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ORIGINAL ARTICLE

Multifocal Contact Lens Myopia Control

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ABSTRACT

Purpose. Previous studies on soft multifocal contact lens myopia control published in the peer-reviewed literature reported findings of noncommercial contact lenses worn for 1 year or less. This study sought to determine the progression of myopia and axial elongation of children fitted with commercially available distance center soft multifocal contact lenses for 2 years.

Methods. Eight- to eleven-year-old children with −1.00 D to −6.00 D spherical component and less than 1.00 D astigmatism were fitted with soft multifocal contact lenses with a +2.00 D add (Proclear Multifocal "D"; CooperVision, Fairport, NY). They were age- and gender-matched to participants from a previous study who were fitted with single-vision contact lenses (1 Day Acuvue; Vistakon, Jacksonville, FL). A-scan ultrasound and cycloplegic autorefraction were performed at baseline, after 1 year, and after 2 years. Multilevel modeling was used to compare the rate of change of myopia and axial length between single-vision and soft multifocal contact lens wearers.

Results. Forty participants were fitted with soft multifocal contact lenses, and 13 did not contribute complete data (5 contributed 1 year of data). The adjusted mean ± standard error spherical equivalent progression of myopia at 2 years was −1.03 ± 0.06 D for the single-vision contact lens wearers and −0.51 ± 0.06 for the soft multifocal contact lens wearers ($p < 0.0001$). The adjusted mean axial elongation was 0.41 ± 0.03 and 0.29 ± 0.03 for the single–vision and soft multifocal contact lens wearers, respectively ($p < 0.0016$).

Conclusions. Soft multifocal contact lens wear resulted in a 50% reduction in the progression of myopia and a 29% reduction in axial elongation during the 2-year treatment period compared to a historical control group. Results from this and other investigations indicate a need for a long-term randomized clinical trial to investigate the potential for soft multifocal contact lens myopia control.

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Key Words: myopia, soft bifocal, contact lens, pediatric

Several studies have investigated the role of a variety of methods for slowing the progression of myopia in children. Gas-permeable contact lenses and the undercorrection of myopia typically do not provide clinically meaningful slowing of progression of myopia over a long period.[1–4] Most studies of bifocal or multifocal spectacles do not report a clinically meaningful treatment effect,[5–8] even for children with near esophoria,[9,10] but Cheng et al.[11] did find a significant treatment effect with +1.50 D executive multifocals for children who exhibit active progression of myopia at the time of treatment. Nonselective muscarinic antagonists, such as atropine, are the most effective method of myopia control but may have some limitations. For example, the treatment effect may not continue to accrue after the first year,[12] the treatment effect after cessation of therapy may not be permanent,[13] and side effects of the treatment may result in only occasional prescribing of the treatment. However, promising results using lower concentrations of atropine have been reported.[14] A selective muscarinic antagonist, pirenzepine, does not significantly affect accommodation or pupil dilation, and it was found to slow the progression of myopia approximately 40% in two studies[15,16]; however, it is not commercially available.

Until recently, it was believed that only optics presented to the fovea controlled eye growth, but the peripheral retina has been shown to also be important for regulating eye growth in monkeys.[17–19] Both corneal reshaping[20–22] and soft distance center multifocal contact lenses[23–25] have been shown to slow the progression of myopia. They may do so by presenting two foci of light: one on the retina and one in front of the retina while looking at distance. The myopic blur focused anterior to the retina has been shown to act as a stimulus to slow eye growth in several animal studies.[26–28]

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Corneal reshaping[20–22,29,30] and soft multifocal contact lenses[24,25,31] have been found to slow the progression of myopia by 36% to 79%, and they may slow the progression of myopia by providing myopic blur or perhaps reducing accommodative effort or error.

