

**NEUROPSYCHOLOGICAL TESTING IN ASYMPTOMATIC HIGH SCHOOL
FOOTBALL PLAYERS**

by

Oscar T. Rau

A thesis submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Master of Science in Exercise Science

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ABSTRACT

Context: Concussion is a growing topic of concern in sports today, especially football. More recently, the topic of subconcussive head impacts (SCHI) and their effect on athletes has been discussed. Some recent evidence has shown that repeated SCHI may have a detrimental effect on the neuropsychological (NP) performance of football players, however these same athletes may not present with any overt concussion-related symptoms.

Objective: The primary purpose of this study was to examine a group of high school football players who are *asymptomatic* for concussion after game play and determine if there are any NP deficits and/or lingering concussion-related symptoms as compared to baseline in the days following a competitive game.

Design: Two-group pretest-posttest design.

Setting: All NP testing was performed in quiet, climate-controlled computer laboratory.

Patients or Other Participants: A total of 28 male student-athletes (Age: 16.3 ± 0.9 years, Height: 69.9 ± 2.9 cm, Mass: 171.6 ± 28.3 kg) were recruited from a local high school to participate in this study. Nineteen of the participants were selected from the interscholastic varsity football team. Simultaneously, a group of nine student-athletes from the interscholastic varsity cross-country served as the counterpart non-collision sport controls.

Main Outcome Measures: A repeated measures MANOVA was run on the dependent variables for this study that involved the four ImPACT composite scores (verbal memory, visual memory, visual speed, and reaction time). Additionally, we used the ImPACT concussion symptom score for comparison. The independent variables included group (football vs. cross-country) and time (test sessions).

Results: There was no significant 3-way Time x Group x Test interaction across all time points ($p = 0.129$). There was a significant group x time interaction at time point 1 in verbal memory composite scores between the groups ($p = 0.020$). We also discovered clinically significant findings using the Reliable Change Index for detecting changes in ImPACT scores when examining the results on an individual subject basis.

Conclusions: The results of our study suggest that although asymptomatic for SRC, there were a large number of football players who demonstrated diminished NP scores on the days between games, yet they continued participating. These results seem to mirror findings in previous research.

Keywords: ImPACT, Traumatic Brain Injury, Sport Related Concussion, Subconcussive Head Impacts, Subconcussive Neurotrauma, Neurocognitive Test

Chapter 1

INTRODUCTION

Concussions are a growing concern in sports today, particularly in American tackle football. In the United States an average of 1.4 million traumatic brain injuries (TBI) occur each year including sport-related concussions (SRC), of which 1.1 million are emergency department visits, 235,000 hospitalizations, and 50,000 deaths.² However, most experts agree that the actual number of TBIs is underestimated.² The high school population, which makes up over one million football players³⁻⁵, reports a high rate of incidence of concussion in sport. Lincoln et al. reported in an 11-year study, that football accounted for 60% of all concussions across high school sports.⁶ The rate of incidence of concussion in the high school population ranges from 3.6% to 5.6%.^{4,5,7,8} This leads to an estimation of 43,200 to 67,200 concussions in high school football each year.^{3,4,7} The true incidence rate is likely much higher because it is suspected that 53% of high school athletes do not report this injury to appropriate medical personnel.^{4,8} In addition to the high occurrence of concussion in football, there may also be associated risks of subconcussive head impacts (SCHI) as a result of the full-collision nature of the sport.

Contemporary research has begun to focus more on the topic of SCHI and their effect on athletes.^{3,9} Subconcussion is a cranial impact that does not result in known or diagnosed concussion on clinical grounds⁹⁻¹¹ and can occur with rapid acceleration-

deceleration of the body or torso, particularly when the brain is free to move in the cranium, creating a “slosh” phenomenon.^{10,12} Subconcussion has its greatest effect through repetitive occurrence whereby cumulative exposure becomes deleterious.^{9,10}

To date, there is research on SCHI that utilizes the Head Impact Telemetry System (HITS - Riddell, Chicago, IL), to track the frequency and magnitude of head impacts.^{3,10} While the magnitude of impact is of interest, frequency of SCHI may be a more important feature as it relates to long-term sequelae of the brain; suggesting that cumulative SCHI may lessen the tolerance to SRC.^{13,14} Additionally, studies have indicated that repeated SCHI might have a detrimental effect on the neuropsychological (NP) testing performance of football players without presenting with any overt concussion-related signs or symptoms.^{3,9-11,14}

Neuropsychological assessment is a recommended testing tool in the National Athletic Trainers’ Association position statement on proper management of concussion.¹⁵ The ImpACT computerized test (ImpACT Applications Inc.- Pittsburgh, PA) is the most commonly used tests by healthcare professionals to assess NP status following a suspected concussion.^{12,16} These NP scores are used by clinicians in conjunction with a thorough clinical evaluation and other assessment tools to determine SRC.^{15,17} In a study by Talavage et al., they discovered a group of asymptomatic high school football players with diminished NP scores; and termed them “asymptomatic concussed” individuals.³ It is suspected that this group experienced some sub-clinical neurological stress, but not enough acute damage to display outward signs of a SRC, and thus continued participating in the high impact sport.³ What is not known however, is whether or not this is a safe

practice and/or detrimental to brain function? Compounding the situation in football players is the fact that many times they participate in weekly full-contact practices in preparation for the next game incurring additional opportunities for SCHI; which could in turn delay recovery and worsen the signs/symptoms typically associated with SRC.

Football relies heavily on protective equipment such as helmets, shoulder pads, and other padding to protect the participants. The very essence of the sport of football creates opportunities for SCHI to the helmeted head that can occur frequently and with great force.⁷ This is particularly true with certain positions including offensive and defensive linemen who sustain the most numerous impacts, nearly one impact every play.¹³ Skilled position players may not be subject to the number of SCHI that their lineman counterparts are involved with, however the impacts they sustain are most likely of higher magnitude. Bailes et al. conducted a study where they recorded the number of impacts high school football players sustained over the course of four competitive seasons.¹⁰ Results determined that there was an average of 652 impacts per player with lineman displaying the highest numbers averaging 868 impacts in a season.¹⁰ Talavage et al. found similar numbers over the course of one season in a cohort of high school football players.³

Another concern in this population is that there is a group of football players who do not report SRC symptoms and continue participation. It has been reported that over 50% of these football players do not inform appropriate medical personnel of SRC symptoms.^{8,18} McCrea et al. found that athletes most commonly did not report their symptoms because they felt their injury was not severe enough to warrant medical

attention or that they did not want to leave the game.⁸ Failure to self-report SRC related symptoms and downplaying the seriousness of SRCs likely result in the underestimation of actual SRCs in sport, especially football.³ Athletes who fail to report a probable SRC put themselves at heightened risk for cumulative or more serious effects associated with a second injury if they continue to participate while suffering from the initial SRC. It is crucial that the athletes are aware of signs/symptoms of SRC and are willing to report them to ensure proper injury management at the time that they occur.

The primary purpose of our study was to assess a cohort of asymptomatic high school football players following a competitive game to determine if NP deficits exist, and whether they returned to baseline levels prior to next week's game. We hypothesized that there would be a subset of football players with diminished NP scores following a competitive game who were otherwise clinically asymptomatic for concussion following a competitive game. Secondly, we were interested in closely examining self-reported symptoms in the week following a competitive football game in our cohort of football players.

Chapter 2

METHODS

2.1 Study Participants

Twenty-eight male student-athletes were recruited from a local high school to participate in this study (Table 1). Nineteen of the participants were from the interscholastic varsity football team. These athletes were chosen based on the head coach's recommendation that they would receive a considerable amount of playing time (i.e. "starters"). Simultaneously, 9 student-athletes from the interscholastic varsity cross-country team were selected to serve as non-collision sport controls. All participants were cleared for participation via the standardized DIAA (Delaware Interscholastic Activities Association) form appropriately filed with the school nurse. All participants provided written informed consent (UD IRB 582675-1) with appropriate parental permission in cases where the student-athletes were under the age of 18. Student-athletes were excluded from participating in the study if at any time they suffered an injury (including SRC) that would restrict "on-field" play thus limiting their potential for SCHI.

2.2 Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)

The ImPACT test (ImPACT Applications Inc.- Pittsburgh, PA) was used to assess neuropsychological test performance. The ImPACT instrument is a computer-based program used to assess neurocognitive function and concussion symptoms. It consists of

three main parts: demographic data, neuropsychological tests, and the Post-Concussion Symptom Scale (PCSS). The software program consists of six neurocognitive test modules that evaluate different aspects of cognitive functioning. The Word Memory and the Design Memory test modules assess immediate and delayed memory for words and designs, respectively. Attention, concentration, and working memory are both measured by the X's and O's and the Three Letters test modules. X's and O's also measure reaction time, whereas Three Letters measures visual-motor speed. Visual processing speed, learning, and memory are assessed through the Symbol Match test module. The Color Match test module serves as a measure of focused attention, response inhibition, and reaction time. Five composite scores (verbal memory, visual memory, reaction time, processing speed, and impulse control) are calculated based on combinations of various aspects of these six test modules. The ImPACT test has been shown to be valid and reliable measure of neurocognitive function and useful in assessing changes post-concussion.¹

2.3 Testing Procedures

Each of the 28 participants took a baseline ImPACT test prior to the start of their competitive season. At three predetermined time points during the course of the fall interscholastic sport season, the participants performed in-season ImPACT tests. The in-season sessions involved testing on Mondays and Fridays after the second, sixth, and tenth football games. A fourth and final session took place one month after the football season concluded. Participants from both football and cross-country underwent the same

sequence of testing depicted in Figure 1. All ImPACT data were analyzed following the fourth and final test session.

2.4 Data Analysis

This study involved two groups: experimental (football players, collision-sport) and control (cross-country, non-collision sport). The ImPACT composite scores including verbal memory, visual memory, visual speed, and reaction time served as the dependent variables. We did not include the impulse control composite score in our analysis because it is only used as a measure of effort. Additionally, we used the ImPACT concussion symptom score for comparison. Data were analyzed using a repeated measures multivariate analysis of variance (MANOVA). The within-subject variable was time, which included the baseline, and three in-season time points only. In order to address the primary aim of this study, only the ImPACT composite scores from the Monday test sessions were used in the repeated measures MANOVA.

