Clinical Trials

The Effect of Bifocal Add on Accommodative Lag in Myopic Children with High Accommodative Lag

David A. Berntsen, Donald O. Mutti, and Karla Zadnik

Purpose. To determine the effect of a bifocal add and manifest correction on accommodative lag in myopic children with high accommodative lag, who have been reported to have the greatest reduction in myopia progression with progressive addition lenses (PALs).

Methods. Monocular accommodative lag to a 4-D Badal stimulus was measured on two occasions 6 months apart in 83 children (mean ± SD age, 9.9 ± 1.3 years) with high lag randomized to wearing single-vision lenses (SVLs) or PALs. Accommodative lag was measured with the following corrections: habitual, manifest, manifest with +2.00-D add, and habitual with +2.00-D add (6-month visit only).

Results. At baseline, accommodative lag was higher (1.72 ± 0.37 D; mean ± SD) when measured with manifest correction than with habitual correction (1.51 ± 0.50; $P < 0.05$). This higher lag with manifest correction correlated with a larger amount of habitual undercorrection at baseline ($r = -0.29$, $P = 0.009$). A +2.00-D add over the manifest correction reduced lag by 0.45 ± 0.34 D at baseline and 0.33 ± 0.38 D at the 6-month visit. Lag results at 6 months were not different between PAL and SVL wearers ($P = 0.92$).

Conclusions. A +2.00-D bifocal add did not eliminate accommodative lag and reduced lag by less than 25% of the bifocal power, indicating that children mainly responded to a bifocal by decreasing accommodation. If myopic progression is substantial, measuring lag with full correction can overestimate the hyperopic retinal blur that a child most recently experienced. (ClinicalTrials.gov number, NCT00335049.) (*Invest Ophthalmol Vis Sci.* 2010;51:6104–6110) DOI:10.1167/iovs.09-4417

The centuries-old association between near work and myopia dates back to the early 1600s.[1] Within the past few decades, based on data from both humans and animal models of myopia, the proposed link between excessive accommodation and myopia has yielded a theory invoking high accommodative lag during near work as a cause of juvenile-onset myopia progression.[2–4] Myopic children have a higher lag of accommodation than do emmetropic children. Therefore, myopic children experience a greater amount of hyperopic retinal blur during near work than do nonmyopic children.[5,6] Lens-induced defocus is known to predictably alter eye growth across animal models, with negative lenses resulting in longer, myopic eyes and positive lenses resulting in shorter, hyperopic eyes.[7–12] Because of the well-established ability of retinal defocus to guide eye growth in young animals and the higher accommodative lag found in myopic individuals, the link between accommodation and myopia in children is currently thought to be that excessive axial growth is caused by hyperopic retinal blur from a high lag of accommodation during near work.[2–4]

In an effort to reduce myopia progression in children, bifocal spectacles and progressive addition lenses (PALs) have been evaluated as a treatment in multiple clinical trials.[13–16] The rationale for wearing bifocal spectacles is that they decrease accommodative lag during near work and therefore reduce hyperopic retinal blur, slowing myopia progression.[15,16] The Correction of Myopia Evaluation Trial (COMET) found that myopic children with a high accommodative lag and near esophoria had the greatest 1- and 3-year PAL treatment effect (0.39 and 0.64 D), and children with high accommodative lag and low myopia (−2.25 D or less spherical equivalent myopia) had significant 1- and 3-year PAL treatment effects of 0.28 and 0.48 D, respectively.[17] Although clinically meaningful treatment effects have been reported in children with a high accommodative lag, there has been limited success when myopic children with all levels of accommodative lag were included in interventions attempting to reduce progression by reducing lag.[13–16] Unfortunately, because no trial has reported the change in accommodative lag in subjects wearing a bifocal add, it is difficult to confirm whether children with a high accommodative lag in previous studies have a greater treatment effect because of a greater reduction in accommodative lag when wearing a bifocal or PAL.

