

Randomized Trial of Effect of Bifocal and Prismatic Bifocal Spectacles on Myopic Progression

Two-Year Results

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Objective: To determine whether bifocal and prismatic bifocal spectacles could control myopia in children with high rates of myopic progression.

Methods: This was a randomized controlled clinical trial. One hundred thirty-five (73 girls and 62 boys) myopic Chinese Canadian children (myopia of ≥ 1.00 diopters [D]) with myopic progression of at least 0.50 D in the preceding year were randomly assigned to 1 of 3 treatments: (1) single-vision lenses ($n=41$), (2) +1.50-D executive bifocals ($n=48$), or (3) +1.50-D executive bifocals with a 3-prism diopters base-in prism in the near segment of each lens ($n=46$).

Main Outcome Measures: Myopic progression measured by an automated refractor under cycloplegia and increase in axial length (secondary) measured by ultrasonography at 6-month intervals for 24 months. Only the data of the right eye were used.

Results: Of the 135 children (mean age, 10.29 years [SE, 0.15 years]; mean visual acuity, -3.08 D [SE, 0.10 D]), 131 (97%) completed the trial after 24 months. Myopic

progression averaged -1.55 D (SE, 0.12 D) for those who wore single-vision lenses, -0.96 D (SE, 0.09 D) for those who wore bifocals, and -0.70 D (SE, 0.10 D) for those who wore prismatic bifocals. Axial length increased an average of 0.62 mm (SE, 0.04 mm), 0.41 mm (SE, 0.04 mm), and 0.41 mm (SE, 0.05 mm), respectively. The treatment effect of bifocals (0.59 D) and prismatic bifocals (0.85 D) was significant ($P < .001$) and both bifocal groups had less axial elongation (0.21 mm) than the single-vision lens group ($P < .001$).

Conclusions: Bifocal lenses can moderately slow myopic progression in children with high rates of progression after 24 months.

Applications to Clinical Practice: Bifocal spectacles may be considered for slowing myopic progression in children with an annual progression rate of at least 0.50 D.

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MYOPIA IS A COMMON REFRACTIVE problem, particularly in East Asia, where reported prevalence values in children can be as high as 50% to 60% by the age of 12 years.¹⁻⁴ Prevalence of myopia is also high among Asian children living in Western countries.⁵ A number of well-designed prospective studies have investigated the effect of positive lenses, in bifocal or multifocal form, on myopic progression in children.⁶⁻¹⁴

However, bifocals and multifocals have proven to be relatively ineffective myopia-control treatments in children.^{15,16} Of the many myopia-control studies, the study by Leung and Brown⁹ showed the greatest

treatment effect (myopia control, -0.47 D per 2 years with multifocals). The high prevalence of myopic subjects in Hong Kong permitted them to recruit only myopic children with a high progression rate (>0.4 D per year). A later multifocal study conducted in Hong Kong¹¹ that did not use myopic progression rate as a selection criterion failed to replicate the results (myopia control, -0.14 D per 2 years with multifocals [no significant treatment effect]). Thus, myopic progression rate appears to be an important factor in the determination of multifocal lens treatment effect in children.

Children with near esophoria have been reported, based on clinical data, to benefit more from bifocal lens wear than

children with other phoria types.¹⁷ Prospective studies also supported this finding.^{10,14} However, other studies^{8,11,12,18,19} have been unable to demonstrate such an effect. Given that myopic children have been found to have high response accommodation convergence to accommodation ratios,²⁰ those with orthophoria and exophoria who wear positive lenses will have a significant exophoric shift resulting in a higher demand for positive fusional vergence.^{21,22} The disrupted oculomotor equilibrium that occurs has been proposed to reduce the positive-lens treatment effect.¹⁶ Furthermore, it has been shown that incorporating near base-in prisms when prescribing near additions for myopic children can reduce their positive lens-induced exophoria.²¹ However, there have been no studies in the literature of a prospective clinical trial to evaluate this potential treatment option in myopia.

The purpose of this study was to determine whether bifocal spectacles could control myopia in children with high rates of myopic progression (≥ 0.5 D in the preceding year) and to investigate the effect of incorporating near base-in prisms along with near-addition lenses (prismatic bifocal spectacles) on myopic progression. This article presents the outcome measurements of cycloplegic autorefraction and ocular components after 24 months of lens wear in a 3-year randomized clinical trial.

