Current Research: Concussion

Safety and Tolerance of Concussion prevention device that provides mild jugular vein compression during Reactive and Neurocognitive Tasks

--Manuscript Draft--

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Abstract:	Background: The Centers for Disease Control and Prevention (CDC) in the United States approximates that upwards of 4 million concussions occur every year during physical and recreational activities. The purpose of the current investigation is to monitor changes in neurological capabilities in a population of athletes wearing a device which provides mild jugular compression. Methods: Twenty normal, healthy volunteers consented to participate and were divided equally between sexes. This study utilized a randomized crossover study design. During one testing session, the subject performed the testing procedures while wearing the jugular vein compression Device under investigation. During the other testing session, the subject was wearing a sham arm device. During each testing session subjects underwent several reaction time and neurocognitive tests. Results: Evaluation of monitored Dynavision (D2) Reaction Time Exam and NIH Cognitive Exam analyses showed no significant effect of wearing a mild jugular vein compressive device compared to a Sham arm band. Discussion: Current concussion prevention strategies such as helmet design, concussion caps or head bands have done little to decrease the incidence of concussion injury. The current study aimed to investigate the effect of collar use on neurocognitive characteristics in athletes. Cumulatively, the pre- and post-safety measures indicate that neurologic parameters of executive function, eye-hand coordination, balance, memory and reaction times were unchanged following physical testing wearing the collar prototype. These findings indicate that the mild jugular venous compression accomplished by the collar device does not compromise vital neurologic capabilities necessary for safe and successful sports participation.

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ABSTRACT

Background: The Centers for Disease Control and Prevention (CDC) in the United States approximates that upwards of 4 million concussions occur every year during physical and recreational activities. Impact dispersion devices (e.g. helmets and headgear) have demonstrated efficacy in the prevention of both superficial and catastrophic head injuries including lacerations and skull fractures, however they have shown limited effect on concussion prevention. The purpose of the current investigation is to monitor changes in neurological capabilities in a population of athletes wearing a device which provides mild jugular compression.

Methods: Twenty normal, healthy volunteers consented to participate and were divided equally between sexes. This study utilized a randomized crossover study design. During one testing session, the subject performed the testing procedures while wearing the jugular vein compression Device under investigation. During the other testing session, the subject was wearing a sham arm device, which was placed on the upper arm and did not cause distal venous engorgement. During each testing session subjects underwent several reaction time and neurocognitive tests.

Results: Evaluation of monitored Dynavision (D2) Reaction Time Exam and NIH Cognitive Exam analyses showed no significant effect of wearing a mild jugular vein compressive device compared to a Sham arm band.

Discussion: Current concussion prevention strategies such as helmet design, concussion caps or head bands have done little to decrease the incidence of concussion injury. The current study aimed to investigate the effect of collar use on neurocognitive characteristics in athletes. Cumulatively, the pre- and post-safety measures indicate that neurologic parameters of executive function, eye-hand coordination, balance, memory and reaction times were unchanged following physical testing wearing the collar prototype. These findings indicate that the mild jugular venous compression accomplished by the collar device does not compromise vital neurologic capabilities necessary for safe and successful sports participation.

INTRODUCTION

The Centers for Disease Control and Prevention (CDC) in the United States approximates that upwards of 4 million concussions occur every year during physical and recreational activities. Over 800,000 of those cases occur in children and direct medical costs exceed $100 million annually.[1-7] This increasing incidence has become a substantial public health burden, with an estimated 75-90% of total traumatic brain injury-related morbidity, hospitalizations, and emergency department visits each year[8]. Incomplete self-reporting of concussion due to pressure to return to play, lack of awareness of potential long-term deficits in the athlete, and lack of recognition of the injury creates barriers to accurate assessment and treatment of concussions.[9,10] More alarming is that multiple, seemingly mild concussions may result in exacerbated and prolonged neurologic deficits, the long-term significance of which have yet to be fully realized, further emphasizing the need for a strategy for preventing these injuries in the first place.[11]

Impact dispersion devices (e.g. helmets and headgear) used in sport have demonstrated effectiveness in the prevention of superficial head injuries including lacerations and skull fractures.[12] However, current efforts focused on concussion mitigation strategies are generally limited to design modifications of these aforementioned equipment items and have demonstrated limited efficacy to date. The Device being tested uses a novel mechanism for reducing or preventing the likelihood of traumatic brain injury (TBI) and may be used in conjunction with other protective equipment. The theory behind the development of this device is to reduce the amount of *slosh* that occurs to the brain within the skull. *Slosh* is the oscillation of a fluid caused by an external force, and occurs when a vessel is only partially, or poorly filled. If the vessel, in this case the skull, can be completely filled, *slosh* will be reduced with resultant decrease in concussive injury. The device is designed to slow the jugular outflow and in essence "pack the brain" with blood in the venous drainage system and reduce the excess compliance of the cranial space. The device developed for evaluation in the current project may provide a valuable adjunctive protection to protect the brain internally against concussive blows. One of the assessment devices used herein is the FDA cleared device; Dynavision. It has been used to assess concussions as well as neurovisual performance[13-18] for TBI and sports concussion. It provides an objective measure of cognitive, sensory and motor performance parameters.

