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ORIGINAL ARTICLE

A Randomized Clinical Trial of Vision Therapy/ Orthoptics versus Pencil Pushups for the Treatment of Convergence Insufficiency in Young Adults

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ABSTRACT: *Purpose.* The purpose of this article is to compare vision therapy/orthoptics, pencil pushups, and placebo vision therapy/orthoptics as treatments for symptomatic convergence insufficiency in adults 19 to 30 years of age. *Methods.* In a randomized, multicenter clinical trial, 46 adults 19 to 30 years of age with symptomatic convergence insufficiency were randomly assigned to receive 12 weeks of office-based vision therapy/orthoptics, office-based placebo vision therapy/orthoptics, or home-based pencil pushups. The primary outcome measure was the symptom score on the Convergence Insufficiency Symptom Survey. Secondary outcome measures were the near point of convergence and positive fusional vergence at near. *Results.* Only patients in the vision therapy/orthoptics group demonstrated statistically and clinically significant changes in the near point of convergence (12.8 cm to 5.3 cm, $p = 0.002$) and positive fusional vergence at near (11.3Δ to 29.7Δ, $p = 0.001$). Patients in all three treatment arms demonstrated statistically significant improvement in symptoms with 42% in office-based vision therapy/orthoptics, 31% in office-based placebo vision therapy/orthoptics, and 20% in home-based pencil pushups achieving a score <21 (our predetermined criteria for elimination of symptoms) at the 12-week visit. *Discussion.* In this study, vision therapy/orthoptics was the only treatment that produced clinically significant improvements in the near point of convergence and positive fusional vergence. However, over half of the patients in this group (58%) were still symptomatic at the end of treatment, although their symptoms were significantly reduced. All three groups demonstrated statistically significant changes in symptoms with 42% in office-based vision therapy/orthoptics, 31% in office-based placebo vision therapy/orthoptics, and 20% in home-based pencil push-ups meeting our criteria for elimination of symptoms. (Optom Vis Sci 2005;82:E583–E595)

Key Words: convergence insufficiency, vision therapy, orthoptics, pencil push-ups, placebo, exophoria, eyestrain, symptoms

There is a lack of consensus regarding the most appropriate treatment for convergence insufficiency (CI) in young adults. Various treatments are prescribed, including base-in prism glasses, home-based pencil push-ups, home-based vision therapy/orthoptics, and office-based vision therapy/orthoptics.[1–11] Recent studies surveying the ophthalmic community to determine the most widespread treatment modality for patients with symptomatic CI have found that pencil pushups is the most commonly prescribed treatment by both ophthalmologists and optometrists for young adults.[12,13] Despite the apparent clinical

popularity of pencil pushups for CI, there has been only a single noncontrolled study of 25 patients that has evaluated the effectiveness of this treatment modality.[11] Of the 25 patients with CI who underwent treatment with pencil pushups, only seven (28%) of them had improved signs and symptoms.

Of the various treatments commonly recommended for CI, only office-based vision therapy/orthoptics has been extensively evaluated. Grisham[14] reviewed the ophthalmic literature relative to treatment results for CI using vision therapy or orthoptics for the years 1940 to 1987 and summarized 17 studies with a total of 1931 patients. He calculated a weighted cure rate of 72%, an improved rate of 19%, and a 9% failure rate. All of the studies reviewed, however, had one or more of the following design flaws: lack of a clear definition of CI, inadequate definition of successful outcome, retrospective design, failure to use masked examiners for outcome measures, small sample size, or no control group. Although two of the studies were prospective, double-blind, placebo-controlled studies showing that vergence therapy increased positive fusional vergence and decreased symptoms in patients with CI, these studies had small sample sizes.[15,16] In a recent randomized, controlled study of 60 adult patients with CI, Birnbaum and colleagues found that office-based vision therapy was successful in 61.9% of patients, whereas home-based vision therapy was successful in only 10.5% of patients.[17] However, the study did not have a placebo control group and the investigators did not use masked examiners to gather outcome data.

Thus, there is both a lack of consensus regarding the most appropriate treatment for CI in young adults and lack of quality scientific data about the various treatments. In a recently published study, we reported the results of a randomized clinical trial of vision therapy/orthoptics versus pencil pushups for CI in children.[18] Vision therapy/orthoptics was found to be more effective than pencil pushups or placebo vision therapy/orthoptics in reducing symptoms and improving signs of CI in children 9 to 18 years of age. Neither pencil pushups nor placebo vision therapy/orthoptics was effective in improving either symptoms or signs associated with CI. The study reported here was conducted simultaneously with young adult patients (ages 19–30 years) using the identical protocol.

The Convergence Insufficiency Treatment Trial (CITT) study group designed this pilot study in preparation for a larger randomized clinical trial. This study was a masked, placebo-controlled, multicenter, randomized clinical trial in which young adults 19 to 30 years of age were randomly assigned to one of three treatments: pencil pushups, office-based vision therapy/orthoptics (vision therapy/orthoptics), or office-based placebo vision therapy/orthoptics (placebo vision therapy/orthoptics). The purpose of this study was to determine if, after 12 weeks of treatment, either or both of two popular treatments for CI (pencil pushups and vision therapy/orthoptics) was more effective than placebo treatment, and if so, whether one treatment was more effective than the other in improving symptoms and signs associated with symptomatic CI in young adults.

PATIENTS AND METHODS

This study, supported by the National Eye Institute of the National Institutes of Health, Department of Health and Human Services, was conducted by the Convergence Insufficiency Treatment Trial Group at six clinical sites at schools and colleges of optometry in California, New York, Ohio, Oregon, Pennsylvania, and Texas (see Appendix 1). The research followed the tenets of the Declaration of Helsinki, and informed consent was obtained from the patients after explanation of the nature and possible consequences of the study. The protocol and informed consent forms were approved by each Institutional Review Board.

Patient Selection

Eligibility testing included administration of the original 13-item version of the CI Symptom Survey (CISS-V13 described subsequently) to identify whether a patient with CI was symptomatic. At the time of eligibility testing, the revised CI Symptom Survey with 15 items (CISS-V15) had not yet been validated. Therefore, the 13-item version was used only for eligibility testing, and subsequently the 15-item version[19] (Appendix 1) was used to assess symptoms at the first treatment visit and changes during treatment, and served as the primary outcome measure.

