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Spectacle Lenses Designed to Reduce Progression of Myopia: 12-Month Results

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Abstract

Purpose—To report the results of 12-month wear of three novel spectacle lens designs intended to reduce peripheral hyperopic defocus and one standard design control lens and their effect on the progression of myopia in Chinese children aged 6 to 16 years.

Methods—Chinese children ($n = 210$) with myopia (-0.75 D to -3.50 D sphere, cylinder -1.50 D) were randomized to one of four groups wearing either one of three novel spectacle lens designs (types I, II, or III) or conventional, single-vision spectacle lenses. Data were collected at 6 and 12 months. Primary and secondary outcome measures were the changes in central cycloplegic auto-refraction and eye axial length, respectively. Peripheral refraction along the horizontal meridian (nasal and temporal) was taken at baseline with and without spectacle lenses. Multivariate linear regression was used to adjust analyses for important covariates.

Results—Progression in eyes wearing control spectacle lenses at 6 and 12 months was -0.55 D $\pm$ 0.35 D and -0.78 ± 0.50 D, respectively. For the entire group, no statistically significant differences were observed in the rates of progression with the novel designs in comparison to control spectacle lenses. However, in younger children (6 to 12 years) with parental history of myopia ($n = 100$), there was significantly less progression (-0.68 D $\pm$ 0.47 D vs. -0.97 D $\pm$ 0.48 D) with lens type III compared with control spectacles (mean difference, 0.29 D, std error, 0.11, $p = 0.038$).

Conclusions—There were no statistically significant differences in the rate of progression of myopia between the control and novel lens wearing eyes for the age group 6 to 16 years. The finding of reduced progression of myopia with type III lens design in younger children with parental myopia needs to be validated in a more targeted study.

Keywords

myopia; spectacle lenses; peripheral refractive errors; parental myopia; children

Myopia is the main global cause of distance vision impairment and the prevalence of the condition is high in many parts of the world.¹⁻⁵ Additionally, high myopia is associated with a higher risk of serious and sight threatening ocular conditions such as cataract, glaucoma, and retinal detachment.^{3,6,7} As a result, there is a great deal of interest in analyzing if there are interventions that can control or limit the progression of myopia. However, previous efforts to curb the progression of myopia with optical and pharmaceutical approaches have produced very limited benefits.⁸⁻¹⁵

More recently, it has been reported that the peripheral retinal image profile plays a significant role in emmetropization. It was demonstrated in infant monkey eyes that peripheral form deprivation can produce axial myopia, even in the presence of unrestricted central vision, and it was further shown that the peripheral retina in isolation can regulate emmetropizing responses.^{16,17}

Human myopic eyes often exhibit relative hyperopia in the periphery, and it has been suggested that the hyperopic defocus at the retinal periphery may act as a signal for increased eye growth.^{16,18,19} It has also been proposed that optical interventions designed to correct myopia should consider the focal state of both central and peripheral retina.¹⁶ In this regard, it was suggested that it may be possible to slow the progression of myopia by altering the curvature of the image shell at the same time as the central refractive error is corrected, thereby either partly or fully correcting any hyperopic defocus at the periphery or even inducing peripheral myopic defocus.²⁰

We present data on the progression of myopia with novel spectacle lens designs that manipulate the curvature of the peripheral image shell while maintaining clear central vision. The location and precise amount of peripheral image shell manipulation required to slow myopia progression is presently unknown. Three investigational spectacle lens designs were used in this study that vary both in the size of the central optic zone and the amount of relative positive power in the periphery. The clinical trial was conducted for 1 year and the results are presented.

