THE EFFECT OF MULTIFOCAL CONTACT LENSES ON ACCOMMODATION
AND PHORIA IN A PEDIATRIC POPULATION

By

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ABSTRACT

The increasing prevalence of the use of distance-centered multifocal (MF) contact lenses as a method of myopia control in the pediatric population calls for a better understanding of binocularity and accommodation in children wearing these lenses. This was a prospective, randomized, crossover, single visit study that enrolled myopic children with normal accommodation and binocular vision and no history of myopia control treatment. All subjects were fitted with CooperVision Biofinity single vision (SV) and MF (+2.50D center distance add) contact lenses. Accommodative responses (photorefraction) and phorias (Modified Thorington) were measured at 4 distances (>3m, 100cm, 40cm, 25cm). Secondary measures included high and low contrast logMAR acuity, accommodative amplitude, and accommodative facility. Differences between MF and SV contact lenses were analyzed using repeated measures regression and paired t-tests.

A total of 16 subjects, aged 10-15 years, completed the study. There was a small decrease in high (SV: -0.08, MF: +0.01) and low illumination (SV:-0.03, MF: +0.08) (both p<0.01) visual acuity, and contrast sensitivity (SV: 2.0 log units, MF: 1.9, p=0.015) with MFs. Subjects were more exophoric at 40cm (SV: -0.41 Δ, MF: -2.06 Δ) and 25cm (SV: -0.83 Δ, MF: -4.30 Δ) (both p<0.01). With MFs, subjects had decreased accommodative responses at distance (SV: -0.04 D; MF: -0.37 D, p=0.02), 100 cm (SV: +0.37 D; MF: -0.35 D, p<0.01), 40 cm (SV: +1.82 D; MF: +0.62 D, p<0.01), and 25 cm (SV: +3.38 D; MF: +1.75 D, p<0.01). There were no significant
differences in accommodative amplitude (p=0.66) or accommodative facility (p=0.54).

Children wearing MF contact lenses exhibited reduced accommodative responses and more exophoria at increasingly higher accommodative demands than with SV contact lenses. This suggests that children may be relaxing their accommodation and using the positive addition or increased depth of focus from added spherical aberration of the MF lenses. Further studies are needed to evaluate other lens designs, different amounts of positive addition and aberrations, and long-term adaptation to lenses.
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CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1.1 Myopia Prevalence

Myopia, or nearsightedness, is a condition in which light rays are focused in front of the retina causing blur in the distance, while objects at near can be focused clearly. It is one of the most common eye conditions in the world (Bourne, 2013) and has significantly increased in prevalence in the past few decades (Vitale, 2009; Holden, 2016). Myopia is commonly diagnosed in childhood and its magnitude is often increased with age during school years (Kleinstein, 2012). The prevalence of myopia in the United States increased from 24% to 34% in children 12-17 years between 1972 and 2008. In Taiwan, the prevalence of myopia increased from 37% to 61% in 12 year olds and, 74% to 84% in 16-18 year olds between 1983 and 2000 (Lin, 2004). According to Holden et al, the prevalence of worldwide myopia in children 10-14 years will increase to higher than 25% in 2050.

The prevalence of high myopia (at least -6.00 D) has also increased in certain parts of the world, especially East and South Asia (Rudnicka, 2016). In Taiwan, the prevalence of high myopia in 12 year old children increased from 0.2% to 3.4% between 1983 and 2000 (Lin, 2004). For 18 year old students, the prevalence of high myopia increased from 11% to 21% during the same time (Lin, 2004). Vitale et al classified high myopia as greater than -7.90 D and still found statistically significant increases across all age groups (12-54 years).
The progression of myopia is concerning due to its association with glaucoma (Mitchell, 1999), retinal detachment (Saw, 2005), choroidal neovascularization (Yoshida, 2003), and other serious ocular pathologies (Celorio, 1991; Wang, 2009), which can cause irreversible vision loss. In Japan, macular degeneration secondary to high myopia was found to be the most common cause of irreversible blindness (Iwase, 2006). Flitcroft pointed out that the calculated risks from developing ocular pathology with myopia are much greater than the associations between hypertension and cardiovascular disease. For example, for any degree of myopia greater than -1.00 D, the odds ratio for retinal detachment was 7.8, while the odds ratio for having a stroke given a systolic blood pressure of 160 mmHg or higher was only 3.2. (The Eye Disease Case-Control Study Group, 1993; Du, 1997; Flitcroft, 2012).

1.2 Myopia Control

Several animal studies have demonstrated that peripheral hyperopic defocus is an independent optical stimulation for axial elongation, leading to myopia (Irving, 1995; Smith 2007). Smith et al. optically imposed peripheral hyperopic defocus on infant rhesus monkeys using -3.00 D spectacle lenses with a 6mm aperture centered on the entrance pupil and showed the development of central axial myopia, despite clear images in the central retina. The same result was true for the monkeys that underwent foveal laser ablation and were subsequently fitted with -3.00 D goggles, indicating that the contribution of foveal signals is not required for axial elongation in response to peripheral hyperopic defocus (Smith, 2007).
There are also studies that theorize that increased near work and accommodative lag in myopes contribute to hyperopic defocus, and therefore lead to myopia progression (Saw, 2003; Allen and O’Leary, 2006). However, there is no consensus whether accommodative lag occurs before or after the onset of myopia (Rosenfield, 2002; Mutti, 2006), so a causal relationship has not been established.

Based on the theories of peripheral defocus and accommodative lag, several promising options to slow down the rate of myopia progression and potentially minimize associated complications have been trialed. These methods include undercorrection (Chung, 2002; Adler and Millodot, 2006), progressive additional spectacle lenses (Hyman, 2001), multifocal contact lenses (Anstice 2011; Walline, 2013; Lam, 2014), anticholinergic agents (Song, 2011; Siatkowski, 2008), and orthokeratology (Cho, 2012).

1.2.1 Pharmaceutical Agents

Atropine is one of the most studied pharmaceutical agents for myopia control (Chua, 2006), and is the preferred method of progressive myopia intervention in parts of Asia, including Taiwan (Fang, 2013). Atropine is a non-selective muscarinic receptor antagonist that when used by ophthalmic route, blocks the accommodative muscle of the ciliary body and leads to accommodative paralysis. Chua et al. proposed that atropine may act on the retina or sclera to decrease the rate of axial elongation (Chua, 2006). Barathi et al. proposes that atropine acts on the GABAergic signaling system to modulate scleral growth, although further studies are needed to better understand the mechanism (Barathi, 2014). Ocular side effects include photophobia, paralysis of accommodation,
and pupil dilation, and systemic side effects include tachycardia, restlessness, and dryness of the mouth, throat, and skin (North and Kelly, 1987).

Chua et al. evaluated the efficacy of once nightly 1% atropine eye drop compared to the vehicle eye drop in 400 myopic children aged 6-12 years for myopia control over 2 years in the Atropine for the Treatment of childhood Myopia (ATOM) study. After 2 years, the atropine-treated eyes progressed -0.28 ± 0.92 D in myopia, while the placebo-treated eyes progressed -1.20 ± 0.69 D; a 77% reduction of progression with atropine 1%. Differences between the two groups were statistically significant. However, a significant rebound effect of myopia progression was present after the one-year wash-out period (Tong, 2009).

ATOM 2 was a subsequent randomized clinical trial that assessed the efficacy and safety of lower doses of atropine for myopia control. Four hundred children aged 6-12 years were randomized to three groups: 0.5% atropine, 0.1% atropine, and 0.01% atropine. At the 2-year follow-up, Chia et al. reported a mean myopia progression of -0.30 ± 0.60 D, -0.38 ± 0.60 D, and -0.49 ± 0.63 D, respectively (Chia, 2012). After the one-year wash-out period, a myopic rebound was present for subjects that received the 0.5% and 0.1% atropine, and the effect of myopia control was more sustained in subjects that received the 0.01% atropine (Chia, 2014). Neither ATOM 1 nor ATOM 2 reported any serious adverse effects for atropine. Pupil dilation and loss of accommodation at near were symptoms that were reported for subjects that received higher dose atropine.

Pirenzepine is has also been shown to be an effective pharmaceutical agent for myopia control (Siatkowski, 2004; Tan, 2005). The mechanism of pirenzepine differs
from atropine in that its effects are selective for M1 muscarinic receptors, which are few in the iris and ciliary muscle. As a result, pirenzepine has a lesser effect of pupillary dilation and accommodation. Studies of myopia control using chick models have suggested that pirenzepine acts directly on the retina and sclera to decrease the rate of axial elongation (Frederick, 2002).

In 2004, Siatkowski et al. published the results of a multi-center randomized clinical trial in the United States, in which myopic children aged 8-12 years received either the 2% pirenzepine ophthalmic gel, or a placebo twice daily (Siatkowski, 2004). At the 1-year follow-up, subjects that received pirenzepine progressed \(-0.26 \pm 0.36\) D in myopia, while subjects that received the placebo treatment progressed \(-0.53 \pm 0.50\) D (p<0.001). The authors concluded that pirenzepine gel had an adequate safety profile for this subset of children, with the most common adverse effects being decreased accommodation, conjunctival reaction, and mydriasis. Neither atropine nor pirenzepine are approved by the United States Food and Drug Administration (FDA) for myopia control.

