Soft Multifocal Contact Lenses for Myopia Control in Children

THESIS

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

By

Jenna M. Korsan

Graduate Program in Vision Science

The Ohio State University

2015

Master's Examination Committee:

Jeffrey J. Walline, OD PhD, Advisor

Donald O. Mutti, OD PhD

Nicky Lai, OD MS
Abstract

Myopia has become a public health problem, affecting nearly one-third of people in the United States. There have been many proposed mechanisms of myopia control, including atropine, undercorrection, corneal reshaping therapy, progressive addition lenses, and soft bifocal contact lenses. Soft bifocal contact lenses are thought to decrease the progression of myopia through peripheral defocus created by the contact lenses. There is currently only peer-reviewed literature on myopia control with center distance soft bifocal contact lenses, so it is unknown whether center near soft bifocal contact lenses slow the progression of myopia. The purpose of this study was to determine if center near multifocal contact lenses (Biofinity “N”) provide comparable vision to center distance multifocal contact lenses (Biofinity “D”), as well as to determine if they provide as much peripheral myopic defocus as the center distance lenses in children aged 8 to 14 years. Both subjective and objective vision was measured while the subject was wearing each type of lens. Peripheral defocus in 4 positions of gaze (central, 10° nasal, 20° nasal, 30° nasal) was measured post-dilation using an autorefractor. It was found that center distance contact lenses provide better overall subjective vision than center near (9.0 /10.0 vs. 6.5/10.0, Wilcoxon rank sum p<0.019), as well as significantly better subjective near vision (9.0/10.0 vs. 6.5/10.0, Wilcoxon rank sum p<0.009). Center distance contact lenses also provided better logMAR high contrast distance acuity (+0.02 vs. +0.14, Wilcoxon rank sum p<0.004), low contrast distance acuity (+0.17 vs. +0.43, Wilcoxon rank sum
rank sum p<0.001), and high contrast near acuity (-0.09 vs. +0.05, Wilcoxon rank sum p<0.023). There was no statistically significant difference between subjective distance vision for center distance (9.0/10.0) and center near contact lenses (6.5/10.0, Wilcoxon rank sum p<0.063). Comfort of the center distance (10.0/10.0) and center near (9.5/10.0) lenses was also not significantly different (Wilcoxon rank sum p<0.579). The center distance contact lenses provided more peripheral myopic defocus at 30° nasal gaze only (-0.84 vs. 0.07, Wilcoxon rank sum p<0.004). With the exception of 30° nasal gaze in the center near lenses, both types of contact lenses provided peripheral myopic defocus. Although center near multifocal contact lenses may provide enough peripheral defocus to decrease the progression of myopia, they would not improve vision or decrease myopia progression more than the center distance contact lenses already found to be effective for myopia control.
Dedication

This document is dedicated to my family.
Acknowledgments

I would first like to thank Dr. Walline for all of his guidance and support through the past few years. I have learned so much from you and could not have gotten through the master’s program without your help. I would also like to thank Dr. Mutti, you are a wonderful teacher and I appreciate the time you are taking to sit on my committee. Thank you, Dr. Lai, for sitting on my committee and also for helping me to become a better clinician.
Vita

2007..............................................................Huntingdon Area High School

2011..............................................................B.S. Chemistry, Gettysburg College

Publications


Fields of Study

Major Field: Vision Science
# Table of Contents

Abstract ............................................................................................................................... ii

Dedication .......................................................................................................................... iv

Acknowledgments ............................................................................................................. v

Vita ..................................................................................................................................... vi

Publications ....................................................................................................................... vi

Fields of Study ................................................................................................................ vi

Table of Contents .............................................................................................................. vii

List of Tables ................................................................................................................ viii

List of Figures .................................................................................................................. ix

Chapter 1: Introduction ................................................................................................. 1

Chapter 2: Methods ........................................................................................................ 10

Chapter 3: Results ......................................................................................................... 13

Chapter 4: Discussion .................................................................................................... 23

Chapter 5: Conclusions ............................................................................................... 33

References ...................................................................................................................... 34

Appendix A: Vision Questionnaire ............................................................................. 39
List of Tables

Table 1. logMAR visual acuity of center near vs. center distance contact lenses. P-value was determined by Wilcoxon Rank Sum. N=10 ............................................................... 14

Table 2. Subjective vision in center near and center distance contact lenses. P-value was determined by Wilcoxon Rank Sum. N=10 ...................................................................... 16

Table 3. Correlation between subjective vision questionnaire and logMAR visual acuity. P-value was determined by Spearman correlation. N=10 .......................................................... 17

Table 4. Over-refraction of each contact lens and comparison between center near and center distance soft multifocal contact lenses. P-value was determined by Wilcoxon Rank Sum. N=10 ........................................................................................................................ 20

Table 5. Peripheral defocus measurements for center near vs. center distance contact lenses ............................................................................................................................... 22
List of Figures

Figure 1. High contrast distance, high contrast near, and low contrast distance logMAR visual acuity for center distance and center near contact lenses in the right eye. Center distance contact lenses had significantly better visual acuity with all three measurements. Error bars represent range. ................................................................. 15

Figure 2. Subjective distance vision, near vision, overall vision, and comfort of center distance and center near contact lenses based upon a vision questionnaire on a scale from 1 to 10. Center distance contact lenses had significantly better near vision and overall vision. Error bars represent range. ............................................................................................ 17

