Effect of Bifocal and Prismatic Bifocal Spectacles on Myopia Progression in Children
Three-Year Results of a Randomized Clinical Trial

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IMPORTANCE Myopia is a significant public health problem, making it important to determine whether a bifocal spectacle treatment involving near prism slows myopia progression in children.

OBJECTIVE To determine whether bifocal and prismatic bifocal spectacles control myopia in children with high rates of myopia progression and to assess whether the treatment effect is dependent on the lag of accommodation and/or near phoria status.

DESIGN, SETTING, AND PARTICIPANTS This 3-year randomized clinical trial was conducted in a private practice. A total of 135 (73 female and 62 male) Chinese-Canadian children (aged 8-13 years; mean [SE] age, 10.29 [0.15] years; mean [SE] myopia, −3.08 [0.10] D) with myopia progression of at least 0.50 D in the preceding year were randomly assigned to 1 of 3 treatments. A total of 128 (94.8%) completed the trial.

INTERVENTIONS Single-vision lenses (control, n = 41), +1.50-D executive bifocals (n = 48), and +1.50-D executive bifocals with 3-Δ base-in prism in the near segment of each lens (n = 46).

MAIN OUTCOMES AND MEASURES Myopia progression (primary) measured using an automated refractor following cycloplegia and increase in axial length (secondary) measured using ultrasonography at intervals of 6 months for 36 months.

RESULTS Myopia progression over 3 years was an average (SE) of −2.06 (0.13) D for the single-vision lens group, −1.25 (0.10) D for the bifocal group, and −1.01 (0.13) D for the prismatic bifocal group. Axial length increased an average (SE) of 0.82 (0.05) mm, 0.57 (0.07) mm, and 0.54 (0.06) mm, respectively. The treatment effect of bifocals (0.81 D) and prismatic bifocals (1.05 D) was significant (P < .001). Both bifocal groups had less axial elongation (0.25 mm and 0.28 mm, respectively) than the single-vision lens group (P < .001). For children with high lags of accommodation (>1.01 D), the treatment effect of both bifocals and prismatic bifocals was similar (1.1 D) (P < .001). For children with low lags (<1.01 D), the treatment effect of prismatic bifocals (0.99 D) was greater than of bifocals (0.50 D) (P = .03). The treatment effect of both bifocals and prismatic bifocals was independent of the near phoria status.

CONCLUSIONS AND RELEVANCE Bifocal spectacles can slow myopia progression in children with an annual progression rate of at least 0.50 D after 3 years. These results suggest that prismatic bifocals are more effective for myopic children with low lags of accommodation.

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Myopia is a significant public health problem, particularly in urban East Asian countries, where at least 50% to 60% of children by the age of 12 years are myopic. The prevalence of myopia is also high among Asian children living in Western countries.5 Bifocal and multifocal spectacles have been assessed as myopia control treatments in children.5-18 Published data support the suggestion that bifocal and multifocal lenses inhibit myopia development in children but only by a small amount and only in a subset of children with particular ocular characteristics (reviewed by Cheng et al19).

Of the many myopia control studies, the study by Leung and Brown20 showed the greatest treatment effect (myopia control of 0.47 D following 2 years of multifocal spectacle wear). The high prevalence of myopia in children living in Hong Kong allowed for the recruitment of only myopic children with a high myopia progression rate (>0.4 D/year). A later multifocal study conducted in Hong Kong41 that did not use myopia progression rate as a selection criteria failed to replicate the results (myopia control was only 0.14 D following 2 years of wear). Thus, the myopia progression rate appears to be an important factor in the determination of a multifocal lens treatment effect in children.

There are also reports12-14 showing that multifocal lenses had a greater treatment effect in myopic children with high lags of accommodation than those with low lags of accommodation. The Correction of Myopia Evaluation Trial (COMET)12,13 showed that multifocal lenses were more effective for children with high lags (myopia control of 0.33 D in 3 years) and the beneficial effect was greatest in children with combined high lags of accommodation and near-point esophoria (myopia control of 0.64 D in 3 years). However, a later clinical trial (COMET2)147 could only produce a smaller treatment effect (myopia control of 0.28 D in 3 years) for children with these binocular vision characteristics. Therefore, the relationships between the treatment effect of multifocal lenses and lag of accommodation and phoria status have yet to be definitively established. In addition, children with near esophoria have been reported, based on clinical data, to benefit more from bifocal lens wear than children with other phoria types.25 This finding is supported by some prospective studies, but not others.8,11,12,21,22 Given that myopic children have been found to have high response accommodation convergence to accommodation ratios,23 children with orthophoria and esophoria wearing positive lenses will have a significant exophoric shift, resulting in a higher demand for positive fusional vergence.24,25 The disrupted oculomotor equilibrium that occurs has been proposed to reduce the positive-lens treatment effect.26 Following on from this proposal, it has been shown that incorporating near base-in prism when prescribing near additions for myopic children can reduce the positive-lens-induced exophoria in children.24

