Myopia Control with Bifocal Contact Lenses: A Randomized Clinical Trial

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ABSTRACT

Purpose. Most studies have reported only minimal reductions in myopia progression with bifocal or progressive multifocal spectacles, although somewhat larger, although mostly still clinically insignificant, effects have been reported in children with nearpoint esophoria and/or accommodative dysfunctions. The CONTROL study was a 1-year, prospective, randomized, clinical trial of bifocal contact lenses for control of myopia in children with eso fixation disparities at near.

Methods. Eighty-six myopic subjects, aged 8 to 18 years, were enrolled in the study after passing the screening examination. Of these, 79 completed lens assignment and 78 completed the study. The mean refractive error of these 79 subjects was $-2.69 \pm 1.40$D (SD), and all had progressed by $-0.50$D or more since their last examination. All subjects also had eso fixation disparity at near. Subjects were randomly assigned to wear either Vistakon Acuvue 2 (single-vision soft contact lenses [SVSCLs]) or Vistakon Acuvue Bifocal (bifocal soft contact lenses [BFSCLs]). Bifocal adds were selected to neutralize the associated phoria. Treatment outcomes included cycloplegic autorefraction and axial length, assessed in terms of changes after 6 and 12 months of treatment from pretreatment baseline values.

Results. The BFSCLs significantly slowed myopia progression, with statistically significant differences between the treatment groups after 6 months. After 12 months of treatment, the SVSCL group had progressed by $-0.79 \pm 0.43$D compared with $-0.22 \pm 0.34$D for the BFSCL group (cycloplegic objective spherical equivalent, average of two eyes). Corresponding axial length changes were 0.24 $\pm$ 0.17 mm and 0.05 $\pm$ 0.14 mm, respectively. All of these differences were found to be statistically significant (unpaired t-tests, $p < 0.001$).

Conclusions. The distance center bifocal contact lenses tested in this study achieved greater control over myopia progression and axial elongation (>70%) compared with most published results with multifocal spectacles. Further studies are warranted to identify the critical factors and mechanisms underlying this myopia control effect.

Key Words: myopia control, myopia, bifocal contact lenses, esophoria, associated phoria, fixation disparity

Myopia is the focus of growing attention and concern because of the now extremely high prevalence of myopia in some East Asian populations. Remarkably, myopia prevalence figures in the mid to high 90 percent have been reported in some studies of university student populations in Taiwan and Shanghai, with a figure of 96.5% being reported for young adult Korean male conscripts in Seoul. Equivalent prevalence figures for the United States have also been trending upward, albeit lagging behind those of East Asia. For example, comparison of data from two studies of the same population across the periods 1971 to 1972 and 1999 to 2004 revealed an increase in the prevalence of myopia from 25% to 41.6% for the 12- to 54-year age range (after adjustment for differences in the methods used to detect myopia). These figures would not be of concern were it not for the well-established link between myopia and sight-threatening ocular pathologies. Importantly, and as well summarized in a recent review by Flitcroft, even low myopia is associated with an increased risk of pathology, with the latter, measured in terms of odds ratios, simply increasing with increasing myopia. Myopes are at an increased risk of myopic maculopathy, retinal detachment, cataracts, and glaucoma, with myopic maculopathy now the leading cause of monocular blindness in Japan and of new cases of blindness in Shanghai.

The rapidly changing myopia prevalence figures are consistent with the increasing acceptance of the role that environmental influences play in the development of myopia. Some but not all...
studies have linked myopia with increased near work, for example, books read, and one recent German study showed a correlation between years of formal education with level of myopia. There are other studies pointing to outdoor activities being protective against the development of myopia. Although unresolved are the specific factors contributing to myopia development and progression, that visual experience seems to play a central role has refocused attention on the possibility that myopia progression can and should be controlled.