Other eligibility testing included best-corrected visual acuity at distance and near, a cycloplegic refraction, and a sensorimotor examination that included cover testing at distance and near, near point of convergence, positive and negative fusional vergence at near, near stereoacuity, monocular accommodative amplitude, and monocular accommodative facility. All testing was performed using standardized protocols and had to be performed no more than 2 months before randomization. The mean time from eligibility testing to randomization was 3.3 days (standard deviation [SD] = 6.2) with a maximum lag in randomization of 30 days. Fifty-two percent (24 of 46) of the patients were randomized on the day of eligibility testing.

The near point of convergence was measured with the Astron International (ACR/21) Accommodative Rule. The device consists of a rod with a movable, single column of letters (20/30 equivalent at 40 cm). Instructions were similar to the ones described by Hayes et al.[20] Three near point of convergence measurements were obtained, and the average value was used to determine eligibility and later to assess the treatment effect. Positive fusional vergence (blur, break, and recovery) was measured with a horizontal prism bar (Gulden B-15 horizontal prism bar—1△ to 45△) while the patient viewed a 20/30 size column of letters (Gulden Fixation Stick no. 15,302) held at 40 cm. Positive fusional vergence was measured three times with at least 30 seconds between each measure; the mean of the three measures was used to determine eligibility.

If a patient was wearing glasses and no change in prescription was necessary, randomization occurred immediately. If a significant refractive error was present or a significant change in refractive correction was required, new glasses were prescribed. A significant refractive error or change in needed refractive correction was defined as ≥1.50 D hyperopia, ≥0.50 D myopia, ≥0.75 D astigmatism, ≥0.75 D anisometropia in spherical equivalent, or ≥1.50 D anisometropia in any meridian (based on cycloplegic refraction). After wearing the glasses for at minimum of 2 weeks, eligibility testing was repeated to determine if the patient still met the eligibility criteria.

Major eligibility criteria for the trial included adults ages 19 to 30 years inclusive, exophoria at near at least 4△ greater than at far, a receded near point of convergence break of 6 cm or greater, and insufficient positive fusional convergence at near (i.e., failing

Sheard's criterion (positive fusional vergence less than twice the near phoria[21] or minimum positive fusional vergence of 15 baseout break), and a score of ≥9 on the CISS–V13. Table 1 provides a complete listing of the eligibility and exclusion criteria.

Treatment Protocols

The Ohio State University Optometry Coordinating Center, the data coordinating center for the study, randomly assigned eligible patients with equal probability to pencil pushups, vision therapy/orthoptics, and placebo vision therapy/orthoptics treatment arms. Randomization was accomplished on the study's web site using blocks of six so the investigator could not predict the sequence of treatment assignments. To ensure approximately equal numbers of patients in each treatment arm at any given clinical center, randomization was performed separately for each site.

TABLE 1.
Eligibility and exclusion criteria

Eligibility criteria
Age 19–30 years inclusive
Best-corrected visual acuity of 20/25 in both eyes at distance and near
Willingness to wear eyeglasses or contact lenses to correct refractive error, if necessary
Exophoria at near at least 4 greater than at far
Insufficient positive fusional convergence (i.e., failing Sheard's criterion21 or less than 15 break)
Receded near point of convergence of greater than or equal to 6 cm break
Appreciation of at least 500 seconds of arc on the forms part of the Randot Stereotest
CI Symptom Survey–V13 (original 13-item version) score 9
Informed consent and willingness to participate in the study and be randomized
Exclusion criteria
CI previously treated with pencil pushups or office-based vision therapy/orthoptics (no more than 2 months of treatment within the past year)
Amblyopia
Constant strabismus
History of strabismus surgery
Anisometropia >1.50 D difference between eyes
Prior refractive surgery
Vertical heterophoria greater than 1
Systemic diseases known to affect accommodation, vergence, and ocular motility such as multiple sclerosis, Graves' thyroid disease, myasthenia gravis, diabetes, and Parkinson disease
Any ocular or systemic medication known to affect accommodation or vergence
Monocular accommodative amplitude less than 4 D in either eye as measured by the pushup method
Manifest or latent nystagmus
Household member already enrolled in the CITT
Any eye care professional, ophthalmic technician, medical student, or optometry student

CI, convergence insufficiency; CITT, convergence insufficiency treatment trial.

Pencil Pushups

Patients in the pencil pushups group were taught a pencil pushup procedure that included monitoring for suppression. The patient was instructed to hold a pencil at arm's length directly between his or her eyes and an index card, which served as a suppression control, was placed on the wall 6 to 8 feet away. The patient was instructed look at the tip of the sharpened pencil and to try to keep the pencil point single while moving it toward his or her nose. If one of the cards in the background disappeared, the patient was instructed to stop moving the pencil and blink his or her eyes until both cards were present. The patient was told to continue moving the pencil slowly toward his or her nose until it could no longer be kept single and then to try to regain single vision. If the patient was able to regain single vision, he or she was asked to continue moving the pencil closer to his or her nose. If the patient could not regain single vision, he or she was instructed to start the procedure again. Patients were instructed to do three sets of 20 pushups per day at home, 5 days per week for 12 weeks, and this treatment required approximately 15 minutes per day. Before performing the procedure at home, the patient had to demonstrate in the office that he or she understood and had the ability to perform the procedure according to the protocol.

Office-Based Vision Therapy/Orthoptics (VT/Orthoptics)

The vision therapy/orthoptics group received therapy administered by a trained therapist during a weekly, 60-minute office visit, with additional procedures to be performed at home for 15 minutes a day, five times per week for 12 weeks. The office- and home-based procedures used are described in detail elsewhere[9] and are listed in Table 2 along with a short description of each procedure. The items listed in Table 2 are the specific procedures performed by each patient in this treatment arm during the weekly, office-based vision therapy/orthoptics sessions. In addition, treatment procedures were practiced at home. During a typical office-based treatment session, the patient practiced four to five procedures with constant supervision and guidance from the therapist. There were no diagnostic tests performed during these sessions. The therapist followed a very detailed and specific protocol from the CITT Manual of Procedures, which described the proper treatment technique, amount of time the technique was to be done, expected performance, and the criteria required to advance to a more difficult level or to the next procedure in the treatment se-

TABLE 2.
Office-based vision therapy/orthoptics procedures

Loose lens accommodative facility
Letter chart accommodative facility
Binocular accommodative facility
Brock string
Barrel card
Vectograms
Computer orthoptics (random dot stereogram procedure)
Aperture rule trainer
Eccentric circles free-space fusion cards
Loose prism facility
Life saver free-space fusion cards

quence. Figure 1 outlines the treatment sequence. When a procedure was prescribed for home treatment, a handout with instructions was given to the patient.

