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## Treatment of Accommodative Dysfunction in Children: Results from an Random Clinical Trial

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### Abstract

**Purpose**—To report the effectiveness of various forms of vision therapy/orthoptics in improving accommodative amplitude and facility in children with symptomatic convergence insufficiency (CI) and co-existing accommodative dysfunction.

**Methods**—In a randomized clinical trial, 221 children 9 to 17 years with symptomatic CI were assigned to one of four treatments. Of the enrolled children, 164 (74%) had accommodative dysfunction; 63 (29%) had a decreased amplitude of accommodation with respect to age, 43 (19%) had decreased accommodative facility, and 58 (26%) had both. Analysis of variance models were used to compare mean accommodative amplitude and accommodative facility for each treatment group after 4, 8, and 12 weeks of treatment.

**Results**—After 12 weeks of treatment, the increases in amplitude of accommodation [office-based vergence/accommodative therapy with home reinforcement group (OBVAT) 9.9D, home-based computer vergence/accommodative therapy group (HBCVAT+) 6.7D, home-based pencil push-up therapy group (HBPP) 5.8D] were significantly greater than in the office-based placebo therapy group (2.2D) ( $p$ -values  $\leq 0.010$ ). Significant increases in accommodative facility were found in all groups (OBVAT: 9cpm, HBCVAT+: 7cpm, HBPP: 5cpm, OBPT: 5.5cpm); only the improvement in the OBVAT group was significantly greater than that found in the OBPT group ( $p = 0.016$ ). One year after completion of therapy, reoccurrence of decreased accommodative amplitude was present in only 12.5% and accommodative facility in only 11%.

**Conclusions**—Vision therapy/orthoptics is effective in improving accommodative amplitude and accommodative facility in school-age children with symptomatic CI and accommodative dysfunction.

### Keywords

accommodative dysfunction; accommodative amplitude; accommodative facility; accommodative insufficiency; convergence insufficiency; vision therapy; orthoptics; vergence/accommodative therapy; HTS

Accommodative disorders are commonly encountered in pediatric eye care practices.<sup>1,2</sup> and the two most common accommodative disorders are accommodative insufficiency and accommodative infacility.<sup>3-5</sup> Accommodative insufficiency is a condition in which the amplitude of accommodation is less than expected for a nonpresbyopic patient's age,<sup>5</sup> whereas accommodative infacility is a condition in which the latency and speed of the accommodative response are abnormal compared to normative clinical data.<sup>5</sup> Associated signs and symptoms are usually related to reading and other close work activities and include: blurred vision at near, intermittent blurred vision when looking up from near work, headaches, watering or burning of the eyes, tired eyes, loss of concentration, and avoidance of near activities.<sup>6-9</sup>

The most commonly prescribed treatments for accommodative dysfunction are a plus lens addition at near or vision therapy/orthoptics.<sup>4,5,10-13</sup> While plus lenses worn for near activities may improve symptoms for some patients, vision therapy/orthoptics has the potential to eliminate the accommodative dysfunction rather than solely providing symptomatic relief.<sup>5</sup>

Studies have shown that voluntary control of accommodation can be learned and transferred to a variety of conditions,<sup>14,15</sup> and objective improvements in the dynamics<sup>16</sup> and accuracy of accommodation following vision therapy have been documented.<sup>17,18</sup>

While clinical studies have reported success rates for the treatment of accommodative dysfunction as high as 96%,<sup>10-13,19,20</sup> methodological limitations have prevented definitive conclusions from being made. A more rigorous scientific base, ideally a randomized controlled trial, is needed to evaluate the effectiveness of vision therapy/orthoptics for the treatment of accommodative dysfunction in children.

The Convergence Insufficiency Treatment Trial (CITT),<sup>21,22</sup> a large-scale, randomized clinical trial evaluating vision therapy/orthoptics modalities for children with symptomatic convergence insufficiency, enrolled 164 children with concomitant deficiencies in accommodative function. Accommodative amplitude and facility measures were prospectively collected using standardized methods. These data provide an opportunity to determine the effectiveness of vision therapy/orthoptics for accommodative dysfunction. Herein, we report the effectiveness of office-based vergence/accommodative therapy (OBVAT), home-based computer vergence/accommodative therapy plus pencil push-ups (HBCVAT+), home-based pencil push-up therapy (HBPP), and office-based placebo therapy (OBPT or placebo therapy) for improving accommodative amplitude and accommodative facility in school-aged children with symptomatic convergence insufficiency and accommodative dysfunction.

## PATIENTS AND METHODS

The institutional review boards of all participating centers approved the protocol and informed consent forms. The parent or guardian of each participant gave written informed consent and each participant gave assent to participate. Health Insurance Portability and Accountability Act (HIPAA) authorization was obtained and the tenets of the Declaration of Helsinki were followed. Oversight was provided by an independent data and safety monitoring committee (see Appendix). This study is registered at ClinicalTrials.gov as the Convergence Insufficiency Treatment Trial (CITT) (NCT00338611).

