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DETERMINING THE FALSE POSITIVE RATE OF A CONCUSSION BATTERY IN HEALTHY DIVISION I COLLEGIATE ATHLETES

by

CAITLYNN HELLWIG
(Under the Direction of Jody Langdon)

ABSTRACT

Context: Athletic participation accounts for 1.6-3.8 million concussions, or mild traumatic brain injuries (mTBI) every year in the United States. Accurate assessment and diagnosis of concussions is critical to protect athletes from further injury. The Fourth International Conference on Concussion in Sport Consensus Statement recommends a multifaceted concussion assessment which includes symptom inventories, postural stability assessment, and neurocognitive testing. The accuracy of each test is vital in correctly diagnosing concussions. The Balance Error Scoring System (BESS), Standardized Assessment of Concussion (SAC), and Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) are among the most commonly used assessment tools by NCAA athletic trainers.

Objectives: (1) evaluate the false positive rate of a clinical concussion assessment battery (BESS, SAC, ImPACT) in a healthy Division I collegiate athlete population and (2) identify trends in pass/fail rates based on months elapsed from baseline testing.

Design: Prospective longitudinal study.

Setting: A large university in southeast Georgia.

Participants: Fifty Division I collegiate athletes were recruited as participants. Forty-eight participants fulfilled the study requirements.

Main Outcome Measure(s): Descriptive statistics were run for all demographic variables, along with scores on the various dependent variables. Failure rates for each test were then determined. Any increase in BESS score, decrease in SAC score, or change in an ImPACT composite score exceeding the reliable change index was classified as a false positive for the concussion battery. A one-way repeated measures ANOVA was run to determine changes in scores by testing time (baseline vs. current) and time elapsed from baseline. Tukey post-hoc testing and planned simple contrasts were evaluated as needed.

Results: The concussion battery produced an 81% false positive rate. BESS produced the most false positives (62.5%), followed by ImPACT (33.3%), and SAC (27.1%). No significant interactions were found between the time from baseline testing and differences in scores from baseline to current testing. There was a significant main effect across time between BESS baseline scores and testing scores.

Conclusions: Eighty-one percent athletes demonstrated a deficit from their baseline scores on one or more of the assessments, thus failing the concussion battery and giving objective evidence of a possible concussion. When a patient fails an objective assessment used to identify and diagnose a concussion, they are at risk of being removed from all participation. To return to participation, the current recommendation is a symptom free graduated return to play protocol taking about seven days to complete. This may result in significant playing time lost for the athlete.

Key Words: Concussion, BESS, SAC, ImPACT, mTBI

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MASTERS IN ATHLETIC TRAINING

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Table of Contents

CHAPTER 1	9
INTRODUCTION	9
Purpose	13
CHAPTER 2	16
METHODS	16
Participants	16
Recruitment	17
Instrumentation	17
Procedures	19
Data Analysis	21
Statistical Analysis	22
CHAPTER 3	23
RESULTS	23
CHAPTER 4	25
DISCUSSION	25
APPENDIX A	30
Limitations	30
Delimitations	30
Assumptions	31
APPENDIX B	32
LITERATURE REVIEW	32
Introduction	32
Assessments	36
APPENDIX C	56
IRB Documents	56
INFORMED CONSENT	60
HEALTH HISTORY QUESTIONNAIRE	63
BORG 10 Scale of Perceived Exercise	66
BESS	67
SAC	68
ImPACT	69
REFERENCES	70
Tables	74
Table 1. Participant demographic information	74

Table 2. Participants by sport.....	75
Table 3. Number of assessments by time elapsed from baseline.....	76
Table 4. Scores and false positive rate by assessment.....	77
Table 5. Scores and false positive rate by ImPACT composite score.....	78
Table 6. Symptom report	79
Table 7. History of concussion	79
Table 8. Frequency of clinical testing after baseline.....	81

CHAPTER 1

INTRODUCTION

In the United States, athletic participation is estimated to account for 1.6 - 3.8 million mild traumatic brain injuries (mTBI) or concussions every year.¹ Concussion is defined in the 2012 Zurich Statement as “a complex pathophysiological process affecting the brain, induced by biomechanical forces.”² Concussion is further characterized by the following criteria: 1) occurs through a direct blow to the head or somewhere else on the body with the force transmitted to the brain, 2) results in the rapid onset of transient neuropsychological symptoms lasting anywhere from a few minutes to months in length, 3) results in neuropathological changes of a functional nature while no structural abnormality can be seen on standard neuroimaging studies. Concussions resolve sequentially and should not be quantified with grading scales.² Clinical presentation of concussion may include loss of consciousness, but it is not required for clinical diagnosis. Other common symptoms of concussion may include headache, cognitive impairment, confusion, dizziness, and vision or balance problems. In most cases, symptoms will resolve completely over time. Sustaining an initial concussion may have long-term implications such as increased risk for future concussions and increased mild cognitive impairment.³ Mild traumatic brain injuries represent one of the most difficult clinical conditions to manage in sports medicine. Traumatic brain injuries mild through severe, are responsible for costs of US \$60 billion in direct and indirect medical costs.⁴ In 2003 the NCAA concussion study was published showing an increase in collegiate concussion rate from 0.7 to 0.81/1,000 athletic-exposures.⁵

Diagnosis of a concussion may be challenging because there is not one tool that represents a gold standard. Clinicians commonly use a number of tests when evaluating

patients with concussion. The specific test methods vary but often include self-reported symptom inventories, cognition and memory assessments, posture/balance assessments, and neurocognitive examinations.⁶ The sensitivity and reliability of each test is vital in accurately diagnosing concussions.

A multifaceted approach (concussion battery) to concussion diagnosis and management is emphasized in the most recent consensus statement on concussion in sport.² The concussion battery McCrea used in his 2005 study of collegiate football players included the graded symptom checklist, Standard Assessment of Concussion, Balance Error Scoring System, and a neuropsychological test battery (Hopkins Verbal Learning Test, Trail Making Test Part B, Symbol Digit Modalities Test, Stroop Color-Word Test, Controlled Oral Word, Association Test). Highly sensitive at the time of injury, the aforementioned battery is 94% accurate in classifying injured participants on balance, cognition, memory, concentration, and symptoms.⁶

Questions have been raised on the specificity of the concussion batteries. Computerized neuropsychological testing alone, up to 46% of healthy participants were identified as having a significant change in their score when compared to their scores from baseline testing. False-positive classifications can lead to misdiagnosis identifying healthy individuals as having a concussion.⁷

To quantify concussive symptoms, clinicians use graded symptom inventories such as the graded symptom checklist (GSC). The GSC is a 22- item list of symptoms on a 7-point Likert scale ranging from zero to six, with zero representing the individual not experiencing the symptom and six representing the most severe manifestation. The total number of symptoms is recorded as well as total severity of all symptoms (maximum 132). With this tool, the clinician

can track each symptom on a day to day basis and monitor resolution. On average, the symptom severity score for GSC increases in severity by 20 points following a concussion and these symptoms may resolve in an average of 3.24 days.^{6,8,9} Ninety-one percent of athletes' symptoms resolved and GSC scores returned to baseline in seven days, leaving only a small percentage facing prolonged symptom recovery.¹⁰ A strength of the GSC is its high sensitivity (89%).⁶ The major limitation of the GSC is the lack of honesty by athletes when reporting symptoms.¹¹ Furthermore, the term 'asymptomatic' has not yet been formally defined within the concussion literature.¹² Acknowledging that post-concussion-like symptoms are present in the non-concussed population at rest and with exercise, the concept of athletes returning to an asymptomatic baseline before return to play may be an unrealistic expectation.¹²

The Balance Error Scoring System (BESS) was originally created to assist clinicians in assessing concussions by quantifying balance deficits. The correct use of the BESS includes accurate baseline testing as well as a post-concussion balance assessment. The athlete is instructed to hold three standing positions (feet together, single leg, and tandem stance) for 20 s each with their eyes closed and hands on their hips on a firm surface. Each position is then repeated on an AIREX (20" L x 16.4" W x 2.5" H) balance pad (SPRI Products, Inc, Libertyville, Illinois) to increase the difficulty. Errors include opening the eyes, hands coming off the iliac crest, a heel or forefoot coming off the ground, stumbling, stepping, or falling out of position, the hip exceeding 30° of abduction, or being unable to hold the test position for 5 s. Errors are scored by the clinician during each of the 20 s periods. If the athlete is unable to hold test position for more than five s, he or she will receive a score of 10 for that portion of the test. The average baseline score is 8 - 14 errors.¹³ When compared to an athlete's baseline score, the post-concussion BESS score increases by an average of six points. Typically BESS scores return

to baseline within three to five days after concussion.^{6,13} BESS demonstrates moderate to good reliability, although a significant practice effect has been demonstrated.^{13,14} Finnhoff established intra-rater reliability of BESS to be 0.74 and inter-rater reliability 0.57.¹⁵ As established previously, the average change in BESS score post-concussion increases by six points, yet based on reliability scores and information calculated via minimum detectable change, an increase of 7.3 points would need to be observed for the change in score to be attributed to the balancer and not scorer error.¹⁵ Similarly, if a different clinician scored the baseline BESS test, the post-concussion score would have to be increased by 9.3 points to be considered a reliable change.¹⁵ Reliability is therefore a significant inherent limitation of the test. In the literature, BESS has 91-97% specificity, but only 34% sensitivity.¹³ An additional limitation of BESS testing is its ability to be influenced by factors such as tape, braces, age, and even fatigue.¹³ When evaluating the effects of a competitive playing season on BESS outcomes, Burk et al. found a 16% false positive rate.¹⁴

The Standardized Assessment of Concussion (SAC) is a widely used tool that evaluates cognition and memory. The tool is most sensitive when administered within 24 hours of the suspected concussive impact. Orientation, immediate memory, concentration, and delayed recall are all aspects of the assessment. The test is scored out of 30 possible points and is then compared to the athlete's pre-activity baseline score. On average, baseline scores across the high school and collegiate football demographic are 26 to 28.¹⁶ Post-concussion scores can be expected to worsen by three to four points from the baseline assessment.^{5,16} Although the SAC has good sensitivity (0.80) and specificity (0.89-0.98), scores consistently returning to baseline after 48 hours or after three trials demonstrates a practice effect that may sway clinical significance of results.^{5,6,16} McCrea found that even a drop of one point from the preseason

baseline score on the SAC was 95% sensitive and 76% specific in accurately classifying injured and uninjured subjects.¹⁷ McCrea's results suggest sideline variables such as fatigue, crowd noise, or distractibility were not factors in the observed decline in SAC score by injured subjects immediately after concussion and therefore the decline can be considered the direct effect of injury on cognitive functioning.¹⁷