Studies involving animal models for myopia (chicks, guinea pigs, marmosets, rhesus monkeys) provide compelling evidence for active emmetropization and a role for optical defocus in ocular growth modulation. Specifically, hyperopic defocus imposed on young eyes accelerates eye growth while imposed myopia slows it. Local retinal mechanisms have been implicated, with the peripheral retina apparently playing an important role in ocular growth regulation. Of relevance to the current study, in recent animal model studies, multifocal lenses incorporating zones of positive power were found to inhibit eye growth, even when these zones are limited to the periphery of the lenses. For already myopic eyes, both stabilization of myopia and reversal have been described.

The above observations with animal models, translated to human myopia, raise the possibility of increased progression with standard corrective spectacle and soft contact lenses, given that the image shell providing accurate on-axis focus typically falls increasingly behind the retina with increasing distance off-axis. Furthermore, more prolate eye shapes, a common finding in myopia, are expected to exaggerate this problem. Conversely, prescribing optical devices that impose peripheral myopic defocus is predicted to slow myopia progression, consistent with results from a number of independent myopia control studies involving orthokeratology, which produces a relative myopic shift in peripheral retinal defocus, a consequence of induced corneal shape changes.

The Control Of Nearsightedness Trial Of Lenses (CONTROL) study reported here investigated myopia progression with distance center multi-ring bifocal soft contact lenses (BFSCSLs) compared with single-vision soft contact lenses (SVSCLs) in children. It was prospective and double masked. Motivation for the study came partly from promising retrospective data collected from the practice of one of the authors (TA), in which BFSCSLs had been prescribed as a substitute for bifocal spectacles to address the compliance issues (Aller et al., OVS 2000;77(12s):182). Emerging results from animal studies showing that imposed myopic defocus is a potent inhibitor of eye growth, as discussed above, provided additional motivation. The study was limited to myopes with associated esophoria at near based on reports from earlier intervention studies that bifocal spectacles were more effective in slowing myopia progression in those with near esophoria and results from subgroup analysis in the original COMET study that revealed subjects with near esophoria to be among those to show least myopia progression.

We report here highly clinically and statistically significant slowing of myopia progression with BFSCSLs, exceeding results from all published optical intervention trials for control of myopia progression to date and directly reflecting a slowing of axial elongation relative to changes with SVSCLs. The study design and results are described in the following sections, and implications are discussed in the context of potential underlying mechanisms and the broader topic of control of myopia progression. Study results have also been reported in abstract form previously.

METHODS

Study Design

This study involved a randomized double-masked design, with two treatment groups of young progressing myopes wearing either distance center (alternating 5-ring) BFSCSLs (Vistakon Acuvue Bifocal) or SVSCLs (Vistakon Acuvue 2). Both were made from 58% etafilcon A visibility tinted material. In both cases, lenses were worn on a daily wear basis for 12 months, with a 2-week replacement schedule and Optifree solutions (provided by Alcon) used for cleaning, rinsing, and disinfection.

The lenses were delivered to the subjects in their original containers with tamper-proof opaque masking labels. Because of the relatively small group (sample) sizes involved, a modified covariate adaptive randomization approach was used to allocate treatments. Specifically, subjects were randomly assigned a treatment by the masked off-site clinical trial coordinator who used an adaptive biased coin toss design to increase the probability that successive subjects were assigned to the group with the smaller sample size with respect to age, refractive error, amount of eso-associated near phoria, sex, and Asian versus non-Asian ethnicity. The study examiner, office staff, subjects, and parents were not aware of the lens assignments before the end of the study.

Subjects were required to attend a maximum of six office visits, which included an initial measurement session to collect baseline ocular biometric and refraction data, and follow-up measurement sessions at 6 and 12 months, at which biometric and refraction data were again collected. Other sessions included a contact lens fitting session, a contact lens dispensing/training session, and a routine contact lens follow-up session to verify that the lenses fit satisfactorily and were without adverse effects on ocular health.