The purpose of this study was to determine whether bifocal spectacles could control myopia in children with high rates of myopia progression (≥0.5 D in the preceding year) and to investigate the effect of incorporating near base-in prisms along with the near-addition lenses (prismatic bifocal spectacles) on myopia progression. Whether the treatment effect was dependent on the children’s lag of accommodation and phoria status was also determined. This article presents the final outcome measurements of cycloplegic autorefraction and ocular biometry for the 3-year clinical trial. A 2-year interim report on the outcomes showed a 0.59-D and 0.85-D myopia control effect of the bifocal and prism bifocal spectacles, respectively.16 The focus here concerns whether the beneficial effect was maintained for the third year of the trial.

Methods

Conduct of the Study
A complete description of the study design, including recruitment methods, sample size determination, characteristics of the participants and inclusion criteria, randomization, lack of masking, and potential bias issues, has been published.16 Myopic children were randomly assigned to 1 of 3 treatment groups: (1) single-vision distance lenses, (2) bifocal lenses with +1.50-D near addition, and (3) prismatic bifocals with +1.50-D and 3-Δ base-in prism in the near segment of each lens. Verbal informed consent to participate was obtained from all children and written consent from their parents. The study followed the tenets of the Declaration of Helsinki and was reviewed and approved by the Queensland University of Technology Human Research Ethics Committee.

Study Population

Chinese-Canadian children were recruited from an optometric practice in Mississauga, Ontario, Canada. The prevalence and degree of myopia determined from subjective refraction data are high in this group of children.5 Clinical records were selected for children who had their eyes examined within 9 to 18 months of the trial start date. Children aged between 8 and 13 years were chosen. Only myopic children (≥0.00 D of myopia) with myopia progression equal to or greater than 0.50 D in the preceding year were recruited. A total of 200 clinical records of myopic children were reviewed, of which 107 met the myopia progression rate criterion (ie, 54% of the myopic had fast progression) and were recruited through letters addressed to their parents. Other children were recruited through the public media (n = 29; eg, via a poster in the optometric practice) or during regular eye examinations (n = 27).

Intervention

The bifocals used were custom-made polycarbonate executive bifocals with a front base curve of +3.25 D supplied by Essilor.16 There were 2 designs: (1) an executive bifocal with an add power of +1.50 D and (2) the same design with 3-Δ base-in prism in the near segment of each lens (6 Δ in total) (Myopilux Max supplied by Essilor). The powers of the near addition and prism were chosen based on outcomes of a previous study in Chinese-Canadian children.24 The +1.50-D near-addition power was chosen because it reduced the accommodation lag but did not induce a large amount of near exophoria in the standard bifocal group.24 The addition of 6-Δ base-in prism to the near segment reduced the lens-induced exophoria to close to zero in the prismatic bifocal group.24
Outcome Variables
The primary outcome variable was myopia progression, which was the difference between the mean cycloplegic spherical equivalent refraction measured by an automated refractor at the baseline visit and subsequent 6-month visits for 36 months. The secondary outcome variable was eye growth, which was the difference between mean axial lengths measured by ultrasonography at the baseline visit and subsequent 6-month visits for 36 months. Only data of the right eye were used.

Protocol Design
At the preliminary visit, a comprehensive oculovisual assessment was conducted to measure baseline readings and to ensure eligibility. Children were reexamined at 6-month intervals for 36 months. These visits included cycloplegic autorefraction, cycloplegic subjective refraction, and A-scan ultrasonography measurement of axial length. A questionnaire was administered to the child and parents to determine whether the child used the spectacles correctly. The distance prescription was upgraded if the equivalent sphere of the subjective refraction changed by 0.50 D or more in either eye.

Cycloplegic autorefraction (average of 5 measurements using Topcon KP7000) and cycloplegic subjective refraction (for determination of the distance prescription for the spectacles) were determined 30 minutes after instillation of 2 drops of cyclopentolate (Cyclogyl, 1%) with 5 minutes between instillations. The axial length of the eyes was then measured with A-scan ultrasonography (average of 10 measurements, Quantel Medical Axis II PR) following topical anesthesia with 1 drop of proparacaine (Alcaine, 0.5%).