Time was the within-subjects (repeated) measure and it was evaluated on four occasions: baseline and three in-season tests. We only assessed the three in-season tests that occurred on the Monday following the competitive game. Results were interpreted using the Greenhouse-Geisser correction based on the fact that sphericity was not assumed. A Student's t-test was run to compare reported concussion symptom averages between groups. All data were analyzed with an alpha level set *a priori* at $p \leq 0.05$.

We also examined our data on an individual subject/test basis using the Reliable Change Index (RCI) (Table 5) created by Iverson et al.¹ Iverson et al. developed the RCI

to assist clinicians in more precise identification of those individuals who have declined or improved scores on the ImPACT computerized test following a concussion.¹

Chapter 3

RESULTS

ImPACT composite scores averages for verbal memory, visual memory, visual speed, and reaction time across all time points are displayed in Figure 2-5 respectively; while Table 2 summarizes the group averages across all time points. There was no 3 way Time x Test x Group interaction with the repeated measures MANOVA ($F_{12,312} = 1.749$, $p = 0.129$) However, there was a significant Time x Group interaction ($F_{3,78} = 4.463$, $p = 0.024$) displayed in Figure 6. One-way ANOVAs were then performed for post-hoc comparisons revealing a significant difference ($p = 0.020$) at time point 1 in verbal memory composite scores between the groups. Interestingly, the football players (89.00) scored higher than their control cross-country (80.89) counterparts.

ImPACT concussion-related symptoms for all subjects are summarized in Tables 3 and 4 (individual subject symptom averages). The results of the independent samples T-test indicated no significant differences between the groups in symptom scores (Football 1.39 ± 3.36 vs. Cross- Country 2.56 ± 2.43); ($p = 0.384$).

When examining the results on individual subject basis utilizing the RCI for examining ImPACT composite scores (Table 5).¹ We compared the total number of tests with deficits (from baseline) on each composite score between the groups. Of the football group, deficits on verbal memory were evident on 25% of the tests, 19% of the visual memory tests, 25% on the visual speed tests, and 39% on the reaction time tests.

Of the cross-country group, deficits on verbal memory were evident on 8% of the tests, 6% on the visual memory tests, 21% on the visual speed tests, and 37% on the reaction time tests. Figure 7 provides a graphical representation of these results.

Chapter 4

DISCUSSION

The primary purpose of this study was to examine a cohort of high school football players following a competitive game to determine if NP deficits exist prior to the next week's game. Utilizing the composite scores from the ImPACT computerized software, we compared the football cohort to a group of cross-country athletes serving as controls at multiple time points throughout the season. Except for one unexpected aberration, our findings resulted in no significant differences in composite scores between groups. The unexpected result from in-season time point 1 indicated the football subjects had higher (better) scores on the verbal memory composite than did their cross-country counterparts.

To our knowledge, this is the first study to examine NP test performance several times throughout the course of a football season. We wanted to determine if NP performance would decline following a competitive game (Monday ImPACT Test), and if their NP performance returned to baseline levels by the end of the week (Friday ImPACT Test), prior to the next game. Although our statistical analysis looking for differences between and within groups was not significant, on close examination of the ImPACT composite scores, we found some individual differences of interest. The lack of differences may be related to the small sample size and strengthens the argument for examining individual versus group differences.

Upon examining the data on an individual subject/test basis we did however, find clinically significant results when using the Reliable Change Index (RCI) for examining ImPACT composite scores at an 80% confidence interval (Table 5).¹ The 80% confidence interval was utilized because this number has been emphasized in previous literature.^{1,19-22} The football cohort demonstrated a higher percentage of players and total number of tests with deficits when compared to the cross-country control group. This was especially true with the verbal memory and visual memory composite scores. When looking carefully at the football players we noted deficits with 25% of the verbal memory test scores and 19% of the visual memory test scores as compared to only 8% of the verbal memory test scores and 6% of the visual memory test scores in the cross-country subjects. With regard to the reaction time composite score, approximately 38% of all the tests taken by both groups showed slower reaction times as compared to baseline using the RCI. We believe this high percentage of fluctuation may suggest a low sensitivity of this portion of the ImPACT neurocognitive test.

Due to the relatively high percentage (38%) of reaction time composite scores in both groups showing deficits, we decided to use only the verbal memory, visual memory, and visual speed composite scores when determining if the subject's ImPACT test results were considered "atypical." Unexpectedly, we found that 80% of our football subjects and 56% of our cross-country subjects demonstrated deficits in one or more of these 3 ImPACT composite scores on a particular test session (of the 7 taken across the season). It is important to consider the false-positives that can occur in concussion assessment, which has been reported in literature as high as 10%-30%.²²⁻²⁴ Upon careful examination

of our subject pool we determined that five of the 19 (26%) football subjects and three of the nine (33%) cross-country subjects demonstrated a decline in only one ImPACT composite score, suggesting that these may not be indications of NP deficits²², but rather false-positive findings. We found that 10 of the 19 (53%) football subjects displayed a deficit on two or more of the ImPACT composite scores on at least one testing occasion compared to two of the nine (22%) cross-country subjects. This may be clinically significant given that evidence shows change in two or more composite scores is more likely to demonstrate neurophysiological changes.^{1,23,25} Iverson et al. specifically reported that athletes with a concussion are 47 times more likely to have deficits on two or more of the ImPACT composite scores than non-concussed individuals.¹ These results do not indicate that our subjects were suffering from a concussion; however, it may suggest that this subset of athletes is experiencing NP deficits previously reported in the subconcussion literature.^{3,10,11,22}

At time point 3 (Monday ImPACT test) we found that three of our football subjects had “atypical” NP scores, and two of these subjects had not returned to baseline levels by the end of the week, prior to their next competitive game. At time point 5 (Monday ImPACT test) we found eight of our football subjects had “atypical” NP scores, and one of these subjects had not returned to baseline levels by the end of the week, prior to their next competitive game. These particular subjects are of concern because they have diminished NP performance just prior to a competitive game where they are likely to encounter more SCHI. These results seem to concur with the findings of Talavage et al. who used a group of asymptomatic football players for a control group in a concussion

assessment study.³ Unexpectedly, they found that 50% of this group, though asymptomatic, displayed deficits on both neurocognitive and neurophysiological testing batteries.³ These deficits were consistent with the results they found in their clinically diagnosed concussion group.³ Talavage et al. termed these individuals “asymptomatic concussed” due to the absence of concussion-related symptoms yet with impairments on NP performance consistent with individuals clinically diagnosed with a concussion.³ This select group may be accruing brain damage that does not immediately result in symptoms that are typically observed by a clinician.³ It is important to determine whether it is a safe practice that these athletes who are “asymptomatic concussed” continue participation in a high impact sport such as football where the likelihood of SCHI is high. Mulligan et al. found that 59.4% of their collegiate football subjects showed a deficit in two or more of the ImPACT composite scores after one season.²² However, this study was limited in that they did not have a control group. Similarly, we reported that 53% of our high school football players showed a deficit in two or more of the ImPACT composite scores during at least one time point over the season. Only 22% of our control group showed deficits in two or more of the ImPACT composite scores across the season.

One of the most difficult aspects of concussion diagnosis and management is the athlete self-reporting concussion-related symptoms. The literature has reported that over 50% of football athletes do not report symptoms to appropriate medical personnel.^{4,8} This may be because they do not feel it is severe enough to seek medical attention, or because they are trying to remain on the field.⁸ In our study we found that our control

group of non-contact cross-country athletes reported concussion symptoms more often on the ImPACT computerized test. Eight of our nine control subjects reported symptoms at least one time throughout the course of our study. In our football control group, more than half of them *did not* report a single symptom throughout the study. The reported symptom averages for each group are displayed in Tables 3 and 4. While this dichotomy was not statistically different, it may support the notion that football players often try to discount or hide concussion-related symptoms.

Though we were able to investigate changes in NP performance over the course of a season, we were not able to quantify the number or magnitude of impacts that the football subjects encountered throughout the season. Although football is a contact sport and cross-country is not, we can only speculate that the results we found are a result of the SCHIs the football players sustained throughout the season. Another limitation is that we are assuming the subjects put forth equal effort on each ImPACT test. A lack of effort on the tests could lead to apparent deficits in NP performance.²⁶ Finally, we only utilized one concussion measurement tool to assess our subjects. The ImPACT test has demonstrated 81.9% sensitivity in identifying concussion²⁴, but a multifaceted concussion assessment has demonstrated a higher sensitivity exceeding 90%.²⁵

Future research should focus on finding clinical tools that are simple, easy-to-use, and effective in identifying individuals who may have NP performance deficits as a result of SCHI. Evidence suggests that measuring postural stability immediately following concussion may be useful in assisting the evaluation of SRC.^{27,28} Perhaps a simple, inexpensive, yet effective tool such as the Balance Error Scoring System (BESS) test may

be effective in identifying those individuals who may be suffering from the effects of subconcussion. Another potentially useful tool in the recognition of subconcussion is the King-Devick (KD) oculomotor test. The KD Test is an inexpensive sideline clinical diagnostic tool effective in rapidly assessing visual processing and performance, which is often impaired following SRC.²⁹ Future research should integrate supplementary concussion assessment tools like the BESS test and KD Test, which can be easily administered on the sideline. This may aid in determining if concussion-like deficits exist with SCHI but in a quicker manner. Often clinicians have a short period of time to assess an athlete on the sideline of the field where a time-consuming NP test like the ImPACT computerized software is not practical and cannot be administered until after the game. A quick sideline tool effective in assessing potential deficits associated with SCHI may be more applicable to these situations.

The results of our study suggest that although asymptomatic for SRC, there are a significant number of football players presenting with diminished NP scores, while continuing participation. Current concussion diagnosis relies heavily on reporting of symptoms to medical personnel, but it appears that this alone may not be sufficient to identify athletes suffering from NP deficits. It is important that future research aims to improve recognition of concussion and deficits from subconcussion.

Chapter 5

LEGEND

Table 1: Demographic data for each group (means \pm standard deviation).

