VISUAL PERFORMANCE OF CENTER-DISTANCE MULTIFOCAL CONTACT LENSES FIT USING A MYOPIA CONTROL PARADIGM

By

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Abstract

Purpose: Multifocal contact lenses (MFCLs) are increasingly being prescribed for non-presbyopic patients (e.g., myopia control, digital eye strain, etc.). It is important to understand how these contact lenses affect visual performance. MFCLs and single vision contact lenses (SVCLs) were evaluated under several illuminations and contrast levels.

Methods: Twenty-five non-presbyopic adults with -1.00 D astigmatism or less and spherical equivalent refraction (SER) between -0.75 DS and -6.00 DS at the corneal plane were enrolled and fitted binocularly in three contact lens designs using a myopia control paradigm. Two lenses were center-distance MFCLs (Biofinity "D" +2.50 add, NaturalVue Multifocal) and one was a spherical SVCL (Biofinity). Subjects were masked to the lens type. High-(HC) and low-contrast (LC) logMAR visual acuity (VA) was measured at distance in photopic, mesopic, and mesopic with glare lighting. Photopic high-contrast acuity and reading speed were measured at near. Data were analyzed using repeated-measures analyses of variance (RM-ANOVA) with adjusted post-hoc t-tests, when appropriate.

Results: The mean (± SD) age and SER were 24.1 ± 1.5 years and OD: –3.38 ± 1.53 DS (range –1.00 to –5.00 DS), OS –3.29 ± 1.66 DS (range –0.75 to –5.75 DS), respectively. HC and LCVA depended on lighting and lens type (lens x contrast x lighting interaction; $P = .015$). HC was always better than low (all $P < .05$). The acuity loss in photopic HCVA between SVCLs and MFCLs was statistically significant, approximately 1.5 to 2 letters ($P = .017$). Mesopic, HCVA with MFCLs was 4 to 5 letters worse than SVCLs ($P < .001$). All lenses performed better in photopic lighting (all $P < .001$). Photopic, LCVA with both MFCLs was 5-6 letters worse than

SVCLs. For mesopic LCVA without glare, loss was just over 2 lines for MFCLs compared to SVCLs. Reductions in LCVA between photopic and mesopic lighting differed by lens types (SVCL versus MFCLs; $P < .0001$). In mesopic lighting, the addition of glare reduced VA by about 3 letters (0.065 logMAR; $P < .00001$); VA reduction did not depend on lens design (SVCL vs MFCLs; $P = .17$). Reading performance in words per minute (WPM) was worse with MFCLs (Biofinity MFCL 144 ± 22 WPM, NaturalVue multifocal 144 ± 28 WPM) than with SVCLs (156 ±23 WPM; $P = .019$) regardless of letter size ($P = .13$). No difference in visual acuity between the MFCLs was detected (all $P > 0.05$).

Conclusion: Compared to the SVCL, both MFCL designs resulted in reductions in distance VA under photopic low-contrast and mesopic, high- and low-contrast conditions. Additional reductions in VA were observed with glare, but these reductions did not differ between lens designs. High-contrast VA does not fully describe the effect of MFCL optics on visual acuity. Additional work is needed to better ascertain visual performance with multifocal lens designs.

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Chapter 1: Introduction

The general goals of this thesis are to determine how center-distance multifocal soft contact lenses affect the visual performance of non-presbyopic patients. Since these lenses are increasingly prescribed off-label for various clinical conditions, such as digital eye strain and myopia control, it is critical to understand how the lenses affect visual function. This thesis will provide a better understanding of how center-distance multifocal contact lenses affect non-presbyopic individuals in more challenging light levels they may encounter in a typical day.

Multifocal soft contact lenses were originally developed to meet the near vision demands of presbyopic patients. Numerous designs have been used, including bifocal contact lenses, multifocal contact lenses, and progressive power contact lenses, also known as varifocal power contact lenses (Remón et al. 2020). These designs function via two optical principals: an alternating image for when a patient looks downward and the contact lens translates up, and a simultaneous image where there are two images are seen at the same time with one image focused for distance and one for near (Remón et al. 2020; Pérez-Prados et al. 2017). There are generally two contact lens designs utilized to achieve simultaneous vision—concentric multifocal designs and aspheric multifocal designs. Concentric multifocal designs have a central zone that corrects either distance or near vision with rings of distance and plus power alternating radially from the lens center. Aspheric designs have either a center-distance zone with increasing plus power toward the periphery, or a center-near zone that transitions to the distance power in the periphery (Remón et al. 2020). These type of contact lenses have been used for more than the correction of presbyopia and are now being prescribed off-label for other demands like myopia control and digital eye strain (Kajita, Muraoka, and Orsborn 2020). The soft contact lens designs used off-label for myopia control are center-distance designs that work through the principal of simultaneous vision while those used for digital eye strain could be either center-distance or center-near designs.

1.1 Digital Eye Strain

Digital eye strain is a highly prevalent condition that many eye care practitioners may encounter in children and adults as the use of digital devices continues to increase (The Vision Council 2019). Digital eye strain is characterized by any visual disturbances or discomfort when using digital devices (Coles-Brennan, Sulley, and Young 2019). Initially, digital eye strain was thought to be affected solely by binocular vision or accommodative disorders; however, current research suggests that binocular vision and accommodative anomalies are not the definitive cause of digital eye strain and that digital eye strain may be due to multiple factors, including symptoms associated with dry eye disease (Sheppard and Wolffsohn 2018). Patients with binocular vision and accommodative issues may or may not experience the signs and symptoms of digital eye strain, the same as patients with normal accommodation or binocular vision systems (Yammouni and Evans 2020). While it is common in clinical practice to fit children in a bifocal or progressive addition spectacle lens for binocular vision or accommodative issues (Chrousos et al. 1988), research has found that an add power in spectacles can help digital eye strain in non-presbyopic patients (Kee et al. 2018). These progressive addition spectacle lenses (ZEISS SmartLife Digital Lenses), with a low add power of +0.75 diopters, were designed specifically for non-presbyopic patients with digital eye strain. The use of these digital eye strain spectacle lenses increased working distance and caused a plus refractive error shift, with both effects decreasing the demand on the ocular system to reduce eye strain (Kee et al. 2018). Contact lenses with incorporated additional plus power have also been examined for the reduction of digital eye strain. A soft aspheric multifocal contact lens designed for non-presbyopic digital device users (Biofinity Energys, CooperVision) has been shown to decrease accommodative fluctuations and decrease eye strain using an aspheric front surface that induces a small amount of plus addition at lens center (Kajita, Muraoka, and Orsborn 2020). A different low-add (+0.50D add power) soft multifocal contact lens (SEED 1dayPure moisture Flex; SEED CO., LTD., Tokyo, Japan) has been shown to decrease accommodative response, alleviating some of the digital eye strain experienced with near tasks using a center-distance aspheric lens design (Koh et al. 2020). Given these findings, clinicians may consider off-label use of soft contact lenses designed for presbyopia correction as a treatment for individuals reporting digital eye strain symptoms.

1.2 Significance of Myopia

Perhaps the most common off-label use for soft multifocal contact lenses is to control myopia progression. Myopia is a significant ocular issue that is increasing in both prevalence and incidence (Holden et al. 2016). The prevalence of myopia has significantly increased in Asia over the past four decades, with approximately 90% of individuals becoming myopic by the time they are in college (Yoon et al. 2011; Jung et al. 2012; Wang et al. 2009; Sun et al. 2012). In a systematic review published in 2016, approximately 1.406 billion people in the world were estimated to have myopia, and 163 million people were categorized as having high myopia (Holden et al. 2016). Myopia is predicted to become an increasingly prevalent condition. It is projected that 50% of the global population will be myopic by 2050, and 10% of the population will have high myopia (Holden et al. 2016).

A consequence of developing myopia is the increased risk of ocular disease such as glaucoma, staphyloma, myopic maculopathy, retinal holes, retinoschisis, and retinal detachments (Tien Y. Wong et al. 2014). Visual impairment is a potential outcome from the ocular complications of these diseases, with risk increasing with higher amounts of myopia (Flitcroft 2012). Patients with high myopia, typically defined as 5 diopters or more myopia, are at a particularly higher risk for sight-threatening complications. Myopic individuals between -6.00 D and -10.00 D have a 3.4 times increased risk of visual impairment, and in individuals with myopia worse than 10.00 D, a 22 times increased risk of visual impairment (Holden et al. 2015). The sight threatening complications associated with myopia development are due to the increased axial length of the eye. It is believed that by limiting axial growth in myopic eyes, the risk of secondary ocular complications and visual impairment can be significantly reduced.