Previous studies on multifocal contact lens myopia control published in the peer-reviewed literature have provided no more than 1 year of myopia control. Because previous studies on myopia control using other treatments have reported a significant treatment effect on myopia control that does not extend beyond the first year,[6,12] studies on the soft multifocal myopia control do not provide the needed information to answer the question of whether the treatment effect decreases or stays the same, as in other myopia control studies, or whether the treatment effect continues to accrue. This is an important piece of information to direct future research in this area. Furthermore, neither of these studies were conducted with lenses that are commercially available in the United States, thereby currently limiting the utility of the information presented.[24,25]

The purpose of this investigation was to compare the progression of myopia and axial elongation of participants fit with commercially available distance center design soft multifocal contact lenses to age- and gender-matched historical control participants who wore single-vision contact lenses for 2 years.

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. The matched study design, using a historical control group, was determined before enrollment of any participant in the soft multifocal group.

Participants

Participants were 8 to 11 years old at the baseline visit. They had between −1.00 D and −6.00 D spherical component myopia and less than 1.00 D of astigmatism by cycloplegic autorefraction. The best spectacle-corrected visual acuity was 20/20 or better in each eye, and no participants had worn contact lenses within 1 month of the baseline examination. All participants were free of systemic or ocular disease that may affect eye growth or contact lens wear, and none were participating in any vision studies. Participants in the soft multifocal group were recruited from June 2007 to May 2009, and participants in the soft single-vision group were recruited for participation in the Adolescent and Child Health Initiative to Encourage Vision Empowerment (ACHIEVE) Study from September 2003 to October 2004.

Participants were fit with Proclear Multifocal (CooperVision, Fairport, NY) contact lenses with the distance center ("D") design in both eyes. A +2.00 D add power was used for all participants. The lenses have a 2.3-mm-diameter spherical central optic zone with a concentric aspheric zone of progressive relative plus power out to a diameter of 8.5 mm. The initial distance prescription was determined by the spherical equivalent of the manifest refraction, adjusted for vertex distance. Adjustments to the distance prescription were based on spherical over-refraction. The lenses were worn on a daily wear basis with monthly replacement. The lenses were cleaned and stored in Optifree Replenish (Alcon, Ft. Worth, TX).

Historical control subjects wore 1 Day Acuvue (Vistakon, Jacksonville, FL) contact lenses, and participants were given Optifree Replenish for occasional use. Given previous reports that show that soft single-vision contact lenses do not alter the progression of myopia compared to single-vision spectacle lenses,[32,33] this is a logical choice for a comparison group. The initial distance prescription was determined by the vertex-adjusted spherical equivalent of the manifest refraction, and adjustments were based on spherical over-refraction. Both groups attended visits every 6 months. Contact lens prescriptions were updated if clinically necessary at each visit, but outcome measures, such as cycloplegic autorefraction and a-scan ultrasound, were performed annually.

Matching

After all participants fit with soft multifocal contact lenses completed the study, they were matched by gender and age category to participants with similar eligibility criteria who were involved in the ACHIEVE Study[34,35] and wore 1 Day Acuvue (Vistakon) contact lenses. There were 58 potential control subjects from which the final 32 control subjects were randomly selected. The epidemiologist was provided with only the age and gender of the soft multifocal participants; neither progression of myopia nor axial elongation was known at the time of matching. Using the demographic information, the epidemiologist compiled a list of the ACHIEVE, soft contact lens–wearing subjects from The Ohio State University ACHIEVE site. Using a random list generator, matches were created for each of the multifocal subjects based on the four groups of potential matches (female/8–9 years, female/10–11 years, male/8–9 years, and male/10–11 years).

Outcomes

Refractive error was measured in 0.12 D steps by cycloplegic autorefraction using the Grand Seiko WR-5100K (Grand Seiko Co., Ltd., Fukuyama, Japan) using the same protocol for both the experimental and control groups. Cycloplegia was achieved using one drop of 0.5% proparacaine followed by two drops of 1.0% tropicamide, separated by 5 minutes. Measurements were taken 25 minutes after the second drop of tropicamide was instilled. At least 10 spherocylindrical autorefractions were recorded while the participant fixated 6/9 (20/30) size letters on a near-point test card viewed through a +4.00 D Badal lens. The letters were presented at optical infinity, then moved to a slightly blurred position to ensure relaxation of residual accommodation.[36] The printed spherocylindrical autorefractions were hand-edited by a masked examiner to eliminate sphere or cylinder readings that were more than 1.00 D from the mode, and the remaining readings were averaged using the power vector analysis described by Thibos et al.[37]