The study was conducted in the clinical practice of TA after the protocol was reviewed and approved by Quorum Review IRB. The study followed the tenets of the Declaration of Helsinki and is listed on clinicaltrials.gov (NCT00214487). Informed assent was obtained from all subjects, and informed consent was obtained from all parents or guardians. All subjects also underwent an on-site vision screening before acceptance into the study. Selection and exclusion criteria covered the refractive error and binocular vision profiles of the subjects, freedom from confounding ocular or systemic diseases, as well as ability to wear soft contact lenses. In brief, based on manifest subjective refractions, eligible subjects were limited to those in whom each eye exhibited −0.50D or more myopia in the least myopic meridian, −6.00D or less myopia in the most myopic meridian, anisometropia of 2.00D or less, refractive astigmatism of 1.00D or less, and best-corrected visual acuity of 20/20 or better in each eye. All refractive error data here and elsewhere are referenced to the corneal plane. In addition, subjects were required to have...
progressed by −0.50D or more in one or both eyes since their last examination based on clinical records, results of spectacle neutralization, or written prescriptions. This selection criterion was included to limit the study to those experiencing myopia progression, and thus the timing of the last eye examination of individual subjects was not itself limited. Only those with near eso-associated phoria through their distance correction, measured as the amount of plus power required to neutralize their fixation disparity at their habitual viewing distance and angle for reading, were included.

Existing soft contact lens wearers, as well as non–contact lens wearers, were accepted into the study, with current wearers being required to discontinue wear for 1 week before initial evaluation. Progressed by the amount of plus power required to neutralize their fixation disparity at their habitual viewing distance and angle for reading, were included. Only objective refraction data were obtained using a Nidek (Marco) ARK 700 auto-refractor, with nine valid readings averaged for each eye. Monocular subjective refractions were followed by binocular Polaroid balance using the endpoint of least minus power for best-corrected visual acuity. Both procedures were repeated after cycloplegia was achieved. Only objective refractive error data obtained under cycloplegia are reported here. The distance powers of selected SVSCL and BFSCL represented in each case the minimum minus power providing monocular visual acuity of 20/30 or better. Axial lengths and anterior chamber depths were measured after cycloplegia using a Zeiss IOLMaster, with reported data for each eye based on an average of 10 and 3 valid measurements for axial length and anterior chamber depths, respectively. Corneal curvatures were measured with a Marco keratometer. Near heterophoria were measured at 33 cm through the subject’s manifest subjective sphero-cylindrical distance correction in a trial frame set to their distance pupillary distance using the alternating cover test method. The minimum amount of binocular plus power, added in +0.25D steps, required to eliminate eso-fixation disparities, that is, near associated phoria, was similarly measured while viewing through Polaroid filters, a Bernell Near Point Examination card in a lighted box at 33 cm at their habitual reading angle. Near associated esophorias were also measured in trial contact lens fitting sessions through both SVSCLs and BFSCLs. In determining the BFSCL prescription, a bifocal add power one step higher than the previously measured near associated phoria was used as a starting point and the add power subsequently adjusted to determine the minimum power necessary to completely eliminate or maximally reduce the near associated esophoria while maintaining acceptable distance visual acuity. Both SVSCL and BFSCL prescriptions were submitted to the off-site clinical trial coordinator responsible for allocating treatments.

Statistical Analysis

Although many ocular parameters were monitored during the treatment period, reported data analyses are limited to those parameters most likely to offer insight into myopia progression. Two primary outcome measures were used: (1) changes from baseline in spherical equivalent refractive errors based on cycloplegic autorefraction measurements and (2) changes in axial length—both parameters being objective and thus free of subjective biases. Anterior chamber depth, corneal curvature, and near associated phoria data were also included in some analyses. Initial comparison of primary outcome data for right and left eyes revealed no significant differences between them, and so the data for the two eyes of individual subjects were averaged for use in subsequent analyses. Follow-up analyses used to evaluate treatment effects included unpaired t-tests with Bonferroni correction to examine differences between the two treatment groups (SVSCLs vs. BFSCLs) in outcome measures at both 6 and 12 months. To understand the origin of refractive error changes, correlations between changes in refractive errors and biometric parameters were analyzed using Pearson correlations. Finally, multivariate analyses of variance were used to examine the influence on treatment outcomes of various factors, including age, sex, baseline refractive error, near associated phorias, and BFSCL add power.