### Patients

Enrolled children at the 9 CITT clinical sites (see appendix) met the following major eligibility criteria: age 9 to 17 years, near exophoria at least 4Δ greater than far, receded near

point of convergence break (6 cm or greater), and insufficient positive fusional vergence at near (PFV) (i.e., failing Sheard's criterion<sup>23</sup> [PFV less than twice the near phoria] or minimum PFV of 15Δbase-out blur or break), a Convergence Insufficiency Symptom Survey (CISS) score of  $\geq 16$ ,<sup>24,25</sup> and monocular accommodative amplitude of  $>5.00$  diopters (D). An optical correction was required for refractive error (cycloplegic refraction) of  $\geq 1.50$  D hyperopia,  $\geq 0.50$  D myopia,  $\geq 0.75$  D astigmatism,  $\geq 0.75$  D of spherical equivalent anisometropia, or  $>1.50$  D of meridional anisometropia. Full correction of myopia, astigmatism, and anisometropia was required. Investigators were permitted to symmetrically decrease the prescription for hyperopia if they believed full correction would have a negative effect on distance visual acuity or treatment. A complete listing of eligibility and exclusion criteria has been reported previously.<sup>21,22</sup>

### Measurement of Accommodative Function

Monocular (right eye) accommodative amplitude and accommodative facility were measured with spectacle correction at baseline and all protocol-specified visits. Amplitude of accommodation was measured by the push-up method using a moveable target of 20/30 letters on the Astron Accommodative Rule (Gulden Ophthalmics, Elkins Park, PA).<sup>22</sup> Decreased accommodative amplitude was defined as  $>2.00$ D below the lowest expected amplitude based on the Hofstetter's formula of  $15 - 1/4$  age.<sup>26,27</sup> Accommodative facility was the speed at which the patient could see 20/30 letters at 40cm clearly through alternating  $+2.00$ D and  $-2.00$ D lenses, measured in cycles (i.e., of  $+2.00$ D and  $-2.00$ D) per minute (cpm). Decreased accommodative facility was defined as  $<6$  cpm, which is 1 standard deviation below the normative value of 11 cpm for school-age children.<sup>7,28,29</sup> Details of the testing protocols for accommodation can be found at <http://optometry.osu.edu/research/CITT/4363.cfm>

### Randomization

Patients were randomly assigned (using a permuted block design stratified by site) with equal probability via the CITT website to either OBVAT, HBCVAT+, HBPP, or placebo. Randomization was achieved using a secure website created and managed by the Data Coordinating Center.

### Treatment Protocols

**Home-Based Pencil Push-ups (HBPP)**—The pencil push-ups procedure used a pencil with 20/60 size letters and a white index card placed in the background to provide a suppression check by using physiological diplopia awareness. The goal of the procedure was to move the pencil to within 2 to 3 cm of the brow, just above the nose on each push up while trying to keep the target single and clear. Patients were instructed to perform the pencil push-ups procedure 15 minutes per day, 5 days per week.

**Home-based Computer Vergence/Accommodative Therapy and Pencil Push-ups (HBCVAT+)**—Patients in this group were taught to perform the aforementioned pencil push-up procedure as well as procedures on the Home Therapy System (HTS/CVS) ([www.visiontherapysolutions.com](http://www.visiontherapysolutions.com)) computer software. Using this program, they performed fusional vergence and accommodative therapy procedures (vergence base in, vergence base out, auto-slide vergence, and jump-ductions vergence) using random dot stereopsis targets. The accommodative rock program was used for accommodative therapy. Patients were instructed to do pencil push-ups 5 minutes per day and the HTS software program for 15 minutes per day, 5 days per week.

**Office-Based Vergence/Accommodative Therapy with Home Reinforcement**

**(OBVAT)**—The office-based vergence/accommodative therapy group received a weekly 60-minute in-office therapy visit with additional procedures prescribed to be performed at home for 15 minutes a day, 5 days per week. The therapy procedures are described in detail elsewhere.<sup>30</sup> At each office-based therapy session, the patient performed 4–5 procedures with supervision and guidance from a therapist.

**Office-Based Placebo Therapy (OBPT)**—Patients in the office-based placebo therapy group received therapy during a weekly 60-minute office visit and were prescribed procedures to be performed at home for 15 minutes per day, 5 days per week. The placebo therapy program consisted of 16 in-office therapy procedures and 4 home therapy procedures, which were designed to look like real vergence/accommodative therapy procedures yet not stimulate vergence, accommodation, or fine saccadic eye movement skills beyond normal daily visual activities. Five procedures were performed during each office therapy visit and 2 procedures were assigned for home therapy each week.

The OBVAT and HBCVAT+ included specific accommodative therapy procedures in addition to vergence procedures, such as clearing progressively greater amounts of plus and minus. The pencil push-up procedure performed by the HBPP and HBCVAT+ groups created a progressive change in stimulus to accommodation as the patient slowly moved the pencil toward his or her face while trying to keep a 20/60 size letter on the pencil single and clear. Full details of the treatment protocols have been described<sup>22</sup> and can be found at <http://optometry.osu.edu/research/CITT/4363.cfm>.