Placebo Office-Based Vision Therapy/Orthoptics (Placebo VT/Orthoptics)

Like the vision therapy/orthoptics group, the placebo vision therapy/orthoptics group received therapy administered by a trained therapist during a 60-minute office visit and were prescribed procedures to be performed at home, 15 minutes, five times per week for 12 weeks. The procedures for placebo vision therapy/orthoptics were designed to simulate real vision therapy/orthoptics procedures without the expectation of affecting vergence, accommodation, or saccadic function. Examples included using stereograms monocularly to simulate vergence therapy, computer vergence therapy with no vergence changes, and using monocular prism (instead of plus and minus lenses) to simulate accommodative treatment.

Because experienced therapists provided the treatments, it was not feasible to mask them to their patients' assigned treatment groups. However, each therapist followed a well-defined protocol for all treatments and was instructed to interact in an identical fashion with patients in all treatment groups. Although patients were obviously aware of whether they were assigned to office-based treatment or pencil pushups, those assigned to office-based treatment were masked regarding whether they were assigned to real vision therapy/orthoptics or placebo vision therapy/orthoptics.

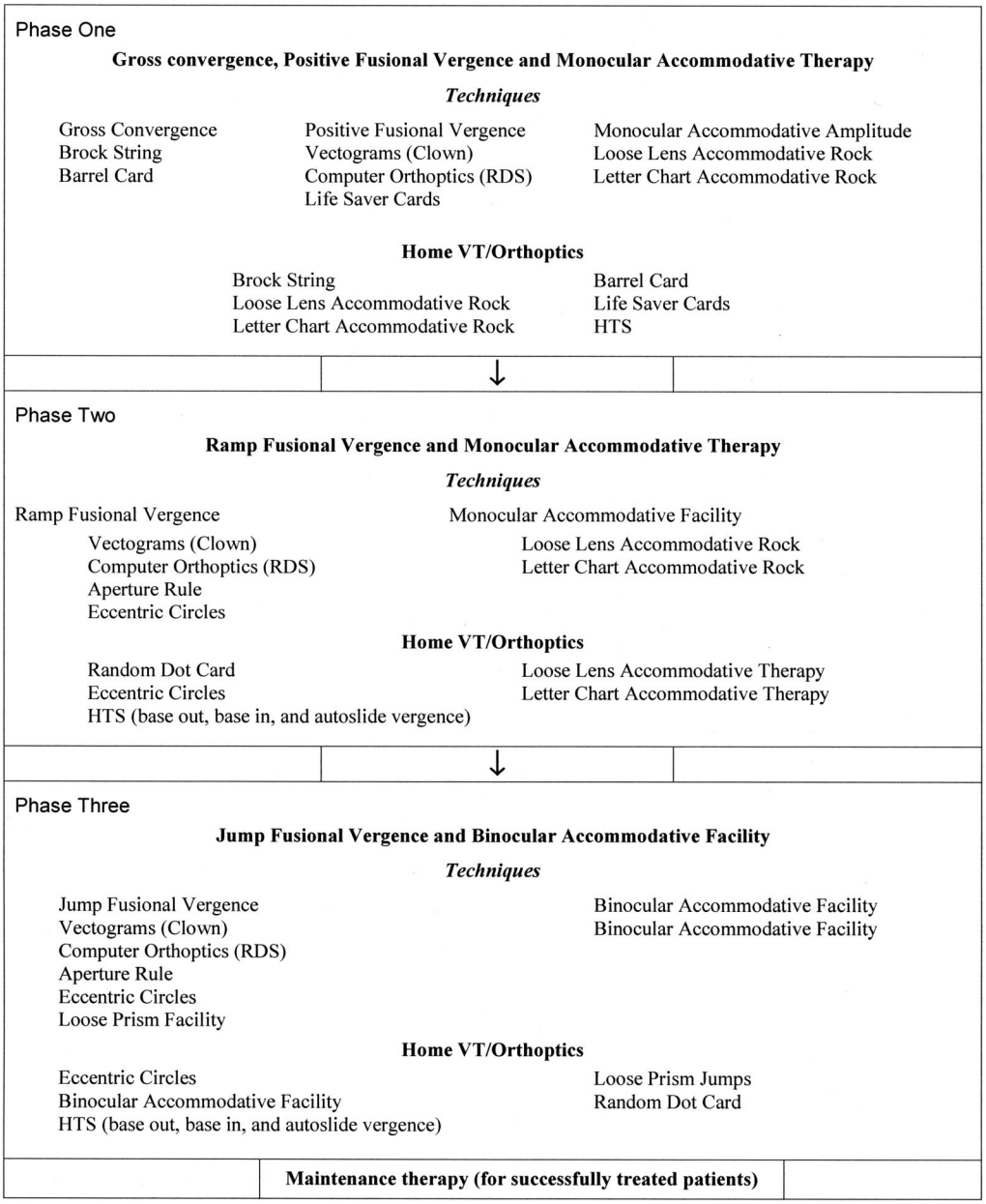

FIGURE 1.
Vision therapy (VT) /orthoptics protocol

TABLE 3.
Study population demographics and clinical measures at enrollment

Characteristic	Overall (n = 46)	Dropouts (n = 6)	Completers (n = 40)
Age in years, mean (SD)	24.3 (3.6)	24.2 (4.1)	24.4 (3.5)
Gender			
% Male	28.3	33.3	27.5
% Female	71.7	66.7	72.5
Race			
% White	56.5	33.3	60.0
% Black	6.5	16.7	5.0
% Hispanic	17.4	16.7	17.5
% Asian	10.9	33.3	7.5
% Other	8.7	0.0	10.0
CISS-V15 score, mean (SD)	37.3 (9.3)	38.0 (11.2)	37.3 (9.1)
Near point of convergence (cm), mean (SD)			
Break	13.5 (7.1)	14.9 (6.6)	13.2 (7.2)
Recovery	17.1 (9.2)	20.2 (7.9)	16.6 (9.3)
Accommodation (OD only), mean (SD)			
Amplitude (D)	13.7 (4.4)	13.4 (4.8)	13.8 (4.4)
Facility (cpm)	7.8 (5.5)	5.1 (4.0)	8.3 (5.6)
Exophoria (△), mean (SD)			
Distance	2.4 (2.9)	1.2 (1.0)	2.6 (3.1)
Near	10.6 (4.8)	6.7 (1.0)	11.2 (4.9)
Positive fusional vergence at near (△), mean (SD)			
Blur	9.4 (4.2)	7.9 (3.0)	9.6 (4.3)
Break	11.8 (5.4)	8.7 (3.4)	12.3 (5.5)
Recovery	7.8 (4.9)	4.6 (2.2)	8.3 (5.0)
Refractive error (spherical equivalent), mean (SD)			
OD	−0.92 (1.9)	0.08 (0.5)	−1.07 (2.0)
OS	−0.97 (1.9)	−0.02 (0.4)	−1.11 (2.0)

△, prism diopter; SD, standard deviation; cpm, cycles/min.

