

The Hong Kong Progressive Lens Myopia Control Study: Study Design and Main Findings

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PURPOSE. To determine whether the use of progressive addition spectacle lenses reduced the progression of myopia, over a 2-year period, in Hong Kong children between the ages of 7 and 10.5 years.

METHODS. A clinical trial was carried out to compare the progression in myopia in a treatment group of 138 (121 retained) subjects wearing progressive lenses (PAL; add +1.50 D) and in a control group of 160 (133 retained) subjects wearing single vision lenses (SV). The research design was masked with random allocation to groups. Primary measurements outcomes were spherical equivalent refractive error and axial length (both measured using a cycloplegic agent).

RESULTS. There were no statistically significant differences between the PAL and the SV groups for any of the baseline outcome measures. After 2 years there had been statistically significant increases in myopia and axial length in both groups; however, there was no difference in the increases that occurred between the two groups.

CONCLUSIONS. The research design used resulted in matched treatment and control groups. There was no evidence that progression of myopia was retarded by wearing progressive addition lenses, either in terms of refractive error or axial length. (*Invest Ophthalmol Vis Sci.* 2002;43:2852-2858)

The notion that myopia is related to near work is far from new; however, the exact nature of the association and whether it is a causal one is still unknown. The prevalence of myopia in young Hong Kong Chinese has increased from approximately 30%, which is similar to the prevalence reported in Western societies, to 70% in just one generation, and this is strong evidence of an environmental causal factor.¹⁻⁴

Leung and Brown reported that when two samples of myopic Chinese children, aged between 9 and 12 years, wore progressive addition lenses (PAL; +1.50 D near addition in 22 subjects and +2.00 D addition in 14 subjects) their myopia progressed less and their axial lengths increased less compared with 32 children in an age-matched single vision (SV) control group.⁵ Furthermore, the effect was "dose-related," with the greatest progression in the SV subjects and the least in the +2.00 D addition PAL subjects.

Three previous well-designed studies of the effects of bifocal lens wear on myopia progression had, however, failed to show definite benefit. The Houston Myopia Control Study used

a block randomized procedure to ensure matching of 207 myopic subjects between the ages of 6 and 15 years, who received either bifocals with +1.00 D addition, bifocals with +2.00 D addition or SV lenses.⁶ After a follow-up period of 3 years there was no evidence that myopia progression had been reduced by bifocal lens wear. This study had subjects with a wide age range and had a high dropout rate.

Pärssinen et al.⁷ also found no difference in progression of myopia, in 240 Finnish children aged between 9 and 11 years, between a bifocal group (wearing +1.75 D addition), an SV group wearing spectacles for constant use, and an SV group wearing spectacles for distance use only.

Jensen used a block randomization method similar to that used in the Houston study.⁸ Children between the ages of 7 and 13 years were allocated at random into one of three groups: a bifocal (+2.00 D addition) group, an SV group or an SV group in which subjects also received twice daily timolol maleate. Jensen measured not only cycloplegic refraction, but also for the first time in such a study, axial length. There were no statistically significant differences in refractive error or axial length between the groups after 2 years.

There are a number of possible reasons why these studies failed to show a difference, whereas the Hong Kong study did. One is that the environmental factors influencing myopia may be different in Chinese and people of European ancestry. In addition, the subjects in the Hong Kong study were known to be actively progressing in their myopia (-0.40 D/year or more) when they were accepted into the study. It is also possible that compliance with lens wear was better in the Hong Kong subjects, because spectacle wear is the rule, rather than the exception, in Hong Kong by the age of approximately 10 years. In addition, progressive lenses are likely to be cosmetically more acceptable than bifocal lenses, and this may encourage compliance.

Several studies are being carried out around the world in the hope of replicating the clearly important findings of Leung and Brown, and this article reports on the design of, and presents initial data from, a study being carried out in the Centre for Myopia Research, The Hong Kong Polytechnic University. The primary aims of the study described here are to examine the changes in refractive error and axial length in a group of myopic children wearing progressive spectacle lenses and to compare these changes with those that occur in a control group of children wearing conventional SV lenses.

This is a masked, prospective, 2-year study characterized by random allocation to treatment and control groups, cycloplegic refraction, objective measures of ocular growth, and sufficient statistical power to detect clinically significant changes in refraction over the study period. All experimental procedures met the tenets of the Declaration of Helsinki and had been approved via institutional review.

METHODS

Study Timetable

Subjects were aged between 7 years and 10.5 years at the time of first data collection and were followed up every 6 months, for a period of 2 years.