RESULTS

Subject Profiles

Eighty-six myopic subjects were recruited, comprising an ethnically diverse group, with 27 white, 24 Asian (Chinese, Japanese, Korean, and Indian), 23 Hispanic, 9 Filipino or Pacific Islander children, and 3 children of African descent. In total, approximately 300 subjects were screened by telephone to determine their potential eligibility, with 125 subjects undergoing in-office screening. Thirty-nine screened subjects (18 male, 21 female) either failed the screening (N = 33) or qualified but declined to participate for various reasons (N = 6). Seventy-eight subjects of the 86 recruited completed all aspects of the study. There were no significant differences in any of the measured baseline measures between these two groups. Five subjects were dispensed lenses, with two completing only the dispensing visit and three completing only the 2-week follow-up visit. The other three subjects wore contact lenses for 6 months or more, one of whom wore lenses for 6 months but declined to undergo cycloplegia as part of
TABLE 1.
Baseline profiles for BFSCL and SVSCL groups (mean ± SD)

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Age, yr</th>
<th>Refractive error, D</th>
<th>Axial length, mm</th>
<th>Associated phoria, D</th>
</tr>
</thead>
<tbody>
<tr>
<td>BFSCL (N = 39)</td>
<td>13.0 ± 2.5</td>
<td>-2.57 ± 1.34</td>
<td>24.68 ± 0.91</td>
<td>1.2 ± 0.6</td>
</tr>
<tr>
<td>SVSCL (N = 40)</td>
<td>13.5 ± 2.2</td>
<td>-2.81 ± 1.46</td>
<td>24.63 ± 0.68</td>
<td>1.2 ± 0.7</td>
</tr>
</tbody>
</table>

the 6-month follow-up visit and was thus dropped from the study; of the remaining two subjects, one completed the 6-month visit but not the 12-month visit and the other completed the 12-month visit only. The data for both of the latter two subjects were included in the analyses. The subject pool had a distinct female sex bias (60 of 86 subjects, 70%), which was preserved within each group; there were 27 females and 11 males in the BFSCL group and 27 females and 13 males in the SVSCL group. The subjects ranged in age from 8 to 18 years, their median age being 13.6 years, with 38 subjects (44%) being 13 years or younger.

Baseline Parameters

Summary statistics for both SVSCL and BFSCL groups are given in Table 1. The groups were not significantly different from each other (p > 0.05, unpaired t-tests in all cases). All subjects fell into the category of low to moderate myopia, based on cycloplegic autorefractions, which ranged from −0.25 to −6.00D in the least myopic meridian, with mean equivalent spherical refractive errors ranging from −0.75 to −5.82D and astigmatism ranging from 0 to −1.00D. Axial lengths ranged from 22.58 to 26.41 mm, with anterior chamber depths ranging from 2.21 to 4.33 mm. Corneal curvatures, averaged across the two principal meridians, ranged from 41.06 to 47.03D. All subjects exhibited near associated esophorias, the plus power required to neutralize the latter ranging from 41.06 to 47.03D. All subjects exhibited near associated esophorias, the plus power required to neutralize the latter ranging from 41.06 to 47.03D. All subjects exhibited near associated esophorias, the plus power required to neutralize the latter ranging from 41.06 to 47.03D.