Accommodation responses were measured with the distance correction using the Shin-Nippon open-field autorefractor (Shin-Nippon SRW-5000). The viewing targets were the numbers on the Howell-Dwyer near phoria card at 33 cm (3-dimensional accommodation demand); print size was approximately 20/50. Typically, for a 3-dimensional accommodation demand a lag of accommodation is measured (ie, the accommodation response is less than the actual demand [ie, underaccommodation]). The measures for demands and responses for each participant were adjusted for lens effectivity.24 The near horizontal phoria was measured through the distance correction using the Howell-Dwyer near phoria card (Cyclopean Designs). The direction (eso or exo) and the magnitude (to the nearest 0.5 Δ) were recorded. The mean luminance of the near target was 100 cd/m² (Luminance meter LS-100, Konica Minolta Sensing Americas Inc).

Statistical Analysis
Data have been expressed as the mean (standard error) of each of the 3 lens treatment groups. The analysis of the data followed the intention to treat approach, and we used the last progression information (ie, carry forward) for participants lost to follow-up.27 For the 2 outcome variables, a multiple linear regression approach was used to test for the treatment effect and to adjust for all potential confounding covariates such as age, sex, degree of myopia, axial length, initial myopia progression, myopic years before trial, near phoria, lag of accommodation, total near work and total outdoor activities per-formed, and number of myopic parents. A backward-stepwise model, which included all covariates initially and then sequentially removed insignificant covariates (P ≥ .05), was used. The significant covariates were then included in the analysis of covariance model for contrast among control and treatment groups. The lag of accommodation and near phoria were further tested in separate interaction models for any differential effect of the bifocal treatment.

Results
Subject Characteristics
One hundred fifty children were recruited and randomized to the single-vision control group (n = 50), bifocal group (n = 50), and prismatic bifocal group (n = 50) (Figure 1). Nine children in the control group did not receive allocation because the parents were disappointed that their child had not been assigned to a bifocal group. Three of these children were lost to the practice and their initial measures of refraction (mean [SE], −2.83 [0.36] D) with an annual increase of −0.83 (0.22) D were carried forward. The other 6 children, who were not officially in the study, were still examined in the practice. They had a mean (SE) initial myopia of −3.27 (0.67) D and average (SE) 36-month myopia progression of −2.10 (0.22) D. Their refraction data were included in the analysis. Two children in the bifocal group and 4 in the prismatic bifocal group did not receive the allocation because of reported ocular surface stinging and blurred vision they experienced following cycloplegia. Their data were excluded from the analysis.

The 36-month follow-up period was completed by 37 of the 41 children in the control single-vision lens group, 46 of the 48 children in the bifocal group, and 45 of the 46 children in the prismatic bifocal group. There were altogether 7 children who did not complete the wearer trial. Two relocated with their families to other areas and 1 was discontinued owing to the effects of cycloplegia. These 3 children were lost to the practice and their most recent measures of refraction and axial length were carried forward. The other 4 children who did not continue commenced orthokeratology contact lens treatment. Because orthokeratology treatment has been reported to temporarily decrease myopia and control myopia progression,28,29 refraction and axial length were measured up to the final pre-contact lens stage and carried forward. All children wore spectacles full time during waking hours. Baseline characteristics of children in the 3 treatment groups can be found in a study by Cheng et al.16 The total number of prescriptions (spectacles) upgraded for the 36-month period was 83 in the single-vision lens group, 62 in the bifocal group, and 55 in the prismatic bifocal group.

Outcome
The mean (SE) total increases in myopia across the 3-year period were −2.06 (0.13) D, −1.25 (0.10) D, and −1.01 (0.13) D for the single-vision, bifocal, and prismatic bifocal groups, respectively. There was a significant effect of lens design (P < .001) on the degree of myopia progression. The magnitudes of mean myopia progression were −0.81 D (P < .001) and
−1.05 D (P < .001) less in the bifocal lens and prismatic bifocal lens groups, respectively, compared with the single-vision lens group. However, there was no significant difference (P = .15) in the treatment effect of the 2 different bifocal lens designs. Both bifocal groups had the greatest treatment effect in the first year, after that, the magnitude of the treatment effect decreased and was sustained in the second and third years (Table).