	Age (yrs.)	Height (cm.)	Mass (kg.)
Football	16.7 \pm 0.7	180.9 \pm 7.6	91.7 \pm 18.9
Cross-Country	16.0 \pm 1.1	174.4 \pm 7.2	64.3 \pm 6.9

Table 2: Means \pm Standard Deviation for each ImPACT Composite Score per group across all time points.

	Football Average	Cross Country Average
Verbal Memory	80.47 \pm 5.43	81.57 \pm 3.37
Visual Memory	72.04 \pm 4.21	71.69 \pm 2.14
Visual Speed	37.31 \pm 1.23	35.56 \pm 1.10
Reaction Time	0.66 \pm 0.05	0.64 \pm 0.03

Table 3: Average reported symptoms for each football subject across all time points.

Football Subject	Avg. Symptoms Reported
1	0.57
2	0
3	1.5
4	0
5	0
6	3.63
7	0.25
8	0
9	0
10	0.25
11	0
12	0
13	14.17
14	0
15	0
16	4.75
17	0
18	0.38
19	1
Average	1.39
Std. Dev	3.36

Table 4: Average reported symptoms for each cross-country subject across all time points.

Cross-Country Subject	Avg. Symptoms Reported
21	3.38
22	1.25
23	7.25
24	1.25
25	4.38
26	0.25
28	0
29	2.75
Average	2.56
Std. Dev.	2.43

Table 5: Iverson et al. Quick Reference Reliable Change Estimates: 80% Confidence Interval for detecting change on the ImPACT Computerized Test. ¹ Postconcussion scale is the ImPACT computerized test's measure of reported symptoms.

Composite	Declined	Inclined
Verbal Memory	9 points	9 points
Visual Memory	14 points	14 points
Reaction Time	0.06 s	0.06 s
Processing Speed	3 points	7 points
Postconcussion Scale	10 points	10 points

Figure 1: Testing Procedures Timeline

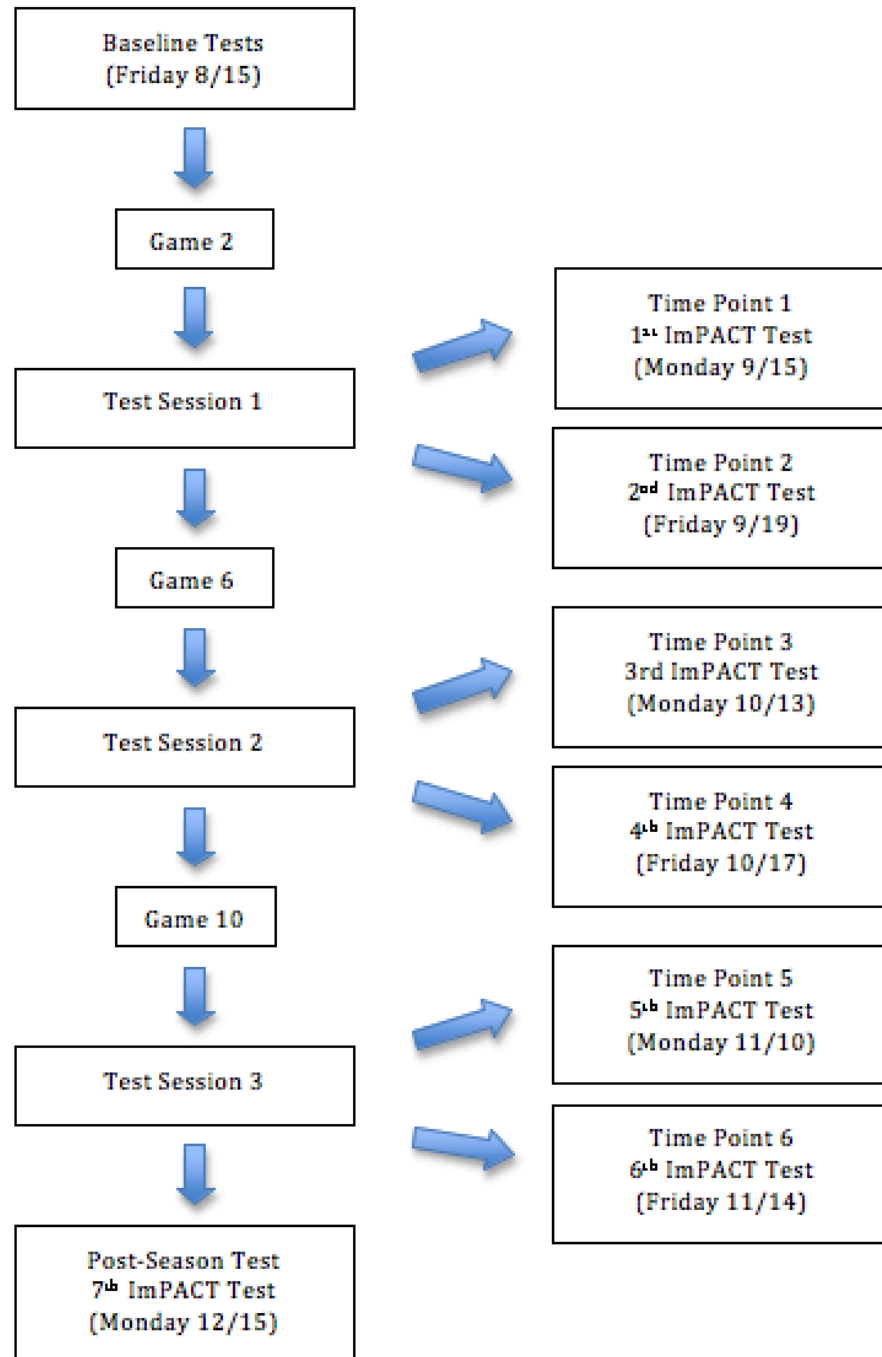


Figure 2: Comparison of Verbal Memory Composite Scores across test time points.

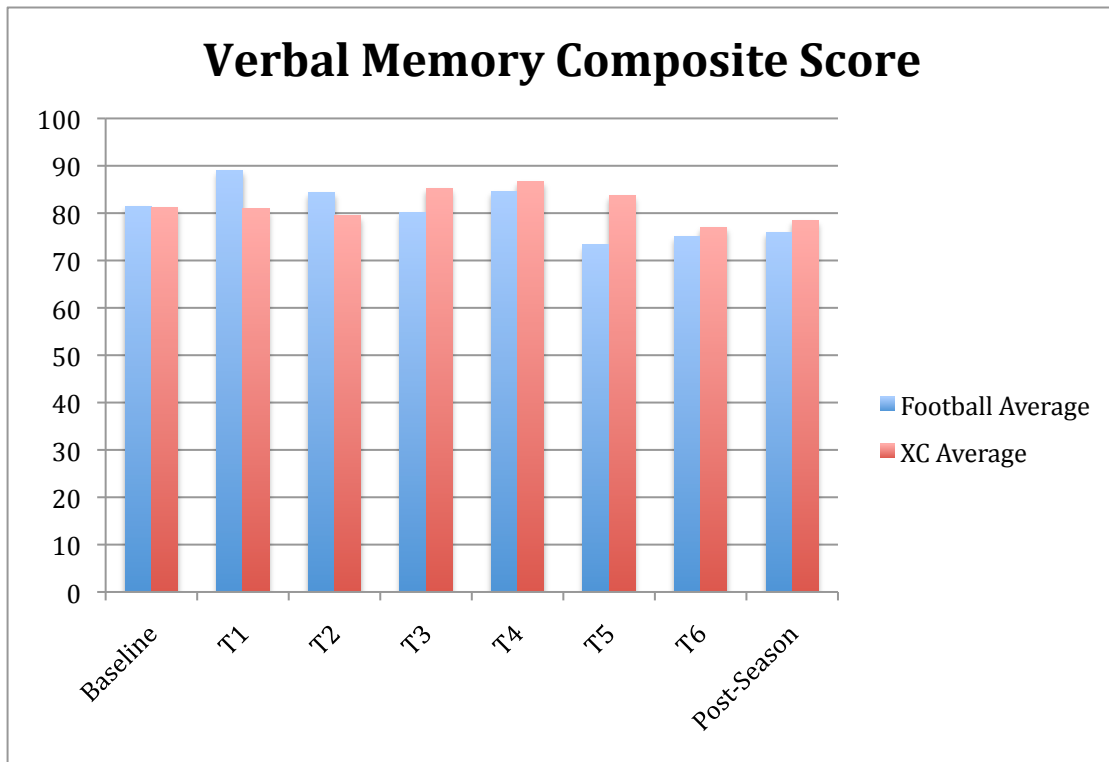


Figure 3: Comparison of Visual Memory Composite Scores across test time points.

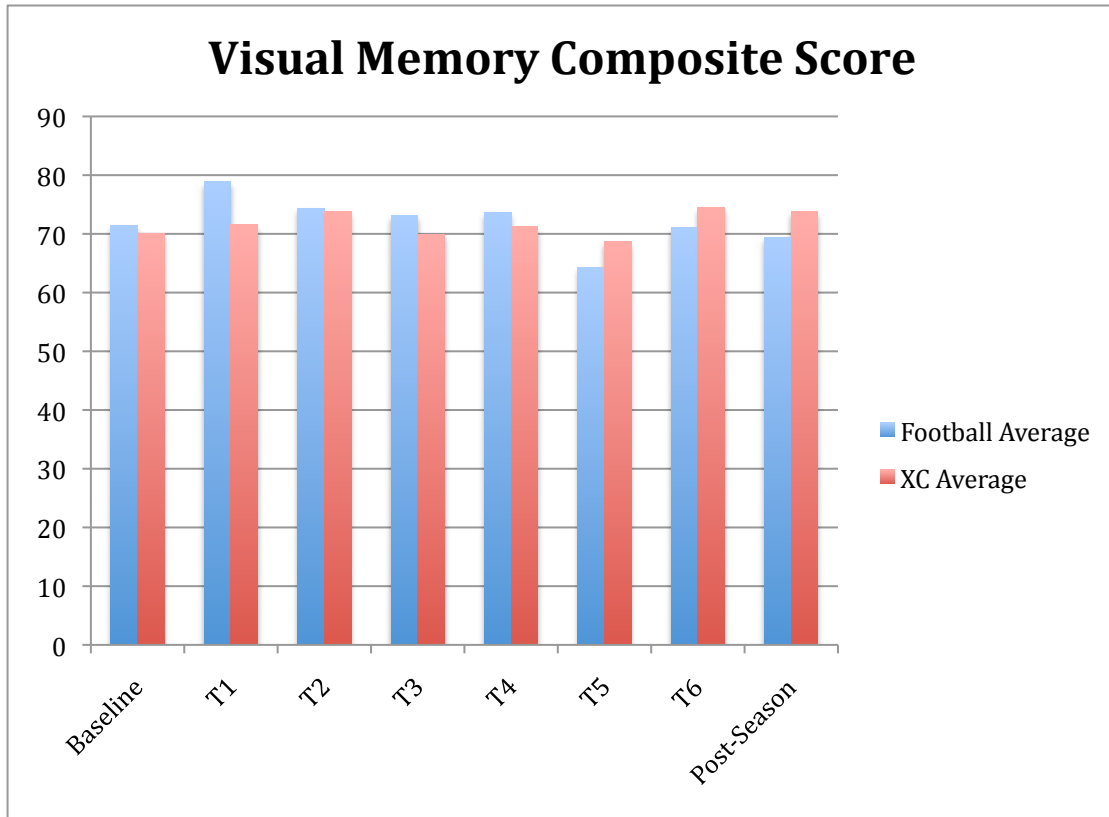


Figure 4: Comparison of Visual Speed Composite Scores across test time points.