Figure 3. Subjective vision vs. logMAR visual acuity at distance while wearing center near multifocal contact lenses. There is no significant correlation between the subjective and objective vision. ........................................................................................................ 18

Figure 4. Subjective vision vs. logMAR visual acuity at near while wearing center near multifocal contact lenses. There is no significant correlation between the subjective and objective vision. ........................................................................................................ 18

Figure 5. Subjective vision vs. logMAR visual acuity at distance while wearing center distance multifocal contact lenses. There is no significant correlation between the subjective and objective vision. ........................................................................................................ 19
Figure 6. Subjective vision vs. logMAR visual acuity at near while wearing center-distance multifocal contact lenses. There is no significant correlation between the subjective and objective vision. .......................................................... 19

Figure 7. Cycloplegic spherical equivalent refractive error measured centrally and at 10, 20, and 30 degrees nasal gaze while wearing center-near and center-distance contact lenses in the right eye. The refractive error is significantly different between the two contact lens types only at 30 degrees nasal gaze. The error bars represent standard deviation................................................................. 23

Figure 8. Cycloplegic J_0 refractive error measured centrally and at 10, 20, and 30 degrees nasal gaze while wearing center-near and center-distance contact lenses in the right eye. The refractive error is not significantly different between the two contact lens types at any eccentricity. The error bars represent standard deviation. ................................................. 24

Figure 9. Cycloplegic J_{45} refractive error measured centrally and at 10, 20, and 30 degrees nasal gaze while wearing center-near and center-distance contact lenses in the right eye. The refractive error is not significantly different between the two contact lens types at any eccentricity. The error bars represent standard deviation. .......................... 25

Figure 10. Location of the autorefractor measurements at 10°, 20°, and 30° nasal on the Biofinity multifocal contact lens, measured from the center of the lens. .............................. 32
Chapter 1: Introduction

Epidemiology of Myopia

For decades researchers have been studying the epidemiology of myopia and possible mechanisms of prevention. Myopia increases the risk of many diseases and pathologies, including retinal detachment and tears, glaucoma, cataract, and myopic macular degeneration (Saw, 1996). It also has economic consequences; it is estimated that myopia is a problem costing approximately $3.8 billion per year to correct in the United States (Vitale, 2006). It is an increasing problem, often referred to as an “epidemic,” with recent escalations in the prevalence of myopia seen in Chinese and Japanese populations (Saw, 1996). A similar increase in prevalence was seen in children aged 7-18 in the United States, in which the prevalence of myopia increased from 12.0% in 1971 to 31.2% in 2004 (Vitale, 2006).

There have been several large, multicenter studies that have looked at the prevalence and epidemiology of myopia. The Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE) study found that the prevalence of myopia varies greatly among different ethnicities (Caucasian 4.4%, African-American 6.5%, Hispanic 13.2%, Asian-American 18.5%) (Klein, 2003). Worldwide prevalence of myopia also differs by region, ranging from as low as 1.2% in rural Nepal to as high as 42.4% in urban China (Pokharel, 2000; He, 2004).
Risk factors for myopia include genetics and time spent outdoors. Myopia is more prevalent in children of myopic parents than children of non-myopic parents (Hui, 1995). Another study by Mutti and colleagues reported the prevalence of myopia to be 6.3% in schoolchildren with two emmetropic parents, 18.2% in children with one myopic parent, and 32.9% in schoolchildren with two myopic parents (Mutti, 2002). It also appears that the amount of myopia in parents correlates to the risk of myopia in children. It was found that the prevalence of myopia was 15% for children of parents with less than 1.00 diopter of myopia compared with 55% for those with parents having greater than 7.00 diopters of myopia (Hirsch, 1969). Over 5 years in children wearing single vision glasses, those with no myopic parents progressed -1.81 ± 0.18 D, similar to those with one myopic parent who progressed -2.04 ± 0.13 D. Both groups progressed significantly less than the group with two myopic parents which progressed -2.59 ± 0.19 D (Kurtz, 2007).

Another risk factor recently investigated by the CLEERE study group was an environmental link. After decades of research, it was found that near work does not significantly contribute to myopia, as was previously thought. Children who became myopic did not spend more time doing near work than those who remained emmetropic (Jones-Jordan, 2012). However, another behavioral factor, time spent outdoors, was found to be protective for myopia. Children with two myopic parents who spent less than five hours per week outdoors had a 60% chance of becoming myopic versus a 20% chance for children with two myopic parents who spent more than 14 hours per week outdoors (Jones, 2007).
Myopia Control

There have been many proposed models of myopia control, including atropine, undercorrection, progressive addition lenses, gas permeable contact lenses, orthokeratology, and soft bifocal contact lenses. However, only orthokeratology, atropine, and soft bifocal contact lenses have been found to have a clinically meaningful effect on reducing myopia progression. It was found that undercorrection of approximately +0.75 D actually causes an increase in myopia progression and axial elongation (Chung, 2002). Rigid gas permeable contact lenses decrease the rate of myopia progression, but they do not slow the axial growth of the eye. They work primarily by flattening the cornea more than soft contact lenses, which creates a temporary reduction of myopic refractive error. The authors concluded that gas permeable contact lenses should not be used to slow myopia progression (Walline, 2004).

Progressive additional spectacle lenses have also been hypothesized to decrease myopia progression by decreasing accommodative lag, but the effect is rarely clinically meaningful (Berntsen, 2013). The Correction of Myopia Evaluation Trial (COMET) found that progressive addition lenses slowed myopia progression 0.2 D compared to single vision spectacles. The results, although statistically significant, do not change clinical practice (Gwiazda, 2003).