Computerized neuropsychological testing is also growing in popularity.¹⁸ The computerized Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT®) quantified a decrease in neurocognitive function in 36-38% of 138 concussed adolescent cheerleaders who reported being asymptomatic.¹⁹ ImPACT is comprised of six test modules that collectively measure multiple aspects of cognitive function including attention span, working memory, sustained and selective attention time, response variability, non-verbal problem solving, and reaction time. Components of the six individual scores are calculated to produce composite scores for verbal memory, visual memory, processing speed, and reaction time. ImPACT also has the option to record a concussion and health history and post-concussion symptom score (PCSS). Although pen and paper assessments of neurocognitive function have demonstrated return to baseline in approximately 5-7 days, ImPACT has shown deficits in neurocognitive function up to two weeks post-concussion.^{10 20}

Purpose

In the clinical setting, a healthy patient is expected to be able to pass all the measures included in the test battery to objectively rule out a concussion. Should the patient demonstrate a deficit from their baseline scores on any one of the assessments, there would be objective evidence that points to a possible concussion and the patient would be regarded as failing the concussion battery. When a patient fails an objective assessment used to identify

and diagnose a concussion, he/she are at risk of being removed from all participation. However, many factors independent of suspected head injury have influence on these assessment measures. Athletes may be losing valuable playing time due to the low specificity of the concussion assessment battery. The concussion assessments are not intended to for use as the singular measure of diagnosis but paired with a comprehensive evaluation completed by an athletic trainer, physician, or other qualified health care provider. Once an athlete is diagnosed with a concussion, he or she will be out of participation until symptom free, key assessment measures return to baseline scores, and they have completed a graduated exertion progression or return to play protocol typically taking 10 to 14 days. Misdiagnosis may therefore result in unnecessary and costly additional testing, treatment and loss of playing time for the athlete. An athlete who is concerned about unnecessarily missing playing time due to being flagged by a testing measure may be less inclined to report injuries to the clinician.

A recent survey of Division I athletic trainers found most respondents reported using multifaceted objective assessment techniques during both baseline testing (71.2%) and during acute concussion evaluation (79.2%).²¹ The BESS is the most widely used balance assessment (73.9%) following a suspected concussion.²¹ Some form of neuropsychological testing is utilized by 90% of clinicians in their assessment battery and cognitive performance was evaluated by 90.7% of clinicians.²¹

The purpose of this study was to determine the false positive rate of a multifaceted concussion battery (SAC, BESS, ImPACT) in a sample of healthy Division I collegiate athletes. The inclusion criteria for the sample included any player who was able to participate in the athletic activity on their scheduled day of testing. While concussion research has commonly excluded participants because of orthopedic injury and/or a history of concussion,

this study will retain them to maintain clinical applicability. As long as participants are able to participate in athletic activity, they are at risk of sustaining a concussion and therefore may have to complete the assessment regardless of previous or current injury.

CHAPTER 2

METHODS

Participants

Seventy-two healthy Division I collegiate athletes between the ages of 18 and 24 showed original interest in participating in the study and supplied the primary researcher with email contact information. Upon email contact, four asked to be removed from the potential participant list, 18 did not respond to attempts to contact, and 50 completed the testing. The inclusion criteria for the study were any student-athlete who was currently an active member of an intercollegiate athletic or cheerleading team and healthy enough to participate in team training (practice, weights, game, conditioning). If an athlete was healthy enough to have had participated in athletic participation on the testing days, they were included in the study regardless of minor, chronic, or history of injury. The rationale for using these liberal inclusion criteria was that if the athlete participated in athletic activity the testing day, he or she was exposed to the potential of sustaining a concussion and, if suspected of sustaining a concussion, would be evaluated using this concussion battery. One participant was excluded due to lack of comprehensive baseline data on file and one participant was excluded due to technical difficulty during the ImPACT assessment resulting in no score being generated.

Forty-eight Division I collegiate athletes (34 female, 14 male, 40 Caucasian, 8 African American) met the inclusion criteria and completed the testing procedures. Athletes' ages ranged from 18 to 24 y with a mean age of 19.81 y (SD = ± 1.21) (Table 1). The sample consisted of athletes from 11 different teams (Table 2). Athletes from each year in school were recruited; freshmen (n=10), sophomores (n=17), juniors (n=12), seniors (n=9). In the self-reported health

history questionnaire, nine athletes reported currently receiving treatment for an upper body orthopedic injury and nine athletes reported currently receiving treatment for a lower body orthopedic injury (Table 1).

Recruitment

The primary researcher asked athletes from male, female and co-ed teams if they would be willing to participate in this study, explaining that it would in no way influence their athletic participation status. Sign-up sheets to collect email contact information from participating athletes were made available to each team.

Instrumentation

The GSC is a 22- item list of symptoms on a 7-point Likert scale ranging from zero to six, with zero representing the individual not experiencing the symptom and six representing the most severe manifestation.^[16] The total number of symptoms is recorded as well as total severity of all symptoms (maximum 132). The GSC was completed by clinician interview. Following the 22-symptom list, additional questions inquire if symptoms get worse with physical or mental activity.

The Standard Assessment of Concussion (SAC) includes measures of Orientation, Immediate Memory, Concentration, and Delayed Recall, which result in a maximum composite score of 30 possible points with one point being scored for each correct answer. McCrea found that even a drop of one point from the preseason baseline score on the SAC was 95% sensitive and 76% specific in accurately classifying injured and uninjured subjects.¹⁷ If an athlete has a deficit from baseline of one point or more their SAC score will be classified as a failed assessment.

The BESS was performed on an AIREX balance pad (SPRI Products, Inc., Libertyville,

Illinois). BESS includes three stances (double, single leg, and tandem stance), each completed twice, first on a firm surface and then on AIREX, for a total of six trials. All trials were completed without shoes, socks, bracing, or other external support to match the conditions of baseline testing. Proper testing stance requires participants to place their hands on both iliac crests and close their eyes. The 20 s trial began after participant was in the testing position the 20 s trial began. Single leg stances require the athlete to maintain the contralateral limb in 20-30° of hip flexion and 40-50° of knee flexion. The participant was asked to complete the single-limb stances on their non-dominant foot. This same foot was placed toward the rear on the tandem stances. Participants were instructed that upon losing their balance, they were to make any adjustments and return to the testing stance as quickly as possible. Each of the six stances was scored by adding one error point for each error observed. If the athlete was unable to hold the test position for a minimum of five s during the entire 20 s testing period, the trial was assigned a standard maximum error score of 10. The maximum score possible is 60. As seen clinically and in previous research, a higher post injury score compared to the athlete's baseline, by even one error, is clinically considered "abnormal."^{14,22,23}

The ImPACT instrument is a computer-based program used to assess neurocognitive function and concussion symptoms. ImPACT is comprised of three main sections; demographic and health history information, a 22-item current symptom inventory, and six test modules that evaluate attention, working memory, and processing speed, yielding composite scores on the areas of verbal memory, visual memory, processing speed, reaction time, and impulse control. ImPACT breaks down each test in the following manner: "Module 1: Word Discrimination evaluates attentional processes and verbal recognition memory utilizing a word discrimination paradigm. Module 2: Design Memory evaluates attentional processes and visual

recognition memory using a design discrimination paradigm. Module 3: X's and O's measures visual working memory as well as visual processing speed and consists of a visual memory paradigm with a distractor task that measures response speed. Module 4: Symbol Matching Evaluates gauges visual processing speed, learning and memory. Module 5: Color Match represents a choice reaction time task and also measures impulse control and response inhibition. Module 6: Three Letter Memory measures working memory and visual-motor response speed.” Components of these six modules are combined to create four composite scores demonstrating processing speed, reaction time, visual memory, and verbal memory. ImPACT Applications has identified “red flags” to assist the test administrator in identifying invalid tests. The four “red flags” include (a) processing speed composite, <25, (b) reaction time composite >0.8 s, (c) verbal memory composite, <70%, and (d) visual memory composite, <60%.²⁴ ImPACT 2.0 Lovell M. ImPACT 2007 (6.0) Clinical Interpretation Manual. Pittsburgh, PA: ImPACT Applications Inc.; 2007.

Procedures

Participants reported to the biomechanics lab following athletic participation, (including but not limited to any one of the following: team practices, captains’ practices, team weights, intercollegiate competition, or conditioning). The primary investigator reviewed the informed consent form with them. Athletes completed the informed consent and a brief health history questionnaire before beginning the concussion testing battery. The testing began no sooner than 20 minutes after the conclusion of physical activity to account for the period fatigue can influence test scores.²⁵ The GSC was completed interview style with the primary investigator asking the participant to grade each of the symptoms on a scale of severity. BESS was administered and scored live by the researcher as well as video recorded for later

assessment of interrater and intrarater reliability. The SAC was administered by the researcher in an interview style.

ImPACT was completed on a desktop computer in a private office located in the same facility as the other tests. The researcher instructed the participant to complete the test as directed by reading all instructions carefully. The participant was alone in the private office for the duration of testing. The researcher followed up with the participant at the conclusion of the test to make sure that there were no technical difficulties during the test. Athletes completed the ImPACT assessment at a time when they had not participated in exercise for at least three hours prior to the test. The entire concussion battery was completed within a 72 hour time period. The order of test completion varied based on the athletes' activity and class schedules. GSC, SAC, and BESS were completed first in 34 of the athlete's procedures. ImPACT was the first assessment completed in the other 14 instances.

All athletes recruited for the study had previously completed baseline concussion testing including SAC, BESS, and ImPACT. All baseline testing was completed within the last four years. There was not a written standard for collecting baseline testing. The majority of incoming athletes completed the baseline battery in coordination with their pre-participation physical exam. The BESS was typically completed in the biomechanics lab with live scoring by a trained researcher or clinician. The SAC was administered by an athletic trainer. Athletes signed up to return a following day to complete ImPACT. Most athletes completed baseline ImPACT testing in a group setting in a computer lab and the test was proctored by an athletic trainer. Some athletes completed all baseline testing with an athletic trainer outside of the previously mentioned normal procedures. There was no record found to signify which participants completed group testing and which participants completed individual testing.

Concussion baseline data for all athletes was on file in the athletic training facility and accessed after participants signed informed consent and completed all the testing for the study.