For both the experimental and control groups using an identical protocol, the Sonomed A-5500 A-Scan (Sonomed, Inc., Lake Success, NY) was used to measure the axial dimensions of the eye with a handheld probe through a dilated pupil. Traces were examined for relatively equal lens peaks and properly marked retinal peaks. Poor traces were replaced with acceptable traces as they

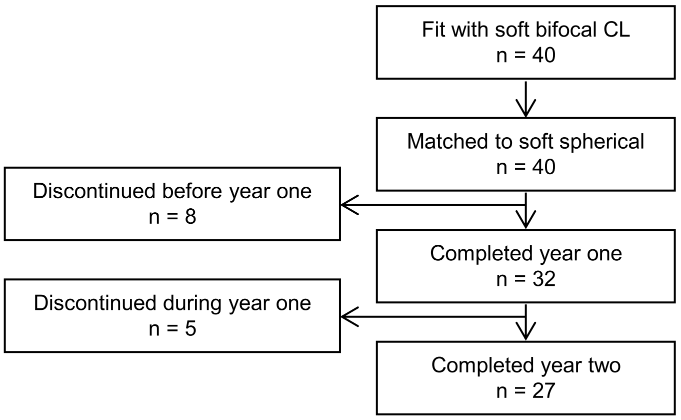

FIGURE 1.

Flow of participants in the study. Twenty-seven participants contributed 2 years of data, and five participants contributed 1 year of data. When a participant was lost to follow-up, both the participant and the age- and gender-matched control were discontinued.

appeared or after five recordings were performed. Mean axial dimensions were calculated as the mean of the five readings.[36]

Sample Size

Sample size was calculated to determine whether the soft multifocal lens wearers progressed slower than the soft single vision contact lens wearers. The standard deviation (SD) of the 2-year change in refractive error was assumed to be 0.75. To have 80% power ($\alpha = 0.05$) to detect a difference of 0.50 D over 2 years (slowing progression by 50%), a sample size of 18 per group was required.

Statistics

All analyses were completed using SAS 9.3. Comparisons at baseline between participants were completed using *t*-tests for the continuous outcomes and χ^2 or Fisher exact test, as necessary, for the categorical data. To use all of the repeated measures collected, we conducted a mixed-model analysis for each outcome variable using the PROC MIXED procedure. This analysis allows us to account for the fact that participants had repeated measures both over time and over eyes, taking into account the correlation between measurements taken in two eyes of the same person. In addition, this model allows us to include the matched nature of the data by accounting for the pairing of soft multifocal and single-vision contact lens wearers. A benefit of the mixed-model analysis is that it allows for the inclusion of incomplete data; that is, a subject may miss visits or miss measurements and can still be used in the analysis.

The process of model term selection was the same for each outcome. Each model included treatment group, visit, and the interaction of treatment group and visit. Important variables that differ between the two groups at baseline may have an impact on the final results and should be controlled for in any analysis. On the basis of the comparisons of the variables between the soft multifocal contact lens group and the soft single-vision contact lens group at baseline, those variables that were statistically significantly different at baseline were controlled for in any multivariate analysis. In addition, baseline refractive error was controlled for since the amount of refractive error at baseline could be related to the amount of progression of myopia experienced by the participants. The eye on which the measurement was taken was also included. The means presented as a result of the analysis are least square means with their associated standard errors (SEs). Because the question of interest was not only the treatment effect of the soft multifocal contact lenses but also the potential accrual of treatment effect, the treatment group-by-visit interaction was of particular importance. Statistically significant differences in this interaction were assessed using the p value from the Tukey post hoc test. $p < 0.05$ was considered statistically significant. Correlation analyses were completed for baseline refractive error and change in axial length-by-treatment group using the PROC CORR procedure in SAS.

