care instructions.

Final Visit

After wearing the second lens pair for two weeks (but no longer than three), subjects returned for their final visit. The CLDEQ-8 and CISS were administered and subjects were asked to report their answers based on the second dispensed pair of lenses. Anterior segment assessment was performed in both eyes to assure no adverse ocular health events had occurred since the last visit. Accommodative measurements, as described above, were performed if necessary. Subjects were asked to state which contact lenses (habitual, first study pair, or second study pair) they preferred for comfort, overall vision, distance vision, intermediate vision, and near vision. After subjects had completed all surveys and answered all subjective questions, they were informed of which lenses were the multifocal and single vision and dismissed from the study.

Data Analysis

Data analysis was performed using SAS (Version 9.3). Generalized linear models were produced to determine if factors like age, refractive error, and accommodative lag influenced symptom survey scores. Chi-Square tests were performed to determine if lens preferences for vision and comfort were different within age groups.

Sample Size Determination

For initial sample size determination, in order to detect a conservative standardized effect size of 0.6 ($\alpha = 0.05$, $\beta = 0.20$), a sample size of 45 subjects was determined to be necessary.[195] A previous crossover trial utilizing the CLDEQ-8 reported a 20% loss-to-follow-up rate.[10] Anticipating and accounting for a similar rate in our subject enrollment, we enrolled 54 subjects (27 in each group).

After these 54 subjects completed the study, preliminary data analyses were performed. In this initial group, the age group-lens type interaction for CLDEQ-8 symptom scores reported in Table 13, while clinically significant,[190] did not reach statistical significance ($p = 0.1$). We hypothesized that an increased sample size may allow us to definitively determine if this age group-lens type interaction exists. Because of the lack of software or well-developed methods for calculating the sample size for an interaction in a crossover study, a simulation study was conducted to estimate this sample size. The simulation assessed adding more subjects to the sample using the subjects currently in the sample. This iterative process was conducted to draw 10 different samples from which sample size was estimated in order to attempt to replicate the original finding with greater power. Given the simulation, it was estimated that an additional 30 subjects (15 in each group) would achieve this. Therefore, an additional 30 subjects were recruited and enrolled. The results section that follows reports results with all 84 subjects that were enrolled in the study over both recruitment periods.

Results

A total of 84 soft contact lens wearers with symptoms of discomfort (CLDEQ-8 score ≥ 12 points[190]) were enrolled. Mean age of enrolled subjects was 34.4 ± 3.2 years (30 to 40 years) and the mean binocular spherical equivalent manifest refractive error was -4.14 ± 2.00 (-10.0 to -1.00 D). All 84 subjects who qualified for the study at the baseline examination completed each of the three required study visits. No subjects dropped out of the study after enrollment and data from all 84 subjects were used in the analyses described below. At the initial baseline examination, 42 potential subjects did not qualify for the study. Figure 12 displays the frequency of reasons (convergence insufficiency, dry eye, etc.) for baseline examination failure.

There were no significant differences in age, spherical equivalent manifest refractive error, habitual CLDEQ-8 score, habitual CISS score, accommodative lag, or power of contact lens dispensed at the baseline visit between the two randomization groups (Table 9). Table 10 reports raw mean survey scores for the habitual, single vision, and multifocal contact lenses. Crossover analyses were performed to determine if, when controlling for order, the mean survey scores for the habitual, single vision, and multifocal lenses were different from one another. For both surveys, both test lenses (single vision and multifocal) performed better than