1.2.2 Undercorrection

Chung et al. randomized 94 myopic children aged 9-14 years to receive either full spectacle correction, or an undercorrection of +0.75 D over a period of 24 months. At the end of the study, the mean progression of myopia in the undercorrected group exceeded that of the fully-corrected group (-1.00 vs -0.77 D, p<0.01). In a similar study, Adler and Millodot randomized 48 myopic children aged 6-15 years to receive either full spectacle correction, or an undercorrection of +0.50 D over a period of 18 months. The
undercorrected group progressed by 0.17 D more than the fully-corrected group by the end of the study. Even though the difference between the two groups were not statistically significant, the same conclusion was drawn in Chung et al’s study, which had a larger cohort and lasted for a longer duration. Based on these clinical trials, undercorrection cannot be considered an effective myopia control treatment option.

A recent study by Sun et al. investigated the effect of uncorrection compared to full correction in myopic children (median age 12.7 years) over a two year period. Their results show that the uncorrected cohort progressed -0.75 ± 0.49 D while the fully corrected cohort progressed -1.04 ± 0.49 D, p<0.01). The efficacy of uncorrection for myopia control was found to increase with increasing amounts of undercorrection; up to 2 to 3 D (Sun, 2017). However, uncorrection of this magnitude may not be feasible for children in the United States. More information is needed to understand the mechanism and feasibility of uncorrection for myopia control.

1.2.3 Bifocal Spectacles

The mechanism of using plus addition lenses for myopia control has been speculated to be the reduction of accommodative demand to lessen the accommodative lag. Rosenfield and Carrel measured the accommodative response of 35 adults (7 emmetropes, 17 myopes, 4 hyperopes) aged 17-40 years wearing adds ranging from +0.75 to +2.00 D. All subjects manifested leads of accommodation when binocularly viewing a 40 cm target (Rosenfield, 2001). While spectacle adds have been shown to reduce accommodative lag, the efficacy of myopia control using spectacle adds is limited.

In 2001, The COMET study group conducted a large multicenter clinical trial to evaluate the efficacy of progressive addition lenses (PALs) compared to single vision
lenses (SVLs) for myopia control. 469 myopic children aged 6-11 years were randomized to either SVL or PALs with +2.00 addition. At the 3 year follow-up, the SVL cohort progressed -1.48 ± 0.06 D, while the PAL cohort progressed -1.28 ± 0.06 D (p=0.004). The effect of the PALs for myopia control, while present, is generally not considered clinically meaningful (Gwiazda, 2003). The 5 year follow-up revealed a 0.06% (0.13 D) difference between the two cohorts in myopia progression (SVL: -1.97 ± 0.09 D; PALs: -2.10 ± 0.09 D), which was not statistically significant (Gwiazda, 2011). Children with reduced accommodative response and near esophoria, however, were found to have a statistically and clinically significant treatment effect of 43% (0.64 D) less progression with PALs compared to SVLs at the 3 year follow-up. This was reduced to 24% (0.50 D) at the 5-year follow-up (Gwiazda, 2011).

Cheng et al. randomized 135 myopic children, aged 8-13 years, into one of three groups for myopia control: SVLs, +1.50 D executive bifocals, and +1.50 D executive bifocals with 3 prism diopters of base-in prism in the near segment (Cheng, 2014). At the 3-year follow-up, myopia progression was -2.06 ± 0.13 D, -1.25 ± 0.10 D, and -1.01 D ± 0.13 D, respectively. The treatment effect of bifocals and prismatic bifocals compared to SVLs was statistically significant. Additionally, children who had larger lags of accommodation benefited from both types the executive bifocal treatments, while children with lower lags of accommodation benefited most from the prismatic executive bifocals. Unlike the result found in the COMET study, the treatment effects of both types of bifocals were independent of the near phoria (Cheng, 2014). The improved efficacy reported with executive bifocals versus PALs could be that the segment line provides
feedback to the subject on where to look, or that the larger portion of the bifocal provides a greater area of defocus on the retina.

1.2.4 Orthokeratology

Orthokeratology is the utilization of a reverse geometry, gas-permeable contact lens to mechanically flatten the central corneal curvature, causing a relative steepening in the peripheral cornea. It has been shown to be an effective method of myopia control (Cho, 2005; Walline, 2009; Kakita, 2011). Several studies have suggested the mechanism of orthokeratology myopia control to be a decrease of peripheral hyperopic retinal defocus resulting in a slowing of axial elongation (Queiros, 2010; Kang, 2011).

Patients typically wear the contact lenses nightly and remove their lenses in the morning upon awakening. Because the effects of orthokeratology are temporary, it is common clinical practice to aim for a correction of +0.50 D hyperopia after an overnight wear. As the day progresses, it is expected for the patient’s refraction to regress, and some patients may experience distance blur at the end of the day. Ideal candidates for orthokeratology are individuals with low to moderate amounts of myopia (< -6.00 D), low amounts of astigmatism (< 2.00 D), and adequate tolerance of and motivation for gas permeable lens wear. Orthokeratology is reported to have a comparable safety profile to overnight soft lens wear, and is generally considered a safe option for myopia correction in children (Santodomingo-Rubido, 2012; Bullimore, 2013).

The Retardation of Myopia in Orthokeratology (ROMIO) study evaluated the efficacy of orthokeratology for myopia control in which 102 myopic children aged 6-10 years were randomized to wear orthokeratology lenses or single vision spectacles. At the
for subjects who wore orthokeratology lenses and single vision glasses, respectively (p<0.01). Cho et al reported that orthokeratology had a 43% reduction effect on axial growth, compared to single vision spectacles (Cho, 2012).

1.2.5 Soft Multifocal Contact Lenses

Soft multifocal contact lenses that are used for myopia control are distance-centered designs, meaning that the central portion of the lens optically corrects for the distance refraction, while a peripheral portion of the lens presents an add power that creates a myopic peripheral defocus on the retina. The myopic defocus formed by the positive spherical or aspheric addition of the contact lens may serve as an optical signal for slowing axial growth (Gwiazda, 2003).

In 2011, Anstice and Philips reported one of the first prospective clinical trials that evaluated the effectiveness of multifocal contact lenses in slowing myopia progression in children. The authors used a dual-focus (DF) lens that had a central zone for distance correction, and multiple concentric zones of +2.00 D that alternated with zones of distance correction. Forty myopic children, aged 11-14 years wore a DF lens in a randomly assigned eye and a single vision distance lens in the fellow eye for 10 months. After 10 months, the lens assignment was switched between eyes and the lenses were worn for an additional 10 months. At the first 10 month follow-up, the myopic progression from baseline was -0.44 ± 0.33 D in the eye that wore the DF lens, and -0.69 ± 0.38 D in the eye that wore the single vision distance lens. Axial elongation and myopic progression was similar in the DF lens at the end of the second 10 months. A 30%
reduction of myopia progression was observed in 70% of the eyes wearing the DF lens in this study (Anstice and Philips, 2011).

A large randomized clinical trial in Hong Kong conducted by Lam et al. utilized a custom Defocus Incorporated Soft Contact (DISC) lens for slowing myopia progression. The DISC lens has a central zone that corrects for distance refractive error and is surrounded by concentric rings of alternating powers of +2.50 D addition and normal distance correction. The study enrolled 221 myopic children aged 8-13 years, who were randomly assigned to receive the DISC lenses or the single vision contact lens. After two years, a 25% reduction in myopia progression for children that wore the DISC lens was observed, compared to those that wore a single vision lens. Additionally, children who wore the DISC lens for more than five hours/day progressed 46% less than those in the single vision group. These differences were statistically significant (Lam, 2013).

In 2013, Walline et al. fitted 40 myopic children aged 8-11 years in Proclear Multifocal +2.00 “D” (CooperVision, Fairport, NY) contact lenses, which is a commercially available soft multifocal lens, unlike previous myopia control studies that used custom lenses. Subjects were age- and gender-matched to participants from a previous study who wore single-vision contact lenses (1-Day Acuvue; Vistakon, Jacksonville, FL). At the 2-year follow-up, the mean myopic progression was -1.03 ± 0.06 D for subjects that wore the single-vision contact lenses, and -0.51 ± 0.06 D for subjects that wore the soft multifocal contact lens (p<0.0001). Walline et al. reported a 50% reduction in the progression of myopia and a 29% reduction in axial growth in this cohort compared to the historical control group (Walline, 2013).
A recent study by Aller et al. compared the effect of spherical lenses (Vistakon Acuvue 2) and the Vistakon Acuvue Bifocal on slowing myopia progression in 78 subjects, aged 8-18 years over a one-year period. All subjects enrolled were myopic and had an eso fixation disparity at near. Subjects who were randomized to the bifocal contact lens cohort wore a bifocal add that neutralized their associated phoria. After 12 months of treatment, the authors reported a mean myopic progression of \(-0.79 \pm 0.43\) D and \(-0.22 \pm 0.34\) D in the single vision and bifocal contact lens groups, respectively (p<0.001) (Aller, 2016).

In 2016, Cheng et al. reported on the efficacy of using a contact lens with positive spherical aberration on myopia control. One hundred twenty-seven myopic children (aged 8-11 years) were randomized to wear either a spherical soft contact lens or a test lens with positive spherical aberration. The authors reported a spherical equivalent cycloplegic autorefraction change in the test lens of 0.21 D less than the control lens from baseline at 6 months (p<0.05), which decreased to 0.14 D at 12 months (p=0.068). The authors suggest that the treatment effect of this soft contact lens with positive spherical aberration may occur in the first 6 months, and diminishes with time (Cheng, 2016).

A number of observational and randomized clinical trials have demonstrated myopia control efficacy with various types of contact lens designs from commercially available multifocal contact lenses to custom lens designs. Figure 1 summarizes the myopia control efficacy on slowing of axial length.
Figure 1: Summary of multifocal contact lens efficacy on myopia control.