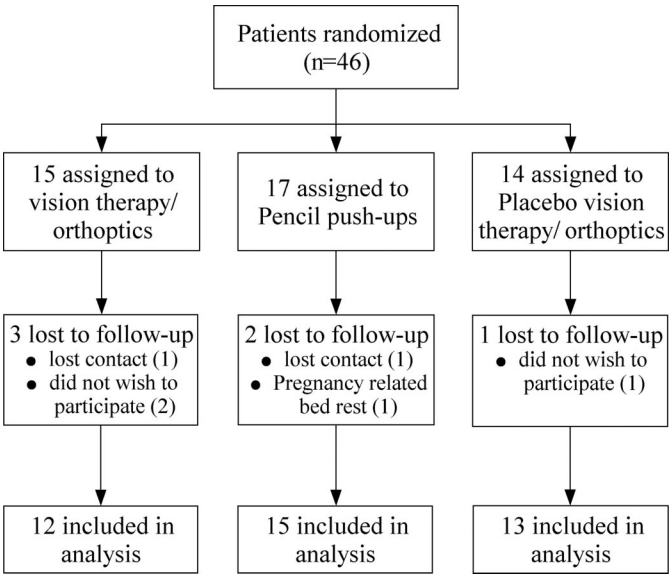

FIGURE 2.
Flowchart showing study completion for each group.

Examination Procedures

Protocol-specified follow-up visits were conducted after 4 ± 1 and 8 ± 1 weeks of treatment. The primary outcome assessment was made at the visit after 12 ± 2 weeks of treatment. At these follow-up visits, an examiner who was masked to the patient's treatment group administered the CISS-V15, cover testing at distance and near, near point of convergence, and positive fusional vergence at near.

Adherence to the Treatment Protocol

Adherence to the home treatment protocol was assessed by having the patient maintain a calendar on which the treatment (minutes of home therapy) performed each day was logged. The calendars were reviewed at follow-up visits, and the therapist made an assessment of the patient's adherence to the prescribed treatment (excellent was 75–100% of prescribed treatment completed, good 50–74%, fair 25–49%, and poor ≤25%).

At the Coordinating Center, each follow-up examination form was reviewed to assess whether the investigator properly followed the examination and treatment protocol, and any necessary feedback was provided to the investigator.

Outcome Measures and Criteria for Success

Patients with CI who seek treatment do so to eliminate their symptoms. Thus, treatment for CI can only be considered successful if the patient has fewer symptoms after treatment. To measure symptoms and changes in symptoms, we used the score on the CI Symptom Survey-V15 as the primary outcome measure. Our pre-

liminary work during this study demonstrated that the majority of these adult patients with CI had CI Symptom Survey scores of 21 or higher (sensitivity = 97.8%), whereas those with normal binocular vision predominantly scored below 16 (specificity = 85.7%).[22] We, therefore, defined a CI Symptom Score of <21 after 12 weeks of treatment as a successful outcome. We also evaluated two secondary outcome measures (near point of convergence and positive fusional vergence at near).

For most clinicians, the goal of the treatment for a patient with CI is not only to eliminate the person's symptoms, but also to improve the patient's near point of convergence and positive fusional vergence at near. Thus, we used another set of criteria to define patients as "cured" or "improved." Patients who achieved scores of <21 on the CI Symptom Survey *and* had a normal near point of convergence *and* normal positive fusional vergence at near were considered "cured." Patients who achieved a decrease in symptoms (<21 on the CI Symptom Survey) and achieved normal values in *either* the near point of convergence (<6 cm) *or* positive fusional vergence at near (passing Sheard's criterion[21]or ≥15△ break) were considered "improved."

Statistical Methods

No formal sample size calculations were performed *a priori* because one of the goals of this pilot study was to estimate the variability of our new outcome measure, the CISS-V15. At study completion, the observed variability in the CISS-V15 was used to determine the statistical power available to detect meaningful differences among the three treatment groups. The calculations were performed using PASS software with $\alpha = 0.05$ and assuming a two-sided test. The group means used in the calculations were obtained from the mean CISS-V15 score of adult patients with normal binocular vision and the mean CISS-V15 score at the 12-week outcome visit of the enrolled patients with CI assigned to the placebo vision therapy group.[22] It was assumed that the posttreatment mean of the most effective treatment group would approximate the mean among patients with normal binocular vision, that the mean for the placebo group would decrease 20% from its baseline value, and that the mean for the remaining treatment group would fall in the middle of these first two groups. By assuming that the mean from the third treatment group would fall in the middle of the other two, the power to detect differences is minimized. That is, these assumptions about the mean values of the CISS for the three groups yield the smallest value for power and are therefore the most conservative. Even using these conservative assumptions, our power to detect differences is extremely high at 99.6%.

RESULTS

Enrollment

A total of 46 patients were enrolled in the study between November 2000 and November 2001. The number enrolled per site at the five sites ranged from one to 15 (median = 7.5). The mean age was 24.3 years (SD = 3.6); 72% were female, 57% were white, 7% black, 17% Hispanic, 11% were Asian, and 9% other. At eligibility, the mean (SD) clinical findings for the enrolled patients were 2^{Δ} (± 2.9) exophoria at distance; 11^{Δ} (± 4.8) exophoria at near; near point of convergence break/recovery of 13 (± 7.1) cm/17 cm (± 9.2); and near positive fusional vergence break of 12^{Δ} (± 5.4) and recovery 8^{Δ} (± 4.9). Table 3 provides the study population demographics and clinical measures at eligibility.