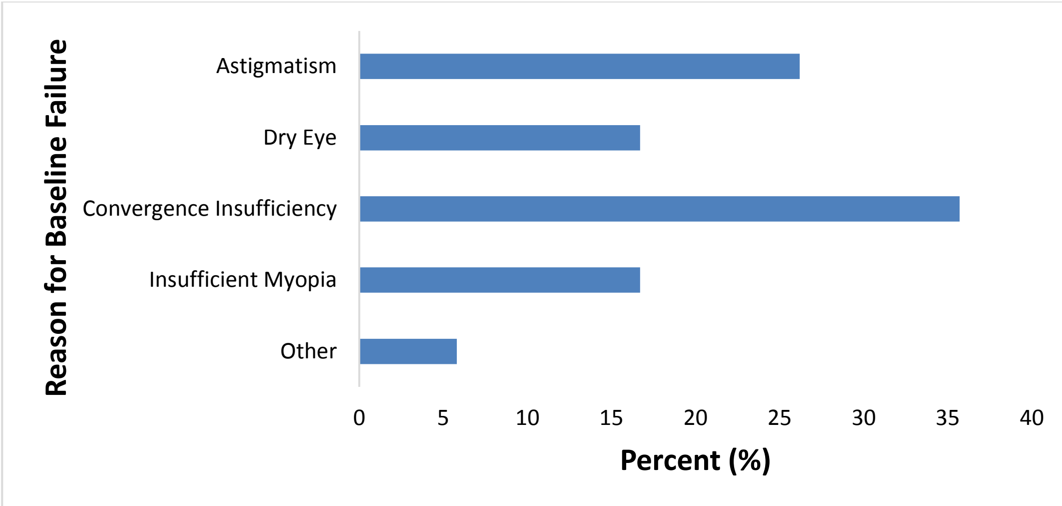

Figure 12: *Reasons for Baseline Examination Failure Reported in Percentages* (n = 42)

Table 9: *Mean Age, Refractive Error, Survey Scores, and Accommodation in the Entire Sample and by Treatment Group.* Mean (± standard deviation) age, spherical equivalent (SEQ) manifest refractive error (OD and OS), habitual Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score, habitual Convergence Insufficiency Symptom Survey Score (CISS), and accommodative lag (at 2 and 4 diopters) at the baseline visit for the overall sample and for the groups that received the single vision and multifocal contact lens first. The last column reports p-values of t-tests performed to determine if there was a statistically significant difference between each parameter in the single vision first and multifocal first group.

Variable	**Overall** (n = 84)	**Single Vision First** (n = 42)	**Multifocal First** (n = 42)	**p-value**
Age	34.4 ± 3.2	34.4 ± 3.4	34.5 ± 3.1	1.0
SEQ OD (D)	-4.1 ± 2.1	-4.2 ± 2.1	-4.0 ± 2.0	0.7
SEQ OS (D)	-4.2 ± 2.0	-4.2 ± 2.0	-4.1 ± 2.0	0.8
CLDEQ-8	19.0 ± 4.7	19.0 ± 4.5	19.1 ± 5.0	0.9
CISS	16.3 ± 8.3	16.0 ± 7.6	16.8 ± 9.2	0.7
Lag at 2 D (D)	0.9 ± 0.6	0.9 ± 0.5	0.8 ± 0.7	0.3
Lag at 4 D (D)	1.4 ± 0.8	1.3 ± 0.9	1.5 ± 0.7	0.2

Table 10: *Mean Survey Scores with Habitual, Single Vision, and Multifocal Contact Lenses.* Mean (± SD) Contact Lens Dry Eye Questionairre-8 (CLDEQ-8) and Convergence Insufficiency Symptom Survey (CISS) scores with each subject's habitual lens at baseline, the single vision test lens (Bausch + Lomb ULTRA®), and multifocal test lens (Bausch + Lomb ULTRA® for Presbyopia).

	Habitual	**Single Vision**	**Multifocal**
CLDEQ-8	19.0 ± 4.7 (12 to 31)	12.8 ± 6.6 (1 to 30)	14.3 ± 7.1 (1 to 24)
CISS	16.3 ± 8.3 (0 to 34)	11.1 ± 8.1 (0 to 35)	11.1 ± 7.9 (0 to 34)

Table 11: *Habitual, Single Vision, and Multifocal Survey Score Crossover Analyses*. Generalized linear models (controlling for repeated measures) of crossover analyses comparing mean Contact Lens Dry Eye Questionaire-8 (CLDEQ-8) and Convergence Insufficiency Symptom Survey (CISS) scores with habitual, multifocal, and single vision contact lenses (controlling for order, which was not significant for either survey).