In summary, it is accepted that atropine/pirenzepine, orthokeratology, and multifocal soft contact lenses are effective methods of myopia control compared to single vision spectacles or single vision contact lenses. Undercorrection is not effective, while bifocal spectacles, and PALs have limited efficacy for slowing myopia progression. Various modalities for myopia control and their efficacy are summarized in Figure 2 (Huang, 2016).

Given the efficacy of soft multifocal lens designs, they are growing in use as an off-label treatment for myopia control. The use of multifocals in children has lead to questions regarding their potential effect on binocular vision and accommodation.

Figure 2: Results of network meta-analysis using single vision spectacle lenses/placebo as referent intervention (adapted from Huang et al., 2016).
Atropine High = 1% or 0.5% Atropine; Atropine Mod = 0.1% Atropine; Atropine Low = 0.01% Atropine; MF = multifocal; PALs = Progressive addition spectacle lenses; SV = single vision

1.3 Binocular Vision and Accommodation in Children

The proliferation of digital devices in the last decade is associated with an increased amount of symptoms of visual stress at near (Rosenfield, 2011). Symptoms of visual stress include blurry vision, fatigue, headaches, double vision, and asthenopia, and are usually caused by an underlying accommodative and non-strabismic binocular dysfunction (Schieman & Wick, 2008). Most children today grow up in media-rich environments in the presence of computers, smartphones, television, and tablets, which is
unprecedented in previous generations (Chaudron, 2015). An underlying accommodative and vergence disorder can interfere with a child’s visual system to function efficiently, and as a result, a child may become symptomatic after prolonged near work (Garcia-Munoz, 2014). Below is a brief literature review on the prevalence, signs, and symptoms of common vergence and accommodation disorders in children. While vergence and accommodative disorders are presented separately, it is important to note that these conditions often co-exist (Schieman & Wick, 2008).

1.3.1 Vergence Disorders

Vergence disorders are often categorized by Duane’s classification, which describes the binocular vision anomaly based on the type of heterophoria measured at distance and near (Scheiman & Wick, 2008). Specifically, Duane’s classification encompasses convergence insufficiency, convergence excess, divergence insufficiency, and divergence excess. However, Wick points out that this classification system does not include other binocular vision anomalies such as basic exophoria, basic esophoria, or fusional vergence dysfunction (Scheiman & Wick, 2008). While these are not as commonly studied, they are encountered clinically.

The most studied binocular vision disorder is convergence insufficiency (CI), which has a reported range of prevalence in children of 2.25% to 33% (Letourneau, 1988; Dwyer, 1992). The reasons of discrepancies in prevalence are due to different diagnostic criteria (i.e. varying number of clinical signs used and cut-off points) and population characteristics of studies (Cacho-Martinez, 2010). Most recently, the Convergence Insufficiency Treatment Trial (CITT) defined the clinical signs of CI to be exophoria
greater at near than at the distance, a receded near point of convergence, and a reduced positive fusional vergence at near (Scheiman & Wick, 2008). Symptoms of CI include, but are not limited to double vision, asthenopia, headaches, and blurry vision typically during near work (Scheiman, 2005; Garcia-Munoz, 2014).

Convergence excess is characterized as esophoria at distance with a normal tonic vergence, or esophoria at near with a high tonic vergence (Scheiman & Wick, 2008). The prevalence of convergence excess in children range from 7.1% to 15% (Dwyer, 1992; Scheiman, 1996). Scheiman et al. investigated the prevalence of visual conditions in 1,650 children aged 6-18 years in an urban population, and Dwyer et al investigated 144 children (mean age 11.5 ± 3.19 years). However, the number of clinical signs in their diagnostic criteria of convergence excess was not reported in either study. Symptoms of convergence excess are similar to that of CI.

Divergence insufficiency is characterized as esophoria at distance with a low tonic vergence (Scheiman & Wick, 2008). The prevalence of divergence insufficiency in children range from 0.1% to 0.7% (Dwyer, 1992; Scheiman, 1996). Symptoms of divergence insufficiency are similar to that of CI, except symptoms typically worsen at the distance (Scheiman & Wick, 2008).

Divergence excess is characterized as exophoria in the distance with a high tonic vergence (Scheiman & Wick, 2008). The prevalence of divergence excess has been reported as 0.7% and 0.5% in non-strabismic populations (Dwyer, 1992; Scheiman, 1996). Associated clinical signs may include suppression in the distance, but normal distance negative fusional vergence ranges and adequate heterophoria and vergence
ranges at near (Scheiman & Wick, 2008). Symptoms of divergence excess are similar to that of divergence insufficiency.

The prevalence of basic exophoria in children 6-18 years has only been reported in one study as 0.3% (Scheiman, 1996). Porcar et al., and Lara et al. reported the adult prevalence of basic exophoria as 3.1% and 0.4%, respectively (Porcar, 1997; Lara 2001). Schieman et al. did not report the number of clinical signs in their diagnostic criteria, while Porcar et al. used three clinical signs to define basic exophoria. These clinical signs are exophoria of equal magnitude at distance and near, a normal AC/A ratio (4/1 ± 2), and reduced positive fusional vergence ranges at distance and near. Lara et al. used a similar diagnostic criteria, but included one more clinical sign (binocular accommodative facility less than 3 cycles per minute, monocular estimate method (MEM) less than 0 D, or NRA less than or equal to 1.50 D) (Lara, 2001). Patients with either basic exophoria symptoms similar to those with CI, or may be asymptomatic (Scheiman & Wick, 2008).

The prevalence of basic esophoria has been reported as 9% by Dwyer et al (Dwyer, 1992) and 0.6% by Scheiman et al (Scheiman, 1996) in children. Schieman and Wick describe basic esophoria as esophoria with a similar magnitude at distance and near, accompanied by reduced negative fusional ranges. Symptoms of basic esophoria include headaches, eyestrain, blur, and diplopia, or patients may be asymptomatic (Scheiman & Wick, 2008).

The prevalence of fusional vergence dysfunction in children has only been reported in one study as 0.4% (Scheiman, 1996). One study reported the adult prevalence of fusional vergence dysfunction as 1.5%, and defined their diagnosis as orthophoria at distance and near, a normal AC/A ratio (4/1 ± 2), and reduced positive and negative
fusional vergences at distance and near (Porcar, 1997). Symptoms of fusional vergence dysfunction are similar to that of basic exophoria or basic esophoria (Scheiman & Wick, 2008).

There are often disparities for the prevalence values between studies due to inconsistencies and a lack of consensus of how a binocular disorder is defined (Cacho-Martinez, 2010). Some studies did not report the number of clinical signs used to define a vergence disorder. A stricter definition of a binocular vision disorder, such as when using more than one clinical sign, is typically correlated with a lower prevalence of the disorder (Cacho-Martinez, 2010).

1.3.2 Accommodative Dysfunction in Children

Accommodative anomalies are typically categorized into accommodative insufficiency (AI), accommodative excess, and accommodative infacility. Symptoms of accommodative deficits include constant or intermittent blur at distance or near, eyestrain, or fatigue during near visual tasks (Schieman & Wick, 2008).

Four studies have reported the prevalence of AI in children, which range from 2% to 61.7% (Schieman, 1996; Rouse, 1999; Abdi, 2005; Borsting, 2003). Similar to prevalence studies of CI, there is a large disparity with regards to prevalence values offered by different authors due to how the condition is defined. Schieman et al. reported a prevalence of 2% in children 6-18 years (n=1,650), but did not report the number of signs needed in their diagnostic criteria, while Abdi et al. reported a prevalence of 61.7% in children 6-16 years (n=120) and defined AI using only one diagnostic criteria, which was having a near point of accommodation via push-up method greater than or equal to
10 cm. Most studies on adults define AI as having a decreased amplitude of accommodation of at least 2.00 below the minimal age-appropriate amplitude (Schieman & Wick, 2008). However, some authors report a multiple sign criteria, including values for positive relative accommodation, MEM, and/or monocular and binocular accommodative facility (Rouse, 1999; Borsting, 2003), but there is no consensus.

Porcar et al. and Schieman et al. reported the prevalence of accommodative excess in children as 1.8% and 8%, respectively. However, neither study reported the number of clinical signs used in their diagnostic criteria in children. Porcar et al also estimated the adult prevalence of accommodative excess to be 10.8% and defined the condition using five clinical signs: variable visual acuity findings, monocular accommodative facility less than or equal to 6 cycles per minute (cpm) and a binocular accommodative facility less than or equal to 3 cpm with a +2.00 D, a MEM of less than or equal to 0.25 D, and a fused cross-cylinder of less than 0 D (Porcar, 1997). The AOA Clinical Guidelines consider the hallmark of accommodative excess to be a lead of accommodation, but may include other signs such as difficulty clearing +2.00 monocularly, and having a reduced negative relative accommodation (AOA, 2010).

The reported prevalence of accommodative infacility in children range from 1.2% and 5% (Scheiman, 1996; Dwyer, 1992). Accommodative facility is traditionally evaluated over a period of one minute using +2.00 and -2.00 D flippers (Wick, 2002). Established normative data report 8 cpm for binocular accommodative facility and 11 cpm for monocular accommodative facility in adults 18-30 years (Zellers, 1984). However, Schieman et al. has shown that children do not perform as well as adults, and
established the norms of children 7-12 as greater than 4.5 cpm for monocular accommodative facility (Schieman, 1988).