All athletes completed baseline concussion tests before their first collegiate practice. Therefore, not all participants had the same baseline test date or the same amount of time elapsed from baseline testing. If an athlete had a history of concussion at the university and improved any of their battery scores in a post-concussion assessment, the improved score became the new baseline, and was used as the baseline score for this study (table 8). For each participant in this study, all testing for the study was completed in a seventy-two hour window and total testing time remained under seventy-five minutes.

Data Analysis

This was a prospective longitudinal study. The independent variable was time from baseline assessment. The dependent variables included: total BESS score, composite SAC score, and the four composite ImPACT scores (verbal memory, visual memory, processing speed, and reaction time). Primarily, SAC, BESS, and ImPACT composite scores were categorized into two groups, “pass” or “fail” when compared to the baseline assessment. If a participant failed one or more of the aspects of the aforementioned battery, he or she was classified as having failed the battery as a collective. Secondly, all scores were evaluated based on the time elapsed from baseline assessment. This was completed to establish trends in false positive rate based on time elapsed from baseline assessment. Of the 48 BESS trials collected on video, 15 were randomly selected by a computer-generated list and independently rescored by the two investigators who did the live scoring. Intrarater reliability and interrater reliability of BESS in this study were 0.98 and 0.88 respectively.

Statistical Analysis

Descriptive statistics were run for all demographic variables, along with scores on the various dependent variables. Failure rates for each test were then determined. The ImpACT composite scores were automatically compared to each participant's baseline values. Values that fell below the reliable change index were considered a failing test. When evaluating the BESS test, any score above each participant's baseline (indicating additional errors) was classified as a failing test. Any SAC test score that was lower than each participant's baseline (indicating a deficit in one or more measures) was classified as a failing test. If even one of the components of the test battery was identified as a failed measure, the athlete was classified as having a false positive of the concussion battery. A one-way repeated measures ANOVA (elapsed time from baseline) was run to determine changes in scores by testing time (baseline vs. current) and time elapsed from baseline. Tukey post-hoc testing and planned simple contrasts were evaluated as needed. For each participant, time elapsed from baseline testing for BESS, SAC, and ImpACT was calculated in months and placed into four categories: baseline 0-12 months, 13-24 months, 25-36 months, and 37-48 months (Table 3). As baseline measurements are taken as part of the pre-participation physical for all athletes, athletes were grouped by when their baseline was collected. This identified if there was a trend in false positive rate congruent with time from baseline testing. An alpha level of .05 was adopted for all analyses involving significance testing.

CHAPTER 3

RESULTS

Of the 48 athletes who completed this study, 39 failed one or more measures of the concussion battery, resulting in a false positive rate of 81%. BESS had the highest percentage of false positive rate (62.5%) with 30 of the 48 athletes failing to reach their baseline score. On average, BESS increased by 2.63 errors from the baseline assessment. Overall, the SAC demonstrated the lowest false positive rate of 27.1%, with 13 of the 48 athletes scoring lower than baseline. On average, SAC scores increased by 0.46 points. With each question valued at one point, the increase of less than half a point is not clinically significant. When looking at ImPACT as a collective assessment, 16 of the 48 participants' scores surpassed the reliable change index in one or more of the four composite categories (verbal memory, visual memory, processing speed, and reaction time) and were flagged by ImPACT as demonstrating a significant deficit. Within this study, the false positive rate of ImPACT was 33% (Table 4). The false positive rate by composite score was as follows: verbal memory 14.6%, visual memory 12.5%, processing speed 6.3%, and reaction time 10.4% (Table 5). All of the ImPACT scores at both baseline and test session were valid meaning no test was flagged by ImPACT for lack of effort or an attempt to sandbag.

Participants were not classified into groups of pass or fail based on reported symptom scores in either the interview style GSC, or the PCSS, which accompanied ImPACT. Athletes reported an average of 2.27 (range 0 - 14) symptoms on the GSC with an average symptom severity score of 3.77 (range 1 - 19) 20 minutes after athletic activity. GSC is not included in the pre-participation baseline assessment.

All participants completed a baseline PCSS at the time of their baseline ImPACT test. The average baseline PCSS was 3.27 (range 0 - 31) symptoms reported at the time of testing. Prior to completing ImPACT for this study, the average PCSS was 5.44 (range 0 - 58) symptoms and average PCSS post ImPACT was 4.08 (range 0 - 43) symptoms (Table 6).

Based on the one-way repeated measures ANOVA there were no significant interactions between the time from baseline testing and differences in scores from baseline to current testing. No significant main effects were found with regard to time from the baseline test. BESS scores demonstrated a main effect between baseline scores and testing scores, yet the interaction of BESS with regard to time from baseline only approached significance. No main effect was observed in SAC or ImPACT scores.

A significant correlation was seen between ImPACT composite for visual memory and both presence of an orthopedic injury ($p=.05$) and BESS outcome ($p=.01$). No correlation was observed between BESS score and orthopedic injury ($p=.17$). Both SAC scores and BESS scores demonstrated a significant correlation with the full concussion assessment battery results: SAC, $p=.04$, BESS, $p < .001$.

CHAPTER 4

DISCUSSION

A multifaceted approach to concussion diagnosis and management is emphasized in the fourth consensus statement on concussion in sport.² In the clinical setting, when a battery of tests such as these is assembled into a protocol, it is expected that a healthy patient will pass all tests to objectively rule out a concussion. Eighty-one percent of healthy participants demonstrated a change from their baseline scores on one or more of the assessments within the battery, objectively indicating a possible concussion and the participant was regarded as failing the concussion battery. When a patient fails an objective assessment used to identify and diagnose a concussion, he or she is at risk of being removed from all physical activity. The current recommendations to return to participation is the completion of a symptom free graduated return to play protocol which takes approximately seven to ten days to complete.² Removing athletes from physical activity then progressing them through a protocol may result in significant playing time lost for the athlete. Playing time lost for athletes may result in missed opportunities to further their athletic career.

The average baseline SAC score in this study was 27.17 (± 1.53) which closely matches SAC baseline scores previously reported in the literature (26.4).¹⁶ The average change in SAC score from baseline to test day was an increase of less than one point while post-concussion scores can be expected to fall another three to four points from the baseline assessment.^{5,16} Practice effect is the major limitation with the SAC, although it did not play a role in the current study. McCrea found that even a drop of one point from preseason baseline score on the SAC was 95% sensitive and 76% specific in accurately classifying injured and uninjured subjects.¹⁷ In

our sample of 48 healthy athletes, the SAC had the lowest false positive rate at 27.1%.

Of all measures, BESS had the highest percentage of false positive rate (62.5%). The average pre-participation BESS baseline score of participants in this study was 12.73 (± 5.91) while in previous literature the average baseline score is 10 points or errors.¹³ Upon completing the trial testing, the average BESS score for the healthy individuals reflected an increase of an average of 15.35 (± 7.02) errors. As established previously, the average change in BESS score post-concussion increases by six points, yet based on reliability scores and information calculated via minimum detectable change, an increase of 7.3 points would need to be observed for the change in score to be attributed to the balancer and not scorer error.¹⁵ Similarly, if a different clinician scored the baseline, post-concussion score would have to be increased by 9.3 points to be considered a reliable change.¹⁵ The range demonstrated by the low reliability of BESS is not accounted for in clinical practice. Reliability of trial scoring in this study was excellent (interrater 0.88, intrarater 0.98), yet multiple clinicians scored the athlete's baseline tests and interrater reliability between all clinicians was not assessed. Low reliability and inconsistency in clinicians could account for the main effect found in the BESS scores. In previous literature it is seen that orthopedic injuries can influence postural control.²⁶ Although 18 athletes reported a current orthopedic injury in this study (9 upper body, 9 lower body), no correlation was found between orthopedic injuries and BESS performance. Fatigue was not a factor contributing to BESS scores due to the 20 minute rest period allotted post athletic activity prior to beginning testing.

Previously published sensitivity of ImPACT is 79-93% when classifying individuals as impaired, but misclassified 22-46% of the healthy sample as impaired.^{7,27,28} Our study demonstrated 33% of healthy participants classified as impaired. Hutchinson demonstrated that

athletes with orthopedic injuries performed significantly worse than healthy controls on the Automated Neuropsychological Assessment Metrics (ANAM).²⁹ The finding that musculoskeletal injured athletes performed worse than healthy controls on cognitive tests suggests that factors other than concussion may influence an athlete's neurocognitive performance over the short term. A significant correlation was found between both ImPACT visual memory and orthopedic injury ($r = -0.29$; $p = .05$) as well as ImPACT visual memory and BESS ($r = -0.36$; $p = .01$). Fatigue, gender, and competitive season of play can also sway neurocognitive scores.³⁰ Evidence of these influencing factors during neurocognitive testing presents a concern for false positives. It is difficult for athletes to deliberately perform poorly on the ImPACT because of the "red flag" validity indicators in place. In a 2012 study, Erdal found that only 11% were able to successfully 'sandbag' ImPACT.²⁴ Moser et al (2011) found that group administration produced significantly lower scores than individual administration on multiple ImPACT measures.³¹ Because the original baseline tests were primarily administered in groups, while the ImPACT test for this study was administered individually, the false positive rate of ImPACT has potential to be even greater than the observed 33% in this study.

Battery test results are considered in diagnosis and play a role in the patients' safe return to play. However, diagnostic test results may hinder clinical decision making if the test is unable to discriminate between patients with and without a concussion. Diagnosis of a concussion is challenging because there is not one tool that represents a gold standard. Current best practice is to use a multifaceted approach to concussion assessment.² The GSC, SAC, BESS, and ImPACT together form a quantifiable multifaceted concussion assessment. As demonstrated by this study, even a multi-faceted concussion assessment battery consisting of GSC, SAC, BESS and ImPACT carries a false positive rate of 81%. Even after removing BESS which carried the

highest lone rate of 62.5%, SAC and ImPACT together still gave a false positive rate of 54%. Clinicians should be able to rely on such battery to produce an accurate assessment. It is important for clinicians to be aware of the false positive rate of such a battery. This knowledge reinforces the role each clinician's judgement plays in interpreting these tests along with their clinical assessment of the athlete. The sensitivity and reliability of each test is vital in accurately diagnosing concussions. Further research is needed to explore the contributing factors to the false positive rate and to identify a concussion assessment battery which can more accurately isolate a concussion diagnosis.