Patient Follow Up and Adherence to Treatment

The primary outcome examination was completed within the 12 ± 2-week window by 12 of 15 (80%) patients assigned to vision

TABLE 4.
Study population demographics and clinical measures at randomization by treatment group assignment

Characteristic	Pencil pushups (n = 17)	Vision therapy/orthoptics (n = 15)	Placebo vision therapy/orthoptics (n = 14)
Mean age (SD)	24.4 (3.4)	23.7 (3.9)	25.1 (3.5)
Gender			
% Male	29.4	26.7	28.6
% Female	70.6	73.3	71.4
Race			
% White	64.7	40.0	64.3
% Black	5.9	6.7	7.1
% Hispanic	11.8	20.0	21.4
% Asian	5.9	26.7	0.0
% Other	11.8	6.7	7.1
Accommodation			
Mean amplitude (D) (SD)	8.0 (2.5)	8.4 (3.3)	8.0 (2.4)
Mean facility (CPM) (SD)	7.6 (5.0)	8.7 (5.8)	7.3 (5.9)
Phoria (△)			
Mean distance (SD)	2.1 exo (2.3)	2.7 exo (4.0)	2.6 exo (2.2)
Mean near (SD)	10.8 exo (4.5)	10.9 exo (5.9)	10.0 exo (4.1)
Refractive error (spherical equivalent)			
Mean OD (SD)	−0.67 (1.7)	−1.31 (2.0)	−0.81 (2.0)
Mean OS (SD)	−0.78 (1.7)	−1.33 (2.0)	−0.81 (2.1)

SD, standard deviation; CPM, cycles/min; △ prism diopter.

TABLE 5.
Comparing treatment groups with respect to clinical measures at eligibility and the 12-week outcome examination

Characteristic	Pencil pushups (n = 15)	Vision therapy/orthoptics (n = 12)	Placebo vision therapy/orthoptics (n = 13)
Mean (SD) CI Symptom Survey-V15 score			
at eligibility	37.6 (7.7)	36.5 (8.7)	37.5 (11.4)
After 4 weeks	30.8 (9.9)	33.0 (9.4)	32.8 (11.6)
After 8 weeks	27.9 (7.3)	26.2 (9.3)	27.3 (11.8)
After 12 weeks	26.5 (7.3)	20.7 (10.2)	25.2 (10.3)
Mean (SD) NPC break			
at eligibility	12.5 cm (6.6)	12.8 cm (7.7)	14.5 cm (7.8)
After 4 weeks	8.3 cm (4.4)	7.4 cm (3.5)	11.5 cm (3.4)
After 8 weeks	8.7 cm (6.4)	6.0 cm (3.8)	10.5 cm (5.1)
After 12 weeks	7.8 cm (4.1)	5.3 cm (1.7)	9.6 cm (4.0)
Mean (SD) PFV break			
at eligibility	13.6△(7.1)	11.3△(4.3)	11.5△(4.4)
After 4 weeks	19.2△(9.6)	17.8△(7.1)	12.9△(5.3)
After 8 weeks	22.6△(11.7)	23.3△(11.0)	16.2△(7.2)
After 12 weeks	24.2△(12.5)	29.7△(10.8)	17.5△(5.7)

△, prism diopter; SD, standard deviation; NPC, near point of convergence; PFV, positive fusional vergence.

therapy/orthoptics, 13 of 14 (93%) patients assigned to placebo vision therapy/orthoptics, and 15 of 17 (88%) patients assigned to pencil pushups. The completion rate was not related to treatment assignment (chi-squared p value = 0.66). Of the six patients not completing the primary outcome examination, two were lost to follow up, two decided they were too busy for the demands of the study protocol, one was put on pregnancy-related bedrest, and one was randomized even though the patient had indicated that he or she was not interested in participating in the study (Fig. 2). There was a statistically significant difference in mean near phoria between those patients lost to follow up (mean = 6.7^{Δ} [± 1.0] exo) and those patients completing the study (mean = 11.2^{Δ} exo, SD = 4.9, p = 0.008). No other statistically significant or clinically relevant differences in demographic or clinical measures at eligibility were found (all p values > 0.10).

Given the relative comparability of those patients who completed the study and those patients who chose to drop out or did not complete the outcome examination within the window, all subsequent results are reported for only those patients with data at the 12-week visit. Further analyses were performed after imputing outcome values for those patients lost to follow up. That is, the value at the last available examination was used for each patient who did not complete the study. For five of the six patients, the only data available were collected at the eligibility visit. When differences in statistical analyses were found, the results from analyses with imputed data are also reported.

Eligibility Data

Eligibility demographic and clinical data for study patients are summarized in Tables 4 and 5 by group assignment. There were no statistically significant or clinically relevant differences between patients assigned to the three treatment groups (p > 0.40 for all comparisons).

Primary Outcome Measure: Convergence Insufficiency Symptom Score

The CI Symptom Survey score showed a significant reduction in symptoms for patients in each of the three treatment groups (p < 0.001 for each group). Patients in the vision therapy/orthoptics group showed a reduction in symptoms from 36.5 ± 8.7 to 20.7 ± 12.2 (Table 5). Patients in the placebo vision therapy/orthoptics and pencil pushups groups also showed a decrease in mean symptom score (placebo from 37.5 ± 11.4 to 25.2 ± 10.3, pencil pushups 37.6 ± 7.7 to 26.5 ± 7.3), although this change was not as large as that observed in the vision therapy/orthoptic group. There were no statistical differences in the CI Symptom Survey score among the three treatment groups at eligibility (p = 0.86) or at the completion of treatment (p = 0.15).