While myopia has become a significant health issue that has a genetic component, the observed increases in myopia prevalence and incidence is attributed to more than genetics. Among the potential causes for the increased incidence of myopia are environmental factors and lifestyle changes that have resulted in decreased time spent outdoors (Morgan, Ohno-Matsui, and Saw 2012). In many Asian countries where increasing myopia prevalence has been observed, early intensive education is implemented with much of a child's time being spent on digital devices at a near viewing distance. Other contributing factors may include diet and light levels, which are also attributable to the decreased amount of time spent outdoors (Lim et al. 2010; Read, Collins, and Vincent 2014). In Singapore, an association was found in school-aged children between a diet consisting of higher levels of cholesterol and saturated fats and longer axial length (Lim et al. 2010). Children in Australia with myopia were found to have a lower amount of light exposure per day compared to their emmetropic-matched counterparts (Read, Collins, and Vincent 2014). Investigators also looked at the activity level of these children, but there were no differences in activity level between myopic and emmetropic children. These observations have prompted the hypothesis that myopia is likely correlated with light exposure, not physical activity.

1.3 Visually-Guided Ocular Growth and Myopia

While no definitive cause has been identified for the initial development of myopia, it is well established that ocular growth is a visually-guided process (Smith 1998). Animals and humans deprived of clear vision at a young age develop myopia (Robb 1977; O'Leary and Millodot 1979; Rabin, Sluyters, and Malach 1981; Hoyt et al. 1981). Because of the vision-dependent nature of ocular growth, scientists have investigated whether optical treatments can slow the progression of myopia. One approach is the use of peripheral retinal defocus to control ocular growth. Animal model research has demonstrated that foveal vision is not required for emmetropization. Animals that have undergone foveal laser photoablation are still able to emmetropize and respond to visual signals presented to the peripheral retina (Smith et al. 2007; Smith, Hung, and Huang 2009). Animal studies have also shown that induced peripheral myopic defocus can slow axial elongation (Smith 2013). This work suggests that center-distance optical treatments that incorporate plus power in the periphery of the optical design could potentially be used to reduce myopia progression in children.

The knowledge gathered from animal model research has led to investigations of optical approaches to slow myopia progression in children. Based on the discovery of peripheral myopic defocus slowing ocular growth in animal models, clinical trials have been performed to evaluate the ability of contact lenses with center-distance, multifocal optics to slow axial eye growth and the progression of myopia in humans. Berntsen and Kramer (2013) examined peripheral retinal defocus in non-presbyopic, young adults wearing a center-distance aspheric multifocal contact lens design. Refractive error measurements taken with a Grand Seiko WAM-5500 open-field autorefractor (Grand Seiko Co., Hiroshima, Japan) centrally and at nasal and temporal retinal locations 20, 30, and 40 degrees from the line of sight found center-distance aspheric multifocal contact lens wear resulted in myopic peripheral defocus as opposed to the hyperopic peripheral defocus measured when wearing a single vision contact lens. Higher amounts of myopic peripheral defocus were observed with the multifocal contact lens at both distance and near when compared to the single vision contact lens. The study found that center-distance aspheric multifocal soft contact lenses can provide the peripheral myopic defocus needed to potentially slow the progression of myopia (Berntsen and Kramer 2013). In a one year study with Chinese children, center-distance multifocal contact lenses were shown to have a decrease in relative peripheral hyperopia, measured with a Shin-Nippon autorefractor, when compared to eyes wearing single vision spectacle lenses (Sankaridurg et al. 2011a). Dual-focus contact lenses, with concentric ring treatment zones of alternating distance power and a plus addition have also been effective in reducing peripheral hyperopic defocus in shorter study durations (Anstice and Phillips 2011).

1.4 Multifocal Contact Lenses and Myopia Control

Multiple treatments have been studied to determine their ability to slow myopia progression such as spectacle lens designs, orthokeratology, pharmacological agents such as atropine, and center-distance multifocal contact lenses (Holden et al. 2015). Concentric ring dual-focus soft contact lenses investigated by Anstice and Phillips resulted in reduced myopia progression and axial elongation (Anstice and Phillips 2011). This study demonstrated that induced myopic defocus, in the presence of a fully corrected foveal image, could slow the progression of myopia (Anstice and Phillips 2011). Sankaridurg examined a center-distance soft multifocal contact lens design for myopia control. Chinese children fit in the center-distance multifocal contact lens design were matched with a control group based on age, sex, axial length, refractive error, and parental history of myopia. Over 12 months, the subjects fitted with the center-distance multifocal contact lenses proved to have a decrease in myopia progression and axial length growth compared to controls (Sankaridurg et al. 2011a).

The Bifocal Lenses in Nearsighted Kids (BLINK) Study was a three-year, double-masked, randomized clinical trial that compared center-distance aspheric multifocal contact lenses with a high add power of +2.50 D (Biofinity Multifocal "D"; CooperVision) to lenses with a medium add power of +1.50 D (Biofinity Multifocal "D"), and a single-vision contact lens (Biofinity Sphere) to examine if center-distance multifocal contact lenses slow the progression of myopia. The BLINK Study group showed that a center-distance multifocal soft contact lens with a +2.50 D add significantly slowed myopia progression versus both a +1.50 add power lens and the spherical lens (Walline et al. 2020). Children fit the +2.50 D add center-distance multifocal soft contact lens achieved acceptable distance vision while reducing myopia progression—the +1.50 D add did not yield a significant reduction in myopia progression (Berntsen and Kramer 2013; Walline et al. 2020; Schulle et al. 2018). Over a three-year period, the study examined the progression of myopia using cycloplegic spherical equivalent auto-refraction and found that progression was lowest for the high-add multifocal contact lens (-0.60 D) compared to progression in the medium-add multifocal lens (-0.89 D) and single vision lens (-1.05 D). This result demonstrates that high add powers center-distance multifocal soft contact lenses are effective in controlling myopia progression, whereas lower add powers did not significantly slow myopia progression compared to a single vision contact lens (Walline et al. 2020).

The use of multifocal contact lens optics for myopia control has led to the FDA approval of the first contact lens approved for managing myopia, the CooperVision MiSight ("Premarket

Approval Misight 1 Day (Omafilcon a) Soft (Hydrophilic) Contact Lenses for Daily Wear" 2019). The MiSight contact lens is a concentric ring design with a fixed add power, unlike traditional multifocal contact lenses which generally have a selectable add power. Compared to the control (Proclear 1-day), the MiSight contact lens wearers had less myopia progression and reduced axial eye growth (Chamberlain et al. 2019).

1.5 Visual Performance of Multifocal Contact Lenses

While results of clinical trials have demonstrated the efficacy of these lenses for slowing myopia progression, questions regarding the overall visual performance of the lenses remain. Comparison of different soft multifocal contact lens designs requires uniform testing procedures to better understand how individual lenses differ in their performance. The most common way of assessing objective visual performance of a contact lens is through visual acuity (Ricci, Cedrone, and Cerulli 1998). Using a uniform progression of optotype size and letter spacing provides a standardized way to assess visual acuity across different contact lenses (Ricci, Cedrone, and Cerulli 1998).

To maximize efficacy of multifocal contact lenses in myopia control, high add power lenses are typically utilized in center-distance contact lens designs to provide distance vision correction in the center of the contact lens. Additionally, unlike the correction of presbyopia, where center-near optical design contact lenses may be used in one or both eyes to provide acceptable near vision, off-label aspheric multifocal contact lenses are commonly fit with center-distance optical designs in both eyes for myopia control patients. To avoid excessive divergent power reducing the potential myopia control effect with center distance multifocal designs, these contact lenses are fit using a maximum plus power to maximize visual acuity. This can lead to the prescription of additional minus to the vertex-corrected refractive error to provide acceptable distance vision.

Children enrolled in a myopia control study who were fitted with the Biofinity Multifocal D (center-distance) +2.50 add based on their distance manifest refraction consistently required a spherical over-refraction ranging from -0.50 to -0.75 DS to provide best distance visual acuity (Schulle et al. 2018). There was no significant correlation or alteration of over-refraction due to level of myopia, astigmatism, or pupil size. With the over-refraction in place, high-contrast logMAR visual acuity was found to be no different from full spectacle correction (Schulle et al. 2018).

Kollbaum et al. evaluated objective visual acuity and patient reported lens performance with a dual focus contact lens (MiSight, CooperVision Inc.) and a center-distance multifocal contact lens with a +2.00 D add (Proclear Multifocal D, CooperVision Inc.), compared to the subject's habitual correction. Objective measurements of visual performance found that there was no difference in high-illumination, high-contrast visual acuity among the habitual correction, dual focus lens, or multifocal lens. Subjects reported poorer viewing quality with both the dual focus and multifocal lenses compared to the subject's habitual correction. Objective measurements of visual acuity in low-illumination, low-contrast settings showed decreased performance with the dual focus and multifocal lenses compared to the habitual correction. In general, patients reported poorer viewing quality with both the dual focus and the multifocal contact lens when compared to habitual correction. However, there was no significant difference in viewing quality, a subjective rating by the patient, between the dual focus and multifocal lenses (Kollbaum et al. 2013). A study by Fedtke et al. found that the visual performance of multifocal contact lenses was correlated with the size of the optic zone or decentration. When these lenses were significantly decentered or the optic zone power variations were larger, the subjects performed worse with the lenses (Fedtke et al. 2016).