A multifaceted approach to concussion diagnosis and management is emphasized in the most recent consensus statement on concussion in sport.² GSC, ImPACT, SAC, and BESS are the most commonly used tools to assess the various signs and symptoms which manifest after an athlete sustains a concussion.²¹ The concussion assessment battery used in this study is not the only battery in use, and although the individual assessments most commonly used, they are not the only acceptable methods of concussion assessment. It is the diagnostic standards set forth by the consensus statement that lack specificity. This is inherent because of the functional nature of concussions. The symptomology of concussion is nonspecific and widely present in the general population.

Concussions manifest in a variety of signs and symptoms. This fact in combination with lack of specificity in testing can lead to athletes suffering from injuries such as whiplash, mood disorders, balance disorders or inner ear pathology as having a brain injury.³² In addition, with the average GSC score on the Likert scale for a healthy athlete falling between three and ten, the concept of asymptomatic must be operationally defined before the rehabilitation goals outlined

are realistic.¹²

Athletes who have sustained concussions may underreport their symptoms to clinicians.¹¹ Report rates can only be expected to decline if athletes find themselves in a culture of misdiagnosis. There has been call for a change in the proposed consensus statement.³² The nonspecific guidelines set forth therein lead to broad diagnosis and narrow therapeutic treatment course.³² A false positive rate of 81% for a widely used and recommended concussion battery demonstrates too broad of criteria into the clinical diagnosis of concussion and therefore may lead to misdiagnosis, unnecessary treatment, and a decline in report rates.

APPENDIX A

Limitations

All participants were recruited from one Division I university in southeast Georgia. The target population was limited by which individuals had baseline concussion testing data available for later review. If a participant was missing a baseline score for any of the assessments within the concussion battery (SAC, BESS, ImPACT), he or she was excluded from the study. All participants were aware the study was evaluating the false positive rate of the concussion battery due to the title of the study. Participants were informed that study would have no influence on their athletic participation and they were directed to give their best effort on all tests. However, the knowledge that false positive rate was being tested may have influenced the effort put forth by the participant. There is no way to control for systematic errors that may have influenced results through hardware and software applications of the computerized neuropsychological testing.¹⁸

Delimitations

To better achieve the purpose of our study, a liberal definition of ‘healthy’ was used in our inclusion criteria. Participants who were mildly injured, but considered healthy enough to participate in the team training (game, practice, weights or conditioning) for the day were included in recruitment and reflected in the sample. Although orthopedic injuries can influence postural control and, in some cases, neuropsychological testing, we purposely selected these criteria because these athletes were still in participation and, therefore, at risk for suffering a concussion.²⁹ These athletes were included to increase the clinical applicability of the assessment. Similarly, we did not exclude athletes from the study based on history of concussion.

Such broad inclusion criteria were selected to more accurately mimic clinical concussion assessments. Should an athlete with current orthopedic injury or history of concussions be suspected of suffering a concussion during athletic participation, they would complete the same concussion battery that an otherwise healthy athlete would.

Assumptions

We assume that all participants gave full effort at their baseline testing. We have no way of knowing whether the participants attempted to sandbag their BESS and SAC baseline assessments with the hope that it would allow them to pass the same assessment when injured. If the participants did not give full effort at the baseline assessment, the overall false positive rate could be a misrepresentation. Likewise, we assume that all participants gave full effort on their study test day. Participants had no external motivation to do well on these assessments because they were not injured and their athletic participation was in no way influenced by the outcomes. We assume all athletes answered the health history questionnaire completely and honestly.

APPENDIX B

LITERATURE REVIEW

Introduction

More than 10 million traumatic brain injuries resulting in death or hospitalization occur annually across the globe.¹ In the United States, athletic participation accounts for 1.6-3.8 million mild traumatic brain injuries (mTBI or concussions) every year.¹ Concussions have been defined by the 4th International Conference on Concussion in Sport as “a complex pathophysiological process affecting the brain, induced by biomechanical forces.”³³ Concussions are further characterized by the following criteria: occur through a direct blow to the head or somewhere else on the body with the force transmitted to the brain, result in the rapid onset of transient neuropsychological symptoms lasting anywhere from a few minutes to months in length, result in neuropathological changes of a functional nature while no structural abnormality can be seen on standard neuroimaging studies, and lastly, concussion symptoms follow a sequential resolution and should be quantified with grading scales.³³ Clinical presentation of concussions may include loss of consciousness, but it is not required for clinical diagnosis. Other common symptoms of concussions may include headache, cognitive impairment, confusion, dizziness, and vision or balance problems. In most cases these symptoms will resolve completely over time, however, sustaining an mTBI may have long-term implications such as increased risk for future concussions and increased mild cognitive impairment with age.³ In addition to representing one of the most difficult clinical conditions to manage in sports medicine, TBI (mild through severe) is responsible for costs of US \$60 billion in direct medical and indirect costs.⁴ In the media, concussions have become the current issue challenging the

safety and future of individuals in high impact situations such as military combat and athletic participation.

Concussions are the most common TBI. In the United States, athletic participation accounts for 1.6-3.8 million mild traumatic brain injuries (mTBI or concussions) every year.¹

In high school athletic populations, 8.9-13.2% of injuries were concussions.^{34,35} Concussion rate of 2.5/10,000 athlete exposures was determined.³⁴ Specifically, competitions had a higher rate of concussions than practices and girls had a higher rate of concussions compared to boys.³⁴ Collegiate rate of injury was higher than high school injury rates.³⁶ When looking at concussions in football, Guskiewicz completed a study in 2000 and found that of the 17,549 football players, 5.1% sustained at least one concussion and 14.7% sustained a second injury in the same season.³⁷ Concussion rates in D III athletics were higher than D II and D I at .68, .69, and 4.49 per 1,000 AE respectively.³⁷ In 2003 the NCAA concussion study was published showing an increase in collegiate concussion rate from .7 to .81/1,000 AE.⁵

Clinical understanding of concussions and proper course of treatment have come a long way since 900 AD when the Arabic physician Rhazes first accurately described the entity of concussions as an “Abnormal transient physiological state without gross brain lesions.”³⁸ Rhazes' term 'Commotio Cerebri' was the common term from 900-1657 AD to describe what are now known as concussions.³⁸ This definition captured the concept of an outside force causing shaking in the brain within the skull. Furthermore, it established concussions as their own entity, distinguishing it from other brain traumas. Looking at 1700 AD to present time, many theories surrounding concussions have been hypothesized. Littre's 1705 AD hypothesis of circulatory failure due to cerebral venous congestion following a blow to the head was dismissed by Witkowski in 1877, while Berengario Da Carpi's theory that concussions result from an ebb and

flow of the nervous tissue in the skull has been incorporated into modern pathophysiologic hypothesis.³⁸ Scientific understanding of concussions has progressed throughout the years aided by developments in technology. Such advances have allowed researchers to look beyond characterization of concussion simply via clinical presentation of transient functional neurological disturbance.

In considering the nature of concussions, research has indicated that concussion symptoms demonstrate a functional change within the brain rather than a structural change. As such, cerebral concussions are followed by a complex cascade of ionic, metabolic, and physiological states. After a biomechanical injury to the brain, there is an influx in K^+ brought about by the combination of opening of voltage-dependent K^+ channels, disruption of neuronal membranes and axonal stretching. This influx of K^+ , increased by early release of glutamate excitatory amino acid (EAA), subsequently causes an activation of kainate, N-methyl-D-aspartate (NMDA), and D-amino-3-hydroxy-5-methyl-4-isoxazole-propionic acid (AMPA). As extracellular K^+ continues to increase, additional neuron depolarization takes place, and more glutamate is released which continues the cycle compounding the extracellular K^+ . Glutamate and K^+ spikes can be detected within the first ten minutes after injury. The brain responds to this process with a period of spreading depression that is hypothesized to account for loss of consciousness, amnesia, and cognitive dysfunction. At this time, there is increased activity of membrane sodium-potassium pumps in an effort to reestablish homeostasis within the cells. The cell reaches a state of hyper glycolysis in an effort to produce more ATP to power the pumps. Lactate production and impaired mitochondria function work against ATP production leaving the cell with decreased energy. As the mitochondria pulls Ca^{2+} into the cell, the influx can, in essence, cause neurofilament compaction inhibiting transmission. Ca^{2+} within the cell also causes

critical enzyme activation and initiation of apoptosis. This calcium influx can be detected up to 4 days post injury. After a concussive blow, cerebral blood flow is decreased up to 50% and remains at this depressed level for up to 10 days. In an environment that is already experiencing hyperglycolysis, decreased cerebral blood flow may cause neurocognitive deficits. After the initial glutamate influx seen in the first 30 min, cerebral glucose is diminished for two to four days. The brain is now in an energy crisis because the supply cannot keep up with the demand. Even with this detailed account of the pathophysiologic process behind concussive brain injuries, it is difficult to match the clinical signs and reported symptoms with one of the steps of these underlying processes.³⁹ This time of energy crisis demonstrates a period of metabolic vulnerability during which the brain is more susceptible to further injury. As evidenced by the pathophysiology of a concussion, changes that occur are not structural and thus cannot be diagnosed by CT scan or MRI imaging.

Concussions may present with altered consciousness and a sampling of additional symptoms including, but not limited to: headache, dizziness, amnesia, sensitivity to light, sensitivity to noise, irritability, vision abnormalities, a feeling of foginess, and trouble concentrating. Other objective signs indicating that an athlete might be suffering from a concussion are balance deficits and delayed cognitive function. Although there is no standard presentation for concussions, research shows an average change in symptoms and function with gradual resolution over time. Loss of consciousness (LOC) is not a required marker to diagnose a concussion; however, when loss of consciousness has occurred after a blow to the head, a concussion is inevitable. On average, only 8%-19.2% of concussions result in loss of consciousness (LOC).^{37,40} Headache is overall the highest reported symptom after concussion at 86%-94%.^{34,37,41} Dizziness is also one of the highest reported symptoms at 64%-75.6%.^{34,37,41}

Assessments

There are a number of tools that have been developed to track and quantify the signs and symptoms of concussions for the purpose of ensuring a safe recovery and return to play. A few of these diagnostic tests include grading symptom checklists, Standardized Assessment of Concussion (SAC), Sensory Organization Test (SOT), Balance Error Scoring System (BESS), computerized Immediate Post-concussion Assessment and Cognitive Testing (ImPACT), and the pen and paper military designed automated neuropsychological assessment metrics test (ANAM). Clinicians typically select a handful of these tests creating a concussion assessment battery. Before the start of play, each athlete should complete the battery supplying the clinician with customized baseline scores.