Table 1: Binocular and accommodative norms in children and adults

<table>
<thead>
<tr>
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<th>Children</th>
<th>Adults</th>
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<tr>
<td></td>
<td>Expected Finding</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>Accommodation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amplitude of accommodation</td>
<td>18-1/3 (age)(^1)</td>
<td>± 2 D</td>
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<tr>
<td>(push-up)</td>
<td></td>
<td></td>
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<tr>
<td>Binocular Accommodative Facility (± 2.00 D Flippers)</td>
<td>8-12 years: 5.0 cpm(^1)</td>
<td>± 2.5 cpm</td>
</tr>
<tr>
<td>Accommodative Lag (Monocular estimation method retinoscopy)</td>
<td>+0.50 D(^1)</td>
<td>± 0.25 D</td>
</tr>
<tr>
<td>Vergence</td>
<td></td>
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<tr>
<td>Horizontal Distance Heterophoria</td>
<td>6-12 years: 0.6 PD esophoria(^2)</td>
<td>± 1.7 PD</td>
</tr>
<tr>
<td>Horizontal Near Heterophoria (40 cm)</td>
<td>6-12 years: 0.4 PD exophoria(^2)</td>
<td>± 3.1 PD</td>
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</table>

cpm = cycles per minute; PD = prism diopter; D = diopter

References: ¹ Scheiman and Wick, 2008; ² Jimenez et al., 2004
1.4 Previous Studies on Accommodation and Binocular Vision in Non-Presbyopic Subjects Fitted with Multifocal Contact Lenses

While multiple studies have demonstrated efficacy in myopia control using multifocal lenses (Walline, 2013; Anstice, 2011; Sankaridurg, 2011; Aller, 2016; Cheng, 2016), only a few studies have evaluated accommodative and binocular outcomes with multifocal contact lenses in non-presbyopic subjects, and with mixed results. Below is a brief literature review of studies that have evaluated the effect of multifocal contact lenses on accommodation and binocular vision in non-presbyopic populations.

In 2008, Tarrant et al. evaluated accommodative response in subjects wearing bifocal soft contact lenses (Tarrant, 2008). Thirty-five young adults, aged 22.8 ± 2.5 years (10 emmetropes and 25 myopes) were enrolled and fitted with single vision distance, single vision near (+1.50 D), and bifocal (distance-center, +1.50 D) soft contact lenses. The reported multifocal lens had a central zone for distance correction, and five alternating distance and near zones extending over an 8 mm diameter optic zone. Emmetropes were fit with +0.25 D lenses as their distance prescription. The authors measured accommodative responses at four distances (100 cm, 50 cm, 33 cm, and 25 cm) using a Grand Seiko WR-5100K refractometer. Under binocular conditions, accommodative response was measured through the non-dominant eye, and under monocular conditions, accommodative response was measured consensually of the fellow eye, which was also occluded by an infrared (IR) filter. The authors reported that both emmetropes and myopes exhibited accommodative lag at all distances when wearing the single vision distance contact lens, with myopes exhibiting more accommodative lag than emmetropes. With the single vision near contact lenses, emmetropes exhibited a lead of
accommodation at 100 cm and 50 cm, and a slight lag of accommodation at 33 cm and 20 cm, while myopes continued to exhibit lags of accommodations at all distances. Based on their assumption that the subjects used the full labeled add, they reported that all subjects exhibited leads of accommodation with bifocal contact lenses. The authors concluded that both single vision near lenses and bifocal contact lenses can reduce or eliminate accommodative lags. The authors attributed accommodative leads found in bifocal contact lenses to be due to increased depth-of-focus and positive spherical aberration found in these lenses. However, in calculating accommodative errors, the authors assumed that the bifocal lens provided the same near add as the single vision near lens. For example, for a 25 cm target, the authors estimated that the accommodative demand was -2.50 D instead of -4 D when subjects were wearing both the single vision near and bifocal contact lens. Because we do not understand how subjects’ accommodative system responds to the bifocality of a contact lens, it is not an appropriate assumption to make. Therefore, the authors’ conclusion that the leads of accommodation observed in bifocal contact lenses may underlie their beneficial effects on myopia progression, should be interpreted with caution.

Anstice and Philips published the only study that evaluated accommodation through bifocal contact lenses in a pediatric population (Anstice, 2008). Forty myopic children, aged 11-14 years wore a DF lens in one eye and a single vision distance lens in the fellow eye for ten months, then switched the lens assignments for a subsequent ten months. While the primary and secondary outcomes were spherical equivalent refraction and axial length, respectively, the authors also measured accommodation through the DF lens using an open-field autorefractor to determine if myopic defocus was presented to
the retina during distance and near viewing (i.e., if the children were accommodating normally). Anstice and Philips suggested that if the children used the treatment zones as a near addition, then the correction zones would have produced a hyperopic defocus on the retina, which may have a myogenic effect on the eye, rather than a protective effect from axial elongation. Accommodative response was measured as a consensual response at a distance target of 4 m and a near target of 40 cm under two binocular conditions. In the first condition, the subjects wore the DF lens in one eye and the single vision distance lens in the fellow eye. In the second condition, the subjects wore the DF lens in one eye and a single vision near (+2.50 D) contact lens in the fellow eye. In the latter condition, the authors expected the stimulus to accommodation to be 0 D when viewing a near target, so any measurable accommodative response was attributed to the eye wearing the DF lens. Accommodative response was measured at three separate visits: 2-weeks, 10 months, and 20 months, statistically significant differences between DF and single vision distance (p=0.81) and DF and single vision near (p=0.31) contact lenses were not found.

Results show that the subjects’ mean accommodative response to the near target was 2.07 D (95% CI: 2.62 – 1.52 D), or an accommodative lag of 0.43 D, when wearing the DF and single vision distance lens combination, and 1.78 D (95% CI: 2.66 – 0.91 D) when wearing the DF and single vision near lens combination. Because the subjects accommodated using the DF/single vision near lens combination, the authors suggested that children accommodated normally through the DF lens using the distance portion of the correction. However, because the viewing conditions were binocular, it is unclear which eye/lens combination was used by the child to focus on the near target.
Madrid-Costa et al. evaluated the accommodative response of ten adults (mean age 28.6 ± 2.72 years) wearing a single vision distance contact lens, and three types of aspheric center-near multifocal contact lenses: PureVision Low Add (Bausch & Lomb, Rochester, NY), PureVision High Add (Bausch & Lomb, Rochester, NY), and Focus Progressives (CIBA Vision, Duluth, GA) (Madrid-Costa, 2011). Accommodative responses were measured monocularly through the right eye at 25 and 40 cm using a Hartmann-Shack aberrometer at 14 Hz. Unlike the bifocal contact lenses mentioned in the previous two studies, these lenses all have a central zone of near addition and provide a continuous myopic power gradient toward the periphery of the lens. The authors did not find statistically significant differences in accommodative response between the single vision distance lens compared with each of the multifocal contact lenses at 40 cm (p=0.212) and 25 cm (p=0.085). However, it is important to note that an accommodative lag was found in all lens modalities and that an increase in accommodative lag was found with an increased accommodative stimulus demand.

Most recently, Kang and Wildsoet evaluated the effects of a single vision distance contact lens and two aspheric distance-centered multifocal contact lenses on accommodation and binocular vision in twenty-four young adults, aged 18-28 years, over a period of two weeks (Kang, 2016). The lenses used were the Proclear (CooperVision, Pleasanton, CA) sphere, and +1.50 D and +3.00 D multifocals. The authors attempted to measure the accommodative response centrally using a high contrast, 20/80 letter target and the Complete Ophthalmic Analysis System (COAS) wavefront analyzer (Abbott Medical Optics, Albuquerque, NM) as well as peripherally using a modified Maltese cross and the Shin-Nippon NVision-K 5001 autorefractor (Tokyo, Japan). The modified
Maltese cross is a high contrast target that span 40° of the visual field with a white circle overlaying the central 20°. Near phoria and near fixation disparity were measured using a working distance of 40 cm.

With the on-axis accommodative targets, subjects exhibited accommodative lags of 0.63 ± 1.36 D, 1.12 ± 0.70 D, and 0.82 ± 1.01 D for a target at 33 cm with single vision distance, +1.50 D, and +3.00 D multifocal contact lenses, respectively. With the modified Maltese cross, subjects exhibited accommodative lags of 1.65 ± 0.94 D, 1.19 ± 0.66 D, and 1.00 ± 0.82 D, respectively, which is greater than the accommodative lags found with the central accommodative target and those found with the standard Maltese cross. It is interesting to note that an increased accommodative lag was found with both multifocal lenses compared to the single vision distance contact lens using a 20/80 letter, but the opposite is true when using the modified Maltese cross. The results of the on-axis accommodative target contrast those of Tarrant et al. who found leads of accommodation in young adults viewing a 33 cm target with bifocal contact lenses. The authors attribute the larger decreased accommodative responses (and hence, a decreased drive for accommodation) found in response to the modified Maltese cross to be the result of relative myopic defocus produced by the multifocal contact lens. With the use of the modified Maltese cross, however, it is unclear where the subject is viewing and whether the subject maintained steady fixation throughout the measurement, and these ambiguities may affect the measured accommodative responses. There were no statistically significant differences reported in any of the accommodation measurements between the baseline visit and the 2-week follow-up visit, suggesting no “adaptation” to the lenses.
Kang and Wildsoet also reported exophoric shifts in near heterophoria and near fixation disparity in both multifocal contact lenses compared to the single vision distance lens (Kang, 2016). These changes were statistically significant for heterophoria (p=0.02 between single vision distance and +1.50 D; p=0.001 between single vision distance and +3.00 D), but not for near fixation disparity (p=0.45 and p=0.18, respectively). Specifically, the authors reported approximately 2Δ, 4Δ, and 5Δ exophoria in single vision distance, +1.50 D, and +3.00 D multifocal lenses, respectively, for a 33 cm target. There were no statistically significant differences in exophoria between the baseline visit and the 2-week follow-up in both multifocal lens types.

