Assessment of Three Multifocal Soft Lens Designs for Myopia Control

Steven Turpin
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Conclusions: Future lens designs will likely be limited to +3.00 D. powers, unless the design is similar to that of Aspheric Add Design. A patient’s visual quality ratings and visual acuity performance in these multifocal soft lenses are expected to be comparable to a single vision soft lens.

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ASSESSMENT OF THREE MULTIFOCAL SOFT LENS DESIGNS FOR MYOPIA CONTROL

by

STEVEN TURPIN

A THESIS

Submitted to the Graduate Faculty of Pacific University Vision Science Graduate Program, in partial fulfillment of the requirements for the degree of
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in
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COLLEGE OF OPTOMETRY
FOREST GROVE, OREGON

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This thesis of Steven Turpin, titled “Assessment of Three Multifocal Soft Lens Designs for Myopia Control”, is approved for acceptance in partial fulfillment of the requirements of the degree of Master of Science.

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ASSESSMENT OF THREE MULTIFOCAL SOFT LENS DESIGNS FOR MYOPIA CONTROL

STEVEN TURPIN

Master of Science in Vision Science
College of Optometry
Pacific University Oregon, 2016

Abstract

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Results: With one exception (CA-2), the majority (>50%) of subjects believed they could be academically successful with any lens design with an add power of +3.00 D or less. All lens designs with either +4.00 or +5.00 D add powers were rated significantly (p<0.05) worse than the control in every visual quality category. However, the majority of subjects thought they could be successful in the Aspheric Add Design in higher powers (+4.00 and +5.00 D). If a subject rated overall vision below 40 or had a low contrast near visual acuity worse than 20/50, they never believed they would be successful wearing that lens. The best objective predictor of subjective success was low contrast near acuity.

Conclusions: Future lens designs will likely be limited to +3.00 D. powers, unless the design is similar to that of Aspheric Add Design. A patient’s visual quality ratings and visual acuity performance in these multifocal soft lenses are expected to be comparable to a single vision soft lens.
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Introduction

Preface

The purpose of this introduction is to provide a brief, non-technical summary of the current information on the disease of myopia and its treatment options. It is by no means complete or exhaustive. Many of the ideas surrounding the topic are nuanced and not totally understand. Our goal is to provide the reader with a background to better understand our study results and similar research. Comprehensive literature is available on all sub topics and should be reviewed to if one wishes to gain a full understanding of the topic.

Epidemiology

Myopia is a concern to both citizens and eye care providers around the world. The prevalence in the United States is approximately 42%, and globally ranges from 3% in rural Nepal to 90% in Taiwanese college students. It appears that the incidence of myopia is increasing in all populations, though individual groups are affected differently. Eastern Asian children comprise the group most commonly affected, followed in order by Hispanics and finally African American and Caucasian kids. No definite consensus has been reached on whether there is a significant difference in prevalence between males and females.

Studies show the refractive errors of most newborns fall on a spectrum, anywhere from +3.00 to -3.00 diopters (D.). As the children develop, most become about one diopter. hyperopic by 12 months of age through a process known as emmetropization. Those who fall outside of this range are more likely to fail in beginning stages of emmetropization and remain either myopic or hyperopic, depending on the sign of their original refractive error. For the myopic children, those classified as congenital or infantile-onset myopia are rare and tend to show more than four diopters of myopia; this sub-type will not be covered in detail in this paper.
The average child who will become myopic tends to be slightly hyperopic (+0.5–1.00D.) after the first year of age and remain this way until 5 to 10 years of age (mean 8.9 yrs). They tend to fail in the later part of the emmetropization process. It is at this time these children are said to fall off the ‘myopic cliff’ and rapidly increase in the amount of myopia until the age of 15 to 18 yrs (Fig. 1). Not surprisingly, those with an early age of onset tend to develop higher amounts of myopia than those with a later onset.

![Graph](image)

**Figure 1 Depiction of a mathematical model developed to illustrate myopia progression as a function of age.**

**Risk factors**

In spite of our current knowledge, the mechanisms or causes of myopia development are still poorly understood. Ultimately, we will likely find a combination of variables that contribute differently in each individual case. For now, we recognize factors that correlate well with myopia progression, but don’t necessarily confirm causation. Parental history of myopia is a known risk factor, approximately 20% increased likelihood if one parent is myopic and 40% if both are myopic. How much of the contribution is purely genetic vs. shared developmental environment is still up for debate as no single locus on a chromosome has been consistently
associated with myopia, though at least 18 different loci are currently under investigation. It has been suggested that genes don’t directly cause myopia development, but influence one’s susceptibility to the environmental factors that are thought to cause myopia.

Our understanding of these environmental factors is increasing very quickly. In recent years, greater time spent outdoors was shown to correlate well with a delay in onset of myopia (resulting in lower amounts of myopia as described above), but not with slowing progression in those children already myopic. Therefore, it is suggested children benefit from outdoor time before they become myopic, but not after the process of myopia development has begun. Additionally, the protective effect observed was independent of the activities done outdoors i.e. children who read outdoors received the same benefits as those who played sports.

One factor not well correlated with myopia development is frequency of near work. For many years, it was accepted that near tasks such as reading and writing increased myopia risk. However, when other factors (genetics, time spent outdoors, etc.) are controlled, the amount of near work a child performs does not predispose her to develop myopia. In addition to physical environment risk, theories concerning nutrition are being investigated. Small groups of nutritional scientist argue that refined sugars and other foods with relatively high glycemic loads may be disrupting normal growth hormone pathways where insulin is involved resulting in axial elongation of the eyes. However, no controlled studies have been conducted to support this theory. All of the risk factors described above have been incorporated into potential explanations for development which will be described in more detail in the following section.