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Supported by Grant 058 from the Centre for Myopia Research (Area of Strategic Development), The Hong Kong Polytechnic University.

Submitted for publication February 15, 2002; revised April 5, 2002; accepted April 25, 2002.

Commercial relationships policy: F.

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Subject Numbers

Based on the findings of previous Hong Kong studies, we anticipated a mean increase in myopia of approximately 1 D in the control group over a 2-year period.^{5,9} We wanted to identify as statistically significant a halving of this progression in the treatment group, that is, a difference of 0.50 D. Assuming a value of 0.75 D for the SD of the difference in refractive error change between the treatment and control groups, 81 subjects are needed in each group for an alpha level of 0.01 and 95% power. In the Leung and Brown study the dropout rate was approximately 15%.⁵

We anticipated that some subjects might take the spectacles provided by the Study to local optometrists or opticians and that families who thereby suspected they were in the control group might withdraw from the Study. In anticipation of a higher loss of control than treatment subjects we recruited 138 subjects into the treatment group and 160 subjects into the control group.

Subject Selection: Ocular Criteria

The following inclusion criteria were applied when subjects were recruited:

- Spherical equivalent refractive error (SER) of -1.25 to -4.50 D (measured under cycloplegia)
- Astigmatism of not more than 1.50 D
- Anisometropia of not more than 1.50 D in spherical or cylindrical error
- Visual acuity with best subjective correction of 0.00 logMAR or better
- No ocular condition that might affect refractive development
- No prior use of bifocal or progressive lenses
- No contact lens experience and willingness not to wear contact lenses

We did not have prior refractive error progression data for the children.

Subject Selection: Nonocular Criteria

- Age 7 to 10.5 years at time of recruitment
- Willingness to wear glasses constantly
- Availability for follow-up for at least 2 years
- Parents' understanding and acceptance that there would be random assignment to one of two spectacle lens groups
- No systemic condition that might affect refractive development

Data Collection and Masking

Two investigators were involved in data collection. One was masked as to group allocation and was responsible for refractive error, axial length, and other measures. The masked investigator (MI) was the same person throughout the study. The unmasked investigator (UMI) was responsible for group allocation, frame selection, providing spectacles with PAL or SV lenses as appropriate, measuring aided VA on arrival, checking fit of spectacles and adjusting spectacles, storing records so as to maintain masking, checks on compliance, responding to questions, dealing with nontolerance cases, and accuracy of data entry. Parents were asked to raise any questions regarding their child's spectacles with the UMI.

Method of Recruitment

Subjects were sought through advertisements in two local newspapers and interested families were asked to contact the research optometrist by telephone. We ascertained on the telephone if the child met the nonocular selection criteria, and if he or she did, then the family was invited to attend a recruitment session.

Recruitment Session

The objectives of the recruitment session were to determine whether the child and family met the ocular criteria for participation, inform the family verbally about the study, provide a written information sheet,

and answer any questions raised. The families were told that if they participated, then "special" spectacles would be provided free-of-charge and that travel expenses for the child and one accompanying adult would be provided for future visits. Families were not told the nature of the two treatments being offered, and it was emphasized that allocation to a treatment would be at random and could not be requested.

A noncycloplegic refraction was then carried out and VA (logMAR) measured with the lowest minus correction. A cover test was carried out to exclude strabismus with the distance correction and with an addition of +1.50 D. Ophthalmoscopy and biomicroscopy were carried out to identify any abnormal ocular condition present.

If the child met the ocular selection criteria, the family wished to participate and informed consent was obtained, then the child was allocated, according to a predetermined random sequence, to either the PAL (treatment) group or the SV (control) group. The UMI was not aware of the group allocation until this point.

Visit Sequence

Figure 1 shows the flow of visits and the flow within a visit. Examination A was carried out by the UMI and comprised measurement of aided VA, checking the spectacle fitting, and carrying out adjustments where necessary. The UMI then escorted the subject and attending parent to the MI but retained the subject's spectacles. Special care was taken at all stages of the study to try to ensure that the spectacles were adjusted properly and that the child was not looking through the distance portion of the lens when reading.

The MI then carried out examination B, which took approximately 1 hour 40 minutes and is described below. Any subject who did not meet the initial refractive criteria when examined using cycloplegia was excluded from the study at this stage. The family and the final prescription were then taken back to the UMI, who advised on frame selection and ordered spectacle lenses according to the group allocation.