Changes in refractive error and axial length during the study period are summarized for both treatment groups in Table 2 and shown graphically in Fig. 1. There were significant changes in both refractive error and axial lengths from baseline in each group and at both 6 and 12 months (p < 0.001 in all cases). However, for both parameters, changes were significantly less for the BFSCL group than for the SVSCL group at both 6 and 12 months (p < 0.001), the finding at 6 months implying a rapid onset of the myopia control effect of the BFSCLs. Note also that at the 6-month time point, hyperopic shifts in refractive error were recorded for five subjects in the BFSCL group compared with one subject in the SVSCL group (Fig. 1, left panel, data above zero). A slightly larger number of subjects in the BFSCL group also recorded reductions in axial length (Fig. 1, right panel). To better illustrate the contrasting effects of the two treatments, refractive error data were categorized according to whether or not there was progression during the treatment period. Using this binary outcome measure, the number of subjects showing either no progression of myopia or a hyperopic shift in refractive error represents 26% and 29% of the BFSCL treatment group at 6 and 12 months, respectively, compared with 5% (two subjects) for the SVSCL treatment group at both time points. Also note that only one subject in the BFSCL group progressed by 1D or more during the 12-month study period compared with 11 subjects in the SVSCL group. These figures further reinforce the significant differences between the two groups in terms of myopia progression.

During the total 12-month study period, changes in refractive error were well predicted by changes in axial length (R² = 0.64, p < 0.001) but not by changes in anterior chamber depth (R² = 0.012; p = 0.79). Indeed, both the BFSCL and SVSCL groups recorded significant reductions rather than increases in anterior chamber depth (p < 0.01), presumably reflecting the growth of the crystalline lens in these young eyes, as the magnitude of the change was not significantly different between the groups (p = 0.94). There was no significant change of corneal curvature for either group during the 12-month treatment period (p = 0.40).

A series of multivariate analyses of variance were also conducted to identify potentially significant associations. Only the most

TABLE 2.
Baseline data and changes in ocular parameters (mean ± SD) for BFSCL and SVSCL groups after 6 and 12 months of lens wear

<table>
<thead>
<tr>
<th>Ocular parameter</th>
<th>BFSCL</th>
<th>SVSCL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Time, months</td>
</tr>
<tr>
<td>Cycloplegic spherical equivalent</td>
<td>2.57 ± 1.34</td>
<td>6</td>
</tr>
<tr>
<td>refractive error, D</td>
<td>12</td>
<td>-0.22 ± 0.34*</td>
</tr>
<tr>
<td>Axial length, mm</td>
<td>24.68 ± 0.91</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>0.05 ± 0.14*</td>
</tr>
<tr>
<td>Anterior chamber depth, mm</td>
<td>3.56 ± 0.47</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>-0.36 ± 0.53</td>
</tr>
<tr>
<td>Corneal curvature, D</td>
<td>43.66 ± 1.45</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>-0.06 ± 0.24</td>
</tr>
</tbody>
</table>

*Significant differences between treatment groups (unpaired t-test, p < 0.001).
efficient model, that is, with the least number of variables without affecting the goodness of fit of the model, is reported, with changes in axial length and in refractive error as dependent continuous variables and six independent variables, treatment, sex, age, baseline refractive error, baseline near associated phoria, and BFSCL add power. Of these six variables, only age, considered as a continuous variable, and contact lens treatment proved to be significantly associated with changes in refractive error and axial length (Wilks $\lambda = 0.579$, $F_{2,74} = 26.86$, $p \leq 0.0001$ for age; and Wilks $\lambda = 0.533$, $F_{2,74} = 32.41$, $p \leq 0.0001$ for contact lens treatment, respectively).

Our study specifically targeted subjects with near associated esophorias based on early reports linking near dissociated esophoria with better myopia control with multifocal spectacle lenses. As expected, the BFSCL group showed a significant reduction in residual associated esophorias (associated phoria measured with contact lenses in place) relative to that of the SVSCL group ($1.10 \pm 0.52$D vs. $0.16 \pm 0.43$D, $p \leq 0.0001$). Nonetheless, neither baseline associated phorias nor residual associated phorias were significantly associated with overall changes in refractive error ($F_{1,73} = 0.17$, $p = 0.68; F_{1,73} = 1.13$, $p = 0.29$ for baseline near associated phoria and change in near associated phoria across 12 months, respectively).