One study comparing single vision and bifocal glasses found that bifocals slow myopia progression by 0.25 D over 30 months in children with near-point esophoria (Fulk, 2000). More recently, Cheng et al. looked at the effect of prismatic bifocals and regular bifocal spectacles on myopia. The average myopia progression over 3 years was -
2.06 D for the single vision group, -1.25 D for the bifocal group, and -1.01 D for the bifocal spectacles with base-in prism in the add portion. They found that prismatic bifocals were more effective at controlling myopia in children with low lags of accommodation, but the treatment effect was not affected by the near phoria of the subject (Cheng, 2014).

Various concentrations of atropine have been studied in regards to myopia control including 0.5%, 0.25%, 0.1%, and 0.01%. A study by Lee et al. found that 0.05% atropine solution is effective at reducing the progression of axial elongation. Over one year in children aged 6-12, those who instilled atropine eyedrops every evening progressed by -0.28 ± 0.26 D. This is a significant difference compared with the control group which progressed -0.75 ± 0.35 D in one year (Lee, 2006). However, it remains controversial whether the positive effects of atropine are long-lasting. It was found that in the 12 months following the cessation of 2 years of atropine treatment, atropine-treated eyes progressed faster than non-treated eyes (-1.14 D vs. -0.38 D). Overall, the atropine-treated eyes progressed less in the three years of the study compared with the control eyes (Tong, 2009).

A 2012 study by Chia and colleagues looked at atropine concentrations of 0.5%, 0.1%, and 0.01% in decreasing myopia progression. They found that there was no significant difference in axial length increase between the groups. The mean myopia progression was -0.30 ± 0.60 D in the 0.5% group, -0.38 ± 0.60 D in the 0.1% group, and -0.49 ± 0.63 D in the 0.01% group. They found that all of the concentrations had an effect on myopia control, but the 0.01% group had the lowest number of side effects (Chia,
Chia et al. then looked at the study group 1 year after stopping the atropine treatment to determine if the effects lasted. They found that 0.01% atropine had the most sustained treatment effect, while 0.5% atropine had the greatest amount of myopic rebound (Chia, 2014).

Orthokeratology contact lenses are thought to slow the progression of myopia through peripheral defocus, the same mechanism as soft bifocal contact lenses. These reverse geometry rigid gas permeable lenses worn overnight have been reported to decrease axial elongation by 32 to 55% compared with children in single vision spectacles or soft contact lenses (Chen, 2013). Compared with gas-permeable contact lenses, orthokeratology lenses exhibit a greater reduction in axial elongation, as well as a decrease in peripheral hyperopic defocus not found in gas-permeable contact lenses (Santodomingo-Rubido, 2012). However, it is not certain whether the results last longer than the two years of the study. This finding points to a peripheral defocus mechanism of myopia control.

The model of peripheral defocus has been studied for decades, beginning in the 1930s (Ferree, 1931). Chick and monkey models have been used to prove that eye growth can be modified depending on peripheral retinal defocus (Smith, 2009). Smith et al. showed that peripheral hyperopic defocus in infant monkeys can increase central myopia. Rhesus monkeys were fit with -3 D lenses that had central apertures without power. The lenses imposed peripheral hyperopic defocus to the peripheral retina but unrestricted vision to the macular area. After 150 days, the experimental group monkeys were significantly more myopic/less hyperopic than the control group, mainly due to increased
axial elongation. Even in the presence of a clear foveal image, peripheral hyperopic defocus can increase the growth and change in myopic refractive error of an eye (Smith, 2009).

Another peripheral defocus study by Liu and Wildsoet also found that it is possible to control refractive error with peripheral defocus. Using a concentric two-zone lens model which compared hyperopic and myopic defocus, as well as peripheral power and central power, they found peripheral power designs had greater effects on refractive error than central power designs. Another finding of the study was that the response to imposed myopia using plus lenses was greater than the response to imposed hyperopia using minus lenses (Liu, 2011). This is an important finding in terms of peripheral defocus principles, as the mechanism of soft bifocal contact lenses involves using peripheral myopic defocus to control increases in axial length.

It has been hypothesized that peripheral defocus not only plays a role in myopia control, but also in the development of myopia. Thought to be due to the less oblate shape of the eye in myopes, it has been found that myopes have greater peripheral hyperopia compared with emmetropes and hyperopes (Santodomingo-Rubido, 2012). In a study comparing eye shape and myopia, there was a significant correlation found between steeper temporal retinas and larger amounts of myopia, resulting in hyperopic peripheral defocus (Schmid, 2003).

Multiple studies have shown a reduction in axial elongation thought to be due to peripheral myopic defocus in human eyes, which provides a stimulus to slow eye growth. In a two-year study by Walline et al., it was found that soft multifocal contact lenses with
a center distance design slowed the progression of myopia by 50% in children ages 8 to 11. However, axial elongation in the subjects was only slowed by 29%, and there is no explanation for the difference in myopia control and control of eye growth (Walline, 2013). Promising results were also found in one year studies, in which the average reduction in myopia progression ranged from 34% to 30% (Sankaridurg, 2011; Anstice, 2011). An identical twin study by Aller and Wildsoet directly compared single vision soft contact lens wear to bifocal soft contact lens wear over two years. In the first year, the child wearing bifocal contact lenses showed no myopic progression with only -0.28 D of progression in the second year. The twin wearing single vision contact lenses progressed -1.19 D in the first year, and after switching to bifocal soft contact lenses, became less myopic by +0.44 D in the second year (Aller, 2008).