Spectacles Provided and Subject Masking

Children in the PAL group were provided with SOLA MC lenses, a progressive lens designed for use in small frames. The SOLA MC lens has wide near and distance zones, a short-corridor, and a near addition of +1.50 D. The design is different for the right and left lenses to maximize the horizontal field of view in the right and left periphery.

One of the uncertainties in the Leung and Brown study was whether the children using the progressive lenses were actually using the near portion of the lens when reading.⁵ The manufacturer designed the MC lens with a short corridor to allow clear intermediate distance but so that the near vision portion of the lens could be reached with minimum eye depression. The near optical center is 10 mm below the distance optical center, whereas PALs for adults normally have corridor lengths of 14 to 16 mm.

The use of a +1.50 D addition (the only addition offered) will reduce but not prevent accommodation and is a compromise between peripheral distortion and wearability on one hand and accommodation reduction on the other.

Children in the SV group were provided with SOLA single vision lenses. All children were measured as if for progressive lenses, using a standardized procedure, regardless of group allocation. All lenses were made from CR-39 polymer with a refractive index of 1.499.

Families were provided with a choice of frame from a selection of fashionable children's frames. Lenses and frames were provided free of charge. The frame was carefully adjusted so that the back vertex distance was 12 to 14 mm and the pantoscopic angle 10 to 15°. The center of the pupil was marked on the lens blank in the frame with a chinagraph pencil, the investigator being careful to position his eyes on the same level as the child's eyes. The distance from the pupil center to the inside lower edge of the frame was measured separately for the R and L eyes, and this measurement was used to define the height of the near portion of the lens.

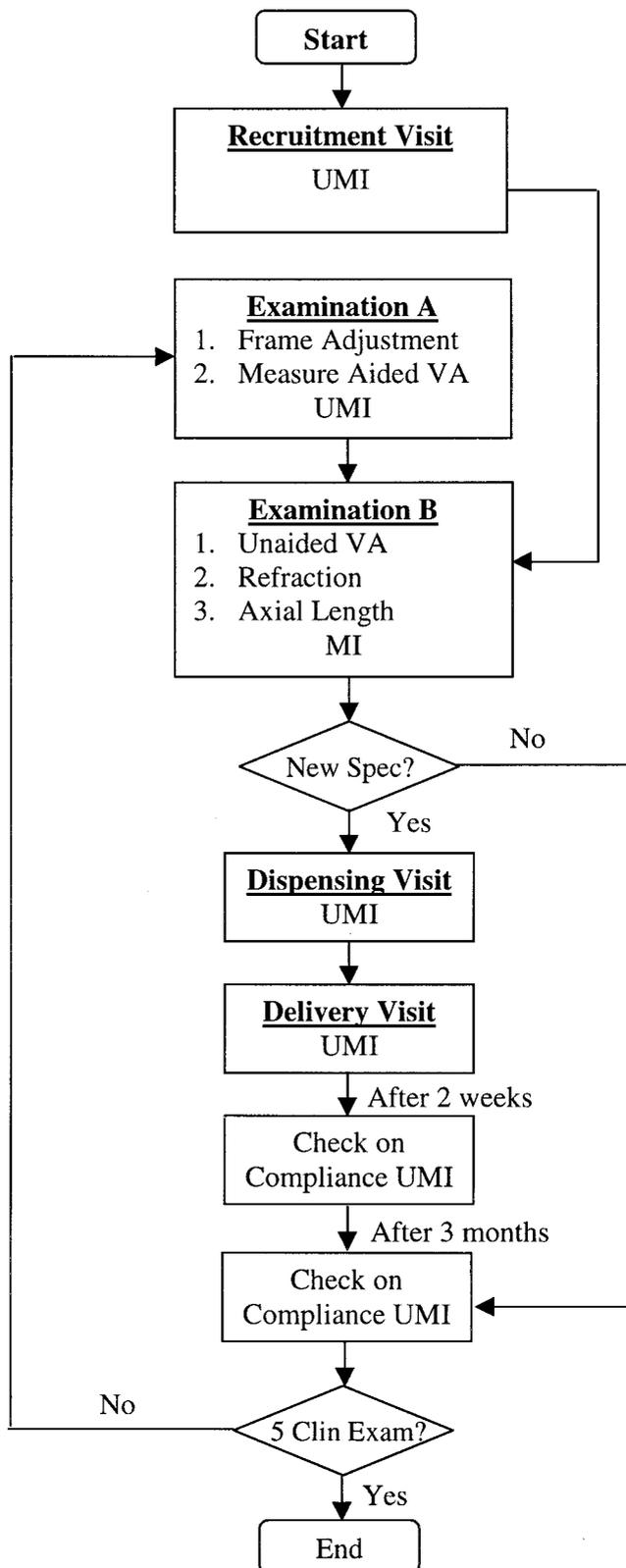


FIGURE 1. The flow of visits, and the flow within a visit. UMI is the unmasked investigator, and MI the masked investigator.