The purpose of the current investigation is to monitor changes in neurological capabilities in a population of athletes wearing a device which provides mild jugular compression.

MATERIALS AND METHODS

Twenty normal, healthy volunteers consented to participate and were divided equally between sexes. All recruited subjects met the following inclusion criteria: 1) aged 18 or older; 2) normal and healthy with no history of injury within the past year, and 3) able to tolerate hypercapnia for 1-2 minutes. All subjects who volunteered to participate and met the study criteria were included in the study, which included two separate testing sessions (Table 1). This study was approved the Cincinnati Children's Hospital Institutional Review Board.

This study utilized a randomized crossover study design. Subjects visited the Human Performance Laboratory on two separate occasions to perform the testing procedures listed in the table below. During one testing session, the subject performed the testing procedures while wearing the jugular vein compression Device under investigation. During the other testing session, the subject was wearing a sham arm device, which was placed on the upper arm and did not cause distal venous engorgement. The order of the testing sessions was randomized prior to the subject's arrival for the first session. The Device incorporated two bulges localized bilaterally over the site of the internal jugular veins. The Device exerted pressure on the region of the neck superficial to the internal jugular veins akin to the pressure felt when a person yawns or wears a snugly fitting necktie. The subjects were outfitted with each device at each testing session by a staff member appropriately trained in fitting the device in the proper location. To ensure proper fitting and Device placement, an ultrasound was performed to examine the immediate effect of Device placement on venous return in the neck or arm. Ultrasound frequency was set at 6.0 MHz to 12 Mhz and the predicted exposure time was 5 minutes per person.

Dynavision (D2) Reaction Time consists of the subject reacting to lights as they illuminate on a board by pressing a button in response (Figure 1). The Dynavision is an eye-hand coordination device that tests and improves visual motor skills [19]. Concentration and cognition were measured by the subjects reacting to the illuminated lights while calling out number, adding numbers, and/or calling out colors. Typically, the Dynavision exam lasted 7 minutes for diagnostics and monitoring. Dynavision included three tests that provided an assessment score for reaction time, cognitive evaluation, and concentration. Each subject's scores from these tests were analyzed by comparing scores with across both intervention conditions: wearing the jugular vein compression device or wearing the sham arm device. The purpose of this analysis was to determine the effect of wearing each device on an athlete's neurocognitive abilities.

Reaction test on Dynavision.

This test was performed using both hands with 5 or 6 hits per hand and assesses visual performance and motor performance. It can be used to demonstrate and assess peripheralization and the left-right symmetry of a subject (Figure 2). The reaction test is the visual motor reaction time for seeing a button light up and moving to hit it.

Concentration, Cognition, and Memory tests performed on the Dynavision.

Instructions for the memory/concussion test have previously been published.[13-15,20,21] The instructions were read to the subject while demonstrating where the lights will be illuminated and showing the tachistoscope screen in the center of the board. "This test uses the middle area of the board (Figure 3). It does not use the outer two rings of lights. This is because we know from A* (the most common Dynavision assessment program) your motor function of hands and eyes, now we want to see if you can concentrate on one area.[15-17] The first test is similar to the A* except you now will have single digit numbers flashing on screen for one second. Call out these numbers. Any questions?" The subjects perform test for 1 minute. Note score, and ability to call numbers. The score is determined by the computer's report of hits per minute.

To perform the second test the following is read to the subject; "This second test is almost exactly the same as the previous test in that single digit numbers will again flash on screen. I want you to call out the first number, remember it, while still hitting buttons and then when the second number flashes, add the first and second numbers. So if the first number is 4 and the second number is 3, you would say "4" followed by "7." You only have to add pairs of numbers, so if the third number on screen is 6, say "6." Then add 6 to the next number and so on. "Any questions?" This test lasted 1 minute, the rater noted the score, and ability to call numbers and add them. If they miss seeing numbers or calculated the wrong sum one hit was subtracted from their score of hits per minute.

To perform the final test the following instructions were read to the test subjects; "This test is just like the last one with one additional task. Now a small number of the red buttons will be green. Hit the green buttons but also call out "green". You must do this while still calling numbers and adding pairs of numbers." Perform test for 1 minute. Rater noted score, ability to call numbers, add them, and call green. See Table 2. Missed calling green, calling green at the wrong time, missed numbers or incorrect sums were tabulated and subtracted from the hit per minute score.

NIH Cognitive Exam

Participants were asked to complete sections 9-11 of the NIH Stroke Scale. For this scale item, the patient was asked to describe what is happening in a provided picture (Figure 4), to name the items on the provided naming sheet, and to read from the attached list of sentences. The subjects were presented with a black and white line drawing and given one minute to memorize it; modified from http://www.thecalculator.co/health/NIH-Stroke-Scale-(NIHSS)-Calculator-774.html. Then the drawing was taken away and they were asked 5 questions to recall from the drawing. Scoring was number of correct responses.

