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Visual Acuity and Over-Refractive in Myopic Children Fitted with Soft Multifocal Contact Lenses

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Abstract

Significance—Practitioners fitting contact lenses for myopia control frequently question whether a myopic child can achieve good vision with a high-add multifocal. We demonstrate that visual acuity is not different than spectacles with a commercially-available, center-distance soft multifocal contact lens (Biofinity Multifocal “D”; +2.50 D add).

Purpose—To determine the spherical over-refraction (SOR) necessary to obtain best-corrected visual acuity (BCVA) when fitting myopic children with a center-distance soft multifocal contact lens (MFCL).

Methods—Children ($n = 294$) ages 7 to 11 years with myopia (spherical component) of -0.75 D to -5.00 D (inclusive) and 1.00 D cylinder or less (corneal plane) were fitted bilaterally with +2.50 D add Biofinity “D” MFCLs. The initial MFCL power was the spherical equivalent of a standardized subjective refraction, rounded to the nearest 0.25 D step (corneal plane). A spherical over-refraction was performed monocularly (each eye) to achieve BCVA. Binocular, high-contrast logMAR acuity was measured with manifest spectacle correction and MFCLs with over-refraction. Photopic pupil size was measured with a pupilometer.

Results—The mean ($\pm$ SD) age was 10.3 ± 1.2 years, and the mean ($\pm$ SD) SOR needed to achieve BCVA was OD: -0.61 ± 0.24 D / OS: -0.58 ± 0.27 D. There was no difference in binocular high-contrast visual acuity (logMAR) between spectacles -0.01 ± 0.06 and best-corrected MFCLs -0.01 ± 0.07 ($p = 0.59$). The mean ($\pm$ SD) photopic pupil size (5.4 ± 0.7 mm) was not correlated with best MFCL correction or the over-refraction magnitude (both $p = 0.09$).

Conclusions—Children achieved BCVA with +2.50 D add MFCLs that was not different than with spectacles. Children typically required an over-refraction of -0.50 D to -0.75 D to achieve BCVA. With a careful over-refraction, these +2.50 D add MFCLs provide good distance acuity, making them viable candidates for myopia control.

Keywords

soft multifocal contact lens; bifocal contact lens; visual acuity; over-refraction; myopia; children

The prevalence of myopia in the United States increased from 25% in the 1970s to over 33% currently.¹ The global prevalence of myopia and high myopia (more myopic than -5.00 D) also increased and is projected to affect five billion and one billion people by 2050, respectively.² Not only does high myopia increase the risk of ocular pathology (including cataract, glaucoma, retinal detachment, and myopic degeneration), even low degrees of myopia are associated with increased risk of ocular disease.³

Peripheral defocus plays an important role in emmetropization of the visual system in non-human primates, and altering peripheral retinal focus influences eye growth even when there is clear central vision.⁴ When reared with dual focus lenses, the more anterior (myopic) defocus signal has also been shown to dominate eye growth.⁵ Although relative peripheral refraction of the uncorrected human eye is not meaningfully associated with myopia progression,^{6–8} there is evidence in humans that peripheral myopic defocus caused by an optical intervention is associated with slower myopia progression.^{9, 10}

There is increasing evidence that orthokeratology and multifocal contact lenses slow myopia progression in children, and it is hypothesized that peripheral myopic defocus is the cause of the observed reduction in progression.^{11–15} A recent report of contact lens prescribing habits of eye care providers in the United States found that 37% of respondents actively practice myopia control with contact lenses, and that soft multifocal contact lenses were the most commonly utilized modality (51%) followed by orthokeratology (44%).¹⁶ Despite there currently being no optical devices in the US with an indication for myopia control from the US Food and Drug Administration, contact lenses are being fitted for this purpose.