Previous studies have mainly reported visual performance on the day of the contact lens dispensing, without addressing if visual performance changes with longer periods of wear. Papas et. al examined the visual performance of multifocal contact lenses 4 days after contact lens dispensing in patients ranging from 40-60 years old, inclusively (Papas et al. 2009). In four different soft multifocal contact lenses, the lenses had a significant difference in range of clear vision and high-contrast, low-illumination, near visual acuity when comparing day one of dispense and day four. Although these lenses are being evaluated for myopia control, the question of long term visual performance may be of interest when evaluating these lenses. Another study that looked at short-term performance of multifocal contact lenses was one done by Diec et al. This retrospective analysis of young adult myopes assessed subjective vision when wearing multifocal lenses. Compared to the initial fit, vision clarity, vision satisfaction, comfort of the lenses, and vision stability were all decreased at the later follow-up for both the single vision and multifocal contact lenses (Diec et al. 2018). Both of these studies raise the question of whether visual performance needs to be evaluated on another date later than the initial fit. A retrospective analysis examining the Acuvue Oasys for Presbyopia (Johnson and Johnson Vision; Jacksonville, FL) and Air Optix Aqua Multifocal (Alcon; Fort Worth, TX) contact lenses followed subjects for 5 days (Diec et al. 2017). This study utilized take home questionnaires to subjectively assess lens performance in participants wearing these lenses. During this study, investigators also found a statistically significant decrease in subjective visual quality and comfort when comparing the fitting and assessment visits (Diec et al. 2017).

Subjective visual quality is another matter that has been questioned when fitting patients in these lenses. A retrospective analysis of subjective vision ratings, visual acuity, and willingness to purchase multifocal lenses found that subjective vision ratings may give a more comprehensive understanding of visual performance (Jong et al. 2019). Their analysis found a weak correlation between visual acuity and subjective description of vision. Moreover, subjective vision ratings were a better predictor of visual performance than visual acuity. This finding could explain why patients often report poor vision in their environment even when they demonstrate good high-contrast visual acuity in office. Their study also found that the best predictor of willingness to purchase the lenses was the overall subjective performance in the contact lenses (Jong et al. 2019). Collectively, these studies demonstrate the importance of subjective visual quality for success and compliance with multifocal contact lens wear.

1.6 Reading Performance

To understand how reading performance may be affected by different factors such as contact lens design or viewing conditions, it is first important to understand the repeatability of the measurements. A study done at Hong Kong Polytechnic University (PolyU) was designed to understand the repeatability of high- and low-contrast visual acuity at near (Lam et al. 2008). To ensure credit for each letter, acuity was documented in logMAR notation with four different near charts: PolyU high-contrast, PolyU low-contrast, Precision high-contrast, and Precision low-contrast. This study looked at acuity with each of the charts in randomized order and was then repeated at another visit within one to two weeks. This study showed that the Precision near chart was found to be better for smaller letters since it can measure down to threshold acuity. An important factor in measuring acuity at near is ensuring correct lighting to compare repeated measurements of acuity (Lam et al. 2008).

When looking at repeatability of near visual performance, another factor is the test modality. A study done by Kingsnorth and Wolffsohn looked at the repeatability and accuracy of an electronic (iPad) mobile application, compared to paper charts, to test reading speed (Kingsnorth and Wolffsohn 2015). The theory is that a mobile application may be more convenient than traditional paper charts for both the patient and the examiner. Positioned at 40 cm, the mobile application presented Radner reading sentences for the subject to read aloud, with the device recording the subject's voice while reading and face-tracking with the device's built-in camera. When comparing paper-based and app-based charts, there was a significant difference for both optimal reading speed (ORS) and critical print size (CPS). While ORS was higher with the mobile chart when compared to the paper chart, CPS was found lower for mobile charts. The repeatability for ORS was as good as the paper test; the repeatability for CPS was better than the paper test. This study demonstrated that mobile charts are repeatable, quick, and convenient; however, the results from the application-based charts cannot be simply interchanged with those from paper charts (Kingsnorth and Wolffsohn 2015).

Another factor that has been thought to affect near visual performance is the type of visual correction. One study evaluated visual performance at distance and near, comparing spectacle correction and the PureVision Multifocal contact lens (Bausch + Lomb, Bridgewater, NJ), a simultaneous vision design (Llorente-Guillemot et al. 2012). This study consisted of measuring both visual acuity and contrast sensitivity at distance and near in presbyopic participants. When comparing visual acuity with both forms of correction, spectacle correction performed superiorly compared to the contact lenses; binocular near acuity was better with the spectacles, differing by about one line with photopic lighting. Under mesopic lighting, the visual acuity differed significantly more with the contact lenses performing worse than the spectacle lenses. Contrast sensitivity at near was also found to be reduced when wearing the multifocal contact lens compared to the spectacle correction. While there is a statistical difference in performance among the correction modalities, performance is still adequate with the multifocal contact lenses for presbyopic patients who prefer contact lenses over spectacles (Llorente-Guillemot et al. 2012).

1.7 Glare Affecting Visual Performance

Overall visual performance in the environment is not captured by simply measuring standard visual acuity in high or low lighting situations. Understanding how glare affects vision of those wearing multifocal contact lenses is important to understand additional environmental factors that can potentially influence visual performance. A study with young adults evaluating disability glare compared how subjects responded in a single vision contact lens, a center-distance multifocal contact lens with a +2.50 D add, and a center-near multifocal contact lens with a +2.50 D add (Wahl et al. 2018). To ensure that pupil size did not affect the optics or glare, all subjects were cyclopleged and an artificial 5 mm pupil was placed in a trial frame. Among the three contact lenses, the single vision lens performed best in glare settings when compared to the multifocal contact lenses. The center-near design showed a significant reduction in contrast sensitivity both with and without glare, while the center-distance design only showed a reduction with glare (Wahl et al. 2018).

A study done by García-Lázaro et. al evaluated four different simultaneous-image multifocal contact lenses in glare situations. The Air Optix Aqua spherical contact lenses (Alcon; Fort Worth, TX), fitted using a monovision strategy, were compared to four multifocal designs, which included the Air Optix Aqua Multifocal (Alcon; Fort Worth, TX), PureVision Multifocal (Bausch & Lomb; Bridgewater, NJ), Acuvue Oasys for Presbyopia (Johnson and Johnson Vision Care; Jacksonville, FL), and Biofinity Multifocal, both center-distance and center-near designs (CooperVision, San Ramon, CA) (García-Lázaro et al. 2015). All lenses were fit on presbyopic participants. The lenses that performed the best in glare situations were those with a continuous power gradient. When evaluating a low add power multifocal in dim lighting conditions with presbyopic patients, the Air Optix Aqua Multifocal and PureVision Multifocal contact lenses had better visual performance at distance when compared to the Biofinity Multifocal and Air Optix for Presbyopia. However, the monofocal contact lenses had the best visual performance when considering contrast sensitivity for higher spatial frequencies (García-Lázaro et al. 2015).

1.8 Pupil Size

Pupil size is an important variable to consider when determining visual performance in multifocal contact lenses. Multifocal soft contact lenses are designed for patients with presbyopia, who have smaller pupils than non-presbyopes (Pérez-Prados et al. 2017). Eyes with smaller pupils experience less glare and ghost images in low lighting settings with multifocal lenses, compared to eyes with larger pupils (Pérez-Prados et al. 2017). Even in more difficult lighting, smaller pupils provide better vision by increasing depth of focus and decreasing the impact of higher-order aberrations (Remón et al. 2020). Compared to larger pupils, eyes with smaller pupils have better visual acuity since they tolerate myopic defocus more than larger pupils with aspheric multifocal soft contact lenses (Pérez-Prados et al. 2017). This may become a more significant consideration as multifocal soft contact lenses are being prescribed more often in children with larger pupil sizes.

The typical pupil size measured in children is commonly larger than in presbyopic patients which has been shown to significantly alter visual quality. During a retrospective chart review, the pupil size of children aged less than 1 year to 17 years was measured with the plusoptiX in dim illumination (Silbert et al. 2013). In general, pupil size increased with age in these children. Measurements ranged from an average of 5.2 mm at the youngest ages to 6.5 mm in the oldest children (Silbert et al. 2013). Since pupil size seems to increase with age in children and a larger pupil size can decrease visual image quality, this raises the question of how pupil size may affect multifocal contact lens performance.

A study done by Hastings et. al. quantified how visual image quality is affected by age and pupil size using the visual Strehl ratio (VSX) (Hastings et al. 2018). The VSX was best in younger subjects, aged 20-30 years, with a small pupil size. VSX was worse in older patients with a larger pupil size. When compared to age, pupil size was a factor that caused a more significant decrease in VSX (Hastings et al. 2018).

