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Reduction of symptoms in binocular anomalies using computerized home therapy—HTS™

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KEYWORDS
Vision therapy;
Orthoptics;
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Eyestrain;
Binocular vision;
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Computer vergence/accommodative therapy;
Placebo therapy;
Exophoria;
Symptom survey

Abstract

BACKGROUND: Asthenopic symptoms often are associated with various accommodative/vergence disorders. Recent studies have found that symptoms associated with convergence insufficiency are reduced by in-office vision therapy with supplemental home therapy. No studies have used standardized symptom questionnaires to evaluate the effectiveness of either in-office or home-based vision therapy in binocular anomalies other than convergence insufficiency. This retrospective study was designed to evaluate the changes in symptoms using an automated, home computer vision therapy program (HTS™) in accommodative/vergence disorders.

METHODS: A retrospective study of 43 prepresbyopic patients who completed the HTS was performed. Before and immediately after treatment all patients in this study completed a 15-question symptom questionnaire (Convergence Insufficiency Symptom Survey). Treatment consisted of various accommodative and vergence activities.

RESULTS: Initial symptoms scores on the scaled questionnaire were 32.8 (SD = 8.1); after therapy they were 20.6 (SD = 11.5). These changes were both clinically and statistically significant. Forty percent were "normalized" and 55% improved. Convergence amplitude improved from 22Δ to 53Δ after treatment, and divergence amplitudes improved from 15Δ to 25Δ. These findings were clinically significant. Lastly, more than 75% of the patients finished the program by 40 sessions (equivalent to 8 weeks).

CONCLUSION: Automated vision therapy delivered by the HTS system improved convergence and divergence amplitudes with a concomitant reduction in symptoms. The HTS system should be used on those patients with symptoms associated with an accommodative/vergence anomaly when in-office vision therapy supplemented with home therapy is not practical.

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Convergence insufficiency (CI), the most common binocular anomaly, occurs in approximately 5% of the population.[1] Patients with convergence insufficiency have more symptoms than patients without a binocular anomaly.[2-4] Generally, the treatment of CI consists of prisms, pencil push-up (PP) therapy, home accommodative vergence therapy, or in-office vision therapy. The majority of optometrists and ophthalmologists recommend PP therapy for CI.[5] However, recent studies have found that pencil push-ups are no more effective than placebo/sham therapy in eliminating symptoms.[6-8] Prism glasses have also been prescribed to decrease symptoms associated with CI. However, a recent clinical trial found that base-in prism in children is no more effective than placebo glasses in eliminating symptoms.[9]

Cooper and Feldman,[10] using random dot stereograms (RDS) presented in an operant conditioning paradigm, found that vergence training increased fusional amplitudes,

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whereas placebo therapy did not. In a subsequent experiment, Cooper et al.[11] used RDS in an operant conditioning paradigm and a scaled questionnaire to compare placebo treatment with vergence treatment in a small cohort of symptomatic CIs. They found that there was a significant improvement of convergence amplitudes and reduction in symptoms in symptomatic CIs compared with placebo therapy. They repeated the study using the same paradigm except with accommodative stimuli in patients with accommodative insufficiency. They noted an improvement in accommodative facility and amplitude with a concurrent reduction in symptoms.[12] Both studies have been criticized because of a small sample size.

Recently, the National Eye Institute supported a number of prospective, randomized clinical trials to evaluate various treatments for CI: PP treatment; base-in prism treatment; home vision therapy; placebo treatment; and in-office vision therapy (OBVT) with supplemental home therapy.[6-9] There were 2 pilot studies; one included children (9 to 17 years) and the other included adults (18 to 30 years). Both had in-office therapy with supplemental home therapy as one of the 3 arms of treatment. In addition, there was the full Convergence Insufficiency Treatment Trial (CITT) study that included 221 children age 9 to 17 years assigned randomly to 4 clinical treatment arms. In these 3 studies, subjects in the OBVT arm showed normalization of accommodative/vergence findings and a reduction of associated symptoms. These findings were both clinically and statistically different than those in the other arms.[6-8] Other therapies, such as PPs, home therapy with PPs, and base-in prism, were no more effective than in-office–based placebo/sham therapy in eliminating symptoms.[3,6-9]