1.5 Purpose of Study and Significance

Since myopia control lenses are intended to be worn by children, who have very different accommodative and binocular systems than adults (Jimenez, 2004; Scheiman and Wick, 2008) it is critical to understand if accommodation and binocular function is affected by multifocal contact lenses in children. The aim of the current study was to examine the effect of a commercial distance-center multifocal contact lens designed for presbyopia on accommodation, heterophoria, and other visual functions in a pediatric, myopic population.
CHAPTER TWO

METHODOLOGY

2.1 Overview

This prospective, randomized, single-visit, cross-over study was conducted in pediatric subjects at the State University of New York (SUNY) College of Optometry. The study was approved by the SUNY Optometry Institutional Review Board, registered on ClinicalTrials.gov (NCT #02180347), and adhered to the tenets established by the Declaration of Helsinki. All subjects and their parents/guardians gave their written assent (Appendix A) and consent (Appendix B) to participate in the study.

2.2 Subject Recruitment and Eligibility

Patients were recruited from the University Eye Center (UEC) at the SUNY College of Optometry. Inclusion criteria were age between 7 and 15 years, best corrected visual acuity of 20/25 or better, refractive error between -1.00 and -8.00 D with less than or equal to 1.00 D of astigmatism, and no history of any ocular condition, binocular vision disorder, prior participation in myopia control, or use of any pharmaceutical agent that is known to affect accommodation. UEC records were reviewed to ensure eligibility. Subjects did not need to have previous experience with contact lens wear.

2.3 Baseline Testing

Snellen visual acuity, non-cycloplegic autorefraction, and slit lamp examination were performed to verify eligibility. Autorefraction was taken as the average spherical
equivalent of three measurements with the Grand Seiko WAM-5500 Binocular Autorefractor (Grand Seiko Ltd., Hiroshima, Japan).

2.4 Contact Lens and Randomization

The study used Biofinity brand sphere and distance-center design multifocal contact lenses with an add power of +2.50 D (comfilcon A, 48% water content, CooperVision; USA). This add power was chosen based on previous research indicating that +2.00 to +2.50 was the maximum visually acceptable add power for children (Bickle, 2013). Both lenses have a base curve of 8.6 mm and a diameter of 14.0 mm. The multifocal lenses are designed with a central distance zone of 3 mm, with a gradually increasing positive power towards the periphery of the optic zone.

Subjects underwent testing with both types of contact lenses, but were randomized to begin with either the spherical single vision distance contact lens, or multifocal contact lens. Contact lenses were worn binocularly throughout all tests except for photorefraction in the multifocal contact lens condition. Under the multifocal condition during photorefraction, the multifocal contact lens on the right eye was switched to a single vision contact lens to allow accurate measurement of accommodative response (see details below). The distance prescription for both lenses was selected as the average spherical equivalent measure obtained from auto-refraction. The contact lenses were allowed to settle for ten minutes before evaluation of fit. During this time, the lighting was dimmed in the examination room and subjects were instructed to refrain from near work. Acceptable contact lens fit was evaluated based on adequate coverage, centration, and movement on the eye. Inadequate corneal coverage, decentration of more
than 1 mm, or movement on blink greater than 1 mm would have disqualified the subject from the study. After adequate fitting was determined, a series of visual functions testing was conducted.

2.5 Outcome measures

2.5.1 Visual acuity

High and low illumination visual acuities were measured binocularly with an electronic logMAR chart using an iPad with Retina display (Apple Inc., Cupertino, CA) at a viewing distance of 3 m (Ridgevue Vision, Denver, CO) using a screen luminance of 150 cd/m². Low illumination logMAR acuity was measured with the subjects holding 2.0 neutral density filters over their eyes, to counter the backlight illumination from the screen and to reduce luminance by a factor of 100 to approximately 1.5 cd/m².

2.5.2 Contrast sensitivity

Contrast sensitivity was measured binocularly at 10 cycles per degree with the validated Ridgevue Contrast Sensitivity Test run on an iPad with Retina display. The scoring system of the Ridgevue Contrast Sensitivity test is based on the scoring system of the Pelli-Robson Chart and has been shown to have good repeatability and similar results as the Freiburg acuity and contrast test (Kollbaum, 2014). Following instrument protocol, a test distance of 1 m was used.
2.5.3 Accommodation

Accommodative responses were measured monocularly through the right eye using a custom built infrared (IR) photorefractor (Camera DMK 22 AUC03 and Cosmica Pentax 50 mm lens, Tubingen, Germany) based on the design of the PowerRefractor used in several studies of human refractive state and accommodation (Choi, 2000; Allen, 2003; Hunt, 2003; Harb, 2006; Schaeffel, 2007). The photorefractor was positioned 100 cm from the subject and recorded measurements at a sampling rate of 76 Hz. Room illumination was adjusted to ensure pupil size was at least 4 mm at all times. The system was calibrated for each subject’s right eye while wearing the single vision distance contact lens. The system gain was determined using ± 3 D lenses to alter the subject’s refraction by a fixed amount and any offset in the infrared reading during calibration was corrected to zero as each subject was distance corrected. Subjects viewed the target through the left eye, which wore either the single vision or the multifocal correction. Consensual accommodative response, refractive state in the vertical meridian, and pupil diameter were measured in the subjects’ right eye, which was corrected for the distance with a single vision contact lens and occluded by an infrared filter.

Accommodative responses were measured at four stimulus distances: distance (>3 m), 100 cm, 40 cm, and 25 cm, giving accommodative demands at 0 D, 1 D, 2.5 D and 4 D, respectively. The near targets consisted of three lines of words in which the letter height of each line subtended 0.31°, 0.36° (roughly a 20/50 letter at 40 cm), and 0.41° of visual angle at each target distance so that the letter sizes were maintained to give the same visual angle at all distances. Subjects were instructed to keep the center word clear at each target distance for 10-15 seconds and close their eyes for 10 seconds between
each target. Photorefraction data were collected continuously over the time period at
which the subjects viewed the target. The data were filtered offline to remove artifacts
created by off-axis fixation, blinks, or glare from the infrared filter using KaleidaGraph
(Synergy Software, Reading, PA) and then averaged. This process was repeated at each
test distance three times and averaged to provide the final measurement.

Binocular push-up accommodation was measured using a Royal Air Force near
point rule (Haag-Streit England, Essex, United Kingdom). The target was the same as the
40 cm target used for the photorefraction. The subject was instructed to keep the center
word clear and report first blur. Three measurements were taken to the nearest half-
centimeter, averaged, and converted to diopters.

Binocular accommodative facility was tested with +2.00/-2.00 D flippers to assess
the dynamics and stamina of the accommodative system. The test was administered at 40
cm and measured in cycles per minute (cpm), using the same target as was used for
photorefraction at 40 cm.

2.5.4 Phoria

Phoria was measured using the Modified Thorington method at four distances:
distance (3 m), 100 cm, 40 cm, and 25 cm (Bernell Muscle Imbalance Card, Bernell
Corp, South Bend, IN). The subject was asked to hold a Maddox rod oriented at 180
degrees over their right eye and to report the location of the vertical red line on the
Modified Thorington card. The modified Thorington card calibrated for 40 cm was used
to measure phoria at 100 cm, 40 cm, and 25 cm. A conversion factor using the definition
of a prism diopter was used to adjust for the different test distances to calculate the subjects’ true phorias at 100 cm and 25 cm (Cebrian, 2014).

2.6 Data Analysis

Descriptive statistics were calculated for demographic and baseline data. Repeated measures analysis of variance (ANOVA) was used to assess changes in accommodative response and phoria by test distance and lens type. Post-hoc testing with Bonferroni corrections for multiple comparisons were done, as appropriate. Paired t-tests were used to compare differences between multifocal and single vision lens conditions in high and low illumination logMAR acuity, contrast sensitivity, amplitude of accommodation, and accommodative facility. A p-value of <0.05 was considered to be statistically significant. All statistical analyses were conducted using SPSS version 19 (SPSS, Chicago, IL).
CHAPTER THREE

RESULTS

3.1 Subjects

Seventeen subjects were enrolled in the study, but one subject did not complete the study due to failure to be able to insert contact lenses. No subjects were disqualified from inadequate fitting of contact lenses. Eleven subjects (69%) were female and the average age was 13.3 ± 1.7 years (mean ± standard deviation; range: 10 to 15 years). The demographic distribution was black, 41%; white, 23.5%; Asian, 12%; other, 23.5%. The mean spherical equivalent refractive error by non-cycloplegic autorefraction was -2.42 ± 0.83 D in the right eye and -2.44 ± 0.73 D in the left eye (range for all eyes: -1.75 to -4.00 D). The pupil size while subjects viewed the distance target under room illumination (6.5 to 7.5 lux) was 6.6 ± 0.31 mm.

3.2 Visual Acuity

Visual acuity measured under high and low illumination is shown in Figure 3. Multifocal lenses reduced visual acuity under both high (single vision: -0.08 ± 0.08, multifocal: +0.01 ± 0.09, p < 0.01) and low illumination (single vision: -0.03 ± 0.08, multifocal: +0.08 ± 0.09, p < 0.01) compared to single vision lenses. Quantitatively, this shows that subjects lost about a line (4-5 letters) of acuity under high or low illumination, but average acuity was always better than about 20/25 Snellen equivalent. Across the same type of contact lens, visual acuity decreased under low illumination (single vision: p < 0.01, multifocal: p < 0.01).
Figure 3. Mean and standard deviation LogMAR visual acuity and Snellen equivalent measured under high (solid fill) and low (pattern fill) illumination with single vision (blue circles) and multifocal (red squares) contact lenses.