METHODS

Study Population

A total of 210 male and female Chinese children aged 6 to 16 years were recruited into the study, which was conducted at the Zhongshan Ophthalmic Center, Sun Yet Sen University, People's Republic of China from October 2007 until January 2009. The study was intended to be 2 years in duration but was discontinued after 12 months because the results of the study found that the progression of myopia was significantly less in the older children (>12 years of age) compared with younger children (<12 years of age). To determine the efficacy during a period of 2 or 3 years, one would need to monitor children who are likely to be progressing during this period (i.e., younger children) and we had not accounted for this in

our original sample size. Eligible children were bilaterally myopic (spherical component range from -0.75 D to -3.50 D inclusive) with astigmatism not exceeding -1.50 D and a maximum of 1.00 D of anisometropia. All had vision correctable to 6/9.5 or better in each eye, had ocular findings considered to be normal, and were willing to wear the study spectacles and adhere to the protocol schedule. The study was approved by the Institutional Ethics Committee of Zhongshan Ophthalmic Centre and adhered to the Declaration of Helsinki for experimentation on human subjects. The study procedures were conducted in accordance to International Conference on Harmonization and World Health Organization Good Clinical Practice Standards guidelines and registered with the China Clinical Trial Registry (ChiCTR-TRC-00000029).

Study Design

This was a prospective, controlled, double-masked, and randomized clinical study. Potentially eligible children attended a screening/baseline visit and, on successful enrolment, were randomly assigned to one of four treatment groups, each group wearing a different spectacle lens design. The four designs (3 novel and one standard) were coded A, B, C, and D and the randomization scheme generated using the web site [randomization.com](http://www.randomization.com) (<http://www.randomization.com>). Subjects were randomized to a single treatment using the method of randomly permuted blocks of a constant size of 20. Access to the study randomization table was restricted to the study optical dispenser who allocated the randomization and coordinated with the laboratory for the delivery of the spectacles. The dispenser was masked to the lens design. Also, the participants and investigators were masked to the spectacle lenses used in the study. At each visit, children were first seen by the dispenser for all fitting and frame adjustments. All participant queries and problems if any were reported to the optical dispenser who attempted to resolve any lens and frame-related queries. Refractive and ocular axial length data were collected at baseline and at 6 and 12 months. Telephone questionnaires were performed at 1 week, and then at monthly intervals by study assistants who were masked. All visits took place in the IER International Clinical Research Center located in Zhongshan Ophthalmic Center, Guangzhou.

Investigational Lenses

The novel spectacle lens designs (types I, II, and III) were intended to reduce peripheral hyperopic defocus. The fourth lens type was a conventional, single-vision design and was included as a control. All spectacle lenses were manufactured by Carl Zeiss Vision, Adelaide, Australia with designs jointly developed by Carl Zeiss Vision and Vision CRC lens designers.

Lens type I was a rotationally symmetrical design that had a clear central aperture of 20 mm diameter. A progressively ramped zone of increasing positive power surrounded the central aperture with a maximum spherical equivalent of $+1.0$ D relative peripheral power (i.e., power increase relative to central power) achieved 25 mm from its axis.

Lens type II, also a rotationally symmetrical design, featured a clear central aperture of 14 mm diameter with a more steeply ramped zone of increasing positive power in comparison

to type I. A maximum spherical equivalent of +2.00 D relative peripheral power was achieved 25 mm from its axis.

Lens type III was an asymmetric design. Its clear central aperture extended approximately 10 mm either side of center along the horizontal meridian and a similar distance inferiorly to provide clear vision for convergence and down-gaze. The design was optimized to achieve reduced astigmatism in the horizontal meridian while attaining a positive additional peripheral power of 1.9 D 25 mm from the axis in that meridian. Being an asymmetric design, different lens blanks for right and left eyes were required.

Lenses were fitted to spectacle frames that ranged in eye-size from 45 mm to 55 mm with depths from 27 mm to 33 mm. As would be expected, the older children were generally fitted with frames that were larger in size in comparison with those fitted to the younger children.

Procedures

The primary outcome measure was a change in cycloplegic auto refraction assessed with an open-field autorefractor (Shin-Nippon NVision-K5001). Cycloplegia in each eye was obtained with 2 drops of tropicamide 1% preceded by 1 drop of a topical anesthetic (proparacaine). Five autorefraction measurements were taken on each eye and the average were recorded as the result. The change in axial length from baseline, as measured by partial coherence interferometry (Carl Zeiss IOLMaster), was an additional outcome measure.

Peripheral refractions of subjects' right eyes were performed without and with the spectacles using the Shin Nippon K5001 autorefractor, using head-turn for off-axis measurements, so the eyes were always in the primary position.