Figure 3 shows the mean CI Symptom Survey score at eligibility and after 4, 8, and 12 weeks of treatment for patients in each

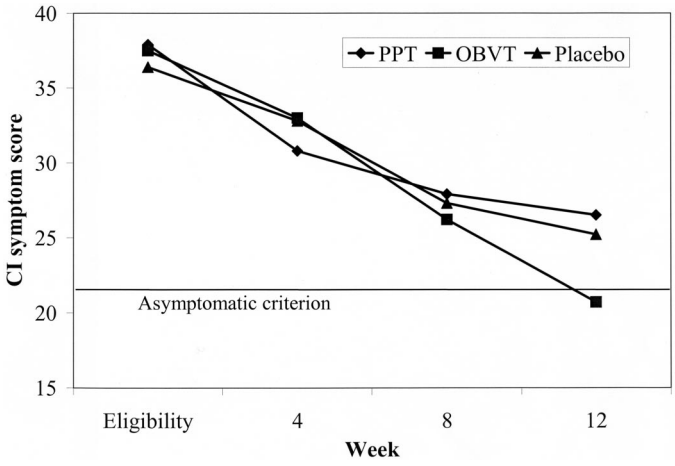

FIGURE 3.
Changes in the symptom score on the Convergence Insufficiency Symptom Survey after 4, 8, and 12 weeks of treatment for each treatment group.

treatment arm. After 12 weeks of treatment, the mean CI Symptom Survey score for patients assigned to vision therapy/orthoptics decreased to a level that would be considered nonsymptomatic (i.e., a CISS-V15 score of <21). Neither the mean score for the pencil pushups group nor placebo vision therapy/orthoptics group ever fell below this level.

Secondary Outcome Measures

Figure 4 shows the mean near point of convergence at eligibility and after 4, 8, and 12 weeks of treatment for patients in each treatment arm. There were statistically significant changes in the near point of convergence in all groups. However, only the vision therapy/orthoptics group showed a clinically significant improvement (6 cm or less). The near point of convergence break improved in the vision therapy/orthoptics group decreasing from 12.8 cm ± 7.7 to 5.3 cm ± 1.7 ($p = 0.002$). There was a statistically significant improvement in the mean near point of convergence break measurement in the pencil pushups group (12.5 cm ± 6.6 to 7.8 cm ± 4.1, $p = 0.001$) and the placebo vision therapy/orthoptics group (14.5 cm ± 7.8 to 9.6 cm ± 4.0, $p = 0.04$), although the changes are not considered clinically significant. Sixty-seven percent (eight of 12) of the patients in the vision therapy/orthoptics group achieved a normal near point of convergence break measurement of <6 cm at the end of treatment, whereas 23.1% (3 of 13) of the placebo vision therapy/orthoptics group and 46.7% (7 of 15) of the pencil pushups group achieved this result.

A comparison of the mean values at the end of treatment demonstrated a significant difference in the near point of convergence break values between the three treatment groups ($p = 0.02$). Post hoc testing revealed that the mean near point of convergence break for the vision therapy/orthoptics group was significantly different from the mean of the placebo vision therapy/orthoptics group ($p = 0.02$). There was no significant difference when comparing the pencil pushups group with the vision therapy/orthoptics group ($p = 0.18$) nor to the placebo vision therapy/orthoptics group ($p = 0.43$). If we compare the near point of convergence break between groups after imputing values for the six patients who did not complete the entire 12 weeks of treatment, the difference between groups becomes nonsignificant ($p = 0.27$). The mean for patients in the vision therapy/orthoptics group increased to 7.1 ± 4.3 cm, which is no longer significantly different from the mean value for patients in the placebo vision therapy/orthoptics group (mean = 9.5 ± 3.9 cm, $p = 0.25$).

Figure 5 shows the mean positive fusional vergence at near at eligibility and after 4, 8, and 12 weeks of treatment for patients in each treatment arm. The positive fusional vergence break at near increased significantly in the vision therapy/orthoptics group from 11.3Δ ± 4.3 to 29.7Δ ± 10.8 ($p = 0.001$). Patients in the placebo vision therapy/orthoptics group experienced a statistically significant improvement from 11.5Δ ± 4.4 to 17.5Δ ± 5.7 ($p = 0.003$) and those in the pencil pushups group improvement significantly from 13.6Δ ± 7.1 to 24.2Δ ± 12.5 ($p < 0.001$). The mean positive fusional vergence break values at the outcome visit differed significantly between the three groups ($p = 0.002$). The mean for patients in the vision therapy/orthoptics group was significantly different (improved) compared with the mean for patients in the pencil pushups group ($p = 0.04$) and those in the placebo vision therapy/orthoptics group ($p = 0.002$). No difference was observed between the pencil pushups and placebo vision therapy/orthoptics groups ($p = 0.36$).

Adherence to Treatment

To assess adherence, the therapist asked the patient questions about the home-based treatment and then answered the following question on the CITT follow-up form: "What percent of the time do you feel the patient adhered to the treatment protocol?" The choices were: 0%, 1–24%, 25–49%, 50–74%, 75–99%, or 100%.

There were no differences in the therapist's assessment of patient adherence between the three treatment groups at any visit. After 4 weeks of treatment, the therapists estimated that 61.5% of patients in the vision therapy/orthoptics group, 91.7% of patients in the placebo vision therapy/orthoptics group, and 61.5% of those in the pencil pushups group were performing their home therapy at least 75% of the time (Kruskal-Wallis $p = 0.12$). At 8 weeks, the therapists' estimates were 69.2% for the vision therapy/orthoptics

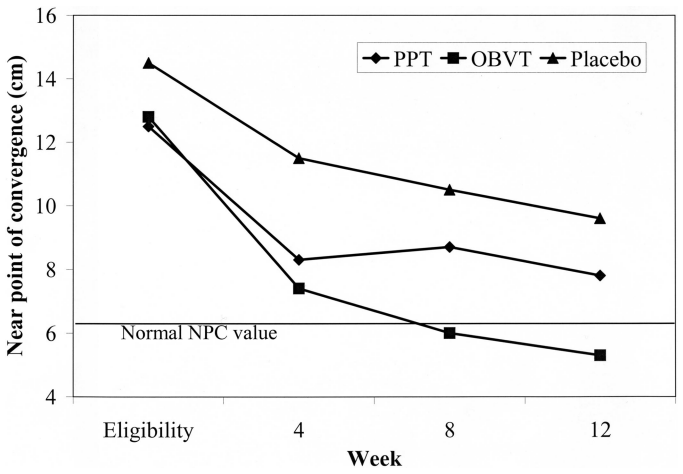

FIGURE 4.
Changes in the near point of convergence after 4, 8, and 12 weeks of treatment for each treatment group.