Papadatou et. al. quantified how pupil size affects the on eye power distribution of multifocal contact lenses (Papadatou et al. 2017). The power profile of several multifocal contact lenses were measured, to the nearest 0.25 D, for several pupil diameters. Pupil size significantly affected the peripheral power profile. In general, a larger pupil had a wider range of power distribution; this finding is consistent among all add powers with center-distance multifocal contact lenses. A subject with a 6.0 mm pupil with a -3.00 D distance prescription had a power profile that ranged across all 3.00 D (Papadatou et al. 2017). This is comparable to an average child's pupil size which has been found to range from 5.2 mm to 6.5 mm in ages younger than 1 year to 17 years (Silbert et al. 2013).

When looking at several contact lenses commonly used for myopia control, power profile is critical in understanding how it will affect the visual performance of younger children. A study done by Nti et. al looked at the power profile of several center-distance multifocal designs: the Biofinity Multifocal D with a +2.50 D add, Proclear Multifocal D with a +2.50 D add, and NaturalVue Multifocal (Nti, Ritchey, and Berntsen 2021). All lenses increased in plus power from the center of the lens to the periphery. Both the Biofinity and Proclear Multifocal had three distinct regions of power divided into a distance, intermediate, and near zone. The NaturalVue

Multifocal had an increase in plus power almost immediately from the center of the lens, but after the maximum plus at approximately a 2.7 mm radius, the outer segment of the lens decreased in plus power. The NaturalVue Multifocal had the highest maximum add power, an average of +3.32 D. Both the Proclear and Biofinity Multifocal lenses on average had a lower maximum add power of +1.84 D and +1.47 D, respectively (Nti, Ritchey, and Berntsen 2021).

1.9 Specific Aims

Research of myopia control with soft multifocal contact lenses is ever evolving and understanding the background of myopia, treatment modalities, and how the optics of these lenses may affect this population is critical when prescribing these lenses. More importantly, knowing that visual function is not significantly affected is critical for clinicians to feel comfortable in fitting children in multifocal contact lenses for myopia control. Given this, my thesis addresses two specific experimental aims:

Aim 1: Determine how varying contrast and illumination levels affect visual performance in myopes wearing center-distance multifocal contact lenses with peripheral plus power using a myopia control fitting paradigm

Aim 2: Determine how near reading performance is affected in subjects wearing center-distance multifocal soft contact lenses using a myopia control fitting paradigm

Chapter 2: Visual Performance of Center-Distance Multifocal Contact Lenses Fit Using a Myopia Control Paradigm

2.1 Introduction

Myopia is an increasingly prevalent condition affecting millions of individuals worldwide. In Asia, prevalence has increased steadily over the last 40 years, with 90% of young people becoming myopic by their college years (Yoon et al. 2011; Jung et al. 2012; Wang et al. 2009; Sun et al. 2012). It is projected that 50% of the world's population will be myopic by the year 2050, with an estimated 1 billion highly myopic individuals (Holden et al. 2015; 2016).

Although traditionally, myopia has been considered a relatively benign condition correctable with spectacles and contact lenses, the increasing axial length observed with myopia heightens the risk of developing multiple ocular diseases, such as glaucoma, cataracts, retinal detachment, and myopic maculopathy ("Risk Factors for Idiopathic Rhegmatogenous Retinal Detachment. The Eye Disease Case-Control Study Group" 1993; Ogawa and Tanaka 1988; Tien Yin Wong et al. 2003; Mitchell et al. 1999; Neelam et al. 2012; Kyoko Ohno-Matsui et al. 2012; K Ohno-Matsui 2003; Yoshida et al. 2003; Shih et al. 2006). As such, there is increasing pressure on clinicians to provide treatment options that not only correct a patient's refractive error but also may slow the progression of myopia to help prevent future vision loss from comorbidities.

Animal models and clinical trials have shown that the application of myopic retinal defocus can slow the progression of myopia (Liu and Wildsoet 2011; Smith, Hung, and Huang 2009; Smith et al. 2010; 2007; Aller and Wildsoet 2008; Anstice and Phillips 2011; Sankaridurg et al. 2011b; Aller, Liu, and Wildsoet 2016; Chamberlain et al. 2019). The discovery of the retina's ability to detect the sign of defocus was key in the development of optical therapies to control myopia progression, culminating with the eventual approval of the first soft contact lens for myopia control in the United States ("Premarket Approval Misight 1 Day (Omafilcon a) Soft (Hydrophilic) Contact Lenses for Daily Wear" 2019). With the exception of the recently approved MiSight contact lens, most soft contact lenses used in the United States to slow myopia progression have been designed for presbyopic patients and are prescribed off-label. In practice, center-distance multifocal contact lenses are used to correct distance vision while simultaneously providing the desired myopic retinal defocus, often using the highest available add power to maximize myopic defocus. For example, the Bifocal Lenses in Nearsighted Kids study group demonstrated that children fit with a +2.50 D add center-distance multifocal contact lens achieved acceptable distance vision while providing relative peripheral myopic defocus and reduced myopia progression, whereas the +1.50 D add did not provide the desired myopia control effect (Berntsen and Kramer 2013; Walline et al. 2020; Schulle et al. 2018).

Despite the rapid adoption of center-distance multifocal contact lenses for myopia control in clinical practice, questions on the visual experience for patients remain. Aspects of visual quality for multifocal contact lenses, such as visual acuity and subjective symptom questionnaires, have been examined in presbyopic and non-presbyopic patients (Diec et al. 2017; 2018; Fedtke et al. 2016; Jong et al. 2019; Papas et al. 2009). Despite these previous investigations, because new multifocal contact lenses are introduced, different visual outcomes may be observed with each unique optical profile. For example, the NaturalVue Multifocal contact lens (Visioneering Technologies, Inc., Alpharetta, GA) reports using an extended depth of focus principle to provide a range of clear vision at near, equivalent to a multifocal add power of up to +3.00 D. It is unknown whether this design may provide different visual outcomes compared with traditional center-distance multifocal designs. In addition, there is little information on the effect of glare on acuity with multifocal lenses. Although glare is commonly associated with tasks performed by adults, patients fit with multifocal lenses for myopia control may encounter various sources of glare in their environment, such as water and snow, or from electronic devices. These lenses, when fit using a myopia control fitting paradigm of over-refraction adjusted maximum plus power to maximum distance visual acuity, paired with the maximum available bifocal add power to provide myopic retinal defocus (García-Lázaro et al. 2015), may significantly reduce visual acuity under glare conditions. For near performance with multifocal contact lenses, there is information on near visual acuity; however, there is little information on how these lenses affect tasks such as reading in non-presbyopes (Jong et al. 2019; Kollbaum et al. 2013).

The purpose of this study was to investigate how two multifocal contact lenses, commonly used off-label indication for myopia control, affect visual performance in nonpresbyopic, myopic subjects. We compare the distance visual acuity performance between a traditional center-distance aspheric multifocal, the Biofinity Multifocal D lens with a +2.50 add (CooperVision, San Ramon, CA) and an extended depth of focus design, the NaturalVue Multifocal, with a single-vision contact lens (Biofinity sphere; CooperVision) under different lighting conditions for high- and low-contrast targets. The effect these lenses have on near visual performance, including visual acuity and reading speed, was evaluated with a validated, novel, iPad application (Kingsnorth and Wolffsohn 2015).

2.2 Methods

This study was conducted in accordance with the tenets of the Declaration of Helsinki. Written informed consent was acquired from all subjects before study participation, and the study was approved by the institutional review board of the University of Houston. Subject demographics are shown in Table 1, including age, sex, refractive error, race, and ethnicity, with race and ethnicity terms used as defined per the 1997 U.S. Office of Management and Budget guidance on classification of data on race and ethnicity (U.S. Office of Management and Budget (OMB) 1997).

Overview

This was a single-site, bilateral, single-masked, non-dispensing two-visit crossover clinical study. Twenty-five adult subjects aged 21 to 29 years were enrolled and completed the study. Each subject was fit binocularly with three different contact lens designs: (1) Biofinity D center-distance multifocal with +2.50 add power (CooperVision), (2) NaturalVue Multifocal contact lens (Visioneering Technologies, Inc.), and (3) Biofinity sphere single-vision contact lens (CooperVision). The Biofinity sphere and the Biofinity multifocal contact lens are silicone-hydrogel lenses made of comfilcon A (48% water) and have a base curve of 8.6 mm and an overall lens diameter of 14.0 mm. The Biofinity multifocal is a progressive aspheric design, with the "D" lens having a spherical central-distance power, surrounded by a zone of progressively increasing plus power before reaching the maximum amount of plus power at the periphery of the optic zone. The NaturalVue Multifocal is a hydrogel lens made of etafilcon A (58% water) and has an 8.3 base curve and an overall lens diameter of 14.5 mm. The NaturalVue Multifocal is described as an extended depth of focus design using a continuous aspheric progression in plus power (Griffin R 2002). This design does not specify a labeled bifocal addition power and is indicated for presbyopic correction of up to +3.00 D add power. The three contact lens designs were fit binocularly, in random order, over two study visits occurring within a 2-week period. Subjects were masked to the contact lens type.