All of the peer-reviewed literature to date has studied center distance soft bifocal contact lenses for myopia control, but center near soft bifocal contact lenses are more readily available. In one study presented by Tom Aller at the British Contact Lens Association meeting, center near contact lenses were reported to slow myopia progression, so it is important to determine whether center near contact lenses provide as much peripheral myopic defocus as center distance lenses to act as a signal to stop axial elongation.

Multiple studies document that soft contact lens wear in children is very successful (Dias, 2013; Rah, 2010; Walline, 2009). One study found that myopic children who wear soft contact lenses were more likely to have higher self-perceptions of their physical appearance, athletic competence, and social acceptance than children who were
eyeglasses (Walline, 2009). Similar results were found in another study which revealed that soft contact lens wear in children leads to higher scores of social acceptance, athletic competence, and behavioral conduct scores compared to children who wore eyeglasses (Dias, 2013). Based on a 3 year survey to compare contact lens wear and spectacle wear in children, those who were randomized to contact lens wear reported higher vision-related quality of life, especially in appearance and athletics. Contact lens wearers also had an improved quality of life in terms of handling contact lenses compared with glasses (Rah, 2010). Another survey, the Contact Lenses in Pediatrics (CLIP) survey, found that 84.3% of children liked to wear contacts often or always and 82.7% of children liked contacts a little or a lot better than glasses. The CLIP survey also assessed frequency of dryness, itching, redness, burning, tearing, and light sensitivity, and found that the frequency of each type of irritation in children was less than the same occurrence in adults (Jones, 2009).

The Contact Lens Assessment in Youth (CLAY) study found that children aged 8 to 15 were actually at a decreased risk of infiltrative events compared with soft contact lens wearers aged 15 to 25, showing that soft contact lenses are a very successful method of myopia correction in children (Wagner, 2011). A study by Walline et al. showed that there was no statistically significant difference in ocular health between subjects fit with contact lenses as a child compared with those fit as a teenager. Both groups had similar frequencies of adverse events, compliance, and wearing time (Walline, 2013).

The purpose of this study was to determine whether center distance soft multifocal contact lenses provide better visual acuity than center near contact lenses, to
determine whether center distance contact lenses provide better subjective vision than center near, and to determine whether center distance contact lenses provide more peripheral myopic defocus than center near contact lenses.
Chapter 2: Methods

The protocol was approved by the Ohio State University Biomedical Sciences Institutional Review Board and adhered to the tenets of the Declaration of Helsinki. All parents provided signed permission for their children to participate and participants provided written assent.

Contact Lens Design

Participants were fit with CooperVision (Fairport, NY) Biofinity Multifocal contact lenses with +2.50 D add power. The base curve of the lenses is 8.6 mm with a diameter of 14.0 mm and optic zone of 8.0 mm. It is a silicone hydrogel, comfilcon A lens with 48% water content. The “D” contact lenses have a central spherical distance zone, a progressive zone of increasing plus power, and an outer zone with full add power. The “N” lenses have a central spherical near zone, a progressive zone of increasing minus power, and an outer zone with the full distance power. The power of the contact lenses was determined by the spherical equivalent of the manifest refraction. Each subject was randomly assigned to wear either “D” lenses or “N” lenses first.
**Procedure**

The subject’s refractive error was determined by retinoscopy followed by subjective refraction. After the first contact lens pair was inserted and allowed 15 minutes to settle, the over-refraction of each eye was determined using trial lenses and recorded. The over-refraction was used only to later compare the contact lens types, it was not incorporated into the visual measurements. The high contrast logMAR distance visual acuity was measured followed by low contrast logMAR distance visual acuity using a Bailey-Lovie chart at 4 meters. High contrast near visual acuity was then measured with a Sloan near card at 40 cm. For each measurement, the subject was stopped after three or more letters were missed after reading an entire row. Full room illumination with a direct spotting light on the chart was used for all measurements. The subject then completed a survey asking four questions about the current contact lenses (Appendix A). The survey asked the subject to respond to each question on a scale from 1 to 10, where 1 is good and 10 is perfect. The survey inquired about clarity of vision when looking far away, clarity of small print when reading, overall vision, and comfort of the contact lenses. The first contact lens pair was removed and the second pair was inserted, and the procedure was repeated.

The second contact lens pair was removed and one drop of 0.5% proparacaine was instilled, followed by two drops of 1.0% tropicamide, separated by five minutes. After waiting 20 minutes from the second drop, the first contact lens pair was inserted and peripheral defocus was measured in the right eye with a Grand Seiko AK-5100 autorefractor at central, 10°, 20°, and 30° nasal gaze. The subjects kept their head
pointing forward for each measurement and turned only their eyes to look at the correct
target. Six measurements were taken at each position and averaged. The first contact lens
was removed, the second one inserted, and peripheral defocus was measured in the same
way for the second contact lens.

Statistics

All analyses were performed using IBM SPSS Statistics version 22. Comparisons
between the two types of contact lenses were completed using non-parametric statistics
due to the small sample size. The Wilcoxon Rank Sum method was applied to the data to
account for the independent nature of the contact lens types.