Variable	**CLDEQ-8**		**CISS**	
	Least Squares Mean ± SE	p-value	Least Squares Mean ± SE	p-value
Habitual Lens	19.0 ± 0.7	$p < 0.001$†	16.3 ± 0.9	$p < 0.001$†
Multifocal Lens	14.3 ± 0.7		11.0 ± 0.9	
Single Vision Lens	12.8 ± 0.7		11.1 ± 0.9	

† Mean survey scores for the habitual lens were significantly different than the multifocal and single vision lens for the CLDEQ-8 ($p < 0.001$ for both comparisons) and the CISS ($p < 0.001$ for both comparisons). The mean single vision and multifocal lens survey scores were not significantly different from one another for the CLDEQ-8 ($p = 0.08$) or the CISS ($p = 0.9$).

the habitual lenses. Mean surveys scores did not differ significantly between the single vision and multifocal lens on either survey. Table 11 reports these crossover analyses.

The single vision and multifocal lenses used in this study were the same brand and material and had identical base curves and diameters. While wearing the test lenses, all subjects used the same solution (Biotrue®) for cleaning and storing. Contact lens powers worn by each subject were determined using objective and subjective measurements of refractive error in the same manner for each subject with all measurements performed by the same examiner. Detailed information (power, material, solution, etc.) regarding the habitual contact lenses worn by each subject was not collected and habitual lens factors like contact lens power, material, and replacement modality were not the same between all subjects. Data analysis from this point on, therefore, will focus on comparing the two test lenses: single vision (Bausch + Lomb ULTRA®) and multifocal (Bausch + Lomb ULTRA® for Presbyopia).

Univariate analyses were performed to determine if CLDEQ-8 or CISS scores were influenced by factors like lens type, order, age (continuous and categorical), mean binocular refractive error (continuous and categorical), accommodative lag, or visit. None of these variables were significantly associated with symptoms for either survey in univariate analyses.

Generalized linear models were produced to determine how refractive error, accommodation, and age affected survey scores. Tables 12 and 13 show the results for the models with interactions for refractive error, accommodation, and age for the CLDEQ-8 and the CISS. These tables report the least squares mean for categorical values, a mean that is estimated from the linear model and adjusted according to the other terms in the model. For continuous variables, the model estimate, which indicates the magnitude and direction the survey score is predicted to change, is reported. For both of these tables of analyses, as denoted in the table legend, the single vision lens is the reference. Therefore, when interpreting the results for continuous variables, the model estimate reported reflects the mean change in score predicted with the multifocal lens per variable unit.

Table 12: *Generalized Linear Models of Contact Lens Dry Eye Questionairre-8 (CLDEQ-8) and Convergence Insufficiency Symptom Survey (CISS) Scores with Interactions for Refractive Error and Accommodative Lag*. These analyses control for order, visit, (which were not significant for any model) and repeated measures. For continuous variables, the model estimate ± SE is reported in the place of the least squares mean ± SE and is denoted by italics. In these models, the single vision lens is the reference.