We made every effort to maintain subject masking, and although we did not describe the nature of the treatments being provided we accept that it is likely that some subject families became unmasked as to group allocation.

Spectacle Wear and Compliance

The tolerance for the height of the addition was 1 mm. The manufacturer's markings were left on progressive lenses until the delivery visit. The tolerances adopted for other lens parameters were according to the locally recommended values. At the delivery visit the frame was adjusted as necessary so that the pupil center was within the oval-shaped fitting mark on the lens.

Children were asked to wear their glasses constantly. Written instructions were provided on spectacle care and use, the same instructions being given to all subjects. Particular emphasis was placed on the need for spectacles to be correctly positioned on the face at all times.

The dates of compliance phone calls were agreed and the importance of contacting the study team immediately in the event of non-tolerance or damage to the spectacles was explained. Compliance was ascertained with both the child and a parent, using a standard set of questions in each case, 2 weeks after spectacle collection, once by telephone between each 6-month visit and in person at the data collection visit. The fit of the spectacle frame and the child's visual posture when reading was checked at data collection visits. The need for compliance was reinforced at every opportunity.

Details of Examination B and the Data Collected

The objectives of examination B, carried out by the MI, were as follows:

- to collect the required data
- to provide a spectacle prescription for dispensing

Measurement Outcomes and Quality Assurance. The primary measurement outcomes were refractive error (by autorefractometry for data analysis and by subjective refraction for spectacle prescription) and axial length, both measured under cycloplegia. Myopia progression was calculated as the difference between the SER found by autorefractometry at the fifth and first (baseline) visits. Standardized operating procedures were developed for all measurements and for all elements of the study, and project personnel were trained in these and required to follow them.

Aided Vision and PD Measures. A logMAR chart was used at 6 m. VA was measured in the RE and then the LE, and the process ended when a line was reached on which no letters could be read.

A Topcon PD-5 pupillometer was used, according to the manufacturer's instructions, to measure monocular and binocular distance and near PD. The means of two sets of measures were used in each case.

Noncycloplegic Refraction. A Shin-Nippon SRW-5000 open-field autorefractor (Shin-Nippon, Tokyo, Japan) was used to measure refractive error first in the right then in the left eye, using the method described by Chat and Edwards.¹⁰ Four readings were taken, and the average as produced by the instrument readout was used. The same autorefractor was used throughout the study and the calibration checked weekly.

Subjective refraction was then carried out, using a phoropter, starting with the autorefractometry result and with an end point of minimum minus dioptric power for best VA. The phoropter was then removed, and the final correction placed in a child's trial frame, which was then carefully fitted on the child's face for heterophoria measurement.

Heterophoria. Horizontal and vertical heterophoria was measured at distance and near using a Howell heterophoria card (Cyclopean Design, Victoria, Australia). This is a direct-reading heterophoria measurement technique that has the advantage that it uses a target in "free-space." Dissociation is carried out using a 6Δ base down prism in front of the right eye with the subject wearing the best subjective correction. Two cards are used: the smaller is calibrated for use at 330 mm, the larger for use at 3 m. When used for measurement of near heterophoria, the card was held, straight in front of the subject, by the examiner.

Cycloplegic Autorefractometry. Cycloplegic was not instilled if intraocular pressure (measured using a Topcon CT-60 noncontact

TABLE 1. The Number of Subjects in the Study at each Data Collection and the Cumulative Percentage of Subjects Lost to Observation

| Visit | PAL Group | SV Group |
|-----------|-------------|-------------|
| Baseline | 138 | 160 |
| 6 months | 129 (6.5%) | 155 (3.1%) |
| 12 months | 124 (10.1%) | 152 (5%) |
| 18 months | 121 (12.3%) | 148 (7.5%) |
| 24 months | 121 (12.3%) | 133 (16.9%) |

PAL, progressive lens group; SV, single vision group.

tonometer, Paramus, NH) was >22 mm Hg and the cup-disc ratio was >0.6 . The purpose of the cycloplegic eyedrops was again explained. An information sheet explaining the normal reaction and giving contact telephone numbers if an untoward reaction occurred was given to the parent.