Emmetropization

In normal development, the rates at which the lens thickens and eye grows are such that the power of the eye and axial length are matched to render the eye emmetropic. In myopic children, this synchronized growth is disrupted anywhere from three months to ten years of age.
(adult onset myopia is another phenomenon observed in the population, but will not be discussed here). The lens stops thickening at a point similar to emmetropic eyes, but the eye continues you to grow and grow quickly (Figure 1). Axial length increases and the eye becomes myopic. We don’t fully understand what causes some eyes to continue to grow, but multiple theories are currently under investigation.

It has been well documented in the past that the components of ocular anatomy that contribute to myopia (axial length, corneal power, etc) across a population are normally distributed. This is the basis of Arnold Sorsby’s theory of normal biological variation. While some myopia may be due to normal variation in a population, it does not explain the rapid increase in prevalence of myopia over the last 40 years. This may indicate that sub-types of the condition exist and are caused by different factors. The rate at which the prevalence of myopia has increased may support the idea that environmental factors play the most significant role in disrupting emmetropization and deregulating eye growth.

One of the most intriguing theories of environmental myopia development involves light or, more specifically, a lack of it. Light from the sun is relatively intense (up to 120,000 lux), full spectrum (all visible wavelengths are present) and present for a specific period of time during a 24-hour period. Light from standard sources of indoor illumination is neither full spectrum nor high intensity (Figure 2) and can be turned on or off at any time.
As a result, illumination-dependent, intra-retinal dopamine release is altered in environments with artificial lighting\textsuperscript{19}. Natural sunlight triggers a relatively high amount of dopamine release during daylight hours which has been shown to correlate well with emmetropization and diurnal eye growth cycles, while lower amounts of dopamine are correlated with more uncontrolled eye growth and myopia in chicks\textsuperscript{20}. However, the exact mechanism by which it may affect growth directly is still unknown\textsuperscript{21}. Administration of ocular dopamine agonists during natural daylight hours in chicks reduced lens-induced myopia compared to controls, which may indicate a partial causative role\textsuperscript{22}. The idea of dopamine playing a regulatory role in emmetropization is also supported by the evidence that time outdoors is protective against myopia onset in children\textsuperscript{11}. Alternative theories have been proposed that other factors associated with time outside, specifically vitamin D regulation of eye growth, may be responsible for the protective effect, but it has not be proven\textsuperscript{23}. As addressed earlier, other environmental theories involving near work contributing to myopia development are not well supported by the literature\textsuperscript{24}. Impacts of diet on eye growth are still unknown, but seem to have potential in explaining the explosion in myopia prevalence in the past few decades.

One factor bringing myopia control to forefront of optometric research is our newly realized associations with other ocular health disorders. In the past, it was understood that high myopes (>\textminus{}6.00 D) were at an increased risk for specific conditions, but low amounts of myopia were simply seen as an inconvenience. We now have evidence suggesting that any amount of myopia increases the risk of potentially blinding ocular pathologies (Table 1).

<table>
<thead>
<tr>
<th>Maculopathy</th>
<th>Retinal Detachment</th>
<th>PSC</th>
<th>Glaucoma</th>
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5
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<th>Odds Ratio</th>
<th>Refractive Error</th>
<th>Odds Ratio</th>
<th>Refractive Error</th>
<th>Odds Ratio</th>
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<td>-9.00 to -14.75</td>
<td>44.2</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>88.2</td>
<td></td>
<td></td>
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Table 1 Odds Ratio (right hand columns) of specific ocular pathologies based on refractive error in diopters (left hand columns). Refractive error categories determined by specific investigators. Relative to other medical conditions that warrant treatment, these risks are high. For example, an individual may be put on hypertension medication to prevent stroke because a systolic pressure of over 160 mm/Hg increases risk 3.3 times. This is comparable to the potentially blinding event of a retinal detachment in even the lowest myopes. Given the risks involved, it may be advantageous for practitioners to stop looking at myopia spectacle prescription and thinking of it as a disease.

**Historical Correction and Control**

Regardless of the initial cause of myopia in an individual, our professions’ historical approach of correcting patients with single vision spectacle or contact lenses has not been shown to slow the progression and may actually facilitate more eye growth. The most common explanation involves the image formed by the lens which falls on the peripheral retina. Single vision lenses create an image focused at the fovea, but the image formed in the periphery is focused behind the retina (Figure 3).
It is thought these blurred peripheral images signal the eye to continue to grow in order to focus the images on peripheral retina. This theory of peripheral retina controlling eye growth is supported by studies which have suggested the fovea plays little to no part in determining eventual refractive error. One significant question remains, how does the peripheral retina alone differentiate between myopic and hyperopic blur? The simple answer is that we don’t know. Is the mechanism localized to retinal regions or is it tied to accommodation? Some evidence from chick studies suggests that color, both through longitudinal chromatic aberration and contrast, plays a role in determining blur sign at the retinal level. It has also been suggested that accommodation, more specifically parasympathetic innervation to the eye, may play a role in determining the blur sign through an unknown feedback mechanism. However, no studies have been able to specifically confirm a single mechanism.