The Bifocal Lenses in Nearsighted Kids (BLINK) Study is an ongoing, three-year, double-masked randomized clinical trial that is investigating whether commercially-available, soft multifocal contact lenses slow the progression of myopia in children.¹⁷ The center-distance soft multifocal contact lens being used in the BLINK Study (Biofinity Multifocal “D” Lens; CooperVision; Pleasanton, CA) creates the desired optical profile of peripheral myopic defocus, making it a good candidate for a study attempting to slow myopia progression in children.¹⁸ While previous studies have described vision with various soft multifocal lens designs,^{19–21} we are aware of no studies that have reported best visual acuity or the over-refraction required to obtain best vision in myopic children fitted with the commercially-available Biofinity Multifocal “D” lens with a high (+2.50 D) add power. This analysis informs eye care providers of the typical over-refraction required to achieve best-corrected visual acuity when fitting myopic children with this center-distance soft multifocal contact lens (+2.50 D add) and reports the high-contrast visual acuity with these lenses compared to spectacles.

METHODS

Two hundred ninety-four myopic children ages seven to 11 years (inclusive) were enrolled in a double-masked, three-year, randomized clinical trial at two sites (University of Houston College of Optometry and The Ohio State University College of Optometry). This research adhered to the tenets of the Declaration of Helsinki. Assent from children and parental permission were obtained from each subject and subject's parent/guardian, respectively. This research was approved by the Institutional Review Boards at the University of Houston and The Ohio State University. Full baseline characteristics and methods have been previously reported;¹⁷ the details and methods relevant to this analysis are described below.

Contact Lenses

For the data described in this report, all subjects were fitted (each eye) with a center-distance, soft multifocal contact lens (Biofinity Multifocal "D" with a +2.50 D add) prior to randomization to a treatment group as part of the baseline visit determining eligibility to participate in the BLINK Study. These silicone-hydrogel lenses are made of comfilcon A (48% water), have an 8.6 base curve, and overall diameter of 14.0 mm. As described by the manufacturer, the "D" lenses have a spherical central distance zone, followed by a zone of progressively increasing plus power before reaching an outer zone with the full add power. Although specific design specifications are not provided by the manufacturer, independently measured metrology of this lens has been published^{22, 23} as well as the on-eye change in defocus experienced when myopic eyes are fitted with this contact lens.¹⁸ All contact lens, visual acuity, and pupil size assessments described in this report were conducted prior to the instillation of cycloplegic agents.

Eligibility Criteria

Eligible subjects had a spherical refractive error component in each eye (corneal plane) of -0.75 to -5.00 D (inclusive), no more than 1.00 D of astigmatism in each eye, and no more than 2.00 D of anisometropia (spherical component), as determined by cycloplegic autorefraction using the Grand Seiko WAM-5500 (Grand Seiko Co., Hiroshima, Japan). All subjects had +0.10 logMAR or better monocular, best-corrected high-contrast distance visual acuity in each eye. Children eligible for inclusion and randomization in the BLINK Study were also required to achieve +0.10 logMAR or better high-contrast visual acuity (binocular) at distance when wearing a +2.50 D add multifocal contact lens on each eye with spherical over-refraction. The study contact lenses had to provide adequate movement and centration for a subject to participate. All subjects were free of eye disease or binocular vision problems (e.g., strabismus, amblyopia, corneal disease, etc.) that could affect vision or contact lens wear and were free of systemic diseases that may affect vision, vision development, or contact lens wear (e.g., diabetes, Down syndrome, etc.). Subjects were not allowed to have had more than one month of gas permeable, soft bifocal, or orthokeratology contact lens wear or more than one month of any myopia control treatment. Subjects were excluded if they chronically used medications that may affect immunity, such as oral or ophthalmic corticosteroids.

Contact Lens Power Determination

The initial contact lens power chosen for each eye was determined by the spherical equivalent power (after referencing to the corneal plane) from a standardized most plus/least minus manifest refraction conducted by a trained and certified study doctor. The initial multifocal contact lens power for each eye was rounded to the nearest 0.25 D step (e.g., a spherical equivalent of -3.12 D would result in an initial contact lens power of -3.25 D while a spherical equivalent referenced to the corneal plane of -4.61 D would result in an initial contact lens power of -4.50 D). Upon insertion of the contact lenses, a spherical over-refraction was performed monocularly for each eye using a distance Snellen chart to determine the power that yielded best-corrected visual acuity. If the subject could read 20/20 prior to over-refraction, plus power in 0.25 D steps was added until the subject could no longer read 20/20, and the most plus over-refraction resulting in 20/20 visual acuity was used. If a subject could not read 20/20, minus power was added in 0.25 D steps until there was no further improvement in visual acuity. The spherical over-refraction for each eye was placed into a trial frame that the subject wore over the multifocal contact lenses for visual acuity testing. The final contact lens powers dispensed in the BLINK Study incorporated the spherical over-refraction that resulted in best-corrected visual acuity.