RESULTS

Forty participants were enrolled, and all were successfully fit with soft multifocal contact lenses during the baseline visit. Eight participants were lost to follow-up before the 1-year visit, so they were not matched to control participants, and their data were not included in the analyses of progression of myopia. An additional five participants were lost to follow-up between the 1-year and 2-year visits, but they were matched to control participants and data from the first year were used in the analyses (Fig. 1). The average ± SD logMAR visual acuities for 10 of the 13 subjects who withdrew and had their visual acuity measured while wearing the contact lenses at their last visit (logMAR visual acuity was not measured at the baseline visit while wearing the contact lenses) was −0.02 ± 0.07 (20/19) at distance and −0.05 ± 0.10 (20/18) at near, indicating that poor vision was unlikely to be the reason for withdrawal. The participants who withdrew did not differ from the soft multifocal participants that completed a 2-year visit based on demographic variables or ocular axial dimensions (*t*-test, $p > 0.05$) (Table 1). Table 2 presents the means from the treatment and control groups at baseline and shows statistical significance

TABLE 1.

Comparison of the mean ± standard deviation or percent baseline demographic and ocular characteristics of the subjects who withdrew before the 2-year visit and the subjects who completed the 2-year visit in soft multifocal contact lenses

	Subjects with incomplete data (n = 13)	Multifocal (n = 27)	p
Age (y)	11.0 ± 0.7	10.8 ± 0.8	0.41
Gender (% male)	23.1	48.2	0.13
Race (% white)	84.6	88.9	0.35
M (D)	−2.41 ± 1.11	−2.32 ± 1.01	0.62
J_0 (D)	−0.09 ± 0.13	−0.09 ± 0.24	0.98
J_{45} (D)	0.009 ± 0.23	0.11 ± 0.23	0.22
Anterior chamber depth (mm)	3.79 ± 0.22	3.84 ± 0.29	0.56
Lens thickness (mm)	3.42 ± 0.14	3.46 ± 0.18	0.48
Vitreous chamber depth (mm)	16.84 ± 1.05	17.02 ± 1.02	0.62
Axial length (mm)	24.05 ± 1.00	24.30 ± 0.95	0.45

Results shown are for the right eye.

TABLE 2.

Comparison of the mean ± standard deviation or percent baseline demographic and ocular characteristics of the soft single-vision and soft multifocal contact lens wearers

	Soft single-vision lenses (n = 32)	Soft multifocal lenses (n = 32)	Differences
Age (y)	10.8 ± 1.0	10.8 ± 0.7	0.89
Gender (% female)	56.3	56.3	—
Race (% white)	78.3	87.5	0.16
M (D)	−2.24 ± 1.02	−2.35 ± 1.05	0.67
J_0 (D)	−0.06 ± 0.16	−0.10 ± 0.18	0.54
J_{45} (D)	+0.06 ± 0.13	+0.10 ± 0.21	0.46
Anterior chamber depth (mm)	4.00 ± 0.24	3.82 ± 0.29	0.01
Lens thickness (mm)	3.37 ± 0.17	3.46 ± 0.17	0.03
Vitreous chamber depth (mm)	16.98 ± 0.86	17.00 ± 0.99	0.94
Axial length (mm)	24.34 ± 0.89	24.27 ± 0.96	0.75

Results shown are for the right eye.

(*t*-test). The anterior chamber depth of the soft multifocal contact lens wearers was shallower at baseline than the soft single-vision contact lens wearers and they had thicker lenses as well. As a result, these variables were controlled for in the multivariate models.

The unadjusted axial elongation of the soft multifocal and soft single-vision contact lens wearers is shown in Fig. 2. The adjusted means ± SEs for spherical equivalent refractive errors and axial dimensions for multifocal and single-vision contact lens wearers at each visit are shown in Table 3, along with the 2-year changes and the associated p values from the mixed-model post hoc tests. Changes from baseline to 2 years in the spherical equivalent refractive error, the vitreous chamber depth, and the axial length were greater for soft single-vision contact lens wearers than for soft multifocal contact lens wearers. Anterior chamber depth did not change in the soft contact lens wearers but deepened slightly more for the soft multifocal contact lens wearers ($p = 0.02$).