Early attempts to slow myopia involved giving the patient ‘less minus’, creating an image focused in front of the retina in order to slow eye growth. One simple way to do this is to under correct the eye. However, multiple studies have produced evidence that this intervention did not slow progression compared to children fully corrected and may actually accelerate growth. The issue is thought to be that children were only ‘under-minused’ by 0.50 D. with a traditional spectacle lens. The image shell of the fully corrected eye (Figure 3) is the same in an
under corrected eye, but under correcting just shifts the shell forward slightly. The images outside of the central 20 degrees are still being formed behind the retina. More simply put, under correction with a spectacle lens does not provide enough desired blur (myopic) to a large enough area of the retina to reduce axial elongation. This may be why no control of myopia has been discovered with under correction as the intervention. Other groups observed a slowing in refractive error progression using rigid gas-permeable contact lenses to fully correct children, but they seem to slow myopia progression only by altering corneal curvature, which quickly returns to its natural shape when wear is discontinued; there was no effect on axial elongation.

The first true success with slowing the progression of myopia was through the use of bifocal and progressive addition spectacle lenses (PAL). The COMET study was able to show a significantly slower progression in the PAL group over a three year time period compared to the control, wearing a single vision lens. However, the statistically significant result was not clinically relevant as the mean difference between groups was approximately 0.20 D. It wasn’t until executive bifocal designs were used that a clinically relevant slowing of progression was noted. A 0.75 D. difference between experimental and control (single vision lenses) groups was measured, which equates to approximately a 39% slowing in progression in the experimental group over a three year period. Many would argue the effect is not large enough to implement clinically. Interestingly, the data do seem to support the idea that a larger add area (executive bifocal) slows progression of myopia better than a lens with a small add area (PAL) even though the accommodative response in each is similar. A problem with spectacle lenses overall is that a patient is not required to look through the center of the lens at all times and the advantageous blurred images are not presented consistently to the peripheral retina. This issue has been
overcome in treatments that use corneal re-shaping and contact lenses to provide the optics to the eye.

*Current Myopia Control Strategies*

In accordance to some of the theoretical mechanisms for myopia development, a handful of treatment strategies have gained traction, including both optical and pharmaceutical modalities. All of the optical treatments in development and early use (off-label) take advantage of the peripheral retinal blur theory described above. The effectiveness of pharmaceutical intervention is reviewed briefly below, but the potential mechanisms of action are beyond the scope of this paper and will not be discussed.

*Orthokeratology*

Ortho-K lenses are rigid contact lenses that reshape the anterior surface of the cornea, changing the refractive properties through pressure and epithelial cell migration. By applying pressure on the central cornea, cells migrate to the periphery of the treatment zone where pressure from the contact lenses is non-existent. This flattens the central cornea, decreasing the corneal refractive power and creating emmetropia at the fovea. The thickening and steeping of the peripheral cornea as a result of this cell migration provides the peripheral retina with myopic blur, creating a stimulus for growth control. Lens fit is essential to ensuring the treatment zone and subsequently the optics created by that zone provide the child with the correct visual stimulus. Children wear the Otrho-K lenses only while sleeping. No lens is worn during the day which makes this modality a popular choice.

*Atropine*

While the exact mechanism by which these drugs slow myopia development is unknown, they have been shown to be most effective. Unfortunately, side effects like light sensitivity and loss of accommodation make extended use difficult and reduce compliance. Historically, 1% atropine
was used and side effects were very common. More recently, concentrations of 0.025% and 0.01% have been used, minimizing the side effects patients experienced with higher concentrations \(^{36}\). Lower concentrations also had a reduced rebound progression effect compared to higher concentrations (Figure 4) \(^{36}\). While most studies involving atropine have shown a reduction in axial length, one study suggested 0.01% atropine did not slow axial length growth as is typical with higher concentrations, and the slowing of myopia progression in that group may be due to changes in crystalline lens curvature changes and tonic accommodation \(^{37}\).

![Figure 4 Change in spherical equivalent (y-axis) in the Atropine for the Treatment of Childhood Myopia study 2 (ATOM2) eyes that received 0.5%, 0.1% and 0.01% atropine. Error bars indicate standard deviation (SD) \(^{36}\). Month 24 indicates the termination of atropine treatment.](image)

**Soft Multifocal Contact Lenses**

The soft multifocal lens modality has become a widely and passionately debated topic in recent years. An advantage of choosing a soft lens to control myopia is the strict control over the lens parameters and the subsequent image presented to the eye. Time of treatment is also very flexible as the child simply removes and inserts lenses as instructed by the doctor. This characteristic is also a potential disadvantage if the child is not wearing the lens enough to
achieve maximum treatment benefit. Additionally, children at risk for developing myopia can be treated before they become myopic with a soft lens while orthokeratology only becomes an option after the child is at least one diopter myopic.

While a few specific practitioners claim very good anecdotal success using soft multifocal lenses to control myopia progression, results from the literature are mixed, as are the lens designs. The parameters of lens designs used in previous studies and progression results are listed below (Table 2). Walline et-al. (2013) achieved the second highest amount of myopia progression reduction of all the studies reviewed with an aspheric add totaling +2.00 diopters and a central distance diameter of 2.30mm\textsuperscript{38}. Theoretically, this lens design (Figure 5) provides the most blur to the peripheral retina of the five designs (concentric rings alternate distance/near sections; therefore, portions of the peripheral retina receive no myopic blur). It is worth noting that lens wear time in this study was relatively low compared to the others. A greater treatment effect may have been achieved if the subjects had worn their lenses for a longer period.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Central Distance Dia.</th>
<th>Add Power (Diopters)</th>
<th>Progression Reduction</th>
<th>Drop Out</th>
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<td>Lam (2014)[40]</td>
<td>Concentric, alternating rings</td>
<td>Not reported</td>
<td>2.5</td>
<td>25%</td>
<td>41%</td>
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*Figure 5  Schematic view of aspheric lens used by Walline et-al. (2013) (A), Anstice et-al. (2013) (B). and our proposed lens design [38], [39] (C). Each has a center distance diameter of 2.30 mm, 3.36mm, and 2.00 mm, respectively. Drawing not to scale.
Table 2 Lens designs used in previous myopia control studies. * indicates the length of the study in months.