To quantify concussive symptoms, clinicians may use a graded symptom checklist (GSC) which lists several symptoms each with a likert scale of severity. Symptoms are graded from mild and moderate to severe. With this tool, the clinician can track each symptom on a day to day basis and monitor resolution. On average the score for GSC increases in severity by 20 points following a concussion and these symptoms may resolve in an average of 3.24 days.^{6,8,9} Furthermore, 91% of athletes achieve baseline GSC in 7 days, leaving only a small percentage facing prolonged symptom recovery.¹⁰ A strength of the GSC is its high sensitivity (89%) and specificity (100%).⁶ The major limitation to GSC is lack of honesty during the self-report.

In an attempt to diagnose concussions by assessing balance deficits, the balance error scoring system (BESS) and sensory organization test (SOT) are commonly used. Somatosensory, visual, and vestibular systems all contribute to postural control and are the aspects objectively examined in the SOT. The comprehensive report is broken down into an equilibrium score, sensory analysis, strategy analysis, and center of gravity alignment. The

equilibrium score is a representation of postural stability maintained during all six conditions while sensory analysis ratios signify impairments of each sensory system individually. Strategy analysis is the report of ankle and hip movement while maintaining balance. Healthy individuals tend to show more movement of the ankles, while those who have impairment demonstrate increased hip movement. Finally, the center of gravity alignment in reference to the center of the base of support is recorded. SOT is a comprehensive static postural control assessment. A balance score change of 3.17 (balance composite), 3.47 (visual), and 6.95 (vestibular) below baseline values is representation of significant postural change.²⁷ SOT is 61.9% sensitive in detecting deficiency with concussions; however, it is not without its limitations. Because of the size of the instrumentation, SOT is not a clinically accessible sideline assessment tool. In addition, it is not a tool able to measure balance throughout functional tasks.⁴²

The balance error scoring system (BESS) was originally created to assist clinicians in diagnosing concussions by quantifying balance deficits. As such, BESS was not intended to be used as a tool used to determine safe return to play. The correct use of BESS assessment includes accurate baseline testing as well as a post-concussion balance assessment. The athlete is instructed to hold three different positions (feet together, single leg, and tandem stance) for twenty seconds each with their eyes closed and hands on their hips. Each position is then repeated on an AIREX piece of foam to increase the difficulty. Errors include opening eyes, hands coming off iliac crest, heel or forefoot coming off the ground, stumbling/step/fall, hip exceeding 30 degrees of abduction, and being unable to hold test position for 5 seconds. These errors are scored by the clinician during each of the 20 second periods. If the athlete is unable to hold test position for more than 5 seconds, they will receive a score of 10 for that portion of the test. Average baseline score sits at 10 points.¹³ When compared to athlete's baseline, athlete's

post-concussion BESS score increases an average of 6 points post concussion. Typically BESS scores return to baseline 3-5 days post concussion.^{6,13} Several studies have been completed assessing reliability and sensitivity of BESS. Although BESS compares to SOT for validity and demonstrates moderate to good reliability, a significant practice effect is demonstrated.^{13,14} In 2009, Finnhoff established intra-rater reliability to be 0.74 and inter-rater reliability 0.57.¹⁵ As established previously, the average change in BESS score post-concussion increases by six points, yet based on reliability scores and information calculated via minimum detectable change, clinicians would have to observe an increase of 7.3 points if they also scored the baseline exam. Similarly, if a different clinician scored the baseline, post-concussion score would have to be increased by 9.3 points to be considered a reliable change.¹⁵ This is a significant inherent limitation of the test. BESS only demonstrates 91-97% specificity but only 34% sensitivity.¹³ An additional limitation to BESS testing is its ability to be influenced by factors such as tape, braces, age, and even fatigue.¹³ An additional limitation to BESS testing is its ability to be influenced by factors such as tape, braces, age, and even fatigue.¹³

Although BESS is widely used, it is not a very accurate assessment of fine postural deficits and it has little practical implications of balance recovery. Functional testing may be more appropriate to assess recovery. Balance and gait testing are means of objectively assessing the stability of an athlete. Through their use, the subjectivity of the assessment and inconsistencies in scoring are being eliminated, ensuring a standardized assessment and informed return to play plan.

Visual, somatosensory and vestibular input collectively influences an individual's postural control. In normal situations, the information from the visual and somatosensory is enough to maintain balance, but vestibular input is necessary when the others are disrupted or

providing conflicting information.⁴³ Following TBI, communication between the three systems is lost, causing moderate to severe postural instability in either the anterior-posterior direction, medial-lateral direction, or both. Symptoms include: dizziness, vertigo, tinnitus, lightheadedness, blurred vision, or photophobia. These symptoms are all associated with visual, vestibular or somatosensory orientation.⁴³

An entropy analysis of COP readily detected postural instability in athletes at least 10 days post-concussion.⁴⁴ Immediately following concussion, the area of COP data increases with data length at least linearly for data length up to two min; therefore, at least two min data is required in order to reliably quantify the effects of mTBI on postural instability.⁴⁴ Therefore, it is suggested that tests using 20 second intervals (ex. BESS) are not a useful and thorough analysis of postural control.⁴⁴

Similarly, motor stability, particularly balance control when attention is divided, can be impaired for up to one month following what is sometimes considered to be a mild concussion. Evaluation of concussion should include assessments of complex motor tasks which test the demands required of an athlete returning to play.⁴⁵ In one study, concussion participants performed worse for gait velocity, propulsion and braking. An alteration in gait termination has been observed, independent of velocity, that continued for at least 10 days post-injury despite recovery on all aspects of a traditional clinical assessment battery.⁴⁶

Williams found, through a three-dimension gait analysis, that people with TBI walked with a significantly slower speed than matched healthy controls. Significant differences were found between groups for cadence, step length, stance time on the affected leg, double support phase, and width of base of support. The most frequently observed biomechanical abnormality was excessive knee flexion at initial foot contact. In this study of 41 participants, gait

abnormalities did not seem to fit into distinct patterns. Slow walking may have been a result of inability to increase gait speed rather than impaired postural control.⁴⁷ This demonstrates that trauma to the brain not only has an effect on cognition, but also influences motor function in tasks as simple as walking. Furthermore, the lack of distinct patterns across the participants reinforces the individuality of how each patient may react to each trauma in a unique and diverse way.

To further examine the influence head injuries have on motor tasks, Shiu-Ling Chiu examined gait inter-joint coordination during divided attention and obstacle crossing. By assessing gait during divided attention and obstacle crossing, Chiu was able to determine a more accurate assessment of functional movement. He determined that the ability to modulate inter-joint coordination patterns when accommodating to gait perturbations is affected by concussion. While the data suggests that both hip–knee and knee–ankle inter-joint coordination are critical for accommodating obstacle crossing and dual-task walking in the stance phase, the knee–ankle inter-joint coordination seems to be a factor in swing phase neuromuscular control.⁴⁸ In activities of daily life individuals may be required to navigate obstacles and complete cognitive tasks while walking. Chiu was able to assess and demonstrate how a concussion may influence and alter their patterns of coordination using tasks that more accurately represent demands of activities of daily life.

Together these studies demonstrate the benefit of technology in assessing posture and gait. Fine changes can be seen in center of pressure, gait termination, and even joint-coordination, all of which are best quantified objectively by sensitive instrumentation. These assessments are able to identify fine changes of motor control which a clinician would not be able to quantify just through observation.

Standardized assessment of concussion (SAC) is a widely used assessment of cognition and memory. This tool is most sensitive when completed within 24 hours of the suspected concussive blow. Orientation, immediate memory, concentration, and delayed recall are all aspects of the assessment. The test is scored out of 30 possible points and is then compared to the athlete's pre-activity baseline score. On average, baseline scores are 26.4.¹⁶ Post-concussion, scores can be expected to fall another three to four points from the baseline assessment.^{5,16} Although SAC has good sensitivity (0.80) and specificity (0.89-0.98), scores consistently returning to baseline after 48 hours or after three trials demonstrates a practice affect that may sway clinical significance of results.^{5,6,16} Practice affect is the major limitation with SAC. In a his study published in 2001, McCrea found that even a drop of one point from preseason baseline score on the SAC was 95% sensitive and 76% specific in accurately classifying injured and uninjured subjects.¹⁷ "These findings also suggest that the decline in SAC score by injured subjects immediately after concussion represents the direct effect of injury on cognitive functioning and is not due to other extraneous factors often encountered on the sport sideline (eg, fatigue, crowd noise, distractibility)."¹⁷

Automated neuropsychological assessment metrics (ANAM) was developed to assess the functional and cognitive changes in attention, concentration, reaction time, memory, processing speed, decision making, and executive functioning. Baseline for testing in neurocognitive assessments such as ANAM is a necessity because test scores may vary based on fatigue, motivation, and intensity of training, as well as sex, standardized test scores, and sport.³⁰ This demonstrates that there are too many variables factoring into neuropsychological test scores to accurately compare an athlete's post-concussion test score to a standard age-matched average. It also demonstrates the need to complete baseline testing as close to season environment as

possible. An athlete may show a failing test score on ANAM because of the fatigue of regular season play if they completed their baseline testing while out of season.

Computerized neuropsychological testing (CNT) is also growing in popularity. The computerized Immediate Post-Concussion Assessment and Cognitive Testing test battery (ImPACT) is able to quantify decrease in neurocognitive function in 36-38% of athletes who reported being asymptomatic.¹⁹ ImPACT comprehensively measures multiple aspects of cognitive function including attention span, working memory, sustained and selective attention time, response variability, non-verbal problem solving, and reaction time. These six individual scores are calculated to produce a composite score represented by verbal memory, visual memory, processing speed, and reaction time. ImPACT also has the option of recording a concussion and health history, as well as post-concussion symptom score (PCSS). Although pen and paper assessments of neurocognitive function have demonstrated return to baseline in approximately 5-7 days, ImPACT has shown deficits in neurocognitive function up to two weeks post-concussion.^{10,20} Furthermore, in adolescent populations impact identifies deficits up to 21 days post-concussion.⁴⁹

On average, a clinician using a concussion assessment battery readily available (which includes both a balance and cognitive assessment) will observe the athlete return to baseline scores across all tests in seven to ten days. Through recent research it has been demonstrated that these baseline numbers may not accurately represent comprehensive healing post-concussion. In adolescents, a widespread change in white matter microstructure can still be seen two months after a concussive blow.⁵⁰ In addition, using diffusion tensor imaging, one can quantify whole-brain fractional anisotropy values significantly increased, and mean diffusivity values decreased.⁵⁰ In Slobounov's research, all 160 of the concussion patients were symptom free in 10

days, yet visual kinesthetic recovery took up to 30 days in athletes who had suffered two or more concussions.⁵¹ A more accurate assessment of postural control and movement strategies following a sports-related concussion can be gathered through the utilization of force plates. Gait termination can detect both acute and lingering motor control strategy alterations following concussion that the BESS test fails to pick up on. Alteration in gait termination performance, independent of gait velocity, persisted for at least 10 days post-injury despite recovery on all aspects of the traditional clinical assessment battery.⁴⁶ These findings suggest that lingering irregularities in concussed individuals may go undetected using conventional assessment and RTP guidelines which puts the athletes at risk for recurrent concussions.

