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Objective Assessment of Vergence after Treatment of Concussion-Related CI: A Pilot Study

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Abstract

Purpose—To evaluate changes in objective measures of disparity vergence after office-based vision therapy (OBVT) for concussion-related convergence insufficiency (CI), and determine the feasibility of using this objective assessment as an outcome measure in a clinical trial.

Methods—This was a prospective, observational trial. All participants were treated with weekly OBVT with home reinforcement. Participants included two adolescents and three young adults with concussion-related, symptomatic CI. The primary outcome measure was average peak velocity for 4-degree symmetrical convergence steps. Other objective outcome measures of disparity vergence included time to peak velocity, latency, accuracy, settling time, and main sequence. We also evaluated saccadic eye movements using the same outcome measures. Changes in clinical measures (near point of convergence, positive fusional vergence at near, Convergence Insufficiency Symptom Survey (CISS) score) were evaluated.

Results—There were statistically significant and clinically meaningful changes in all clinical measures for convergence. Four of the five subjects met clinical success criteria. For the objective measures, we found a statistically significant increase in peak velocity, response accuracy to 4° symmetrical convergence and divergence step stimuli and the main sequence ratio for convergence step stimuli. Objective saccadic eye movements (5° and 10°) appeared normal pre-OBVT, and did not show any significant change after treatment.

Conclusions—This is the first report of the use of objective measures of disparity vergence as outcome measures for concussion-related convergence insufficiency. These measures provide additional information that is not accessible with clinical tests about underlying physiological mechanisms leading to changes in clinical findings and symptoms. The study results also demonstrate that patients with concussion can tolerate the visual demands (over 200 vergence and versional eye movements) during the 25-minute testing time and suggest that these measures could be used in a large-scale randomized clinical trial of concussion-related CI as outcome measures.

Keywords

convergence insufficiency; vision therapy; concussion; vision rehabilitation

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Convergence insufficiency (CI) is a common binocular vision disorder that often results in visual symptoms including headaches, eyestrain, blurred vision, loss of place while reading, and diplopia during near visual activities.[1,2] These symptoms may interfere with reading performance and other near-related activities.[3] The prevalence of CI in the general population has been estimated to be about 2.25% to 8.3%.[4–6] However, the prevalence of CI after mild traumatic brain injury (mTBI) has been reported to be considerably higher. Studies of US military personnel indicate a prevalence between 28% to 42%.[7–10] Suchoff[11], Ciuffreda[12], and Alvarez[13] have found similar prevalence rates in the civilian, adult population (23% to 42%). A recent study of the prevalence of concussion-related vision problems in children and adolescents found that 49% of the sample had CI.[14]

This high prevalence of CI in both the general and the mTBI populations has led to an interest in studying the effectiveness of treatment for CI. Three recently completed randomized clinical trials completed by the Convergence Insufficiency Treatment Trial Investigator Group (CITT) demonstrated that office-based vergence/accommodative vision therapy combined with home reinforcement is the most effective treatment for symptomatic CI in people 9 to 30 years of age.[3,15–17] The CITT studies used traditional clinical measures of vergence and accommodation, along with a validated symptom questionnaire score, as outcome measures. However, both the symptom questionnaire and clinical measures are subjective measurements that depend on the patient's ability to accurately report what he/she is experiencing and seeing. The use of objective measures of oculomotor function may provide additional valuable information about the underlying mechanisms leading to a decrease in symptoms after office-based vision therapy (OBVT). In addition, objective measures may be useful in clinical trials because they are not prone to bias by either participants or examiners.

There is a paucity of studies using objective eye movement recordings of vergence as outcome measures after treatment for CI.[18–20] Alvarez, et al., [20] studied 13 adult control participants and 4 adult participants with symptomatic CI and no history of brain injury. They used traditional clinical measures for assessing CI, objective measures of convergence and divergence step responses, and fMRI to study the hemodynamic response of the neural substrates used to mediate a vergence response. Pre-OBVT, the convergence average peak velocities to symmetrical 4 degree step stimuli were significantly slower ($p= 0.016$) in CI participants compared with controls, while significant differences in average peak velocities were not observed for divergence step responses ($p=0.30$). The CI participants received 18 hours of vision therapy (1 hour per session) and the results showed that a reduction in symptoms was associated with the following: 1) a decrease in the near point of convergence, 2) an increase in positive fusional amplitude, 3) a reduction in the amount of exophoria at near, 3) an increase in convergence peak velocity, and 5) an increase in the percent signal change of functional activity in the frontal eye fields, posterior parietal cortex and the cerebellar vermis. In a more recent study in the same laboratory, investigators studied the same disparity vergence parameters after vergence therapy in participants with normal binocular vision. They found a significant decrease in response latency, time to peak velocity, settling time, and an increase in response accuracy after 12 hours of vergence therapy.[21]

Bucci et al [19] studied four children (ages 8–16 years) with CI, and administered a 12-session, vergence orthoptic program. In addition to marked improvement in clinical signs and reduction of symptoms after the therapy, the objective measures of vergence revealed somewhat faster responses: peak velocity increased and duration decreased. In another study of 8 children (ages 9–16 years) with clinical vergence deficits, Jainta et al [18] had the children perform a simple oculomotor task in which they executed 80 convergence and 80 divergence responses to midline targets at distances of 25, 68, and 153 cm in a single session. Immediately following this task, there were small but significant improvements in vergence dynamics with a decrease in duration and an increase in peak velocity for both convergence and divergence. Latency was normal and remained constant in all cases. Scheiman et al[22] recently published a case report of a 10 year old child with CI that documented improvements in laboratory-based objective, dynamic measures of both accommodation and vergence following conventional office-based optometric vision therapy for CI.

In the only study to date on patients with mild traumatic brain injury (mTBI), Thiagarajan, Ciuffreda, et al.,[23] used a strong cross-over, placebo-controlled design to investigate the effectiveness of oculomotor therapy in 12 adult participants with mild traumatic brain injury and vergence dysfunction. They found that after oculomotor training, the peak velocity for both convergence and divergence increased significantly. Increased peak velocity was significantly correlated with increased clinically-based vergence prism flipper rate. Steady-state response variability for convergence reduced significantly following training. None of the measures was found to change significantly following the placebo training. This study did not specifically target CI as a diagnostic condition, but did demonstrate that the use of laboratory-based therapy clearly led to objective improvements in vergence function. To our knowledge, the Thiagarajan et al., report is the only study in the literature to date that used objective measures of vergence and version eye movements as outcome measures after vision therapy in a sample of patients with mTBI. However, we were unable to find any study specifically using objective eye movement recording with patients with concussion-related, symptomatic CI that used traditional clinical vision therapy procedures

Thus, there is a need for additional research to evaluate the use of objective measures of vergence and saccadic eye movements as an outcome measure for the treatment of CI after concussion. The primary objective of this study was to determine whether OBVT affects various objectives vergence parameters (i.e., response latency, time to peak velocity, settling time, response amplitude, peak velocity, and main sequence ratio). Secondary objectives were to gather preliminary information about the feasibility of using these measures as outcome measures in a large-scale, randomized clinical trial studying concussion-related CI, and to produce pilot data about effect size and variability that can be used in future studies for sample size estimation. In addition, this study was designed as an effectiveness study using traditional clinical treatment, rather than an efficacy study using laboratory-based therapy.[24]

METHODS

The tenets of the Declaration of Helsinki were followed throughout the study. The institutional review board of Salus University approved the protocol and written informed

consent and assent as well as Health Insurance Portability and Accountability Act (HIPAA) authorization were obtained before participation.