		CLDEQ-8		CISS	
		Least Squares Mean ± SE *(Model Estimate ± SE)*	p-value	Least Squares Mean ± SE *(Model Estimate ± SE)*	p-value
Model 1: Refractive Error (RE) (mean binocular spherical equivalent [SEQ], continuous)					
Mean SEQ		*(-0.2 ± 0.4)*	0.9	*(-0.3 ± 0.4)*	0.4
Lens* Mean SEQ		*(0.3 ± 0.5)*	0.5	*(0.1 ± 0.4)*	0.8
Model 2: Refractive Error (RE)(mean binocular SEQ, dichotomous)					
RE Categories	-6.0 to -0.75 D	13.3 ± 1.0	0.9	11.0 ± 1.4	0.9
	< -6.0 D	13.6 ± 0.6		11.1 ± 0.7	
Lens*RE	MF*-6.0 to -0.75 D	12.6 ± 1.8	0.1	10.3 ± 1.7	0.4
	MF*<-6.0 D	14.7 ± 0.8		11.2 ± 0.8	
	SV*-6.0 to -0.75 D	14.1 ± 1.8		11.7 ± 1.7	
	SV*<-6.0 D	12.5 ± 0.8		11.0 ± 0.8	
Model 3: Accommodative Lag (2D)					
Lag (2D)		*(-0.7 ± 1.4)*	0.7	*(-1.2 ± 1.3)*	0.1
Lens*Lag		*(0.6 ± 1.8)*	0.7	*(-1.5 ± 1.5)*	0.3
Model 4: Accommodative Lag (4D)					
Lag (4D)		*(-1.6 ± 1.2)*	0.4	*(-1.6 ± 1.2)*	0.1
Lens*Lag		*(1.6 ± 1.6)*	0.3	*(0.1 ± 1.4)*	0.9

Table 13: *General Linear Models of Contact Lens Dry Eye Questionairre-8 (CLDEQ-8) and Convergence Insufficiency Symptom Survey (CISS) Scores with Interactions for Age.* These analyses control for order, visit (which were not significant for any model), and repeated measures. For continuous variables, the model estimate ± SE is reported in the place of the least squares mean ± SE and is denoted by italics. Statistically significant differences are bolded. In these models, the single vision lens is the reference.

		CLDEQ-8		**CISS**	
		Least Squares Mean ± SE *(Model Estimate ± SE)*	p-value	Least Squares Mean ± SE *(Model Estimate ± SE)*	p-value
Model 1: Continuous Age					
Age		*(-0.1 ± 0.2)*	0.2	*(0.2 ± 0.2)*	1.0
Age*Lens		*(-0.3 ± 0.3)*	0.3	*(-0.5 ± 0.3)*	0.07
Model 2: Age Categories					
Age Categories	30 to <35 years	13.9 ± 0.8	0.5	11.0 ± 0.8	0.8
	≥ 35 years	13.1 ± 0.8		11.3 ± 0.9	
Age*Lens	MF * <35 years	**15.7 ± 1.0•†**	**0.047**	**11.8 ± 1.0**	**0.03‡**
	MF * ≥35 years	**12.9 ± 1.1•**		**10.3 ± 1.0**	
	SV * <35 years	**12.2 ± 1.0†**		**10.2 ± 1.0**	
	SV * ≥35 years	**13.3 ± 1.1**		**12.2 ± 1.0**	

• CLDEQ-8 MF scores in the < 35 age group appear to be higher (more symptomatic) than the ≥ 35 years age group according to clinical standards,[190] but this difference only approached statistical significance (p = 0.07).
† CLDEQ-8 MF scores were higher (more symptomatic) than SV scores in the <35 years age group (p = 0.01).
‡ Post-hoc testing did not result in p-values that indicated differences that approached statistical significance at the 0.05 level between the CISS survey scores and age groups.

At the completion of the study, each subject was asked which lenses (habitual, single vision, or multifocal) they preferred for overall comfort and vision at various distances (near, intermediate, distance, overall). Overall, the single vision lens was selected most for each vision condition and comfort, roughly half of the time for each. The multifocal lens was chosen second most, and the habitual lens was chosen least. Figure 13 shows the overall lens preferences at the end of the study. Recognizing the interaction between age group and lens type reported in Table 13, we analyzed lens preference by age group. Figures 14 and 15 compare lens preferences in the <35 years and ≥35 years age groups.

Chi-square testing was performed to determine if there were preference differences within the age groups. For the <35 year age group, there was a significant difference in lens preference for intermediate vision ($p = 0.02$), distance vision ($p = 0.003$), and overall vision ($p = 0.002$). No lens was significantly preferred for near vision ($p = 0.05$) or comfort ($p = 0.1$) in this younger age group. In the ≥ 35 years age group, no lens was significantly preferred for near vision ($p = 0.2$), intermediate vision ($p = 0.4$), distance vision ($p = 0.3$), overall vision ($p = 0.2$), or comfort ($p = 0.8$).