Table 2.1. Subject Demographics

Subject Demographics	
Age (mean ± SD)	24.08 ± 1.53 years
Sex	Male: 7 (28%) Female: 18 (72%)
Refraction OD (mean ± SD)	−3.38 ± 1.53 DS. Range −1.00 to −5.00 DS
Refraction OS (mean ± SD)	−3.29 ± 1.66 DS. Range −0.75 to −5.75 DS
Race	
White	16 (64%)
Asian	6 (24%)
African American	2 (8%)
Other	1 (4%)
Ethnicity	
Hispanic or Latino	18 (72%)
Non-Hispanic	7 (28%)

Eligibility

Eligible subjects were required to have a spherical equivalent refraction between −0.75 and −6.00 diopter sphere at the corneal plane, refractive astigmatism of −1.00 diopter cylinder or less, and best-corrected visual acuity of at least 20/30 in each eye. Exclusion criteria included the presence of a significant anterior segment disease, a history of ocular trauma or surgery, a history of refractive surgery, or current rigid gas-permeable contact lens wear. Subjects were excluded if they were pregnant or nursing.

Contact Lens Power Selection

Initial refractive error for each subject was measured using an open-field autorefractor (Grand Seiko WR-5100 K; Grand Seiko Co., Hiroshima, Japan), followed by maximum plus power to maximum visual acuity subjective refraction. Initial contact lens power selection for the Biofinity contact lens products was determined using the spherical equivalent spectacle refraction (Sphere + 0.5*Cylinder), vertex corrected for prescriptions beyond −4.00 diopter sphere. Initial lens selection for the NaturalVue Multifocal lens was determined using the

NaturalVue Multifocal QuickStart Calculator (Visioneering Technologies, Inc.), where the spectacle refraction and the vertex distance to the corneal plane are inputs to determine contact lens power. After initial power selection, the contact lenses were inserted by study personnel, and fit was assessed. Once an acceptable fit was achieved, spherical contact lens over-refraction was performed. Distance vision was optimized using the maximum plus to maximum visual acuity approach for each lens type, and contact lens power was changed if indicated by the over-refraction.

Contact Lens Assessment

Contact lens movement in primary gaze and with push-up test was assessed using a 5-point scale:

- Excessive: movement with the blink that produces limbal exposure
- Moderate acceptable: substantial movement that does not produce limbal exposure but does not immediately return to the original lens edge position
- Optimal movement: a freely mobile lens with the blink that immediately returns to the original lens edge position
- Minimal acceptable: slight movement with the blink that is less than optimal movement (this movement is less than that observed with a freely mobile lens)
- Insufficient: no lens movement or barely detectable movement with the blink (the lens appears adhered to the ocular surface)

Contact lens centration was determined via measurement of contact lens corneal overlap from the corneal limbus to contact lens edge measured to the nearest 0.1 mm, using a Haag-Streit slit-lamp reticule under 10 magnification. Contact lens decentration was calculated as the difference between temporal and nasal overlaps (i.e., temporal overlap − nasal overlap), with positive values representing temporal contact lens decentration and negative values representing nasal contact lens decentration.

Visual Acuity and Reading Performance

After a minimum contact lens settling period of 10 minutes, logMAR distance visual acuity was measured monocularly and binocularly using the M&S Technologies Clinical Trial Suite (M&S Technologies, Niles, IL). High- and low-contrast (11% Michelson contrast) logMAR visual acuity was measured at distance with each lens type under photopic lighting (~367.0 lux), mesopic lighting (<1.0 lux), and mesopic lighting with a glare source consisting of four lights shining at the patient located at the plane of the acuity monitor (~2.0 lux). Lighting levels were measured with a Sekonic L-758DR photometer (Sekonic Corporation, Tokyo, Japan) at the eye plane of the subject.

Near high-contrast logMAR visual acuity and mean reading speed were evaluated using an iPad application developed by Kingsnorth and Wolffsohn (Kingsnorth and Wolffsohn 2015). Subjects were seated 40 cm from a 9.7-inch sixth-generation iPad (Apple, Cupertino, CA) on a reading stand under photopic lighting conditions. With the display brightness of the iPad set to maximum, a measurement of the subject's interpupillary distance was acquired using the iPad FaceTime camera. Subjects were instructed that they would be presented a series of sentences on the iPad. They were instructed to be as accurate as possible while reading the sentence at a normal cadence. Subjects were instructed that, if they made a reading error during the test, they should not go back and correct an error from a previous point in the sentence. Subjects were then presented a series of sentences ranging in letter size from 0.9 to −0.2 logMAR. Beginning at 0.9 logMAR, each subsequent sentence decreased in size by 0.1 logMAR. Subjects read the sentence aloud and immediately pressed a "Read" button after completion of the sentence. Once the text became too small to read, the subject pressed a "Cannot Read" button. Upon completion of the test, the examiner identified words that the subject read incorrectly with the option to play back the recorded audio and noted the incorrect words, and the iPad software calculated the near logMAR acuity and mean reading speed in words per minute from the automatically timed audio trace (Fig. 2.1).

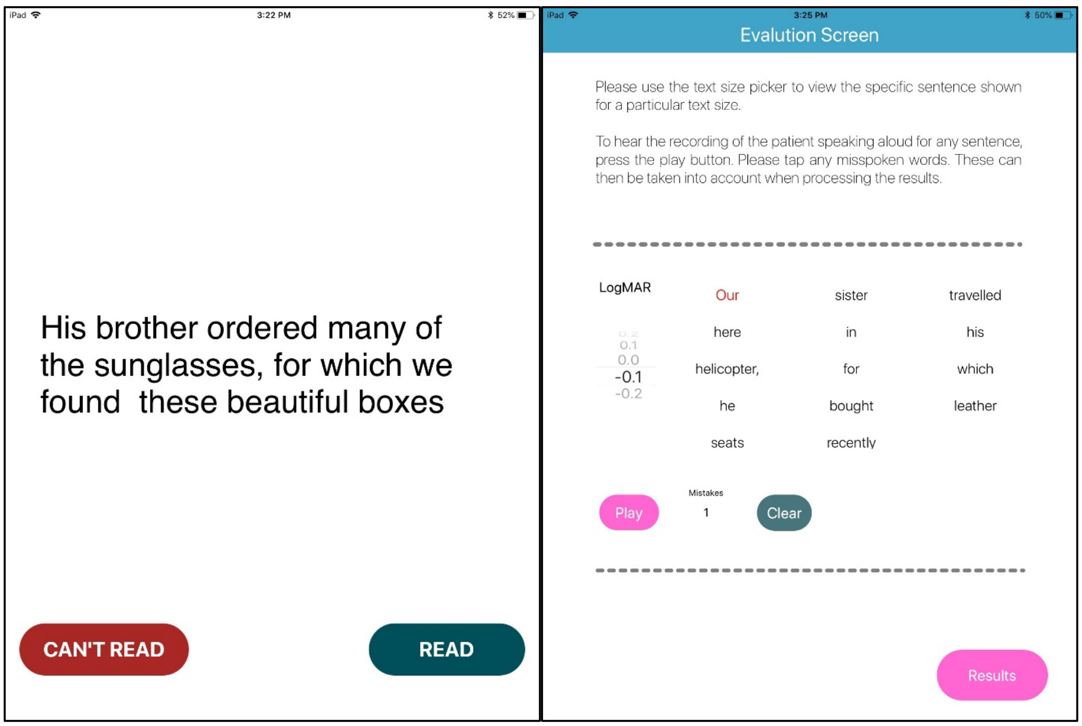

Figure 2.1. Example of the Wolffsohn iPad application for evaluating near visual acuity and reading speed. (A) A representative reading task at 0.9 logMAR. The subject reads the randomized passage aloud and presses "Read" upon completion of the task or "Cannot Read" if the presented text size is too small to discern. (B) The grading interface. The investigator reviews the subject's recording of the passage (Play) and selects the words misread by the subject (red) versus correctly read words (black).

Pupil Size

Pupil size was measured at both study visits under photopic and mesopic lighting conditions with the NeurOptics VIP-300 Pupillometer (NeurOptics, Laguna Hills, CA). Subjects fixated on a distance target with the left eye, and pupil size was measured for the right eye under photopic and mesopic conditions. Pupil size was measured to the nearest 0.1 mm.

Statistical Analyses

A sample size of 24 subjects was determined to adequately detect a 0.1 logMAR (one line) difference in low-contrast visual acuity between lens designs with 90% power at an α level of 0.05, assuming a standard deviation for the change in visual acuity of 0.15 logMAR. Because the data were not significantly different from a normal distribution, statistical analyses were conducted using repeated-measures ANOVA, with adjusted post hoc t tests, when appropriate. For distance visual acuity, the repeated-measures ANOVA included three repeated factors: lens type (Biofinity sphere, Biofinity Multifocal, NaturalVue Multifocal), letter contrast (high contrast and low contrast), and lighting condition (photopic, mesopic, mesopic with glare). Near visual acuity was analyzed using repeated-measures ANOVA with one repeated factor (lens type). Repeated-measures ANOVA for reading speed included two factors: lens type and letter size (logMAR).