Per protocol, masked examiners evaluated all participants after 4, 8, and 12 weeks of therapy (hereafter referred to as week 4, week 8, and week 12 examinations, with the latter being the primary outcome examination). Although not feasible to mask the therapists to patients' assigned treatment, the therapists followed well-defined, sequential treatment protocols. Patients receiving office-based treatment were masked regarding whether they were assigned to OBVAT or placebo therapy.

**Long-Term Follow-up**

At completion of the 12-week treatment programs, patients were classified as either asymptomatic (CISS score < 16) or symptomatic (CISS score ≥ 16). Symptomatic patients were offered alternative treatment at no cost. Asymptomatic patients were assigned home maintenance therapy for 15 minutes per week for the initial 6 months following treatment discontinuation; no therapy was prescribed between the 6- and 12-month follow-up visits. This maintenance schedule was consensus-based and was used in our earlier pilot study.<sup>31</sup> A masked examiner performed a sensorimotor examination including accommodative amplitude and facility testing, and administered the CISS at the 6- and 12-month follow-up visits. Long-term stability of treatment effectiveness was assessed by comparing accommodative amplitude and facility measures from treatment completion to those at the 12-month follow-up examination. Patients with decreased accommodative amplitude and/or facility at treatment completion, or who were classified as symptomatic and underwent subsequent treatment were excluded from the long-term analyses.

**Statistical Methods**

Because the treatments used in the CITT were not specifically designed as primary treatments for accommodative dysfunction, we compare each of the 3 therapy groups (OBVAT, HBCVAT+, HBPP) to placebo treatment rather than comparing the 3 treatments to each other. Changes across visits (baseline, week 4, week 8, and week 12) for each treatment group were compared using a 4 group x 4 time-point analysis of variance model.

A 4-group x 3-time point analysis of covariance model was used to compare mean accommodative amplitude and facility for each treatment group at the 4, 8, and 12-week examinations while controlling for differences at baseline. Tukey's method was used to control the overall error rate (alpha level) for post-hoc pair-wise comparisons. A one-sample t-test was used to compare the mean long-term change in accommodative amplitude and facility to zero. Models for accommodative amplitude and accommodative facility included only those patients with decreased accommodative amplitude and decreased accommodative facility, respectively.

Analysis of variance and chi-square tests were performed to compare baseline demographics between the four treatment groups.

The original CITT sample size was determined to ensure 90% power to detect treatment group differences with respect to CISS score, near point of convergence, and positive fusional vergence at near. Post-hoc calculations were performed to assess the power to detect between-group differences in total change (baseline to week 12) of both accommodative amplitude and facility. Estimates of variability were obtained from a previous pilot study.<sup>31</sup> Because the treatment groups for this analysis were of unequal size, a conservative estimate of power was determined using the placebo group sample size and the smallest sample size of the 3 active treatment groups. Using only the patients with decreased accommodative amplitude, this study has 82% power to detect a 4D difference in total amplitude improvement and 81% power to detect a 5cpm difference in total facility improvement. All analyses were performed using SAS version 9.2 (Cary, NC) following the intention-to-treat principle and using an alpha level of 0.05 to assess statistical significance.

## RESULTS

Between July 2005 and October 2006, 221 patients were enrolled. The number of patients enrolled at the 9 sites ranged from 14 to 35 (median = 25). Sixty were assigned to OBVAT, 53 to HBCVAT+, 54 to HBPP, and 54 to placebo therapy. Baseline demographic and clinical data have been reported previously. Retention was excellent with 219 of the 221 patients remaining in the study through the week 12 examination (99%). Two children missed their week 4 examination (1 HBCVAT+, 1 OBVAT) and 1 child (OBVAT) missed the week 12 examination. Less than 2% of all study visits through week 12 were missed. Of the enrolled children, 164 (74%) had accommodative dysfunction; 63 (29%) had a decreased amplitude of accommodation, 43 (19%) had decreased accommodative facility, and 58 (26%) had both. Among the 121 (63+58, 55%) with decreased amplitude, 36 were assigned to OBVAT, 30 to HBCVAT+, 27 to HBPP, and 28 to OBPT. Of the 101 (43+58, 46%) with decreased accommodative facility, 23 were assigned to OBVAT, 30 to HBCVAT+, 22 to HBPP, and 26 to OBPT. There was no statistically significant difference in the proportion of children in each treatment group with decreased accommodative amplitude or facility (p-values > 0.20), or in mean accommodative amplitude or facility at baseline (p-values > 0.15) among the 4 treatment groups (Tables 1 and 2). For both patients with decreased AA and those with decreased AF, there were no significant treatment group differences in baseline characteristics.