**DISCUSSION**

The CONTROL study described here provides compelling evidence for the efficacy of bifocal contact lenses as a myopia control treatment. The strong myopia control effect found in this study, that is, an overall 72% reduction in progression, based on cycloplegic autorefraction, and 80% reduction in the rate of axial elongation, far exceeds the size of treatment effects reported in previous myopia control studies involving optical devices in humans, and only daily 1.0% topical atropine has comparable results of the pharmacological treatments studied. Nonetheless, the results are consistent with an already published identical twin case study by the authors. However, the CONTROL study provides more convincing evidence that myopia progression can be effectively controlled through optical intervention, being a well-controlled, albeit small-scale, double-masked clinical trial with treatments randomly assigned and groups well matched with regard to sex, ethnicity, refractive error, and degree of near associated phoria. As a 12-month study, it is not possible to comment on the enduring nature of this treatment effect, although related more recent contact lens studies have reported significant treatment effects beyond the first year.

Given that many of the sight-threatening ocular complications of myopia are linked to excessive ocular elongation, it is also important to note that the BFSCL control effect reported here was achieved through reduced ocular elongation.

The large control effects reported here contrast with the somewhat small effects reported in two COMET studies, which represent the largest and best-controlled of clinical trials involving multifocal spectacle lenses for myopia in children to date. Both COMET studies used progressive addition lenses (PALs). In the first study, subgroup analyses revealed that subjects with either low baseline levels of myopia and reduced accommodative responses or near esophoria and larger than normal lags of accommodation all benefited significantly from PALs, recording treatment effects of 0.55 and 0.64D less myopia progression, respectively, across 3 years compared with that of single-vision spectacle wearers. The reduction in progression rates with PALs was 0.20D overall, and for near exophores, 0.05D. Cursory, in a 3-year follow-up study (COMET II), which was limited to children with high accommodative lags and near esophoria, the treatment effect was very small, averaging 0.28D, and another shorter study (STAMP), which was likewise limited to children with high accommodative lags, also reported only a small, 0.18D, treatment effect across 12 months. Additional selection criteria for the latter study included either myopia less than any other associated phoria, and change in near associated phoria across 12 months, respectively).
−2.25D or myopia higher than −2.25D combined with esophoria at near. Although all three studies were United States based, results from studies involving multifocal spectacles in East Asia have also not revealed consistent clinically significant myopia control benefits for those with near esophorias or high lags of accommodation.48,49

Since the completion of the study reported here, there have been a number of other myopia control–related bifocal contact lens studies, and as reported here, most have demonstrated better efficacy than related multifocal spectacle lens studies. Two such studies, the DISC study50 and the Dual Focus51 study, involved two different custom multifocal soft contact lens designs, which both had distance and near powers arranged in some form of multiple concentric rings, as with the lens design used in the current study. Both studies reported significant slowing of myopia progression in the wearers of their device relative to those receiving the single-vision control treatment, although less than in the current study, that is, 36% slower progression in both the DISC study overall and in the first 10 months of the crossover Dual Focus study. In the first year of yet another multiyear study comparing myopia progression with a soft contact lens design with peripheral plus power and single-vision soft contact lenses, an adjusted 34% relative reduction was reported.52 Finally, a 1-year study comparing myopia progression in wearers of a distance center multifocal soft lens with a +2.00D add with historical controls involving wearers of single-vision daily disposable soft contact lenses reported a 50% relative reduction in myopia progression and a 29% relative reduction in axial elongation.53