A modified, "bench-style" chin-rest allowed a greater range of head turn than was possible with the original, standard cup-style chin-rest, and a custom-developed, automated, computer-driven system was used both for fixation target sequencing and data recording. Targets for fixation were provided by an array of 1 mW lasers projecting on to a wall 2.5 m from the instrument. The upper instrument cowling was replaced with a more compact design which, along with the modified chin-rest, allowed fixation of the measured eye out to 40°. For peripheral refraction with spectacles, small triangular stickers were placed below the optical centers of the spectacle lenses to aid in facial alignment at the various off-axis positions. The square reticule mark of the instrument's LED screen was aligned with the pupil center for off axis measurements. For each child, one measurement was taken at each fixation point, and the sequence repeated five times.

Lenses were dispensed based on cycloplegic subjective refraction at baseline and also subsequently if the spectacle prescription was changed. At the follow-up visits, children received new lenses if their visual acuity had dropped by more than a full line of logMAR chart letters, if there had been a change in refractive error of -0.50 D or greater, or at the clinician's discretion (e.g., if these criteria did not apply but the child had visual complaints).

Children were requested to wear their spectacles for all waking hours. Compliance was monitored by telephone questionnaires that were conducted at 1 week and then at monthly

intervals except for 6 and 12 months when this information was gathered during the participant visit at the clinic. The duration of lens wearing time was obtained separately from both the participant and a parent or guardian.

Statistical Analysis

Study Hypotheses—The null hypothesis was that the progression of myopia for each of the groups wearing one of the three novel lens design types would not be different from that of the control single-vision spectacle lens wearing group.

Sample Size Calculation—Assuming an annual progression of refractive error in the control arm of at least $0.5 \text{ D} \pm 0.4 \text{ D}$, approximately 50 children were required in each study arm to demonstrate a statistically significant difference of at least 50% reduction after adjusting for a 20% drop-out rate. However, to accommodate an anticipated greater drop-out rate in the group with the most radical lens design (type II), an additional 10 children were enrolled.

Statistical Analysis Methods—Children who completed the 12-month study treatment period were included in the analysis dataset. Reasons for children discontinued are reported in results. Data were summarized as means $\pm$ standard deviations for variables measured on a continuous scale. At the baseline visit, the four study groups were compared for differences in the outcome variables and demographic factors such as age, gender, phoria, and parental myopia.

Progression of myopia at each study visit was computed for each subject-eye and averaged between right and left eyes for each subject and for each study group. The effect of demographic factors on the progression of myopia was assessed. Demographic factors that were associated with progression were included in the overall analysis to compare the four study groups. Myopia progression was compared among the four study groups using linear mixed models to account for the within-subject inter-eye correlation. Estimated means and 95% confidence limits of myopia progression for each study group were also computed. The overall level of significance for the entire sample for each outcome variable was set at 5%. After the overall analysis, all post hoc multiple comparisons were adjusted using Bonferroni correction. For subgroup analysis, the overall level of significance was also set at 5% and after an overall analysis, all post hoc multiple comparisons were adjusted using Bonferroni correction. Similarly, central and peripheral refractive errors with correction were compared among the study groups using linear mixed models and if significant at the 5% level, post hoc multiple comparisons were adjusted using Bonferroni correction.

RESULTS

Table 1 details the biometric data of the 210 subjects that were enrolled in the study. Mean age was 11.0 ± 2.3 years (range, 6 to 16 years), 52.4% were men and all children had best-corrected visual acuity of 6/9.5 or better in each eye.

The subjects were randomized into four groups, and there were no differences between the groups in terms of refractive error or axial length ($p > 0.05$). Of the 210 children who were

enrolled in the study, 201 completed the 12-month visit. Fig. 1 details the flow of the participants during the study. Of the remaining nine, seven were lost to follow-up at 12 months (two wearers of type I, one each of type II and control, and three wearers of type III). One child wearing type II withdrew complaining of headaches and dizziness and the remaining subject, who had been assigned to type III lenses, withdrew consent. The anticipated high drop-out rate of wearers of type II lenses did not eventuate.