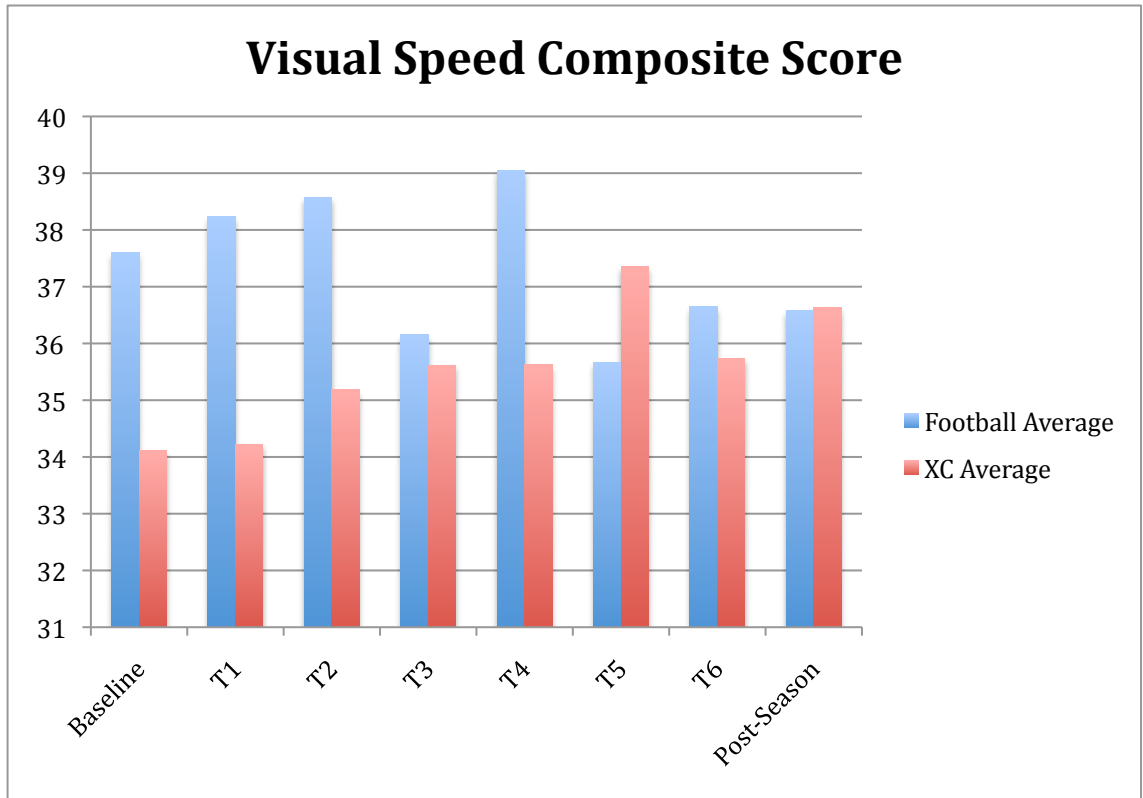


Figure 5: Comparison of Reaction Time Composite Scores across test time points.

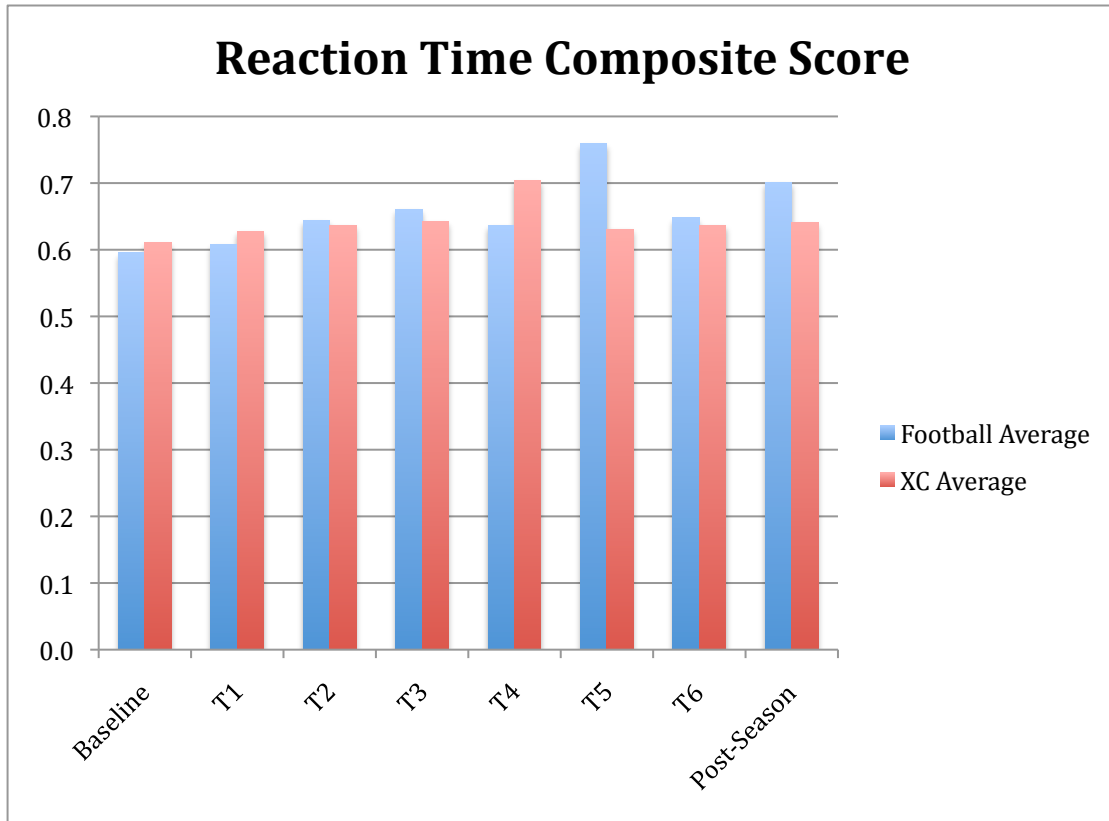


Figure 6: Time x Group interaction on the Verbal Memory Composite Score

*
 $p = 0.024$

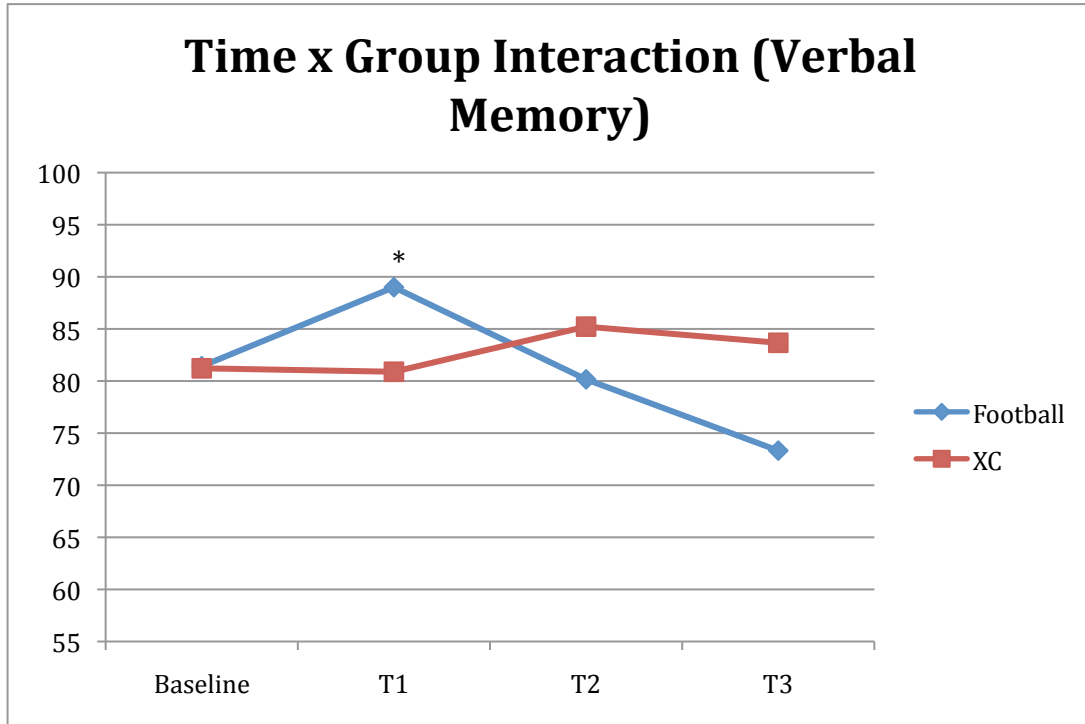
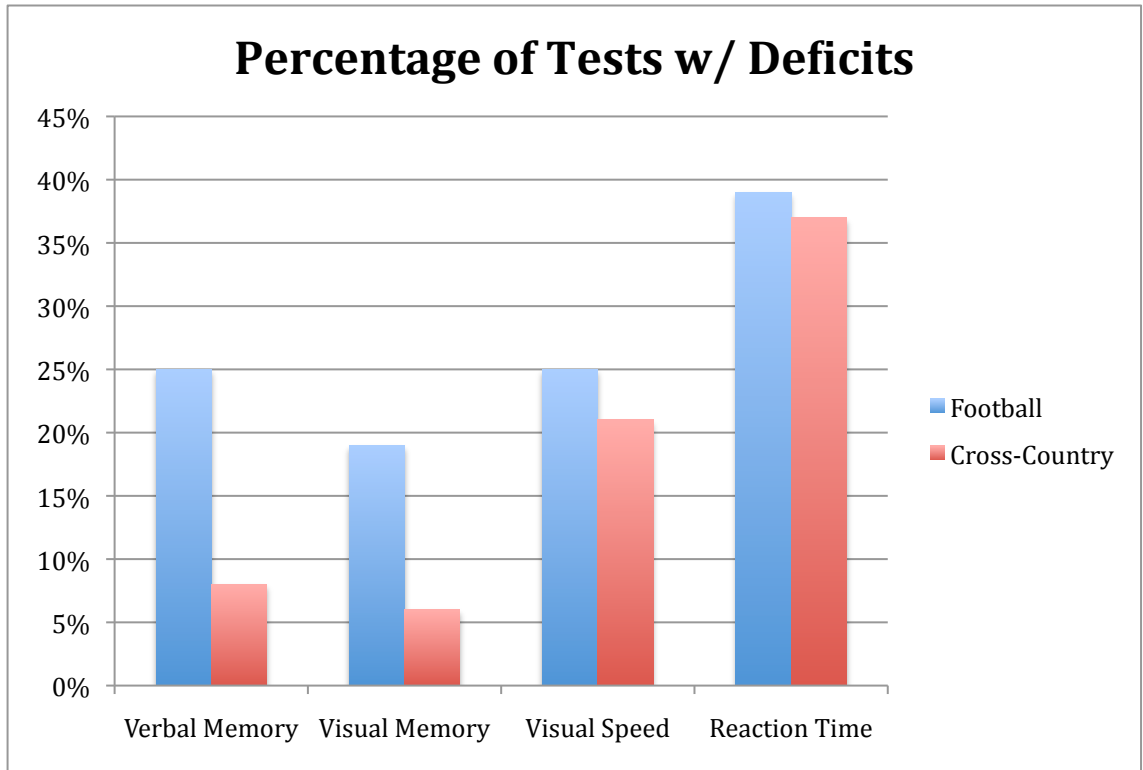