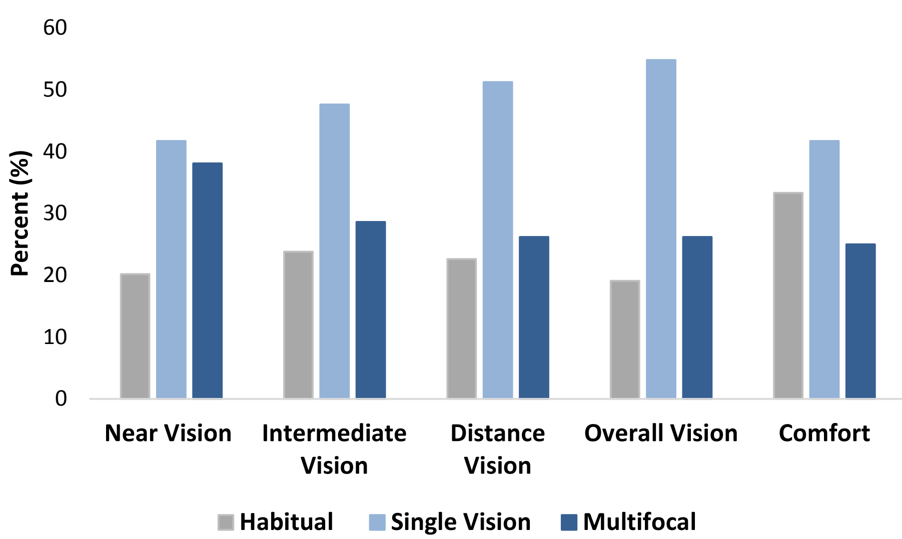

Figure 13: *Lens Preferences for Comfort and Vision in the Overall Sample* (n = 84)

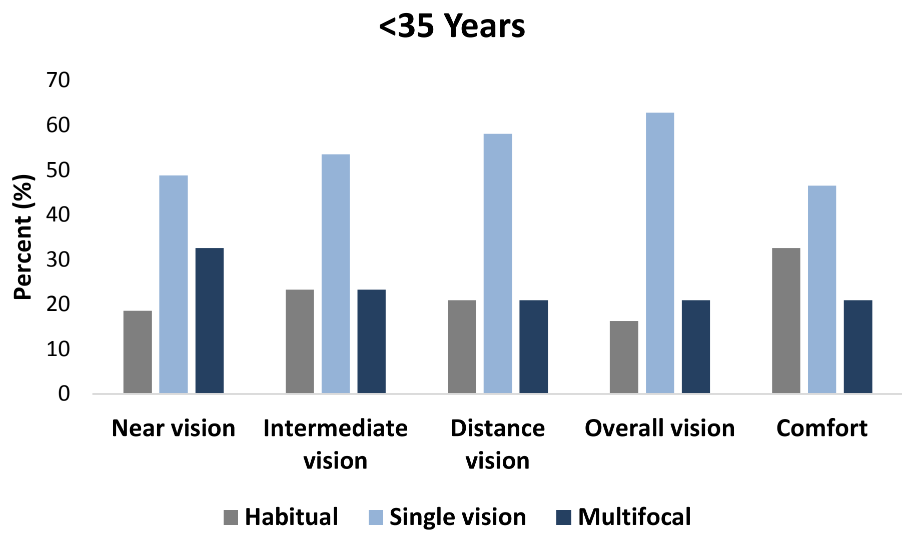

Figure 14: *Lens Preferences for Comfort and Vision in the < 35 Year Age Group* (n = 43)