Vector analysis was used to convert refractive error into three dioptric powers
using the following formulas:

\[
M = \text{Sphere} + \text{Cylinder}/2 \\
J_0 = (-\text{Cylinder}/2)\cos(2*\text{axis}) \\
J_{45} = (-\text{Cylinder}/2)\sin(2*\text{axis})
\]

where M represents the spherical equivalent, \(J_0\) is the power at axis 180°, and \(J_{45}\) is the
power at axis 45°. This vector analysis allows for statistical analysis of each component
separately.
Chapter 3: Results

Participants were 8 to 14 years old at the time of their visit. They had between –0.75 and –5.00 D of refractive error with no more than 0.75 D of astigmatism as determined by non-cycloplegic refraction. All subjects had best-corrected visual acuity of 20/25 or better and no previous experience with bifocal contact lens wear. However, previous single vision soft contact lens wear was allowed. All participants were free of systemic or ocular disease that would affect contact lens wear.

Ten subjects were enrolled in the study and all ten completed all measurements. The sample was 60% female and 60% white, with smaller proportions of African-American (20%) and Native Hawaiian or other Pacific Islander (20%) subjects. The median non-cycloplegic spherical equivalent refractive error of the subjects’ right eye was –2.94 ± 1.07 D, and for the left eye was –2.56 ± 1.25 D.

Of the three objective methods to determine visual acuity, all showed a significantly better acuity in center distance compared with the center near multifocal contact lenses (Table 1). The median logMAR high contrast distance visual acuity for center distance lenses was +0.02 (Snellen 20/21; range –0.14 to +0.08), while for center near lenses it was significantly higher, at +0.14 (Snellen 20/28; range –0.02 to +0.48). Somewhat surprisingly based upon the optics of the lenses, high contrast near visual acuity for center distance contact lenses was better than for center near contact lenses.
The greatest difference in mean acuities arose from the comparison of low contrast distance visual acuities in the two types of lenses. The median low contrast logMAR acuity for center near lenses was +0.43 (Snellen 20/54; range +0.28 to +0.68) versus +0.17 (Snellen 20/30; range +0.06 to +0.48) for the center distance lenses (Figure 1). The difference between the high contrast distance acuity and low contrast distance acuity for the center near contact lenses is not statistically significant (p<0.139). The difference between the high contrast distance and high contrast near acuities for center distance lenses is also not significant (p<0.059).

<table>
<thead>
<tr>
<th></th>
<th>Center Near</th>
<th></th>
<th>Center distance</th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Range</td>
<td>Median</td>
<td>Range</td>
<td></td>
</tr>
<tr>
<td>High contrast</td>
<td>+0.14</td>
<td>-0.02 - +0.48</td>
<td>+0.02</td>
<td>-0.14 - +0.08</td>
<td>0.004</td>
</tr>
<tr>
<td>distance visual acuity</td>
<td>+0.05</td>
<td>-0.1 - +0.42</td>
<td>-0.09</td>
<td>-0.12 - +0.12</td>
<td>0.023</td>
</tr>
<tr>
<td>High contrast near</td>
<td>+0.43</td>
<td>+0.28 - +0.68</td>
<td>+0.17</td>
<td>+0.06 - +0.48</td>
<td>0.001</td>
</tr>
<tr>
<td>visual acuity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low contrast distance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>visual acuity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. logMAR visual acuity of center near vs. center distance contact lenses. P-value was determined by Wilcoxon Rank Sum. N=10
Figure 1. High contrast distance, high contrast near, and low contrast distance logMAR visual acuity for center distance and center near contact lenses in the right eye. Center distance contact lenses had significantly better visual acuity with all three measurements. Error bars represent range.

The vision questionnaire used to determine the subjective vision of the subjects also revealed statistically significant differences between the two types of contact lenses. Both near vision and overall vision were significantly better in the center distance lenses compared with the center near lenses (Table 2). On a scale from 1 to 10, the center distance lenses provided a median value of 9.0 (range 7.0 to 10.0) for near vision, while the center near lenses were significantly worse, at 7.0 (range 3.0 to 9.0). In terms of overall vision, the center distance lenses had an average value of 9.0 (4.0 to 10.0) versus 6.5 (3.0 to 8.0) for the center near lenses. There was no statistically significant difference between the mean distance vision of the center distance contact lenses (9.0, range 4.0 to
10.0) and center near contact lenses (6.5, range 3.0 to 8.0). As expected, the comfort of the center distance contact lenses was not different from the comfort of the center near contact lenses (Figure 2).

<table>
<thead>
<tr>
<th></th>
<th>Center near</th>
<th>Center distance</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Range</td>
<td>Median</td>
</tr>
<tr>
<td>Distance vision</td>
<td>6.5</td>
<td>2.0 – 9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Near vision</td>
<td>7.0</td>
<td>3.0 – 9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Overall vision</td>
<td>6.5</td>
<td>3.0 – 8.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Comfort</td>
<td>9.5</td>
<td>3.0 – 10.0</td>
<td>10.0</td>
</tr>
</tbody>
</table>

Table 2. Subjective vision in center near and center distance contact lenses. P-value was determined by Wilcoxon Rank Sum. N=10
Figure 2. Subjective distance vision, near vision, overall vision, and comfort of center distance and center near contact lenses based upon a vision questionnaire on a scale from 1 to 10. Center distance contact lenses had significantly better near vision and overall vision. Error bars represent range.