2.3 Results

Contact Lens Fitting Characteristics

All lenses fit were determined to have acceptable movement in primary gaze. Spherical over-refraction was performed in a phoropter using a maximum plus to maximum visual acuity approach with binocular blur balance under photopic conditions. Of 50 total eyes, 3 eyes in the single-vision lens required a power modification, with a mean ± standard deviation over-refraction of +0.33 ± 0.12 diopter sphere. Twenty-nine of 50 eyes wearing the Biofinity multifocal required over-refraction, with an average over-refraction of −0.37 ± 0.13 diopter sphere. Only one eye wearing the NaturalVue Multifocal required an over-refraction of power −0.50 diopter sphere to optimize distance visual acuity.

Slight temporal contact lens decentration was observed throughout the study. For the right eye, the mean ± standard deviation contact lens decentration were +0.28 ± 0.23 mm temporal for the Biofinity sphere contact lens, +0.28 ± 0.28 mm temporal for the Biofinity Multifocal, and +0.28 ± 0.21 mm temporal for the NaturalVue Multifocal. There was no significant difference in contact lens centration between the three contact lenses ($P = .99$). All lenses evaluated in the study had adequate paralimbal coverage, and no lens in the study was evaluated as having excessive contact lens decentration that would warrant lens discontinuation.

Visual Acuity

LogMAR visual acuity under high- and low-contrast conditions depended on the lighting condition (photopic, mesopic, mesopic with glare) and the lens type (lens-contrast-lighting interaction; $P = .02$).

High-Contrast Visual Acuity

High-contrast visual acuity is shown in Fig. 2.2. Regardless of contact lens type, high-contrast distance visual acuity was always better than low-contrast acuity (all, $P < .05$). All three contact lens designs provided mean ± standard deviation photopic distance acuity better than −0.1 logMAR (Biofinity sphere, −0.18 ± 0.06; Biofinity Multifocal, −0.14 ± 0.08; NaturalVue Multifocal, −0.15 ± 0.03). A statistically significant but clinically insignificant difference in visual acuity between the single-vision lens and the multifocal contact lenses was observed ($P = .02$), with each multifocal contact lens performing approximately 1.5 to 2 letters worse than the single-vision lens. Under mesopic conditions, a statistically significant and clinically meaningful difference in high-contrast visual acuity was observed (P < .0001), with both multifocal contact lens designs performing approximately one line worse than the single-vision contact lens (Biofinity sphere, −0.05 ± 0.09; Biofinity Multifocal, 0.03 ± 0.09; NaturalVue Multifocal, 0.05 ± 0.09). With the addition of a glare source under mesopic conditions, there was no difference in mean visual acuity, and multifocal contact lens designs continued to perform approximately one line worse than the single-vision contact lens (Biofinity sphere, −0.05 ± 0.081; Biofinity Multifocal, 0.05 ± 0.08; NaturalVue Multifocal, 0.06 ± 0.08).

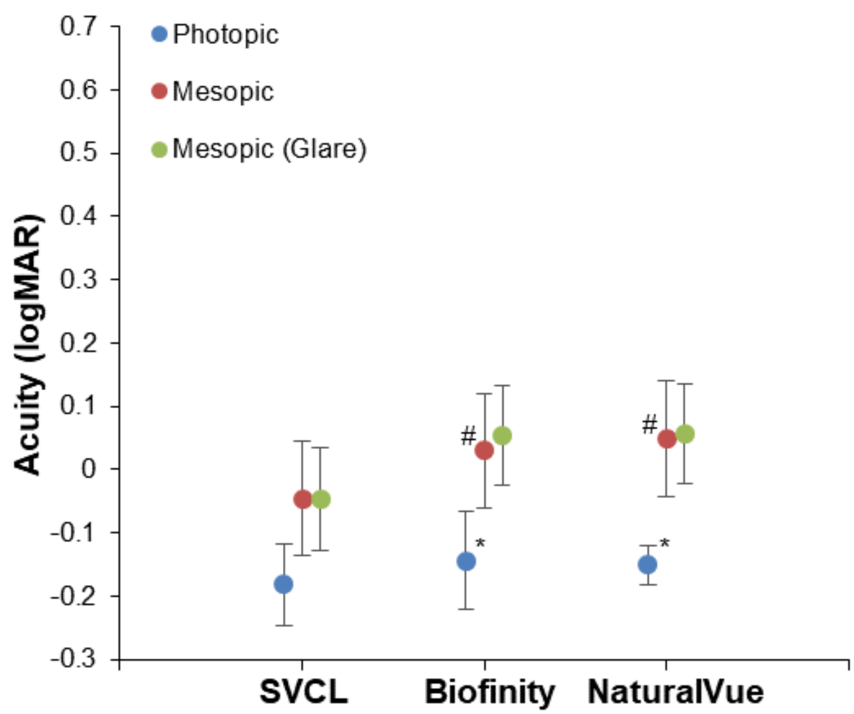

Figure 2.2. High-contrast visual acuity (logMAR) with a SVCL and MF contact lenses under various lighting conditions. A statistically significant difference in visual acuity between the single-vision lens and the multifocal contact lenses was observed under photopic (*P = .02) and mesopic (#P < .001) conditions. No difference in visual acuity was observed for mesopic versus mesopic plus glare conditions for any lens type. Error bars represent standard deviation. MF = multifocal; SVCL = single-vision contact lens.

Low-Contrast Visual Acuity

Low-contrast visual acuity is shown in Fig. 2.3. Low-contrast distance visual acuity under photopic conditions was better than under mesopic conditions for all lenses (all, $P < .001$). Mean photopic, low-contrast visual acuity with the multifocal contact lens designs performed five to six letters worse than with the single-vision lens (Biofinity sphere, -0.02 ± 0.09; Biofinity Multifocal, 0.08 ± 0.09; NaturalVue Multifocal, 0.10 ± 0.09). Under mesopic, low-contrast conditions without glare, acuity was reduced approximately two lines with the multifocal contact lenses compared with the single-vision lens (Biofinity sphere, 0.18 ± 0.096; Biofinity Multifocal, 0.40 ± 0.09; NaturalVue Multifocal, 0.42 ± 0.09). Lighting change from photopic to mesopic conditions led to an approximate two-line reduction in visual acuity with the single-vision lens ($P < .001$) and an approximate three-line reduction with multifocal contact lenses ($P < .001$). The addition of a glare source resulted in additional reduction in visual acuity of approximately 0.5 line logMAR for all lens types (Biofinity sphere, 0.24 ± 0.06; Biofinity Multifocal, 0.45 ± 0.14; NaturalVue Multifocal, 0.51 ± 0.11; $P < .001$). There was no significant difference in visual acuity between the two different multifocal contact lenses regardless of testing condition (all, $P > .05$).

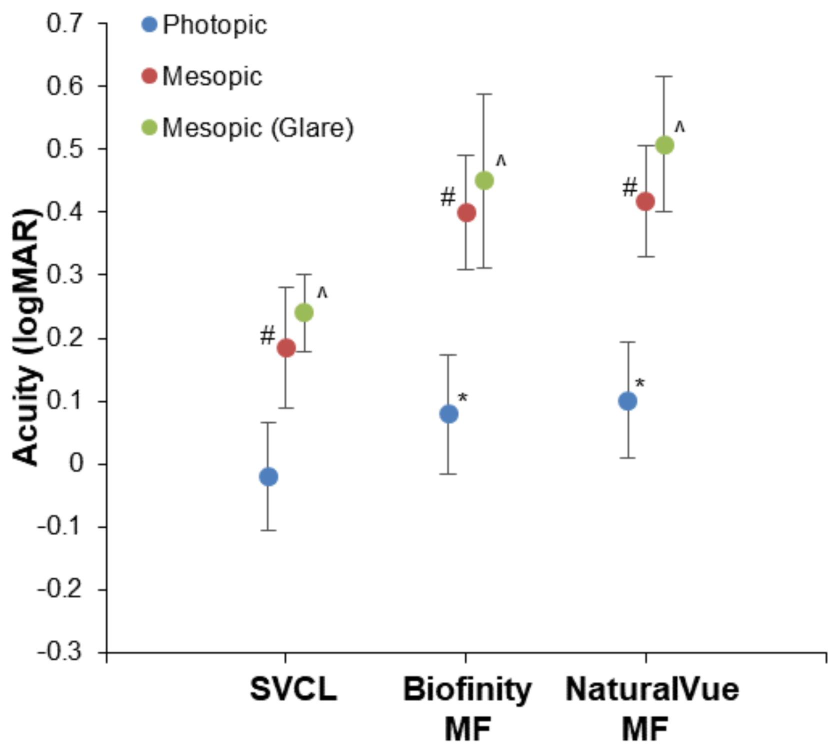

Figure 2.3. Low-contrast visual acuity with SVCLs and MF contact lenses under various lighting conditions. Photopic low-contrast acuity was worse with multifocal lenses (*P < .001) compared with SVCL. Comparing mesopic to photopic conditions, a two-line reduction in visual acuity was observed for the SVCL lens and a three-line reduction was observed for each MF contact lens (#P < .001). Glare further reduced acuity by 0.5 logMAR for all lenses compared with photopic conditions (^P < .001) There was no significant difference in visual acuity between the two multifocal contact lenses for any lighting condition (P > .05). Error bars represent standard deviation. MF = multifocal; SVCL = single-vision contact lens.