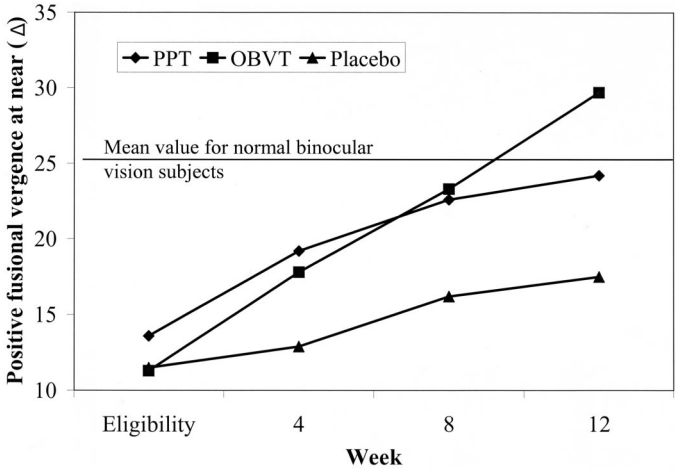

FIGURE 5.
Changes in the positive fusional vergence at near after 4, 8, and 12 weeks of treatment for each treatment group.

group, 91.7% for the placebo vision therapy/orthoptics group, and 61.5% for the pencil pushups group (Kruskal-Wallis p = 0.07). The percentage of patients estimated to adhere to home therapy at least 75% of the time decreased for all three treatment groups at the 12-week visit, but the estimates were still not significantly different from each other. In the vision therapy/orthoptics group, therapists estimated that 50.0% of the patients performed their home therapy at least 75% of the time. This compares with the 69.2% estimated for patients in the placebo vision therapy/orthoptics group and 86.7% estimated for patients in the pencil pushups group (Kruskal-Wallis p = 0.08).

Placebo Treatment—Were Patients Masked?

To determine the effectiveness of masking the patients assigned to the two office-based treatments (i.e., vision therapy/orthoptics and placebo vision therapy/orthoptics), patients were asked at the 12-week examination if they thought they were randomized into the "true" or the "placebo" treatment. In addition, they were asked how sure they were about their answer. The results (Table 6) indicated that 75% of the patients assigned to placebo vision therapy/orthoptics believed they had been assigned to the real vision therapy/orthoptics group and 44% of these were very sure or pretty sure of their answer. Of the patients assigned to real vision therapy/orthoptics, 90% believed they had been assigned to real vision therapy/orthoptics group and all were very sure or pretty sure of their answer.

It could be argued that if a patient was successfully masked to treatment assignment, that the patient would be equally likely to choose "vision therapy" or "placebo" when asked about perceived group assignment. This would equate to a 50/50 split in the percentage responding "vision therapy" or "placebo." For those patients assigned to vision therapy, significantly more chose "vision therapy" than would have been expected by chance (p = 0.011).

TABLE 6.
Perception of treatment group assignment versus actual assigned treatment group—week 12 visit

Patients assigned to vision therapy/orthoptics		
Patients believing they were assigned to:	Percent reporting specific group	Percent pretty sure or very sure of answer
Vision therapy/orthoptics	90.0	100.0
Placebo vision therapy/orthoptics	10.0	0.0
Patients assigned to placebo vision therapy/orthoptics		
Patients believing they were assigned to:	Percent reporting specific group	Percent pretty sure or very sure of answer
Vision therapy/orthoptics	75.0	44.4
Placebo vision therapy/orthoptics	25.0	33.3

However, among those patients assigned to placebo vision therapy, the percentage choosing "placebo" was not significantly different from 50% (p = 0.083). This lack of significance could certainly be attributed in part to the small sample size (n = 13). Although not significant, it is important to note that patients assigned to placebo were more likely to respond "vision therapy." Thus, it would appear that successful masking of treatment assignment was achieved in the group assigned to placebo vision therapy.

"Cured" and "Improved" Criteria

Patients who achieved a score of <21 on the CISS-V15 and had both a normal near point of convergence and normal positive fusional vergence at near were considered "cured." In the vision therapy/orthoptics group, three of 12 (25.0%) patients achieved these criteria, whereas no patients in the placebo vision therapy/orthoptics group or in pencil pushups did so. Patients who achieved a decrease in symptoms (<21 on the CI Symptom Survey–V15) and achieved normal values in either the near point of convergence or positive fusional vergence at near were considered "improved." In the vision therapy/orthoptics group, three of 12 (25%) patients achieved this criteria, whereas two of 13 (15.4%) in the placebo vision therapy/orthoptics group and two of 15 (13.3%) in pencil pushups group did so.

DISCUSSION

In this first randomized, placebo-controlled, multicenter clinical trial studying the treatment of symptomatic CI in young adults, office-based vision therapy/orthoptics improved the signs associated with CI. Both the average near point of convergence and the average positive fusional vergence at near improved to roughly normal clinical values, although 58% of the patients in this group were still considered to be symptomatic after 12 weeks of treatment. There were statistically significant but not clinically relevant improvements in both the mean near point of convergence and the mean positive fusional vergence break at near in the pencil pushups and placebo office-based vision therapy/orthoptics groups. In addition, 80% of those in the pencil pushups treatment group and 69% of those in the placebo vision therapy/orthoptics group were still considered to be symptomatic after 12 weeks of treatment.

If we instead consider both symptom level and clinical findings to classify patients as "cured" or "improved," patients receiving vision therapy/orthoptics again fared better than patients in either of the other two treatment groups. After 12 weeks of treatment, 50% of patients in the vision therapy/orthoptics group were either "cured" (three of 12 or 25%) or "improved" (three of 12 or 25%). In contrast, none of the patients assigned to pencil pushups and placebo vision therapy/orthoptics group were "cured," and only two of 13 (15%) in the pencil pushups and two of 15 (13%) in the placebo vision therapy/orthoptics group were "improved."

These findings are surprising in light of previous studies demonstrating a significant decrease in symptoms after orthoptic treatment for CI in adults. Both Cooper[23] and Grisham,[14] in reviewing the literature, reported that over 90% of patients with CI reported elimination of their symptoms. Most of the studies reviewed by these authors reported on adult patients with CI. However, these findings were based on papers that were retrospective, uncontrolled and did not

use a valid instrument to assess symptoms before and after treatment. In these studies, patients simply reported their symptoms verbally to the doctor before and after treatment. This approach is prone to interpretation error and experimenter bias.