METHODS

CONDUCT OF THE STUDY

Myopic children were recruited to the study and randomly assigned to 1 of 3 treatment groups: (1) single-vision distance lenses, (2) bifocal lenses with +1.50 D near addition, or (3) prismatic bifocals with +1.50 D and a 3-prism diopters (Δ) base-in prism in the near segment. Verbal informed consent to participate from all children and written consent from the parents were obtained. The study followed the tenets of the Declaration of Helsinki and was reviewed and approved by the Human Research Ethics Committee Queensland University of Technology.

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 reported to be high in this group of children.⁵ Clinical records were selected for children who had their eyes examined in the last 9 to 18 months. Only myopic children (≥ 1.00 D of myopia) with myopic progression equal to or greater than 0.50 D in the preceding year were recruited. Myopic progression at the time of recruitment was determined by analysis of the refractive change (noncycloplegic subjective refraction) reported in previous clinic records during the preceding 9 to 18 months. A summary of the inclusion criteria is presented in **Table 1**.

RANDOMIZATION

Children were primarily selected through review of their clinic records ($n=200$) and were recruited through letters addressed to their parents. Other children were recruited through public media (eg, via a poster in the optometric practice [$n=29$] or during regular eye examinations ($n=27$)). Children who ap-

Table 1. Inclusion Criteria for Children Recruited to the Trial

Age of 8-13 y
Myopia of -1.00 to -5.50 D
Myopia progression of ≥ 0.50 D in preceding year
Astigmatism and anisometropia of ≤ 1.50 D
Distance monocular visual acuity of 6/6 or better
Near monocular visual acuity of 6/6 or better
Stereoacuity of ≤ 40 s of arc at 40 cm
No strabismus
Able to respond to subjective testing
No history of systemic or ocular diseases
Single-vision distance lens wear
No history of bifocal lens wear and/or contact lens use
Consent of the child and parent to participate in the study

Abbreviation: D, diopter.

peared to meet the inclusion criteria for eligibility underwent an ocular assessment to determine final eligibility.

Randomization was implemented by putting the subjects' file numbers on slips of paper and drawing them from a container at random (conducted by D.C.). The first 50 subjects drawn were assigned to the control group; the second 50 were assigned to the bifocal group, and so forth.

OUTCOME VARIABLES

The primary outcome variable was myopic progression, which was the difference between the mean cycloplegic spherical equivalent measured by an automated refractor at the baseline visit and subsequent 6-month visits for 24 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 24 months. Only the data of the right eye were used.

MASKING

The subjects and the investigator were aware of the treatment assignments. Masking was difficult to achieve in a practice-based intervention, particularly when the lens treatments were visually very different. The investigator was not masked, as he was the only clinician available to dispense the lenses, perform the examinations, and address any issues that arose. Therefore, the primary and secondary outcome variables were measured by objective methods to minimize possible bias of the unmasked investigator (D.C.).

PROTOCOL DESIGN

At the preliminary visit, a comprehensive oculo-visual assessment was conducted to measure baseline readings and to ensure eligibility. Children were reexamined at 6-month intervals during 24 months. The 5 examinations conducted were denoted baseline (1), 2, 3, 4, and 5. These visits included cycloplegic autorefraction, cycloplegic subjective refraction, and A-scan ultrasonography to measure axial length. A questionnaire was administered to the child and parents to determine if 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, Tokyo, Japan) and cycloplegic subjective refraction (for determination of the distance prescription for the

spectacles) were determined 30 minutes after instillation of 2 drops of cyclopentolate, 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, Bozeman, Montana) following topical anesthesia with 1 drop of proparacaine, 0.5%.

Accommodation responses were measured using the Shin-Nippon SRW-5000 open-field autorefractor (Shin-Nippon, Tokyo, Japan). The viewing target was numbers on the Howell-Dwyer near phoria card at 33 cm (approximately 3 D accommodation demand), a print size of approximately 20/30. Near horizontal phoria was measured using the Howell-Dwyer near phoria card (Cyclopean Designs, Melbourne, Australia). The direction (esophoria or exophoria) and the magnitude (to the nearest 0.5Δ) of the heterophoria were recorded. The mean luminance of the accommodation target was 100 candelas/m² (Luminance meter LS-100; Konica Minolta Sensing Americas Inc, Ramsey, New Jersey). Both accommodation and phoria measurements were performed a minimum of 1 week after any new spectacles were dispensed.