At a telephone questionnaire undertaken at 1-week postdispensing, 10 children reported that they were aware of blurred side vision (two were assigned to lens type I, two to lens type II, five to lens type III, and one wearing control lenses). By 1-month post-dispensing, only one of these subjects continued to notice the effect (lens type I). At 1 week, three children reported visual distortion (one assigned to lens type I and the other two wearing control lenses) when looking down but there were no similar reports at 1 month. One child complained of dizziness at 1 week with lens type II but did not report this at the 1-month telephone questionnaire. The study also monitored likely adverse events with the use of these spectacles such as unexpected falls and related injuries. Only two falls were reported, both with lens type II and both occurred during the first weeks of wear and while the children were running. In both cases injuries were minor. At 12 months of lens wear, both the parents and children reported an average spectacle wearing time of 11.3 ± 1.5 h/d with no differences between the groups.

Change in Spherical Equivalent Refractive Error: All Study Subjects

Fig. 2 details the change in spherical equivalent refractive error for each of the groups at 6 and 12 months. For the control group (wearing single-vision spectacle lenses), the mean spherical equivalent myopic progression at 6 months was $-0.55 \text{ D} \pm 0.35 \text{ D}$ and $-0.78 \text{ D} \pm 0.50 \text{ D}$ at 12 months.

At 6 months, there was a significant difference among the four groups ($p = 0.032$). Eyes wearing the type III design lens showed least progression ($-0.47 \text{ D} \pm 0.30 \text{ D}$), and eyes wearing type II design showed the most progression ($-0.60 \text{ D} \pm 0.34 \text{ D}$); however, the differences in comparison with control lens wearing eyes were not statistically significant ($p = 0.811$ and 0.559). No differences were seen among the four groups at 12 months ($p = 0.262$).

Change in Axial Length: All Study Subjects

Fig. 3 details the change in axial length for each of the groups at 6 and 12 months. The change for the control lens wearing group was $0.25 \text{ mm} \pm 0.13 \text{ mm}$ at 6 months and $0.36 \text{ mm} \pm 0.22 \text{ mm}$ at 12 months. No differences in axial length increase were seen for eyes wearing lens types I, II, or III in comparison with control lens wearing eyes at both 6 and 12 months ($p = 0.262$ and 0.686).

Progression of Myopia with Age

A linear mixed model analysis showed a strong association between age and myopia progression ($p < 0.001$). An analysis comparing the 6- to 12 year olds with the older children, i.e., 13 to 16 year olds (Table 2) showed that the rate of progression was

significantly greater in the younger children ($p < 0.001$). As it was determined from these data that progression was more likely and more rapid in the younger age group, we analyzed the younger age group separately to determine the differences, if any, between the four treatment groups.

Peripheral Refraction: All Study Subjects

Fig. 4 shows the spherical equivalent (M) values at baseline and with spectacles (corrected) for the four groups at each of the central and peripheral angles that were assessed. At baseline, M values for peripheral angles were less myopic (relative hyperopia) in comparison with central M and relative hyperopia increased with increasing eccentricity. When wearing the correcting lenses, the peripheral refraction profiles were similar for all spectacle groups. An absolute hyperopic defocus was found for all peripheral angles except for 20° in the nasal field where there were no differences between the profiles for eyes with type I and control lenses.

In the temporal field, the magnitude of hyperopic defocus seen in eyes with lens types II was lower (0.25 D , $p < 0.05$) in comparison with controls, especially at 30° and 40° eccentricities. In the nasal field, lens type II showed less hyperopic defocus ($>0.25\text{ D}$, $p < 0.05$) in comparison with the other lens types at all angles.

The mean J_0 values changed from positive (on-axis) to negative (off-axis) values for all lens types, and increased with increasing eccentricity (up to -1.50 D at 40°). They were not however different between the four groups with and without correction. Variation in J_{45} values was very small across the peripheral field angles measured. A small asymmetry was observed between the nasal and temporal fields with the temporal field values showing negative sign. There were no differences among the four groups with and without correction.