The multiple linear regression analysis showed that age (higher progression with lower age, P < .001), baseline myopia progression (higher progression with higher baseline progression, \( P = .03 \)), and parental myopia (higher progression the greater the number of myopic parents, \( P = .04 \)) were associated with the magnitude of the treatment effect. The model-adjusted mean (SE) myopia progressions after 36 months were −2.07 (0.13) D, −1.25 (0.10) D, and −1.01 (0.13) D in the single-vision, bifocal, and prismatic bifocal groups, respectively (Figure 2). Controlling for the significant covariates did not greatly change the mean myopia progression or group differences compared with the unadjusted means.

The mean (SE) increases in axial length across the 3-year period were 0.82 (0.05) mm, 0.57 (0.07) mm, and 0.54 (0.06) mm in the single-vision, bifocal, and prismatic bifocal groups, respectively. Lens design appeared to have an effect (P = .002) on the degree of axial elongation. A significant difference was
not identified ($P = .66$) in the treatment effect of the 2 bifocal lens designs. Axial elongations during this period were 0.25 mm and 0.28 mm less in the bifocal and prismatic bifocal groups than in the single-vision lens group, respectively ($P < .005$ for both comparisons). Similar to the control of refraction, both bifocal groups had the greatest treatment effect on axial elongation in the first year, after that, the magnitude of the treatment effect decreased and was sustained in the second and third years (Table). The multiple linear regression analysis found that only the covariate of age (higher axial elongation with younger age, $P < .001$) was significant in the model. The model-adjusted mean (SE) increases in axial length after 36 months were 0.83 (0.05) mm, 0.57 (0.07) mm, and 0.52 (0.07) mm in the single-vision, bifocal, and prismatic bifocal lens groups, respectively. Myopia progression was significantly correlated with change of axial length (Pearson correlation: $r = 0.65$ for single-vision lens, $r = 0.74$ for bifocal lens, and $r = 0.72$ prismatic bifocal lens; $P < .001$).

Ancillary Analyses
A median split method by the number of children was used to test for interaction of lag of accommodation and near phoria with the treatment effects. Based on this, the lags of children were characterized as high ($\geq 1.01$ D) or low ($< 1.01$ D). Near phoria was analyzed as orthophoria ($-1.5 \Delta$ to $+1.5 \Delta$), esophoria ($> +1.5 \Delta$), or exophoria ($< -1.5 \Delta$). For these 2 covariates tested in the interaction analysis, only lag of accommodation showed evidence of interaction with the treatment effect ($P = .04$); there was no interaction of near phoria with treatment ($P = .39$). For that reason, the impact of lag of accommodation was further analyzed and the mean total increase of myopia over a 3-year period for high- and low-lag subgroups plotted in Figure 3. In the high-lag subgroup, the mean (SE) myopia progressions over 3 years were $-2.26 (0.22)$ D for the single-vision lens group (n = 20), $-1.12 (0.12)$ D for the bifocal group (n = 23), and $-1.13 (0.14)$ D for the prismatic bifocal group (n = 24). For children in the high-lag subgroup, the treatment effect of bifocals was 1.14 D ($P < .001$) and of prismatic bifocals was 1.13 D ($P < .001$), with both bifocal lens designs having a similar effect ($P = .99$). In the low-lag subgroup, mean (SE) myopia progressions over 3 years were $-1.87 (0.18)$ D for the single-vision lens group (n = 21), $-1.37 (0.15)$ D for the bifocal group (n = 25), and $-0.88 (0.16)$ D for the prismatic bifocal group (n = 22). The treatment effect of bifocals was 0.50 D ($P = .03$) and of prismatic bifocals was 0.99 D ($P < .001$); prismatic bifocals appeared to be the most effective design ($P = .03$) for children in the low-lag subgroup.

The interaction between the lag of accommodation and the treatment effect was further tested by assessing the change of axial length over the 3 years (Figure 4). In the high-lag subgroup, mean (SE) axial elongations were $0.87 (0.07)$ mm for the single-vision lens group (n = 20), $0.52 (0.06)$ mm for the bifocal group (n = 23), and $0.56 (0.08)$ mm for the prismatic bifocal group (n = 24). For children in the high-lag subgroup, the treatment effect of bifocals was $0.35$ mm ($P < .001$) and of prismatic bifocals was $0.31$ mm ($P < .001$), with both bifocal lens designs having a similar effect ($P = .50$). In the low-lag subgroup, mean (SE) axial elongations over 3 years were $0.78 (0.08)$ mm for the single-vision lens group (n = 21), $0.62 (0.07)$ mm for the bifocal group (n = 25), and $0.52 (0.07)$ mm for the prismatic bifocal group (n = 22). The treatment effect of bifocals was $0.16$ mm ($P = .14$) and of prismatic bifocals was $0.26$ mm ($P < .05$). This confirmed that prismatic bifocals were more effective for myopic children with low lags of accommodation.