Patient Selection and Definition of CI

To be eligible, individuals had to be between 9 to 35 years old, have a medically-documented diagnosis of concussion and symptomatic CI. Symptomatic CI was defined as (1) a score of 16 or higher for children and 21 or higher for adults; (2) exophoria at near at least 4 prism diopters (Δ) greater than at distance; (3) a receded near point of convergence (NPC) of ≥ 6 cm break, and (4) insufficient positive fusional vergence (i.e., failing Sheard's criterion or positive fusional vergence < 15Δ base-out) at near. Participants had to have 20/25 visual acuity or better with best correction. Participants with a previous history of vision therapy were excluded. The participants also had to have stable general health, intact cognitive function, and no other neurological conditions.

Eligibility Exam/Baseline Clinical CI Testing for Enrollment

After obtaining written consent/assent, a vision examination was performed to determine if the patient was eligible for the study. Eligibility testing included administration of the CI Symptom Survey (CISS) to identify whether or not the patient was symptomatic.[25,26] Other eligibility tests included best-corrected visual acuity at distance and near, a sensorimotor examination (cover test at distance and near, NPC, positive and negative fusional vergence at near, vergence facility at distance and near, near stereoacuity, monocular accommodative amplitude, monocular accommodative facility), cycloplegic refraction, and an ocular health evaluation. This test battery is identical to that used in previous randomized clinical trials of symptomatic CI.[3,15,27] Eligibility criteria are listed in Table 1.

Objective Outcome Measures of Disparity Vergence: Instrumentation

The experimental set-up is illustrated in Figure 1. For this study, the ISCAN RK-826PCI binocular tracking system (Burlington, MA, USA) objectively recorded horizontal vergence eye movements. This system utilizes an infrared emitter and camera (receiver) to capture the eye movement data at 240 frames per second (fps). The infrared source emits infrared light at a wavelength of 950 nm with a power of 1.2 mW/cm^2, which is considerably lower than the ANSI Z136 specification safety limit of 10 mW/cm^2. The manufacturer reported accuracy is 0.3° over a ± 20° horizontal and vertical range.

VisualEyes Software, Calibration, Stimuli Presentation, and Data Collection

A custom LabVIEW™ (National Instruments, Austin, TX, USA) program named VisualEyes controlled the stimuli presentation and data collection from the instrumentation.[28,29] This software was designed to independently generate visual stimuli to the left and right eye with the use of two monitors and two partially (50%) reflecting mirrors. The VisualEyes program produces a stimulus in each monitor that is transposed onto reflective mirrors. A vertically oriented 'difference of Gaussians' (DOG) target was used, that only contains low spatial frequencies and yet provides effective vergence information when viewed binocularly. This target was designed to minimize blur cues and feedback to produce virtually accommodation 'open loop' conditions.[30]

The distance from each eye to the monitors was 40 cm, the same distance used clinically as 'near'. Upon proper set-up, the mirrors reflect the stimulus to each eye, simulating a disparity vergence stimulus along the subject's midline. A 12-bit digital acquisition (DAQ) card (National Instruments 6024 E series, Austin, TX, USA) digitized the eye movement data recorded from each eye from the ISCAN instrumentation using a range of ±5 volts.

Selection of Experimental Design Parameters

Three Separate Experiments—Three experiments were necessary to achieve the objectives of this study. These include presentation of disparity vergence stimuli as well as presentation of saccadic stimuli. CI participants are known to have more difficulty with convergence at close compared to far distances. Thus, the use of both far and near disparity vergence stimuli allowed an objective determination of this expected pattern. Stimuli were presented at binocular vergence angles from 6° to 12° (referred to as "near" stimuli) and binocular vergence angles from 2° to 8° (referred to as "far" stimuli). The three experiments were sequenced to begin with far disparity vergence, which is expected to be easier for CI participants. This was followed by near vergence and finally the presentation of saccadic stimuli. The closest vergence angle displayed to the subject was 12º. This vergence angle was chosen because it is the average NPC plus two standard deviations away from the average NPC recorded from the randomized clinical trial CITT.

Disparity Vergence Symmetrical Step Stimuli—The use of 4° and 6° symmetrical disparity steps were chosen to maximize the ability to gather quality data for each observation. A number of previous studies have used these parameters and found that these values minimize the likelihood of loss of data because of an inability to fuse the targets.[20,31–35] Based on previous studies, 4° disparity vergence stimuli provide the highest likelihood of obtaining meaningful data from CI participants.

The disparity vergence stimuli remained visible to the participant for 3–5 seconds to allow enough time for the participant to attempt to fuse the symmetrical binocular visual stimuli presented along the subject's midline. Prior research shows a binocularly normal control fuses typically well within 2 seconds, typically within the first half of the first second.[21] Hence, for this study, we approximately doubled the amount of stimulus presentation time for CI patients to allow adequate time for them to fuse the symmetrical binocular vergence stimuli. The variability in duration of the presentation was designed to try to prevent anticipatory responses that are known to affect vergence responses.[36–38]

Number of Observation for Various Stimuli—Because we hope to use this protocol in a randomized clinical trial to study children, a decision was made to try to limit the total experimental time to 30 minutes or less. This meant limiting the number of observations presented to the participants. Given the results from previous studies, demonstrating that a 4° disparity vergence stimulus is most useful for CI participants, and the time constraints, a protocol with twice as many 4° stimuli was designed. This sequence required about 23 minutes if the participant did not require any breaks.

Prior to the experimental session, the stimuli presented on the computer screens and partially reflecting mirrors were adjusted to calibrate the visual stimuli with real targets located at

measured distances from the subject's midline. An inter-pupillary distance of 6 cm was assumed. Although this assumption had an effect on the absolute amount of vergence, since the outcome was a measure of change in vergence parameters, it did not affect the study results. The subject's head was restrained using a chin/head rest to try to minimize head movement and influence from the vestibular system. A midline adjustment procedure was performed to insure proper positioning within the chinrest. All experiments are conducted in the dark to reduce influence from proximal vergence and the "DOG" pattern visual stimulus displayed on the haploscope was used to reduce accommodative vergence.

Two separate calibrations were performed for each of the three experiments (vergence at far, vergence at near, and saccades). Six calibrations in total. Calibration for far vergence step responses consisted of a six-point, monocular calibration (1°, 3°, and 5° monocular, corresponding to 2°, 6°, 10° binocular vergence angle demand). Calibration for near vergence step responses consisted of a six-point, monocular calibration (4°, 5°, and 6° monocular, corresponding to 8°, 10°, 12° binocular vergence angle demand). Calibration for saccade responses consisted of a four-point, monocular calibration (5°, and 10° monocular into the left and right visual fields). These calibrations were performed before and after completion of each experimental group.

After the initial calibration was complete the experiment began, and 12 disparity vergence stimuli were presented (combination of convergence and divergence), followed by an opportunity to rest. This was repeated 6 times for a total of 72 pseudo-random observations for the far disparity vergence experiment, 72 pseudo-random observations for the near disparity vergence, and 40 observations each of 5° and 10° pseudo-random into the left and right visual fields.

Eye Movement Analyses

Eye movement data were processed and analyzed with a custom MATLAB program (Waltham, MA, USA). For all individual left and right eye movement responses, inward convergent rotation was plotted as positive to facilitate direct comparison between left and right eye movement responses. Blinks were easily identified based on manual inspection of the left and right eye movement responses. Responses with blinks within the transient portion of the movement were omitted because the peak velocity cannot be measured due to the loss of signal. However, blinks within the steady state portion of the response were analyzed. The eye movements were filtered with a 4^{th} low pass order Butterworth, with a cut off frequency of 40Hz to eliminate instrumentation noise that is probably not physiological in nature.