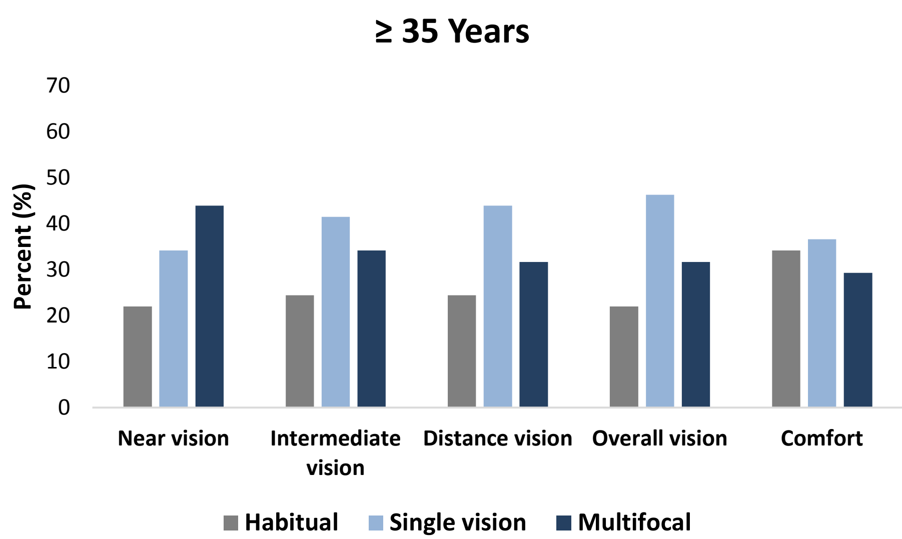

Figure 15: *Lens Preferences for Comfort and Vision in the ≥ 35 Year Age Group* (n = 41)

Discussion

Contact lens comfort improved with both test lenses. Mean CLDEQ-8 and CISS scores decreased significantly between habitual lenses and both the single vision and the multifocal lenses. The single vision lens, overall, was preferred subjectively for comfort and vision, but both the single vision and multifocal lenses improved symptoms of discomfort in the overall sample. These results may indicate that the material or physical design of the study lenses provide better comfort than other soft lenses.

Age Interaction

When determining what factors may affect comfort, age appears to influence both comfort and lens preference. Survey scores were significantly different between age groups for the single vision and multifocal lenses. On the CLDEQ-8, a clinically meaningful score difference is 3 points.[190] For subjects in the <35 year age group, the single vision lens provided approximately 3.5 points in comfort improvement compared to the multifocal. As well, the older age group (≥ 35 years) had approximately 2.8 points of improved comfort with the multifocal compared to the younger age group. A similar trend was observed with CISS scores, although post-hoc comparisons did not reach statistical or clinical significance. These results suggest that multifocal contact lens correction may not improve discomfort symptoms in younger non-presbyopic contact lens wearers as much as the single vision aspheric lens. Those wearers approaching age 40 years may have similar improvement in symptoms with either the multifocal or single vision design.

When asked about lens preference, the younger age group (<35 years) appeared to prefer the single vision lens for vision. In the older age group, however, preference for the single vision lens became less pronounced. For comfort and other visual distances in this age group, the difference between preference for single vision and multifocal lenses was not as distinct as in the younger group. For near vision preference in the older group, for instance, the multifocal appeared to be preferred over both the single vision and habitual lenses. Comparison of the differences in lens preferences between the two age groups supports the trends seen in the survey score interaction results for age and lens type.

For the both age groups, comfort improved with both the single vision and multifocal lens. In the younger age group, comfort was best and vision was preferred with the single vision lens. In the older age group, however, there was no significant comfort difference between the two lens types, and no significant preference was found for single vision or multifocal. These results suggest that those uncomfortable wearers approaching 40 year may benefit from a multifocal contact lens earlier than what is typically practiced clinically.