Change in Spherical Equivalent Refractive Error: 6- to 12-Year-Old Children

In the younger children, the change in spherical equivalent with the control lens was $-0.61\text{ D} \pm 0.35\text{ D}$ at 6 months and $-0.90\text{ D} \pm 0.48\text{ D}$ after 12 months of spectacle wear. Similar to the trend observed for the entire group, at 6 months, there was a significant difference among the four groups ($p = 0.013$). Eyes wearing the type III design lens showed least progression ($-0.52\text{ D} \pm 0.35\text{ D}$) and eyes wearing type II design showed the most progression but the differences in comparison with control lens wearing eyes were not significant ($p = 0.704$ and 0.633). No differences were seen among the four groups at 12 months ($p = 0.093$). Fig. 5 records the change in mean spherical equivalent for each of the groups at 6 and 12 months.

Change in Axial Length: 6- to 12-Year-Old Children

Fig. 6 records the change in axial length for each of the groups at 6 and 12 months. The change in axial length for the control lens wearing group was $0.29\text{ mm} \pm 0.12\text{ mm}$ at 6 months and increased to $0.43\text{ mm} \pm 0.20\text{ mm}$ at 12 months. There were no differences among the four groups at both 6 and 12 months ($p = 0.174$ and 0.385).

Because parental myopia and gender were identified as strong risk factors, we assessed the difference in progression of myopia in children with these risk factors. Table 3 details the progression in eyes of children with a history of parental myopia vs. those with no history of parental myopia. In children with no parental myopia, the largest difference in progression is 0.24 D between the control lens and type III lens with the control lens wearing eyes showing the least progression. However, there were no significant differences among the groups. In eyes where there was parental history, the largest difference in progression between lens types was 0.29 D with lens type III showing significantly less myopia progression in comparison with control ($-0.68 \text{ D} \pm 0.47 \text{ D}$ vs. $-0.97 \text{ D} \pm 0.48 \text{ D}$, $p = 0.038$; Table 3).

Peripheral Refraction: 6- to 12-Year-Old Children

Fig. 7 shows the spherical equivalent (M) values without and with study spectacles at each of the central and peripheral angles for the four groups. At baseline, as with all subjects, relative hyperopia was seen in both nasal and temporal fields, and there were no differences in the magnitude of relative defocus between eyes assigned to various groups.

When spectacle lenses were worn, absolute hyperopic defocus was seen at all peripheral angles except 20° nasally. When differences among groups were assessed, the magnitude of hyperopic defocus seen with lens type II was less in comparison with other groups nasally (0.25 D at 30° , $p < 0.05$).

As with the results observed for the entire group, mean J_0 values changed from positive (on-axis) to negative (off-axis) for all lens types, increased with increasing eccentricity and were not different between the four groups with and without correction. Also, variation in J_{45} values was very small across the peripheral field angles measured, and there were no differences between the four groups with and without correction.

DISCUSSION

At both 6 and 12 months, there were no statistically significant differences in the rates of progression of myopia between eyes wearing novel spectacles to those wearing standard single vision spectacles. But within a subgroup of younger children with parental history of myopia (49% of entire study population and 68% of the younger subgroup), a reduced progression of 0.29 D was found with eyes wearing a novel rotationally asymmetric lens (type III) in comparison with control lenses and was statistically significant for this subgroup of children ($p = 0.038$). The results are of interest but need to be validated in a more targeted study. The type III design limited astigmatism aberration along the horizontal meridian (was 0.5 D along the horizontal across the whole lens surface compared with 1.57 D with type II lenses) and also permitted the central clear zone to extend slightly inferiorly to allow for some degree of down-gaze such that astigmatism is limited in a corridor extending downward.

Progressive addition lenses (PALs) were used in an attempt to reduce myopic progression.^{8–12} Gwiazda et al. reported a 0.18 D reduction in progression of myopia at the end of 1 year with a conventional PAL having $+2.00 \text{ D}$ addition and fitted 4 mm higher than the recommended value (to encourage viewing through the near add) in comparison with

