CLINICAL SCIENCE – EXTENDED REPORT

Randomised clinical trial of the effectiveness of base in prism reading glasses versus placebo reading glasses for symptomatic convergence insufficiency in children

M Scheiman, S Cotter, M Rouse, G L Mitchell, M Kulp, J Cooper, E Borsting, and the Convergence Insufficiency Treatment Trial (CITT) Study Group*

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See end of article for authors' affiliations

Correspondence to: Professor M Scheiman, Eye Institute, Pennsylvania College of Optometry, 1200 West Godfrey Ave, Philadelphia, PA 19141, USA; mscheiman@pco.edu

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Purpose: To compare base in prism reading glasses with placebo reading glasses for the treatment of symptomatic convergence insufficiency (CI) in children aged 9 to <18 years.
Methods: In a randomised clinical trial, 72 children aged 9 to <18 years with symptomatic CI were assigned to either base in prism glasses or placebo reading glasses. Symptom level, measured with a quantitative symptom questionnaire (CI Symptom Survey-V15), was the primary outcome measure. Near point of convergence and positive fusional vergence at near were secondary outcomes.
Results: The mean (SD) CI Symptom Survey score decreased (that is, less symptomatic) in both groups (base in prism glasses from 31.6 (10.4) to 16.5 (9.2); placebo glasses from 28.4 (8.8) to 17.5 (12.3)). The change in the CI Symptom Survey scores (p = 0.33), near point of convergence (p = 0.91), and positive fusional vergence (p = 0.59) were not significantly different between the two groups after 6 weeks of wearing glasses.
Conclusions: Base in prism reading glasses were found to be no more effective in alleviating symptoms, improving the near point of convergence, or improving positive fusional vergence at near than placebo reading glasses for the treatment of children aged 9 to <18 years with symptomatic CI.

There is a lack of consensus regarding the most appropriate treatment for convergence insufficiency (CI). Various treatments are commonly prescribed including home based pencil push ups, vision therapy/orthoptics, and base in prism reading glasses.[1–11] Base in prism reading glasses are commonly recommended in ophthalmic textbooks[2 8 9 12 13] as part of "conventional" wisdom in ophthalmic practice.[14] This treatment is cost effective and easy to administer. However, all of the published research on the effectiveness of base in prism for the treatment of CI has fundamental design flaws including lack of a control group, no randomisation, and non-masked outcome examinations.[14–16] Thus, in spite of the common use and rather broad acceptance of base in prism for the treatment of CI, there is little scientific evidence showing its effectiveness.

This prospective randomised, double blind, placebo controlled clinical trial was designed to evaluate the effectiveness of base in prism for the treatment of children with symptomatic CI. The purpose of the study was to determine whether base in prism reading glasses were more effective than placebo reading glasses in improving the symptoms and signs associated with symptomatic CI in children aged 9 to <18 years.

METHODS

The study was conducted by the Convergence Insufficiency Treatment Trial (CITT) Group at nine clinical sites (see Appendix 1). The research followed the tenets of the Declaration of Helsinki and the protocol and informed consent forms were approved by each institutional review board. The parent or guardian (referred to subsequently as "parent") of each study patient gave written informed consent and the child gave written assent, as required.

Patient selection

Children aged 9 to <18 years with symptomatic CI were eligible for the study. The eligibility criteria are listed in table 1. The 15-item version of the CI Symptom Survey (CI Symptom Survey-V15) was administered to determine if the child was symptomatic (fig 1).[17 18] Each answer was scored 0–4, with 4 representing the highest frequency of symptom occurrence (that is, always). The 15 items were then summed to obtain the CI Symptom Survey score (range 0–60).

Other eligibility tests included best corrected visual acuity, cover testing, near point of convergence, positive and negative fusional vergence at near, near stereoacuity, monocular accommodative amplitude, monocular accommodative facility (accommodative facility testing evaluates the speed and latency of the accommodative response by testing the patient's ability to alternately clear +2.00/−2.00 lenses over a 1 minute time span),[19] and a cycloplegic refraction. All testing was performed using previously reported standardised protocols.[20]

If a patient had clinical emmetropia or was wearing glasses and no change in prescription was necessary, randomisation occurred immediately. If a significant change in refractive correction was required, new glasses were prescribed. Refractive errors requiring correction were defined as ⩾1.50 D of hyperopia, ⩾0.50 D of myopia, ⩾0.75 D of astigmatism, or ⩾0.75 D of anisometropia in spherical equivalent, or ⩾1.50 D of anisometropia in any meridian After wearing the new glasses for at least 2 weeks, eligibility testing was repeated to determine if the patient still met the eligibility criteria before he or she could be randomised.