Peak velocity was the primary outcome measure in this study. Velocity was computed by taking the derivative of the position response using a two-point central difference algorithm.[39] Each individual left-eye and right-eye convergence movement response was manually inspected for the presence of a blink or a saccade during the transient portion of the vergence eye movement. Saccades were easily identified because saccade dynamics are an order of magnitude greater than vergence. Only when saccades obstruct the convergence peak velocity was the response omitted from the peak velocity analysis because several studies support that saccades facilitate the maximum velocity of vergence.[33,34,40] The peak

velocity of the left-eye, right-eye, and combined vergence response were quantified as the maximum value within the transient portion of the vergence movement.

Other objective eye movement parameters assessed included time to peak velocity, latency, response amplitude, settling time. These parameters are illustrated in Figure 2A. Peak velocity was defined as the maximum value within the transient portion of the vergence movement. Time to peak velocity was defined as the time when the movement reaches its peak velocity within the transient portion of the response (green line in 2A). Latency was defined as the time at which the average positional data deviates 5% from the stimulus amplitude. Hence, for our study this threshold is at 0.2º away from the initial response position. An example of the average response latency is illustrated by the purple arrow and lines in Figure 2A. The settling time was defined as the time when the response was within the 5% error band (black dashed lines Figure 2A) of the stimulus target amplitude (red line Figure 2A). Figure 2B is the phase plane where velocity is plotted as a function of position. This plot allows a detailed analysis of the first order dynamics of an eye movement response. We fit the transient portion of the subject's eye movement data (blue line Figure 2B) with a second order polynomial (red line Figure 2B). The roots of the polynomial were then calculated to determine which amplitude the response would attain when the response returns to zero º/sec velocity depicted as an 'X' in Figure 2B. This point represents the response amplitude when the vergence system was presented with a 4º symmetrical vergence step along midline. This analysis has been used in several other studies.[41,42] Accuracy was defined as the difference between the stimulus and response (Figure 2B). The last analysis is a main sequence analysis. The main sequence is an assessment of the first order dynamics of eye movement responses.[43]

Treatment

Office-based Vision Therapy with Home Reinforcement (OBVT)—OBVT was administered by a trained therapist (residency-trained optometrists) weekly, for 60-minute office visits with 45 minutes of therapy time, combined with procedures to practice at home (15 minutes, 5 times per week). This treatment sequence is a well-accepted approach for treatment of CI[44] and has been successfully implemented in four previous studies.[3,15,45] The number of office-based visits ranged from 12 to 20 with the endpoint dependent on the participants' ability to reach pre-determined endpoint criteria for each prescribed therapy procedure. This variation in amount of therapy required is not unusual with the concussion population because some of these patients are so symptomatic that therapists typically have to slow the pace of the treatment. Fifteen minutes of home-based therapy was prescribed to be performed 5 days per week, and compliance with home-based therapy was monitored at each visit using a home-based therapy log that was completed by the participant.

Follow-up Visit—All participants were re-examined after completion of OBVT. Both the clinical and objective testing performed at enrollment were repeated at the outcome examination.

Determination of Outcome—To evaluate improvement in clinical measures and symptoms, we used the following criteria used in the CITT studies. A "successful" outcome

was a score of <16 on the CI Symptom Survey for children or <21 for adults, a normal NPC (i.e., less than 6 cm), and normal PFV (i.e., greater than 15Δ and passing Sheard's criterion). "Improved" was defined as a score of <16 (children) or <21(adults) *or* a 10 point decrease in the CI Symptom Survey score, *and* at least one of the following: normal NPC, an improvement in NPC of more than 4 cm, normal PFV or an increase in PFV of more than 10Δ. Patients who did not meet the criteria for "successful" or "improved" were considered "non-responders."

Statistical Analysis

All analyses will be performed using SAS Version 9.3 with an alpha level of 0.05 used to determine statistical significance. Statistical significance of the improvement in clinical findings after OBVT was tested using a two-tailed paired *t*-test. For the main sequence analysis, a group level analysis was accomplished by averaging the 4 and 6 deg convergence movements recorded from near and far space for each subject and plotting the peak velocity as a function of response amplitude. This analysis was repeated for divergence movements. A main sequence analysis using the 5 and 10 deg saccadic eye movement responses was also calculated. To determine whether significant differences were observed within the main sequence plots the ratio of peak velocity divided by response amplitude was computed for each type of movement (convergence, divergence and saccade) and significance was assessed using a two tailed paired t-test.

RESULTS

Three of the participants were adults and the mean age of the five participants was 22.2 years old with a range from 13 to 28 years old. The number of visits varied from 12–20 (mean 13.6). The number of visits was related to the subject's ability to complete all the assigned therapy tasks. The causes of the concussion were sports-related (2) automobile accident (3). The mean time between the concussion and the first vision examination was 11.6 months with a range from 2 months to 24 months.

Clinical Measures

The clinical measures before and after treatment are illustrated in Table 2. The mean CISS score was 33 before treatment and decreased significantly to 14 after OBVT (t=4.5, p=0.011). All four adults had CISS scores <21 after treatment and the child's score was <16 after OBVT. A paired *t*-test revealed a significant difference comparing the pre-OBVT and post-OBVT parameters for NPC break (t=4.8, p=0.008), positive fusional vergence (t=5.2, p=0.006), and vergence facility (t=3.9, p=0.017). The near phoria decreased in 4/5 participants, but the amount of change was not clinically significant (2.2Δ) although it approached statistical significance (t=2.7, p=0.051).

Four of the five participants were categorized as "successful" based on the pre-determined composite criterion (CISS, NPC, PFV). Subject 5 had a normal CISS score and positive fusional vergence, but his NPC was still >6cm after treatment. Thus, he was considered "improved" but not "successful".

Objective Measures - Convergence

Both 4º and 6º convergence and divergence movements were evaluated in our study protocol. We only report the results for the 4º data because 3 of the 5 participants had difficulty responding to the 6º stimuli at baseline. Figure 3 illustrates an ensemble plot of multiple, 4º symmetrical convergence movements in a subject with normal binocular vision. The plot shows that there is very little variance in the responses and the response amplitude closely matches the 4º symmetrical binocular visual stimulus.

In contrast, all of the concussion patients studied here have impaired convergence responses before therapy. Figure 4 shows the subject who exhibited the greatest impairment of convergence (Figure 4A) and a typical subject (Figure 4B). Figure 4 represents an ensemble plot showing significant changes in the positional variance of 4º symmetrical, convergence eye movements before (Figures 4A and 4B) compared to after therapy (Figures 4C and 4D) for these two participants. In Figure 4A, the convergence response within the steady state reaches only 2º on average and it takes almost 3 seconds for the convergence response to reach that level. The second subject illustrated in Figure 4B demonstrates a high degree of variance in the convergence responses. While the average response amplitude within the steady state is about 3º degrees, it is apparent that some responses were greater than 4.5º and others less than 2º. In addition, the two lower movements indicate that the subject attempted to converge, could not fuse, and then tried to converge again over the 3 second period of time. After therapy (Figures 4C and 4D), the convergence response amplitudes for both participants are more accurate and the maximum response is achieved in less than 1 second. The responses after OBVT look more similar to the subject with normal binocular vision (Figure 3).