single-vision lenses and a more recent study reported a 0.30 D reduced progression with juvenile use adapted +1.50 D addition Myopia Control (MC) 1 PALs during the first 18 months of the cross-over design trial.^{11,12} Also, a greater effect in terms of retardation of progression of myopia was reported with PALs and bifocal lenses in children exhibiting near esophoria.^{8,9,21} For example, Edwards et al.⁹ reported retardation of myopia progression of 0.37 D during 2 years in an esophoric subgroup of 7- to 10.5-year-old children treated with MC PALs and Yang et al.⁸ reported a retardation of myopia progression of 0.77 D over 2 years with MC PALs. A small reduction of myopia progression of 0.20 D over 3 years was observed in near esophores with conventional PALs,¹¹ and this reduction increased to 0.64 D in esophoric subjects who also had large accommodative lag.²² The prevalence of esophoria in myopic eyes was reported to be 14.8%.²³ Given the small number of esophores, the benefit of the greater treatment effect with PALs remains limited.^{23,24}

In this study, manipulation of the peripheral image shell was not optimized for individual eyes. All lenses had a clear central aperture that enabled clear distance central vision while the amount of additional positive power required in the periphery was chosen according to (a) the average amount of hyperopic defocus found in myopic populations,^{25,26} and (b) subjective tolerance for the magnitude of positive power in the lens periphery as determined from non-dispensing trials where subjects trialed spectacle lenses with varying amounts of positive power/design for 8 h/d per lens design.

Peripheral refraction was conducted to determine if there was evidence of a decrease in peripheral hyperopic defocus with the novel lens designs and whether any decrease was correlated with the progression of myopia. However, results of peripheral refraction suggest that, except for a reduction in the temporal field (0.84 D for type II and 0.49 D for type III in younger children), there were no consistent differences in the amount of hyperopic defocus with the different lens designs. However, technical issues may have limited our ability to detect differences in the peripheral refractive errors measured through the treatment lenses. One such issue is the limited range of field angles that could be measured through the lens compared with the extent of the lens.

Owing to restrictions imposed by the aperture of the K5001 autorefractor's view window, the most peripheral refractions possible were at 40° from the instrument's measurement axis. Approximate calculations based on a flat lens of 2 mm thickness, a representative spectacle vertex distance of 11 mm and an assumed distance of 3 mm from the corneal apex to the entrance pupil, suggested that the chief ray for a 40° eccentricity peripheral field would intersect the lens at between 13 and 14 mm from its optical center. At 10-mm radial distance from the axis, predicted vertometry readings derived from the lens design program indicated a spherical equivalent for lens type I of +0.00 D, +0.49 D for type II, and +0.10 D for lens type III. At 15 mm, these values became +0.49 D, +1.22 D, and +0.49 D, respectively. Thus, the peripheral refractive error measurements obtained through the spectacle lenses do not appear to match the predicted behavior at the more peripheral field angles.

Although there are potential problems associated with wearing these lenses, this study establishes that, once adapted, the vast majority of the children do not have significant difficulties in wearing these novel designs, and in terms of wearability, there were no

differences between groups. Although we have not rigorously evaluated the head and eye movements during lens wear, we observed that children predominantly used head movement rather than down gaze when reading and this minimized the use of lens areas outside the central zone of relatively constant power.

This study determined that the treatment effect was greater for lens type III in children with parental history of myopia (0.29 D) and in younger females (0.25 D). Kurtz et al.²⁷ found a similar effect for PALs wherein the effect for PALs was greater in children with both parents myopic and hypothesized that wearing of PALs counteracted or cancelled out the parental myopia effect. The mechanism of action by which the novel designs reduce myopia progression in these subgroups is unclear. However, given the significant reduction in myopia obtained in these groups, it appears that such lenses may play a role in the management of myopia for those at-risk groups and further work is needed in the area to confirm the trend observed with these novel designs.

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FIGURE 1.
Participant flow in the study.

FIGURE 2.

Progression in myopia plotted as the change in mean spherical equivalent (M) with time for all subjects. Error bars are standard deviations.

FIGURE 3.

Change in axial length with time for all subjects. Error bars are standard deviations.

FIGURE 4. Central and peripheral mean spherical equivalent (M) component of refractive errors with (gray lines) and without correction (dark lines) for all subjects. Error bars are standard deviations.

FIGURE 5.

Change in mean spherical equivalent (M) for subjects aged 6 to 12 years. Error bars are standard deviations.