Why are bifocal soft contact lenses apparently more effective in controlling myopia progression than bifocal or PAL spectacles? While the current study was relatively short-term (12 months), and it is possible that treatment effects may have declined with time, had our study been extended, the picture is likely more complex. In this context, the practical limitations of bifocal and PAL spectacles for children and adolescents and their implications for compliance cannot be ignored. Once inserted, contact lenses are more likely to be left in place throughout the day than spectacle lenses for practical reasons, thereby favoring compliance. Furthermore, assuming that the maximum treatment effects of multifocal spectacle lenses requires children to use the near addition during near work, then compared with presbyopic adults, children are likely to be less compliant because of the unusual head and eye postures required (head up and eyes lowered) and because of the optical distortions encountered in viewing obliquely through the lower regions of such spectacle lenses. Indeed, video monitoring of children participating in one myopia control study found that they commonly dropped their heads while reading.54 Thus, although most studies report training their subjects in the proper use of multifocal spectacles and many of them also sought to monitor compliance, it is not clear how effective these strategies were in ensuring their proper use in everyday tasks. Furthermore, with the extensive use by today’s children and adolescents of computers with screens at or above eye level, one could argue that the more traditional multifocal spectacle lens designs are not practical for these age groups. Lending weight to these arguments is the impressive sustained myopia control reported in a study using high-set executive-style bifocal spectacles with or without base-in prism for rapidly progressing Chinese Canadian children with high accommodative lags and/or with esophoria at near,55 that is, 39 and 51% slowing in myopia progression and 30 and 34% slowing in axial elongation, respectively, relative to changes with single-vision spectacles across 3 years. The children are likely to have had difficulty in looking over the top of the near segments during reading, and the addition of base-in prism may have improved visual comfort and thus compliance in those with induced near esophoric tendencies. The bifocal soft contact lenses used in the current study represent the end of this continuum, exposure to the near addition having no dependence on gaze direction and/or training, the only requirement being that the lenses are worn on a daily basis.

The arguments presented above rest on an assumption that accommodative lags stimulate eye elongation, that the adds in bifocal lenses and PALs served to correct them, and that the superiority of bifocal contact lenses reflects the near addition being available at all angles of gaze and near distances. A number of studies have attempted to directly measure the effects of bifocal soft contact lenses on accommodation, with significant differences in their outcomes. In one such study, myopes as well as emmetropes were reported to overaccommodate when wearing bifocal soft contact lenses, whereas only emmetropes showed this behavior for single-vision contact lenses incorporating the near addition power and only at some distances.56 However, two other studies have reported near normal accommodation in nonpresbyopic users of bifocal contact lenses,50,51 suggesting that they ignored the near zones of the lenses. Although different methodologies, including instrumentation, were used in these three studies, nonetheless, taken together, these results suggest that a simple analogy between bifocal spectacles and bifocal contact lenses is not appropriate here. Induced changes in net optical aberrations, including spherical aberration, are likely to also impact on accommodation, greater in the case of bifocal contact lenses than equivalent spectacle lenses, and these effects are also likely to be lens design dependent.57,58 a subject of an ongoing study. The possibility that such changes might contribute to the apparently greater efficacy of some bifocal contact lens designs cannot be ruled out.58

It is perhaps important to note that all CONTROL subjects exhibited near associated esophorias, with the bifocal adds being selected to maximally neutralize them and without which they could be expected to exhibit larger lags of accommodation as reduced accommodative effort is one way of reducing accommodative convergence by way of compensating for near esophorias. Based on animal model studies, the resulting retinal (hypercentic) defocus can be expected to contribute to myopic progression and bifocal adds to slow progression by attenuating such focusing errors. In this context, myopes exhibiting near esotropia disparities may represent a special subset likely to benefit significantly from near additions. Note also that most other multifocal lens studies have used standardized additions, with no selection criteria related to binocular vision status, perhaps contributing to the lower efficacies reported.

Other characteristics of bifocal soft contact lenses may also have contributed to their apparently greater effectiveness than spectacle lenses as myopia control treatments. Specifically, the improved efficacy of bifocal contact lenses over their spectacle lens equivalents may be related to differences in the defocus experience,
including more sustained myopic defocus provided with the former. Animal studies have shown that the imposition of sustained myopic defocus over a sufficiently large area of retina (central or peripheral) strongly inhibits eye growth. The designers of the DISC study have argued that their contact lens imposes frequent near constant myopic defocus, distributed relatively evenly across the retina, thereby providing a robust stop signal to eye growth. The bifocal contact lens design used in the current study included alternating rings of distance and near powers. Interestingly, Fresnel spectacle lens designs incorporating rings of positive power have also been shown to have strong inhibitory effects on eye growth in both chick and guinea pig models. The prolate eye shape commonly linked to human myopia may also be of relevance, as it is generally coupled to peripheral hyperopic defocus, which will be reduced, or even reversed in sign, at least during distance viewing, with bifocal contact lens designs incorporating peripheral adds, as used in the current study. The myopia control effect of such lenses would also be improved further if, during near viewing, nonpresbyopic wearers did not reduce their accommodation, as reported in two of the studies described above.