*A list of the investigators who participated in the study appears in Appendix 1.

Abbreviations: CI, convergence insufficiency; D, dioptre; Δ, prism dioptre

Convergence Insufficiency Symptom Survey – V15

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.

Response options:
Never
Infrequently (not very often)
Sometimes
Fairly often
Always

Survey items:
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?

Figure 1 CI Symptom Survey (CI Symptom Survey-V15).

Treatment protocols

The data coordinating centre randomly assigned eligible patients with equal probability to either base in prism reading glasses or placebo reading glasses. Randomisation was accomplished with the study's website using a permuted block design stratified by site.

Base in prism reading glasses

Patients in this group received glasses that corrected for the patient's refractive error, if necessary, and base in prism. The amount of prism was based on the minimum amount necessary to meet Sheard's criterion,[21] with no less than 1 Δ prescribed. Sheard[21] suggested that, for a patient with a significant phoria to be comfortable, the fusional reserve must be at least twice the amount of the phoria. To determine the amount of prism necessary to achieve this relationship he proposed the following formula: prism to be prescribed = 2/3 phoria – 1/3 compensating fusional vergence. The amount of prism was rounded up to the nearest half prism dioptre and split equally between the two eyes if the magnitude exceeded 1 Δ. The patient was asked to wear these glasses for all reading and near tasks requiring more than 5 minutes.

Placebo reading glasses

Patients in this group received glasses that corrected their refractive error, or plano lenses were prescribed for those who did not require a refractive correction. The patient was asked to wear these glasses for all reading and near tasks requiring more than 5 minutes.

Masking

Neither the patient nor the examiner performing testing at the outcome examination was aware of the treatment assignment. To prevent potential examiner unmasking by observation of the glasses, the study coordinator placed Tac 'N Stik® reusable adhesive around the edges of the eyeglasses (fig 2). The edges of the lenses were therefore obscured, making it impossible for the examiner to see the edge thickness of the lenses.

Outcome examination procedures

The primary outcome examination was conducted after a mean (SD) of 6 (1) weeks of study glasses wear. At this visit an examiner who was masked to the patient's treatment group administered the CI Symptom Survey-V15, the cover test at distance and near, near point of convergence, and positive fusional vergence at near. Testing was performed with the assigned glasses.

Outcome measures

The CI Symptom Survey-V15 score was the primary outcome measure. Secondary outcome measures were the near point of convergence and positive fusional vergence at near.

Table 1 Eligibility and exclusion criteria

Eligibility criteria:
- Age 9 to <18 years.
- Best corrected visual acuity of 20/25 or better in both eyes at distance and near.
- Willingness to wear eyeglasses to correct refractive error, if necessary.
- Exophoria at near at least 4 Δ greater than at far.
- Insufficient positive fusional convergence at near (fails Sheard's criterion).
- Receded near point of convergence of ⩾=6 cm break.
- Appreciation of at least 500 seconds of arc on the forms part of the Randot Stereotest.
- CI Symptom Survey-V15 score ⩾16.
- Informed consent and willingness to participate in the study and be randomised.

Exclusion criteria
- CI previously treated with prism, pencil push ups, 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 (spherical equivalent) difference between eyes.
- Previous refractive surgery.
- Vertical heterophoria greater than 1 Δ.
- Systemic diseases known to affect accommodation, vergence, and ocular motility such as multiple sclerosis, Grave's thyroid disease, myasthenia gravis, diabetes, and Parkinson's 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 push up method.
- Manifest or latent nystagmus.
- Attention deficit hyperactivity disorder or learning disability diagnosis by parental report that, in the investigator's opinion, would interfere with treatment.

Adherence to the treatment protocol

Adherence to treatment was assessed by asking the patient: ''What percentage of the time did you wear the glasses we gave you while you were reading or doing near work (0%, 25%, 50%, 75%, or 100%)?'' We also asked the child: ''How sure are you about this answer (very sure, pretty sure, somewhat sure, a little sure, not sure at all)?'' Parents were asked the same questions about their child's wearing of the reading glasses.