There are a growing number of incidents of recurrent and multiple concussions in athletics. One study by McCrea suggests that six percent of athletes start their collegiate career with three or more concussions.⁵² Athletes who have suffered multiple mTBIs experience slower recovery. Second impact syndrome has also become a concern for fatality in athletes. Standard concussion baseline tests and return to play protocols are not sensitive enough to pick up on lingering deficits following concussions. Unfortunately, the average clinician does not have access to diffusion tensor imaging, virtual reality system and “flock of birds” motion analysis or force plates to run these more sensitive tests. Knowing if an athlete is projected to have a prolonged recovery following concussion would have significant clinical implications. However, there is conflicting evidence on the topic, mostly due to an inconsistent definition of prolonged recovery. In some cases it is classified as more than ten days and others classify it as past the 14-day mark.

In an attempt to identify factors contributing to prolonged recovery, Lau (2012) examined 108 concussed football players who had been referred out to a concussion clinic. The purpose

was to determine cutoff scores in neurocognitive and post-concussion symptom cluster scores when classifying protracted recovery in concussed athletes. Prolonged recovery was set at greater than 14 days (46.3%). ImPACT testing was completed two post injury. Lau found no statistical difference between group participants in pre injury history of migraine, headache, ADHD, learning disability, and one previous concussion. However, cutoffs were significant for: migraine ($p=0.01$), cognitive ($p=0.04$), visual ($p=0.01$), and processing speed ($p=0.02$). These measures correctly identified 80% of concussed athletes with prolonged recovery. Specific cutoff scores on post-concussion ImPACT and post-concussion symptom scale may help to set numerical thresholds for clinicians to predict which concussed athletes will have a protracted recovery.⁵³

Meehan also sought to identify risk factors that predispose patients to experience prolonged recovery. However, he defined prolonged recovery as still experiencing symptoms after 4 weeks. Meehan collected data on 172 patients seen in two sport concussion clinics, presented within 3 weeks of injury. The results demonstrated significance between PCSS initial visit between patients with and without symptoms for more than 28 days ($p<0.01$) as well as co linearity between total PCSS score and total ImPACT score. However, only PCSS score is independently associated with prolonged symptoms after recovery.⁵⁴

McCrea categorized the players in the prolonged recovery group if their change score on the GSC from baseline through day seven was six or higher. Results demonstrated acute injury characteristics of unconsciousness (4.15x more likely), posttraumatic amnesia (1.81x more likely), retrograde amnesia (2.19x more likely), and an increase of 20 points or more over baseline on GSC at the most acute time point following concussion (2.56x more likely) were the factors most strongly associated with prolonged recovery. Subjects in prolonged recovery also

demonstrated deficits in SAC score through day seven.⁵⁵ Unconsciousness, post traumatic amnesia, retrograde amnesia, and 20+ point increase on GSC are all assessments that are made shortly after impact. No extra equipment or time consuming testing is needed to indicate increased risk for prolonged recovery.

In an attempt to explore the associations between the presence of posttraumatic migraine characteristics and a history of concussion, Mihalik compared balance performance, cognitive function, and symptom recovery in concussed athletes with no headache, those with posttraumatic headache, and those with characteristics of posttraumatic migraine following a sport related concussion. Posttraumatic migraine was defined as a headache and 1+ of following symptoms: nausea, photophobia, or phonophobia. Athletes who experienced posttraumatic migraine took longer to recover in terms of overall symptom severity, including cognitive, neurobehavioral, and somatic symptoms and demonstrated elevated overall post injury symptom severity compared with the other groups. There may be the potential for pharmacological interventions during the acute recovery phase in athletes suffering from post-concussion migraines. Knowing that these migraine symptoms can persist up to seven days, pharmacological agents may allow for more rest from acute symptoms allowing for faster healing. Along with this, there were no group differences in SAC and BESS related to symptom score. This suggests that concussion may functionally affect the brain in a global fashion, resulting in deficits in mental status and balance evaluations that likely are not affected by the specific symptoms used to categorize the athletes in this study. There are significant clinical implications demonstrated in the results of posttraumatic migraine characteristics leading to prolonged symptom recovery after sport-related concussion. In addition, although headache reporting at baseline did not differ between the sexes, female patients were more likely to report characteristics of posttraumatic

migraine after concussion than were males.⁸ With the knowledge of which cluster of symptoms may result in prolonged recovery, the clinician may more effectively create a treatment plan and facilitate recovery through use of pharmacological intervention early on.

It has been determined that concussions may result from direct or indirect biomechanical forces transmitted to the brain.³³ Through the use of accelerometers, the rotational and impact forces applied to the head during an impact can be measured and recorded. By examining this data and matching acceleration forces to collisions that resulted in concussions, researchers have tried to identify the acceleration threshold of concussions.

A study by Mihalik in 2007 investigated the difference in severity between head impact intensity during various event types in NCAA football athletes. He found the mean acceleration (g) of head impacts during helmets only practice was 22.47 g while impacts in scrimmages and games was only 21.12 g.⁵⁶ This demonstrates that light days in practice may pack more punch than game day. Limiting “light” contact practices per week may not address the real problem behind head impacts and mTBI. On average Mihalik’s study recorded acceleration forces for DI football players at 21-23 g. Although previous studies had suggested a peak acceleration of 78g to be the theoretical concussion threshold, only .35% of impacts greater than 80g resulted in a concussion during Mihalik’s study.^{56,57} Similar research has been done at the high school level examining accelerative impact forces during football events. At the high school level mean linear acceleration recorded in both practices (23.26 g) and games (24.76 g) exceed the forces observed in collegiate competitions.⁵⁶ Once again, this demonstrates that even younger athletes are capable of delivering and receiving blows of high acceleration despite the perceived lower level of play. Breedlove’s examination of sub concussive blows found there was a stepwise regression that demonstrated the number of hits sustained indicates abnormalities in fMRI scans, which

measures oxygenated blood flow to the brain. Alterations in blood flow indicate a functional adaptation, not a structural change. This would support the notion that it is beneficial to limit the number of contacts in playing environments. Limiting the number of full contact practices during the week may decrease the instances of concussions.⁵⁸ With studies published supporting opposing views, more research needs to be done to gain an accurate assessment of subconcussive blows.

Eisenberg specifically looked at a younger population to assess if children with a previous history of concussion have a longer duration of symptoms after a repeat concussion than those without such a history. All subjects in this study answered a 16-item GSC and sought medical care at an emergency facility within 72 hours of injury. Predictors of longer symptom resolution time were found to be previous history of concussion, age thirteen and older, initial RPSQ score >18, females, history of depression, no LOC, and an abnormal neurologic exam. Patients with concussions in the last year had 3 times the median duration of symptom resolution time; while patients with two or more previous concussions had double the median duration of symptoms. These results support the theory of dose-response as well as temporal vulnerability.⁵⁹

Common trends in the literature include history of concussion, PTA, LOC, and an increased symptom score of 20 or more increasing an athlete's chance of facing a prolonged recovery. Again, each study may define prolonged recovery different than the last so it is important not to lump all data together unless it is standardized.

Mismanagement of mTBI can be life threatening or life altering. As evidenced through the neurometabolic cascade, there is a period of metabolic vulnerability due to increased demand and decreased supply of oxygen to the brain. This period of vulnerability lasts approximately seven to ten days. During this time of metabolic vulnerability, 70.8%-91.7% of repeat

concussions occurred within the first 10 days and 75% of repeat concussions occurred within 7 days.^{9,60}

With each successive concussion an athlete experiences, there is an expectation of worse presentation and prolonged resolution. Although completely symptom free 10 days after injury, athletes who have experienced two or more concussions show balance deficits at least 30 days after injury. Furthermore, the athletes with a history of 2+ concussions demonstrate significantly slower rates of resolution of neurological functions after the second mTBI.⁵¹ Athletes with three or more previous concussions performed more poorly on Verbal Memory composite score than athletes with fewer concussions.⁶¹ Once an athlete has suffered from their third concussion, they are 3-6x more likely to suffer additional concussions.⁶⁰

To identify long-term effects of concussions in the retired football population, Guskiewicz developed a survey to collect data including history of concussions and current health status. All participants had spent at least two years playing in the National Football League and were over the age of 50. Specifically, the study was completed to investigate the relationship between clinical depression and history of concussion, and to identify possible associations between the prevalence of Alzheimer's and mild cognitive impairment (MCI) in former athletes with a history of concussions.^{3,62}

The standing literature linking Alzheimer's to mTBI during Guskiewicz's study claimed individuals who have experienced mTBI had a 2.3x-increased risk of developing Alzheimer's.⁶³ Overall, NFL retirees had a high prevalence of early onset Alzheimer's disease, yet no relationship was found between onset of Alzheimer's and number of previous concussions.³ Of retirees who responded to Guskiewicz's survey, those who had suffered three or more concussions were 5x more likely to suffer from mild cognitive impairment and 3x more likely to

suffer from memory problems.