The full CITT study included a home treatment arm that consisted of the HTS™ computerized home therapy program plus PPs.[8] The results from this treatment arm were not statistically different than those in the placebo/sham arm. This was surprising because previous studies of vergence training using identical RDS stimuli and therapy protocols have found a statistically significant reduction of symptoms with vergence therapy compared with placebo therapy.[11-13] One major difference in the CITT study was compliance. At the end of treatment, the percentage of patients rated by therapists as being compliant with home therapy performed at least 75% of the time for the home therapy group plus push-ups was only 67%, whereas for the OBVT group it was 91%.[8] It was noted in the study that this difference in compliance did not affect the comparisons between treatment groups' outcome measures. The in-office group only missed 2.4% of their in-office therapy visits. Although the home therapy group missed 1.4% of their appointments, these were appointments in which no treatment occurred.

One component of the CITT in both the OBVT and the home therapy arm was the automated HTS. This computer program used RDS in an operant conditioning paradigm to improve accommodation, convergence, and divergence fusional amplitudes. In any treatment program, repetitive therapy is necessary to permanently change reflexive responses. The HTS program includes a variety of stimuli and performance graphs to make the HTS program more interesting for the patient. Compliance is believed to be very important. If a prescribed treatment regimen is not carried out, then studies of its effectiveness are of questionable interpretation. In an independent non-CITT study, the HTS system was administered to groups of third- and fourth-graders. One group received placebo/sham therapy in which correct responses did not alter vergence or accommodative demand. A second group received therapy in which correct responses resulted in an increase in vergence and accommodative demand.[14] Reading performance on the STAR Reading Test™ was used as the primary outcome measure. They found no statistical difference after treatment between the 2 groups; however, the authors of the study noted that none of the subjects completed the program.

They then performed a second study in which they had a "no treatment group" and a "treatment group." The second study was designed to promote completion. Analysis of their data showed no significant difference in reading scores among the control group, the placebo/sham group, or the initial HTS group that did not complete therapy. As expected, reading performance increased by 0.8 years. during the 9-month experiment (maturation). In the second part of the study, they analyzed the results of both those who completed the HTS program (14 of 34 completed the program) and those who did not. Those who completed the program had a 1.8-year improvement on the STAR, whereas those who did not complete therapy had a 1.1-year improvement (similar to that of the control group). These differences were statistically significant. Their findings showed the importance of compliance. It has been postulated that a failure to complete therapy can actually induce more symptoms.[1]

In the current study, RDS stimuli were presented 3 different ways to improve compliance of the HTS program: the "classical way" in which an RDS was presented with a stereoscopic square in 1 of 4 positions and the patient responds to the position; "clicker," a gamelike method whereby the patient found an area of depth and used a moveable paddle to locate the position of the stereoscopic object; and, lastly, a "spaceship" game format whereby the patient shot down a descending spaceship. The patient chose which RDS presentation they preferred. All 3 RDS stimuli were initially presented using the same size stimuli. However, only the "classical" method altered the size of the RDS based on responding, i.e., the target got smaller after the initial vergence criterion was reached. In the clicker or spaceship programs, the size of the target remained stable during therapy. Feldman et al.[15] have shown previously that the size of the vergence amplitudes is related to the size of the target. The larger the target, the larger the measured fusional amplitude, irrespective of size, detail, or retinal disparity. This difference phenomenon was more notable with patients who had a vergence anomaly.[16,17]

CI, although the most common binocular anomaly, is not the only binocular anomaly that causes symptoms. Visual symptoms have been associated with a number of other accommodative/vergence binocular anomalies.[18] No studies have used scaled symptoms questionnaires evaluating accommodative/vergence treatment in other non-CI binocular anomalies.

The current study was designed to investigate: (1) the effectiveness of an accommodative-vergence home-based computerized treatment program to a group with an accommodative/vergence disorder with associated symptoms; (2) the amount of time needed to meet criterion, i.e., finish the program; and (3) the effect of size on re-establishing vergence amplitudes and its subsequent effect on symptoms.