3.3 Contrast Sensitivity

A statistically significant, but clinically small, difference in contrast sensitivity between multifocal and single vision was found. Mean contrast sensitivity decreased from $2.0 \pm 0.1$ log units with single vision lenses to $1.9 \pm 0.1$ log units with multifocal contact lenses ($p = 0.015$).

3.4 Accommodation

Photorefractor data were only available for 15 of the 16 subjects because we did not obtain sufficient data for one subject. Individual accommodative responses for all
subjects are shown in the single vision and multifocal contact lens conditions (Figure 4a). The gains of the accommodative stimulus-response functions were estimated by the slopes of linear regressions fit to each individual’s data. The slope of the stimulus response function flattened under multifocal compared to single vision condition (multifocal: 0.55 ± 0.20, single vision: 0.82 ± 0.17, p < 0.01). The inset figure shows the relative accommodative gain with multifocal compared to single vision contact lens wear (Figure 4a). The gains were reduced for all eyes wearing the multifocal compared to the single vision contact lens. As expected, the mean accommodative response decreased with increasing target demand (Figure 4b). Post-hoc testing showed reduced refractive states with multifocal contact lenses at distance (single vision: -0.04 ± 0.43 D; multifocal: -0.37 ± 0.72 D, p = 0.02), 100 cm (single vision: +0.37 ± 0.44 D; multifocal: -0.35 ± 0.70 D, p < 0.01), 40 cm (single vision: +1.82 ± 0.53 D; multifocal: +0.62 ± 0.63 D, p < 0.01), and 25 cm (single vision: +3.38 ± 0.52 D; multifocal: +1.75 ± 0.62 D, p < 0.01) (Figure 4b).

Binocular push-up amplitude of accommodation was normal for the subject age (Larsson, 2015). There was no significant difference in binocular accommodative amplitude (single vision: 13.1 ± 2.2 D; multifocal: 13.2 ± 2.5 D, p = 0.66) or accommodative facility (single vision: 8.9 ± 3.7 cpm; multifocal: 8.6 ± 2.7 cpm, p = 0.54).
Figure 4. (a) Accommodative responses for subjects wearing single vision (blue solid) and multifocal (red dashed) contact lenses. Inset shows the gain for each subject ($n = 15$). (b) Mean (± standard deviation) accommodative response at each stimulus demand and mean accommodative stimulus response function for single vision (blue) and multifocal (red) contact lens conditions. The black solid line shows the 1:1 line.
Figure 5. (a) Lateral phoria for subjects wearing single vision (blue solid) and multifocal (red dashed) contact lenses ($n = 16$). (b) Mean ($\pm$ standard deviation) phoria at each stimulus demand with single vision (blue) and multifocal (red) contact lens conditions. Esophoria indicated as positive and exophoria as negative.
3.5 Phoria

As expected, most subjects exhibited more exophoria with greater near demands. Mean phorias were significantly more exophoric with multifocal contact lenses at 40 cm (single vision: -0.41 ± 2.91 Δ; multifocal: -2.06 ± 2.49 Δ, p < 0.01), and 25 cm (single vision: -0.83 ± 3.23 Δ; multifocal: -4.30 ± 4.32 Δ, p < 0.01) (Figure 5b). Phorias were not significantly different at distance (p = 0.19) or 100 cm (p = 0.06).
CHAPTER FOUR

DISCUSSION

4.1 Overview

The purpose of this study was to evaluate the effect of multifocal contact lenses on accommodation, phoria, and visual function in a normal population of myopic children. The results of this study showed that the multifocal contact lenses used in this study alter binocular posture and some aspects of accommodation when compared to single vision contact lenses. Specifically, when viewing through the multifocal lenses accommodative response was reduced, the eyes were more exophoric, and visual acuity was reduced.

4.2 Visual Acuity and Contrast Sensitivity

As seen in other studies of presbyopia (Madrid-Costa, 2013) and myopia control (Kollbaum, 2013) contact lenses, both visual acuity and contrast sensitivity were slightly degraded with the multifocal contact lenses used in this study. Decreased visual acuity and contrast sensitivity were also consistent with previous findings on young adults wearing multifocal lenses (Kang, 2016; Bickle, 2013, Fedtke, 2015). Our findings and those of others (Bickle, 2013), showed that contrast sensitivity is reduced in children wearing multifocal contact lenses compared to single vision lenses. However, these results are generally limited to a few spatial frequencies and further research is needed to understand the effect of multifocal contact lenses across all spatial frequencies in children.
4.3 Accommodation

A recent study of adults by Kang et al. also reported increased accommodative lag of 1.12 D and 0.82 D at near (33 cm) with multifocal contact lenses (+1.50 and +3.00 D Proclear multifocal, respectively) compared to 0.63 D of lag with single vision (Proclear sphere) (Kang, 2016). The present study found similar but slightly larger lags of accommodation in children wearing +2.50 D Biofinity multifocal lenses. Two possible reasons may explain the decrease in accommodative response with multifocals. Non-presbyopic wearers may be utilizing the positive addition of the lens to relax their accommodation, and the positive spherical aberration induced by the aspheric design of the multifocals may increase their depth of focus. Children typically exhibit little to no spherical aberration (+0.018 µm) (Papamastorakis, 2015), compared to the average adult who has about +0.18 µm for a 6 mm pupil (Kingston, 2013). Multifocal lenses induce additional spherical aberration of up to about +0.20 µm (Legras, 2010; Bakaraju, 2010; Gifford, 2013). Specifically, the distance-center +2.00 D Proclear multifocal lenses (similar in design to Biofinity) induced an average of +0.11 µm of spherical aberration (Legras, 2010). Adaptive optics simulations in adults demonstrated that the depth of focus reached a maximum at about 2 D with about 0.6 µm of spherical aberration (Rocha, 2009). The combination of ocular and multifocal contact lens induced spherical aberration creates an enlarged depth of focus. This effect would be expected to be less in children than adults based on spherical aberration population averages. Nevertheless, a larger range of clear vision would lessen the need to accommodate for any non-presbyopic wearer.
Children also seemed to relax accommodation through the multifocal at distance (-0.37 D), which was not found with single vision contact lenses (-0.04 D, Figure 4b). This discrepancy is likely explained by the power profile of the Biofinity multifocal. For a plano labeled multifocal lens, the central 3 mm zone shows a positive power of +0.67 D (Plainis, 2013).

Accommodative amplitude and facility were taken binocularly to assess “real-world” testing conditions. Accommodative facility through single vision and multifocal contact lenses for our subjects (8 cpm) was found to be higher than the expected norms (5 cpm) in 8 to 12 year old children (Scheiman, 2008). The higher values found in our study may be due to using a 20/50 Snellen acuity target, larger than the traditional 20/30 target used to measure accommodative facility in adults or that we did not require the subjects to read the words aloud (Scheiman, 2008). A suppression check was not utilized and may also be a potential explanation for the above average performance on this test. Our accommodative amplitude results were consistent with previous studies in normal children (Larsson, 2015). While the binocular push-up amplitude of accommodation was greater in children wearing multifocal contact lenses, the difference between amplitudes in multifocal and single vision lenses was not statistically significant, likely due to the poor repeatability of this measurement and the subjective nature of these tests where children have to appreciate and respond quickly to clinical endpoints (Anderson, 2008).

4.4 Phoria

The modified Thorington card provides a quick and simple method of measuring horizontal phoria that has shown to be repeatable within and across examiners (Cebrian, 2014). The distance and near lateral phoria with single vision contact lenses showed good
agreement with previous studies in children (Jimenez, 2004). Because the modified Thorington method is performed in free space and provides peripheral cues to accommodation, it is possible that more esophoric posture may be measured compared to an in-instrument method such as Von Graefe (Maples, 2009). While normative data for adults typically show range between orthophoria and 6 PD exophoria at near, Jimenez et al found in 1,016 pediatric subjects that children showed exophoria of about 0.4 ± 3.1 PD at near, consistent with what we found in our study (Jimenez, 2004). The increase in exophoria induced by multifocal contact lenses at near is in agreement with previous studies and supports the hypothesis that the children are utilizing the positive addition or increased depth of focus provided by the multifocal design to relax their accommodation (Aller, 2016, Kang, 2016).

4.5 Study Limitations

One limitation in this study is the use of a non-cycloplegic spherical equivalent auto-refraction to select the distance power of the contact lens. It is possible that children may have been slightly over-corrected in both the single vision and multifocal lenses. This is also supported by the three subjects who had gains larger than 1.0 (Figure 4a). Children may have accommodated through the single vision contact lenses to keep the target clear but, due to the inherent distortion of aspheric multifocal contact lenses, they may have more readily relaxed their accommodation with multifocals. While performing a cycloplegic refraction may have provided some additional insight into refractive state in the distance, any difference in refractive error following cycloplegia would likely be
small and clinically insignificant in this myopic population with normal binocularity and accommodation.

Pupil size has an effect on higher order aberrations of the eye and the amount of plus power and aberrations experienced from multifocal contact lenses (Plainis, 2013). One of the limitations of photorefraction, is that it measures over the entire pupil and does not allow analysis of higher order aberrations at various pupil diameters as can be achieved with aberrometry. While we are unable to quantify the changes in higher order aberrations in this study, the power profile of the Biofinity +2.50 D lens, suggests that the children would be experiencing the majority of the plus power and asphericity (spherical aberration) in the lens with pupil sizes as small as about 4 mm (Plainis, 2013).