Assessment of success of masking

To assess the success of masking we asked the examiner to report what treatment he/she thought the child had received or if he/she was unsure. This question was asked after testing with the assigned reading glasses was completed. In addition, the children and parents were asked which treatment they thought they had received or if they did not know. The children and parents were also asked to report how sure they were about this answer (very sure, pretty sure, somewhat sure, a little sure, not at all sure).

Figure 2 Tac 'N Stik® reusable adhesive around the edges of the eyeglasses used to prevent unmasking.

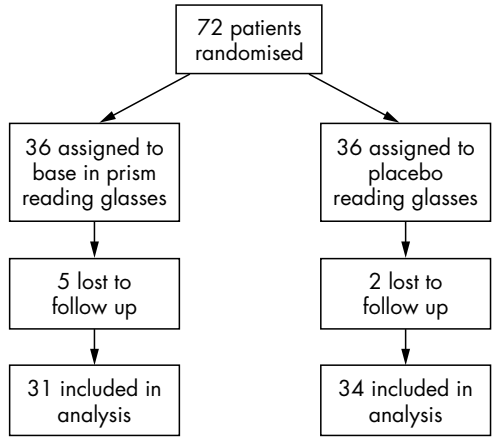

Figure 3 Flow chart showing study completion for each group.

Statistical methods

One sample *t* tests were used to compare the mean change in each outcome measure. Two sample *t* tests were used to make comparisons between the two groups when the outcome of interest was interval scaled. χ^2 tests were used to compare groups when the outcome of interest was a categorical variable, and a Wilcoxon rank sum test was used to compare groups in the case of ordinal scaled outcome variables. The Pearson correlation coefficient was used to assess the association between amount of prism and CI symptom score.

RESULTS

Enrolment and follow up

Seventy two children were enrolled at nine clinical sites. Thirty one of the 36 patients (86%) assigned to receive base in prism reading glasses and 34 of the 36 (94%) assigned to placebo reading glasses completed their 6 week outcome examination (fig 3). There was no statistically significant difference in the percentage loss to follow up between the two treatment groups ($p = 0.43$, χ^2 test)

Baseline data

Demographic data for patients assigned to the two treatment groups are shown in table 2. The only statistically significant difference at baseline between the groups was accommodative amplitude ($p = 0.011$), although this was not clinically significant (table 3).

Prism prescribed

In the group receiving base in prism, the mean (SD) prism prescription was 4.14 (2.4) Δ (range 1–10) and in the placebo group the mean (SD) prism prescription that would have been prescribed was 3.78 (2.4) Δ (range 1–11). There was no statistically significant difference in these values ($p = 0.48$).

Adherence to treatment

In the base in prism group, 90% of patients reported wearing their glasses at least 75% of the prescribed time and 81% of parents said their child wore his or her glasses at least 75% of the prescribed time. There was agreement between child and parent on percentage of time worn for 55% of the responses. In the placebo group, 79% of patients reported wearing their glasses at least 75% of the prescribed time and 79% of parents said their child wore his or her glasses at least 75% of the prescribed time. Patient and parent agreed on the percentage of time the placebo glasses were worn 42% of time. Reported

Table 2 Demographic data of study groups and clinical measures at randomisation

Characteristic	Base in prism reading glasses (n = 36)	Placebo reading glasses (n = 36)
Mean (SD) age (years)	11.5 (2.3)	11.0 (2.0)
Sex (%)		
Boys	36.1	52.8
Girls	63.9	47.2
Race (%)		
African American	36.1	36.0
American Indian	2.8	2.0
White	55.6	61.1
Other	5.6	0.0
Mean (SD) accommodative amplitude (D)	8.5 (4.3)	10.8 (4.3)
Mean (SD) accommodative facility (cycles/min)	6.6 (4.6)	6.7 (5.0)
Mean (SD) exophoria (Δ)		
Distance	2.36 (2.9)	1.61 (1.9)
Near	11.19 (3.7)	10.44 (3.9)
Mean (SD) refractive error (spherical equiv) (D)		
OD	0.30 (0.84)	0.17 (1.09)
OS	0.23 (0.84)	0.20 (1.04)

D, dioptre; Δ, prism dioptre; OD, oculus dexter; OS, oculus sinister.

wearing time was not statistically different between the two groups using the patients' ($p = 0.18$) or parents' responses ($p = 0.24$).