INTERVENTION

The bifocals used in this trial were custom-made polycarbonate executive bifocals with a front base curve of +3.25 D supplied by Essilor (Etobicoke, Ontario, Canada). The single-vision lens was also made from polycarbonate and manufactured with the same front base curve as the bifocal lenses. There were 2 bifocal lens designs: an executive bifocal with a near-addition power of +1.50 D and an executive bifocal with a near-addition power of +1.50 D and 3Δ base-in prism in the reading segment of each lens (6Δ in total). The bifocal segment height was set 2 mm above the lower limbus to increase the likelihood that subjects used the near segment of the lens for near vision. The powers of near addition and prism chosen were based on outcomes of a previous study in Chinese Canadian children.²¹ 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.²¹ The addition of a 6Δ base-in prism to the near segment reduced the lens-induced exophoria to close to 0 in the prismatic bifocal group.²¹

AUXILIARY DATA

Parents and/or guardians completed a questionnaire regarding the child's vision habits and birth parents' refractive errors. Questions regarding how much time the children spent reading and outdoors were included. The number of years the subjects were myopic before they enrolled in the trial was estimated from the clinical records (myopic duration before trial) and analyzed as a covariate in the regression statistics. This information was included to test the hypothesis that the bifocal treatment would be more effective with a shorter duration of myopia.

STATISTICAL ANALYSIS

Sample size estimation is dependent on the expected difference between the means and the within-group variability of individual measurements.²³ Based on published data on the effect of multifocals on myopic progression in those with fast-progressing myopia,^{9,11} the following calculation was performed. The expected increase in myopia was 1.88 D during a 3-year period, and a statistically significant myopia-control treatment effect was considered to be slowing progression by half, ie, 0.94 D. With an assumed standard deviation of 0.75 D for the refractive error change, 28 subjects were needed for a 95% chance of finding a statistically significant difference

between 2 sample means, at a 2-sided .01 α level test of significance.²⁴ To allow for probable subject dropout (approximately 14% in Leung and Brown⁹ and approximately 15% in Edwards et al¹¹), the study aimed to recruit 50 children per treatment group.

Study results are expressed as mean (standard error). The analysis of the data followed the intent-to-treat approach, and we used the last progression information (ie, carry forward) method for subjects lost to follow-up.²⁵ 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 of myopic progression, such as age, sex, degree of myopia, axial length, initial myopic progression, myopic duration before trial, near phoria, lag of accommodation, total near work and total outdoor activities performed, and number of myopic parents. A backward stepwise model that included all covariates initially and then sequentially removed insignificant covariates ($P \geq .05$) was used. The significant covariates were then included in the analysis of covariance model for contrast among control and treatment groups. All of the covariates 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 accept allocation because the parents were disappointed that they were not assigned to a bifocal group. However, 6 of these 9 children, who were not officially in the study, were still examined annually in the practice. These 6 children had an average initial myopia of -3.27 D (0.67 D) and average 24-month myopic progression of -1.83 D (0.21 D). Two children in the bifocal group and 4 in the prismatic bifocal group were excluded because of anterior eye stinging and blurred vision following cycloplegia. The 24-month follow-up period was completed by 38 of the 41 children in the control single-vision lens group, all 48 children in the bifocal group, and 45 of the 46 children in the prismatic bifocal group. Of the 4 children who did not complete the wearer trial, 2 relocated with their families and 2 commenced orthokeratology treatment. Data from the questionnaire indicated that all children who completed the study wore the spectacles full time during waking hours. No adverse events were reported in the intervention group. Baseline characteristics of children in the 3 treatment groups are presented in **Table 2**. The total number of prescriptions (spectacles) upgraded for the 24-month period was 58 in the single-vision lens group, 44 in the bifocal lens group, and 35 in the prismatic bifocal lens group.

OUTCOMES

The average increase in myopia across the 24-month period was -1.55 D (0.12 D), -0.96 D (0.09 D), and -0.70 D (0.10 D) for the single-vision lens, bifocal lens,