RESULTS:

Evaluation of monitored Dynavision (D2) Reaction Time Exam and NIH Cognitive Exam analyses showed no significant effect of wearing a mild jugular vein compression device compared to a Sham arm band (p>0.05). As shown in Table 2, there were no statistically significant differences in any of the Dynavision, cognition, or concentration scores between the two comparison groups. Bland Altman plots provided a visual depiction of each reported measurement's validity and confirmation of equivalence between test conditions (jugular vein compression device vs. Sham arm band) and confirmed that there was no systematic shift between conditions nor any association between difference and average. Figure 5 (A-C) depicts the Bland Altman plots for the Reactive Index components of the testing. The Dynavision # of Hits (A) and Average Reaction Time (B) showed no association between the difference and the mean. The reaction Time Score (C) did have one data point that fell outside of the 95% CI. Concentration and Cognition scores (Figure 6) again showed no clinically significant interactions. For the

Concussion testing both number of Hits (Figure 7) and overall Time (Figure 8) for each of the 3 trials is also represented in Bland Altman plots. The distribution of data points within 95% CI confirm equivalence between both test conditions the Device and sham arm device.

DISCUSSION

Current concussion prevention strategies such as helmet design, concussion caps or head bands have done little to decrease the incidence of concussion injury[12]. This lack of prevention coupled with the greater awareness that concussion injury may have long-term consequences not previously understood, make it apparent that new, innovative approaches to concussion prevention are essential. The development of this collar device that applies mild external jugular compression thereby reducing jugular outflow and "packing the brain" may be the answer to true reduction of concussions. Previously published randomized controlled trials in ice hockey and American football cohorts have begun to elucidate the potential of this Device. Athletes wearing the device have demonstrated fewer white matter structural changes relative to controls who sustained head impacts of similar frequency and force over the course of a season.[22,23] The current study aimed to investigate the effect of collar use on neurocognitive characteristics in athletes. Cumulatively, the pre- and post-safety measures indicate that neurologic parameters of executive function, eye-hand coordination, balance, memory and reaction times were unchanged following physical testing wearing the collar prototype. These findings indicate that the mild jugular vein compression accomplished by the collar does not compromise vital neurologic capabilities necessary for safe and successful sports participation.

Reaction time is frequently used to characterize baseline and recovery of neurological function before and after TBI and is undoubtedly important when reacting to stimuli during contact sports participation or on the battlefield. Simple visuomotor reaction time, similar to that which was measured by the Dynavision, correlates with a head-protective response of blocking a ball fired at the face from an air cannon.[24] This correlation highlights the interplay between reaction time and physiological responses aimed at head protection; the current report demonstrates that this response is likely unaltered in those who wear the collar device. In addition, athletes and soldiers alike must comprehend and react optimally to a multitude of complex stimuli in real-time. No adverse effect on memory or cognition was observed in athletes wearing the jugular vein compression device versus the sham arm band, making it unlikely that these fundamental capabilities are altered by the Device.

The Device has the promise of providing a novel mechanism for reducing or preventing the likelihood of TBI, and may be used in conjunction with other protective equipment. Traumatic brain injury is the leading cause of death in individuals under age 45. The cost of TBI in the U.S. is estimated at anywhere from $50 to $150 billion, annually.[25] Many TBI injuries occur in military service members; approximately 25% of servicemen evacuated from battle in Iraq and Afghanistan are reported to have sustained such injuries.[26-28] The vast majority of these injuries have resulted from exposure to improvised explosive device (IED) blast waves. Head injuries, concussions, and the resulting pathology have been in public discussion recently as the National Football League (NFL) deals with a lawsuit regarding head injuries by about one-third of living former NFL players.

Although the skull, blood, and brain are almost incompressible, the vasculature tree of the cerebrum is not and actually quite reactive. As volume is added to the cranium, eventually the compensatory reserve volume is surpassed and the intracranial pressure increases slightly. Increasing cerebral blood volume by just 1-3% safely and reversibly reduces compliance of the cerebral vascular tree and may diminish the *slosh* energy absorbed by the brain tissue during a concussive or sub-concussive event[29]. Jugular compression increases cerebral blood volume almost instantaneously. This degree of increase has significantly mitigated *slosh* and TBI in laboratory animals.[30]

A landmark article, published in the *Journal of Neurosurgery*, used a standard acceleration-deceleration impact laboratory model of mild TBI. The study showed a successful and marked reduction of axonal injury following internal jugular vein (IJV) compression as indicated by immunohistochemical staining of amyloid precursor proteins (APP) [30,31]. It is argued that IJV compression reduces *slosh*-mediated brain injury by increasing intracranial blood volume and reducing the compliance and potential for brain movement within the confines of the skull. The reduced compliance results in better packaging on the brain and less extraneous movement of the brain and brain tissue following a hit. The potential for such a technique to mitigate both linear and rotational brain injury in humans by "internal protection" represents the most novel approach to mitigating TBI. Sindelar et al also found that IJV compression reduced hemorrhage in a procine study when applied prior to injury.[32] Protection of the brain from the inside by enhancing the packaging that already exists to protect the brain appears to be a novel and safe strategy to protect the brain from concussive injury. The decreased or altered compliance could work by decreasing the propagation of concussive waves within the brain. These concussive waves are thought to produce the coup and contrecoup injury that occurs in many head injury patients. Further studies to examine the propagation of concussive waves, coup and contrecoup are needed to assess the mechanisms by which the collar functions.