<table>
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<th>2.0</th>
<th>37%</th>
<th>15% (12m)*</th>
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<tr>
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<td>2.30 mm</td>
<td>2.0</td>
<td>50%</td>
<td>33% (24m)*</td>
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<tr>
<td>Sankaridurg (2011)[41]</td>
<td>Linear progressive (1.00D to 5mm then 2.00D)</td>
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<td>34%</td>
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<td>9% (12m)*</td>
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</tbody>
</table>

Dr. Thomas Aller’s 2016 soft bifocal lens study was recently published, reporting the greatest amount of myopia control and lowest dropout rates of any soft lens study to date[42]. He states the advantage of a concentric ring design is its pupil independence. Where aspheric optics are affected by a patient’s angle kappa (angle between line of sight and the center of the pupil), concentric ring designs have multiple areas of distance vision correction that a patient may use and the centration of lens optics on the patient’s line of sight is less important. The low dropout rates and high rates of reduction may be due to the fact all subjects had eso fixation disparity[42]. Those with eso fixation disparity tend to be more accepting of a near add than those with an exo fixation disparity. It has also been shown those with esophoria have a stronger treatment effect compared to exophoric subjects in multifocal spectacle lens studies for myopia control[26]. This may simply be due to the fact that the exophoric subjects did not look through the total add area of their progressive lens as the full add power will relax accommodation and reduce convergence through the near triad. Exophoric subjects are more likely to lose binocular fusion of the target compared to esophoric patients when looking through an add. The measured difference between the two groups may be due to one group not using their lenses, not because of some intrinsic physiological difference between the groups. Regardless of factors that potentially influenced the impressive results, the lens Aller used in his study is no longer commercially available.
Ultimately, the techniques used in myopia control will likely be used synergistically, not competitively. Each has advantages and disadvantages and practitioners should gain an in-depth understanding of them all before making a decision as every patient’s situation is unique. If we compare them individually, Figure 6 summarizes the studies of the current treatment modalities described above.

![Figure 6 Percent slowing of myopia progression by atropine, soft bifocal, or orthokeratology contact lenses in controlled studies published in the literature. Notes: Percent slowing is calculated as the difference in progression between the experimental and control group, divided by the progression of the control group. The overall average for each type of correction (shown on the right side of the figure) is the simple mathematical average of the percent slowing for each study that used that type of correction. Axial elongation was used when available, but myopia progression was used if axial elongation was not available.](image)

Whereas the multifocal lens studies reviewed above assessed the myopia control properties of each lens design, our goal was to evaluate each subject’s visual quality and visual acuity. To guide our study design, we reviewed previous studies that assessed multifocal lens performance. Based on objective measures used in the past, we selected those which we believed would provide the most information about the functional vision of the subject during testing (Table 3).
Goals for this Study

The fact that none of the modalities described above have been approved by the FDA for specific use as myopia control treatments is evidence that our understanding of controlling the disease is not complete. This study was conducted with the intention of gaining a basic understanding of which characteristics of soft multifocal contact lenses influence a patient’s functional vision. Our intention was not determine which lens controls axial length elongation; it was to help limit the number/type of lenses being investigated in the future. The goals of our study were as follows:

1. Improve understanding of lens design limitations (how much add is too much?)
2. Improve the ability to predict lens acceptance and compliance
3. Maximize add area without compromising functional vision

The last point is our primary directive. By shrinking the central distance diameter compared to other lenses studied in the past, creating designs with larger add areas, and increasing the add...
power, our designs should present a larger area of myopic blur to the peripheral retina of our subjects (Figure 5). Our prediction was that the large area of myopic blur from our lens designs would slow myopia progression to an even greater degree than lenses used in the past. Future studies measuring peripheral refraction while wearing lenses and clinical treatment trials will need to be performed to confirm this.

**Materials & Methods**

The contact lens material used throughout this study was Contaflex 38(polymacon). Contaflex 38 is a hydroxyethylmethacrylate (HEMA) material developed specifically to be lathe cut. Lenses were manufactured by Soflex Contact Lenses in Israel. Parameters of the material are listed in Table 4.

<table>
<thead>
<tr>
<th>Classification – (ISO 18369-1:2009)</th>
<th>Filcon 1</th>
<th>Oxygen Permeability (ISO)</th>
<th>7.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Approved</td>
<td>Yes</td>
<td>Tensile Strength</td>
<td>0.44MPa</td>
</tr>
<tr>
<td>USAN</td>
<td>Polymacon</td>
<td>Elongation to break</td>
<td>136%</td>
</tr>
<tr>
<td>Ionic or non-ionic</td>
<td>Non-Ionic</td>
<td>Hardness (Shore D)</td>
<td>88</td>
</tr>
<tr>
<td>Swell Factor</td>
<td>1.20 at 20°C</td>
<td>Handling tints</td>
<td>Blue/Violet/Green</td>
</tr>
<tr>
<td>Water Content</td>
<td>38% at 20°C</td>
<td>UV Blocker</td>
<td>On request</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.51 Dry - 1.438 Hydrated</td>
<td>Diameter</td>
<td>12.70mm</td>
</tr>
<tr>
<td>Light Transmission</td>
<td>&gt;96%</td>
<td>Thickness</td>
<td>5.00mm</td>
</tr>
<tr>
<td>Density</td>
<td>1.27g/cm³ - 1.17g/cm³ Hydrated</td>
<td>DK</td>
<td>9</td>
</tr>
</tbody>
</table>

*Table 4 Contaflex 38 material parameters (FDA 511 approval summary).*

**Lens Design**

Three different lens designs were tested in our study. An aspheric add design (LA), linear add design (LA), and constant add design (CA) were manufactured in add powers of +1.00, +2.00,
+3.00, +4.00 and +5.00 D. (Figure 7). A total of 15 experimental lenses and one plano control lens were worn and evaluated by each subject. Every lens manufactured had a base curve of 8.6mm and a diameter of 14.2 mm. Each experimental lens contained a 2.00 mm diameter plano powered center.