Primary outcome measure: CI symptom survey score

There were statistically significant changes in the mean CI Symptom Survey score in both the base in prism group ($p<0.001$) and placebo group ($p<0.001$). The CI Symptom Survey score decreased to less than 16 (previously found to differentiate children with symptomatic CI from those with normal binocular vision[18]) at the outcome examination in 51.6% of the base in prism group and 47.1% of the placebo group. This difference is not statistically significant ($p = 0.71$).

Pearson correlation coefficients were calculated to assess the relationship between amount of prism prescribed and the primary outcome. In the base in prism group, neither the CI Symptom Survey score at the 6 week visit ($R = 0.263$, $p = 0.15$) nor the change in CI Symptom Survey score ($R = -0.078$, $p = 0.68$) were related to the amount of prism prescribed.

Secondary outcome measures

There were no clinically significant changes in either near point of convergence or positive fusional vergence at near. Few patients in either group achieved a normal near point of convergence or positive fusional vergence at near (table 3).

Placebo treatment: assessment of masking

Examiners performing the outcome examination correctly identified group assignment for 23 of the 64 patients (36%) who completed the outcome examination (information was not collected for one patient); 39% of these were in the base in prism group and 33% were in the placebo group. The percentage correctly identified was significantly lower than would have been expected by chance ($p = 0.024$).

Sixteen of the 65 patients (25%) correctly identified their group assignment which is significantly less than would be expected by chance ($p<0.001$). Eleven of the 31 (35.5%) assigned to base in prism and five of the 34 (14.7%) assigned to placebo reading glasses responded correctly (table 4). Forty of the 65 patients (61.5%) responded ''don't know''.

Thirty two percent of the parents correctly identified their child's group assignment. This is significantly less than expected by chance ($p = 0.004$). Twelve of the 31 parents (38.7%) whose child was assigned to base in prism and nine of the 33 parents (27.3%) whose child was assigned to placebo reading glasses correctly identified the assigned treatment (table 4; data missing for one parent). Thirty four of the 64 parents (53.1%) responded ''don't know''.

DISCUSSION

In this prospective, randomised, placebo controlled clinical trial, the prescription of base in prism reading glasses (based on Sheard's criterion) was no more effective than placebo reading glasses for the treatment of symptomatic CI in children. Although neither treatment group showed clinically

Table 3 Comparison of treatment groups with respect to clinical measures at baseline and the 6 week outcome examination

Characteristic	Base in prism reading glasses (n = 31)	Placebo reading glasses (n = 34)
CI symptom score		
Baseline	31.63 (10.41)	28.38 (8.79)
Outcome	16.53 (9.25)	17.54 (12.26)
Change	−15.10 (11.91)	−10.84 (13.41)
Near point of convergence break (cm)		
Baseline	17.95 (11.56)	15.87 (7.17)
Outcome	13.81 (8.24)	14.54 (10.58)
Change	−4.14 (9.99)	−1.33 (8.25)
Positive fusional vergence break (Δ)		
Baseline	10.55 (4.13)	10.05 (3.49)
Outcome	12.56 (5.76)	12.71 (7.16)
Change	1.97 (4.65)	2.66 (8.43)

Data shown as mean (SD) values.

Table 4 Perception of treatment group assignment versus actual assigned treatment group (week 6 visit)

Patients/parents believed assigned to	Reporting a specific group (%)	Pretty sure or very sure of answer (%)
Patient's response		
Patients assigned to base in prism reading glasses		
Base in prism reading glasses	35.5	90.9
Placebo reading glasses	3.2	100.0
Patients assigned to placebo reading glasses		
Base in prism reading glasses	23.5	75.0
Placebo reading glasses	14.7	100.0
Parent's response		
Child assigned to base in prism reading glasses		
Base in prism reading glasses	38.7	91.7
Placebo reading glasses	12.9	75.0
Child assigned to placebo reading glasses		
Base in prism reading glasses	15.2	100.0
Placebo reading glasses	27.3	88.9

significant changes in the near point of convergence or positive fusional convergence at near, nearly half of the children assigned to each of the two treatment groups reported a statistically significant decrease in symptoms (although neither group achieved a decrease in symptoms to a level considered clinically asymptomatic).