All outcomes but lens thickness demonstrated a statistically significant treatment-by-visit interaction, indicating that the pattern of growth between different visits was dependent on the assigned treatment group. The average axial elongation was 0.06 mm/y faster for soft single-vision contact lens wearers than it was for soft multifocal contact lens wearers (visit-by-treatment interaction, $p = 0.0048$). Post hoc analysis showed that the rate of axial elongation was greater for soft single-vision contact lens wearers after 2 years, but the yearly comparisons between the two groups were not statistically significantly different. The rate of vitreous chamber depth increase was an average of 0.08 mm/y faster for soft single-vision contact lens wearers than it was for soft multifocal contact lens wearers (visit-by-treatment interaction, $p < 0.0001$), and it was faster during both the first year and the second year. The overall average rate of spherical equivalent refractive error progression was 0.26 D/y faster for soft single-vision contact lens wearers than soft multifocal contact lens wearers (visit-by-treatment interaction, $p < 0.0001$), and it was greater during both the first and second years of the study. No changes in lens thickness were exhibited by either group (no visit effect, treatment effect, or visit-by-treatment interaction) (Table 4). Anterior chamber depth showed a statistically significant growth in the soft multifocal contact lens wearers, with a difference of 0.05 mm over 2 years (visit-by-treatment interaction, $p = 0.0299$). The difference occurred between years 1 and 2 when the anterior chamber depth of the soft single-vision lens wearers did not grow while the anterior chamber depth of the soft multifocal contact lens wearers did.

There was a significant correlation between the baseline refractive error and axial elongation for the soft multifocal contact

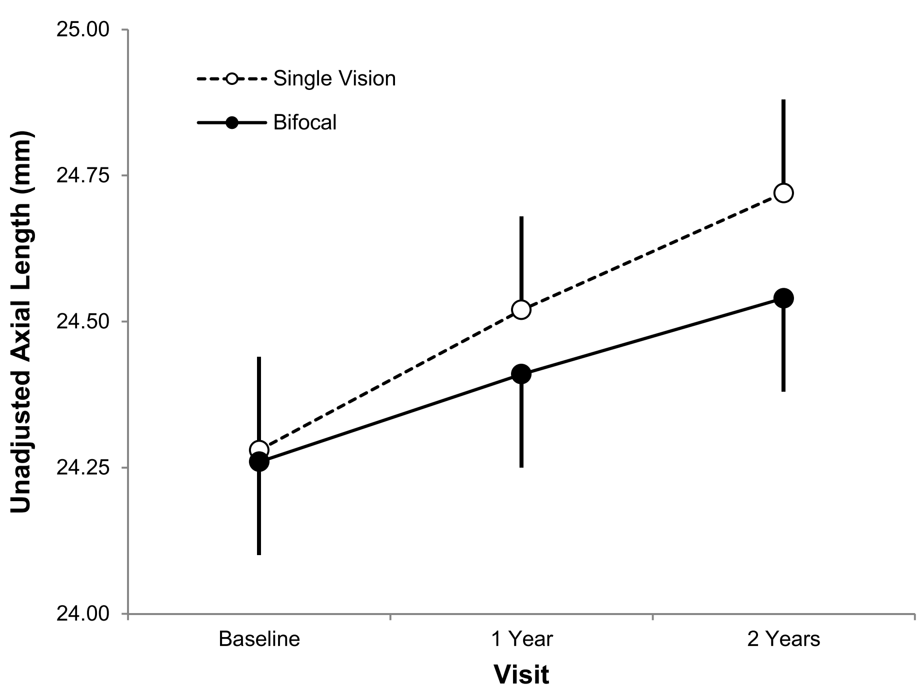

FIGURE 2.
Mean ± standard deviation unadjusted axial length of multifocal and single-vision contact lens wearers.