While the current evidence demonstrates no difference in neurocognitive function or reaction time between testing sessions when subjects wore either the jugular vein compression device or the sham arm band, one limitation is the small sample size. A larger scale study is warranted to corroborate these current findings. In addition, future research is warranted to determine if there are any long term effects on neurocognitive function following extended exposure to increased cerebral blood volume.

CONCLUSION

Based on the outcomes of interest measured in the current investigation, the jugular vein compression device did not alter human physiological responses to neurocognitive or reaction time testing. Future research exploring the use of this jugular vein compression device in both laboratory and field settings is warranted.

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Table 1: Subject Demographics

Table 1A							
Female	N	Range	Minimum	Maximum	Mean	Std. Error	Std. Deviation
Age (years)	8.0	2.8	21.5	24.3	22.9	0.4	1.1
Height (cm)	8.0	12.5	157.5	170.0	163.4	1.8	5.0
Weight (kg)	8.0	54.2	57.2	111.4	70.5	6.5	18.3
Body Mass Index	8.0	16.8	21.7	38.5	26.2	1.9	5.5
Body Composition (% Body Fat)	8.0	22.0	24.8	46.8	30.5	2.6	7.4

Table 1B							
Male	N	Range	Minimum	Maximum	Mean	Std. Error	Std. Deviation
Age (years)	10.0	7.2	21.3	28.5	24.2	0.6	1.9
Height (cm)	10.0	18.0	169.0	187.0	176.5	2.1	6.6
Weight (kg)	10.0	36.1	68.2	104.3	82.5	3.9	12.5
Body Mass Index	10.0	13.3	22.4	35.7	26.4	1.2	3.9
Body Composition (% Body Fat)	10.0	29.7	3.6	33.3	18.9	2.3	7.3

Table 2. Comparison of mean scores for reaction, concentration and cognition, and memory Dynavision tests between arm and neck bands.

Reaction	**Mean ARM**			**Mean NECK**			**mean diff**	**p-value**
Hits per Minute	78.471	±	10.660	75.412	±	7.946	-3.059	0.267
Dynavision Average Reaction Time	0.786	±	0.108	0.804	±	0.093	0.018	0.502
Reaction Test Score	0.389	±	0.052	0.391	±	0.070	0.002	0.783
Concentration and Cognition	**Mean ARM**			**Mean NECK**			**mean diff**	**p-value**
Concentration Score 1	34.765	±	28.444	40.882	±	35.052	6.118	0.851
Concentration Score 2	66.235	±	12.483	64.529	±	15.677	-1.706	0.764
Memory								
Cognitive Score	4.765	±	5.562	5.000	±	4.330	0.235	0.726
Concussion Trial 1 # of Hits	94.000	±	10.069	91.647	±	7.615	-2.353	0.334
Concussion Trial 1 Test	0.640	±	0.073	0.648	±	0.056	0.008	0.562
Concussion Trial 2 # of Hits	94.471	±	11.136	90.882	±	11.050	-3.588	0.303
Concussion Trial 2 Test	4.362	±	15.368	0.653	±	0.075	-3.709	0.327
Concussion Trial 3 # of Hits	86.647	±	11.576	87.588	±	11.297	0.941	0.941
Concussion Trial 3 Test	0.648	±	0.073	0.672	±	0.100	0.024	0.311

Figure Legends:

Figure 1: Dynavision (D2). Subject pushes the button when it is illuminated.
Figure 2: Explanation of Reaction Time Testing on the Dynavision (D2)
Figure 3: Memory/Concussion Test using the screen in the center to add multitasking to the test
Figure 4: Cognitive Exam
Figure 5: Dynavision Reactive Index
Figure 6: Concentration and Cognition
Figure 7: Concussion Trials # of Hits
Figure 8: Concussion Trials Time