Interestingly, there were no significant correlations between subjective vision from the vision questionnaire and objective logMAR vision (Table 3). As seen in Figures 3 through 6, no correlations reach significance.

<table>
<thead>
<tr>
<th>Correlation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance vision of center near lenses</td>
<td>0.28</td>
</tr>
<tr>
<td>Near vision of center near lenses</td>
<td>-0.62</td>
</tr>
<tr>
<td>Distance vision of center distance lenses</td>
<td>0.29</td>
</tr>
<tr>
<td>Near vision of center distance lenses</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Table 3. Correlation between subjective vision questionnaire and logMAR visual acuity. P-value was determined by Spearman correlation. N=10
Figure 3. Subjective vision vs. logMAR visual acuity at distance while wearing center near multifocal contact lenses. There is no significant correlation between the subjective and objective vision.

Figure 4. Subjective vision vs. logMAR visual acuity at near while wearing center near multifocal contact lenses. There is no significant correlation between the subjective and objective vision.
Figure 5. Subjective vision vs. logMAR visual acuity at distance while wearing center distance multifocal contact lenses. There is no significant correlation between the subjective and objective vision.

Figure 6. Subjective vision vs. logMAR visual acuity at near while wearing center distance multifocal contact lenses. There is no significant correlation between the subjective and objective vision.
There was no difference in over-refraction between the two types of contact lenses (Table 4). While wearing center near contact lenses, subjects accepted a median of -0.25 D (range –0.75 to +0.50 D) over both the right eye and -0.25 D (range –2.50 to +0.25 D) over the left eye. With center distance lenses, they accepted -0.50 D (range –0.75 to +0.25 D) over the right eye and -0.13 D (range –0.75 to +0.25 D) over the left eye.

<table>
<thead>
<tr>
<th></th>
<th>Center near</th>
<th></th>
<th>Center distance</th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Range</td>
<td>Median</td>
<td>Range</td>
<td></td>
</tr>
<tr>
<td>Right eye</td>
<td>-0.25</td>
<td>-0.75 - +0.5</td>
<td>-0.50</td>
<td>-0.75 - +0.25</td>
<td>0.247</td>
</tr>
<tr>
<td>Left eye</td>
<td>-0.25</td>
<td>-2.50 - +0.25</td>
<td>-0.13</td>
<td>-0.75 - +0.25</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Table 4. Over-refraction of each contact lens and comparison between center near and center distance soft multifocal contact lenses. P-value was determined by Wilcoxon Rank Sum. N=10

The center near multifocal contact lenses do provide small amounts of myopic peripheral defocus in all gazes except 30° nasal gaze in the M, spherical equivalent, component (Table 5). The center distance multifocal contact lenses also provide myopic peripheral defocus, with the greatest amounts seen in the spherical equivalent component. Small amounts of peripheral myopic defocus were found for J₀ and J₄₅ in central gaze, J₀ in 20° nasal gaze, and J₀ in 30° nasal gaze.
When comparing the peripheral defocus of the center near and center distance contact lenses, only one of the values reaches statistical significance, based upon p<0.0125 after applying a Bonferroni correction. The only difference in peripheral defocus between the two types of lenses occurs in the M component at a gaze of 30° nasal, in which the center distance lenses provide more peripheral myopic defocus (Figure 3). The cylindrical component J₀ is the same for each type of contact lens (Figure 4), as is J₄₅ (Figure 5).
<table>
<thead>
<tr>
<th>Angle</th>
<th>M</th>
<th>J₀</th>
<th>J₄₅</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center near</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>-0.64±0.86</td>
<td>+0.22±0.34</td>
<td>+0.13±0.26</td>
</tr>
<tr>
<td>10° nasal</td>
<td>-0.50±0.80</td>
<td>+0.19±0.48</td>
<td>+0.24±0.28</td>
</tr>
<tr>
<td>20° nasal</td>
<td>-0.62±0.70</td>
<td>+0.06±0.36</td>
<td>-0.16±0.30</td>
</tr>
<tr>
<td>30° nasal</td>
<td>+0.07±0.38</td>
<td>+0.13±0.36</td>
<td>+0.06±0.72</td>
</tr>
<tr>
<td>Center distance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>-0.76±0.50</td>
<td>-0.16±0.37</td>
<td>-0.19±0.40</td>
</tr>
<tr>
<td>10° nasal</td>
<td>-0.70±0.62</td>
<td>+0.01±0.38</td>
<td>+0.03±0.50</td>
</tr>
<tr>
<td>20° nasal</td>
<td>-0.82±0.59</td>
<td>-0.13±0.28</td>
<td>+0.22±0.47</td>
</tr>
<tr>
<td>30° nasal</td>
<td>-0.84±0.99</td>
<td>-0.27±0.55</td>
<td>+0.07±0.33</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P-value</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Central</td>
<td>0.05</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>10° nasal</td>
<td>0.44</td>
<td>0.32</td>
<td>0.35</td>
</tr>
<tr>
<td>20° nasal</td>
<td>0.97</td>
<td>0.32</td>
<td>0.04</td>
</tr>
<tr>
<td>30° nasal</td>
<td>0.004</td>
<td>0.03</td>
<td>0.63</td>
</tr>
</tbody>
</table>