### Results for Accommodative Amplitude

**Within Group Comparisons: Change in Accommodative Amplitude Between Exams by Treatment Group**—The mean increase in accommodative amplitude (range of 4.5 to 4.7 D) from baseline to week 4 for the active therapy groups was significantly greater than zero (p-values<0.0001), whereas the change in the placebo group was not (1.8 D, p=0.057) (Table 3). Between weeks 4 and 8, only the OBVAT group showed a significant improvement in accommodative amplitude (2.8 D, p<0.001), whereas in the 8- to

12-week interval, both the OBVAT and HBCVAT+ groups showed significant improvements (2.0 D,  $p=0.02$  and 2.0 D,  $p=0.037$ , respectively).

**Increased Accommodative Amplitude: Vision Therapy/Orthoptics Therapy Compared to Placebo Therapy**—

Significant treatment group differences in mean accommodative amplitude were present only at weeks 8 and 12 ( $p < 0.001$  and  $p < 0.0001$ , respectively) (Figure 1). At the 8-week visit, the mean accommodative amplitude of the OBVAT group was approximately 5D greater than that of the placebo group ( $p < 0.0001$ ), with the difference increasing to more than 7D at week 12 ( $p < 0.0001$ , Table 1). The improvement in accommodative amplitude for the HBCVAT+ group was significantly different from that of the placebo group only at week 12 (difference=4.3D,  $p=0.002$ ), while the HBPP group showed a significantly greater mean amplitude (difference = 3.6 D) at both weeks 8 and 12 ( $p=0.009$  and  $p=0.010$ , respectively) when compared to placebo.

At study completion, the mean increases in accommodative amplitude (9.3 D for OBVAT, 6.8 D for HBCVAT+, 5.9 D for HBPP) were significantly greater than the 2.4 D gain found for the placebo group ( $p$ -values  $\leq 0.01$ ; Table 1, Figure 3). A decreased amplitude of accommodation was no longer present in 91.4% (32/35) of the patients in OBVAT, 79.3% (23/29) in HBCVAT+, and 74.1% (20/27) in HBPP, compared to 35.7% (10/28) of those assigned to placebo treatment ( $p < 0.003$ ).

Of the patients who no longer had a decreased amplitude of accommodation at treatment completion ( $n=85$ ) and did not undergo subsequent treatment during the 1-year follow-up period ( $n=44$ ), the mean decrease in accommodative amplitude was 1.4 D ( $p=0.044$ ). A recurrence of decreased accommodative amplitude occurred in 11% (5/44) (1 of 21 in OBVAT and 4 of 12 in HBPP).

### Accommodative Facility

**Within Group Comparisons: Change in Accommodative Facility Between Exams by Treatment Group**—

The OBVAT group showed significant improvement in accommodative facility (4.4 cpm,  $p < 0.0001$ ) from baseline to 4 weeks and between 4 and 8 weeks (4.4 cpm,  $p < 0.0001$ ), with no significant improvement between 8 and 12 weeks (0.8 cpm,  $p = 0.39$ ) (Figure 2). The HBCVAT+ group showed significant improvements from baseline to week 4 (3.3 cpm,  $p < 0.0001$ ) and showed smaller, but statistically significant improvements of approximately 2 cpm between weeks 4 to 8 ( $p=0.002$ ) 8 to 12 ( $p=0.029$ ). The HBPP group only showed significant gains between weeks 4 and 8 (2.1 cpm,  $p=0.004$ ). The placebo group showed significant improvements only at week 4 (2.8 cpm,  $p = 0.002$ ).

**Active Vision Therapy/Orthoptic Therapies Compared to Placebo Therapy after 4, 8, and 12 Weeks of Treatment**—

There was no difference in mean accommodative facility between treatment groups at week 4 ( $p = 0.30$ ), however, significant differences were found at weeks 8 ( $p=0.010$ ) and 12 ( $p=0.037$ ) (Figure 2 and Table 2). Compared to the placebo group, only the OBVAT group's mean accommodative facility was significantly better at the 8-week visit (mean difference of 4.7 cpm;  $p = 0.003$ ) and the 12-week visit (mean difference of 3.9 cpm;  $p = 0.016$ ).

At treatment completion, accommodative facility increased by 9.5 cpm in the OBVAT group, 7.0 cpm in the HBCVAT+ group, 4.9 cpm in the HBPP group, and 5.5 cpm in the placebo group (Table 2). Only the OBVAT group showed a significantly greater improvement in accommodative facility than the placebo group ( $p = 0.016$ ) (Figure 4).

After 12 weeks of treatment, decreased accommodative facility was no longer present in 87% (20/23) of OBVAT patients, 70% (21/30) of the HBCVAT+ patients, and 63.6%

(14/22) of the HBPP patients, as compared to 57.7% (15/26) of those assigned to placebo treatment ( $p=0.15$ ).

### Long Term Results

Among the patients who did not have reduced accommodative facility at week 12 ( $n=70$ ) and performed no other treatments during subsequent 1-year follow-up period (32, 46%) there was a small, non-significant decrease in facility found at the 12-month follow-up visit ( $-0.7$  cpm, range  $-12.0$  to  $9.5$  cpm,  $p=0.41$ ). Of these 32 patients, 4 (12.5%) regressed sufficiently to be diagnosed with deficient accommodative facility (1/11 OBVAT, 2/7 HBPP, and 1/6 OBPT).