![Figure 7 A 3-dimensional and graphical depiction of each lens design. As the power of the add increases, the add area of the constant addition design is much larger than the add area of the aspheric design.](image)

**Subject Pool Determination**

We recruited ten (10) experienced spherical soft contact lens wearers from the Pacific University College of Optometry class of 2017 to participate in our study. Eight females, five of whom identified as Asian, participated in the study. The remaining three females and two males identified as Caucasian. All subjects were between the ages of 23 and 26.

Sample size was determined using a sample size calculator\(^5\). An effect size of 1.25 or larger was sufficient to demonstrate a difference between the experimental and control groups of 10 subjects each. The other parameters used in the power calculation included alpha $z$: 1.96 and power $z$: 0.84.

The benefits of subject pool (optometry class of 2017) are three fold. First, all members of the class received comprehensive vision exams within the last year and had current spectacle lens correction. We were able to ensure unknown ocular pathology (amblyopia, macular disease, tear film insufficiency, etc.) would not alter results of the study. Secondly, familiarity with all testing procedures, vocabulary necessary to subjectively describe lens fit and vision effects, and
sensitivity to power changes are all attributes these subjects possessed. As a result, an experimental lens given a satisfactory rating by these subjects would likely be accepted by members of the general population who have, arguably, less sensitive visual systems. Lastly, the experience of the subjects on insertion and removal of the lenses decreased risk of corneal insult and increased efficiency of data collection.

Selection Criteria

Subjects were selected based on type of refractive error (myopia only) and severity of refractive error. The goal range was -0.50 to -6.00 to ensure we measure the effects of the lenses on the range of refractive errors that will be potential candidate for myopia control therapy. Table 5 shows the subjects’ refractive errors.

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Rx OD</th>
<th>Rx OS</th>
<th>Study ID</th>
<th>Rx OD</th>
<th>Rx OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>-1.00</td>
<td>-0.50</td>
<td>10</td>
<td>-2.75</td>
<td>-2.75</td>
</tr>
<tr>
<td>7</td>
<td>-1.00</td>
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<td>-4.00</td>
</tr>
<tr>
<td>1</td>
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<td>-0.50</td>
<td>6</td>
<td>-4.25</td>
<td>-4.00</td>
</tr>
<tr>
<td>2</td>
<td>-2.50</td>
<td>-2.50</td>
<td>9</td>
<td>-5.00</td>
<td>-5.00</td>
</tr>
<tr>
<td>5</td>
<td>-2.50</td>
<td>-2.75</td>
<td>3</td>
<td>-5.75</td>
<td>-5.75</td>
</tr>
</tbody>
</table>

Table 5 Refractive conditions for subjects in the study. Colors indicate grouping used to calculate ANOVA (see results).

Study Exclusions

Subjects excluded from participation in the study included - women who were pregnant or nursing, individuals with systemic disease that can alter ocular health (e.g. diabetes, high blood pressure) or conditions that may alter tear film physiology (Sjogren’s syndrome or other autoimmune diseases).

Study Location

All data collection and analysis was performed on the second floor of the Pacific University College of Optometry building, Jefferson Hall in the Contact Lens Research Institute, room 234.

Methods of Data Collection
Distant Acuities (100% contrast/high and 10% contrast/low): Binocular distant acuities were measured at a distance of 6m using the ClearChart 2 (Reichert Inc.). Five, random letter optotypes were presented. Letters were scaled using logMAR definitions. Results of the test were recorded in logMAR notation, where 1 letter is equal to 0.02 on the scale and 1 line is equal to 0.1. If subjects correctly identified three of the five letters correctly, they were given credit for that line and the subsequent smaller row of letters was presented. However, subjects were only given credit for correctly identified letters on the next line i.e. 20/20 or -0.02.

Near Acuities (100% contrast- high and 10% contrast- low): Binocular near acuities were measured at a distance of 40cm using the ETDRS near card. One side displayed 100% contrast letters, while the other side displayed 10% contrast letters. The near card was placed on a meter stick at 40 cm to ensure correct testing distance. Scoring was the same as described above in the distant acuity testing section. See Table 6 for Snellen to logMAR Acuity conversion.

<table>
<thead>
<tr>
<th>Snellen</th>
<th>20/10</th>
<th>20/12.5</th>
<th>20/16</th>
<th>20/20</th>
<th>20/25</th>
<th>20/32</th>
<th>20/40</th>
<th>20/50</th>
<th>20/63</th>
<th>20/80</th>
<th>20/100</th>
</tr>
</thead>
<tbody>
<tr>
<td>LogMar</td>
<td>-0.3</td>
<td>-0.2</td>
<td>-0.1</td>
<td>0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Table 6. Snellen acuity to logMAR acuity equivalents.

Stereopsis: Near (40 cm) Stereopsis was measured using the random dot, global stereopsis side of the Super Stereo test which requires polarized filters and tests down to 20 sec arc stereo acuity.