Figures 5A–B represents data from one subject with less impaired convergence before and after OBVT. In these figures, we combined information about eye position (solid lines) during the 3-second recording, as well as velocity (dotted lines) on the same graph. The blue, solid and dotted lines show the mean pre-therapy response and the red, solid and dotted lines, show the mean post-therapy response at the “near” (Figure 5A) and the “far” (Figure 5B) distances. In both cases, one can observe changes in a number of response parameters such as peak velocity, time to peak velocity, response accuracy. The divergence responses for this same subject are shown in Figure 5C (near space) and 5D (far space). We included these figures to demonstrate that while there are some changes after therapy for divergence, the magnitude of change is less than that of the change observed in convergence eye movement responses.

Figures 6A–D show similar data from the subject who exhibited the greatest changes in objective measures after OBVT. One can see very significant changes in peak velocity and position in both “near” and far” convergence responses to 4º symmetrical, step stimuli (Figures 6A and 6B). This subject was unable to make any measurable divergence responses to “near” stimuli before therapy (Figure 6C), but could do so after OBVT (Figure 6D).

Tables 3 and 4 show the mean values and mean change for all five objective measures of disparity vergence for “far” and “near” stimuli before and after OBVT. There were statistically significant changes in peak velocity (p=.004) and accuracy (p=.011) for “far” 4°

convergence movements as well as the peak velocity (p=.011), and accuracy (p=.032), for "near" convergence movements. For 4° symmetrical divergence steps there were statistically significant changes in peak velocity (p=.009) and accuracy (p=.033 as well as the peak velocity (p=.013), for "near" divergence movements (data not shown).

Objective Measures - Saccades

Unlike convergence movements, which were markedly abnormal before treatment, the saccadic eye movements closely resembled eye movements from participants with normal binocular vision. Statistical analysis indicated no significant changes were observed in any of the five parameters for the saccadic eye movement after OBVT compared to baseline ($p>0.05$).

The main sequence plots for convergence, divergence and saccades are illustrated in Figures 7A–9C respectively. We plotted the peak velocity as a function of the response amplitude for all five participants for all types of movements. To perform a group level analysis, each type of eye movement was averaged as a ratio of the peak velocity divided by the response amplitude. The following types of eye movements ratios were calculated for each subject, 4º and 6º convergence at near and at far (Figure 7A), 4º and 6º divergence at near and far (Figure 7B), as well as 5 º and 10 º saccades (Figure 9C). A two tailed paired t-test showed that a significant change in the main sequence ratio was observed for convergence after OBVT compared to baseline measurements ($p<0.05$). The average main sequence ratio was 5.9 deg/sec^2 ± 0.33 before and changed to 6.9 ± 0.98 deg/sec^2 after OBVT for convergence eye movements. Conversely, divergence and saccades did not exhibit significant changes in the main sequence ratio after OBVT compared to the baseline measurements. Before OBVT, the divergence main sequence ratio was 5.2 deg/sec^2 ± 0.79 and after OBVT the main sequence ratio was 5.1 deg/sec^2 ± 0.78 (p=0.8). For saccades, the main sequence ratio was 41.5 deg/sec^2 ± 1.5 before OBVT and 43.9 deg/sec^2 ± 2.6 after OBVT (p=0.1).

DISCUSSION

Clinical and Objective Findings

In this pilot study, we found significant changes in symptoms and both clinical and objective measures of disparity vergence after completion of OBVT in a small group of participants with concussion-related symptomatic CI. To our knowledge, this is the first report on the treatment of concussion-related CI in which both clinical and objective eye movement measurements have been used to evaluate the results of treatment.

The changes observed after OBVT for concussion-related CI are comparable to those reported in previous randomized clinical trials with participants with symptomatic CI, unrelated to concussion. For example, in the CITT study the mean CISS score at outcome was 15.1 (change of 14.8 from baseline), the mean NPC at outcome was 4 cm (change of 11.7 cm from baseline), and the mean PFV at outcome was 30.5Δ (change of 19.7Δ from baseline). The findings were very similar for this sample with a final CISS of 14 (change = 14), NPC 5 cm (change=12 cm), and PFV 33Δ (change=26.6 Δ). Although the sample size is small in this study, these findings are encouraging and suggest that even though the

underlying etiology of the CI is likely different in concussion-related CI, OBVT seems to be an effective treatment approach.

Objective Measures

The unique aspect of this study was the addition of objective measures of temporal (response latency, time of peak velocity, settling time) and accuracy measurements (peak velocity, response accuracy) of disparity vergence as well as an analysis of the main sequence of convergence, divergence, and saccades. The use of objective recording of vergence and versional eye movements allows the investigator to access additional, more subtle information about the physiology of these eye movements that is not available with traditional clinical testing. We found statistically significant improvements in both peak velocity and response accuracy after OBVT for 4º convergence steps with “far” and “near” targets. This finding is consistent with the limited previous literature. There were also comparable changes in 4º divergence for “far” targets. There is only one previous report of the use of objective measures of disparity vergence in participants who have had binocular vision problems associated with mild traumatic head injury/concussion. In this previous report, the authors[23] found a significant increase in convergence peak velocity. In a study of four participants with CI without a history of concussion, Alvarez, et al.[20] found a significant increase in peak velocity. Specifically, the average peak velocity before vision therapy was 10.7 ± 4.3 deg/s which increased to 14.3 ± 4.6 deg/s after vision therapy where a two-tailed paired t-test showed the change was significant ($p=0.015$).[46]

Although our main objective was to study disparity vergence, we included an assessment of 5º and 10º saccadic eye movements into the left and right visual field from an initial midline position to demonstrate that our calibration protocol was effective and to determine whether significant changes would occur within saccadic responses after OBVT compared to the baseline measures. In participants with CI and no history of concussion, objective measures of saccades resemble those from participants with normal binocular vision. [47] Specifically, if vergence responses were abnormal, while saccadic responses were normal it would demonstrate our ability to gather valid data from a subject. This is precisely what we found with our five participants. In all 5 participants with significant abnormalities in disparity vergence, the saccadic data appeared normal. It is also interesting to note that there were no significant changes in objective measures of saccadic function after OBVT ($p>0.5$). Previous studies have reported significant abnormalities in saccadic function using both clinically- and laboratory-based testing[48] in patients soon after the concussion occurs. The patients in this study all had sustained a concussion at least 2 months before participating in this study.

Main Sequence and the Dynamic Neural Control of Disparity Vergence: Dual Mode Theory

We included an analysis of the main sequence for convergence, divergence, and saccades in an attempt to decipher the underlying physiological mechanism that may lead to improved outcomes after OBVT. Disparity vergence can be described using a two-component model. The first experimental behavioral support for this concept was reported by Jones who showed when two non-fusable lines (horizontal and vertical) were abruptly moved there was a fusion-initiating component to begin a vergence response but the response was not maintained. Hence, he described vergence as a system containing two components – the

fusion-initiating component (FIC) and the fusion-sustaining component (FSC).[49] A few years later Semmlow and colleagues used a disappearing step stimulus and confirmed that when two vertical lines were abruptly moved and disappeared within 200 ms, the disparity vergence system initiated a vergence response but did not maintain it.[50] Neurophysiological evidence also support there are burst and tonic cells observed within the midbrain of primates through the study of local field potentials.[51] We interpret the burst and tonic cells to encode for the preprogrammed and feedback controlled components, respectively. In addition, patients with pontine lesions[52] as well as different set of patients with cerebellar lesions[53] have demonstrated impaired ramp (feedback controlled) vergence but normal responses to step vergence responses (initially preprogrammed controlled). Such clinical data further support two components are present within the neural control of vergence.