Figure 1

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Figure 2

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Figure 3

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Figure 4

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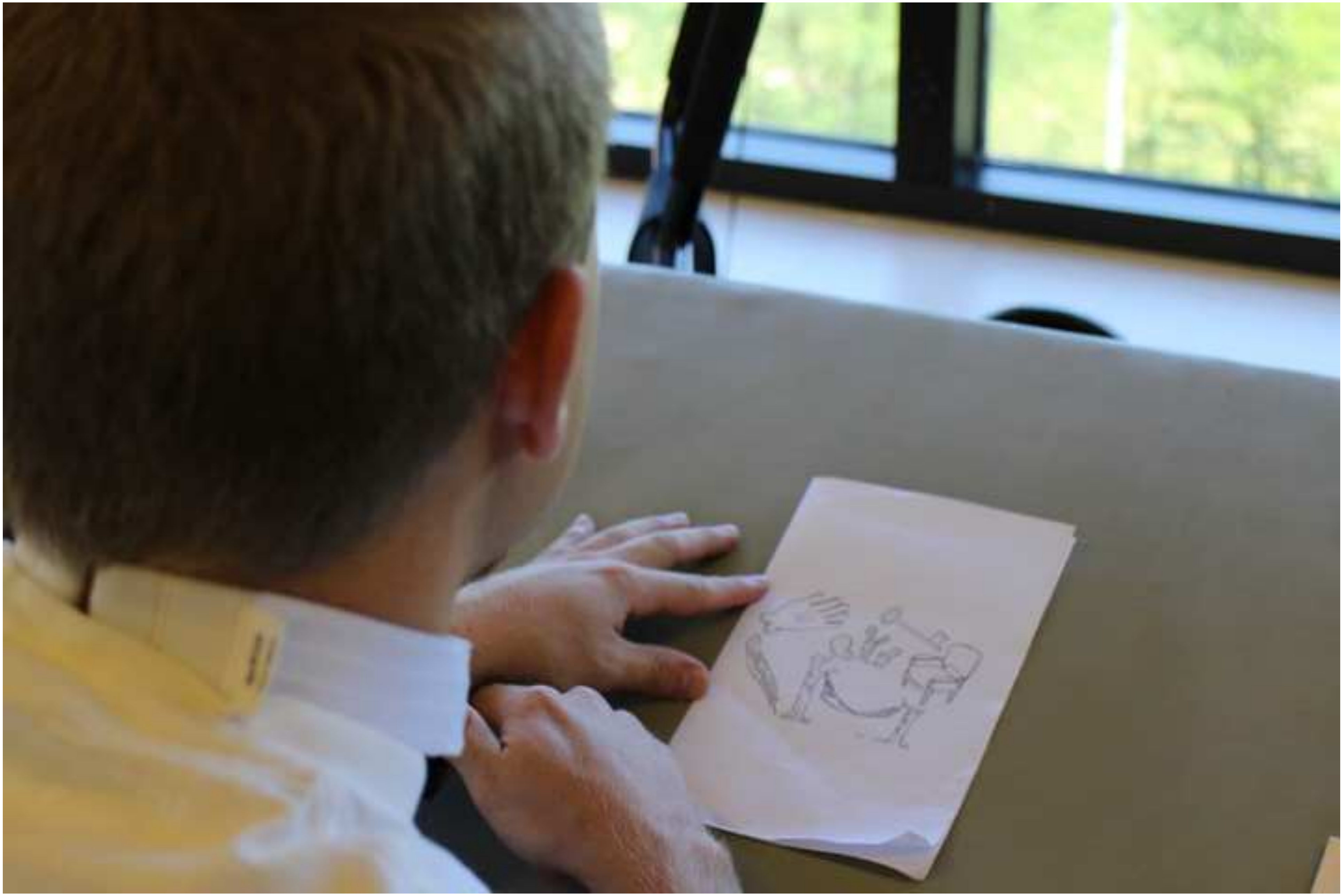