### Adverse Events

There were six vision- or eye-related events among the 221 patients enrolled in the study. All were unexpected and further evaluations determined all six were not serious and unrelated to the study treatment.

## DISCUSSION

We compared the effectiveness of OBVAT, HBCVAT+, and HBPP to office-based placebo therapy for improving accommodative amplitude and facility in children with both symptomatic convergence insufficiency and accommodative dysfunction who were enrolled in the Convergence Insufficiency Treatment Trial. While the primary objective of the study was the comparison of the effectiveness of active treatments for symptomatic convergence insufficiency, accommodative function was measured at baseline and at all subsequent study visits, and each active therapy program included accommodative therapy. This allowed us to evaluate the kinetics of change in accommodative function and the effectiveness of the three therapy modalities in improving accommodative amplitude and facility.

All three of the vision therapy/orthoptic treatments were significantly more effective than placebo therapy for improving accommodative amplitude in patients with decreased accommodative amplitude while only OBVAT was significantly more effective than placebo therapy in improving accommodative facility in patients. In addition, at the end of the 12-week treatment period, significantly fewer patients had a decreased amplitude of accommodation or subnormal accommodative facility in the active therapy groups compared to the placebo. Finally, the gains demonstrated at 12 weeks were still present in the majority ( $>87\%$ ) of patients after 1-year off treatment.

Although all three active treatment modalities included some form of accommodative therapy, there were differences in the type of the accommodative procedure, format of the therapy (monocular, bi-ocular, and binocular), and time spent performing the therapy. Accommodative therapy for accommodative insufficiency and infacility traditionally includes procedures designed to increase both the amplitude of accommodation and the dynamics of the accommodative response.<sup>5</sup> The objectives of the latter type of accommodative therapy, also referred to as accommodative facility therapy, are to decrease the latency and increase the speed of the accommodative response. Procedures designed to increase the amplitude of accommodation use an accommodative stimulus that is increased in a slow, gradual manner while procedures used to improve the dynamics of the accommodative response alter the accommodative stimulus in large discrete steps. Generally accommodative amplitude procedures are emphasized initially and once the amplitude normalizes, facility procedures are introduced. In addition, accommodative therapy is generally sequenced so that accommodative function is improved and equalized in each eye monocularly before beginning binocular accommodative therapy.<sup>5</sup> Of the three active

treatments used in this study, only OBVAT incorporated both accommodative amplitude and facility procedures and used a monocular to binocular therapy sequence. The OBVAT treatment sequence used monocular accommodative amplitude and facility techniques during the first 8 weeks, and binocular accommodative facility techniques between weeks 8 and 12. The HBCVAT+ group performed bi-ocular (both eyes open, but no fusion) accommodative facility therapy for the entire treatment period. Although there was no specific accommodative therapy procedure per se for the HBPP group, pencil push-up therapy involved maintaining clarity as the accommodative target was moved towards the child's eyes, and thus can be considered a binocular accommodative amplitude procedure. These differences in therapy may explain some of the apparent differences in effectiveness.

In terms of the kinetics of change in accommodative amplitude during the 12-week treatment program, there was a significant improvement in amplitude from baseline to week 4 in all groups except the placebo group but only the OBVAT group demonstrated continued improvements between weeks 4 to 12. For accommodative facility most improvements occurred during the first 8 weeks of therapy for all 3 active therapy groups. The treatment kinetic data reported herein provide guidance regarding the timing of follow-up visits. Because the largest changes in both accommodative amplitude and facility occurred by 4 weeks for all 3 treatment groups, 4 weeks appears to be an appropriate time for a progress evaluation. Absence of any improvement after 4 weeks of treatment might suggest poor adherence to therapy or cast doubt on the accuracy of the diagnosis.

Although previous studies have reported that active vision therapy is an effective treatment for accommodative dysfunction, these studies suffer from a variety of design limitations including retrospective design,<sup>10,19,20</sup> small sample size,<sup>12,20,32</sup> lack of a placebo group,<sup>10,19,20</sup> and use of unmasked examiners.<sup>10,12,19,20,32</sup> In addition, some of the studies used adult patients<sup>17,19</sup> and only investigated home-based therapy.<sup>12,19</sup> Thus, there are no other data from well-designed, randomized clinical trials showing the effectiveness of vision therapy/orthoptics compared to a placebo control group for accommodative dysfunction in children.