These experimental and clinical findings lead to the Dual Mode Theory, which states when the disparity vergence system is stimulated to change gaze in 3D space (near to far space or vice versa) then two components are activated. The fusion-initiating component (FIC) is preprogrammed and is mainly active within the transient portion of the vergence response. It allows the eyes to quickly rotate inward or outward to the new visual target but does not always yield accurate movements. The second component is the fusion-sustaining component (FSC) which is feedback controlled. A feedback controlled system samples the error by computing the difference between where the eyes are currently located in space and where the desired target is located. The FSC provides high accuracy but requires time to guide the eyes to the desired target. When the FIC is optimized meaning it brings the eyes closer to the intended visual stimulus then less adjustment is needed by the FSC to have the eyes fuse on the final vergence angular demand. Our laboratory has provided substantial experimental and modeling research to support the Dual Model Theory of vergence.[54–56]

The main sequence quantitatively analyzes the transient portion of the movement when the FIC dominates the response.[42,43,57] Our results support a significant change in the main sequence ratio of convergence after OBVT compared to the baseline measurements ($p<0.05$). Conversely, the main sequence ratio of divergence and saccades did not significantly change ($p>0.1$) after OBVT compared to the baseline measurements. These results support that one of the potential underlying mechanisms by which OBVT is leading to a sustained reduction in visual symptoms may be through the change in the neural control of the FIC. When the FIC is optimized meaning the eyes are brought close to the intended visual stimulus, then less modification is required from the FSC, which may be a factor leading to the sustained reduction of visual symptoms. Our laboratory has published other investigations showing optimization of the FIC in binocular normal controls after vergence therapy[21] and in those with CI.[58] A randomized clinical trial is needed to further confirm whether it is the FIC of vergence that is being optimized by OBVT in patients with CI and concussion.

Study Limitations and Future Direction

One limitation of this study is the small sample size. It is possible that because of the small sample size, we may have missed a significant effect of OBVT on other objective measures and may see a larger effect size on the parameters that did show a significant change. We are

planning to use this objective assessment protocol with a larger sample size in a randomized clinical trial that is actively being planned. The pilot data from this study is sufficient to help us plan sample size and validate that patients with concussion and symptomatic CI can complete the 25–30 minute testing protocol without excessive discomfort. Another potential issue is that the time from injury to the start of therapy varied from 2 to 24 months. A criticism might be that the natural recovery process for PCS-CI may have confounded the results. However, as Pearce et al, state "Little is known about the spontaneous recovery and functional adaptation of CI after a concussion. Therefore, researchers should examine NPC across different post-injury time intervals including acute, subacute, and chronic." [59] Given the lack of data, we think that the wide range of time elapsed from injury to treatment in this study provides useful information. The fact that some participants were still suffering from the symptoms related t0 PCS-CI as long as 2 years post-concussion argues against the natural healing process.

CONCLUSIONS

This is the first report of the use of objective measures of disparity vergence as outcome measures for concussion-related CI. These measures provide additional information about underlying physiological mechanisms leading to changes in clinical findings and symptoms. The study results also demonstrate that patients with concussion–related CI can tolerate the visual demands (over 200 vergence and versional eye movements) during the 25-minute testing time and suggest that these measures could be used in a large-scale randomized clinical trial of concussion-related CI as outcome measures. Finally, the data from this study can be used in future large scale clinical trials to develop sample size estimates.

Acknowledgments

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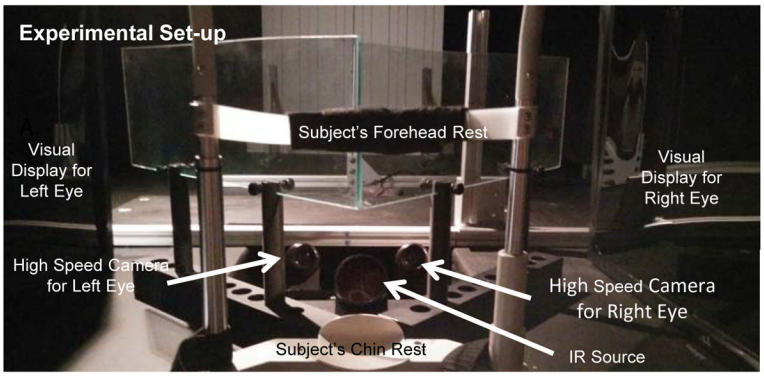

Figure 1.
Experimental set-up of haploscope used to record disparity vergence eye movements.

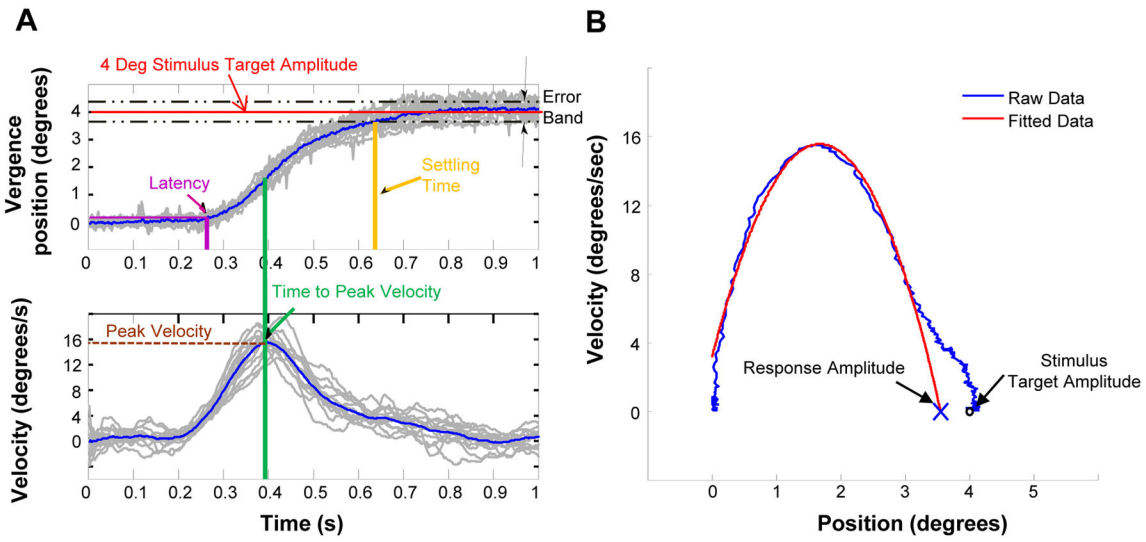

Figure 2.

Data analysis of objective eye movements. **(A)** The temporal properties where the position is plotted as a function of time (upper) and the velocity is plotted as a function of time (lower). **(B)** The phase plane, which is a plot of velocity as a function of position to calculate the accuracy of the movement.