Figure 5

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Reactive Index

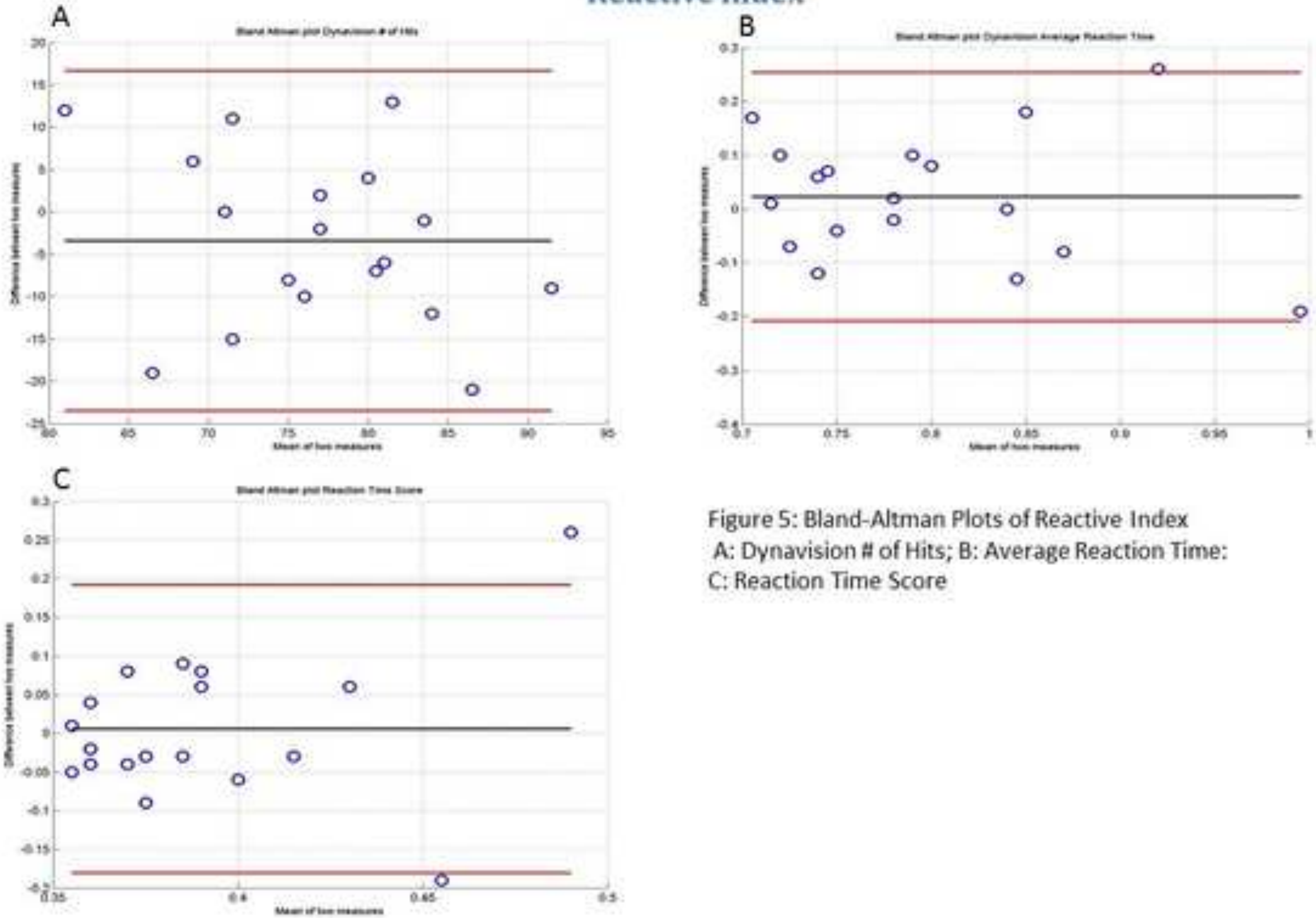

Figure 5: Bland-Altman Plots of Reactive Index
A: Dynavision # of Hits; B: Average Reaction Time:
C: Reaction Time Score