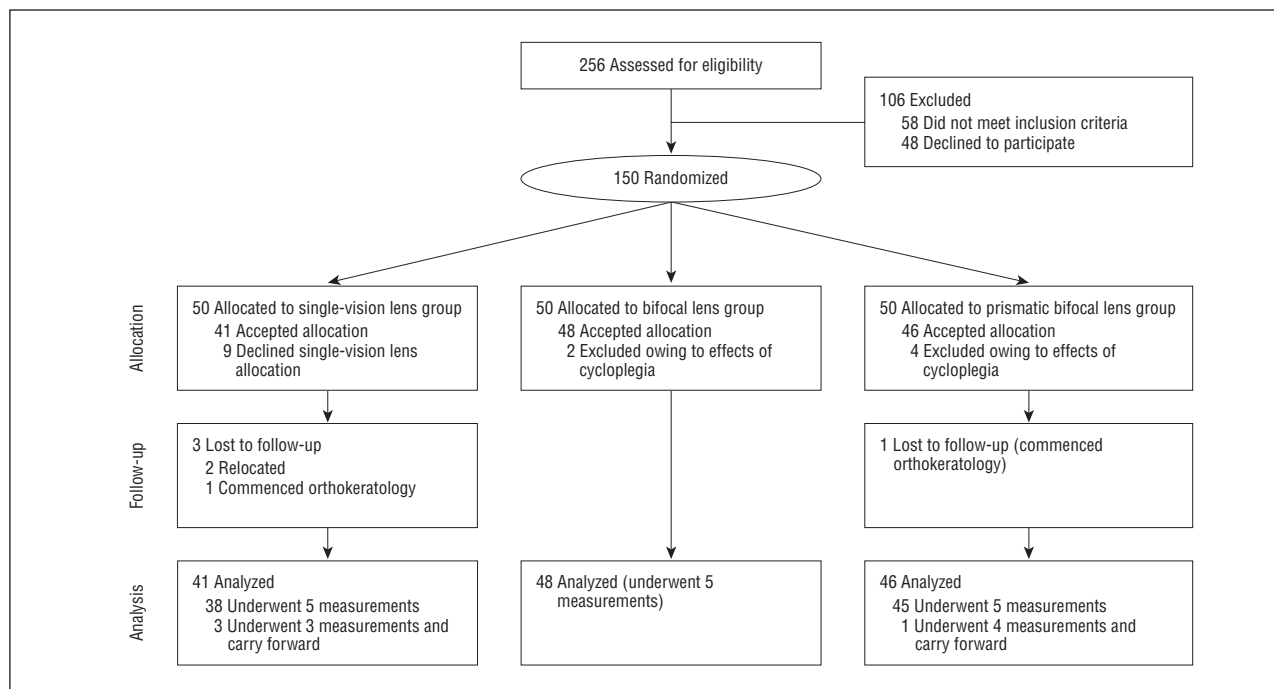


Figure 1. Flowchart of randomization, assignment, follow-up, and analysis of participants.

Table 2. Baseline Characteristics of Myopic Children by Treatment Group

Characteristic	Mean (SE) by Treatment Group		
	Single-Vision Lens (n=41)	Bifocal Lens (n=48)	Prismatic Bifocal Lens (n=46)
Age, y	10.34 (0.28)	10.12 (0.25)	10.42 (0.27)
Female sex, No. (%)	24 (59)	24 (50)	25 (54)
Spherical equivalent, D ^a	-2.92 (0.19)	-3.03 (0.16)	-3.27 (0.16)
Axial length, mm ^a	24.21 (0.12)	24.63 (0.11)	24.74 (0.12)
Progression in preceding year, D ^a	-1.06 (0.05)	-0.94 (0.05)	-1.02 (0.07)
Myopic duration before trial, y	1.73 (0.18)	2.04 (0.19)	2.14 (0.19)
Near phoria, Δ	-1.34 (0.84)	-3.08 (0.67)	-1.39 (0.63)
Lag of accommodation, D	0.98 (0.05)	1.17 (0.07)	1.04 (0.06)
Total near work, h/wk	19.64 (1.71)	22.00 (1.92)	23.24 (1.74)
Total outdoor activities, h/wk	4.83 (0.56)	4.55 (0.57)	4.85 (0.47)
No. of children by No. of myopic parents			
0	3	2	3
1	10	16	15
2	28	30	28

Abbreviations: D, diopter; Δ, prism diopters.

^aReported for right eyes.

and prismatic bifocal lens groups, respectively. There was a significant effect of lens design on the degree of myopic progression ($P < .001$). The magnitude of mean myopic progression was -0.59 D ($P < .001$) and -0.85 D ($P < .001$) less in the bifocal lens and prismatic bifocal lens groups, respectively, compared with the single-vision lens group. Mean myopic progression during the 24 months was 0.26 D less with the prismatic bifocal lens compared with the bifocal lens ($P = .03$). The multiple linear regression analysis found that only the covariates of age, with a coefficient of 0.11 (higher progression with lower age, $P < .001$), sex, with a coefficient of 0.29 (higher progression in boys, $P = .009$), and baseline myopic progression, with a coefficient of 0.36

(higher progression with higher baseline progression, $P = .01$), were significant in the model. The model-adjusted mean myopic progression after 24 months was -1.56 D (0.10 D), -0.96 D (0.09 D), and -0.70 D (0.09 D) in the single-vision lens, bifocal lens, and prismatic bifocal lens groups, respectively (Figure 2). Controlling for the significant covariates did not greatly change the mean myopic progression or the group differences compared with the unadjusted means.