Visual Acuity

Binocular, high-contrast logMAR visual acuity at distance was measured prior to fitting contact lenses with the child's full spectacle correction in a trial frame (as determined by the manifest refraction described above) and again with the best-corrected multifocal contact lenses (multifocal contact lenses with the final over-refraction for each eye in a trial frame). Bailey-Lovie visual acuity charts were placed four meters from the subject. Chart luminance was set to between 75 to 120 cd/m^2 . Subjects read the first letter of each line until a letter was missed and then began reading all five letters on every line, beginning two lines above the first incorrectly read letter. If a letter was missed on the first full line attempted, the subject moved to the line above until successfully reading all five letters on the line. The stopping point for visual acuity testing was the point at which three or more letters were missed on the same line. If a child read three or more letters on the bottom line of the chart, retesting was performed with the subject six meters from the chart. The total number of letters correct was recorded and converted to logMAR acuity, accounting for the testing distance.

Pupil Size Measurements

Photopic pupil size measurements of the right eye were made using the NeurOptics VIP-200 Pupillometer (NeurOptics, Inc., Irvine, CA). Subjects stood directly in front of and facing away from the Bailey-Lovie distance visual acuity charts under the same lighting conditions described above that yielded chart luminance of 75 to 120 cd/m^2 . Pupil size measurements from the pupillometer were recorded to the nearest 0.1 millimeter.

Contact Lens Fit

Contact lens centration of both the right eye and the left eye was graded by slit lamp. Lens centration for each eye was graded as one of the following: optimum (symmetric about the

center of cornea), slightly decentered (no limbal exposure), or extremely decentered (limbal exposure). Subjects with extremely decentered contact lens fits were ineligible for this study. Other aspects of the contact lens fit including movement and ease of pushup were also assessed to ensure an acceptable fit.

Statistical Tests

Frequency distributions and descriptive statistics were used to summarize the over-refraction data. The difference in best-corrected visual acuity between the two correction types (full manifest spectacle correction minus multifocal contact lenses with over-refraction) was calculated for each child, and a t-test was used to compare the mean difference to zero. Correlation analyses were used to evaluate relationships between best-corrected visual acuity, photopic pupil size, over-refraction, and astigmatic cylinder correction. A t-test was also used to evaluate changes in visual acuity between spectacle and contact lens correction after grouping subjects based on lens centration. Data distributions were sufficiently symmetrical to satisfy the normality assumptions of parametric testing.

RESULTS

A total of 294 eligible, myopic children were enrolled in the BLINK Study, of which 177 (60%) were female. The mean ($\pm$ SD) age and spherical equivalent manifest refraction at the corneal plane were 10.3 ± 1.2 years and right eye: -2.57 ± 1.07 D (range: -0.87 D to -5.92 D) / left eye: -2.53 ± 1.07 D (range: -0.74 D to -5.38 D), respectively. Note that the non-cycloplegic spherical equivalent manifest refraction was used to determine the initial contact lens power placed on the eye. The amount of myopia for eligibility purposes in the BLINK Study was determined by the spherical component of cycloplegic autorefraction.

Spherical Over-refraction

The mean ($\pm$ SD) spherical over-refraction needed to achieve best-corrected distance visual acuity with the multifocal contact lens was right eye: -0.61 ± 0.24 D / left eye: -0.58 ± 0.27 D / both eyes: -0.59 ± 0.25 D. The spherical over-refraction distribution for both eyes is shown in Figure 1. There was no correlation between the spherical over-refraction for each eye and either the amount of myopia (right eye $r = -0.01$; left eye $r = -0.05$; both $P > .10$) or the amount of refractive cylinder (right eye $r = 0.02$; left eye $r = -0.05$; both $P = .36$) based on non-cycloplegic manifest refraction.