Near Visual Acuity and Reading Performance

Mean near reading visual acuity was better than −0.10 logMAR for all three lenses (Fig. 4A). A statistically significant but not clinically meaningful difference was observed in acuity between the lens types (single-vision lens, −0.16 ± 0.06; Biofinity Multifocal, −0.17 ± 0.04; Biofinity Multifocal, −0.13 ± 0.08; P = .02). Letter size (P < .0001) and contact lens type (P = .04) each had an effect on words read per minute under binocular viewing conditions; however, the effect of letter size on reading speed did not differ by lens type (lens–letter size interaction, P = .18). Mean reading speed at each letter size for each lens is presented in Fig. 4C. Average reading speed across all letter sizes was better with the Biofinity single-vision contact lens (156 ± 23 words per minute) compared with the Biofinity Multifocal contact lens (144 ± 22 words per minute) and the NaturalVue Multifocal contact lens (144 ± 28 words per minute; both, P < .05; Tukey WSD adjusted). There was no difference in reading speed between the two multifocal contact lenses (P = .95; Fig. 4B).

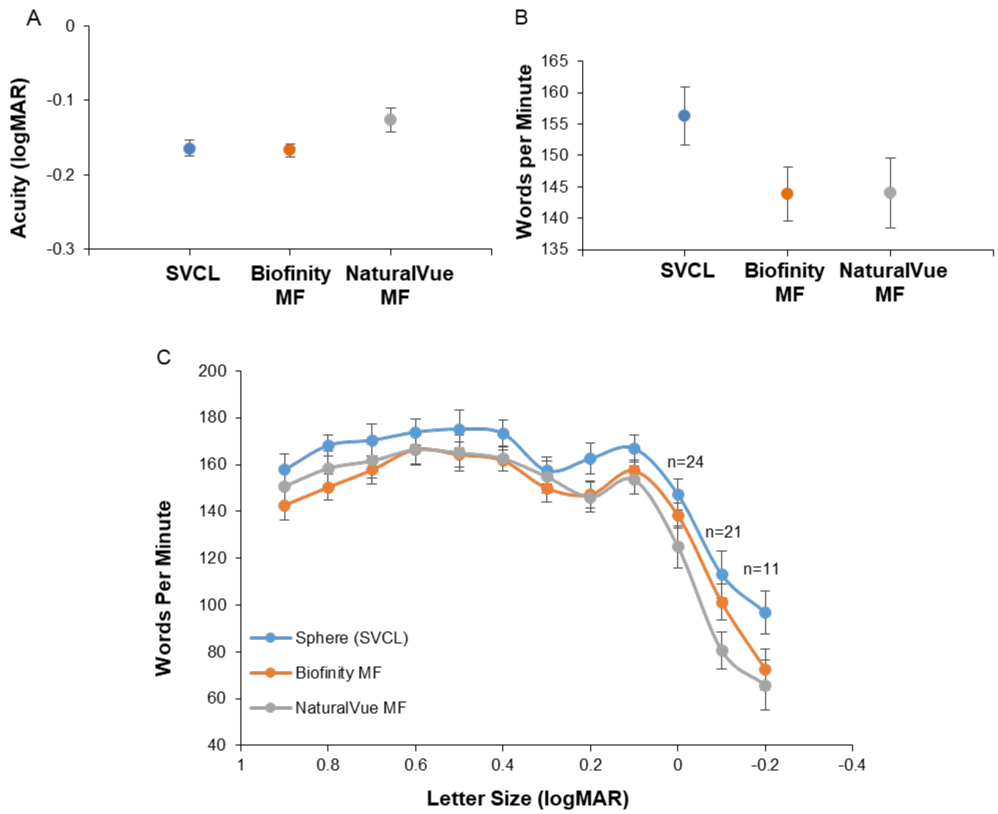

Figure 2.4. Near binocular reading acuity (A), Radner reading speed (B), and mean reading speed by letter size (C) with single-vision and multifocal con- tact lenses. Radner reading speed was significantly reduced with multifocal contact lenses compared with the single-vision contact lens; however, no difference was observed between the Biofinity D multifocal and the NaturalVue Multifocal (P = .95; panel B). Multifocal contact lenses displayed a reduced reading speed for all letter sizes compared with single-vision lenses (P < .05). (C) Sample size reduces as subjects reach threshold acuity. Error bars represent standard error of the mean.

Pupil Diameter

A statistically significant but clinically insignificant difference in pupil size under photopic conditions of 0.18 mm was observed between visits 1 and 2 (4.25 ± 0.57 vs. 4.07 ± 0.50 mm; P = .02). There was no difference in pupil size under mesopic conditions between visits (5.82 ± 0.73 vs. 5.78 ± 0.62 mm; P = .68).

2.4 Discussion

With increasing use of multifocal contact lenses for myopia control, eye care practitioners will be asked how this technology may affect the vision of their patients. In our study, multifocal contact lenses displayed slight but clinically acceptable reductions in visual acuity compared with single-vision contact lenses under most conditions. Letter contrast had the greatest impact on visual performance. When letter contrast was reduced, an expected reduction in performance was observed, and this effect was more pronounced for multifocal lenses. Although this reduction in vision with reduced target contrast may not be a significant concern for young children, this could become significant when patients wearing these contact lenses become older. There is no consensus best practice for when to discontinue multifocal contact lens wear in myopia control patients. As such, eye care practitioners are likely to encounter teenage myopia control patients who report visual difficulty with multifocal lenses in low light conditions because they assume more tasks that occur under these conditions, such as night driving.

Although the addition of a glare source was expected to negatively affect visual performance (Fedtke et al. 2016), we only observed small reductions in visual acuity and the magnitudes of these reductions were consistent across lens designs. For high-contrast optotypes, glare resulted in no significant clinical reduction in binocular visual acuity for any lens design. When letter contrast was reduced, the addition of glare did not precipitously drop acuity, with only an approximate 0.5 line logMAR reduction for all lens types. The similar magnitude of reduction with the glare source for all designs suggests that the multifocal optical profiles assessed in our study did not result in a significant increase in intraocular stray light compared with single-vision optics. Although no significant objective reduction in performance was observed, patients may report subjective symptoms of glare, ghosting, or halos when wearing these lenses (Diec et al. 2017; 2018; Jong et al. 2019).

When considering near vision performance, all of the lenses in this study provided similar binocular reading acuity, and the bifocal addition in multifocal contact lenses did not provide additional near vision resolution. This most likely represents a floor effect, where the vision achieved with all three lenses approached the limit of visual resolution for the retina, which is approximately 20/ 13 Snellen equivalent in young adults (Charman and Chateau 2003). Despite achieving good acuity with all three lens designs, reading speed with multifocal contact lenses was reduced compared with single-vision lenses. This reduction in reading speed occurred regardless of text size, suggesting that the multifocal lens optical profiles assessed did have an effect on the identification of text during reading. When considering the use of multifocal contact lenses for myopia control, near visual acuity may only provide a partial picture of what these patients encounter in a real-world environment. The impact of multifocal contact lenses on critical near vision tasks, such as reading, should be investigated further.

An interesting finding of the study was that similar distance visual acuity, near visual acuity, and reading performance were achieved with both multifocal contact lens designs, despite the reported difference in optical profiles. Although the optical profiles of the two multifocal contact lenses may not result in differing performance, these profiles do affect how eye care practitioners fit the respective lenses. When fitting multifocal contact lenses for myopia control, eye care practitioners are balancing the distance vision requirements of their patients with the need to maximize the peripheral myopic defocus. Eye care practitioners should fit lenses using maximum plus power to best distance acuity to prevent over-minusing the patient and potentially negating the desired peripheral myopic defocus. When selecting the initial contact lens power for the Biofinity +2.50 D add multifocal, the vertex-corrected spherical equivalent contact lens power did not achieve acceptable distance for 58% of eyes (29/50). On average, these eyes required additional minus power to achieve acceptable distance vision, consistent with a previous report (Berntsen and Kramer 2013). Despite this additional minus power, these lenses have been shown to reduce myopia progression while providing acceptable distance vision when fit using this approach (Walline et al. 2020). An alternative approach to achieve acceptable distance vision with the Biofinity Multifocal could be to reduce the bifocal add power. In this situation, you could achieve acceptable distance vision without additional minus added to the distance prescription; however, this could lead to a reduction in myopia control treatment efficacy, as was observed when subjects wearing a +1.50 D bifocal add displayed more myopic progression than subjects fit with a +2.50 D add (Walline et al. 2020).