Surprisingly little has been published on the effect of a bifocal spectacle add on measured accommodative lag in children. Nearly all published reports on the effect of a bifocal add on accommodative lag examine adults with emmetropia or myopia.[18–23] Although interstudy variations exist in the testing methodology, including the dioptric amount of both the bifocal add and the test stimulus used, these studies consistently find that a bifocal add of +2.00 D or less either eliminates accommodative lag or results in a lead of accommodation. The effect of a bifocal add on accommodative lag in myopic children has been examined in only two studies, and their results conflict. Cheng et al.[24] reported that accommodative lag for a binocular, 3-diopter stimulus was not eliminated in children with progressing myopia until they wore a bifocal add higher than +2.50 D.[24] A +2.00-D add reduced accommodative lag from 1.00 to 0.22 D according to their modeled data, but did not eliminate accommodative lag. Sreenivasan et al.[25] also examined the effect of a +2.00-D add on accommodative lag with a binocular, 3-diopter stimulus in myopic children and found that the bifocal essentially eliminated the initial 1.10-D accommodative lag.[25] It is noteworthy that their sample in-

From The Ohio State University College of Optometry, Columbus, Ohio.

Supported by National Institutes of Health/National Eye Institute Grant K12-EY015447, Essilor of America, Inc., and an American Optometric Foundation (AOF) Ezell Fellowship sponsored by the AOF Presidents Circle (DAB).

Submitted for publication July 31, 2009; revised December 23, 2009, and June 9 and July 15, 2010; accepted July 18, 2010.

Disclosure: **D.A. Berntsen**, Essilor of America, Inc. (F); **D.O. Mutti**, Essilor of America, Inc. (F); **K. Zadnik**, Essilor of America, Inc. (F)

Corresponding author: David A. Berntsen, University of Houston, College of Optometry, 505 J Davis Armistead Building, Houston, TX 77204-2020; dberntsen@optometry.uh.edu.

Investigative Ophthalmology & Visual Science, December 2010, Vol. 51, No. 12

cluded no children with near esophoria, because, as just described, children with near esophoria and a high lag of accommodation in COMET had the largest PAL treatment effect.[17] Based on the literature, it is uncertain whether accommodative lag is significantly decreased in children who are reported to benefit most from PALs.

It is important to understand the effect of a bifocal on accommodative lag in these children. Without knowing the reduction in accommodative lag in subjects wearing bifocal spectacles, it is not possible to state definitively whether the reduction in myopia progression found in previous trials using bifocal spectacles was due to decreased hyperopic retinal blur during near work or whether other mechanisms should be explored to explain the bifocal treatment effect.

It is also not known how factors such as the accuracy of a child's myopic correction affects accommodative lag. Because myopia in childhood progresses on average by −0.50 D per year,[14,15] myopic children spend a significant amount of time wearing a less than optimal distance correction. With the exception of one of the studies mentioned so far,[22] accommodative lag was measured with the subject's full correction in place. The basis of the theory that accommodative lag during near work causes myopia progression rests on the amount of hyperopic retinal blur present during near work; therefore, it may be important to know both the "new" amount of accommodative lag present after updating a child's spectacles to the full correction and the habitual lag most recently experienced before updating the spectacle prescription. Longitudinal studies of juvenile-onset myopia progression typically measure accommodative lag in spectacle-wearing children with full correction in place.[6,26,27] To the best of our knowledge, no studies have been conducted to examine the effect of measuring myopic children's accommodative lag with habitual correction versus their full correction to determine whether there are significant differences in lag in these two viewing conditions.

The purposes of these analyses were to determine the effect of bifocal add on the amount of accommodative lag in children with progressing myopia with a high accommodative lag, who have been selected as most likely to benefit from PALs, and to determine the effect of correction type (habitual versus full manifest) on accommodative lag.