The strengths of our study include its prospective design, adequate sample size, randomization of patients, having a placebo control for the OBVAT group, evidence of successful masking of examiners and patients in the OBVAT and OBPT groups, and outstanding follow-up.<sup>22</sup> Because the study was not designed specifically to investigate the effectiveness of therapy for accommodative function, one might argue that the data do not demonstrate whether office- or home-base therapy are effective for patients with accommodative dysfunction alone. However, because the therapy procedures that would be prescribed for children with accommodation dysfunction alone would actually be more extensive, there is good reason to believe that the results of this study may underestimate the potential for success. Only approximately half of the subjects could be included in the analyses of long-term follow-up because subjects had to be both asymptomatic and have normal accommodative function. We are also unable to comment about the effect of therapy on symptoms related to accommodative problems because the patients all had convergence insufficiency as well. Because a natural history group was not included in the study, it is unknown if the small and generally nonsignificant improvements in the placebo group were due to placebo effect or regression to the mean. We can conclude, however, that meaningful and significantly greater improvements in accommodative amplitude and facility can be achieved using vision therapy/orthoptics, and that the gains cannot be attributed to the placebo effect. Furthermore, these gains are maintained for a least a year in the majority of subjects. Future studies should consider including objective measures of accommodative function and additional studies are necessary to compare office-based vs. home-based treatments specifically designed to address accommodative dysfunction. Our data

demonstrate improvement of accommodative function in children with poor accommodative amplitudes or facility, and should be the impetus for a new randomized clinical trial studying the effectiveness of various therapies for the treatment of symptomatic accommodative dysfunction in children.

## CONCLUSIONS

In this first large-scale randomized clinical trial in children with convergence insufficiency and accommodative dysfunction, vision therapy/orthoptics was effective for improving decreased accommodative amplitude and accommodative facility. Further study is required to determine the most effective treatment approach (office-based vs. home-based), most effective therapy procedures, effect of accommodative therapy on symptoms in patients with symptomatic accommodative dysfunction alone, and the optimum duration of therapy.

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## The Convergence Insufficiency Treatment Trial Study Group

### Clinical Sites

Sites are listed in order of the number of patients enrolled in the study with the number of patients enrolled is listed in parentheses preceded by the site name and location. Personnel are listed as (PI) for principal investigator, (SC) for coordinator, (E) for examiner, and (VT) for therapist.

**Study Center: Bascom Palmer Eye Institute (35)**

Susanna Tamkins, OD (PI); Hilda Capo, MD (E); Mark Dunbar, OD (E); Craig McKeown, MD (CO-PI); Arlanna Moshfeghi, MD (E); Kathryn Nelson, OD (E); Vicky Fischer, OD (VT); Adam Perlman, OD (VT); Ronda Singh, OD (VT); Eva Olivares (SC); Ana Rosa (SC); Nidia Rosado (SC); Elias Silverman (SC)

**Study Center: SUNY College of Optometry (28)**

Jeffrey Cooper, MS, OD (PI); Audra Steiner, OD (E, Co-PI); Marta Brunelli (VT); Stacy Friedman, OD (VT); Steven Ritter, OD (E); Lily Zhu, OD (E); Lyndon Wong, OD (E); Ida Chung, OD (E); Kaity Colon (SC)

**Study Center: UAB School of Optometry (28)**

Kristine Hopkins, OD (PI); Marcela Frazier, OD (E); Janene Sims, OD (E); Marsha Swanson, OD (E); Katherine Weise, OD (E); Adrienne Broadfoot, MS, OTR/L (VT, SC); Michelle Anderson, OD (VT); Catherine Baldwin (SC)

**Study Center: NOVA Southeastern University (27)**

Rachel Coulter, OD (PI); Deborah Amster, OD (E); Gregory Fecho, OD (E); Tanya Mahaphon, OD (E); Jacqueline Rodena, OD (E); Mary Bartuccio, OD (VT); Yin Tea, OD (VT); Annette Bade, OD (SC)

**Study Center: Pennsylvania College of Optometry (25)**

Michael Gallaway, OD (PI); Brandy Scombordi, OD (E); Mark Boas, OD (VT); Tomohiko Yamada, OD (VT); Ryan Langan (SC), Ruth Shoge, OD (E); Lily Zhu, OD (E)

**Study Center - The Ohio State University College of Optometry (24)**

Marjean Kulp, OD, MS (PI); Michelle Buckland, OD, MS (E); Michael Earley, OD, PhD (E); Gina Gabriel, OD, MS (E); Aaron Zimmerman, OD, MS (E); Kathleen Reuter, OD (VT); Andrew Toole, OD, PhD (VT); Molly Biddle, MEd (SC); Nancy Stevens, MS, RD, LD (SC)

**Study Center: Southern California College of Optometry (23)**

Susan Cotter, OD, MS (PI); Eric Borsting, OD, MS (E); Michael Rouse, OD, MS, (E); Carmen Barnhardt, OD, MS (VT); Raymond Chu, OD (VT); Susan Parker (SC); Rebecca Bridgeford (SC); Jamie Morris (SC); Javier Villalobos (SC)

**Study Center: University of CA San Diego: Ratner Children's Eye Center (17)**

David Granet, MD (PI); Lara Hustana, OD (E); Shira Robbins, MD (E); Erica Castro (VT); Cintia Gomi, MD (SC)

**Study Center: Mayo Clinic (14)**

Brian G. Mohny, MD (PI); Jonathan Holmes, MD (E); Melissa Rice, OD (VT); Virginia Karlsson, BS, CO (VT); Becky Nielsen (SC); Jan Sease, COMT/BS (SC); Tracee Shevlin (SC)