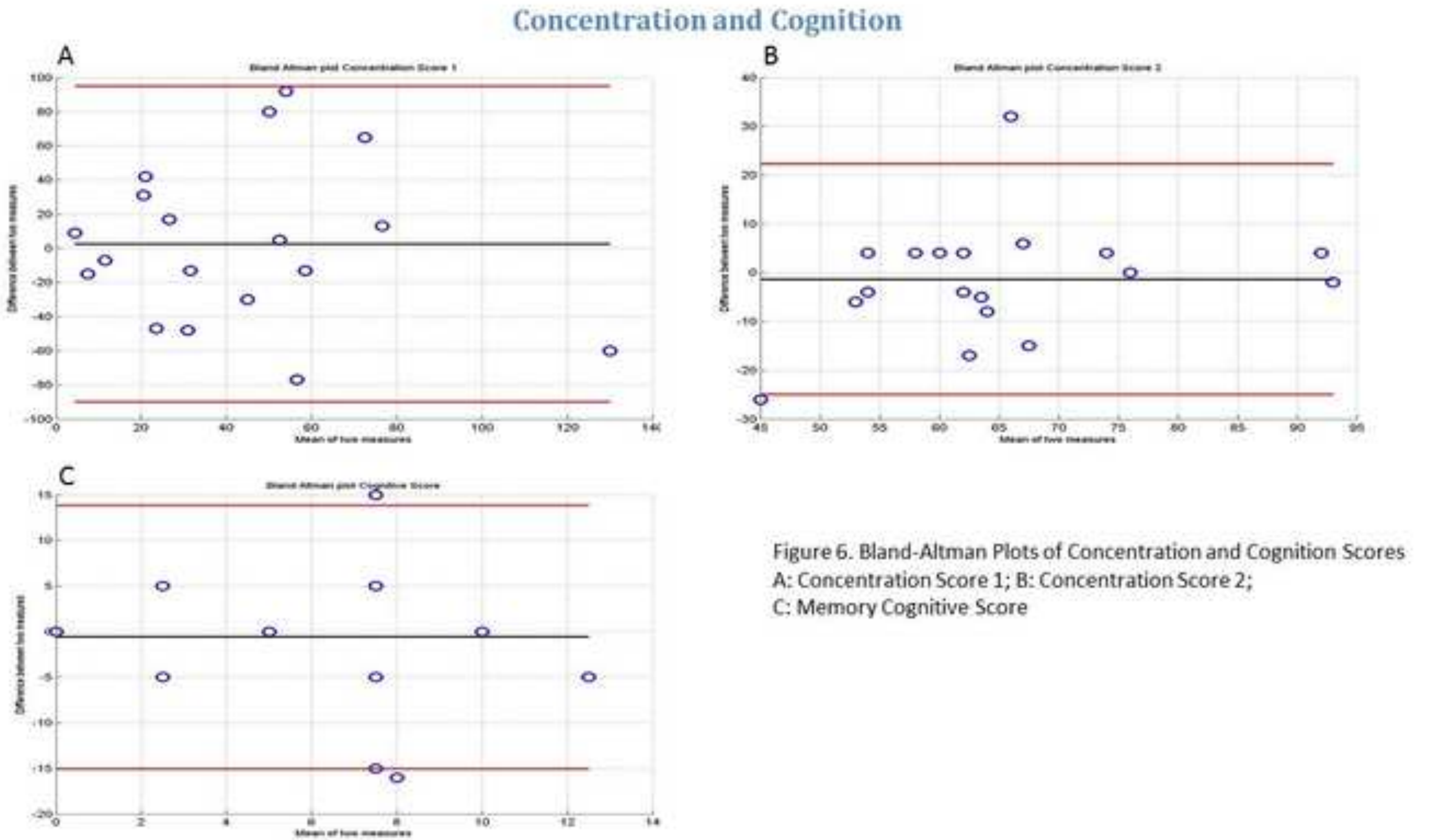

Figure 6. Bland-Altman Plots of Concentration and Cognition Scores
A: Concentration Score 1; B: Concentration Score 2;
C: Memory Cognitive Score