Visual Acuity

The mean binocular, high-contrast distance visual acuity with full manifest refraction in a trial frame (spectacles) and with multifocal contact lenses with spherical over-refraction are shown in Figure 2. The distribution of visual acuity with spectacles and multifocal contact lenses is shown in Figure 3. Visual acuity with spectacles ranged from -0.20 to $+0.16$ logMAR, and acuity with multifocal contact lenses ranged from -0.20 to $+0.10$ logMAR. There was not a significant difference in visual acuity between correction types (mean $\pm$ SD difference with spectacles minus contact lenses = 0.002 ± 0.056 logMAR; $P = .59$).

Pupil Size

The mean ($\pm$ SD) photopic pupil size of the right eye was 5.4 ± 0.7 mm (range: 3.1 to 7.2 mm). There was no evidence of an association between photopic pupil size and best-corrected visual acuity with the multifocal contact lens ($r = -0.06$; $P = .30$) or between photopic pupil size and the magnitude of the over-refraction required to achieve best vision ($r = 0.10$; $P = .09$).

Contact Lens Centration

Contact lens centration and high-contrast, best-corrected visual acuity with multifocal contact lenses were analyzed to determine if lens centration had a clinically meaningful influence on visual acuity. Subjects were not eligible for the BLINK Study if a lens was graded as extremely decentered (limbal exposure), which only occurred in three subjects. The change in binocular visual acuity between correction modalities was calculated (multifocal contact lens minus best spectacle correction). Across all subjects, contact lenses were graded as optimum (symmetric about center of cornea) in both eyes of 247 subjects (mean $\pm$ SD logMAR acuity = 0.00 ± 0.05), optimum in one eye and slightly decentered in the fellow eye of 15 subjects (logMAR acuity = -0.01 ± 0.04), and slightly decentered in both eyes of 32 subjects (logMAR acuity = -0.01 ± 0.07). Subjects with slight contact lens decentration in one or both eyes were combined ($n = 47$) for analysis. There was no evidence that the mean change in visual acuity between spectacles and multifocal contact lenses was different between subjects with optimally centered lenses versus those with at least one lens that was slightly decentered ($P = .50$). Restating this result, we found no evidence that contact lens centration affected visual acuity in children with an acceptable contact lens fit.

Vision in Ineligible Children

Because the BLINK Study eligibility criteria included minimum visual acuity requirements, we also report how often children were not eligible due to poor vision with multifocal contact lenses. In addition to the 294 children who were eligible for and enrolled in the BLINK Study, there were 87 children who were screened for study eligibility who reached the multifocal contact lens fitting step of the initial exam but ultimately did not qualify to participate. Across all subjects screened for the BLINK Study (eligible and ineligible) for whom best-corrected visual acuity with multifocal contact lenses was assessed ($n = 381$), only three subjects (0.8%) did not achieve $+0.10$ logMAR (20/25) or better visual acuity. The primary reason these 87 ineligible subjects did not qualify for enrollment was that either their amount of myopia or astigmatism were later determined to be outside of the study eligibility criteria as determined by cycloplegic autorefraction after the contact lens fitting step. Poor binocular, high-contrast distance vision (worse than $+0.10$ logMAR) with the $+2.50$ D add multifocal contact lenses was rarely the reason that a child did not qualify.

DISCUSSION

Center-distance, soft multifocal contact lenses are becoming more popular as an off-label method of myopia control in clinical practice. This is the first study of which we are aware to determine the spherical over-refraction and high-contrast distance visual acuity to expect when myopic children are systematically fitted with commercially-available, high-add

(+2.50 D) soft multifocal contact lenses. The typical spherical over-refraction necessary to achieve best-corrected visual acuity when fitting the +2.50 D add Biofinity Multifocal “D” contact lens in this study was between -0.50 D and -0.75 D in each eye. We found no evidence that the amount of myopia or astigmatism was associated with the magnitude of the spherical over-refraction. We also found no evidence that children with larger pupils needed a more negative over-refraction to reach the same level of acuity as children with smaller pupils.