**CITT Study Chair**

Mitchell Scheiman, OD (Study Chair); Karen Pollack (Study Coordinator); Susan Cotter, OD, MS (Vice Chair); Richard Hertle, MD (Vice Chair); Michael Rouse, OD, MS (Consultant)

### **CITT Data Coordinating Center**

Gladys Lynn Mitchell, MAS, (PI); Tracy Kitts, (Project Coordinator); Melanie Bacher (Programmer); Linda Barrett (Data Entry); Loraine Sinnott, PhD (Biostatistician); Kelly Watson (student worker); Pam Wessel (Office Associate)

### **National Eye Institute, Bethesda, MD**

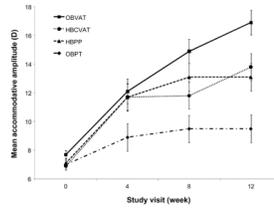
Maryann Redford, DDS, MPH

### **CITT Executive Committee**

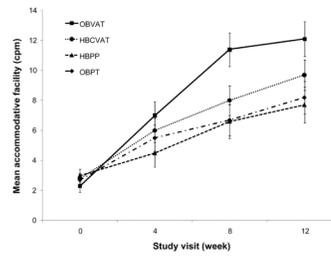
Mitchell Scheiman, OD; G. Lynn Mitchell, MAS; Susan Cotter, OD, MS; Richard Hertle, MD; Marjean Taylor Kulp, OD, MS; Maryann Redford, DDS., MPH; Michael Rouse, OD, MSEd

### **Data and Safety Monitoring Committee**

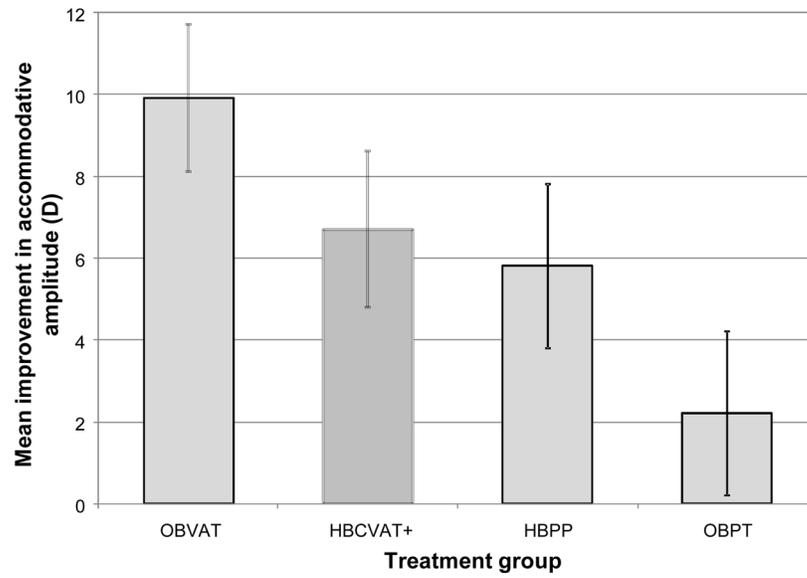
Marie Diener-West, PhD, Chair, Rev. Andrew Costello, CSsR, William V. Good, MD, Ron D. Hays, PhD, Argye Hillis, PhD (Through March 2006), Ruth Manny, OD, PhD



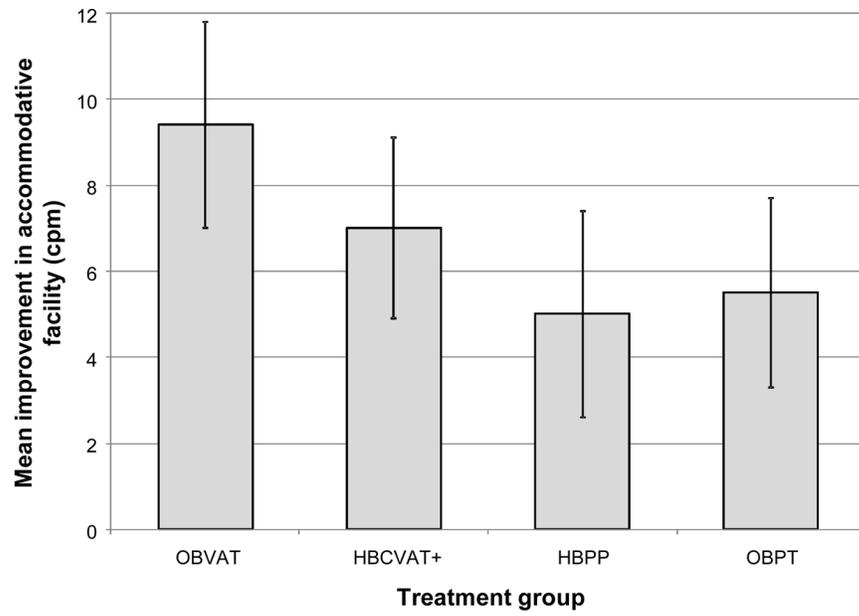
**Figure 1.** Mean accommodative amplitude (D) for patients with decreased accommodative amplitude by study visit and treatment group.