Previous research demonstrates those who have suffered a TBI face a 1.5x increased risk of depression.⁶² Guskiewicz determined that retired NFL players who had suffered one to two concussions were 1.5x more likely to suffer from depression and players who suffered three or more concussions were 3x more likely to be diagnosed with depression.⁶² Although the initial symptoms of a concussion are transient, at some point retired athletes seem to be paying for a life of impact. Clinical depression is life altering not only for the one diagnosed, but also for friends and family members. It can disrupt daily routines including the ability to hold a job, which comes with its own lasting repercussions. One of the limitations to this study is the retrospective self-report design of the survey. In an effort to verify the reported data, the same survey was also sent to a spouse or relative. A follow-up study was done in 2012 to examine the reliability. The survey and data was considered to have moderate reliability with 62.1% of players demonstrating consistency in their concussion history between 2012 and 2005.⁶⁴

McAllister found repetitive head impacts over a single season of Division I collegiate sports do not have widespread short-term detrimental effects on all athletes. However the article does suggest that there may be a subgroup of athletes for whom repetitive head impacts affect learning and memory at least on a temporary basis.⁶⁵ Gysland was also interested in the effects of sub concussive blows. He examined 46 DI athletes' pre- and post-competitive season looking for changes from baseline values demonstrating effects of sub concussive blows sustained throughout the playing season. On average each player sustained more than 1000 blows over the course of the season, none of which resulted in a clinical diagnosis of concussion.³⁰ An extensive battery was used for evaluation including ANAM, SOT, BESS, SAC, and GSC. The SOT composite was significantly lower, BESS scores decreased statistically significant, and GSC also

showed an increase on average of one. Repetitive sub concussive head impacts over a single season do not appear to result in short-term neurologic impairment.⁶⁶

Athletes at every level of competition are faced with concussions, yet there has been some debate over which level of competition is at higher risk. There are obvious differences in the physical stature and training levels between each level of play. Children may begin participating in youth sports around the age of six. During junior high and high school, athletes are largely under the age of 18 and their bodies are still maturing and developing as play intensity increases. Collegiate sports are considered to have a much more competitive and strenuous playing season across all divisions. Once athletes make it to the professional level, their bodies and technique have already developed at which point they are capable of producing much greater forces. Following this concept would lead to the assumption that greater forces are produced in higher levels of competition by the bigger and stronger athletes leading to increased rate of concussions as the level of play increases.

For some years health care providers have endorsed cognitive rest following a concussion. Considering both mental and physical exertion can change the metabolic activity of the brain, there is potential for cognitive activities to exacerbate the metabolic mismatch after concussion.⁶⁷ Patients who suffer from a concussion will often complain of worsening symptoms following both physical and mental activity; however, little research has been done on the benefits of rest and the role it plays in symptom resolution. Studies have presented everything from no independent relationship between recommendation for cognitive rest and the duration of symptoms, to significant improvement in the group who rested suggesting rest is beneficial to concussion recovery.^{68,69} In Majerske's study on cognitive rest published in 2008, athletes with concussions were retrospectively categorized into an activity level and periodically asked to

complete the ImPACT test. The five groups were assigned the following levels of activity: no school or exercise activity (0), school activity only (1), school activity and light activity at home (2), school activity and sports practice (3), and school activity and participation in a sports game (4). Although there was not a statistically significant relationship between symptom scores and levels of activity following injury, the patients who participated in school activity and light home activity (group 2) did better overall on the neurocognitive assessment.⁶⁷ As research in this area is limited, the scientific understanding of rehabilitation activity in the setting of concussion is inconclusive at best.

The first step in proper management of a concussion is proper education. Although symptoms such as headache, dizziness, and confusion have become hallmark indicators of concussions in the sports medicine world, athletes often fail to acknowledge them as such. If an athlete does not know how to identify the signs and symptoms of an mTBI, they will not seek help. Athletes in all levels of participation should be provided with a basic concussion education. Coaches and parents should also be well informed so they are able to step in and protect an athlete that may be suffering from a concussion.

Athletics can be very physically demanding and athletes may experience one or more symptoms indicative of concussion on any given competition day. Additional markers of a concussion such as fatigue and emotional variation including sadness and irritability also change day to day. Tumbling often produces headaches and dizziness in gymnasts and cheerleaders leaving them less inclined to report such symptoms following a blow to the head because of the belief that it is normal. An exit survey showed that 26.1% of collegiate athletes sustained a potential concussion during their collegiate career that went unrecognized.⁷⁰

The second step in proper treatment of a concussion is reporting the symptoms after they

have been identified. In a survey of collegiate athletes, knowledge did not translate to report rate. Only 17% of athletes reported sustaining a concussion while 48% admitted concussive symptoms after receiving a blow to the head during play.⁷¹ At the high school level 53% of concussions go unreported and untreated.⁵² A survey given to high school athletes demonstrated the disconnect between knowledge of concussions and report rates: 100% of the groups recognized an altered mental status as a symptom of a concussion, yet 66% said they would continue to play regardless.⁷² Reasons athletes may give for not reporting a suspected concussion include not wanting to let their team or coach down, not recognizing the seriousness of concussions, and not wanting to be held out of play. Positive attitudes toward reporting have the greatest impact on intention to report concussion symptoms. Concussion education initiatives should focus on cultivating attitudes and beliefs among athletes, coaches and parents to encourage better care-seeking behaviors among young athletes.⁷²

There are more than 3.5 million youth coaches throughout the United States, yet there is not a standardized certification to hold a coaching position. Each state regulates coaching requirements individually. Often times the coach is the first responder to medical crises during sporting events because of the lack of athletic trainer coverage. Recent surveys have demonstrated that less than half of coaches have first aid or CPR certification.⁷³ The concern becomes that these coaches are not prepared to identify harmful situations and may encourage an athlete to continue to play despite signs of a concussion. When asked, 42% of coaches thought that loss of consciousness was required to diagnose a concussion.⁷³

Application

A wide variety of tests have been developed to objectively measure changes in a patient who has received a concussive blow. Test results may lend themselves to assist in diagnosis or

play a role in the patients' safe return to play. However, diagnostic test results may hinder clinical decision making if the test is unable to accurately discriminate between patients with and without a concussion. These concerns may present themselves if the results are inconsistent with the clinical case. GSC, SAC, BESS, and ImPACT all represent results as a quantitative score. Clinicians use the scores from these assessments, along with others, to diagnose concussions by requiring that the result be categorized as negative or positive. Their classification is based on comparison of the results to a recognized cutoff point. Cut off points may either be baseline scores for each individual patient or in cases with no baseline data, normative data is sometimes used.

Sensitivity is the probability of a positive test outcome in a patient with the specified pathology or disease- also known as the true-positive rate; a test that is positive in six of ten patients with a disease has a sensitivity of 0.6. In short, sensitivity denotes how well a test identifies the disease. Specificity is the probability of a negative test outcome in patients without the specified pathology or disease- also known as the true-negative rate; a test that is negative in seven of ten patients without disease has a specificity of 0.7. A test with low specificity diagnoses many healthy patients as having the specified disease. It is the complement of the false-positive rate. Together, the specificity and the false positive rate combined accounts for all of the patients.

Diagnosis of a concussion may be challenging because there is not one tool that represents a gold standard. Clinicians commonly use a number of tests when evaluating patients with concussion. The specific test methods vary but often include symptom inventories, posture assessment, and neurocognitive examinations. The sensitivity and reliability of each test is vital in accurately diagnosing concussions.

The balance error scoring system was originally created to assist clinicians in diagnosing concussions by quantifying balance deficits. BESS was not intended to be used as a tool used to determine safe return to play. Several studies have been completed assessing reliability and sensitivity of BESS. Although BESS compares to SOT for validity and demonstrates moderate to good reliability, a significant practice effect is demonstrated.¹³ As established previously, the average change in BESS score post-concussion increases by six points, yet Finnhoff established in 2009 intrarater reliability to be 0.74 and interrater reliability 0.57.¹⁵ Clinicians would have to see an increase of 7.3 points if they also scored the baseline exam, and if a different clinician scored the baseline, post-concussion score would have to be increased by 9.3 points to be considered a reliable change.¹⁵ Yet as previously stated, BESS only increases by an average of six points. The test scoring method does not match up to its low reliability. There was a significant decrease in scores over a playing season suggesting BESS also has a significant practice effect.¹⁴

Although computerized neurological testing has grown in popularity over the past few years, there are some concerns with relying too heavily on the results. ImPACT, exhibits a sensitivity of approximately 79-93% when classifying individuals as concussed, but misclassified 22-46% of the healthy sample as impaired. An additional concern with ImPACT is the evidence of a moderate practice effect. Hutchinson examined athletes with musculoskeletal injuries and athletes with concussions using the ANAM. Even though the athletes with musculoskeletal injuries had not been diagnosed with a concussion, they performed significantly worse on the ANAM assessment than the healthy controls. As expected, concussion also did significantly worse than the control group. Fatigue, sex and season of play also sway ANAM scores.³⁰ Evidence of these influencing factors during neurocognitive testing presents a concern

for false positives.

In 2007 Broglio published a study in which he investigated the sensitivity of neurocognitive injuries functioning, concussion-related symptoms, and a postural control evaluation in concussed collegiate athletes. Individual tests and the complete battery were evaluated for sensitivity to concussion. ImPACT testing, including GSC, was found most sensitive to concussion 79.2 %. Self-reported symptoms came in second at 68.0% sensitivity and the postural control evaluation (SOT) even lower at 61.9%.⁷⁴ However, when the complete battery was assessed, sensitivity exceeded 90%.⁷⁴ The sensitivity and reliable change of an alternate battery (ANAM, SOT, and GSC), was examined by Register-Mihalik in 2012. Once again, the sensitivity of the entire battery was significantly higher than the individual rates.

Currently recommended concussion assessment batteries accurately identified decrements in one or more areas in most of the athletes with concussion. Sports-related concussions should be approached through a multifaceted assessment with components focusing on individual aspects of the athlete's function. Clinicians should use diagnostic tests as an addition to their clinical examination. Clinical examination should never be replaced by an objective test. If athletes are completing baseline testing before their freshman season begins, and then asked to achieve their baseline score mid competitive season after musculoskeletal injuries or other factors, deficits in their score could be contributed to a number of things and not mTBI.

APPENDIX C

IRB Documents

GEORGIA SOUTHERN UNIVERSITY INSTITUTIONAL REVIEW BOARD PROPOSAL NARRATIVE

Personnel. Primary investigator- Caitlynn Hellwig will be responsible for project design and conception, recruitment, testing, statistical analysis, and reporting results. Secondary investigators, Kelsey Evans, will be assisting in data collection by administering and proctoring a number of the concussion assessments. Investigators will have access to information as given in informed consent. Dr Jody Langdon will be assisting in statistical analysis- access to test scores after personal information has been coded and will be acting advisor over the study and will have access to information as needed and allowed by informed consent. Dr Thomas Buckley, Dr Barry Munkasy and Vicky Graham will be advising and serving on the thesis committee.