TABLE 3.
Adjusted mean ± standard error ocular parameters for each treatment group at each annual visit

	M (D)	Anterior chamber depth (mm)	Lens thickness (mm)	Vitreous chamber depth (mm)	Axial length (mm)
Multifocal					
Baseline (n = 32)	−2.24 ± 0.06	3.90 ± 0.01	3.42 ± 0.01	16.99 ± 0.14	24.29 ± 0.13
Year 1 (n = 32)	−2.57 ± 0.06	3.93 ± 0.01	3.40 ± 0.01	17.12 ± 0.14	24.44 ± 0.13
Year 2 (n = 27)	−2.75 ± 0.06	3.93 ± 0.01	3.41 ± 0.01	17.24 ± 0.14	24.58 ± 0.13
2-year change	−0.51 ± 0.06	0.04 ± 0.02	−0.007 ± 0.01	0.25 ± 0.03	0.29 ± 0.03
Single vision					
Baseline (n = 32)	−2.26 ± 0.06	3.94 ± 0.01	3.39 ± 0.01	16.94 ± 0.14	24.28 ± 0.13
Year 1 (n = 32)	−2.86 ± 0.06	3.93 ± 0.01	3.39 ± 0.01	17.17 ± 0.14	24.50 ± 0.13
Year 2 (n = 27)	−3.28 ± 0.06	3.92 ± 0.01	3.39 ±0.01	17.36 ± 0.14	24.69 ± 0.13
2-year change	−1.03 ± 0.06	−0.01 ± 0.02	0.008 ± 0.01	0.41 ± 0.03	0.41 ± 0.03
p for the 2-year change between groups	<0.0001	0.0204	0.4202	<0.0001	0.0012

Change represents the adjusted change from baseline to year 2. p values for differences in the 2-year change between the two groups are from a model accounting for both eyes, the paired study design, the baseline refractive error, the anterior chamber depth, and the lens thickness.

lens wearers ($r = -0.39$, $p = 0.04$), but not soft single-vision contact lens wearers who wore lenses for 2 years ($r = -0.02$, $p = 0.94$) (Fig. 3).

DISCUSSION

Soft multifocal contact lenses with a distance center design slowed the growth of the eye by approximately 29%, and they slowed the progression of refractive error by approximately 50%. It is unknown why progression of myopia was slowed nearly twice as much as axial elongation. Perhaps the less precise measurement of axial elongation with a-scan ultrasound, as compared to partial coherence interferometry, was less capable of determining the true axial elongation exhibited by participants, perhaps soft multifocal lenses result in changes to eye shape that affect ciliary tonus and therefore refractive error more than axial length, or perhaps it is due to measurement error.

These findings support the effect of a distance center (with concentric rings of relative plus power) design of soft multifocal contact lens on myopia control reported over a shorter period by Anstice and Phillips,[24] an introductory case report by Aller and Wildsoet[23] (with concentric rings of relative plus power), and a 1-year trial reported by Sankaridurg et al. (with a progressive increase in relative plus power).[25] The results of these four reports indicate a strong need for a long-term randomized clinical trial to determine the effect of soft multifocal contact lenses on myopia control and to determine the mechanism of treatment effect. Sankaridurg et al.[25] examined the potential role of peripheral refraction while wearing the contact lenses and found a significant correlation between relative peripheral refractive error and progression of myopia when measured through the multifocal lenses at 30° and 40° in the nasal retina and 40° in the temporal retina. However, they did not rule out the potential myopia control effect of reduced accommodative effort or error (lag of accommodation). Anstice and Phillips[24] found significantly slower progression of myopia for the soft multifocal contact lens–wearing eye, even after switching the multifocal contact lens to the contralateral eye. The slower progression of myopia solely in the soft multifocal contact lens–wearing eye indicates the effect may be due to the peripheral refractive error, but that was not directly measured. They also reported that the children accommodated for near, even when they were wearing the multifocal lens. However, the study did not measure peripheral refractive error, so the relative influence of peripheral refractive error and altered accommodation cannot be examined. None of the current studies have measured both peripheral refraction and accommodation while wearing the soft multifocal contact lenses, so more information is needed to determine how soft multifocal contact lenses may slow eye growth. Furthermore, differences in myopia control may be observed for the different soft multifocal contact lens designs (concentric rings of relative plus power versus progressive increase in relative plus power).