**Figure 2.** Mean accommodative facility (cpm) for patients with decreased accommodative facility, by study visit and treatment group.



**Figure 3.** Mean improvement in accommodative amplitude (D) for patients with decreased accommodative amplitude by treatment group.



**Figure 4.** Mean improvement in accommodative facility (cpm) for patients with decreased accommodative facility, by treatment group.

**Table 1**

Mean (95% confidence interval) for accommodative amplitude (D), by treatment group and time for those patients with decreased accommodative amplitude at baseline (n=121).

Treatment group	Baseline	Time			Total change
		Week 4	Week 8	Week 12	
OBVAT (n=36)	7.7 (7.2, 8.2)	12.1 (10.4, 13.6)	14.9 (13.2, 16.6)	16.9 (15.2, 18.6)	9.9 (8.2, 11.7)
HBCVAT+ (n=30)	6.9 (6.4, 7.5)	11.7 (9.9, 13.5)	11.8 (10.0, 13.7)	13.8 (12.0, 15.7)	6.7 (4.8, 8.6)
HBPP (n=27)	7.1 (6.5, 7.7)	11.7 (9.8, 13.6)	13.1 (11.2, 15.0)	13.1 (11.2, 15.0)	5.8 (3.9, 7.8)
OBPT (n=28)	7.0 (6.5, 7.6)	8.9 (7.1, 10.8)	9.5 (7.7, 11.4)	9.5 (7.6, 11.4)	2.2 (0.3, 4.2)

**Table 2**

Mean (95% confidence interval) for accommodative facility (cpm), by treatment group and time for those patients with decreased accommodative facility at baseline (n=101)

Treatment group	Time				Total change
	Baseline	Week 4	Week 8	Week 12	
OBVAT (n=23)	2.3 (1.5, 3.1)	7.0 (5.1, 8.8)	11.4 (9.2, 13.6)	12.1 (9.8, 14.4)	9.4 (7.1, 11.8)
HBCVAT+ (n=30)	2.8 (2.0, 3.5)	6.0 (4.5, 7.6)	8.0 (6.0, 9.9)	9.7 (7.7, 11.7)	7.0 (4.9, 9.1)
HBPP (n=22)	3.0 (2.2, 3.8)	4.5 (2.6, 6.3)	6.6 (4.4, 8.8)	7.7 (5.3, 10.0)	5.0 (2.6, 7.4)
OBPT (n=26)	2.7 (2.0, 3.5)	5.5 (3.8, 7.2)	6.7 (4.6, 8.8)	8.2 (6.0, 10.4)	5.5 (3.3, 7.7)

**Table 3**

Treatment group differences at successive examinations.

Comparison	Difference	95% confidence interval	p-value
<b>Accommodative amplitude (D) for OBVAT</b>			
Week 4 – Baseline	4.5	2.8, 6.2	<0.0001
Week 8 – Week 4	2.8	1.4, 4.3	<0.001
Week 12 – Week 8	2.0	0.3, 3.7	0.020
<b>Accommodative amplitude (D) for HBCVAT+</b>			
Week 4 – Baseline	4.7	2.9, 6.5	<0.0001
Week 8 – Week 4	0.1	-1.5, 1.7	0.91
Week 12 – Week 8	2.0	0.1, 3.9	0.037
<b>Accommodative amplitude (D) for HBPP</b>			
Week 4 – Baseline	4.6	2.6, 6.5	<0.0001
Week 8 – Week 4	1.4	-0.3, 3.1	0.11
Week 12 – Week 8	-0.02	-2.0, 1.9	0.99
<b>Accommodative amplitude (D) for OBPT</b>			
Week 4 – Baseline	1.8	-0.1, 3.7	0.057
Week 8 – Week 4	0.6	-1.1, 2.3	0.48
Week 12 – Week 8	-0.01	-1.9, 1.9	0.99
<b>Accommodative facility (cpm) for OBVAT</b>			
Week 4 – Baseline	4.4	2.5, 6.2	<0.0001
Week 8 – Week 4	4.4	3.0, 5.8	<0.0001
Week 12 – Week 8	0.8	-1.0, 2.5	0.39
<b>Accommodative facility (cpm) for HBCVAT+</b>			
Week 4 – Baseline	3.3	1.7, 4.9	<0.0001
Week 8 – Week 4	2.0	0.7, 3.2	0.002
Week 12 – Week 8	1.7	0.2, 3.2	0.029
<b>Accommodative facility (cpm) for HBPP</b>			
Week 4 – Baseline	1.7	-0.2, 3.6	0.072
Week 8 – Week 4	2.1	0.7, 3.6	0.004
Week 12 – Week 8	1.1	-0.7, 2.8	0.23
<b>Accommodative facility (cpm) for OBPT</b>			
Week 4 – Baseline	2.8	1.1, 4.5	0.002
Week 8 – Week 4	1.2	-0.1, 2.5	0.075
Week 12 – Week 8	1.5	-0.1, 3.1	0.075