Methods

A retrospective study was performed on 43 prepresbyopic patients (24 males and 19 females) age 9 to 33 (31 were between the ages of 9 and 18, and 12 were between the ages of 19 and 33), who had completed the HTS protocol during a 6-week recruitment window. All patients included in this study had been prescribed the HTS for a presumed accommodative/vergence disorder by their doctor. We did not have any of the specific diagnostic findings from the prescribing doctor because this was a retrospective study in which we accessed the data of any patient using the HTS program via the Internet. Program manipulation, control of stimuli, and presentation of questionnaires were controlled by a remote computer. All patients completed an online pre- and post-treatment symptoms questionnaire that was exactly the same as used in the CITT.[8] To be included in our study, all patients had to have an entering symptom score of higher than 21 (the value initially found in a previous CITT adult study that separated normal subjects from patients with symptoms)[7] and a base out convergence amplitude equal to or less than 30Δ. A positive fusional convergence limit of 30Δ or less was selected because large-size RDS fusional amplitudes are larger than those obtained using a single line of letters in a phoropter, and we wanted to make sure that our patients exhibited both symptoms and reduced convergence amplitude.[15,19]

Prior to beginning therapy, patients completed an online Health Insurance Portability and Accountability Act form in which they agreed to allow their data to be used for research purposes as long as their names and other private information were not disseminated. If patients requested their data not be used for research purposes, their ability to use the program was not affected. The patients were instructed to use the program 5 days a week.

The HTS was used according to the manufacturer's design and instructions. There were 3 parts to the program: eye movement, accommodation, and vergence. There were 3 different large stimulus types used in a task. Patients chose which RDS presentation they preferred. Patients (N = 16) who used the "classical targets" had the target size decrease upon reaching a pre-determined criterion. The other 2 tasks, "spaceship" (N = 16) or "clicker" (N = 11) did not alter the size of the stimulus during training. Step duction techniques were performed with only large targets for all 3 targets. When the auto program was completed, i.e., criteria were met on monocular accommodative rock, convergence and divergence fusional training, jump ductions/step vergence, and auto-slide, a post-training second CITT questionnaire exactly the same as the pretraining questionnaire, was automatically administered online.

Results

Data from 43 subjects were collected. The initial mean symptoms score for all patients before treatment was 32.8 (SD = 8.1), and the post-treatment symptoms score was 20.6 (SD = 11.5). This difference was statistically significant (t = 6.67, df = 42, $P < 0.001$) and clinically meaningful according to the criterion established by the CITT study, i.e., a difference of 10 points on the CITT questionnaire was deemed clinically meaningful.[8] Using the CITT criterion, 55% achieved a clinically significant improvement (an improvement of at least 10 points on the symptom score), and 40% were cured (symptoms score <16 and an improvement of at least 10 points on the symptoms score). Our final symptoms mean score of 20.6 was between 21 (the number found in the adult's pilot study, which differentiated asymptomatic from symptomatic adults)[7] and 16 (the number found in the children's pilot study, which differentiated asymptomatic from symptomatic children).[6]

Table 1 shows a direct comparison (nonadjusted scores) between the percentage of subjects improved in the current study compared with various treatment arms in the CITT study. Because our baseline scores (32.8) were not exactly the same as those reported in the CITT study (30.2),[20] we transformed the symptoms scores of the current study by taking the percentage difference between our baseline score and that of the CITT score and multiplied the final symptom score of this study by this correction factor (30.2/32.8 = 0.92). By doing this, we calculated an adjusted score of 18.9 (20.6 x 0.92), which compares favorably with the final score in the OBVT arm of the CITT study, which was 15.1.