One drop of proparacaine 0.4% was instilled, and then 2×1 drop of cyclopentolate HCl 1% were instilled with 5 minutes between instillations. Gentle pressure was applied to the puncta to minimize systemic absorption.

The pupils were checked 30 minutes later. If they were dilated, then the amplitude of accommodation was measured using the push-up method. If the pupils were not dilated, then 1 additional drop of cyclopentolate was instilled, and amplitude was rechecked every 10 minutes until it was <2 D. Autorefractometry was then carried out using the Shin-Nippon SRW-5000 open-field autorefractor as described above.

Axial Length Measurement. Axial length was measured under cycloplegia, using an A-2500 A-Scan (Sonomed, NY). One drop of proparacaine 0.4% was instilled into each eye to produce corneal anesthesia. Axial length was measured in both eyes following the manufacturer's instructions, and five scans were stored with an SD of <0.05 mm. Readings were accepted when anterior and posterior lens reflections were observed and a sharp retinal spike was visible.

Criterion for Change of Prescription. The criterion used for a change of spectacles at the second and subsequent visits was a reduction in aided vision of ≥ 0.10 logMAR units.

RESULTS

Data input was carefully checked, and statistical analyses were carried out independently by two investigators. Data from the right eyes only are presented here. All treatment subjects adapted successfully to their progressive lenses.

Subjects Lost to Observation

Table 1 shows the number of subjects recruited and the numbers at each stage of the study. There was no statistically

significant relationship between whether or not a subject was retained in the study and the group allocation (Fisher's exact test: $P = 0.33$).

Baseline data for the children who completed the study and those who were lost to observation are shown in Table 2. There were no statistically significant differences in the data for either group between those retained and those lost except that the subjects lost to observation in the PAL group had a more myopic initial cycloplegic autorefractometry than those retained (unpaired t -test: $t = 2.04$, $df = 136$, $P = 0.04$).

Baseline Measures in Retained Subjects

There were no statistically significant differences between the PAL and SV groups in relation to gender distribution, age, SER, axial length, or distance or near heterophoria, either for the subjects initially recruited or for those who completed the study (data for the latter shown in Table 2).

Progression of Myopia by Gender

The PAL and SV groups completing the study comprised 61 boys/60 girls and 61 boys/72 girls, respectively. There was no statistically significant association between treatment group and gender (Fisher's Exact Test: $P = 0.53$). Table 3 shows the myopia progression in the girls and boys who completed the study. There were no statistically significant differences in progression between boys and girls either overall or in the PAL or SV groups.

Progression of Myopia

The distributions of myopia progression are shown in Figure 2. Visual inspection suggests that fewer children progressed by -1.75 or 2.00 D in the PAL group, but the distributions appear otherwise similar.

The differences between 24-month and baseline SER measures (myopia progression) were -1.26 ± 0.74 D (mean \pm SD) in the SV group and -1.12 ± 0.67 D in the PAL group, and these differences were statistically significant for both groups (paired t -tests: $t > 18$, $P < 0.001$). There was, however, no statistically significant difference in the myopia progression between the two groups (unpaired t -test: $t = 1.61$, $df = 252$, $P = 0.11$).

The mean cycloplegic autorefractometry values (SER) in the two groups over the 2-year period is shown in Figure 3a. The mean and SD of the SER values at each stage will be of interest to researchers presently carrying out similar studies, and we have therefore provided these in Table 4.

Change in Axial Length

The total increase in axial length was 0.63 ± 0.28 mm (mean \pm SD) in the SV group and 0.61 ± 0.24 mm in the PAL group, and

TABLE 2. Baseline Data (Right Eyes Only) for Subjects Retained and Those Lost to Observation

| Variable | PAL Group | | SV Group | |
|-------------------------------|-------------------------------|----------------------------------|-------------------------------|----------------------------------|
| | Completed Study ($n = 121$) | Lost to Observation ($n = 17$) | Completed Study ($n = 133$) | Lost to Observation ($n = 27$) |
| Age (y)* | 8.92 (7-10.5) | 9.33 (7-10) | 9.17 (7-10.5) | 9.33 (7.17-10.5) |
| Cyclo. autorefractometry (D)† | $-2.82 (0.90)†$ | $-3.31 (1.12)†$ | $-2.92 (0.99)$ | $-3.19 (1.02)$ |
| Axial length (mm)‡ | 24.40 (0.69) | 24.32 (0.69) | 24.44 (0.77) | 24.57 (0.56) |
| Distance phoria*§ | 0 (2 to -5) | 0 (5 to -5) | 0 (3 to -8) | 0 (3 to -6) |
| Near phoria*§ | -3 (7 to -14) | -2 (13-12) | -2 (5 to -12) | -2 (3 to -16) |

* Range in parentheses.