Subjective Visual Quality Rating

Each participant recorded their subjective ratings on a questionnaire for each set of lenses. Language for the questions is consistent with that used in previous studies. It included the following questions:
• How would you rate your OVERALL satisfaction with vision? (any integer 0-100)
• How satisfied are you with your DISTANCE vision? (any integer 0-100)
• How satisfied are you with your vision for COMPUTER use? (any integer 0-100)
• How satisfied are you with your near vision for READING / CLOSE UP work? (any integer 0-100)
• How satisfied are you with your ability to CHANGE YOUR FOCUS from items up close to those at a distance? (any integer 0-100)
• Do you believe you could be ACADEMICALLY SUCCESSFUL wearing these lenses on a daily basis? (yes or no)

Each question also included the following anchors to guide the subjects on choosing an accurate integer for each question. The 0-100 scale with anchors was developed by Johnson and Johnson/Vistakon for use in their FDA trials of contact lenses.

• 00 - Extremely poor vision all the time. Cannot function
• 20 - Frequently annoying vision problems.
• 40 - Occasionally annoying vision problems.
• 60 - Occasionally noticeable but not annoying vision problems.
• 80 - Rarely noticeable vision problems
• 100 - Excellent vision.

Study Protocol
On arrival at the research lab, subjects were screened for the inclusion/exclusion criteria described above. Subjects were then given a brief tutorial on safe insertion and removal of study lenses. Subjects then inserted the first experimental lenses in both eyes. The order in which lenses were evaluated was randomized for each subject using a random sequence generator. A five-minute settling period was observed in order to ensure equilibration of the lens on the eye. Patients then put on their spectacle lenses to provide artificial emmetropia at the fovea. High contrast distant acuity was measured first, followed by low contrast distant acuity, high contrast near visual acuity, low contrast near visual acuity, and stereopsis. At that time, subjects had been wearing the lens for approximately 15 minutes and were then asked to take as much time as they needed to complete the questionnaire described above, which was presented electronically on laptop LCD screen. The questionnaire was completed with experimental lenses.
still in place. The lenses were then taken out, cleaned and stored in BioTrue™ multipurpose cleaning solution. This sequence was repeated for all 16 lenses in one visit.

**Acronyms Used**

- HCDVA – High Contrast Distant Visual Acuity
- LCDVA - Low Contrast Distant Visual Acuity
- HCNVA - High Contrast Near Visual Acuity
- LCNVA – Low Contrast Near Visual Acuity

**Results**

Subjective rating of vision quality at different distances and visual performance tests were compared for the three lens designs; aspheric (AA), linear (LA), and constant (CA) at every add power +1.00 to +5.00 D. ANOVA was run to determine if there was a difference in either subjective rating or objective measures based on subjects’ refractive error (Table 5). There was no significant difference between groups on either parameter. Mean (SD) subjective ratings of vision quality overall, when viewing a distant object, when working on the computer, when reading and changing focus are illustrated in Figure 8A-8E. There was no statistically significant difference between any of the mean visual quality ratings when comparing to the control lens to any of the multifocals for lenses with a +1.00 D. add. For add powers of +2.00 and +3.00 in all designs, each lens rated significantly worse than the control in at least one category and as many as five. The mean ratings for all experimental lenses with a +4.00 or +5.00 add were significantly lower than the control in every visual quality category. Comparing the lens designs across all add powers, the aspheric add design was rated most similarly to the control and the
constant add design was rated most differently.
Figure 8A-8E Mean visual quality ratings for overall vision, distance vision, computer vision, near vision and ability to change focus. Each figure represents the three experimental lens designs, aspheric add (AA), linear add (LA) and constant add (CA) compared to the control for a given add power. Error bars represent ± 1 standard deviation.

Mean (SD) high and low contrast distance visual acuity measurements are illustrated in Figure 9A-9E. The mean high contrast distance acuity for all powers of the aspheric and linear designs was not statistically different from the mean control measurement. Low contrast distance acuity was not significantly reduced for these lens design until they reached powers of +4.00 and +5.00 with the exception of the +2.00 D linear add lens. Conversely, all powers of the constant add design reduced both high and low contrast distance acuity significantly compared to the control. It should be noted, no experimental lens reduced the mean high contrast distance acuity by more than 1.5 lines compared to the control, except the +5.00 constant add lens.
Mean (SD) high and low contrast near visual acuity measurements are illustrated in Figure 10A-10E. The mean high contrast near acuity measurements for all powers of the aspheric and linear designs were not statistically different from the mean control measurement; except for the linear design with +5.00 add. Constant add lenses reduced high contrast near acuity measurements at all powers except +1.00 D. Low contrast near acuity was significantly reduced for all lens designs with +2.00 D add powers or higher. For add powers equal to or less than +3.00 D, mean high contrast near acuity was reduced less than one line of acuity compared to control mean measures.
Near Acuity (+1.00)

Near Acuity (+2.00)

Near Acuity (+3.00)
Figure 10A-10E Mean high and low contrast near visual acuity. Each figure represents the three experimental lens designs, aspheric add (AA), linear add (LA) and constant add (CA) compared to the control for a given add power. Error bars represent ± 1 standard deviation.

Mean (SD) stereo acuity measurements of all lenses compared to the control are represented in Figure 11. The +4.00 and +5.00 add lenses of the CA design were the only two lenses to reduce the stereo acuity to worse than 80 arc seconds, on average. With the exception of the linear +5.00 lens, subjects wearing any of the other experimental lenses were able to achieve a mean stereo acuity measurement of 40 arc seconds or better.
Figure 11 Mean stereo acuity of the three experimental lens designs, aspheric add (AA), linear add (LA) and constant add (CA) in add powers 1-5 D compared to the control. Error bars represent ± 1 standard deviation.