Methods

Baseline and 6-month data from children enrolled in the Study of Theories about Myopia Progression (STAMP)[28] were used in these analyses. STAMP is a double-masked, randomized clinical trial in which PALs were used to evaluate two theories of juvenile-onset myopia progression. Myopic children between the ages of 6 and 11 years were enrolled and had at least −0.75 D of myopia in each meridian but not more than −4.50 D of myopia in either meridian of either eye, as determined by cycloplegic autorefraction. In addition, eligible children had a high accommodative lag (> 1.30 D for a 4-D stimulus) and also had near esophoria if their cycloplegic spherical equivalent refractive error was more myopic than −2.25 D. These criteria were selected so that only children with high accommodative lag and low myopia (less myopic than −2.25 D spherical equivalent) and children with high accommodative lag and near esophoria were enrolled, because these two subgroups of myopic children had statistically significant and clinically meaningful 1- and 3-year PAL treatment effects in COMET. High accommodative lag was defined as greater than a median split of data, the same criterion used to define high accommodative lag in COMET. The median of 1.30 D for a 4-D Badal stimulus was chosen from myopic children in the Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE) Study, because the CLEERE protocol was used to measure lag in STAMP.[6] Near phoria was measured with full correction using the modified Thorington method.[29] Enrollment was restricted to children meeting these criteria because myopic children in these subgroups had significant 1- and 3-year PAL treatment effects in a previous, large-scale clinical trial.[17]

At the baseline visit, children were randomly assigned to wear either single-vision lenses (SVLs) or a PAL with a +2.00-D add (Ellipse; Essilor of America; Dallas, TX). The Biomedical Sciences Institutional Review Board at The Ohio State University reviewed and approved the study protocol and informed consent documents, according to the tenets of the Declaration of Helsinki. Written informed consent was provided by the subjects' parents, and verbal assent was obtained from the children.

Accommodative response was measured monocularly (right eye) by an examiner masked to the child's spectacle assignment with an autorefractor (model WV-500; Grand Seiko Co., Ltd., Hiroshima, Japan) using a 4-D Badal letter stimulus. Accommodative error was calculated as the difference between the accommodative demand and the accommodative response where positive values indicate a lag of accommodation (i.e., underaccommodation). The accommodative stimulus during testing was a 4-by-4 grid of letters with each letter and the space between the letters subtending 38.75 minutes of arc (20/155 Snellen equivalent) with luminance between 65 to 85 cd/m^2. The 4-D Badal stimulus was chosen instead of a target in real space at a 4-D accommodative demand, because the Badal stimulus was more sensitive to the significant differences in accommodative lag between emmetropic and myopic children and to the changes in accommodative lag associated with the onset of myopia in children in CLEERE.[6] Habitual correction was determined by lensometer neutralization of the spectacles worn to the examination. The manifest correction was determined by the same examiner at each visit using a standardized refraction protocol with the sphere endpoint being the most plus that yielded the best visual acuity. The sphere and cylinder determined for each correction type was placed in a trial frame during accommodative testing. Accommodative lags were adjusted for lens effectivity.

At the baseline visit, the habitual correction was whatever spectacle correction the child wore to the visit. If the child had never worn spectacles or did not have spectacles at the baseline visit, the habitual correction was plano. By study design, the habitual correction at the 6-month follow-up visit was the baseline manifest correction prescribed to the child at the baseline visit and worn over the preceding 6 months, which allowed ample time for the child to adapt to the new prescription. The order of testing and the correction type conditions tested at each visit are shown in Table 1. The habitual and manifest testing conditions at baseline were "real world" in that, typical in a longitudinal observational study, variable amounts of time had elapsed since glasses-wearing children had had their prescriptions updated, whereas some children had never worn glasses. The manifest and habitual corrections at the 6-month visit were more typical of the controlled environment of an interventional study, such as a clinical trial, because all children had worn and adapted to the full correction prescribed 6 months earlier.

A repeated-measures analysis of variance (ANOVA) was used to determine whether there was a significant difference between the accommodative lag conditions common to both the baseline and 6-month visits either by visit, by correction type (manifest, habitual, and manifest with +2.00-D add), or by treatment group (PALs or SVLs). When appropriate, post hoc *t*-test comparisons were performed by

Table 1. Correction Types Used to Measure Accommodative Lag at Each Study Visit

Baseline Visit		6-Month Visit
Manifest	→	Habitual
Habitual	→	Habitual w/ +2.00 D add
Manifest w/ +2.00 D add		Manifest
		Manifest w/ +2.00 D add

The study design dictated that the manifest conditions at the baseline visit be the same as the habitual lens conditions at the 6-month visit (indicated by the arrows).