Although the add power of all three studies was +2.00 D, the results varied. To readily compare studies, the results are often

TABLE 4.
The difference in rate of progression between soft multifocal and soft single-vision contact lens wearers (positive difference indicates control subjects progress faster) during each year of the study from a model accounting for both eyes, the paired study design, and the baseline refractive error, anterior chamber depth, and lens thickness

	M (D)	Anterior chamber depth (mm)	Lens thickness (mm)	Vitreous chamber depth (mm)	Axial length (mm)
Year 1 (n = 32)	+0.28 ± 0.06	+0.05 ± 0.02	−0.02 ± 0.02	+0.09 ± 0.03	+0.07 ± 0.03
p	<0.0001	0.03	0.17	0.0032	0.06
Year 2 (n = 27)	+0.24 ± 0.09	−0.004 ± 0.02	−0.01 ± 0.02	+0.07 ± 0.03	+0.06 ± 0.04
p	0.0002	0.84	0.62	0.04	0.13

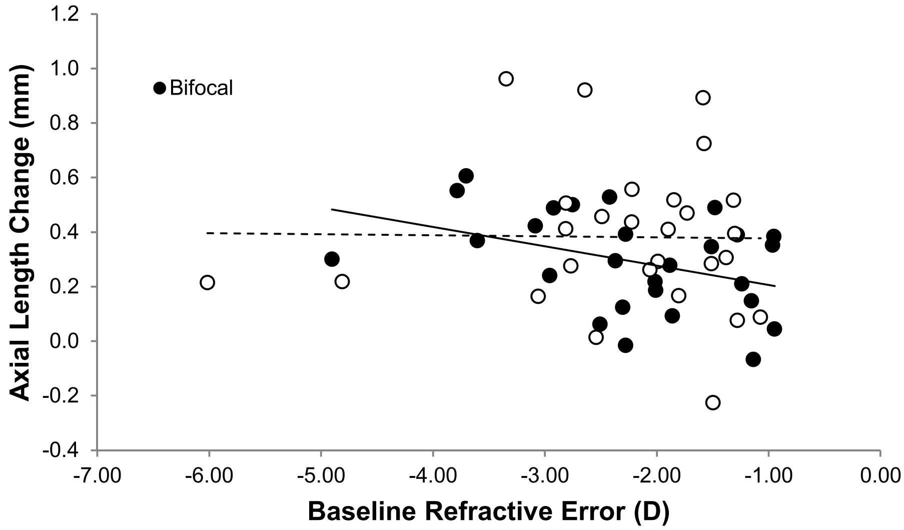

FIGURE 3.
Relation between the baseline refractive error and axial elongation for soft multifocal and soft single-vision contact lens wearers.

described in terms of percentage change in progression by dividing the difference in progression of the experimental and control groups by the progression of the control group. In terms of progression of myopia, this study found a 51% treatment effect over 2 years, compared to 36% (−0.69 D versus −0.44 D over 10 months) and 34% (−0.86 D versus −0.57 D over 1 year) for Anstice and Phillips[24] and Sankaridurg et al.,[25] respectively. We found 29.3% slower axial elongation over 2 years, compared to 50% slower axial elongation (0.22 versus 0.11 mm over 10 months) reported by Anstice and Phillips[24] and 33% slower axial elongation (0.40 versus 0.27 mm over 1 year) reported by Sankaridurg et al. The multifocal contact lenses varied by design (progressive increase in add power for the study of Sankaridurg et al. and this study, compared to concentric rings of relative plus power for the study of Anstice and Phillips), as well as the size of the central distance zone. The contact lenses used in this study had a 2.3-mm diameter central zone, compared to a 3.0-mm-diameter reported by Sankaridurg et al. and a 3.36-mm-diameter reported by Anstice and Phillips. Each of these factors could potentially play a role in slowing the progression of myopia, so an investigation to optimize myopia control with a soft multifocal contact lens should be conducted.