The mean increase in axial length during the 24 months of the study was 0.62 mm (0.04 mm), 0.41 mm (0.04 mm), and 0.41 mm (0.05 mm) in the single-vision lens, bifocal lens, and prismatic bifocal lens groups, respectively. There was a significant effect of

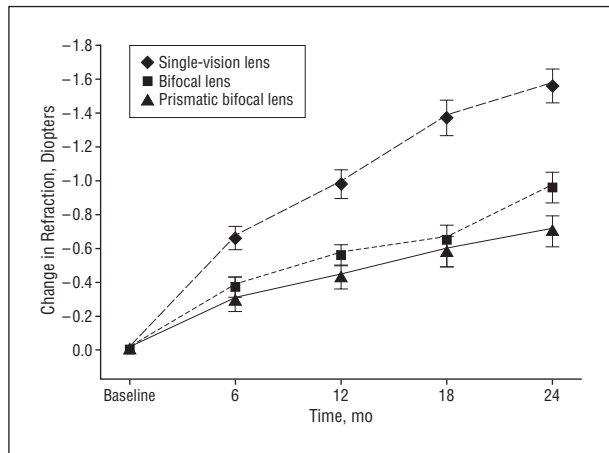


Figure 2. Model-adjusted mean change of refraction from baseline to 24 months.

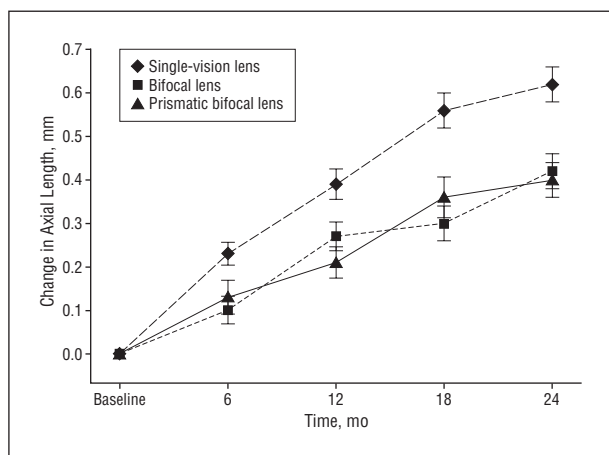


Figure 3. Model-adjusted mean change of axial length from baseline to 24 months.

lens design on the degree of axial elongation ($P = .001$). Axial elongation during this period was 0.21 mm less in both the bifocal lens and prismatic bifocal lens groups ($P < .005$ for both comparisons). The multiple linear regression analysis found that only the covariate of age, with a coefficient of -0.064 (higher axial elongation with lower age, $P < .001$), was significant in the model. The model-adjusted mean increase in axial length after 24 months was 0.62 mm (0.04 mm), 0.42 mm (0.04 mm), and 0.40 mm (0.04 mm) in the single-vision lens, bifocal lens, and prismatic bifocal lens groups, respectively (**Figure 3**). Adjusting to a common age did not greatly change the mean increase in axial length or the group differences compared with the unadjusted means. Myopic progression was significantly correlated with change in axial length (Pearson correlation $r = 0.62$ for single-vision lens; $r = 0.68$ for bifocal lens; and $r = 0.62$ for prismatic bifocal lens; $P < .001$).

ANCILLARY ANALYSES

Baseline characteristics were tested for possible interaction with the treatment effects. A median split method

Table 3. Interaction Analysis of Covariates and Treatment

Covariate	P Value
Age	.38
Sex	.90
Baseline refraction	.32
Baseline axial length	.27
Baseline myopic progression	.61
Myopic duration before trial	.34
Near phoria	.55
Lag of accommodation	.09 ^a
Close work	.53
Outdoor activities	.40
Parental myopia	.30

^aIndicated some evidence of significance.