Figure 7: Comparison of number of tests with a deficit represented as a percentage (# of tests with a deficits / total # of tests taken).



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Appendix A

SPECIFIC AIMS

Concussion is a growing topic of concern in sports today, especially in football. More recently, the topic of sub-concussive head impacts (SCHI) and their effect on athletes has been discussed.^{3,10} Subconcussion is a cranial impact that does not result in known or diagnosed concussion on clinical grounds.¹⁰ It can occur with rapid acceleration-deceleration of the body or torso, particularly when the brain is free to move within the cranium, creating a “slosh” phenomenon.⁷ Subconcussion has its greatest effect through repetitive occurrence whereby cumulative exposure becomes deleterious.¹⁰ Some recent evidence has shown that repeated SCHI may have a detrimental effect on the neuropsychological (NP) performance of football players^{3,10,30}, however these same athletes may not present with any overt concussion-related symptoms.^{3,30} Recognition and awareness of these symptoms from a clinical perspective is difficult.

The very essence of the sport of football creates numerous opportunities for SCHI to the helmeted head. The game is played in a high intensity manner where blows to the head may occur frequently and with great force.³¹ American football has a high incidence of concussion, largely because of the style of play, high rate of impacts, and

extent of participation.⁹ As clinicians, we begin to question whether or not this accumulation of SCHI may be detrimental to the brain? It has been shown that cumulative SCHI may produce diminished NP scores putting these athletes at increased risk.^{3,12,14} There is also concern over the long-term effects of SCHI and Mild-Traumatic Brain Injury (MTBI). Previous research has shown that history of MTBI is a risk factor for repeat concussions, early-onset Alzheimer's disease, chronic depression, epilepsy, and chronic traumatic encephalopathy (CTE).³ Of special importance is the young developing brain of adolescent (i.e. high school) football players. With participation in football at younger age levels nationwide declining³², it is especially crucial that we gain a greater understanding of the outcomes SCHI have on the developing brain.

Concern over SCHI and the developing brain evolves from the potential to impact a number of physiological and musculoskeletal systems in the youth football player. Specifically, it has been suggested that underdeveloped neck musculature in the youth population does not cushion head impacts well enough resulting in the brain taking more of an impact.³³ These impacts are the same head traumas sustained at the college and professional level, but to an immature brain. While high school players may have more developed neck and shoulder muscles, their brains are still developing leaving them vulnerable to brain injury.^{31,33} Despite the prevailing attitude that the magnitude of impact is of greatest concern with concussion, it may be that the lesser but more cumulative impacts over a playing career should warrant our attention. Some have suggested that cumulative impacts lessen the tolerance for concussion; similar to an athlete whose risk for subsequent ankle sprains increases substantially following the first

episode of a sprain.³⁴ Furthermore, those who sustain numerous SCHI may then be at risk for concussion from impacts that would have previously been thought of lesser, non-violent hits. From a clinical perspective it is important to identify those with a concussion to remove them from play in order to allow for proper neurocognitive recovery.

Concussion-related symptoms are a very important piece in the detection and treatment of sport-related concussions (SRC). Depending on the specific tool utilized, symptom checklists have ranged from 12-24 different symptoms typically associated with SRC. Modes of administration include paper/pencil, while others have imbedded a symptom checklist into a computerized program. Careful monitoring of concussion-related symptoms is a cornerstone of clinical management. Despite efforts to carefully monitor SRC symptoms there still may be situations whereby asymptomatic athletes are considered concussed due to diminished NP scores. The clinical conundrum that may exist is that these athletes may not present with any overt concussion-related symptoms but may have diminished NP scores perhaps due to cumulative SCHI. The ability to gain a greater understanding of the severity of SCHI must be examined further. Therefore the primary purpose of this study is to examine a group of high school football players who are *asymptomatic* for concussion after game play and determine if there are any NP deficits and/or lingering concussion-related symptoms as compared to baseline in the days following a competitive game.

Specific Aim 1: To determine whether or not asymptomatic (for SRC) high school football players present with diminished NP testing scores (ImPACT composite scores) in the week following a competitive football game.

Hypothesis 1: While we hypothesize that the majority of these asymptomatic football players will perform similar to baseline, we contend that there will be a small subset who will indeed demonstrate diminished NP testing scores as compared to baseline. Based on the research by Talavage et al who demonstrated 50% of their asymptomatic football players had significant NP deficits; we hypothesize a similar result will occur in this study.

Specific Aim 2: To monitor SRC symptoms (ImPACT symptom score) in asymptomatic high school football players in the week following a competitive football game.

Hypothesis 2: We hypothesize that this group of asymptomatic high school football players will not present with any SRC symptoms that are elevated above their baseline score.

Specific Aim 3: To determine in the subset of high school football players who have decreased NP test scores (ImPACT composite scores), if on their subsequent follow-up NP test (prior to the next game) they have returned or surpassed their baseline values.

Hypothesis 3: We hypothesize that this subset group of asymptomatic high school football players with decreased NP test scores (ImPACT composite scores) will return to baseline prior to their next football game.

Appendix B

BACKGROUND AND SIGNIFICANCE

B.1 Concussion Epidemiology Involving the High School Athlete:

Recently there has been a growing concern over the effects of concussions and sub concussive impacts (SCHI) on football players. Annually there is a range from 1.6 to 3.8 million sport-related concussions (SRC) in the United States.² This concern has recently shifted to the high school population, which makes up over one million football players.³ The average incidence rate of SRC in this population is 3.6% to 5.6% of the 1.2 million high school football players, which corresponds to an estimation of 43,200 to 67,200 concussions every year.³¹ The true SRC incidence is likely much higher because it is suspected that 53% of high school athletes do not report this injury to appropriate medical personnel.¹⁸ The Centers for Disease Control and Prevention suggests that every year there are more than 170,000 emergency department visits for SRC for those under the age of nineteen.²⁹ Between 2001 and 2009 there was an increase of 62% of those in this population reporting to the emergency room for SRC.²⁹ This large increase during this time period may be a result of the increased awareness of SRC and the increase in health care professionals available at the time of injury.^{3,29} This age group is also more vulnerable to SRC and typically has a longer recovery period than adults.^{17,29} High school football players have a higher incidence of SRC than any other sport. In fact, an

11-year study on concussion in high school sports conducted by Lincoln et al. reported that football accounted for 60% of all concussions, and males as a group accounted for 75%.⁶ The vulnerability of the maturing and growing brain in this population demands further study.

B.2 Subconcussive Head Impacts:

It is important to understand the differences in our youth/developing population when compared to adults. Children are not “little adults,” they are actively developing organisms who respond differently, have different needs, and face different expectations following injury.³⁵ The rotational acceleration and/or deceleration forces associated with SCHI and SRC produces stress on the brain tissue, vasculature, and other neural elements.³⁵ The incidence of brain swelling and cerebral edema in SRC is higher in children than it is in the adult population.³⁶ It is also important to note that the musculature in the youth population differs from adults. Children have less developed neck and shoulder musculature, which means that they are unable to transfer energy directed to the head throughout the body.^{33,35} This puts their risk of SRC higher in certain circumstances.³⁵

Football is a sport unlike others and relies heavily on protective equipment such as helmets, shoulder pads, and other padding to protect participants. The very essence of the sport of football creates numerous opportunities for SCHI to the helmeted head. The game is played in a high intensity manner where blows to the head may occur frequently and with great force.³¹ This is especially true with certain positions including offensive and defensive linemen who sustain the most numerous impacts, with nearly every play.