Because the children assigned to placebo reading glasses were just as likely to report a decease in symptoms as were those assigned to the base in prism reading glasses, these data suggest that the ''placebo effect'' was probably responsible for the reduction in symptoms in the base in prism group. The placebo effect has been viewed as a change in a patient's illness attributable to the symbolic aspect of a treatment and not to any specific pharmacological or physiological property.[22] In his review of 15 studies of treatment for a variety of medical disorders ranging from angina pectoris and headaches to the common cold, Beecher[23] found the placebo response rate ranged from 15% to 58% with an average effectiveness of 35%. We are unaware of any studies related to placebo effect and the use of spectacles in ophthalmic care.

Only one other study has investigated the effectiveness of base in prism glasses for the treatment of CI. In this study[15] patients reported subjective improvement in asthenopic symptoms and headaches after 2 weeks of wear. However, the authors did not have a placebo control group, so there is no way of knowing whether the reported improvement in symptoms was due to a placebo effect.

One of the primary challenges of this study was to maintain masking of the examiners, children, and parents. Our data suggest that the majority of examiners, patients, and parents were successfully masked to treatment assignment.

We could identify no sources of bias or confounding factors to explain our findings. The follow up visit rate was high in both groups and missing data from patients who dropped out of the study did not influence the interpretation of the results. Baseline findings were similar between the two treatment groups, with the exception of accommodative amplitude which was lower in the base in prism group to a statistically but not clinically significant degree.

Potential limitations of the study may be related to the method used for determining the magnitude of prism prescribed and the length of follow up. There is no consensus about the best method for prescribing prism for patients with CI. Our decision to use Sheard's criterion was based on previous research indicating its value as a discriminator of symptomatic from asymptomatic exophoric patients,[24 25] and its perceived wide acceptance in the optometric community. We chose to re-evaluate our patients after 6 weeks of prism use based on the assumption that, if symptomatic relief occurred, it would be likely to happen within 6 weeks.

In conclusions, this first prospective multicentre, masked, randomised clinical trial of the treatment of symptomatic CI in children aged 9 to <18 years shows that base in prism reading glasses prescribed on the basis of Sheard's criterion are not an effective treatment. Our data suggest that the placebo effect of prescribing glasses was most probably responsible for the decrease in symptoms achieved in the base in prism reading glasses group. Based on these findings, investigators may want to evaluate other spectacle lens treatments such as low plus lenses and yoked prism, which are anecdotally reported by some clinicians to be beneficial for the treatment of various vision disorders in children. It should be noted that the results of our study can only be applied to children aged 9 to <18 years with symptomatic CI, and treatment effects may be different in other populations such as adults.[26]

Authors' affiliations
M Scheiman, Eye Institute, Pennsylvania College of Optometry, Philadelphia, PA, USA
S Cotter, M Rouse, E Borsting, Southern California College of Optometry, Fullerton, CA, USA
G L Mitchell, M Kulp, Optometry Coordinating Center, The Ohio State University, Columbus, OH, USA
J Cooper, College of Optometry, State University of New York, New York, NY, USA

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APPENDIX 1: CLINICAL SITES
Sites are listed in order of number of patients enrolled into the study, with city, state, site name and number of patients in parentheses. PI = principal investigator; I = investigator; C = coordinator; M = masked examiner.

- NOVA College of Optometry (13): R A Coulter (PI), A Bade (C), M Taub (M), M Bartuccio (M)
- Pennsylvania College of Optometry (11): M Scheiman (PI), T Yamada (M), K Pollack (C)
- Bascom Palmer (10): S Tamkins (PI), C Cannon, (M), J Del Pino (M), N Oveido, (I), E Olivares (C)
- The Ohio State University College of Optometry (10): M Kulp (PI), A Toole (M), M Earley (M), G Gabriel (M), K Reuter (M), M Ackerman-Hemmer (M)

- University of Alabama, Birmingham (10): K Hopkins (PI), M Frazier (M), C Baldwin (C)
- Southern California College of Optometry (9): R Chu (PI), C Barnhardt (I), E Borsting (I), S Cotter (I), M Nguyen (I), M Rouse (I), S Shin (I), Y Flores (C)
- State University of New York, College of Optometry (5): J Cooper (PI), E Samonte (C), A Steiner (I), H Friedman (I)
- Indiana University College of Optometry (3): D W Lyon (PI), D Plass (M), D Warren (M), M Varvel (C)
- University of Houston (1): J Wensveen (PI)
- The Ohio State University Optometry Coordinating Center: G L Mitchell (PI), L Barrett (data entry operator)

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Authors Queries

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