Aspheric Optics

The single vision and multifocal lenses are physically similar with the only major difference being optical design. The multifocal lens is a center-near aspheric multifocal with a "3-Zone Progressive" design aimed at maximizing near, intermediate, and distance vision.[196] Negative spherical aberrations are introduced to the center of the lens to increase depth of focus. The single vision lens, while not considered a multifocal or presbyopic lens, has a small amount of negative asphericity[197] aimed at correcting the positive spherical aberrations present in the majority of normal, healthy eyes.[198] It has been reported that aspheric single vision contact lenses do not affect or interfere with accommodation in adult eyes,[131] so it is unlikely that the single vision lenses significantly affected accommodation in this study. With optical design being the only notable physical or lens design difference between the two study lenses, any significant interactions between comfort scores and lens type and/or differences in preference for lens type were likely a result of the optical differences between the single vision and multifocal designs.

The multifocal lens induces the greatest change in depth of focus, aiming to provide a clear near image without accommodation. While the asphericity of the single vision lens is meant to only correct higher order aberrations, it is possible that this optical design provided some sort of visual fatigue relief. The data describing the age and lens type interactions and preferences support this idea. As discussed above, in the younger age group, the single vision lens produced better comfort scores than the multifocal. In the older age group, there were no comfort differences between the single vision and multifocal lenses. The preference results reflect these trends, as well. It is possible that, in the younger age group, the aspheric single vision lens provided an optimal amount of asphericity to relieve visual fatigue, but the greater magnitude of asphericity in the multifocal was too much for these younger wearers. Recognizing the natural decrease in accommodative amplitude with age, the older group may have been better able to appreciate and utilize the greater asphericity of the multifocal and the optical differences between the two lenses did not influence comfort. Future studies should examine how the small amount of asphericity in designs like the single vision lens used in this study affect comfort compared to single vision lenses that do not have aspheric optics.

Accommodation

Accommodative lag was measured after adaptation to the single vision study lens to determine if subjects with particular magnitudes of accommodative lag showed differences in comfort. No interactions were found between accommodative lag (at two and four diopters) and discomfort symptoms. These results could, in part, be due to the accommodative measurement technique. Accommodation was measured for a period of a few seconds and at different times of day for each subject. Perhaps the accommodation captured in the brief moments of the autorefraction measurement did not represent each subject's true accommodative posture. Because it was hypothesized that accommodative fatigue was contributing to symptoms of discomfort, more effective accommodative measurements may have been taken after periods of accommodative stress (i.e. long periods of reading, at the end of the work day). These measurements may have more accurately captured subjects who lagged more or less, and allowed more informed analyses of how accommodation affects comfort and lens preference. A future study could recruit subjects with confirmed accommodative insufficiency to determine if multifocal contact lens correction eases symptoms in these types of patients.

Refractive Error

Magnitude of refractive error did not influence mean CLDEQ-8 or CISS scores. Myopes must exert more accommodation when corrected with contact lenses compared to spectacles, and this discrepancy increases with magnitude of myopia. We hypothesized that, because the multifocal decreases the need to accommodate, myopes with higher amounts of refractive error may have improved comfort and/or prefer the multifocal lens. The mean refractive error of our sample was approximately -4.00 D. While our sample did include subjects with myopia a high as -10 D, the majority of subjects had refractive error in a more moderate range. In order to better explore this relationship, it may be more effective in future studies to recruit subjects based on refractive error to ensure each level and magnitude, especially those higher myopic ranges, are fully represented.

Baseline Failures

The results describing why potential subjects did not qualify for the study at baseline examination are notable and clinically relevant. Subjects had to achieve a significantly symptomatic score (≥ 12 points[190]) with their habitual lenses on the CLDEQ-8, ensuring that all enrolled subjects actually had contact lens discomfort. At that baseline exam, however, subjects could still be excluded if they had signs of binocular vision disorders and/or dry eye. While contact lens discomfort is often associated with presumed ocular dryness, the majority of baseline failures in this group of uncomfortable contact lens wearers were caused by signs of convergence insufficiency. Recognizing the similar symptoms of convergence insufficiency and contact lens discomfort and dry eye,[22] it is possible that some discomfort symptoms in this group may have been caused by convergence insufficiency.