Skilled position players may not be subject to the amount of SCHI that their lineman counterparts are involved with, however the impacts they do sustain are most likely of higher magnitude. In a study conducted by Bailes et al. they recorded the number of impacts sustained by high school football players over the course of four seasons. The results showed an alarming average of 652 impacts per player.¹⁰ Lineman showed even higher numbers where they sustained an average of 868 impacts per season.¹⁰ Talavage et al. also found similar numbers while using similar technology to record number of impacts over a season in a cohort of high school football players.

Recent research has also shown that SRC and diminished NP status can be the result of cumulative SCHI.^{3,12,14} Subconcussion is a cranial impact that does not result in known or diagnosed concussion on clinical grounds.¹⁰ In other words, as clinicians we would not observe any overt signs or symptoms of a SRC, and in most cases the athletes themselves do not report any clinical indicators. To date, there is research on SCHI that utilizes the Head Impact Telemetry System (HITS)(Riddell, Chicago, IL), to track frequency and magnitude of head impacts.^{3,14} While magnitude of impact is important, the frequency of head impacts may also be a critical feature in the tracking process of SRC. It may indicate that magnitude of impact isn't the only cause of SRC, but cumulative impacts may lessen the tolerance of each athlete.¹⁴ Broglio et al. have suggested that athletes who sustain multiple SCHI are also presenting with diminished NP scores.³ It could be extrapolated that those who have suffered numerous SCHI may then be at risk for SRC from an impact that may be portrayed as being less violent.

Although not the population of interest in the present study, there is some alarming evidence as to the number of head impacts sustained by youth football players (ages 7-14) who account for 70% of all football participants in the United States.³⁷ A recent study conducted on seven youth football players ages 7-8, showed that over the course of a season they sustained an average of 107 impacts per player.³⁸ While this group is sustaining a lower number of impacts, high magnitude impacts may occur, and their long-term implications remain uncertain.¹⁰ It is important to identify those with a SRC to remove them from play in order to allow for proper recovery of the brain. Those athletes who continue to participate with already diminished NP status are putting themselves in a position to encounter more severe injuries such as secondary impact syndrome, chronic traumatic encephalopathy (CTE), depression, and post-concussion symptoms.^{3,17,30,39}

The design of this study is to test a cohort of asymptomatic high school football players throughout their season in order to determine whether or not there are athletes with diminished NP levels who show no overt signs/symptoms of SRC. These diminished NP scores are used in diagnosing a SRC and these athletes may bring about a whole new category of SRC, “asymptomatic concussed.”³ It is suspected that this group has experienced some sub-clinical neurological stress to the brain due to repeated SCHI, therefore Talavage et al. termed these individuals “asymptomatic concussed.”³ These athletes have not sustained enough acute neurological damage to display outward signs of a SRC and therefore continue full-contact participation in a high-impact sport such as football.³ What is not known however, is whether or not this is a safe practice, and

detrimental to brain function. Compounding the situation in football players is the fact that practicing all week prior to the next game they have additional opportunities for SCHI which could in turn delay recovery and worsen the signs/symptoms typically associated with SRC. Of greater concern is the student-athlete who has had previous SRCs and whether or not the effects of SCHI are heightened in this particular cohort. It has been reported that athletes who have suffered three or more SRCs can have long-term changes in brain neurophysiology, symptoms, and NP test performance.⁴⁰ These same athletes are then at increased risk for additional SRCs, have worse presentation on their next SRC, have greater acute changes in memory, and are more at risk for a slowed recovery.⁴⁰

B.3 Concussion Diagnosis

The standard of care for SRC management involves a multifaceted approach. There are a variety of tools available to assist in SRC diagnosis including a thorough history, monitoring of symptoms, evaluation of mental status, eye examination, muscular strength assessment, motor control including balance, and an analysis of cognitive function.¹⁵ Acute SRC evaluation following injury in sport can be made difficult because of elevated heart rate levels as well as external environmental factors out of the control of the clinician. Additionally, pressures to return athletes to competition as quickly and safely as possible are elevated and come from a variety of sources including coaches, student-athletes, parents, and administrators. Furthermore, not all symptoms present immediately, and may take hours or days following a concussive event to manifest.^{3,17} From a clinician's viewpoint return-to-

play decisions are critically important because the fear of further brain damage looms. In a recent study conducted by Talavage et al., a cohort of 11 asymptomatic high school football players were evaluated for potential changes in NP status throughout a football season. In this group there were an alarming four players who did not display outward signs of SRC, but when NP tested displayed statistically significant reductions in their ImpACT scores. Particularly, the verbal and visual memory composite scores were affected.³ This same study also used functional MRI (fMRI) as a tool to determine alterations in the brain due to head impacts. There were a total of 3 players who were clinically diagnosed with a SRC during the course of the season and all of these players displayed changes in their fMRI results. The four players who did not display outward signs of SRC yet had diminished ImpACT scores were also assessed using fMRI and displayed similar alterations to those of the “clinically diagnosed” group. To the practicing clinician these results are of great importance because they suggest that current SRC evaluation methods may not be sufficient enough in diagnosing every SRC. A SRC may result in rapid onset impairment of neurological function, but may take hours to manifest. The definition proves a multi-dimensional approach to SRC management is warranted and that strictly using outward signs/symptoms may not be sufficient enough for an accurate diagnosis.

Another concern is that there is a group of football players who do not report SRC symptoms and continue participation. It has been reported that over 50% of these athletes do not inform appropriate medical personnel of concussion-related

symptoms.^{18,41} McCrea et al. found that athletes most commonly (66.4%) did not report their symptoms because they felt their injury was not severe enough to warrant medical attention. The second most common response was that they did not want to leave the game. Athletes who fail to report a probable SRC put themselves at heightened risk for cumulative or more serious effects associated with a second injury if they continue to participate while still suffering from the initial SRC. The ultimate concern is second impact syndrome; a condition that occurs when an athlete sustains a second concussion while still symptomatic from an earlier head injury.⁴¹ These tend to be catastrophic in nature. It is crucial that athletes are aware of signs/symptoms of SRC and are willing to report them to appropriate medical personnel for proper injury management at the time at which they occur.

B.4 Innovation

The high school football population represents a large, yet understudied group, especially with regard to SRC in their management. The interscholastic football season is unique in that there is one game per week with a routine practice schedule in between that includes a recovery day immediately following a game with a graduated practice schedule with regard to player-to-player contact. In other words, football contact and collisions occur mid-week with a lessening of those contacts in the days leading up to the next game. Our study is designed to take advantage of this “football week” enabling us windows to assess NP status throughout. We aim to determine whether or not at the start of the practice week

following a game that the athletes NP status is at baseline level (“normal”) and that no deficits in NP performance are evident. Additionally, the NP testing protocol will also enable us to monitor NP status prior to the start of the next game, where the athletes will be sustaining the most impacts with the greatest magnitude. There is not sufficient current research involving high school football players and the monitoring of NP status throughout the season to determine if there are any detrimental changes to the brain. This study can provide direction for further research in this field pending any significant result.

B.5 Clinical Relevance

Research must continue in order to refine SRC diagnostic and management guidelines. If it is determined that there are football players who are clinically asymptomatic but who might have damage to the brain due to SCHI, that interventions must transpire to protect them from further brain damage. Furthermore, this study has the potential to shape current standards of care related to SRC.

Appendix C

IRB PROTOCOL

HUMAN SUBJECTS PROTOCOL

University of Delaware

Protocol Title: Neuropsychological Testing in Asymptomatic High School Football Players

Principal Investigator:

Name: Oscar T. Rau (Graduate Student)

Contact Phone Number: 856-834-3224

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Advisor:

Name: Thomas Kaminski, PhD, ATC

Contact Phone Number: 302-831-6402

Email Address: kaminski@udel.edu

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

1. Is this project externally funded?

N/A

2. Research Site(s)

Hodgson Vo-Tech High School

3. Project Staff

Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING COMPLETE?
Oscar T. Rau	Principal Investigator	Yes
Thomas W. Kaminski	Advisor	Yes

4. Special Populations

Does this project involve any of the following:

Research on Children?

Yes

Research with Prisoners?

No.

Research with Pregnant Women?

No.

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe

No.

5. RESEARCH ABSTRACT Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

Concussion is a major issue in sports today, primarily football. Athletes are routinely given baseline neuropsychological testing (NP) prior to their seasons, and then should they sustain a concussion during the season, follow-up NP tests can help guide return-to-play in these athletes.

Despite education involving physicians, athletic trainers, coaches, parents, and heavy publicity, there are many times when athletes discount concussion symptoms during a game. These “unreported” concussions may predispose athletes to more numerous and/or severe concussions in the future. As yet, there have been no reports examining players who are asymptomatic after game play, and whether they are experiencing neuropsychological deficits without outward signs of a concussion.

Our hypothesis is that in asymptomatic, football players after game play, there will be a significant decrease in NP scores when compared to a control group of non-contact sport athletes.

6. PROCEDURES Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

This will be a prospective, case-control study involving student-athletes from Hodgson Vo-Tech’s high school **VARSITY** football team. A control group of varsity cross-country athletes will also be tested. As per the normal medical screening protocol, the student-athletes at the Hodgson Vo-Tech will have baseline NP using the ImPACT® software done prior to their competitive season at the high school. ImPACT (Immediate Post-Concussion Assessment and Cognitive Testing) is a computerized test program consisting of three parts and includes: (1) sports and health history, (2) current symptoms and conditions, and (3) neurocognitive testing [8 modules]. The neurocognitive test domains measured include memory, processing speed, motor functioning, executive functioning, and attention. Student-athletes (and their

parents for those < 18 y.o.) selected to participate will be asked to sign an approved consent agreement prior to beginning the study.

A group of players from the **VARSIY** football team designated as “starters” (our goal is to recruit 22 players) will be selected to participate in additional ImPACT® NP during the competitive season; specifically on Monday’s and Friday’s after the first, fifth, and final game of the season. A final ImPACT® NP will be conducted 1 month after the season concludes. All follow-up ImPACT® NP will take place using a computer interface in a quiet environment, free from distractions.

Concurrently, 11 male members of Hodgson Vo-Tech’s varsity cross-country team will be recruited to serve as control subjects to their football counterparts and undergo testing on the same sequence of days indicated above.