Several myopia control methods, including multifocal spectacles[6] and atropine,[12] have reported that the myopia control effect is demonstrated only during the first year of treatment. After the first year, the experimental and control participants progress at similar rates. That was not the case for soft multifocal contact lens myopia control. The refractive error and vitreous chamber depth increased more slowly for the soft multifocal contact lens wearers than for the control participants during both the first and second years of the investigation. Axial growth was significantly greater for the control participants than for the soft multifocal participants over the 2-year period, but there was no significant difference between the two groups for either of the 1-year periods.

Fig. 3 indicates that soft multifocal contact lenses with distance center design may provide slightly better myopia control for low myopes than high myopes. None of the previous soft multifocal contact lens studies examined the effect of baseline myopia on the treatment effect, so more work must be conducted to determine whether this relationship truly exists.

Limitations

Thirteen (32.5%) participants did not provide two complete years worth of data to the study, but the reasons for withdrawals and data on contact lens wear compliance were not collected. Anecdotally, subjects did not complain of poor vision while wearing the soft multifocal contact lenses, and this is confirmed by the fact that subjects who withdrew from the study exhibited better than 20/20 vision at distance and near during their last visit. Although those 13 were similar to the soft multifocal contact lens wearers who remained, there is a greater potential for bias when participants do not complete the study. The treatment groups were matched on age and gender to a historical control group, and statistical adjustment controlled for differences in anterior chamber depth and lens thickness as well as potential differences in spherical equivalent refractive error. However, the treatments were not randomly allocated, which increases the chance of bias due to unmeasured variables.

Data were collected on the historical controls 5 years before the enrollment of the soft multifocal contact lens wearers, and the 2-year data on the progression of myopia were available at the time of matching but were not evaluated before the matching process. The progression of myopia of the soft single-vision contact lens wearers does not explain the observed treatment effect because they progressed precisely at the rate expected for young myopes, −0.50 D per year in the United States.[6,10] Furthermore, the mechanism of the treatment effect was not examined, so changes in accommodative effort or error (lag of accommodation) cannot be ruled out as potential causes of slowed progression of myopia.

In a small study such as this one, the presence of subjects with results farther from the mean has the potential to influence the results disproportionately. While within the range of axial length change reported within other studies, we investigated the impact of two potential outliers on the results identified by using an interquartile range. To accomplish this, the 25th and 75th percentiles for the distribution of axial elongation were determined. The difference between the two percentiles represents the interquartile range. To determine the limits for potential outliers, 1.5× the interquartile range is subtracted from the 25th percentile to find the lower bound. This quantity is added to the 75th percentile to find the upper bound. One observation was outside the upper bound. The other fell on the upper bound. The elimination of either outlier with its accompanying matched pair did not change the results as reported. Elimination of both outliers changed the statistical significance for the visit-by-treatment interaction for axial length (now $p = 0.086$) and anterior chamber depth (now $p = 0.056$). The difference in axial elongation between the two groups over the 2 years was still statistically significant, but the difference between the two groups from baseline and 1 year decreased from 0.065 mm to 0.051 mm with the elimination of the two subjects. Given that statistical interaction tests possess lower statistical power, it is not surprising the deletion of data from four subjects (two pairs) could result in a change in statistical significance.

CONCLUSIONS

Soft multifocal contact lenses with a distance center design may slow the average growth of the myopic eye, and this study suggests that the treatment effect for axial elongation continues to accrue beyond the first year of treatment. The average myopia control effect is similar in magnitude to corneal reshaping contact lens wear and greater than several other types of myopia control. Although this was not a randomized clinical trial, it agrees with the results of Anstice and Phillips[24] as well as those of Sankaridurg et al.[25] Eye care practitioners may tell parents that soft multifocal contact lenses provide clear vision, and they may also provide myopia control, although not for everyone.

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