Discussion
Both bifocals and prismatic bifocals were found to significantly inhibit myopia progression in children compared with
single-vision lenses over the 3-year treatment period; the magnitude of myopia inhibition with both bifocal designs was similar. The observed treatment effect of both bifocals and prismatic bifocals accumulated over time but was greatest in the first year and then decreased and was sustained in the second and third years. The results also suggested that bifocals were as effective as prismatic bifocals for myopic children with high lags of accommodation, whereas for children with low lags, prismatic bifocals produced a greater treatment effect.

Children recruited in this study had myopia progression of at least 0.50 D in the preceding year. This resulted in a mean initial myopia progression rate of about –1 D per year at baseline for each group. Such an inclusion criterion would avoid children with low rates of myopia progression being recruited to the study and allow the treatment effect of bifocals to be more effectively evaluated. Our study supports the findings of Leung and Brown,9 who used a similar inclusion criterion; progressive lenses are effective at inhibiting myopia progression for myopic children with high myopia progression. The better myopia control effect could also be related to the use of executive bifocal lenses instead of multifocal lenses because the segment line provides feedback to the children to ensure that they can deliberately use the reading portion of the bifocal lenses whenever close work is performed. In contrast, children who wear multifocal lenses do not consistently use the near-addition portion of the spectacles during reading.30 Also, in the executive design, the entire lower portion of the lens has the positive power and this may possibly impact effectiveness owing to a greater visual field extent of the lens-induced peripheral myopic defocus.19

Our study did not find the treatment effect dependent on the near phoria status. Therefore, bifocal lenses were not more effective in children with esophoria. The lack of an effect may be related to the fact that a large portion of esphoric children will have significant lens-induced esophoria with the bifocals in place because of the high response accommodation convergence to accommodation ratio usually found in this group of children.23 The oculomotor interactive theory26 has proposed that a disrupted oculomotor equilibrium will reduce the positive-lens treatment effect. This also explains why previous studies of bifocals on esphoric children did not show a strong myopia control effect.10,20 Furthermore, COMET12 did not show that esophoria alone has an effect. We speculate that in prescribing bifocals for myopia control, it is the state of lens-induced near phoria instead of baseline near phoria that plays a role in determining success because it is this uncontrolled phoria that disrupts the oculomotor equilibrium.

The differential analysis for children with high and low accommodative lags showed that interaction existed between the lag and treatment effect. Both bifocals and prismatic bifocals decreased myopia progression by a similar degree (1.1 D over 3 years) for children with high lags (Figure 3). However, the 2 bifocal designs produced different outcomes for children with low lags. The treatment effect of bifocals (0.50 D) was less than prismatic bifocals (0.99 D) over 3 years for children with low lags. This implied that standard bifocals were more effective for children with high lags; a finding in agreement with the reported outcomes of COMET.11 These findings were also confirmed with the interaction analysis between lag and change in axial length. For children with high lags, both bifocals and prismatic bifocals were effective at controlling axial elongation with a similar treatment effect (0.35 mm vs 0.31 mm over 3 years). However, for children with low lags, only prismatic bifocals appeared to have an effect on the degree of the axial elongation (decreased 0.26 mm over 3 years). We speculate that for children with high lags, reducing the accommodation lags with standard bifocals is adequate to control myopia progression. The greater treatment effect of prismatic bifocals for children with low lags could be related to the fact that both the convergence and lens-induced esophoria are reduced by the base-in prism.

Conclusions

A possible limitation of this study was that only Chinese-Canadian children were participants. Although living in urban centers in East Asia countries appears to increase the prevalence and degree of myopia in children, there is little reason to think that ethnicity changes the fundamental characteristics of myopia progression. Therefore, the findings of this study could reasonably be generalized to fast-progressing myopes irrespective of ethnicity, although this clearly has to be tested.

In conclusion, bifocal lenses can slow myopia progression in children with high rates of myopia progression even during the third year of treatment. The results suggest that prismatic bifocals are more effective for myopic children with low lags of accommodation.
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