Due to the small number of subjects evaluated the effect size of each lens design on both subjective and objective measurements were calculated and illustrated in Table 7. Similar to a t-test, effect size statistics compare means from two populations and predicts whether the two groups are likely to be different. It is more robust against very large and very small sample sizes compared to a t-test, leading to a lower probability of making a type I or type II error. For our sample size, an effect size of 1.25 or greater reduced the probability of making a type II error to 20% (40% with p-value = 0.05). More simply put, the effect size calculations predict differences between means with more confidence than p-value calculations. It also illustrates the magnitude of that difference on a standard scale.
Table 7 Calculated effect size for each experimental lens on each parameter. Subjective measures are in light blue and objective measures are in purple. The number indicates the number of average standard deviations away the experimental mean was from the control mean for each measurement. Color coding according to magnitude of the effect size is depicted. White text denotes p < 0.05 as seen on graphs for comparison. See methods section for acronym definitions.

The last item on the questionnaire asked patients if they believed they could be academically successful wearing that lens, to which they responded either yes or no. This measure is referred to as projected success. The sums of ‘Yes’ responses given by the 10 subjects for each lens design are illustrated in Figure 12. The majority of subjects believed they could be successful in any lens design with a +3.00 D. add or lower, except in the constant add design with a +2.00 D. add. Additionally, the majority of subjects believed they could be successful in any of the aspheric lens designs, regardless of power. Interestingly few thought they could wear the constant add design in powers of +2.00, +4.00, or +5.00 D., but 9 of 10 believed they could wear and be successful in the constant add design with a +3.00 D. add power.
To the question, “Do you believe you could be ACADEMICALLY SUCCESSFUL wearing these lenses on a daily basis?” each subject answered either yes or no and the sums of yes answers were plotted; i.e., 8 of the 10 subjects thought they could be successful wearing the linear add design with a +3.00 D. add power.

**Binary Logistic Regression**

We then used our projected success results as the dependent variable to create binary logistic regression models. Binary regression analysis used the objective measures in univariate models to predict projected success. Sensitivity and specificity of each measure’s model in predicting the projected success outcome is illustrated in Table 8. Multivariate models were no more predictive than single variable models. The measure that best predicted projected success was low contrast near visual acuity, though all models predicted over 70% of cases correctly.

<table>
<thead>
<tr>
<th>Objective Measure</th>
<th>Model Sensitivity</th>
<th>Model Specificity</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCDVA</td>
<td>86.5</td>
<td>51.6</td>
<td>72.5</td>
</tr>
<tr>
<td>LCDVA</td>
<td>84.4</td>
<td>50.0</td>
<td>70.6</td>
</tr>
<tr>
<td>HCNVA</td>
<td>93.8</td>
<td>35.9</td>
<td>70.6</td>
</tr>
<tr>
<td>LCNVA</td>
<td><strong>83.3</strong></td>
<td><strong>64.1</strong></td>
<td>75.6</td>
</tr>
<tr>
<td>Stereo</td>
<td>84.4</td>
<td>60.9</td>
<td>75.0</td>
</tr>
</tbody>
</table>

Table 8 Sensitivity and specificity of univariate models generated to predict projected success.
Looking at the projected success data another way, we determined the minimum value of each measure that resulted in a subject’s projected success response to be yes. The mean results for both visual quality measurements and objective visual acuity measurements were given as a reference in Table 9. Put another way, if any one of the individual’s measures was worse than the values in the right hand column for a given lens, they never believed they could be successful wearing that lens i.e. if their high contrast near visual acuity was measured to be 0.15, they would predict they could not wear the lens.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Mean</th>
<th>Low Range Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>77.60</td>
<td>40.00</td>
</tr>
<tr>
<td>Distance</td>
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<tr>
<td>Computer</td>
<td>87.50</td>
<td>40.00</td>
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<tr>
<td>Near</td>
<td>87.20</td>
<td>45.00</td>
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<tr>
<td>Focus Change</td>
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<td>HCDVA</td>
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<td>HCNVA</td>
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<td>LCNVA</td>
<td>0.12</td>
<td>0.40</td>
</tr>
<tr>
<td>Stereo</td>
<td>22.5</td>
<td>70.00</td>
</tr>
</tbody>
</table>

Table 9 The minimum values of any measurement which still resulted in a yes response to the projected success item on the questionnaire.

Discussion
The current study is the first to evaluate such a large number of experimental lenses using both subjective assessment of vision quality and objective measures of visual acuity and stereopsis.

Through the study, we have documented that as add power and add area increased, both subjective rating of vision and measured visual acuity decreased. When comparing the three designs across all add powers, the aspheric design, which had the smallest add area/power ratio, affected vision the least followed by the linear design and constant add designs. The
constant add design had the largest area/power ratio. Simply put, the more peripheral myopic blur generated by the lens, the larger the reduction in perceived visual quality and visual acuity.

Interpreting the mean data, subjects rated all the lens designs similarly to the control for add powers up to +3.00 D. and rated all lens designs with a +4.00 D. add power or more significantly worse than the control in every category. The one exception, the +2.00 constant add design, rated significantly worse than the control in all categories. We believe this may have been due to a manufacturing defect in the lens.

High contrast visual acuity results indicated no significant loss of acuity when subjects were wearing either the aspheric or linear add design, regardless of add power. The mean loss in acuity for those lenses was less than one line compared to control. On average, a subject with 20/15 best corrected visual acuity would not likely see worse than 20/20 in any one of the lens designs. This was true for both distance and near visual acuity with 100% contrast optotypes.

Low contrast visual acuity measured through the experimental lenses differed more from the control compared to high contrast measurements. The constant add design differed significantly from the control for all add powers. Low contrast distance acuity was not significantly different from control for the aspheric and linear designs for the add powers equal to or less than +3.00 D. Low contrast near acuity was significantly reduced in all designs except for the aspheric and linear designs with +1.00 D. add powers. In other words, a larger reduction in functional vision was measured when contrast was not 100%, especially during near tasks.