Table 2. Accommodative Lag at the Baseline and 6-Month Visits by Correction Type and Treatment Assignment

	Baseline		6 Months	
	SVL	PAL	SVL	PAL
Habitual	1.48 ± 0.54	1.53 ± 0.45	1.55 ± 0.45	1.55 ± 0.38
Manifest	1.65 ± 0.35	1.79 ± 0.39	1.54 ± 0.42	1.65 ± 0.42
Manifest/+2	1.26 ± 0.30	1.27 ± 0.27	1.22 ± 0.30	1.29 ± 0.28

Data are the mean accommodative lag (±SD).

using the test described by Tukey and the proper mean squared error from the analysis of variance.[30,31] A Pearson correlation was used to determine whether there was a relationship between spherical undercorrection and differences in accommodative lag with habitual and manifest corrections at baseline. Linear regressions were used to determine whether accommodative lag at the 6-month visit helped predict the reduction in accommodative lag with a +2.00-D add for both the habitual and manifest corrections.

Results

Baseline and 6-month data from 83 of the 85 children enrolled in STAMP were available for inclusion in the analyses. (One child withdrew from the study after the baseline visit, and a second child moved out of state after being enrolled and was not seen at 6 months.) The mean (±SD) age was 9.9 ± 1.3 years, and the mean cycloplegic spherical equivalent refractive error at baseline (right eye) was −1.96 ± 0.79 D (range, −0.83 to −4.02 D). Forty-two children (51%) were girls, and 52 (63%) were esophoric at near. The mean near phoria at baseline was 0.67 ± 4.27 prism diopters of esophoria (mean ± SD; range: 16 prism diopters of exophoria to 17 prism diopters of esophoria). The mean (±SD) accommodative lag by visit, correction type, and treatment group assignment are shown in Table 2.

Accommodative Lag at the Baseline and 6-Month Visits

Accommodative lag measured with each type of correction depended on the visit (Fig. 1, correction type by visit interaction; $P = 0.018$). Accommodative lags measured with each of the three correction types at baseline were significantly different from each other (all $P < 0.05$; Tukey's HSD) with accommodative lag highest when measured with the manifest correction, followed by the habitual correction, and lowest with the manifest/+2.00-D correction. At the 6-month visit, there was no difference between the manifest and habitual correction types, but lag was significantly lower with the manifest/+2.00-D and habitual/+2.00-D corrections than with their respective distance corrections ($P < 0.05$; Tukey's HSD). Lag with manifest and habitual corrections were similar at 6 months, whether children wore SVLs or PALs (treatment group by correction type interaction; $P = 0.25$).

For the previous and all subsequent analyses, lag values from children wearing SVLs and children wearing PALs were pooled and averaged because the correction type-dependent differences in lag measured across visits did not depend on the child's treatment group (correction type by visit by treatment group interaction; $P = 0.62$). Differences in accommodative lag over time also did not depend on the child's treatment group (visit by treatment group interaction; $P = 0.92$), indicating that bifocal adaptation was not responsible for the differences found in accommodative lag over time.

Lag with each correction type was consistent across visits except for the manifest correction. Accommodative lag with the manifest correction was higher at the baseline visit than at the 6-month visit by 0.13 ± 0.50 D (mean ± SD; $P < 0.05$; Tukey's HSD). The mean (± SD) reduction in accommodative lag between the manifest and manifest/+2.00-D testing conditions was also greater at the baseline visit (0.45 D ± 0.34 D) than at the 6-month visit (0.33 D ± 0.38 D; $P < 0.05$; Tukey's HSD). Overall, regardless of whether children wore their habitual or manifest correction, a +2.00-D bifocal add slightly reduced (by approximately 0.4 D), but did not eliminate, hyperopic retinal blur due to accommodative lag. This small reduction in accommodative lag indicates that children mainly responded to the bifocal add by decreasing accommodation (by ~1.6 D).

As described earlier, COMET found that the PAL treatment effect was largest in children with a high accommodative lag and near esophoria. In the present study, an analysis was performed to mine whether near phoria affects accommodative lag. Near phoria had no significant effect on accommodative lag, either by itself as a main effect ($P = 0.79$) or in any two- or three-way interactions with correction type and/or visit (all $P \geq 0.08$). This finding suggests that children with high accommodative lag and near esophoria would not experience any greater reduction in defocus from lag while wearing a +2.00-D add than would children without near esophoria. An explanation other than greater reduction in lag may be needed for the larger PAL treatment effect seen in children with high accommodative lag and near esophoria.