Mean positive fusional amplitudes were also analyzed, mean = 22Δ (SD = 5.6) before treatment and mean = 53Δ (SD = 10) after treatment, i.e., a mean improvement of 31Δ ($P < 0.001$). Initial mean negative fusional divergence amplitudes were 15Δ (SD = 5) and then improved to a mean of 25Δ (SD = 7), a mean difference of 11Δ ($P < 0.001$). This difference was significant over all 3 target-type groups, i.e., classical, spaceship, and clicker. Pearson's r was used to compare before and after treatment findings. The correlation between pre- and post–negative fusional amplitudes resulted in r = 0.19 ($P = 0.21$), and the correlation between pre- and post–positive fusional amplitudes resulted in r = 0.43 ($P = 0.004$).

Table 1 Percentage improved for various treatment arms

Treatment group	N	CISS still ≥ 16 *but* improved ≥ 10 **(A)**	CISS < 16 *but* improved < 10 **(B)**	CISS < 16 *and* improved ≥ 10 **(C)**	CISS < 16 *and/or* improved ≥ 10 **(A+B+C)**
HTS+PP	52	15	6	17	38
Office VT	59	17	7	49	73
HTS completed	43	12	2	40	55

Note. The first 2 groups are the subjects' data reprinted from the CITT clinical trial.[8] The last group (HTS Completed) are the data derived from this study. We compared the HTS and pencil push-up (PP) arm and the in-office vision therapy arms and our findings in this study – HTS completed. It is readily apparent that our cure rate is similar, i.e., 49 versus 40, but our improved rate is less, i.e., 55 versus 73. Both asymptomatic or improved and "normalized" are substantially higher than the HTS + PP group of the CITT.

We also looked at the final fusional amplitudes at the end of each session. Fusional amplitudes improved rapidly for convergence and somewhat slower for divergence. Before the patient progressed from fusional amplitude training (ramp) to more dynamic jump duction (step) and auto-vergence training, the subject had to meet criteria of 35Δ positive fusional convergence and 13Δ negative fusional convergence. It took 14 sessions (approximately 5 weeks) for 75% of our subjects to meet these criteria. To complete the program, our subjects needed to meet criteria on the "auto slide" portion and "jump duction." The criteria established were the same as the first part, i.e., 35Δ positive fusional convergence and 13Δ negative fusional convergence. Seventy-five percent of our subjects met these criteria after 18 sessions (7 weeks). Figures 1 and 2 depict the percentage of patients reaching criterion for each phase of therapy, e.g., for convergence and jump duction per treatment session.

Patient data were analyzed further according to which of the 3 targets they used most often during therapy. A 2-way analysis of variance (ANOVA) with repeated measures on one factor showed no significant differences between various therapy targets or the interaction with pre–post symptom score, but a significant main effect for pre–post symptom score, $F = 37.72$, $df = 1$, $P < 0.001$. Similarly, there were significant overall main effects differences found between pretreatment and post-treatment negative fusional amplitude scores ($F = 58.06$, $df = 1$; $P < 0.001$) and positive fusional amplitude scores ($F = 405.17$, $df = 1$; $P < 0.001$). However, further analyses to determine if the target types (classical, spaceship, and clicker) differed from each other revealed no significant differences in the main effect or their interaction.

Discussion

Accommodative/vergence therapy reduces symptoms in patients with presumed accommodative/vergence anomalies on a scaled questionnaire, as defined by the prescribing doctors. The results are both statistically and clinically significant. Although we did not use a control group, the improvement in symptoms was much larger than reported in previous studies using placebo/sham arms and/or HTS therapy arms.[6-9,11,12] In each of those studies placebo/sham therapy resulted in a range of improvement from 21% to 43% improvement.[6-9,11,12] In our study, HTS treatment showed a cure rate of 40%, and the asymptomatic or improvement rate of 55%. This compares with the data in the CITT study in which 49% were cured, and the asymptomatic or improved rate was 73% (*see* Table 1).[8]

The final mean symptoms score of 20.6 falls between the 2 scores established to differentiate between normals and 3-sign CI patients considered symptomatic in children (16) and adults (21).[2,3,21,22] Our patients were made up of a mixture of both adults and children (72% were children), thus one would expect a higher post-treatment symptoms score in our study compared with either children's study.[6,8] We began treatment with patients who had a higher pretreatment symptoms score, thus they required a larger change in symptoms to have a final score similar to the children's OBVT CITT score.[8] When the scores were adjusted for statistical comparison to equalize the starting baseline, the final OBVT CITT score of 15.1 and our adjusted HTS score of 18.7 were clinically similar. Also, one might expect

