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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*

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.

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). 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 stereoaucuity, 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), and a cycloplegic refraction. All testing was performed using previously reported standardised protocols.

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 ≥1.50 D of anisometropia in spherical equivalent, or ≥1.0 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.

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?

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**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, with no less than 1 D prescribed. Sheard 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 D. 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.
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%, 23%, 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 if they did not know. The examiners were asked whether they had used any other methods to prevent unmasking.

Figure 2 Tac ‘N Stick® reusable adhesive around the edges of the eyeglasses used to prevent unmasking.
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 vision18) 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”.

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

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

children. Although neither treatment group showed clinically 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 decrease 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. 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 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, 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, 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.

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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)
REFERENCES