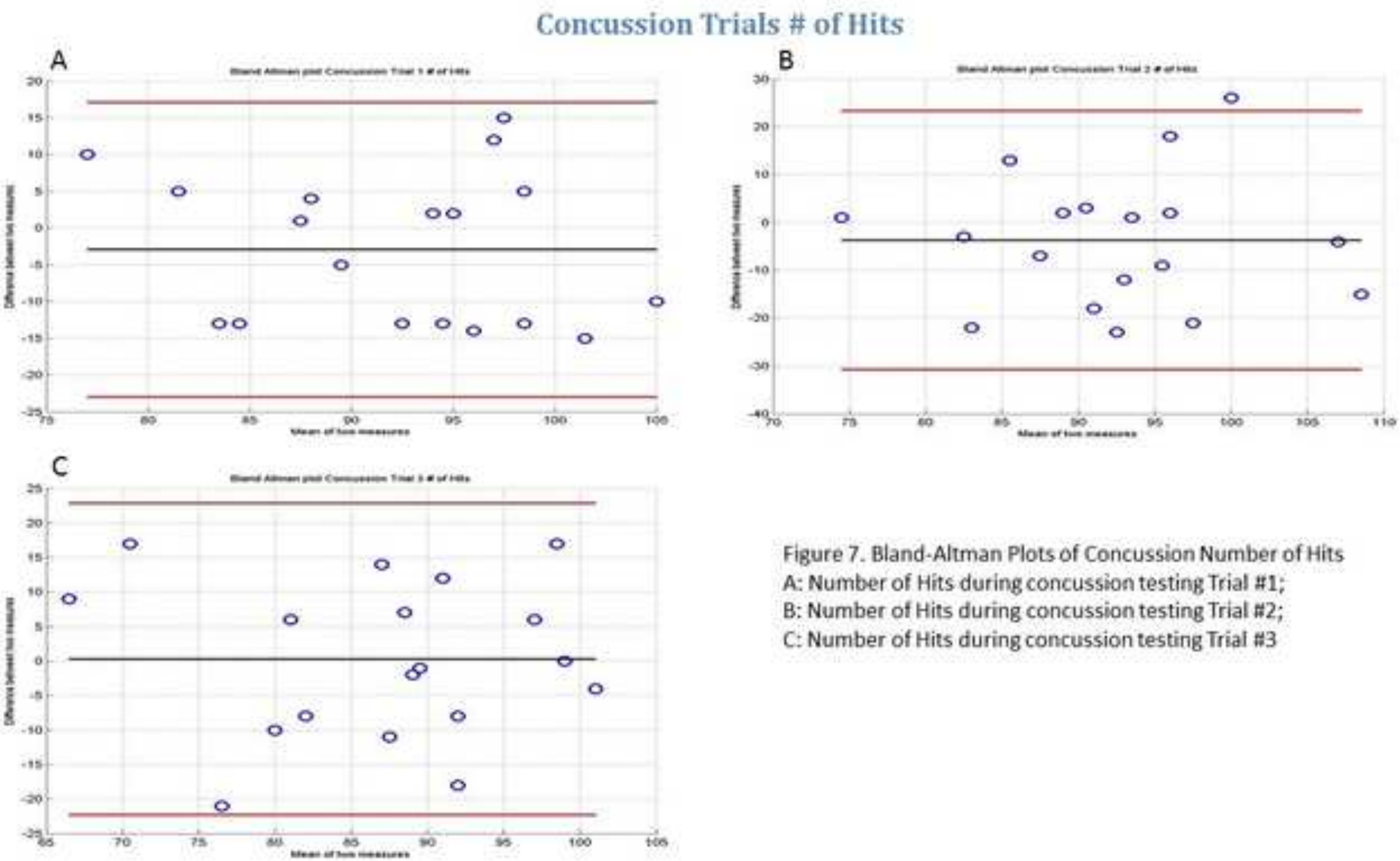

Figure 7. Bland-Altman Plots of Concussion Number of Hits
A: Number of Hits during concussion testing Trial #1;
B: Number of Hits during concussion testing Trial #2;
C: Number of Hits during concussion testing Trial #3

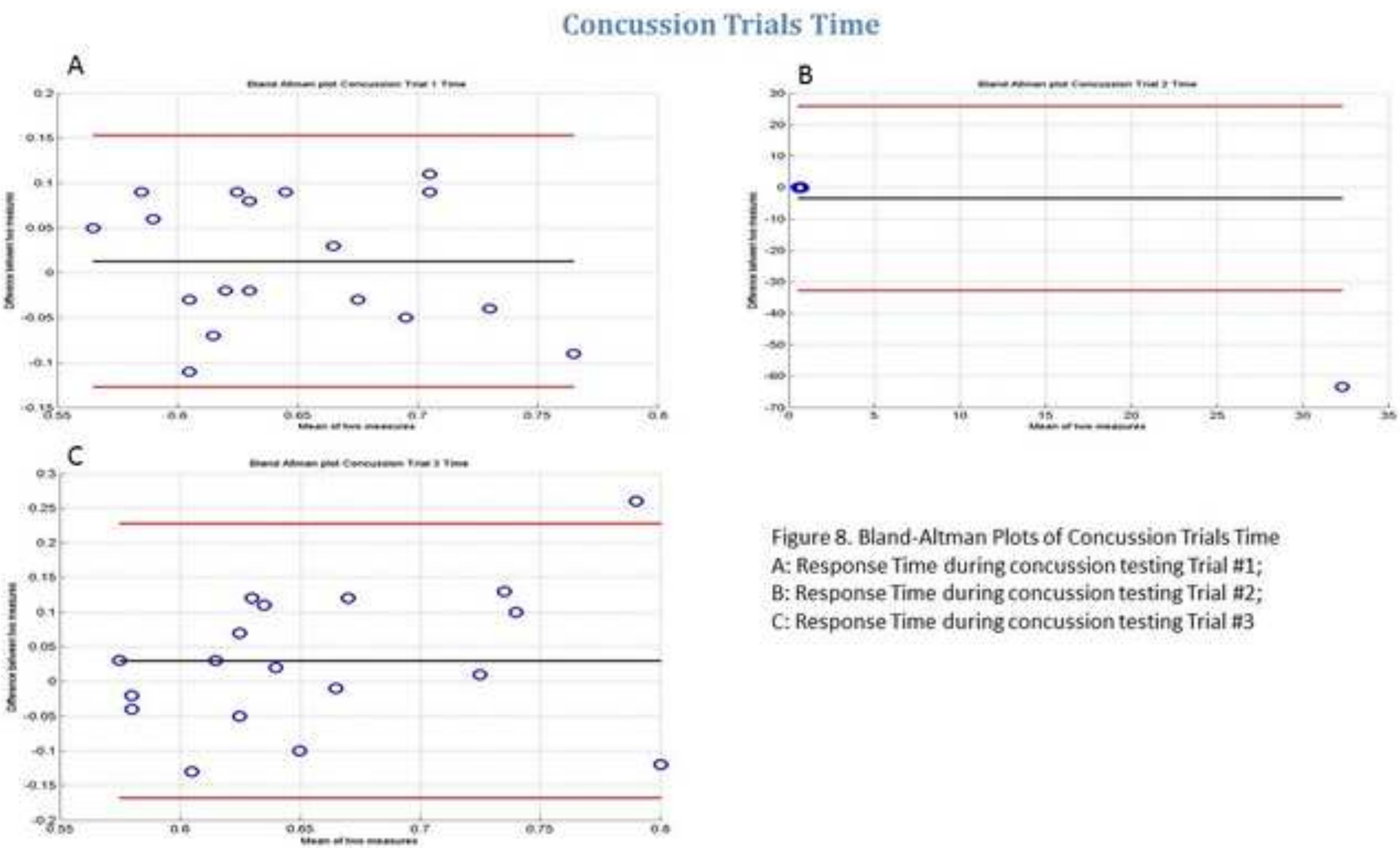

Figure 8. Bland-Altman Plots of Concussion Trials Time
A: Response Time during concussion testing Trial #1;
B: Response Time during concussion testing Trial #2;
C: Response Time during concussion testing Trial #3