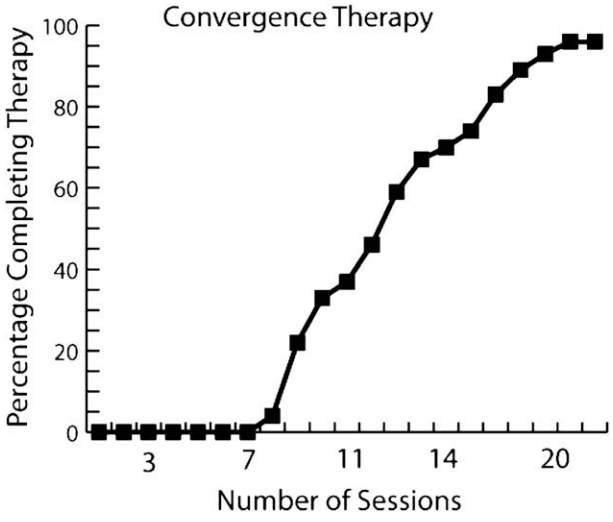

Figure 1 Percentage of patients reaching convergence fusional amplitude criterion per number of completed sessions. Most patients reached criterion by 14 sessions.

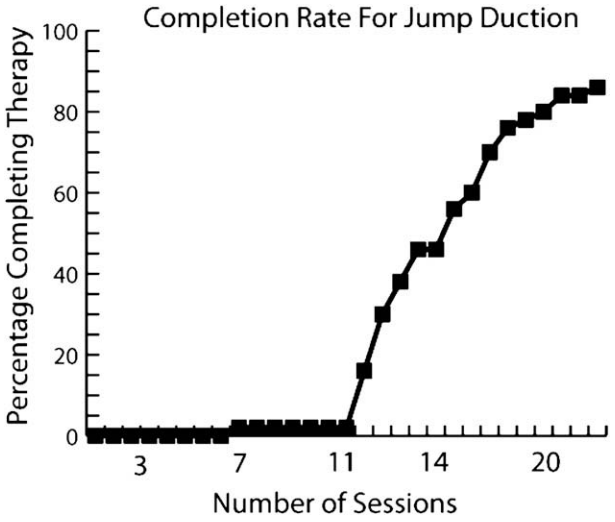

Figure 2 Percentage of patients completing jump ductions criterion per number of completed sessions. Most patients reached criterion by 17 sessions.

poorer results in our population because they were presumably made up of a mixture of accommodative and vergence anomalies, not just the classic CIs that were treated in the CITT studies. Treatment was prescribed by a variety of private-practice optometrists, most of whom were not residency-trained optometrists who participated in the CITT study.[8] Lastly, the CITT study maximized investigator interaction in the in-office arms, which might have resulted in a stronger placebo effect.

In our study, positive fusional amplitudes were initially 22Δ and improved to 53Δ, and negative fusional amplitudes were initially 15Δ and improved to 25Δ. These findings are both statistically and clinically significant. The findings from the Atzmon et al.[23] study suggested that convergence amplitudes needed to improve to 60Δ to be considered normal. In the CITT study, the OBVT arm improved convergence amplitudes from 11Δ to 30Δ, and the HTS + PP demonstrated an improvement from 10Δ to 22Δ.[8] The poor improvement rate for the HTS + PP in the CITT study suggests that the majority of patients either did not comply or failed to improve by performing therapy. Evidence for reduced compliance in the HTS treatment is shown by the finding that 91% of the OBVT group did their homework 75% of the time, whereas only 67% of the home vision therapy group did their homework 75% of the time as assessed by the patient report. Our findings are similar to those of previous studies indicating that fusional amplitude therapy when performed is very effective in increasing fusional amplitudes.[10,11] Noncompliance is probably the most common reason for failure to improve fusional amplitudes.