FIGURE 6.
Change in axial length for subjects aged 6 to 12 years. Error bars are standard deviations.

FIGURE 7.

Central and peripheral mean spherical equivalent (M) component of refractive errors with (gray lines) and without correction (dark lines) for 6- to 12-year-old subjects. Error bars are standard deviations.

TABLE 1

Biometric data of subjects enrolled in the study

Statistics	Units	Group (type I)	Group (type II)	Group (type III)	Group (control)
Enrolled	No	50	60	50	50
Age (mean $\pm$ SD)	Years	10.7 $\pm$ 2.4	11.1 $\pm$ 2.2	11.4 $\pm$ 2.3	10.8 $\pm$ 2.5
Gender—male: female	%	46:54	57:43	50:50	56:44
Spherical equivalent (mean $\pm$ SD) [range]	D	−1.82 $\pm$ 0.62 [−0.56 to −3.93]	−1.81 $\pm$ 0.67 [−0.56 to −3.75]	−1.82 $\pm$ 0.66 [−0.68 to −3.63]	−1.87 $\pm$ 0.68 [−0.43 to −3.87]
Axial length (mean $\pm$ SD) [range]	mm	24.33 $\pm$ 0.66 [23.09 to 25.85]	24.47 $\pm$ 0.70 [23.15 to 27.08]	24.51 $\pm$ 0.63 [23.04 to 26.60]	24.55 $\pm$ 0.77 [22.98 to 26.41]
Subjects with parental myopia (one or both parents myopic)	%	62	63	58	64
Eyes wearing spectacles at baseline ^a	%	84	82	88	76

^aNone of the subjects were wearing contact lenses at baseline.

TABLE 2

Linear mixed model showing progression of myopia at 12 months in 6- to 12 year old versus 13- to 16-year-old subjects

Variable	Design	n	Age group—6–12 years	n	Age group—13–16 years
Autorefraction (spherical equivalent) difference from baseline (D)	Control	72	-0.90 ± 0.48	26	-0.44 ± 0.38
	Type I	76	-0.85 ± 0.45	20	-0.64 ± 0.31
	Type II	86	-0.92 ± 0.38	30	-0.50 ± 0.51
	Type III	62	-0.75 ± 0.43	30	-0.49 ± 0.31
Axial length difference from baseline (mm)	Control	72	0.43 ± 0.20	26	0.15 ± 0.11
	Type I	76	0.40 ± 0.21	20	0.21 ± 0.13
	Type II	86	0.39 ± 0.18	30	0.24 ± 0.16
	Type III	62	0.36 ± 0.17	30	$0.21 \pm .12$

TABLE 3

Progression of myopia in 6- to 12-year-old subjects: analysis by parental history of myopia and gender

Variable	Design	Parental history of myopia				Gender			
		n	No parental myopia	n	Parental myopia (one or more)	n	Male	n	Female
Autorefracton (spherical equivalent) difference from baseline (D)	Control	18	-0.69 ± 0.43	54	-0.97 ± 0.48	38	-0.76 ± 0.50	34	-1.07 ± 0.41
	Type I	24	-0.80 ± 0.46	52	-0.87 ± 0.45	28	-0.85 ± 0.41	48	-0.85 ± 0.48
	Type II	30	-0.93 ± 0.41	56	-0.92 ± 0.37	48	-0.88 ± 0.39	38	-0.98 ± 0.38
	Type III	24	-0.85 ± 0.36	38	-0.68 ± 0.47	30	-0.66 ± 0.38	32	-0.82 ± 0.47
Axial length difference from baseline (mm)	Control	18	0.36 ± 0.13	54	0.45 ± 0.21	38	0.38 ± 0.23	34	0.49 ± 0.15
	Type I	24	0.40 ± 0.20	52	0.40 ± 0.22	28	0.40 ± 0.18	48	0.40 ± 0.22
	Type II	30	0.37 ± 0.18	56	0.40 ± 0.18	48	0.37 ± 0.20	38	0.41 ± 0.15
	Type III	24	0.37 ± 0.15	38	0.36 ± 0.19	30	0.33 ± 0.16	32	0.39 ± 0.18