Undercorrection and Accommodative Lag

The role played by distance undercorrection in creating the higher lag at baseline for manifest compared with habitual corrections was evaluated in more detail. At baseline, the mean (± SD) amount of spherical undercorrection when wearing the habitual correction was −0.79 ± 0.67 D (mean ± SD; $P < 0.0001$; *t*-test) versus −0.18 ± 0.30 D at the 6-month visit. Reasons for undercorrection at the baseline visit included myopic progression since receiving the spectacles worn to the visit or having no correction at all at the baseline visit. Children with no correction included both established myopes who did not have glasses at baseline and children who had never worn glasses. At 6 months, any uncorrected myopia was due to myopic progression. The mean amounts of undercorrection at each visit were significantly different from each other ($P < 0.0001$; paired *t*-test). A statistically significant correlation was found between the amount of undercorrection at baseline and the difference in accommodative lag measured with the baseline manifest and habitual corrections ($r = -0.29$; $P = 0.009$;

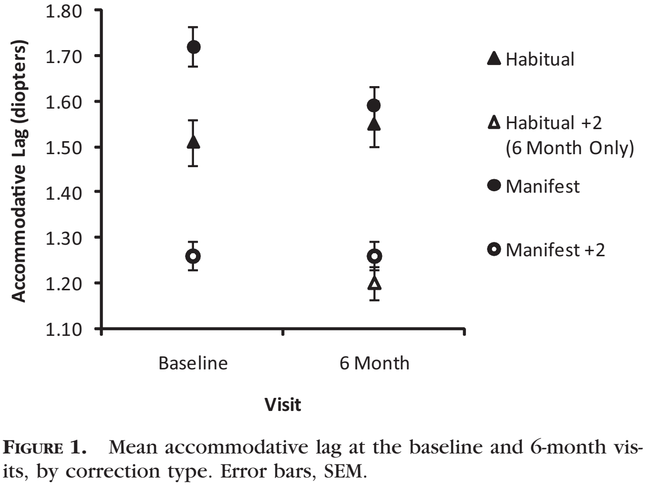

Figure 1. Mean accommodative lag at the baseline and 6-month visits, by correction type. Error bars, SEM.

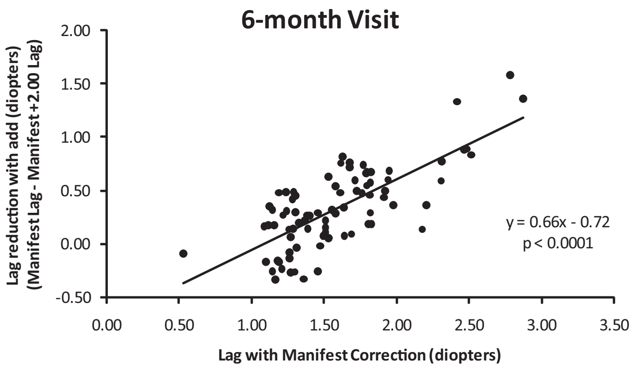

FIGURE 2. Relationship between accommodative lag measured with the manifest correction and the reduction in accommodative lag when a +2.00-D bifocal add was introduced.

Pearson correlation); however, the correlation accounted for only 8% of the variance in the data. Therefore, the larger amount of undercorrection in habitual conditions at baseline explains in part why lag with manifest correction was higher than all other conditions.

The Relationship between Initial Lag and Reduction in Lag with a Bifocal

The reduction in accommodative lag when introducing a +2.00-D bifocal was assessed at the 6-month visit after all children had worn and adapted to their prescribed correction for a uniform period. For both the manifest correction (Fig. 2) and habitual correction (Fig. 3), children with a higher accommodative lag with their distance correction had a greater reduction in lag when a +2.00-D bifocal was introduced (both $P < 0.0001$). As can be seen in the figures, some children experienced little to no change in accommodative lag when wearing a +2.00-D add, whereas other children experienced greater decreases in lag when wearing a +2.00-D add. A significant correlation between lag measured with the manifest and habitual distance correction indicates that this relationship is not merely regression to the mean ($r = 0.49$, $P < 0.0001$). The x-intercepts in Figures 2 and 3 suggest that a lag of approximately 1.00 D would be unaffected by a +2.00-D bifocal add. The slopes indicate that only 52% to 66% of each diopter of lag above approximately 1.00 D was eliminated by a +2.00-D bifocal add.