It is clear in this study that all the patients improved their vergence amplitudes using an RDS. This was deliberate. We only included patients who completed the therapeutic regimen. Thus, to go from one stage to another, they had to achieve a criterion guaranteeing that their fusional amplitudes improved. However, the amount of improvement is impressive, with the mean change in convergence improving by 31Δ. Similar findings were found with divergence. Because the treatment effect was much larger than previous placebo/sham studies, the effect must be related to the combined effect of improving both accommodation and vergence.

These findings show the need for improved compliance by better monitoring. Better monitoring can be done by watching performance on the Internet or by having the patient return for monthly visits. It should also be noted that in the CITT home therapy arm, the patients were prescribed both the HTS and PP therapy.[8] In this study they only had HTS.

In this study, improvement was not as large as the arm of those who participated in the CITT OBVT arm. Thus, in-office therapy using the Computer Orthopter™ and supplemental home therapy including HTS remains the gold standard. Contrary to Wallace,[24] our findings provide indirect evidence that OBVT should be offered as the treatment of choice to our patients. The CITT study chose 12 weeks as endpoint to accomplish the best chance of keeping the sham/placebo group from dropping out of the study, a point at which differences between the various arms of the CITT could be detected and a realistic time frame to get real changes in objective and subjective findings. The CITT study was not designed to determine the optimum length of therapy. As a matter of fact, the continuing improvements noted at 12 weeks suggest that further treatment might have resulted in continued improvement. Lastly, none of these studies evaluated changes that were not quantified by the symptom questionnaire. All of these findings strongly advocate for OBVT as the treatment of choice.

However, OBVT is not always practical. In-office therapy may be too expensive, in-office therapy may not be locally available, or the patient or parent may not have the time or inclination for in-office therapy. Thus, it is important for the clinician to have an alternative therapy to OBVT, if it exists. The HTS treatment *when completed* resulted in mean decrease in symptoms with 55% reaching either normal or clinically significant improved symptoms levels. HTS offers a cost-effective reasonable alternative to reduce symptoms in a host of binocular anomalies. It also may be used as a first line of treatment, when OBVT is not initially practical; however, if a patient does not achieve normalization of the vergence and symptoms, then active in-office vision therapy should be prescribed.

We also looked at the rate of completion of the various segments of the program. The first portion of the program, which resulted in a slow increase in isotonic vergence amplitude, occurred relatively rapidly. By 14 sessions, 75% of the patients had met the criterion of at least 30Δ of convergence with the majority achieving a base-out amplitude of 45Δ. Similar findings were found with base-in fusional amplitudes. After 13 sessions, 75% of the patients met the criterion of 14Δ with the majority achieving a base-in amplitude of 18Δ. After achieving the first criterion, the

second phase of treatment was automatically begun. This phase, which consisted of jump or step vergence and autoslide vergence, lasted for 23 sessions before 75% met criterion. Thus, by the end of 40 sessions, the majority of our patients had finished the HTS program.

There was no difference in the change in symptom scores based on which type of treatment stimulus (classical, clicker, or spaceship) was used.

There are clearly limitations of this study. We realize the importance of obtaining a specific diagnosis using standardized clinical findings before treatment and the need for a better control group. However, we believe that this study provides some important information and the foundation for future studies. This is the first study to investigate the effect of the use of a computerized home vision therapy program in a group of patients having accommodative/vergence anomalies that are not exclusively restricted to "classic" convergence insufficiency. It is also the first study to look at the relationship of size of stimuli in therapy in reducing symptoms. This is the first study to evaluate only those patients completing therapy, eliminating compliance factors. Lastly, this is the first study performed in which the patients are primarily from private practices rather than vision clinics associated with universities. In this study, there was neither financial remuneration nor free treatment factors that might affect treatment results.

Conclusions

This is the first study to look at a variety of nonstrabismic accommodative/vergence anomalies treated with home-based computerized accommodative/vergence treatment regimen. The results show that most patients who complete therapy experience a decrease in symptoms while concurrently improving convergence and divergence fusional amplitudes.

Competing interests

Jeffrey Cooper, O.D., has financial interests in the HTS.

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