7. STUDY POPULATION AND RECRUITMENT

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

We will be studying a select group of 22 student-athletes aged 14-18 and designated as “starters” on Hodgson Vo-Tech’s high school **VARSIY** football team. Simultaneously we will recruit a group of 11 male student-athletes from Hodgson Vo-Tech’s varsity cross-country team to serve as control subjects. We will exclude all those players sustaining a head injury, and those who do not play the entire game due to another injury. These student-athletes have all been cleared to participate in activities surrounding their sport by their physician prior to the start of the season and the appropriate DIAA form has been filed.

Verbal recruitment:

(1) Script Football Players:

“You are being asked to participate in a study to determine whether your performance on the ImPACT test changes during the course of the season, despite not showing any outward signs of a concussion. If you choose to participate, you will be one of 22 **VARSIY** football players in the study. You will be required to come to the computer lab on Monday and Friday three separate times during the season. One final test will be conducted 1 month after the season ends. In a manner similar to the baseline ImPACT® test you previously took, you will be asked to test again using a designated computer. The test requires approximately 25 minutes to complete. Your participation in this study is purely voluntary and **WILL NOT** affect your playing status on your respective team. You **WILL NOT** be compensated for your time and efforts. Do you have any questions?”

(2) Script Male Cross-Country Runners:

“You are being asked to participate in a study to determine whether performance on the ImPACT test changes during the course of the season in contact sport athletes, despite not showing any outward signs of a concussion. If you choose to participate, you will be one of 11 runners who will serve as the non-contact control subjects to the contact sport (football) athletes. You will be required to come to the computer lab on Monday and Friday three separate times during the fall sport season. A final test will be conducted 1 month after the

season ends. In a manner similar to the baseline ImPACT® test you previously took, you will be asked to test again using a designated computer. The test requires approximately 25 minutes to complete. Your participation in this study is purely voluntary and **WILL NOT** affect your playing status on your respective team. You **WILL NOT** be compensated for your time and efforts. Do you have any questions?"

Describe what exclusionary criteria, if any will be applied.

Athletes will be excluded from participating in the study if they are currently, or would have suffered a head injury, at any time during the study period.

Describe what (if any) conditions will result in PI termination of subject participation.

If at any time during the study subjects fail to take a follow-up ImPACT NP, the PI could terminate them from the study.

8. RISKS AND BENEFITS

List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here should be included on the consent form).

The only risk for the participant is as follows: If they have sustained a concussion and fail to disclose their symptoms, taking the NP may make their symptoms worse for a short period of time.

In your opinion, are risks listed above minimal* or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

The risks stated above are **minimal**.

*(*Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)*

What steps will be taken to minimize risks?

All student-athletes will be asked if they have any symptoms of concussions before and after the test. If so, they will immediately be sent to the school nurse or family physician for evaluation.

Describe any potential direct benefits to participants.

Athletes will be able to see if there have been any changes in their baseline neuropsychological testing after game play. Athletes performing poorly on the testing in relation to their baseline testing, may have occult concussion symptoms, which they would then be examined for and potentially be held out of play until their concussion symptoms have resolved. All return-to-play decisions will be at the discretion of their attending physician.

Describe any potential future benefits to this class of participants, others, or society.

If it is found that asymptomatic collision athletes have deficits in their NP, this may help prevent future exposures to mild traumatic brain injury especially in this group of high school football student-athletes.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

N/A

9. **COMPENSATION**

Will participants be compensated for participation?

No

If so, please include details.

10. **DATA**

Will subjects be anonymous to the researcher?

No.

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how)

Subjects will be identified only by subject number (1-33). Age, gender, sport, and variables of interest measured will be recorded for data collection.

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see <http://www.udel.edu/research/preparing/datastorage.html>)

Records of this information will be kept in a password-protected electronic file, available only to those directly associated with the research. The consent form will be the only document with the subjects name and personal information. The consent form will be locked in a file cabinet in the Athletic Training Research Lab (Room 160 of the Human Performance Laboratory). No personal information will be shared when the results of this study are reported.

How long will data be stored?

The consent form and data collected will be stored for three years.

Will data be destroyed? YES NO (if yes, please specify how the data will be destroyed)

Yes. After the three years have passed, both electronic data and consent forms will be destroyed. The electronic data will be securely removed and the consent forms will be shredded.

Will the data be shared with anyone outside of the research team? YES NO (if yes, please list the person(s), organization(s) and/or institution(s) and specify plans for secure data transfer)

No.

How will data be analyzed and reported?

One-way ANOVA tests and Intraclass correlation coefficients will be performed using SPSS software (version 20.0; SPSS Inc, Chicago IL). Data will have no subject identifiers associated. When the data are reported, in both publication and potentially at the American Medical Society for Sports Medicine Annual meeting, results will have no subject identifiers included.

11. **CONFIDENTIALITY**

Will participants be audiotaped, photographed or videotaped during this study?

No.

How will subject identity be protected?

Subjects' names will only be kept on the consent form. The consent form will be locked in a file cabinet in the Athletic Training Research Lab (Room 160 of the Human Performance Laboratory). After completing the consent forms, subjects will be identified by their randomly assigned numbers. No personal information will be shared when the results of this study are reported.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).

No.

12. **CONFLICT OF INTEREST**

(For information on disclosure reporting see:
<http://www.udel.edu/research/preparing/conflict.html>)

Do you have a current conflict of interest disclosure form on file through UD Web forms?

No.

Does this project involve a potential conflict of interest*?

No.

* As defined in the University of Delaware's Policies and Procedures , a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment, actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

13. CONSENT and ASSENT

Consent forms will be used and are attached for review

14. Other IRB Approval

Has this protocol been submitted to any other IRBs?

No.

15. Supporting Documentation

Please list all additional documents uploaded to IRBNet in support of this application.

Consent Form

Assent Form

Parental Consent Form

Appendix D

INFORMED CONSENT FORM

University of Delaware Informed Consent Form

Title of Project: Neuropsychological Testing in Asymptomatic High School Football Players

Principal Investigator (s): Oscar Rau B.S. ATC CSCS (graduate student)

Advisor: Thomas Kaminski, PhD, ATC (advisor)

You are being asked to participate in a research study. This form is designed to tell you about the study including its purpose, what you will do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and feel free to ask the research team questions about anything you do not understand before you decide whether or not to participate. Your participation is completely voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you and your guardian will be asked to sign this form and a copy will be given to you for your records.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to monitor performance on the ImPACT test in the week following three (3) football games during the season.

You are being asked to be a participant in the study because you are a high school football player and will take a baseline ImPACT test should you agree to participate in this study. We are also recruiting a separate group of non-contact sport athletes (cross-country runners) to participate in this study as control subjects who will also take a baseline ImPACT test should they agree to participate in this study.

WHAT WILL YOU BE ASKED TO DO?

All student-athletes (both football and cross country runners) selected to participate will be asked to report for ImPACT testing on Monday's and Friday's in the week immediately following football games from week 1, 5, and the final game of the season. The ImPACT test is completed while sitting at a desktop computer. The computer program asks a series of questions enabling you to respond to whether or not you have any "concussion-related" symptoms (headache, dizzy, etc...). In addition, there are several modules that will test your reaction time, memory, and simple math processing. The test requires about 20-25 minutes to complete. One month after the football season concludes you'll be required to perform one final ImPACT test. The format of the test will be the same as it was for your baseline ImPACT test and will require about 25 minutes to complete each test.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS? There are no known risks associated with the ImPACT test, however the risk that if you have sustained a concussion and fail to disclose your symptoms, taking the ImPACT test may worsen your symptoms for a short period of time. All student-athletes will be asked if they have any symptoms of concussions before and after the test. If yes, they will immediately be sent to a physician for evaluation.

WHAT ARE THE POTENTIAL BENEFITS?

Results from this study may help to benefit clinicians in managing sport-related concussions in the future.

HOW WILL CONFIDENTIALITY BE MAINTAINED?

If you choose to participate in this study, you can be assured your information is kept confidential. For this study, you will be identified only by your subject number. Records of this information will be kept on electronic file, available only to those directly associated with the research. This consent form will be the only document with your name and personal information.

This consent form and data collected will be stored for three years. The consent form will be locked in a file cabinet in the Athletic Training Research Lab (Room 160 of the Human Performance Laboratory). No personal information will be shared when the results of this study are reported.

Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

There will be **no** cost to you for participating in the study.

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

There will be **no** financial compensation for completion of this study.

WHAT IF YOU ARE INJURED BECAUSE OF THE STUDY?

If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time you wish. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the University of Delaware.

As a student-athlete, if you decide not to take part in this research, your choice will have no consequence on your academic status, your grade in class, and **WILL NOT** affect your playing status on your respective team. Your participation may be terminated by

investigators if you are not cooperating with the instructions given. You have the right to cease participation at any time during the study.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Oscar Rau at 856-834-3224, or my advisor, Thomas W. Kaminski at 302-831-6402.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

Your signature below indicates that you are agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

By signing this consent form, you indicate that you voluntarily agree to participate in this study.

Signature of Participant

Date

Printed Name of Participant

Signature of Principle Investigator

Date

Printed Name of Principle Investigator

Appendix E

ASSENT FORM

Assent Form for Youth Ages 14-18

Your parent(s) has given permission for you to take part in a research study at the University of Delaware. But first, we want to tell you all about it so you can decide if you want to be a part of it. If you do not understand, please ask questions. You can choose to be in the study, not be in the study, or take more time to decide.

What is the name of the study?

Neuropsychological Testing in Asymptomatic High School Football Players

Who is in charge of the study?

Oscar Rau, ATC CSCS (graduate student) and Dr. Thomas W. Kaminski, PhD (advisor)

What is the study about?

The purpose of this research study is to monitor performance on the ImPACT test in the week following three (3) football games during the season. We would like to determine whether or not there are student-athletes who are considered asymptomatic that are participating with diminished neuropsychological (NP) status. If it is found that asymptomatic collision athletes have deficits in their NP, this may help prevent future exposures to mild traumatic brain injury especially in this group of high school football student-athletes.

Why are you asking me to be in this study?

You are being asked to be a part of this study because you are: (1) A high school football player who sustains multiple impacts during athletic participation putting you at risk for mild traumatic brain injury (MTBI) or (2) A high school cross-country runner (non-contact sport) serving as the control group.