The observed decreases in axial length and apparent myopia regression, mostly limited to the BFSCL group, warrant some comment. A similar pattern of response was observed previously by us in a myopia control case study involving BFSCLs and identical twins, as well as in both an unrelated study involving orthokeratology and the ATOM 1 study. In the current study, 13 subjects in the BFSCL group recorded reductions in axial length, and eight subjects recorded hyperopic shifts in cycloplegic spherical equivalent refractive error, that is, regression in myopia, based on the average for the two eyes. These observations contrast with findings for the SVSCL group, in which only one subject showed a decrease in axial length and one subject showed a decrease in myopia. Such changes were more commonly encountered in older (13 years and older) subjects, with both cases in the SVSCL group, as well as 11 of 13 cases of axial “shrinkage” and 5 of 8 cases of myopia regression in the BFSCL group falling within this age range. Reductions in accommodative tone across the treatment period may have contributed to these refractive error changes, that is, apparent myopia regression, although such effects are expected to be very small, given that reported refractive error data were obtained under cycloplegia. Also no treatment-induced corneal changes were observed to provide an alternative optical explanation for this finding. Noteworthy and more challenging to explain are the observed decreases in axial length in some of our subjects, given that a small amount of eye elongation, not shrinkage, can be expected among growing children, even in the absence of myopic progression. Indeed, in a study involving Nepalese children aged 6 to 18 years, the vitreous chamber depths of nonmyopic subjects were reported to increase at a rate of 0.07 mm/year. Because the average axial length change for the BFSCL group is very small, that is, 0.05 mm, measurement error cannot be ruled out as the explanation for some of the cases of apparent shrinkage. However, choroidal thickening in response to imposed myopic defocus is offered as one of two alternative explanations of some of these cases. First reported in chicks, defocus-driven choroidal thickening has since been reported in other animal models and most recently in young adult subjects. The effect of choroidal thickening is to move the retina forward, thereby leading to a reduction of axial length as referenced to the retinal pigment epithelium and measured with the IOLMaster. As the second more speculative explanation, it is plausible that co-contraction of resident myofibroblasts in the human sclera could lead to a decrease in axial length, although little is known about the role of these cells and the signal pathway that regulates their activity. Suffice it to say, it remains beyond the scope of this report to conclusively identify the mechanism underlying the observed reductions in axial length in otherwise growing children.

No clinical trial is without its limitations. Limiting our subjects to those having eso fixation disparity at near prevents generalization of our conclusions about the treatment effects found with BFSCLs. The relatively short duration of our study is also a limitation. A follow-up longer-term study is needed to address the question of whether good control over myopia progression is maintained with BFSCLs beyond 12 months. Future studies should also aim for a more balanced representation by sex and include a wider range of ethnicities to cover the possibility of genetic differences in the evolution of myopia, as proposed by Yang et al., among others. Finally, it will also be important to understand how early intervention influences the course of later progression on discontinuation of treatment.

CONCLUSIONS

Acuvue BFSCLs, prescribed to maximally neutralize near associated esophoria in children and adolescents, are effective in limiting the rate of myopia progression and axial elongation relative to conventional single-vision contact lenses during a 12-month treatment period. Understanding the specific factors contributing to the efficacy of this contact lens design in controlling myopia progression will be important for refining related clinical protocols.

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Myopia Control with Bifocal Contact Lenses—Aller et al.

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