† Different at the 0.05 level.

‡ Values are mean \pm SD.

§ Esophoria shown as positive and exophoria as negative.

TABLE 3. Mean Myopia Progression by Gender and Group (Right Eyes Only)

| | Mean Myopia Progression (D)* | | t-Test Results |
|-----------|------------------------------|--------------|---------------------------------|
| | Girls | Boys | |
| Overall | -1.18 ± 0.75 | -1.20 ± 0.69 | $t = 0.19, df = 252, P = 0.86$ |
| PAL group | -1.16 ± 0.69 | -1.07 ± 0.66 | $t = -0.71, df = 119, P = 0.48$ |
| SV group | -1.20 ± 0.80 | -1.33 ± 0.66 | $t = 0.98, df = 131, P = 0.33$ |

PAL, progressive lens group; SV, single vision group.
* Values are means ± SD.

the increases were statistically significant (paired *t*-tests: $t > 26, P < 0.001$). There was no statistically significant difference in the axial length increase between the two groups (unpaired *t*-test: $t = 0.5, df = 252, P = 0.62$). The mean axial length in the two groups over the 2-year period is shown in Figure 3b and further details are provided in Table 4.

Progression of Myopia by Heterophoria in PAL Group

In the light of previous reports that multifocal lenses may be more effective in retarding myopia in children with esophoria,¹¹⁻¹³ we examined the myopia progression in the esophoric subgroup. By chance, both treatment groups in the esophoric subgroup had 21 subjects. The myopia progression in the SV group was -1.26 ± 0.90 D (i.e., similar to that in the overall sample), and the change in the PAL group was -0.89 ± 0.67 D. The difference was not statistically significant (unpaired *t*-test: $t = 1.51, df = 40, P = 0.14$).

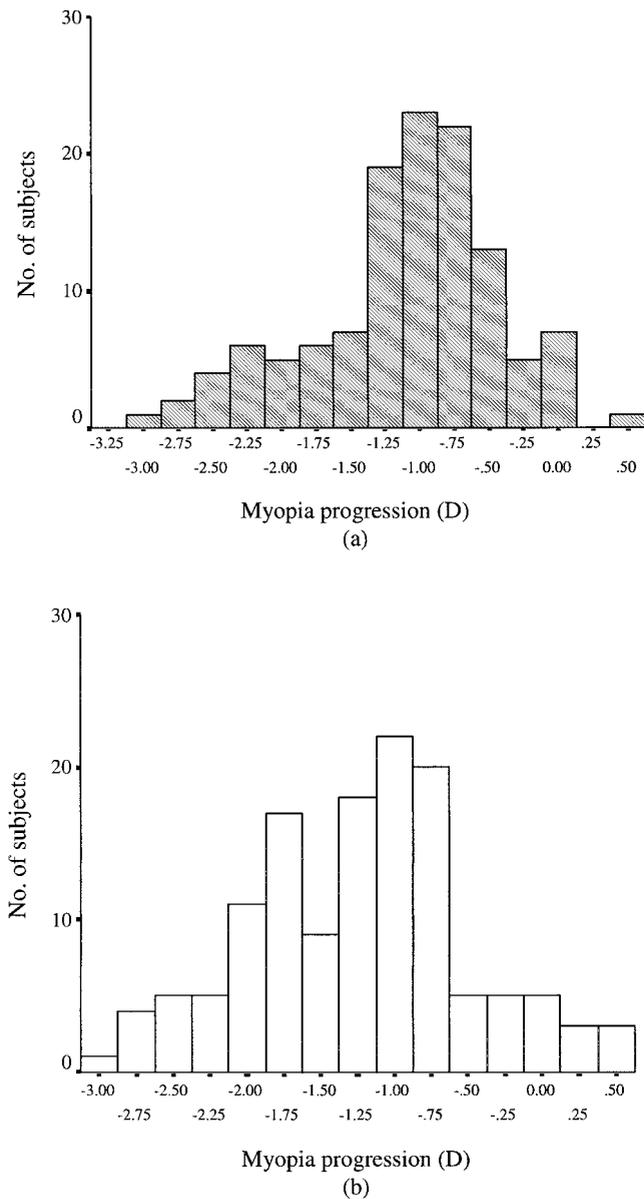


FIGURE 2. Distribution of myopia progression for (a) PAL and (b) SV subjects.