DISCUSSION

Bifocal Effect on Accommodation

To be included in this study, myopic children had to have a high lag of accommodation. In addition, a large percentage of the children were esophoric at near. Both of these characteristics have been identified as important when determining whether a myopic child will experience a decrease in myopia progression when wearing PALs[17]; however, the reduction in these children's accommodative lag when wearing a +2.00-D bifocal in this study was modest. Wearing a +2.00-D add over the manifest correction resulted in a decrease in the mean accommodative lag from 1.72 to 1.26 D at baseline and from 1.59 to 1.26 D at the 6-month visit. Even though enrollment was restricted to children reported to benefit most from wearing PALs, a +2.00-D bifocal yielded a reduction in accommodative lag that was less than 25% of the bifocal power. This result is drastically different from the elimination of accommodative lag and the lead of accommodation (myopic retinal defocus) with a +2.00-D bifocal that is consistently reported in adults.[18–23]

Only two studies have reported the effect of a bifocal add on accommodative lag in myopic children.[24,25] Cheng et al.[24] found that accommodative lag for a 3-D binocular stimulus was not eliminated until children wore an add power of +2.50 D over the manifest correction. Their modeled data showed that a +2.00-D add reduced accommodative lag by 0.78 D, which is greater than the reductions in lag found in this study. Differences such as a lower dioptric near demand and binocular viewing of the target[18,32,33] may partially account for the greater reduction in accommodative lag found with a +2.00-D add by Cheng et al.[24] The smaller target size (20/30 letters) used in their study and the inclusion of all myopic children regardless of the amount of accommodative lag may also have contributed to differences found between the studies. Regardless, the current results are consistent with those of Cheng et al. in that a +2.00-D add did not eliminate accommodative lag in either study.

Sreenivasan et al.[25] reported that a +2.00-D bifocal add nearly eliminated accommodative lag for a 3-diopter stimulus under monocular conditions and completely eliminated accommodative lag under binocular viewing conditions. Although myopic children in their study were either orthophoric or exophoric at near, the myopic children in the present study and the study by Cheng et al.[24] included children with near esophoria. Because an association between near esophoria and more rapid myopia progression has been reported,[14,17,34–36] it is plausible that the difference in the children's phoria status between studies could account for the difference in the effect of a +2.00-D add on accommodative lag. One would expect all nonesophoric children to experience a reduction in myopia progression when wearing a bifocal based on the findings of Sreenivasan et al.[25]; however, this was not the case in COMET.[17]

Although most of the children in this study experienced a reduction in accommodative lag of less than 0.50 D with a +2.00-D bifocal, children with a higher lag of accommodation did have a greater reduction in lag with a bifocal (Figs. 2, 3). It could be that the greater reduction of accommodative lag with a bifocal in myopic children with higher amounts of lag explains why such children had a greater bifocal treatment effect in COMET.[17] This interpretation supports the COMET rationale that children with a higher lag of accommodation benefit more from wearing bifocal spectacles. That having been said, there were still many children with high accommodative lag in this study who experienced only a minimal reduction in the lag with a bifocal. There was a floor effect at approximately 1.00 D of lag where the +2.00-D add had no impact and then only

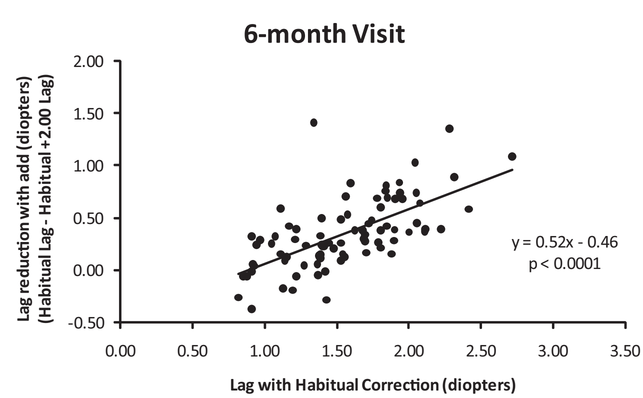

FIGURE 3. Relationship between accommodative lag measured with the habitual correction and the reduction in accommodative lag when a +2.00-D bifocal add was introduced.

about a 50% reduction in lag for every diopter of lag above the 1.00-D floor.