One might question whether the Biofinity Multifocal “D” lenses used in this study still result in peripheral myopic defocus after accounting for a negative-powered over-refraction. Each child screened for this clinical trial was fitted with +2.50 D add multifocal contact lenses prior to randomization to ensure that children would attain acceptable visual acuity if enrolled and randomly assigned to the +2.50 D add multifocal group. Peripheral refraction data were only collected in the BLINK Study after each child was fitted with their randomized lens assignment. The mean over-refraction found in the BLINK Study across both eyes with the +2.50 D add lenses (-0.59 ± 0.25 D) during the eligibility visit is consistent with Grand Seiko cycloplegic autorefractometer measurements made over the same multifocal design and add power before over-refraction in a previous study by Berntsen and Kramer.¹⁸ In this previous study of myopic young adults, the residual central autorefractometer for subjects wearing the Biofinity Multifocal “D” (+2.50 D add) contact lens prior to over-refraction was (mean $\pm$ SD) -0.66 ± 0.35 D. When viewing a distance target, even after accounting for the residual over-refraction, the peripheral plus power of these same multifocal lenses caused an on-eye anterior shift in peripheral focus that resulted in myopic defocus at 30° and 40° on the nasal retina and at 20° , 30° , and 40° on the temporal retina.¹⁸ These data demonstrate that myopic peripheral defocus can reasonably be expected even after applying the over-refraction needed to optimize visual acuity with this lens. The peripheral defocus data being collected in the BLINK Study after randomization while children wear their assigned study contact lenses will be presented upon study completion.

High-contrast best-corrected visual acuity at distance with the +2.50 D add multifocal contact lenses used in this study was not different than with full spectacle correction (mean = -0.01 logMAR for each correction type). We also found no evidence in these myopic children that best-corrected visual acuity was influenced by pupil size or lens centration. It is important to note that children were excluded from our study if a contact lens significantly decentered (e.g., crossed the limbus). These data demonstrate that, on average, myopic children with 1.00 D of cylinder or less can be expected to achieve high-contrast visual acuity that is not different than with spectacle correction.

While we are unaware of previous studies reporting the over-refraction and best visual acuity when myopic children are fitted with the +2.50 D add Biofinity Multifocal “D” lens, high-contrast visual acuity with various multifocal or dual-focus contact lens designs has been reported by several studies. Generally, studies of both children^{10, 24} and young adults^{21, 25} find no difference in high-contrast visual acuity between multifocal contact lens designs with a labeled add power of +2.50 D or less when compared to either spherical contact lenses or spectacles. Exceptions where a reduction in high-contrast visual acuity has been

reported involve add powers that are +3.00 D or higher²⁵ or studies in which no over-refraction was performed over the multifocal contact lens to optimize visual acuity.¹⁹

Kang et al. fit young adults (18–28 years) in Proclear Multifocal “D” contact lenses (center-distance design; CooperVision) with a +1.50 D add and a +3.00 D add and measured high- and low-contrast distance visual acuity at an initial visit and after 2 weeks of wear.²⁵ They found no significant difference in high- or low-contrast visual acuity with the +1.50 D add lenses at either visit compared to a spherical soft contact lens. They did find a statistically significant decrease in high- and low-contrast VA at both visits with the +3.00 D add lenses, although the average acuity change was less than one line (3.5 letters). It is also unclear if an over-refraction was performed prior to measuring visual acuity. Fedtke et al. conducted a study of multiple single vision and multifocal soft contact lens designs (both center-distance and center-near) fitted monocularly.¹⁹ They reported that monocular high-contrast visual acuity was significantly worse with all multifocal lenses; the reductions were just under one line of acuity with what they described as the “high” and “low” add Proclear Multifocal “D” lens, which is similar to the Biofinity Multifocal “D” design. It is important to note that the monocular nature of the acuity measurements combined with not conducting an over-refraction likely resulted in the visual acuity reductions reported in their study. As found in the current study, a negative power over-refraction optimizes visual acuity. Based on the previous work measuring the on-eye peripheral focus profile of the Biofinity Multifocal “D” lens with a +2.50 D add described earlier, peripheral myopic defocus is still present after accounting for the over-refraction amount that was typically found in children when fitting the Biofinity “D” lens.¹⁸