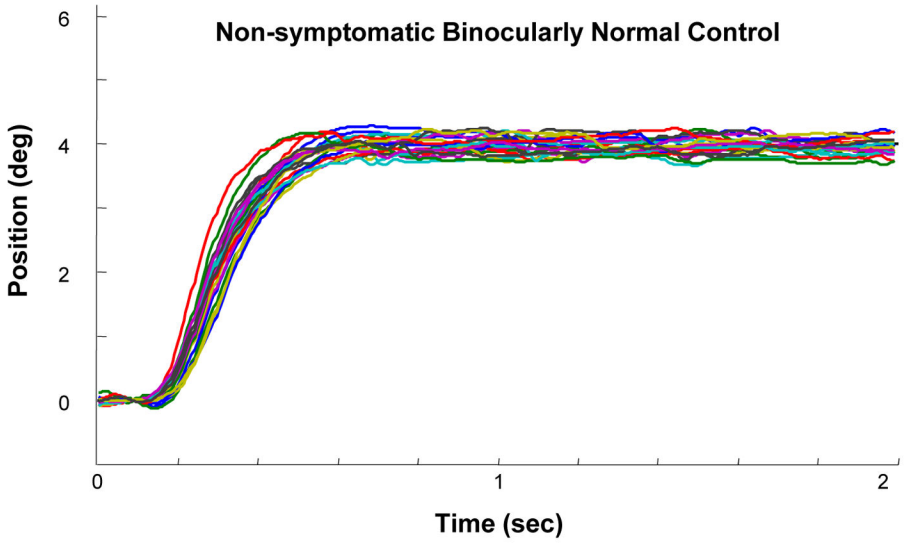

Figure 3.

Each colored trace is an individual convergence eye movement response to a 4º symmetrical binocular disparity vergence step stimulus from a non-symptomatic binocularly normal control subject.

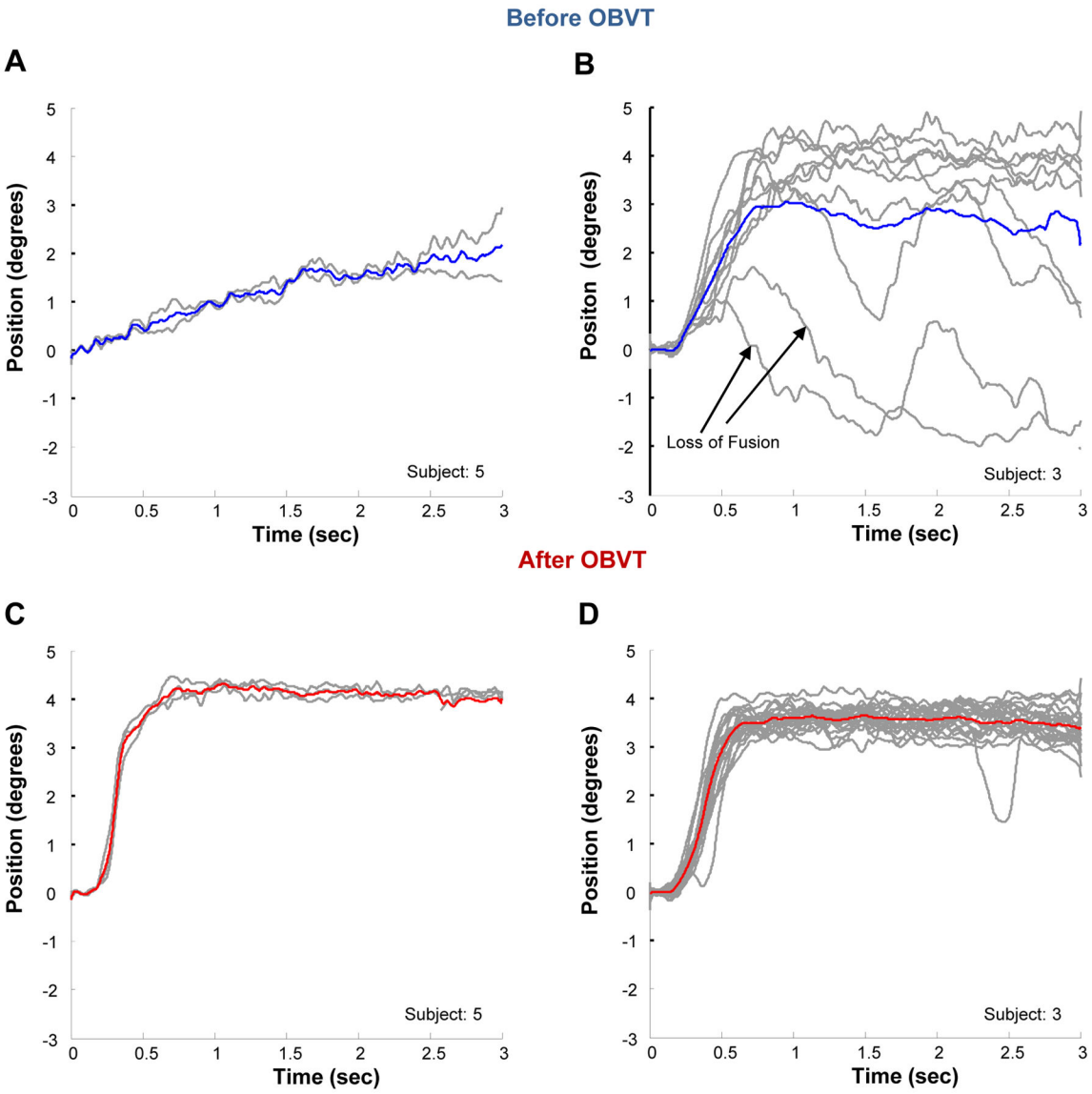

Figure 4.

Each gray line is an individual eye movement response from a 4° symmetrical binocular disparity vergence step stimulus. The blue traces show the average position before OBVT for subject 5 **(A)** and subject 3 **(B)**. The red traces show the average position after OBVT for subject 5 **(C)** and subject 3 **(D)**.