Moreover, this study was a single-visit study using one type of positive addition, and does not offer insight into the long-term effect of multifocal contact lenses on binocular vision and accommodation or any potential “dose” effect with different amounts of peripheral addition.

4.5 Conclusion and Clinical Implications

Myopia control using multifocal contact lenses is becoming an acceptable option for reducing myopia progression and more clinical trials are underway (Lam, 2014; Walline, 2013; Anstice, 2011). This study demonstrated that children wearing multifocals exhibited decreased accommodative response and more exophoria than when wearing single vision contact lenses. They also experienced a slight reduction in visual acuity, particularly under low lighting and contrast. When fitting children in multifocal contact lenses, it is important to consider these expected changes in order to properly evaluate
and manage patients. For example, children with high exophoria or who experience double vision at near with multifocal contact lenses may have their myopia better managed with other forms of myopia control such as orthokeratology or atropine. Our findings of reduced accommodative stimulus-response slopes and greater exophoria at near are consistent with the notion that children are using the positive addition at near. This potentially reduces the therapeutic effect of myopia control during near viewing. We speculate that the benefit of the near addition may be achieved mainly when viewing at distance.

Kang et al. measured accommodation and visual function in young adults wearing +1.50 D and +3.00 D distance-center multifocal lenses over a two week period and found no statistically significant difference in accommodative response and phoria between the first visit and after two weeks of daily contact lens wear (Kang, 2016). Further studies are needed to evaluate long-term adaptation to multifocal contact lenses, other multifocal lens designs, and different amounts of positive addition and spherical aberration in children. These findings also suggest that multifocal contact lenses may be useful for children with accommodative insufficiency or vergence disorders and further research in this area is also warranted.
REFERENCES


APPENDIX

Appendix A: Informed Consent Form

CONSENT FORM

Title of Project: Contact Lenses and Myopia (CLAM) Study
Name of Principal Investigator: Kathryn Richdale, OD PhD

1. What you should know about research studies:
   - This consent form gives you information about the study. It tells you about the purposes, risks, and benefits of this research study.
   - Your participation is voluntary. You don’t have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your clinic care will not change.
   - Please read this consent form carefully. Ask any questions you have before you make a decision. The study investigator will answer your questions. You may consult with your family or friends.

2. Why are we doing this research?
The purpose of the project is to learn more about how a special type of commercially available contact lenses (multifocals) affect the way children focus up close and how their eyes work together.

3. What will happen to you if you decide to be in this study?
There is only one study visit which will take about 2 hours to complete. At this visit, we may do the following:
   - Check the child’s vision
   - Have the child wear two types of contact lenses.
   - Examine the front of the child’s eyes using a microscope
   - While wearing each pair of contact lens, we will ask the child to look at targets that are far away or up close while we do measurements to see how their eyes focus and work together.

Your child is a potential subject because they are:
   - Near-sighted with a prescription between -1.00 and -8.00 D with less than or equal to 1.00 D astigmatism
• Between the ages of 7 and 15 years
• Able to see the 20/25 line on the eye chart with glasses or contact lenses
• Healthy with no history of eye disease or abnormal eye turns
• Not using any medications that affect the way they focus

4. Possible Benefits:
There are no direct benefits for participation in this study. Multifocal contact lenses have been shown in some studies to slow down the progression of nearsightedness. Based on the results of this study, multifocal contact lenses may be used as a more widespread treatment option for nearsightedness. If you are interested in contact lenses after the study, we can make a referral to our clinic if you wish.

5. Possible Risks:
The risks associated with this study are the same as for wearing contact lenses outside of the study. Risks associated with daily contact lens wear may include tearing and irritation to the eye, light sensitivity, itching, burning, redness, blurred vision, eye infection, or eye abrasion. Risks are limited since you will only be wearing the lenses during the study visit. If any eye-related complications arise, you will be offered the option of being treated at the College and you will be billed accordingly. You may also elect to see another doctor of your choosing.

Our study team is experienced in maintaining the confidentiality of our subjects. In any research study, however, there is also a risk that data from the study visit might accidentally identify participants. The study team will do everything possible to maintain the confidentiality of study records.

6. Voluntary Consent:
You do not have to be in this study. You can decide to be in the study now and then change your mind. Your decision to be in the study or not will have no effect on any treatment or benefits you are entitled to from us or this institution.

7. What are your other choices?
The alternative to being in this study is to not participate.

8. Who to Contact:
If you have questions about this project, please contact Kathryn Richdale, OD PhD (212-938-4165). If you have any questions about your rights as a participant, contact the Chairman of the Institutional Review Board (212-938-5770) or the Office of Research Administration and Research Privacy Officer (212-938-5532).

researchprivacy@sunyopt.edu.

9. Confidentiality of Records and Authorization to Use/Share Protected Health Information for Research
If you agree to be in this study, identifiable health information about you will be used and shared with others involved in this research. We need your permission to
collect and share this information if you decide to be in this study. Federal law protects your right to privacy about this information.

Individually identifiable health information under the Federal Privacy Law is considered to be any information from your medical record, or obtained from this study, that can be associated with you, and relates to your past, present, or future physical or mental health or condition. We call this protected health information (PHI). PHI can include things like your name, date of birth, address, and medical information.

When you sign this consent form, it means that you have read this section and authorize the use and/or sharing of your protected health information as explained below.

Your protected health information will be kept confidential. Your identity will not be included in any publication or presentation about this research.

10. Why do we need to use/share your protected health information with others?

The main reason to use and share your protected health information (PHI) is so we can do the research described earlier in this form. Your information may also be shared with people and organizations that make sure the research is being done correctly. We may have to report unexpected or bad side effects you have while in the study. We may be required by law to release protected health information about you. An example may be if a judge requires such release in a lawsuit.

11. What protected health information about you will be collected for this study?

For this study we will create, use or report the following (PHI):

Demographic information (i.e. age, race/ethnicity) your eye and general health history and contact lens information will be recorded.

12. Who will be able to look at your protected health information?

The researchers, their staff, and the staff of SUNY College of Optometry participating in this project will use your protected health information for this research study.

You can ask the person telling you about this study for a list of other study members.

Your protected health information may also be shared with:

The SUNY College of Optometry Institutional Review Board (IRB), Associate Dean for Graduate Studies and Research.

Federal agencies that supervise the way the research is conducted, such as the Department of Health and Human Services Office for Human Research Protections, the Food and Drug Administration (FDA), the National Institutes of Health, or other offices as required by law.

Representatives of GreenPhire, Inc., the company that handles this site’s research.
participant payments for this study.

The researchers, their staff, and the staff of SUNY College of Optometry Clinical Vision Research Center. You can ask the person telling you about this study for a list of other study members.

All reasonable efforts will be used to protect the confidentiality of your protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Once your protected health information is disclosed, i.e., leaves SUNY College of Optometry, the Federal privacy law may not protect it.

13. How long will your protected health information be used or shared with others?

We will use and report your health information for as long as the study is ongoing.

14. Can you withdraw your authorization to collect/use/share your protected health information?

You can tell us not to use your PHI by writing to the investigator in charge of the study. This means that no further private health information will be collected. Once you withdraw your permission, you will no longer be in the study. Your regular care and any other benefits you would receive outside this study will not change. Withdrawing your permission only affects the use and sharing of information obtained after your written request has been received. We will still be able to use the information collected before you withdrew permission.

Even after you withdraw your permission, we may have to use and share your information. An example of this would be if we needed to collect information about an unexpected or bad side effect you had because of being in the study.

Withdrawal from the study will not affect any benefits or reimbursements that are due to you for the portion of the study you have already completed.

15. Can you have access to your health information?

You may have the right to see and copy health information about you at the end of the study. This will depend on SUNY College of Optometry policies. Your access may be limited while the study is in progress.

16. What else should you know?

You will receive $100 for participation in this study. You will be paid at the end of the study visit. If you are unable to complete the visit for any reason, you will be compensated $20 for your travel.

By accepting payment for participating in this study, certain identifying information about you may be made available to professional auditors to satisfy Federal and State reporting requirements, but confidentiality will be preserved. Please note that if you earn $600 or over in a calendar year as a research subject, these earnings will be reported to the Internal Revenue Service.
SUNY College of Optometry does not have a formal plan or program to provide for
the cost of medical treatment or compensation in the unlikely event of an injury that
may occur as a result of your participation. Although there is limited potential for
injury anticipated in this research, if such injury occurs you should immediately
notify the principal investigator of the study.

17. Participant / Parent Consent

I give my consent to participate in this research study and agree that my personal
health information can be collected, used, and shared by the researchers and staff
for the research study described in this form. I will receive a signed copy of this
consent form.

____________
Printed Name of Subject (Child)       Child’s Date of Birth

____________________
Printed Name of Parent/Guardian

____________________
Signature of Parent/Guardian       Date

____________________
Printed name of Person Obtaining Consent

____________________
Signature of Person Obtaining Consent       Date

SUNY College of Optometry:RB
Approved on: 27/MAY/2014
Expires on: 26/MAY/2016

IRB Consent Template version 01/APR/2012
Appendix B: Informed Assent Form

Title of Project: Contact Lenses and Myopia (CLAM) Study

Name of Principal Investigator: Kathryn Richdale, OD PhD

We are asking you to be in a research study. This study is to find out how different types of contact lenses change how you focus and turn your eyes in to read. You can be in this study because you are between 7 and 15 years old and you are nearsighted.

You can say yes or no to being in this study. You can ask as many questions as you like.

If I join this study, what will happen to me?