However, in one cohort of symptomatic patients with CI, Cooper[15] used an automated computer program to present vergence stimuli in an A–B crossover design to systematically treat eight adult patients. Positive reinforcement, time of treatment, and therapy stimuli used were the same in the two groups except that half of the patients received vergence therapy, whereas the other half received placebo nonvergence therapy. After end-point criteria were achieved, the two treatment groups were reversed, i.e., those receiving vergence therapy received placebo and vice versa. Those patients receiving vergence therapy demonstrated a mean 18r increase in positive fusional vergence to a posttreatment mean of 30r BO and a change in symptom score from moderately uncomfortable to almost symptom-free. It is surprising that in our slightly larger cohort, we did not achieve a comparable decrease in asthenopia, especially in light of the fact that various accommodative and vergence treatment procedures were performed.

One could argue that a longer treatment period may have resulted in additional changes. After 12 weeks of treatment, the mean symptom score for the patients in the vision therapy/orthoptics group decreased below 21 (i.e., considered asymptomatic) for the first time and did not appear to have reached a plateau yet. Perhaps additional improvement would have occurred after more treatment visits. We struggled with determining the appropriate length of treatment time when we were planning this study. Although traditional in-office vision therapy/orthoptics for patients with CI may require anywhere from 12 to 24 office visits,[8,9] we selected the minimum number of visits because we thought it would 1) be sufficient length of treatment time for adult patients with CI and 2) because we wanted to minimize the number of treatment sessions for those assigned to placebo treatment. We were also concerned that the longer the treatment program, the more the potential for retention problems with the placebo treatment group.

Another issue is what happens to symptoms, near point of convergence, and positive fusional vergence at near over time. The CITT study was not designed to look at long-term results. This question needs to be answered in a prospective, large-scale, randomized clinical trial.

The results from this study of young adults with symptomatic CI are also different from the results we reported for children with symptomatic CI.[18] In the previous study of children with CI, we found a statistically significant improvement in both clinical signs and symptoms using the same 12-week vision therapy/orthoptics regimen. Pencil pushups treatment was not found to be effective in decreasing signs or symptoms in children with CI, and in fact, pencil pushups was no more effective than placebo vision therapy/orthoptics. One simple explanation for the treatment differences found between the children and adults in these two studies is that CI can be more effectively treated in children than adults. However, previous retrospective research described here suggests that this may not be true. Because clinical findings improved in the vision therapy/orthoptics group to approximately the same degree in both children and adults, the two groups may have responded differentially to the CI Symptom Survey. Perhaps young adults in college or in the work force spend more time reading or using computers or experience more nonvisually related symptoms that might mimic the visual symptoms tested on the CI Symptom Survey and thus remain symptomatic even after treatment. The higher mean scores for patients 19 to 30 years of age compared with those 9 to 18 years of age[18] and the higher cut point for an asymptomatic score on the CISS V-15[19] suggest that this may be true.

We attempted to control for the effect of the "therapist as a placebo"[24] because it has been reported that the enthusiasm, caring, and compassion of a therapist may play a key role in treatment outcome.[25] We did this by designing placebo therapy that simulated bona fide procedures, and training the therapists to behave identically for patients in both the vision therapy/orthoptics and placebo vision therapy/orthoptics groups. We believe that the data reported here confirms that we were successful in achieving this objective because 75% of the patients assigned to placebo vision therapy/orthoptics believed they had been assigned to the vision therapy/orthoptics group.

This study was designed as a pilot study to prepare the CITT Study Group for a large-scale randomized clinical trial. As such, there are a number of limitations that must be considered when interpreting the results of this study. First, the sample size of 46 patients was small, which affects the precision of our treatment effects. Second, although the retention rate for this study was acceptable and patient loss was not related to treatment assignment, six of 46 (13%) patients were dropped from the study or did not complete the 12 weeks of treatment within the window for the outcome visit. A third potential issue was the 12-week treatment period. Perhaps a longer treatment period may have resulted in additional changes in signs and symptoms. Finally, it will be critical in future studies to investigate the long-term outcome of any treatment for CI.

CONCLUSIONS

This first multicenter, randomized clinical trial of the treatment of symptomatic CI in young adults demonstrated that of the three treatment modalities, only vision therapy/orthoptics was effective in achieving normal clinical values for both the near point of convergence and positive fusional vergence. Patients in the pencil pushups group achieved normal values only for positive fusional vergence at near and patients in the placebo vision therapy/orthoptics group did not achieve normal findings for either the near point of convergence or positive fusional vergence at near. Therefore, the effectiveness of vision therapy/orthoptics in improving the near point of convergence and positive fusional convergence values at near in adults cannot be explained on the basis of a placebo effect. Based on the results of this preliminary study, it would appear that pencil pushups, the most popular treatment for CI, is not effective for achieving clinically significant improvements in symptoms or signs associated with CI in young adults.

THE CONVERGENCE INSUFFICIENCY TREATMENT TRIAL (CITT) STUDY GROUP CLINICAL SITES

Listed in order of number of patients enrolled into the study, with city, state, site name, and number of patients in parentheses. Personnel are listed as

(PI) for principal investigator, (I) for investigator, (C) for coordinator, and (T) for therapist.

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APPENDIX

Convergence Insufficiency - Symptom Questionnaire

Name _____ DATE __/__/__

Clinician instructions: Read the following subject instructions and then each item exactly as written. If subject responds with "yes" - please qualify with frequency choices. **Do not give examples.**
Subject instructions: Please answer the following questions about how your eyes feel when reading or doing close work.

		Never	(not very often) Infrequently	Sometimes	Fairly often	Always
1.	Do your eyes feel tired when reading or doing close work?					
2.	Do your eyes feel uncomfortable when reading or doing close work?					
3.	Do you have headaches when reading or doing close work?					
4.	Do you feel sleepy when reading or doing close work?					
5.	Do you lose concentration when reading or doing close work?					
6.	Do you have trouble remembering what you have read?					
7.	Do you have double vision when reading or doing close work?					
8.	Do you see the words move, jump, swim or appear to float on the page when reading or doing close work?					
9.	Do you feel like you read slowly?					
10.	Do your eyes ever hurt when reading or doing close work?					
11.	Do your eyes ever feel sore when reading or doing close work?					
12.	Do you feel a "pulling" feeling around your eyes when reading or doing close work?					
13.	Do you notice the words blurring or coming in and out of focus when reading or doing close work?					
14.	Do you lose your place while reading or doing close work?					
15.	Do you have to re-read the same line of words when reading?					
		__ x 0	__ x 1	__ x 2	__ x 3	__ x 4

Total Score: ____

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