Table 5. Peripheral defocus measurements for center near vs. center distance contact lenses
Figure 7. Cycloplegic spherical equivalent refractive error measured centrally and at 10, 20, and 30 degrees nasal gaze while wearing center-near and center-distance contact lenses in the right eye. The refractive error is significantly different between the two contact lens types only at 30 degrees nasal gaze. The error bars represent standard deviation.
Figure 8. Cycloplegic J₀ refractive error measured centrally and at 10, 20, and 30 degrees nasal gaze while wearing center-near and center-distance contact lenses in the right eye. The refractive error is not significantly different between the two contact lens types at any eccentricity. The error bars represent standard deviation.
Figure 9. Cycloplegic J_{45} refractive error measured centrally and at 10, 20, and 30 degrees nasal gaze while wearing center-near and center-distance contact lenses in the right eye. The refractive error is not significantly different between the two contact lens types at any eccentricity. The error bars represent standard deviation.
Chapter 4: Discussion

The results of this study show that children aged 8 to 14 years are able to wear center distance soft multifocal contact lenses more successfully than center near soft multifocal contact lenses, based on the improved objective and subjective vision of the center distance lenses. There has been little research regarding center near contact lenses for myopia control, but this finding supports the high compliance rate of studies performed by Walline, Aller, and Anstice. It is likely that a long-term study using center near contact lenses would result in a higher drop-out rate due to the decreased subjective and objective vision experienced by the subjects.

There was no significant difference in the over-refraction found between the two types of contact lenses. In both types of lenses, the subjects accepted slightly more minus over the lenses that they were wearing, a common finding amongst young myopes. In practice, the over-refraction may be incorporated into the contact lens prescription if there was an improvement in vision. However, as there was no difference in over-refraction between the center near and center distance lenses, incorporating the over-refraction would not change the comparisons of the objective vision of the lens types.

The low contrast distance vision was especially affected by the center near contact lenses. This finding suggests that subjects would have difficulty with contrast sensitivity while wearing center near lenses. Children may notice difficulty with certain activities
which require good low contrast acuity, such as playing sports and facial recognition, especially at night or in other low-lighting situations.

The median value for each category of the vision questionnaire was at least 9.0 out of 10 for the center distance contact lenses, so children should be able to easily perform all visual functions required throughout the day. Each logMAR acuity measured for the center distance lenses supported the hypothesis that the subjects would have comfortable daily vision. With the center near lenses, the subjects may experience some mild blur throughout the day, which could cause some difficulties trying to read for extended periods of time or see the board at school.

The blurred vision is due to the simultaneous focus created by the multifocal contact lenses. As young myopes do not like to be undercorrected, it is likely that they are experiencing more blur at distance and near with the center near lenses because they are forced to look mainly through the central, near, portion of the lenses while in primary gaze. The near portion of the lens is forming the retinal image at the fovea, causing blur at all distances.

The comfort of the two lenses was subjectively fairly good for both types of lenses, with the subjects rating it 8.2 out of 10 for the center near lenses and 9.0 out of 10 for the center distance lenses. This suggests that children, even those without previous contact lens experience, could successfully wear multifocal contact lenses. In a previous study, there was no difference in subjective comfort found between Biofinity multifocal contact lenses compared with single vision contact lenses in presbyopic subjects (Fernandes, 2013). Although we did not compare our young subjects’ comfort in the
multifocal contact lenses to single vision lenses, we know that children are successful contact lens wearers with few adverse reactions, so there is no reason that multifocal contact lenses would cause discomfort or other reactions (Dias, 2013; Rah, 2010; Walline, 2009).

The fact that there was no difference in comfort between the two lenses shows that the subjects did not allow one area of the questionnaire to sway their opinions about another question. Although the subjects had an overall decreased opinion about the vision of the center near contact lenses, they did not allow this opinion to change how they felt about the comfort of the lenses.

The finding that overall vision is better in center distance contact lenses is contradictory to most studies regarding the vision of different types of bifocal contact lenses in adults. One study used Fourier optics to determine that overall visual performance is better in center near designs in presbyopic eyes (Baude, 1997). Another study comparing monovision, concentric center near lenses, and a combination of center near and center distance contact lenses found that center near lenses only had a higher success rate than the combination of the two types (Back, 1989). The difference between children and adults is likely due to the effects of accommodation, as well as the increased pupil size of children compared to adults.

In one study examining accommodation in pre-presbyopic adults, it was found that young subjects accommodate the same amount while wearing a bifocal contact lens as they do when wearing a single vision contact lens (Pettersson, 2011). A separate study looked at center near multifocal contact lenses and found a similar result in pre-
presbyopic patients: there was no difference in accommodation between single vision lenses and multifocal contact lenses (Madrid-Costa, 2011). These studies explain why near vision is better in center distance than center near contact lenses in our subjects; the children are accommodating the same amount as they would in a single vision contact lens, so as the pupil constricts and accommodation occurs, the retinal image from the central distance portion of the lens is clear on the retina.

Presbyopic adults likely respond better to center near contact lens designs due to their decreased pupil size compared with children. While in primary gaze looking at distance, more of the peripheral distance portion of the lens reaches the retina. While looking at a near object, the pupils constrict and rays mainly from the center of the lens reach the fovea. However, as children have larger pupils and their accommodation does not change based on the type of multifocal contact lens they are wearing, while looking at objects at near more rays from the peripheral distance portion of the lens will reach the retina, leading to decreased near vision in center near contact lenses. This is consistent with our findings, in which both objective and subjective near vision were better in center distance lenses.