This study will take up to 2 hours to complete. If you decide to be in this study, we will ask you to sign this form. After you do that, we will check your vision and look at the health of your eye. We will have you wear two types of contact lenses and focus on things far away and up close. We can help you put on contact lenses if you have not worn contact lenses before.

You will be paid $100 for your time at the end of the visit. If you do not complete the visit, you will be paid $20 for your travel.

Will this study help me?

While this study will not help you directly, it will help us learn more about how contact lenses affect how you focus on things.

Can anything bad happen if I join this study?

There is a risk that someone outside the study might find out that you were in the study. The study team will do their best to make sure this doesn’t happen.

There is also a risk of your eyes getting teary, uncomfortable, red, or getting infected. We will check to make sure that your eyes are okay after the study. You should tell the study team if you have any problems during the study.

Do I have to be in this study?

It is up to you to decide if you want to be in this study. No one will be mad at you if you say no. If you say yes, you can change your mind at any time.

Who to Contact:

The doctor in charge of this study is Kathryn Richdale, OD PhD. You can call her at 212-938-4165 or KRichdale@SUNYopt.edu if you have any questions about this study.

Who will be able to see my personal information?

If you join this study, we will keep a record of your study information. We will do everything we can to make sure your personal information is not shared with anyone not involved with the study.
Assent to be in a research study & to use and share Personal Health Information:
I have been told about the study and have read the information in this form. I agree to be in this study. I will let study staff collect, use and share my personal information for the research described in this form. I understand that I will be given a copy of this form.

________________________
Printed Name of Subject

________________________
Signature of Subject Date

________________________
Printed Name of Person Obtaining Assent

________________________
Signature of Person Obtaining Assent Date
Appendix C: Informed Consent Checklist

Study Title: Contact Lenses and Myopia (CLAM)  Date: __/___/____  
Subject ID: __________________

INFORMED CONSENT CHECKLIST
Informed Consent Version Date: __________

Date informed consent signed: __________(DD/MON/YY)
Time informed consent signed: ___________ AM / PM

Were the risks and benefits explained to patient/parent?  □ yes  □ no
Was patient/parent allowed time to read/review the consent?  □ yes  □ no
Did patient/parent have a chance to ask questions?  □ yes  □ no
Was consent form signed prior to study participation?  □ yes  □ no
Was a copy of the signed ICF provided to the patient/parent?  □ yes  □ no
Was HIPAA authorization included in the informed consent discussion?  □ yes  □ no

Any other notation of informed consent process:

___________________________________________________________________________________

___________________________________________________________________________________

DEMOGRAPHIC INFORMATION

Study personnel should ask for participants’ demographic information instead of making assumptions about race and ethnicity.

Age: ________  Sex:  M  □  F  □

RACE
White  □  Black or African American  □
American Indian or Alaska Native  □  Asian  □
Native Hawaiian or Other Pacific Islander  □
Other or denied  □

ETHNICITY
Hispanic/Latino  □  Non-Hispanic/Latino  □

Name of person conducting screening  Signature  __________ Date __________
Appendix D: Exam Forms

Study Title: Contact Lenses and Myopia (CLAM)  

FORM 1: SINGLE VISION CL

Subject ID: ___________________  
Date: _____/_____/______  
DD / Mon / YY

FORM TO BE COMPLETED BY STUDY PERSONNEL

Consent/Assent Procedure
- [ ] Informed consent
- [ ] Informed assent

Baseline measurements

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<th>OS</th>
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Entering Snellen VA with current Rx  
Distance OD 20/  
Distance OS 20/

Refractive Error by autorefraction  
- [ ] Taped on back

Ocular Dominance (Circle One)  
OD  
OS

Anterior Segment Slit-lamp examination

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<tr>
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Contact Lens Prescription (from spherical equivalent autorefraction)

OD

OS

! WAIT 10 MINUTES FOR CONTACT LENSES TO SETTLE IN DARK
Checking Fit of Contact Lens
Do not enroll if any of the criteria are unsatisfied

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Subjective Binocular Assessment
Equipment: Modified Thornton card, Maddox Rod, String, Transilluminator

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Subjective Accommodative Assessment
Equipment: RAF rule

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Other tests
Equipment: Pad, Flippers (+/- 2.00D), Timer

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2
Contrast Sensitivity
(distance, 1m)

OU
C (# correct)
CX 0.05
(Threshold = 10^-C x 0.05)
Threshold:

Accommodative Facility
(40cm)

OU

Objective Accommodative and Binocular Assessment

Equipment: Photorefractor, Sunglasses

☐ Powerrefigractor is positioned on both eyes
☐ Measure at accommodative stimulus at distance (> 4m), 1D, 2.5D, and 4D
☐ Save the file on the computer in the format SubjectID_CLtype

Objective Accommodative and Binocular Assessment

Equipment: Open-field automated refractor, Sunglasses

☐ Measure at accommodative stimulus at distance (> 4m), 2.5D, and 4D
☐ Print and tape output on back

Switching to Multifocal Contact Lenses

Reminder: Save single vision CL OD

OD
ADD

OS
ADD

⚠️ WAIT 10 MINUTES FOR CONTACT LENSES TO SETTLE IN DARK

Checking Fit of Contact Lens

Do not enroll if any of the criteria are unsatisfied

<table>
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Subjective Binocular Assessment

**Equipment:** Modified Thorton card, Maddox Rod, String, Transilluminator

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<tr>
<td>Distance (3m)</td>
<td></td>
</tr>
<tr>
<td>1D</td>
<td></td>
</tr>
<tr>
<td>2.5D</td>
<td></td>
</tr>
<tr>
<td>4D</td>
<td></td>
</tr>
</tbody>
</table>

Subjective Accommodative Assessment

**Equipment:** RAF rule

<table>
<thead>
<tr>
<th>Binocular Push-Up Amplitude</th>
<th>OU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(cm)</td>
</tr>
</tbody>
</table>

Other tests

**Equipment:** Pad. Flippers (+/-2.00D), Timer

### LogMAR Acuity (distance, 3m)

<table>
<thead>
<tr>
<th>OU</th>
<th>High Lighting:</th>
<th>LogMAR</th>
<th>Low Lighting:</th>
<th>LogMAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># incorrect</td>
<td></td>
<td># incorrect</td>
<td></td>
</tr>
<tr>
<td>U P F R N</td>
<td>+0.5</td>
<td>U P F R N</td>
<td>+0.5</td>
<td></td>
</tr>
<tr>
<td>D F H N R</td>
<td>+0.4</td>
<td>D F H N R</td>
<td>+0.4</td>
<td></td>
</tr>
<tr>
<td>Z H D P F</td>
<td>+0.3</td>
<td>Z H D P F</td>
<td>+0.3</td>
<td></td>
</tr>
<tr>
<td>D V R N U</td>
<td>+0.2</td>
<td>D V R N U</td>
<td>+0.2</td>
<td></td>
</tr>
<tr>
<td>R D H E U</td>
<td>+0.1</td>
<td>R D H E U</td>
<td>+0.1</td>
<td></td>
</tr>
<tr>
<td>H V N E D</td>
<td>0.0</td>
<td>H V N E D</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Z H F E D</td>
<td>-0.1</td>
<td>Z H F E D</td>
<td>-0.1</td>
<td></td>
</tr>
<tr>
<td>R N D P Z</td>
<td>-0.2</td>
<td>R N D P Z</td>
<td>-0.2</td>
<td></td>
</tr>
<tr>
<td>N V D Z P</td>
<td>-0.3</td>
<td>N V D Z P</td>
<td>-0.3</td>
<td></td>
</tr>
<tr>
<td>D Z V E N</td>
<td>-0.4</td>
<td>D Z V E N</td>
<td>-0.4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Base logMAR N (# incorrect)</th>
<th>Base logMAR N (# incorrect)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N x 0.02</td>
<td>N x 0.02</td>
</tr>
<tr>
<td>logMAR VA</td>
<td>logMAR VA</td>
</tr>
</tbody>
</table>

### Contrast Sensitivity (distance, 1m)

<table>
<thead>
<tr>
<th>OU</th>
<th>(# correct)</th>
<th>(Threshold = 10⁻⁰·⁰·⁰)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C x 0.05</td>
<td></td>
</tr>
</tbody>
</table>

### Accommodative Facility (40cm)

<table>
<thead>
<tr>
<th>OU</th>
<th>(cpm)</th>
</tr>
</thead>
</table>

Replace OD with single vision lens

**Reminder:** Wait 10 minutes for CL to settle
Objective Accommodative and Binocular Assessment

**Equipment:** Photorefractor, Sunglasses

- Powerrefractor is positioned on both eyes
- Measure at accommodative stimulus at distance (> 4m), 1D, 2.5D, and 4D
- Save the file on the computer in the format SubjectID_CLtype

Objective Accommodative and Binocular Assessment

**Equipment:** Open-field automated refractor, Sunglasses

- Measure at accommodative stimulus at distance (> 4m), 2.5D, and 4D
- Print and tape output on back

End of experiment

- Pay subject
Does Your Child Wear Glasses or Contact Lenses?

What is the CLAM study?

CLAM stands for Contact Lenses and Myopia (nearsightedness). We’re looking to enroll patients for a study to learn about how multifocal contact lenses affect how children focus their eyes. This 2 hour study involves trying on contact lenses and participating in focusing activities.

Who can participate?

Children and teens age 7 to 15 years who are nearsighted, and have no major health or eye problems. A parent must be present during the study visit.

Additional Information

You will receive up to $100 for your participation in the study.

Questions?

SUNY College of Optometry
Clinical Vision Research Center
33 West 42nd Street
New York, NY 10036
Phone: 212-998-4050

Contact Us!