Refractive error factors like uncorrected astigmatism and myopia that did not reach the study entry criterion were as or more influential as dry eye in excluding uncomfortable wearers from the study. Subjects who failed due to too much astigmatism reported that they were wearing non-astigmatic contact lens designs habitually. Subjects who were disqualified based on insufficient myopic refractive error were wearing corrections that they reported were -0.75 D or more myopic. Eyestrain related to uncorrected astigmatism or accommodative fatigue induced by overcorrection of myopia could certainly induce symptoms of discomfort. These findings should encourage eye care providers to ensure proper refractive error correction when investigating contact lens discomfort causes.

Conclusion

In conclusion, contact lens comfort improved with both the single vision and multifocal contact lenses in this study. Multifocal contact lens correction may induce discomfort symptoms in younger non-presbyopic contact lens wearers, but those wearers approaching age 40 years may have similar comfort improvement with either the multifocal or single vision design. Aspheric optics, while known to affect vision quality, may also influence comfort in contact lens wearers and future studies could investigate how aspheric optics influence visual fatigue in contact lens wearers of all ages.

In the older age group, there was no significant difference in comfort or preference for single vision or multifocal lens design. Uncomfortable wearers approaching 40 years may benefit from a multifocal contact lens earlier than what is typically practiced clinically. While obvious presbyopic symptoms like near blur do not present until after age 40 years, it is possible that symptoms of visual fatigue associated with presbyopic accommodative decline emerge in the years preceding 40. Our results suggest that patients approaching presbyopia may achieve vision and comfort benefits by trying a multifocal sooner in life.

Chapter 10: Summary and Final Discussion

The studies described in this dissertation, while testing various hypotheses, support the idea that contact lens discomfort may not caused by dry eye and ocular surface issues alone. Vision and symptoms associated with visual fatigue may affect a wearer's satisfaction and comfort with their contact lenses. Contact lens correction that fully addresses refractive error issues and accounts for presbyopia and visual fatigue may influence a wearer's perception of comfort and their overall satisfaction with contact lens correction.

Despite discomfort being the primary reason for discontinuation, patients want to wear contact lenses. The study presented in Chapter 8 showed that even spectacle wearers would prefer to wear contact lenses if they could achieve good comfort and vision. As well, demographic factors like age, gender, presbyopic status, or refractive error do not appear to influence a patient's desire to wear contact lens correction.

In presbyopes, a group of lens wearers known for being particularly uncomfortable, vision and discomfort were cited equally as reasons for discontinuation (Chapter 7). Considering the low rate of presbyopic contact lens prescribing, this finding could indicate that some discomfort related to contact lens wear in presbyopes is, at least in part, related to visual discomfort associated with accommodative decline and eye strain. It is possible that addressing the presbyopic visual needs of this population could improve comfort and allow these wearers to maintain comfortable contact lens wear.

Presbyopes may not be the only group of contact lens wearers who experience discomfort relief from contact lens modalities that alleviate accommodative fatigue and visual discomfort. The study reported in Chapter 9 showed that multifocal contact lenses may improve comfort in wearers before the age of 40 years. Specifically, those patients between the age of 35 and 40 years may have improved comfort in a multifocal contact lens. Because near presbyopic blur is not typically experienced until the early to mid-40's, multifocal contact lens correction is not commonly utilized before the age of 40 years. The conclusions of this study are clinically relevant because they encourage the utilization of multifocal corrections earlier in life to combat symptoms of discomfort and prevent near blur as presbyopia progresses.

Contact lens discomfort, while typically attributed to dry eye, is influenced by visual correction, especially in presbyopic wearers and those wearers approaching presbyopia. When addressing comfort complaints in these wearers, eye care providers must address binocular vision status, accommodative ability, and refractive error completely in order to determine if symptoms associated with visual fatigue are contributing to perceived contact lens discomfort. When fitting contact lenses, appropriate visual correction is as important as lens fit in achieving comfortable contact lens wear.

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