These data gives insight on the limitations of designs for future myopia control lenses. Add powers of +4.00 or +5.00 in any design performed poorly and should be used with caution in the clinic setting. Aspheric designs have the best chance of the three designs of being accepted by patients. The constant add design was rated much lower compared to the other two designs for
a given power and is likely not a primary lens design option. However, the independent variables of the study lens designs are only part of the picture when deciding which lens to use for myopia control. Central distance zone diameter likely plays a large role as well. Alternating, concentric ring designs, similar to those used in previous studies might be advantageous because of their proposed ‘pupil independence’. Ultimately, it is likely that lenses will be customized based on individual patient characteristics to maximize the treatment effect.

In terms of predicting success, simply taking account the number of subjects who believed they could be successful in a particular lens is helpful. The majority of subjects thought they could wear any of the lenses with add powers up to +3.00, with one exception (CA +2.00). The majority also believed the high add power (+4.00 and +5.00D) aspheric lenses were acceptable, though their visual quality ratings of these two lenses were significantly lower than the control and the low contrast acuity and stereo acuity were significantly reduced. These inconsistencies indicate projected success is likely not a perfect predictor of actual success. The logistic regression information may help practitioners when their pediatric patients don’t have the vocabulary to articulate how a lens is affecting their vision. Low contrast near visual acuity was the best predictor of projected success. Stereo acuity was similarly predictive. This is consistent with the fact that reduced contrast and stereo measurements are arguably more realistic estimates of function in the natural environment compared to high contrast measurements alone. Based on our results, practitioners should consider using some form of low contrast near visual acuity testing to assess visual function of these lenses. For those that want a cut-off value for these tests, Table 8 is the closest we were able to come during this small study. The values are not meant to serve as a hard and fast rule, but give an individual a starting a point when assessing a child’s vision through a particular lens. For example, if a child’s potential stereo acuity is 25 seconds arc, a lens where only 80 seconds arc stereo acuity is achieved will likely not
be comfortable for the child and compliance. But, if the lens yields 40 seconds arc stereo acuity, it is likely the child will not be able to tell the difference. Both Table 8 and Table 9 should serve to help the clinician decide what specific tests to use during evaluation as well as the meaning of those measurements in order to maximize wear time and comfort in future myopia control lenses.

Our study’s primary goal was to come closer to determining the ‘sweet spot’ of lens design. That is, the maximum add area/power ratio that would not degrade a patient’s vision. With a central lens diameter of 2.0 mm, the data seem to show that just about any lens up to +3.00 D. add power will be accepted. Higher adds may work if done in the aspheric design or if the central distance zone diameter is increased, increasing the area of the retina receiving a focused image. If the decision had to be narrowed to a single lens and the higher add area/power ratio (more peripheral myopic blur) theory holds true, designs similar to the +3.00 D. add power linear design might provide the most myopic blur stimulus without compromising the patient’s vision quality. That said, future lens design parameters will likely be customized to fit individual’s needs with the cost of custom designed lenses dropping significantly. The one-design-fits-all theory will be modified, but our hope is to provide a point for clinicians and manufacturers to start.

Limitations

There are a number of significant limitations to our study. The primary limitation is sample size. While the significance and effect size values were adjusted to fit our limited sample size, ten subjects reduces the confidence we have that these data adequately represent a larger population. Additionally, our study population of adults is not representative of the population of children in need of myopia control treatments. One should use caution generalizing between the two groups. Our study also is not intended to determine which lens controls myopia the
best. While we are working under the pretense that larger add areas in the periphery will provide more robust myopia control, the reader should not come away thinking Lens X is the best for myopia control. The reader should also use caution extrapolating the information concerning projected success. While the measurement is potentially powerful, it is also potentially misleading. Projected success does not guarantee actual success with a particular lens design.

**Future Studies**

The essential next step is to evaluate the actual image shell each of the acceptable lenses provides to the eye. Peripheral refraction can be measured through various techniques, but can be contaminated by peripheral astigmatism. Researchers in Spain showed that an aspherical lens similar to those used in our study (2.3 mm diameter center distance) did not provide a significant change in the peripheral image shell compared to control for add powers of +1.00 and +2.00. However, +3.00 and +4.00 add powers did change the image shell significantly, though there was no difference between the two. The implication of this is simple if it holds true for all of our lens designs. If larger add powers (+4.00 or +5.00) do not change the image shell any more than moderate powers (+3.00) there is no reason to use them since they perform more poorly both subjectively and objectively. Ultimately, peripheral refraction won’t prove efficacy either. The answer to the question of which lens design is best for myopia control will require a longitudinal, multi-center, randomized controlled trial to compare lenses. Some of these trials are currently underway.
Conclusions

Below is information gained in this study as it relates to our study goals.

- Improve understanding of lens design limitations (how much add is too much?)
  - +4.00 and +5.00 in any of the current designs is not likely to be well accepted by patients and should be used with caution.
- Improve ability to predict visual comfort
  - Stereo acuity and low contrast visual acuity measurements are likely more predictive of success than high contrast acuity tests.
- Maximize add area without compromising functional vision
  - The +3.00 D. add power linear design was the lens with the largest add power/ratio that would likely be successfully worn by future patients.

References


[37] A. Chia, W. Chua, L. Wen, A. Fong, Y. Y. Goon, and D. Tan, “Atropine for the Treatment of Childhood Myopia: Changes after Stopping Atropine 0.01%, 0.1% and 0.5%,” *Am. J.*