Increases in glare and halos have been reported with both orthokeratology²⁶ and multifocal / dual focus contact lenses.^{21, 25} A study limitation is that low-contrast visual acuity was not part of the screening exam prior to randomization; therefore, these data are not available for this analysis. In the BLINK Study, low-contrast visual acuity data were collected after each child was randomly assigned to a contact lens group and is being actively measured with the assigned lens throughout the study. We will be able to report low-contrast visual acuity changes by treatment group upon completion of this clinical trial. Additional limitations are that low luminance acuity and contrast sensitivity were not assessed, both of which provide further information on visual quality. Including these measurements in future studies would provide a more comprehensive understanding of the effects of these lenses on visual quality.

In practice, high-contrast visual acuity is routinely checked and is typically similar to spectacle correction. Clinicians should be aware that if patients report a change in the quality of their vision, this is likely due to changes in contrast sensitivity and low-contrast vision, which has been well documented with multifocal lens designs.^{21, 25, 27} Multifocal soft contact lenses generally reduce low-contrast visual acuity by approximately one line, which is similar to the reductions reported due to other contact lens myopia control modalities such as orthokeratology.²⁸

An additional study limitation is that contact lens decentration was evaluated using a categorical scale as opposed to measuring the actual amount of decentration in millimeters. Although we did not find evidence that the mean change in visual acuity between spectacles

and multifocal contact lenses differed between subjects with contact lenses graded as optimally centered versus those with at least one lens graded as slightly decentered, it is important to note that results could be different if the actual decentration amount were evaluated. Additionally, this analysis included no lenses that were graded as having extreme decentration (limbal exposure). Clinicians should keep in mind that an analysis using a more detailed measurement of the amount of decentration could yield a different result.

It is also important to note that the results of our study are specific to the +2.50 D add multifocal lens design used in this study. Visual acuity with other lens designs could certainly differ, as could visual acuity for refractive errors outside of our study eligibility criteria. For example, because the lens design used in this study is rotationally symmetric and does not correct astigmatism, visual acuity differences would be expected if the lens were fitted on a child with greater amounts of astigmatism. If visual acuity was unacceptable with a +2.50 D add contact lens after spherical over-refraction, an alternative approach would be to lower the add power of the contact lens and again prescribe any spherical over-refraction needed to achieve acceptable visual acuity. There is currently not evidence in the literature that there is a better myopia control effect with higher add powers. In the BLINK Study, children are randomly assigned to either a spherical contact lens control group, a +1.50 D add contact lens group, or a +2.50 D add contact lens group.¹⁷ The influence of add power on myopia control will be reported at the completion of the BLINK Study.

CONCLUSIONS

Children achieved high-contrast, best-corrected distance visual acuity with Biofinity Multifocal “D” contact lenses with a +2.50 D add that was not different than when wearing best spectacle correction. Most children required an over-refraction of between -0.50 D and -0.75 D to obtain best visual acuity with the contact lenses used in this study. When fitting this specific contact lens and add power in children, practitioners should perform a careful over-refraction and prescribe any minus power found necessary to achieve best distance visual acuity. The good distance visual acuity combined with the myopic peripheral defocus previously reported with this lens make it a viable candidate for myopia control in children. While the BLINK Study will ultimately determine whether these commercially-available multifocal lenses slow myopia progression, the results presented here describe the over-refraction and acuity practitioners can expect when fitting this +2.50 D add lens.

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Figure 1.
Frequency distribution of spherical over refraction values for each eye (588 eyes of 294 subjects).

Figure 2. Binocular best-corrected distance visual acuity with best spectacle correction and with +2.50 D add center-distance soft multifocal contact lenses with spherical over-refraction (n = 294). Error bars represent SD.

Figure 3.

Frequency distribution of binocular, high-contrast distance visual acuity (logMAR) when wearing best spectacle correction (gray bars) and with +2.50 D add center-distance soft multifocal contact lenses with spherical over-refraction (black bars; 294 subjects per distribution).