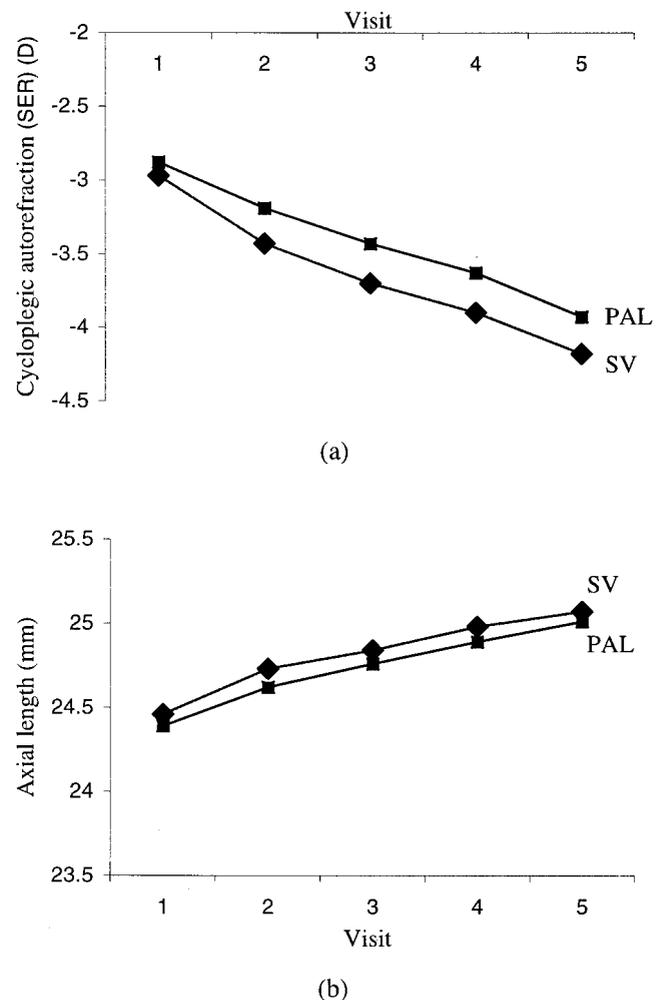


FIGURE 3. (a) Mean cycloplegic autorefraction (SER) and (b) mean axial length for both groups at each visit.

TABLE 4. SER and Axial Length at Each Stage of the Trial

| | PAL | SV |
|-------------------|----------------|----------------|
| SER (D) | | |
| Baseline | -2.816 ± 0.895 | -2.922 ± 0.992 |
| 6 months | -3.150 ± 0.932 | -3.371 ± 1.076 |
| 12 months | -3.412 ± 1.060 | -3.625 ± 1.135 |
| 18 months | -3.625 ± 1.097 | -3.838 ± 1.201 |
| 24 months | -3.932 ± 1.183 | -4.181 ± 1.311 |
| Axial length (mm) | | |
| Baseline | 24.398 ± 0.694 | 24.441 ± 0.766 |
| 6 months | 24.632 ± 0.691 | 24.692 ± 0.785 |
| 12 months | 24.759 ± 0.703 | 24.812 ± 0.793 |
| 18 months | 24.892 ± 0.705 | 24.952 ± 0.813 |
| 24 months | 25.013 ± 0.725 | 25.072 ± 0.841 |

Values are means ± SD. PAL, progressive lens group ($n = 121$); SV, single vision group ($n = 133$).

DISCUSSION

Our randomized allocation resulted in two groups that were initially alike in regard to all outcome measures under consideration here. This was the case both for the subjects initially recruited and for those who completed the study. Loss to observation was quite low, being approximately 12% in the PAL group and 17% in the SV group over the 2-year period. It is possible that some families in the SV group, finding out that they had been provided with regular lenses, opted for some other form of myopia prevention treatment, and this had been anticipated. Subjects in the PAL group who were lost to observation were more myopic at the start of the study than those who remained in the study, but surprisingly there was no difference in axial length between these two groups (Table 2). It seems unlikely that this has biased the samples in any way.

Progressive lens wear was well accepted, and the care taken in dispensing lenses, the explicit instructions given regarding frame position and the need for frame adjustment, and the careful checking of compliance with these instructions at and between data collection visits should have resulted in children in the PAL group reading through the near portions of their lenses.