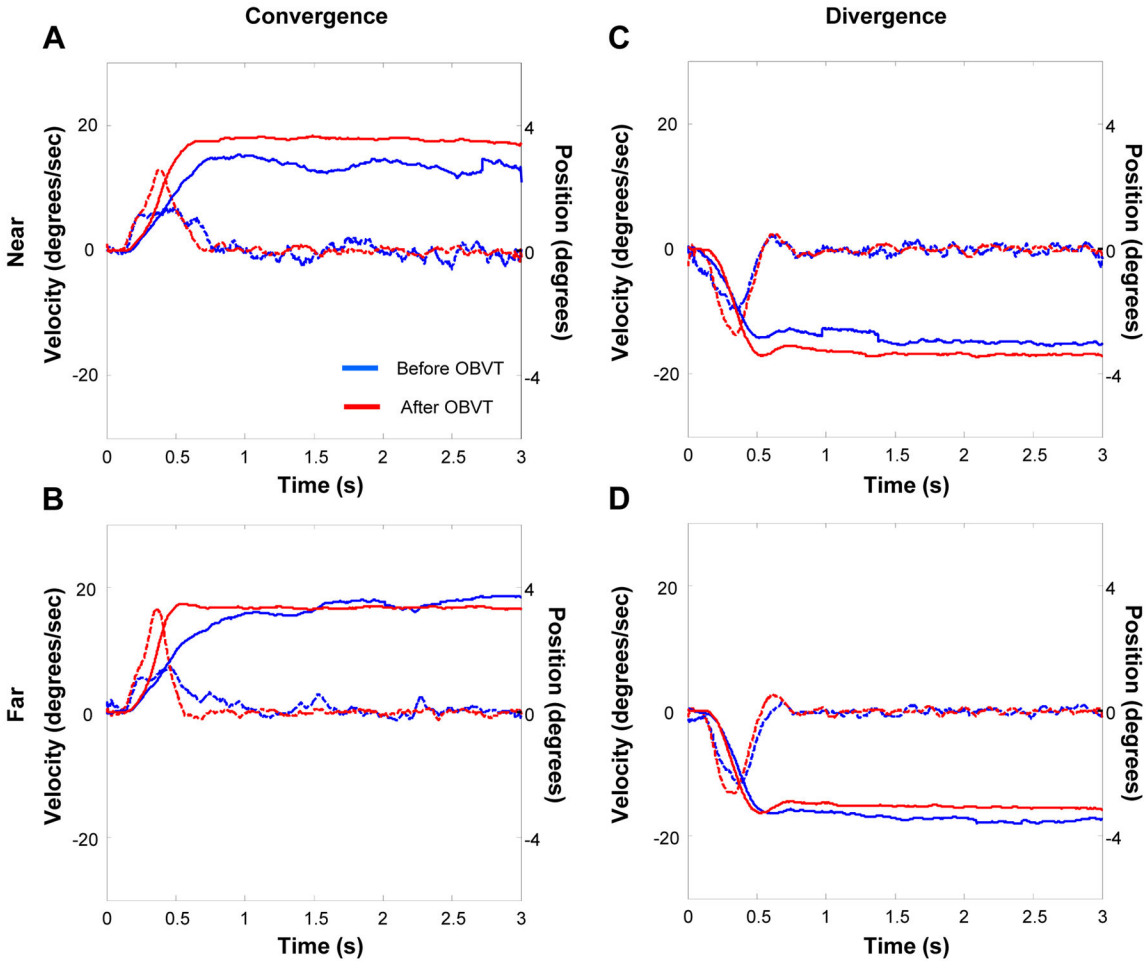

Figure 5.

Typical CI subject's eye movement responses before and after OBVT. Position (solid) and velocity (dotted) as a function of time before (blue) and after (red) OBVT for convergence in near space **(A)**, convergence in far space **(B)**, divergence in near space **(C)** and divergence in far space **(D)**.

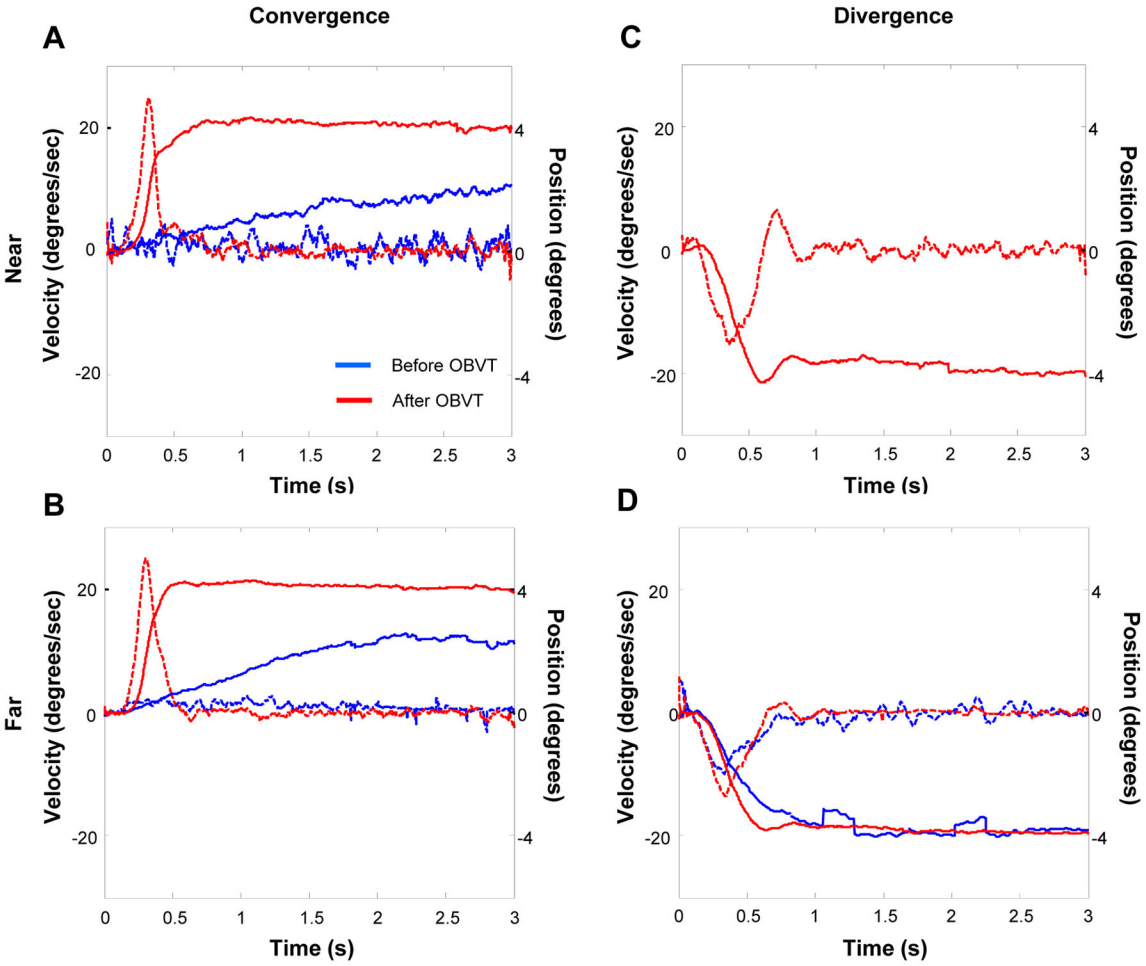

Figure 6.

Eye movement responses before and after OBVT from the CI subject who exhibited the greatest change in position and velocity eye recording traces. Position (solid) and velocity (dotted) as a function of time before (blue) and after (red) OBVT for convergence in near space **(A)**, convergence in far space **(B)**, divergence in near space **(C)** and divergence in far space **(D)**.

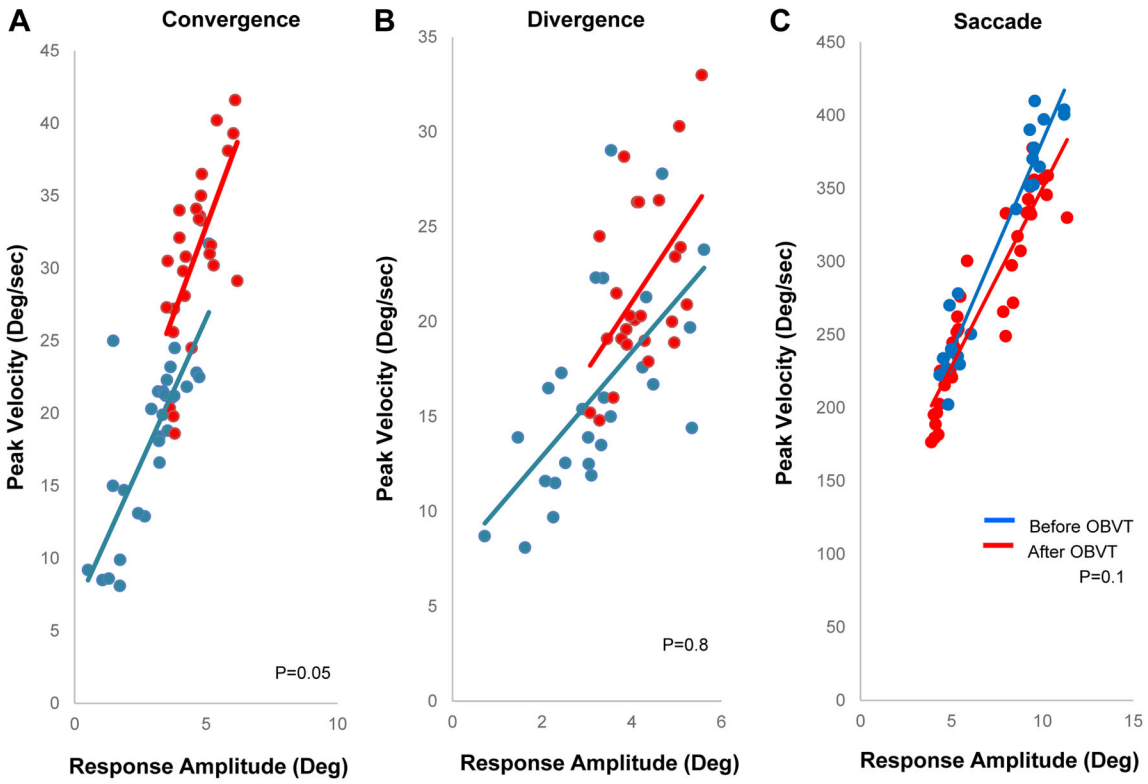

Figure 7.
Main sequence analysis of **(A)** convergence, **(B)** divergence, and **(C)** saccades

Table 1

Eligibility and exclusion criteria.