The peripheral myopic defocus of the center distance multifocal contact lenses was similar to the peripheral defocus of the center near lenses for all directions of gaze, except for the 30° nasal gaze, where the center distance design had more myopic defocus. There has been very little research on the peripheral defocus of center near contact lenses for myopia control, so it is difficult to compare the results. Both lens types did follow a similar trend in which there was less defocus at 10° nasal gaze than at central, but more
defocus at 20° nasal than 10° nasal. At 30° nasal gaze, the myopic defocus of the center distance lenses was much greater than that of the center near design. It was expected that center distance contact lenses would have greater myopic defocus with greater eccentricity, while center near would show less myopic defocus with greater eccentricity. However, this hypothesis was not supported by the data. This could be due to the subjects turning their eyes rather than their heads to measure the peripheral refractive error. The eye movements could have slightly shifted the lenses with the eyelids, so that the correct portion of the lens was not measured.

Previous studies have shown that center distance bifocal contact lenses provide more peripheral myopic defocus than single vision contact lenses in young adults. A study by Berntsen and Kramer found that a center distance contact lens provides significantly more myopic defocus at 30° and 40° on the nasal retina as well as 20° and 30° on the temporal retina (Berntsen, 2013). The results of our study show peripheral myopic defocus of the center distance contact lenses as well, but the correct portion of the lens may not have been measured due to lens movements by the eyelids.

Overall, the greater peripheral myopic defocus of the center distance design would contribute to the hypothesis that center distance lenses are more effective at myopia control than center near lenses. Because not all of the eccentricities show significant differences in the peripheral defocus of the two designs, more research is required to determine if this hypothesis remains true.

Despite the uncertainties remaining in regards to the comparison between the center distance and center near designs, both designs did show peripheral myopic
defocus, supporting previous studies that soft multifocal contact lenses can help control myopia progression. The 2013 study by Walline found a 50% reduction in the progression of myopia, while Anstice found a 30 to 34% reduction in the progression (Walline, 2013; Anstice, 2011). The results of this study support the proposed mechanism of peripheral myopic defocus for these decreases in progression.

The main limitation to this study is the small sample size. A larger sample could lead to higher significance of the results and more accurate measurements of the amounts of peripheral defocus. The design of the autorefractor also limited the number of data points we were able to measure, as we were unable to measure temporal defocus or greater than 30° nasal gaze while turning the eyes. The autorefractor did not allow for temporal gaze measurements because the sides of the instrument were blocking any fixation targets. Another limitation of the study design was moving the eyes rather than the head, although the autorefractor design would have made moving the head difficult as well. The lenses were likely shifted by the eyelids, so that the measurements were taken at a slightly different portion of the lens than intended. Since the pivot point of the eye is the center of the entrance pupil which is 3.05 mm behind the cornea, for each 10° shift in gaze, the measurement on the contact lens should be 0.54 mm from the center of the lens. A study by Plainis et al. found that Biofinity multifocal contact lenses have a central region of 1.5 mm radius, while the intermediate zone has a linear increase in power over 0.6 mm, and the outer zone also has a linear increase in power until it reaches the add power (Plainis, 2013). Therefore, our 10° and 20° nasal gaze measurement should measure the refractive error of the central portion of the lens, while the 30° nasal gaze
measurement should measure the intermediate portion of the lens (Figure 10). It is for this reason that measurements greater than 30° are important for future studies to measure peripheral defocus of multifocal contact lenses.

Figure 10. Location of the autorefractor measurements at 10°, 20°, and 30° nasal on the Biofinity multifocal contact lens, measured from the center of the lens.

Future studies would be necessary to determine whether the smaller amounts of peripheral myopic defocus found with the center near multifocal contact lenses are sufficient to reduce the progression of myopia in children. However, due to the fact that subjective and objective vision is better in center distance lenses, and that there are greater amounts of peripheral myopic defocus in these lenses, it is doubtful that center near lenses would provide any benefit over center distance lenses to children looking to decrease myopia progression.
Chapter 5: Conclusions

The results of this small study show that children aged 8 to 14 years have increased distance visual acuity, near visual acuity, and low contrast visual acuity with center distance soft multifocal contact lenses compared with center near. They also have better subjective overall vision and near vision with the center distance contact lenses. Therefore, children would experience more success with center distance multifocal soft contact lenses. Both lenses provide peripheral myopic defocus, but distance center lenses provide more peripheral defocus at 30° nasal gaze. Although center near multifocal contact lenses may provide enough peripheral defocus to decrease the progression of myopia, they are unlikely to improve vision or decrease myopia progression more than the center distance contact lenses already found to be effective for myopia control.
References


Chia A, Cheung YB, Wong WL, Lingham A. Atropine for the treatment of childhood myopia: safety and efficacy of 0.5%, 0.1%, and 0.01% doses. Ophthalmol 2012; 119: 347-54.

Chia A, Chua WH, Wen L, Fong A, Yen Y. Atropine for the treatment of childhood myopia: changes after stopping atropine 0.01%, 0.1%, and 0.5%. Am J Ophthalmol 2014; 157: 451-7.


Appendix A: Vision Questionnaire

Please circle only one number for each answer below. When answering each question, only think about the contact lenses you are wearing at that time.

1. How clear is your vision when looking far away?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good</td>
<td>Perfect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. How clear is small print when you tried to read up close?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good</td>
<td>Perfect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Overall, what do you think of your vision?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good</td>
<td>Perfect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. How is the comfort of your contact lenses?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good</td>
<td>Perfect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>