Gender Balance and Comparison of Progression in Boys and Girls

The PAL and SV groups initially comprised 71 boys and 67 girls, and 73 boys and 87 girls, respectively; the corresponding numbers retained in the project were 61 boys and 60 girls, and 61 boys and 72 girls, respectively. Although there were no statistically significant associations between gender and group, we nevertheless considered the possibility of a gender difference in myopia progression. There is some evidence in the literature of an age-related gender difference during the years when myopia first occurs. Girls may become myopic at an earlier age, presumably related to earlier onset of puberty and the associated spurt of general growth.¹⁴ Suppose that girls progress more quickly than boys in the age groups being considered here. A bias toward more girls in the control group would result in a higher progression rate for that group and thus exaggerate any difference in progression between the treatment and control groups. Because we found no difference in progression between the genders, it turned out that this was not an issue. We did not find any difference in myopia progression between boys and girls, at least for the age and refractive error ranges in the study.

Our results lend no support to the idea that myopia can be retarded by the use of progressive lenses. Unfortunately, the question of whether progressive lenses are effective in esophores has not been unequivocally answered by our findings,

as the power of the statistical test used was only 0.27. The difference in myopia progression between the SV and PAL subjects in the esophoric subgroup (0.37 D) was less than the value of 0.50 D, which we considered would be clinically significant and on which we had based our subject number calculations. On that basis we consider that the difference between the two groups was not clinically significant, although of course ultimately eye care practitioners will make this judgment individually. A recent randomized prospective study comparing the progression of myopia in 36 esophoric children wearing bifocal lenses and 39 esophoric children wearing single vision lenses found that mean myopia progression in the bifocal group was 0.25 D less than in the single vision group, after 30 months. Although the difference in this case was statistically significant ($P = 0.046$), again it may be of little clinical significance, given that it represents the average retardation under optimum supervision conditions.

It is possible that the Correction of Myopia Evaluation Study (COMET) underway in the United States may provide an unequivocal answer to this question.¹⁵

Leung and Brown found a myopia progression of -1.23 ± 0.51 and -0.76 ± 0.43 D in their SV group and $+1.50$ D addition PAL group, respectively, compared with our findings of -1.26 ± 0.74 and -1.12 ± 0.67 D. The progression in the two SV control groups was very similar. Leung and Brown⁵ recruited progressing myopes. We did not have access to previous eye examination records and have no data characterizing prior progression; however, families are more likely to be interested in joining a myopia control study if they are concerned about progression, and the similarity in progression in the two SV groups suggests that our SV group was very similar to theirs. Subjects were aged 9 to 12 years at recruitment in the Leung and Brown study, compared with 7 to 9.5 years in the present study, and it is possible that the older subjects were more compliant in regard to the use of their spectacles.

We used the Sola MC lens, whereas Leung and Brown used Essilor lenses. The Sola lens has been specially designed for use by children and has a short corridor so that the near portion of the lens can be used with minimum eye depression. We await with interest the results of the COMET Study, in which Essilor lenses are being used.¹⁵

Leung and Brown had two PAL groups, one wearing a near addition of $+1.50$ D and the other using $+2.00$ D. The lenses used in the present study had an addition of $+1.50$ and it is possible that $+2.00$ is more effective. However, Leung and Brown found a significantly lower increase in myopia in the $+1.50$ add bifocal group compared with the single vision group, and the difference was 0.47 D compared with only 0.14 D in the present study. It is difficult, therefore, to explain the difference in our results and those of Leung and Brown.

The change in SER that occurred was less than that expected in the light of the increase in axial length. In PAL subjects the mean change in axial length between baseline and 24 months was 0.615 mm, with an expected resultant change in SER of -1.66 D.¹⁶ The corresponding values for the SV group were 0.631 mm and 1.70 D. The observed changes in SER, however, were -1.12 D in the PAL group and -1.26 D in the SV group. Normal eye growth continues until the age of approximately 13 years,¹⁷ and so a proportion of the axial length increase seen here may be eye growth unaccompanied by refractive change (i.e., the axial length change is offset by other ocular component changes).

CONCLUSIONS

The research design used in this masked, randomized trial resulted in matched SV and PAL groups. Although both groups experienced statistically significant increases in myopia and in axial length, there was no statistically or clinically significant

difference in the increases between the groups and we therefore found no evidence that progressive lenses reduce the progression of myopia. We found no difference in the progression of myopia in boys compared with girls. Findings in regard to whether or not there was a difference in progression between the PAL and SV groups in the esophoric subgroup, are equivocal, because of the low power of the statistical test.

Acknowledgments

Progressive and single vision lenses were kindly provided by Sola (Hong Kong) Ltd.

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