Only one longitudinal report in children examining the relationship between accommodative lag and myopia progression has been published, and that study found no association.[27] Given that reducing hyperopic retinal blur is a proposed rationale for why bifocal spectacles slow myopia progression, that reports in the literature regarding the effect of a bifocal on lag disagree, and that a bifocal only yielded a small reduction in lag in the present study, it will be important for future clinical trials to report the reduction in accommodative lag when wearing a bifocal. To determine whether reducing hyperopic retinal blur is in fact responsible for the bifocal effect, future clinical trials should determine whether there is an association between lag reduction and the magnitude of the treatment effect in the bifocal group. In addition, if one intends to generalize the results of an accommodation study to myopic children, the present results demonstrate the importance of studying myopic children as opposed to adults and nonmyopic subjects.

The Influence of Correction Type on Accommodative Lag

As discussed earlier, studies typically measure accommodative lag with full distance correction. In this study, when the children were measured in real-world conditions (i.e., the baseline visit where children were undercorrected by various amounts), the manifest correction yielded significantly higher lags of accommodation than did the child's habitual correction. Because measurements made with the habitual correction represent what the child has most recently experienced, measuring accommodative lag only with the manifest correction may not accurately describe the amount of hyperopic retinal blur that the child has been experiencing when performing near tasks. These results indicate that it is important in observational studies to also perform accommodative testing with the child's habitual correction (what the child has been experiencing). Making measurements solely with a full manifest correction may result in an overestimation of the amount of hyperopic retinal blur that the child has most recently experienced when performing near tasks if substantial progression has taken place or the child does not yet wear correction. These small overestimations could lead to an inaccurate interpretation of the relationship between accommodative lag and the progression of myopia, especially in emerging myopic children who do not yet wear correction.

Bifocal Adaptation and Accommodative Lag

There was no evidence that bifocal adaptation was responsible for differences observed in accommodative lag over time or by correction type. Bifocal wear for 6 months did not result in different lag values compared with SVL wear. This result is consistent with a study of emmetropic adults that found no effect of bifocal adaptation on accommodation after 30 minutes of near work.[19] Although both a study of emmetropic adults and a study of emmetropic and myopic children reported a small improvement (0.25 D) in binocular accommodative accuracy within the first 3 minutes of wearing spectacles with a +2.00-D add, the adaptation effect was not observed with monocular viewing.[20,25] Overall, the current results do not suggest that bifocal adaptation-related accommodative lag changes occurred over a 6-month period.

Although the results of this study are specific to myopic children with a high accommodative lag, COMET identified these children as having the most optimal PAL treatment effect.[15,17] For this reason, the application of these data to the effect of a bifocal on accommodative lag is valid. The present study also used a 4-D accommodative stimulus rather than a 3-diopter stimulus. The 4-D stimulus level is appropriate, given that COMET reported that children with a high lag of accommodation and a reading distance of less than 31.2 cm had a significant 3-year PAL treatment effect, whereas children with a longer working distance did not.[17]

A limitation of this study is that we do not know what accommodative lag would have been if tested with a real target. Measurements of accommodation in this study were made using a 4-D Badal target, which eliminates cues to accommodation that are present with a real target. Because defocus is the only accommodative cue when using a Badal system, the viewing environment is not the same as viewing a real target at a set distance. Although one study of adolescents and young adults reported no significant difference between accommodation to real targets and Badal targets,[37] most studies have found that children accommodate less accurately to minus-lens–induced blur[5,38,39] and Badal targets[6] than to real targets. The CLEERE Study measured accommodative lag monocularly using both the 4-D Badal target used in the present study and a 4-D real target, and their data show that the Badal target resulted in accommodative lags that were generally approximately 0.10 D greater than with the real target (a difference that is roughly 10% of the average lag that they measured with the two targets).[6] Testing with a real target most likely would have resulted in more accurate accommodation to the target; however, it is unknown to what extent the increased accommodative accuracy to a real target would have eliminated the roughly 1.25 D of accommodative lag measured in the present study when children viewed the Badal target through a +2.00-D bifocal add.