What will happen to me in the study?

If you choose to be a part of this research study you will be a part of one of two groups: (1) Testing group: Hodgson Vo-Tech Football Players or (2) Control group: Hodgson Vo-Tech Cross-Country Runners. As per the normal medical screening protocol, you will have a baseline NP test using the ImPACT® software done prior to the competitive season at the high school. ImPACT (Immediate Post-Concussion Assessment and Cognitive Testing) is a computerized test program consisting of three parts and includes: (1) sports and health history, (2) current symptoms and conditions, and (3) neurocognitive testing [8 modules]. The neurocognitive test domains measured include memory, processing speed, motor functioning, executive functioning, and attention.

A group of players from the **VARSITY** football team designated as “starters” (our goal is to recruit 22 players) will be selected to participate in additional ImPACT® NP during the competitive season; specifically on Monday’s and Friday’s after the first, fifth, and final game of the season. A final ImPACT® NP will be conducted 1 month after the season concludes. All follow-up ImPACT® NP will take place using a computer interface in a quiet environment, free from distractions.

Concurrently, 11 male members of Hodgson Vo-Tech’s varsity cross-country team will be recruited to serve as control subjects to their football counterparts and undergo testing on the same sequence of days indicated above.

What are possible risks of being in this study?

The only risk for you is as follows: If you have sustained a concussion and fail to disclose symptoms, taking the NP may make your symptoms worse for a short period of time.

These risks are considered minimal. You will be asked if you have any symptoms of concussions before and after the test. If so, you will immediately be sent to the school nurse or family physician for evaluation.

What are possible benefits of being in this study?

You will be able to see if there have been any changes to your baseline neuropsychological testing after game play. Should you perform poorly on the testing in relation to your baseline test, you may have occult concussion symptoms, which would then prompt further examination and potentially cause you to be held out of participation until your concussion symptoms have resolved. All return-to-play decisions will be at the discretion of the attending physician.

Will I be paid to be in this study?

You will **NOT** be paid for being in this study. There are no other incentives for participating.

How will confidentiality be maintained?

Data will be kept confidential and your information will be assigned a code number. The list connecting your name to this number will be kept in a locked file. When the study is completed and the data have been analyzed, the list will be destroyed. Data will be kept securely in electronic storage formats and saved indefinitely. Your name will not be used in any report. We will make every effort to keep all research records that identify you confidential to the extent permitted by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

Do I have to be in the study?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time you wish. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the University of Delaware.

As a student-athlete, if you decide not to take part in this research, your choice will have no consequence on your academic status, your grade in class, and WILL NOT affect your playing status on your respective team. Your participation may be terminated by investigators if you are

not cooperating with the instructions given. You have the right to cease participation at any time during the study.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

Adolescent's Signature Date

Name of Person Obtaining Assent Signature of Person Obtaining Assent Date

Appendix F

PARENTAL CONSENT FORM

Parental Permission for Participation in a Research Study

Title of Project: Neuropsychological Testing in Asymptomatic High School Football Players

Principal Investigator:

Name: **Oscar Rau, ATC CSCS (graduate student)**
Department/Center: Kinesiology & Applied Physiology
Contact Phone Number: 856-834-3224
Email Address: orau22@icloud.com

Advisor:

Name: **Thomas Kaminski, PhD (professor)**
Department/Center: Kinesiology and Applied Physiology
Contact Phone Number: 302-831-6402
Email Address: kaminski@udel.edu

You have been asked to permit your child to be in a research study at the University of Delaware. This form explains the research, your child's rights as a research participant, and any responsibilities that you may have as a result of your child's participation. You should understand the research study before you agree to permit your child to be involved. Read this permission form carefully. You may also talk with your family or friends about this study. A research team member will answer any questions you have before you make a decision.

1. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your child's rights as a research subject, what to do if your child is injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed above.

2. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to monitor performance on the ImPACT test in the week following three (3) football games during the season. We would like to determine whether or not there are student-athletes who are considered asymptomatic that are participating with diminished neuropsychological (NP) status. If it is found that asymptomatic collision athletes have deficits in their NP, this may help prevent future exposures to mild traumatic brain injury especially in this group of high school football student-athletes.

3. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The Department of Kinesiology & Applied Physiology at the University of Delaware is sponsoring this study.

4. WHO CAN BE IN THE STUDY?

Male student-athletes who are a part of Hodgson Vo-Tech's high school football team or cross-country team.

5. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

A total of **33** participants are being recruited for this study. Testing will take place in the computer lab at Hodgson Vo-Tech High School.

6. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation will begin during preseason of the competitive season and continue until 1 month following the end of the fall sport season. During this time each subject will take a baseline NP test during preseason, six NP testing sessions that will take place during the 1st, 5th, and final week of the football season, and one follow-up NP test one month following the end of the football season.

7. WHAT ARE THE RESEARCH PROCEDURES?

If you choose to be a part of this research study you will be a part of one of two groups: (1) Testing group: Hodgson Vo-Tech Football Players or (2) Control group: Hodgson Vo-Tech Cross-Country Runners. As per the normal medical screening protocol, you will have a baseline NP test using the ImPACT® software done prior to the competitive season at the high school. ImPACT (Immediate Post-Concussion Assessment and Cognitive Testing) is a computerized test program consisting of three parts and includes: (1) sports and health history, (2) current symptoms and conditions, and (3) neurocognitive testing [8 modules]. The neurocognitive test domains measured include memory, processing speed, motor functioning, executive functioning, and attention.

A group of players from the **VARSITY** football team designated as "starters" (our goal is to recruit 22 players) will be selected to participate in additional ImPACT® NP during the competitive season; specifically on Monday's and Friday's after the first, fifth, and final game of the season. A final ImPACT® NP will be conducted 1 month after the season concludes. All follow-up ImPACT® NP will take place using a computer interface in a quiet environment, free from distractions.

Concurrently, 11 male members of Hodgson Vo-Tech's varsity cross-country team will be recruited to serve as control subjects to their football counterparts and undergo testing on the same sequence of days indicated above.

8. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?

The only risk for you is as follows: If you have sustained a concussion and fail to disclose symptoms, taking the NP may make your symptoms worse for a short period of time.

These risks are considered minimal. You will be asked if you have any symptoms of concussions before and after the test. If so, you will immediately be sent to the school nurse or family physician for evaluation.

9. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

You will be able to see if there have been any changes to your baseline neuropsychological testing after game play. Should you perform poorly on the testing in relation to your baseline test, you may have occult concussion symptoms, which would then prompt further examination and potentially cause you to be held out of participation until your concussion symptoms have resolved. All return-to-play decisions will be at the discretion of the attending physician.

10. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?

If your child is injured during research procedures, they will be offered first aid at no cost to you. If they need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights your child may have if injury was the result of negligence of the university or its investigators.

11. IS BEING IN THE STUDY VOLUNTARY?

Taking part in this research study is entirely voluntary. Your child does not have to participate in this research. If you allow your child to take part, you have the right to stop at any time you wish. If you decide not to allow your child to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which your child is otherwise entitled. Your refusal to allow your child to participate will not influence current or future relationships with the University of Delaware.

As a parent/guardian, if you decide not to allow your child to take part in this research, your choice will have no consequence on their academic status, grade in class, and WILL NOT affect their playing status on their respective team. Investigators may terminate your child's participation if they are not cooperating with the instructions given. You have the right to cease participation at any time during the study

12. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

In the event your child sustains a concussion during the length of this study they will be removed from the study. If your child sustains an injury causing them a lengthy absence from participation they will also be removed from the study.

13. WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There will be no costs associated with participating in this study.

14. WILL PEOPLE BE PAID FOR BEING IN THIS STUDY?

There are no financial gains associated with participation in this study.

15. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO PERMIT MY CHILD TO STAY IN THE STUDY?

Any new information that may change your mind about allowing your child to be in this study will be given to you. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

16. WHAT INFORMATION ABOUT MY CHILD WILL BE USED OR DISCLOSED?

All subjects participating in the proposed research can ensure confidentiality outside of those directly associated with the research. No names will be utilized in data analysis. Paper tests will be identified by randomly assigned subject identifiers, and all names and codes will be kept solely by the primary investigator or advisor in a locked cabinet.

Each subjects' information will be assigned a code number. The list of codes and the names they correspond to will be kept in a locked file. Subject's names will not be used in any report whatsoever.

The data will be stored for a minimum of three (3) years for any future research. Upon completion of the study, all hard copy documents will be destroyed in a paper shredder. No data will be shared with anyone outside of the research team.

Limits on Protection of Privacy and Confidentiality

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

SIGNATURES:

I am making a decision whether or not to permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before he/she will be allowed to be in this study. I have read this form, or have had it read to me in a language that I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw permission for participation in this study by contacting the person in charge of the study listed on the first page of this form.
- I have the right to refuse to sign this permission form.
- If I refuse to sign this permission form, my child will not be allowed to be in this research study.

My signature indicates that:

- As his or her parent or guardian, I give my permission for the minor child named below to participate in the research study described in this Parental Permission Form.

_____		_____
Name of Participant (Print)		Participant Date of Birth:
_____		_____
Signature of Parent / Guardian	Printed Name of Parent / Guardian	Date

Check Relation to Participant: Parent Guardian: (Guardians must have documented authority to give permission for participation in a research study according to the laws of the State in which the treatment occurs.)

I the undersigned, certify that to the best of my knowledge the parent/legal representative signing this permission had the study fully and carefully explained and that he/she understands the nature, risks and benefits of participation in this research study.

Name of Person Obtaining
permission (Investigator or
Designee)

Signature of Person Obtaining
permission

Date

Appendix G

IRB Approval



RESEARCH OFFICE

210 HULLIHEN HALL
UNIVERSITY OF DELAWARE
NEWARK, DELAWARE 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE: May 7, 2014

TO: Oscar Rau
FROM: University of Delaware IRB

STUDY TITLE: [582675-1] Neuropsychological Testing in Asymptomatic High School Football Players

SUBMISSION TYPE: New Project

ACTION: APPROVED
APPROVAL DATE: April 19, 2014
EXPIRATION DATE: April 18, 2015
REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # (7)

Thank you for your submission of New Project materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