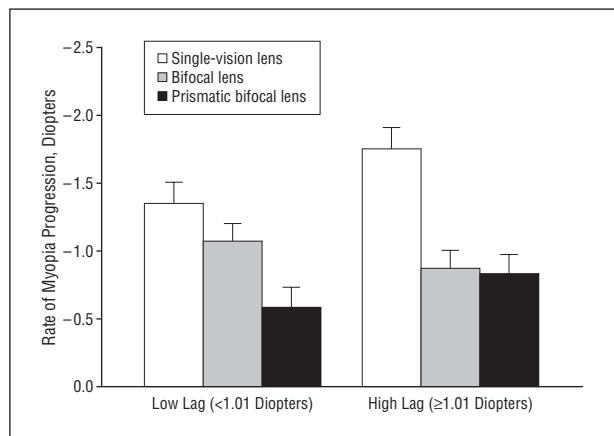


Figure 4. Rate of myopia progression in children with high and low lags of accommodation. Both bifocal groups had significantly reduced myopia progression in children with high lags compared with single-vision lenses ($P < .001$). For children with low lags, those wearing prismatic bifocal lenses had a lower rate of myopia progression compared with those wearing single-vision lenses ($P = .001$) and bifocal lenses ($P = .02$). Bifocal lenses did not significantly reduce myopia progression compared with single-vision lenses ($P = .18$).

by number of children was used to divide the characteristics: age (<10.33 years vs ≥ 10.33 years), baseline refraction (<-3.00 D vs ≥ -3.00 D), baseline axial length (<24.52 mm vs ≥ 24.52 mm), initial myopic progression (<1.00 D vs ≥ 1.00 D), myopic duration before trial (<2 years vs ≥ 2 years), lag of accommodation (<1.01 D vs ≥ 1.01 D), hours of close work conducted per week (<18.5 hours vs ≥ 18.5 hours), hours of outdoor activities per week (<4.5 hours vs ≥ 4.5 hours), and parental myopia (2 myopic parents vs 0 or 1 myopic parents). Near phoria was divided into 3 groups: orthophoria (-1.5Δ to $+1.5\Delta$), esophoria ($>+1.5\Delta$), and exophoria ($<-1.5\Delta$). Of all the covariates tested in the interaction analysis, only lag of accommodation showed some evidence of interaction with the treatment effect ($P = .09$) (**Table 3**). For that reason and given the data of other studies,²⁶ the lag of accommodation was further analyzed by dividing the children into high- and low-lag subgroups.

The rate of myopic progression (per 2 years) for high- and low-accommodation lag subgroups has been plotted in **Figure 4**. For children with high lags of accommodation, the mean rate of myopic progression

was -1.76 D (0.18 D) in the single-vision lens group ($n=20$), -0.88 D ($0.0.11$ D) in the bifocal lens group ($n=23$), and -0.84 D (0.14 D) in the prismatic bifocal lens group ($n=24$). The effect of treatment was statistically significant ($P < .001$) and both of the bifocal lens types significantly reduced the myopic progression compared with single-vision lenses ($P < .001$ for both bifocal groups). In contrast, there was no difference between the effect of the 2 bifocal lens types on myopic progression ($P = .84$).

For children with low lags of accommodation, the mean rate of myopic progression was -1.35 D (0.15 D) in the single-vision lens group ($n=21$), -1.07 D (0.13 D) in the bifocal lens group ($n=25$), and -0.58 D (0.15 D) in the prismatic bifocal lens group ($n=22$). The effect of treatment was statistically significant ($P = .001$); those with prismatic bifocals had a lower rate of myopic progression than those with single-vision lenses ($P = .001$) and bifocal lenses ($P = .02$). For children with low lags of accommodation, bifocal lenses did not significantly reduce myopic progression compared with single-vision lenses ($P = .18$).

The mean rate of myopic progression based on near phoria status has been plotted as a function of lens treatment (**Figure 5**). For children with baseline esophoria, the mean rate of myopic progression in 2 years was -1.19 D (0.26 D) with single-vision lenses ($n=8$), -0.84 D (0.14 D) with bifocal lenses ($n=12$), and -0.68 D (0.24 D) with prismatic bifocal lenses ($n=9$). Bifocal lenses and prismatic bifocal lenses did not significantly reduce myopic progression in esophoric children ($P = .27$); however, this is likely due to a lack of power as a result of the small number (total 29) of esophoric children in this study. For children with orthophoria, the mean rate of myopic progression in 2 years was -1.58 D (0.16 D) with single-vision lenses ($n=20$), -1.10 D (0.11 D) with bifocal lenses ($n=25$), and -0.76 D (0.13 D) with prismatic bifocal lenses ($n=19$). Bifocal lenses ($P = .01$) and prismatic bifocal lenses ($P < .001$) significantly inhibited myopic progression in the orthophoric children; there was statistically no difference between the 2 bifocal lens types ($P = .08$). For children with exophoria, the mean rate of myopic progression in 2 years was -1.73 D (0.24 D) with single-vision lenses ($n=13$), -0.80 D (0.22 D) with bifocal lenses ($n=11$), and -0.65 D (0.19 D) with prismatic bifocal lenses ($n=18$). Bifocal lenses ($P = .007$) and prismatic bifocal lenses ($P = .002$) significantly inhibited myopic progression in the exophoric children; there was statistically no difference between the 2 bifocal lens types ($P = .64$). Collectively, there was no consistent interaction of phoria with treatment ($P = .55$); the 2 bifocal lens types reduced myopic progression regardless of the near phoria position.