The order of testing with each correction type in this study was not randomized. Because the lag measurements were collected at the beginning of a nearly 2-hour study visit, it was decided that randomization of the testing sequence would have greatly increased the potential for data collection errors; however, it is unlikely that a testing order effect is present. Examination of the lag data as a function of correction type and the amount of spherical undercorrection found that when a child was already fully corrected at the baseline visit, there was no difference in accommodative lag when tested with the habitual and manifest corrections. Furthermore, if a child presented to the first visit and was undercorrected by 2.00 D (i.e., the child's habitual sphere value was the same as the child's sphere value for the manifest/+2.00-D correction), there was no difference in accommodative lag when tested with the habitual correction and the manifest/+2.00-D correction.

Because COMET was a large-scale, well-executed clinical trial, there was adequate statistical power to perform meaningful subgroup analyses to determine which children responded to the environmental influence of PALs. Children were enrolled in STAMP only if they had high accommodative lag and low myopia or high accommodative lag and near esophoria because of their statistically significant and clinically meaningful PAL treatment effects in COMET. Although the hypothesis in COMET was that PALs reduce myopia progression by decreasing accommodative lag (and therefore hyperopic retinal blur) during near work,[15] the effect of a +2.00-D PAL on accommodative lag in COMET was not reported. Our results suggest that accommodative lag was not eliminated. Further, it is unclear whether the modest reductions in accommodative lag found in STAMP with a +2.00-D add can account for the treatment effects seen in COMET. On the basis of our results, it appears that careful measurement of the effect that PALs have on the eye is necessary to definitively explain the mechanism responsible for the PAL treatment effect. It is important that future myopia trials measure the effect of any optical intervention on accommodative lag to determine whether the change in lag is related to the observed reduction in myopia progression, noting that the reduction in lag may be less when measured with the child's habitual versus manifest correction. Future trials should also measure the effect of any optical intervention on peripheral retinal defocus, which has recently been shown to influence refractive error development in animal models.[40,41]

In summary, a +2.00-D bifocal did not eliminate accommodative lag at a 4-D demand in children selected as most likely to benefit from wearing PALs. A bifocal add resulted in only a modest reduction in the amount of accommodative lag, approximately 25% of the bifocal add amount. More than 1.00 D of accommodative lag remained when children wore a +2.00-D bifocal add. Chronic undercorrection at distance resulted in greater accommodative lag when measurements were made with a manifest distance correction. There was no effect of bifocal adaptation on accommodative lag. These results indicate that studies of myopic children that use a bifocal should report the reduction in accommodative lag when wearing the bifocal. These results also suggest that it is important to evaluate accommodative lag with a child's habitual and manifest corrections if the goal is to understand the retinal blur experienced during near work.

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Appendix

STAMP Study Group

Data and Safety Monitoring Committee: Mark A. Bullimore (chair); Leslie Hyman, and Melvin L. Moeschberger

Masked examiners: Bradley Dougherty (2007–present), Kerri McTigue (2008–present), Donald O. Mutti, (2008–present), Kathryn Richdale (2007–present), Eric Ritchey (2007–present), and Aaron Zimmerman (2007–2008)

Opticians: Melissa Button (2007–present), Aaron Chapman (2006–2007), Melissa Hill (2006–2008), Brandy Knight (2008–present), Scott Motley (2007–2009), and Jeff Rohlf (2006–present)

Optometry Coordinating Center: Lisa Jones-Jordan (Director, 2005–present), G. Lynn Mitchell (Biostatistician, 2005–present), Loraine Sinnott (Biostatistician, 2005–present), Linda Barrett (Data Entry; 2005–2007), Austen Tanner (Data Entry, 2005–present), Melanie Schray (Database Management, 2005–present)