Eligibility Criteria
Medical diagnosis of concussion of at least 2–4 weeks (+/−1 week) duration
Age 11 to <35 years
CI Symptom Survey score ≥16 for ages <18 years old
CI Symptom Survey score ≥21 for ages >18 years old
Exophoria at near at least 4Δ greater than at far
Receded near point of convergence (NPC) of ≥ 6 cm break
Insufficient positive fusional vergence (PFV) at near (i.e., failing Sheard's criterion or PFV ≤15Δ base-out break)
Best-corrected distance visual acuity of 20/25 or better in each eye
Random dot stereopsis appreciation of 500 seconds of arc or better
Willing to wear refractive correction for any of the following uncorrected refractive errors (based on cycloplegic refraction within prior 6 months). (Correction must be worn for at least 2 weeks):
Myopia ≥ −0.75 D spherical equivalent in either eye
Hyperopia ≥ +1.50 D spherical equivalent in either eye
Anisometropia ≥1.00 D spherical equivalent or ≥1.50 D in any meridian
Astigmatism ≥ 1.00 D in either eye
Willing to discontinue BI prism or plus add at near for duration of study
Normal pupils
Comitant deviation
Exclusion Criteria
Any strabismus at distance
Constant strabismus at near
Esophoria of ≥2Δ at distance
Vertical heterophoria ≥2Δ at distance or near
≥2 line interocular difference in best-corrected visual acuity
Manifest or latent nystagmus
History of strabismus surgery or refractive surgery
Previous history of CI before concussion
Diseases known to affect accommodation, vergence, or ocular motility

Table 2

Mean for each clinical outcome measure, before and after OBVT.

Test/Time	Subject 1 17 years old	Subject 2 13 years old	Subject 3 31 years old	Subject 4 28 years old	Subject 5 22 years old	Mean
Near Phoria (Δ)						
Pre-OBVT	6	8	10	16	6	9.2
Post-OBVT	5	4	8	16	2	7.0
Total Change	1	4	2	0	4	2.2
CISS score						
Pre-OBVT	25	32	24	40	43	32.8
Post-OBVT	16	13	12	20	10	14.2
Total Change	−9	−19	−12	−20	−33	−18.6
Near point of convergence break (cm)						
Pre-OBVT	8	22	20	12	24	17.2
Post-OBVT	4	5	3.5	3	8	4.7
Total Change	−4	−17	−16.5	−9	16	−6.1
Positive fusional vergence blur or break (Δ)						
Pre-OBVT	10	2	6	8	6	6.4
Post-OBVT	30	20	25	50	40	33.0
Total Change	20	18	19	42	34	26.6
Vergence Facility at Near (Flips/minute)						
Pre-OBVT	34	0	0	0	0	6.8
Post-OBVT	34	32	32	31	33	32.4
Total Change	0	32	32	31	33	25.6
Near Point of Accommodation (cm)						
Pre-OBVT	10	19	20	13	24	17.2
Post-OBVT	10	13	13	12	11	11.8
Total Change	0	−6	−7	−1	−13	−5.4

Test/Time	Subject 1 17 years old	Subject 2 13 years old	Subject 3 31 years old	Subject 4 28 years old	Subject 5 22 years old	Mean
Accommodative Facility (Flips/minute)						
Pre-OBVT	32	20	20	22	19	22.6
Post-OBVT	30	31	28	38	31	31.6
Total Change	2	11	8	16	12	9.0

Table 3

Mean for each objective outcome measure, before and after OBVT for 4 degree symmetrical convergence (far).

Objective	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	
Measure/Time	**17 years old CMB**	**13 years old FEM**	**31 years old MXC**	**28 years old PDJ**	**22 years old SKH**	**Mean**
Peak Velocity (°/sec)						
Pre-OBVT	20.1	12.4	5.7	15	20.9	14.8
Post-OBVT	31.4	20.8	27.2	27.7	32.9	28.0
Total Change	11.3	8.4	21.5	12.7	12	13.2
Time to Peak Velocity (sec)						
Pre-OBVT	0.4	0.5	0.6	0.5	0.3	0.5
Post-OBVT	0.4	0.4	0.3	0.3	0.3	0.3
Total Change	0	−0.1	−0.3	−0.2	0	0.12
Accuracy (°) (Stimulus –Response)						
Pre-OBVT	−0.3	1.1	1.0	1.1	2.6	1.0
Post-OBVT	−1.1	0.2	−0.5	−0.3	−0.1	−0.5
Total Change	−0.8	0.9	0.5	0.8	2.5	0.5
Latency (sec)						
Pre-OBVT	0.2	0.3	0.2	0.2	0.2	0.22
Post-OBVT	0.2	0.2	0.2	0.2	0.2	0.20
Total Change	0	0.1	0	0	0	−0.02
Settling Time (sec)						
Pre-OBVT	2.5	2.6	2.7	3.0	2.6	2.7
Post-OBVT	3.0	2.9	2.2	2.9	1.7	2.5
Total Change	0.5	0.3	−0.5	−0.1	−0.9	−0.3

Table 4

Mean for each objective outcome measure, before and after OBVT for 4 degree symmetrical convergence (near).

Objective	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	
Measure/Time	**17 years old CMB**	**13 years old FEM**	**31 years old MXC**	**28 years old PDJ**	**22 years old SKH**	**Mean**
Peak Velocity (°/sec)						
Pre-OBVT	18.9	13.7	6.0	13.4	14.8	13.4
Post-OBVT	26.2	18.4	25.2	29.0	30.6	25.9
Total Change	7.3	4.7	19.2	15.6	15.8	12,5
Time to Peak Velocity (sec)						
Pre-OBVT	0.3	O.5	0.5	0.6	0.4	0.5
Post-OBVT	0.4	0.4	0.3	0.3	0.3	0.3
Total Change	0.1	−0.1	−0.2	−0.3	−0.1	−0.2
Accuracy (°) (Stimulus –Response)						
Pre-OBVT	3.6	2.9	0.8	2.7	2.8	2.6
Post-OBVT	3.8	3.8	3.5	4.3	4.5	4.0
Total Change	0.2	0.9	2.7	1.6	1.7	1.4
Latency (sec)						
Pre-OBVT	0.2	0.2	0.2	0.2	0.2	0.2
Post-OBVT	0.3	0.2	0.2	0.2	02	0.2
Total Change	0.1	0	0	0	0	0
Settling Time (sec)						
Pre-OBVT	2.8	2.7	2.8	2.9	2.5	2.7
Post-OBVT	3.0	2.9	2.5	2.9	2.5	2.8
Total Change	0.2	0.2	−0.3	0	0	0.1