COMMENT

Both bifocals and prismatic bifocals were found to significantly control the rate of myopic progression compared with single-vision lenses. Prismatic bifocals significantly slowed myopic progression compared with

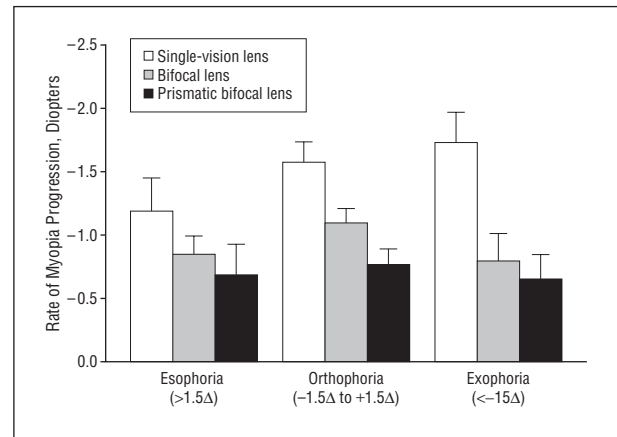


Figure 5. Rate of myopia progression based on near phoria status. Neither bifocal nor prismatic bifocal lenses were significant at reducing myopia progression in esophoric children ($P = .27$). For those with orthophoria, bifocal ($P = .01$) and prismatic bifocal ($P < .001$) lenses significantly inhibited myopic progression compared with single-vision lenses, but there was no difference between the 2 bifocal groups ($P = .08$). For those with exophoria, bifocal ($P = .007$) and prismatic bifocal ($P = .002$) lenses significantly inhibited myopic progression compared with single-vision lenses, but there was no difference between the 2 bifocal groups ($P = .64$). Δ Indicates prism diopters.

standard bifocals. Therefore, adding a base-in prism to the bifocal lens design improved the bifocal treatment effect. However, the prism effect was small and was not demonstrated in the outcome measure of axial length. For that reason, prismatic bifocals should not be prescribed for all children with myopia.

Our study recruited children with myopic progression of at least 0.50 D in the preceding year. This resulted in a mean initial myopic progression rate of about -1 D per year at baseline for each group. Such an inclusion criterion would avoid the recruiting of children with low rates of myopic progression and allow the treatment effect of bifocals to be more effectively evaluated. It is also possible that children with lower annual progression rates are closer to the end of their myopia development process and that treatment would be ineffective or less effective in such a child. The value of using this selection criterion to identify children with high myopic progression is confirmed: the 24-month rate of myopic progression of -1.55 D in the single-vision lens group (control group) is greater than those of previous myopia-control studies.⁸⁻¹³ Our study supports the findings of Leung and Brown,⁹ who used a similar inclusion criterion; progressive lenses are effective at inhibiting myopic progression for myopic children with high myopic progression.

The differential analysis for children with high and low accommodative lags showed that interaction existed between the lag and treatment effect. Standard bifocals were only effective for children with high lags, a finding that agrees with the reported outcomes of the Correction of Myopia Evaluation Trial.²⁶ For children with low accommodative lags, prismatic bifocals produced the superior control effect. We speculate that for children with high lags, reducing the accommodation lags with standard bifocals is adequate to control myopic progression. In contrast, for children with low lags, bifocals are more effective if the convergence

demand and lens-induced exophoria are also reduced; such a state of oculomotor equilibrium could be achieved with the addition of base-in prisms. Given that these ancillary analyses are based on a subgroup with a smaller number of subjects, the conclusion for prismatic bifocals should be further investigated.

This clinical trial measured near phoria and lag of accommodation for a minimum of 1 week after any new spectacles were dispensed to give the children enough time to adjust to the new prescription (vergence and accommodative adaptation). As a result, the number of children measured with esophoria in this study should be less than those in studies that measured phoria right after the subjective refraction procedure. Our study did not find that bifocal lenses were more effective in children with esophoria, which may be related to the fact that a large portion of esophoric children will have significant lens-induced exophoria with the bifocals in place because of the high response accommodation convergence to accommodation ratio usually found in this group of children.²⁰ The oculomotor interactive theory¹⁶ has proposed that a disrupted oculomotor equilibrium will reduce the positive-lens treatment effect. This also explains why previous studies of bifocals in esophoric children do not show a strong myopia-control effect.^{10,17} The Correction of Myopia Evaluation Trial²⁶ did not show that esophoria alone had an effect. We speculate that in prescribing bifocals for myopia control, the state of lens-induced near phoria instead of baseline near phoria plays a role in determining success, because this uncontrolled phoria disrupts the oculomotor equilibrium.