When fitting the NaturalVue Multifocal, the add power cannot be changed and the only option to achieve acceptable distance vision is to change the distance prescription. There is little published literature regarding use of the NaturalVue Multifocal for myopia control. A retrospective case series on the use of the NaturalVue Multifocal for myopia control did not detail how contact lens power was selected, except for stating that the lenses were prescribed "within their indicated use for the correction of myopia" (Cooper et al. 2018). In our study, we used the company published fitting application to determine the initial lens power, as recommend for the correction of myopia. This application calculates the vertex-corrected spherical equivalent refraction and tells the eye care practitioner which lens to select. In our study, the initial contact lens power selected by the application subsequently became the final power for 49 of 50 eyes. During over-refraction, these eyes did not accept additional plus power without a reduction in distance acuity, whereas one eye required additional minus power to achieve acceptable distance acuity. The difference in the required over-refractions for the two lens designs suggests that the optical profiles between the two multifocal lenses are indeed different; however, this difference did not affect objective visual performance.

Other studies have examined aspects of visual performance with multifocal contact lens use in non-presbyopes. Kollbaum et al. (2013) evaluated the visual performance of the center-distance concentric ring multifocal MiSight contact lens (CooperVision) and the Proclear D progressive aspheric design with a +2.00 D bifocal addition (CooperVision). They found no difference in high-illumination, high-contrast vision with multifocal contact lenses compared with spectacle correction; however, patient-reported measures of lens performance were lower with multifocal contact lenses. Kang and Wildsoet reported that the Proclear D multifocal with bifocal additions of +1.50 and +3.00 D did little to reduce visual acuity in young adult myopes (Kang and Wildsoet 2016). The DIMENZ study reported that children wearing a center-distance, concentric-ring multifocal contact lens design with a +2.00 D bifocal addition had no difference in distance visual acuity or contrast sensitivity (Anstice and Phillips 2011).

Compared with other reports, our findings were consistent with the vision obtained with the Biofinity D multifocal. The Bifocal Lenses in Nearsighted Kids study found no difference in best-corrected, high-contrast acuity after contact lens over-refraction with the Biofinity D +2.50

D add lens compared with spectacles; however, their average over-refraction was higher (average, −0.50 to −0.75 D) than that observed in our study (Schulle et al. 2018). Gong et al. (Gong, Troilo, and Richdale 2017) found that the +2.50 D add Biofinity D multifocal caused an approximate one-line reduction in acuity under high- and low-illumination conditions compared with single-vision contact lenses. Our findings with the NaturalVue Multifocal suggest that the extended depth of focus design provides vision comparable with reported vision for center-distance aspheric and center-distance concentric ring designs. This is consistent with a meeting abstract reporting that a prototype myopia control lens similar to the NaturalVue Multifocal provided subjective vision similar to that provided by spherical optics (Miller J, et al. Optom Vis Sci 2011;88:E-Abstract 115896).

Potential limitations of the study include that the age of the patient population, 21 to 29 years, does not reflect the age patients will be fit for myopia control in clinical practice. In addition, the study was a non-dispensing assessment of vision, and visual quality at the fitting visit may overestimate or underestimate final visual performance with multifocal lenses (Diec et al. 2017; 2018; Jong et al. 2019). One other potential limitation of the study is that accommodation and phoria status were not evaluated during the reading performance task. Although there are reports that multifocal contact lenses affect accommodation and phoria status in non-presbyopes, others have indicated that dual-focus lenses do not prevent children from accommodating for near tasks (Anstice and Phillips 2011; Gong, Troilo, and Richdale 2017). It remains unclear how these changes may affect reading speed. Because reading speed in our study was reduced regardless of font size, the observed reduction may not be due to a change in the binocular status of the subjects and could represent the impact of multifocal optical profiles on functional near performance.

The use of multifocal contact lenses for myopia control is projected to increase as health care providers recognize the potential health implications of unchecked myopia. We found that multifocal contact lenses achieved vision that is slightly reduced compared with single-vision contact lenses; however, the different optical profiles of the two multifocal lenses provide similar vision across test conditions. Multifocal contact lenses may impact reading performance in nonpresbyopic patients, and this reduction does not seem to be font size dependent. Based on our observations, it is important that practitioners fitting these lenses recognize that high-contrast acuity alone does not fully describe the effect of multifocal contact lenses on visual performance. When discussing the risks and benefit of multifocal contact lenses for myopia control, eye care practitioners should educate parents and patients on the potential visual impact of these lenses to ensure informed decision making before initiating treatment.

Chapter 3: Conclusions

The purpose of this thesis was to determine how visual performance is affected when wearing multifocal contact lenses, fitted using a myopia control paradigm, compared to a single vision contact lens. Because most multifocal soft contact lenses have been designed to meet the needs of presbyopic patients, there is limited information on how multifocal soft contact lenses affect non-presbyopic eyes where the goal is not replicating a normal accommodative posture. With increasing use of these lenses on an off-label basis in clinical practice, eye care practitioners need to better understand how these optics affect the daily experience for their patients.

There have been a number of optical designs used for the correction of presbyopia. One of the contact lenses used in this study, the NaturalVue Multifocal, reports utilizing a novel extended depth of focus design that corrects presbyopia without the need for the eye care practitioner to determine a bifocal add amount. If near vision is unacceptable, the eye care practitioner adjusts the distance power of the lens. This differs from the approach of the Biofinity Multifocal contact lens, which utilizes a more traditional aspheric optic design where the eye care practitioner can select one of two aspheric power distributions (center-distance or center-near) and 4 different bifocal addition powers. This approach gives eye care practitioners more flexibility in prescribing the Biofinity Multifocal, but adds complexity to the fitting process. Limited research has been done to know if the extended depth of focus optics will affect visual performance differently from a standard aspheric multifocal soft contact lens.

Another aspect to consider with multifocal lenses is the impact of environmental factors on visual performance. One issue that is increasingly of concern is the effect of glare on multifocal lens performance in non-presbyopes. With increasing age, pupil size decreases, and multifocal contact lenses are designed to take advantage of this anatomical change to meet the visual needs of presbyopes. When used off-label in non-presbyopes, the larger pupil size may alter the visual experience. As the use of digital devices continues to increase for children and young adults, these glare sources may have a significant effect on visual performance with these contact lens designs. Currently, there is limited information on how glare affects vision with multifocal contact lenses in non-presbyopes. With these lens deigns being fitted on children for myopia control, it is important to understand how the lens optics affect visual performance in non-presbyopic patients to ensure eye care providers understand the effect these optical designs.

In this thesis project, visual performance was measured in three contact lens modalities, a Biofinity spherical lens, Biofinity Multifocal D center-distance lens with a +2.50 D add, and the NaturalVue Multifocal lens. The lenses were fit using a myopia control fitting paradigm, with the maximum plus refraction for best distance visual acuity. Visual performance at distance was quantified via high- and low-contrast logMAR visual acuity under photopic, mesopic, and mesopic with glare lighting. At near, visual performance was tested through the measurement of high-contrast logMAR visual acuity and reading speed using an iPad application developed by Kingsnorth and Wolffsohn.

The main findings of this thesis were as follows:

- LogMAR visual acuity depended on both lighting condition and lens type, both under high- and low-contrast testing conditions
- High-contrast distance visual acuity was always better than low-contrast acuity, regardless of contact lens type

- Low-contrast distance visual acuity under photopic conditions was better than under mesopic conditions for all lenses
- Near reading visual acuity was better than -0.10 logMAR for all three lenses. There was no clinically meaningful difference in acuity between all three lens types. Letter size and contact lens type affected reading speed, with reduced reading speed with both multifocal lens designs versus the spherical design, but the effect of letter size on reading speed did not differ by lens type.
- Letter contrast had the greatest impact on visual performance when comparing the single vision and multifocal contact lenses; the reduction in acuity was greater with the use of multifocal contact lenses. Eye care providers need to be aware of reductions in low-contrast vision and the effects of mesopic lighting when prescribing multifocal designs, especially for older teenage patients who are more likely to encounter a lower lighting condition and poorer contrast, such as with night driving.
- The addition of glare caused a reduction in visual acuity that was equal among all lens types. This finding suggests that the loss of acuity due to glare was independent of the contact lens optical design (sphere versus multifocal).
- Overall, high-contrast acuity alone does not fully describe the effect of multifocal contact lenses on visual performance. Eye care practitioners should be aware of the potential visual impact of these contact lenses when fitting them. Additional work on visual performance with multifocal contact lenses should be performed using a pediatric population to better ascertain the visual outcomes associated with using these lenses for myopia control.

- When fitting these contact lenses, clinicians need to understand that many multifocal lenses were initially designed for presbyopic patients with smaller pupils, likely affecting visual performance in dimly lit settings. Additionally, clinicians need to understand that fitting certain multifocal lens designs may require an over-refraction to achieve optimal distance vision, such as was observed with the Biofinity Multifocal D +2.50 add lens.
- Finally, clinicians need to remember that most lenses currently being used for myopia control are being used off label. With the exception of the MiSight contact lens that was recently FDA approved specifically for myopia control in children, all other lens designs are currently an off-label treatment. Understanding how each lens design affects vision in non-presbyopic patients is important for eye care providers to understand as standard Snellen acuity does not describe all aspects of visual function.

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