It is apparent that the bifocal spectacles will only work in those with rapidly progressing myopia. Although living in urban centers in East Asian 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 myopic progression. Therefore, the findings of this study could reasonably be generalized to those with fast-progressing myopia irrespective of ethnicity, though this clearly has to be tested.

Of the 200 clinical records of myopic children reviewed in the study, 107 had at least 0.50-D myopic progression in the preceding year. The proportion of myopic children in this practice with fast myopic progression, therefore qualifying for bifocal treatment, was estimated to be about 54%. Therefore, the bifocal treatment could benefit a large number of myopic children. To date, there has been no consensus on what magnitude of myopic reduction constitutes a clinically significant control effect. In our opinion, the treatment effect of bifocal and prismatic bifocal lenses of 38% and 55%, respectively, in this study, though greater than those of others,^{6-8,10} is still modest. Whether or not the effect tapers off will decide clinical significance. If the treatment effects continued over time, then the treatment could have a significant role in preventing the development of very high pathologic myopia. Given that the pathologic outcomes seem to rise almost exponentially with the degree of high myopia,

this could be of considerable clinical benefit. Even the benefit of 1-D myopia reduction could be useful. Therefore, the long-term effect of the treatment needs to be more rigorously analyzed. At the current stage, bifocal spectacles, as a myopia-control treatment, should be offered to myopic children with caution in clinical practice. As has been suggested,¹⁰ the modest benefit of bifocals should be weighed against factors like the increased cost of the lenses, poor cosmetic appearance, and attitude of the parent and child.

The limitations of this study included its atypical randomization scheme used to assign subjects to treatment groups; there was a possibility of the paper slips being taken from the container in a nonrandomized fashion. That the investigator was not masked could introduce potential bias and is not considered best practice in research. Future clinical trials should consider a more standardized randomization method, such as computerized random-number generation, and use masked investigators. In conclusion, bifocal lenses can moderately slow myopic progression in children with high rates of myopic progression after 24 months.

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1815 Version of Phacoemulsification?

Francis B. Shaw, Esq, formerly of Easton, Pennsylvania, having for upwards of 2 years been deprived of sight by a cataract . . . submitted himself to an operation on one of his eyes, performed by Dr Physick [Dr Philip Syng Physick is often referred to as the father of American ophthalmology as well as the father of American surgery¹], which succeeded in an instantaneous and wonderful manner.

The method of operation is of his own invention. . . . The advantages of it are; that it is much less difficult than that by depression or extraction, is neither tedious, painful or hazardous, is less liable to be succeeded by violent inflammation, and, in certainty and celerity, is in every respect preferable to Dr Adam's method of puncturing the capsule, so much in vogue at present, but which in this city has not been uniformly successful.

The patient . . . was 3 times very skillfully operated upon by Dr Dorsey, according to Dr Adam's method above mentioned, without experiencing the least relief, or having the smallest prospect of being restored to his sight.

Under the gloomy reflections incident to his situation, an idea suddenly struck him of effecting a complete cure, by drawing away the cataract and completely emptying the capsule of the lens. . . .

A detailed account of his plan was communicated to Dr Physick . . . and after much urgent solicitation, he prevailed on that gentleman to attempt it, very freely offering himself as the first subject of the experiment. Dr Physick . . . with his usual skill and promptitude, completely removed every vestige of the cataract, and the patient was once more restored to sight, which gave him the more gratification, as it was owing to his own ingenuity and perseverance . . . and as far as he has indulged himself, his sight is as completely restored as previous to the first appearance of the disease.

This invention, which deserves to be placed on a level with Dr Jenner's great discovery of vaccination, will form a new era in the annals of surgery, and will no doubt be the means of restoring that most useful of our faculties to many who now suppose themselves doomed to a life of darkness. Mr Shaw was fully of opinion that it may be advantageously used in almost every state of the cataract. He intends to procure from the proper authority a patent for his invention, and is justly entitled to all the advantage which his useful and ingenious discovery merits. . . .

Source: Interesting surgical operation. *Independent Chronicle.* 1815;47(3548).

Courtesy of: Charles E. Letocha, MD, and Daniel M. Albert, MD, MS.

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