Purpose. The purpose of the study will be to determine the false positive rate of a concussion battery in healthy Division I collegiate student-athletes. Based on the 4th Consensus statement published in 2013, the International Conference on Concussion in Sport support a multifaceted approach to concussion assessment, which incorporates graded symptom inventories, balance assessment, and neurocognitive examinations. The accuracy of each test is vital in correctly diagnosing concussions. We hypothesize that healthy Division I collegiate athletes will fail the concussion battery. This will determine the specificity and false positive rate of the concussion battery.

Literature Review. In the United States, athletic participation accounts for 1.6-3.8 million mild traumatic brain injuries (mTBI or concussions) every year.¹ A multifaceted approach to concussion diagnosis and management is emphasized in the fourth consensus statement on concussion in sport.² The specific test methods vary but often include self-reported symptom inventories checklists, posture balance assessment, and neurocognitive examinations.⁶ The multifaceted assessment battery is highly specific, sensitivity at the time of injury of 94% accuracy in classifying injured participants on balance, cognition, memory, concentration, and symptoms. However, questions have been raised on the specificity of the battery; in computerized neuropsychological testing alone, 46% of healthy participants were misclassified by one or more measures and were misclassified as having a concussion. Diagnosis of a concussion may be challenging because there is not one tool that represents a gold standard. Clinicians commonly use a number of tests when evaluating patients with concussion. The specific test methods vary but often include symptom inventories, cognitive assessment, postural control assessment, and neurocognitive examinations. The sensitivity and reliability of each test is vital in accurately diagnosing concussions.

Outcome. Participants will likely receive no direct benefit from participating in this study. We expect healthy Division I athletes will fail one or more of the assessments resulting in a failed

battery. International recommendations are to remove an athlete who is suspected of concussion from play and use a battery of tests to assist in diagnosing the severity of the concussion. Should the athlete fail the battery, a return to play protocol is warranted before the athlete can return to participation. A recognized false positive rate will establish specificity of the battery when testing healthy Division I athletes. This may generate understanding there is a need for a more comprehensive test battery, which is not just highly sensitive, but also highly specific.

Describe your subjects. We aim to recruit fifty male and female Division I collegiate athletes between the ages of eighteen and twenty-four. The inclusion criteria for this study will be any student athlete who is currently an active member of intercollegiate athletics or cheerleading and healthy enough to participate in team training (practice, weights, game, conditioning). The exclusion criteria will be if they are currently in a concussion return to play protocol, and if there is not baseline scores on file for BESS, SAC, and ImPACT. In addition, if the participant's ImPACT test scores return as invalid, the participant's entire battery will be excluded. Participants who participated in previous concussion study with GSU (H14119).

Recruitment and Incentives. The primary investigator will be providing the athletic training staff with sign-up sheets for athletes who are interested in participating in the study. The athletes who are interested will provide their name and email. The primary investigator will then collect the contact information from the athletic trainer and contact the athletes to schedule their individual testing day and time. There will be no incentives given to participants.

Research Procedures and Timeline. Participants will first complete informed consent and health history questionnaire. The following assessment tools will be completed taking no more than a total of 90 minutes: graded symptom checklist (GSC), Standardized Assessment of Concussion (SAC), Balance Error Scoring System (BESS), and ImPACT. They are completed as follows:

GSC will be completed interview style with the clinician asking the participant to grade each of the 22 symptoms on a 7 point scale of severity. (Appendix B)

To complete the BESS assessment the athlete is instructed to hold three different positions (feet together, single non dominant leg, and tandem stance) for twenty seconds each with their eyes closed and hands resting on their hips. Each position is then repeated on an AIREX piece of foam to increase the difficulty. Errors include opening eyes, hands coming off iliac crest, heel or forefoot coming off the ground, stumbling/step/fall, hip exceeding 30 degrees of abduction, and being unable to hold test position for 5 seconds. These errors are scored by the clinician during each of the 20 second periods. If the athlete is unable to hold test position for more than 5 seconds, they will receive a score of 10 for that portion of the test. See attachments for example of score sheet. In addition to life scoring, the trials will be videotaped to check intrarater and interrater reliability. This is consistent with other studies which have included BESS. Access to this video will be restricted to the approved individuals who are listed on the IRB.

SAC will also be administered by the clinician in an interview style. Orientation, immediate memory, concentration, and delayed recall are all aspects of the assessment. The test is scored out of 30 possible points and is then compared to the athlete's pre-activity baseline score. See attachments for score sheet including assessment questions.

For ImPACT, the participant will use a computer in a private office located the same facility just down the hall. The clinician will log onto the ImPACT website to access the assessment. The participant's profile will be selected so their test score will accurately be compared to their pre participation baseline. The clinician will take the athlete through the demographic information that precedes the testing phase then instruct the participant to complete the test as directed reading all instructions carefully. After ImPACT is completed, the participant will follow up with the clinician proctoring the test to make sure that there were no technical difficulties during the test.

Following athletic participation (including but not limited to any one of the following: team practices, captains' practices, team weights, intercollegiate competition, or conditioning) the athlete will come into the Hanner biomechanics lab where GSC, SAC, and BESS will be completed. ImPACT will be completed in a private office prior to exercise or a minimum of 3 hours after exercise. The entire battery will be completed within a 72 hour window- actual test time still no greater than 90 minutes. Once testing is done, the participant's test day information will be compared to their baseline scores. The clinician administering the tests and collecting the data will be the primary investigator, Caitlynn Hellwig, or the secondary investigator, Kelsey Evans.

Data Analysis. This is a prospective longitudinal study. The independent variable is time from baseline assessment. The dependent variables include: GSC symptom and symptom severity score, total BESS score, composite SAC score, and the four composite ImPACT scores - verbal memory, visual memory, processing speed, and reaction time. Primarily, all dependent variables will be categorized into two groups, pass or fail, when compared to baseline assessment. Secondly, all participants who have failed the test battery will be evaluated based on time elapsed from baseline assessment.

Statistical Analysis. Descriptive statistics will be run on all demographic variables, along with scores on the various dependent variables. Failure rates for each test will then be determined. The ImPACT test scores are automatically run against each participant's baseline values. Values that fall below the accepted range will be flagged as a failing test. When evaluating the BESS test, any score above each participant's baseline (indicating additional errors) will be classified as a failing test. The SAC test will be assessed in a similar fashion, any test score that is lower than each participant's baseline (indicating a deficit in one of more measures) will be classified as a failing test. If even one of the components of the test battery is identified as a failed measure, the subject will be classified as having a false positive of the concussion battery and be flagged for further analysis. A one-way repeated measure ANOVA will be run to determine changes in scores by time elapsed from baseline. As baseline measurements are taken as part of the pre-participation physical for all athletes, participants will be grouped by when their baseline was collected. This will identify if there is a trend in false positive rate congruent with time from baseline.

Special Conditions.

Risk. There is minimal risk associated with participation in this study. There may be risk of falling during the balance assessment (BESS). ImPACT is an approximately 30-40 min

computerized test which may cause a headache due to concentration on the computer screen. All participants have completed all measures at least once as part of Georgia Southern Athletics baseline collection.

Deception. It is understood that there is no deception in this study.

Medical procedures. N/A

INFORMED CONSENT

COLLEGE OF HEALTH AND KINESIOLOGY

DEPARTMENT OF ATHLETIC TRAINING

CONSENT TO ACT AS A SUBJECT IN AN EXPERIMENTAL STUDY

1. Title of Project: Determining the False Positive Rate of a Concussion Multifaceted Assessment in Healthy Division I Collegiate Student-Athletes.

Investigator's Name: Caitlynn Hellwig, ATC, LAT

Phone: 303-621-5826

Participant's Name: _____

Date: _____

2. Purpose of the Study: The purpose of this research is to determine the false positive rate of a multifaceted concussion battery on healthy Division I collegiate student-athletes.
3. Participation in this research will include a one day assessment lasting no longer than two hours, completing a concussion battery made up by 4 individual tests as well as access to the baseline scores for those tests.

Graded Symptom Check list is used to quantify concussive symptoms. Clinicians may use a graded symptom checklist (GSC) which lists several symptoms each with a Likert scale of severity ranging from 0 to 6, most severe represented by 6. GSC will be administered in an interview style with the clinician asking the athlete to rate each individual symptom with the appropriate severity which the clinician will then record.

Balance Error Scoring System The athlete is instructed to hold three different positions (feet together, single nondominant leg, and tandem stance) for twenty seconds each with their eyes closed and hands resting on their hips. Each position is then repeated on an AIREX piece of foam to increase the difficulty. Errors include opening eyes, hands coming off iliac crest, heel or forefoot coming off the ground, stumbling/step/fall, hip exceeding 30 degrees of abduction, and being unable to hold test position for 5 seconds. These errors are scored by the clinician during each of the 20 second periods. If the athlete is unable to hold test position for more than 5 seconds, they will receive a score of 10 for that portion of the test. In addition to live scoring, the BESS trials will be videotaped to check intrarater and interrater reliability. Access to this video will be restricted to the approved individuals who are listed on the IRB.

Standardized assessment of concussion (SAC) is a widely used assessment of cognition and memory. This tool is most sensitive when completed within 24 hours of the suspected concussive blow. Orientation, immediate memory, concentration, and delayed recall are all aspects of the assessment. The test is scored out of 30 possible points and is then compared to the athlete's pre-activity baseline score. SAC will be administered by the clinician in an interview format and answers will then be scored by the clinician.

The ImPACT instrument is a computer-based program used to assess neurocognitive function and concussion symptoms. It consists of 6 tests that evaluate attention, working memory, and processing speed, yielding composite scores on the areas of verbal memory, visual memory, processing speed, reaction time, and impulse control. ImPACT breaks down their test in the following manner: “Module 1: Word Discrimination evaluates attentional processes and verbal recognition memory utilizing a word discrimination paradigm. Module 2: Design Memory evaluates attentional processes and visual recognition memory using a design discrimination paradigm. Module 3: X's and O's measures visual working memory as well as visual processing speed and consists of a visual memory paradigm with a distractor task that measures response speed. Module 4: Symbol Matching Evaluates gauges visual processing speed, learning and memory. Module 5: Color Match represents a choice reaction time task and also measures impulse control and response inhibition. Module 6: Three Letter Memory measures working memory and visual-motor response speed.” Additional information can be found on the official ImPACT website <https://www.impacttest.com/about/?The-ImPACT-Test-4>.

4. There is minimal risk associated with participation in this study. There may be risk of falling during the balance assessment (BESS). ImPACT is an approximately 30-40 min computerized test which may cause a headache due to concentration on the computer screen. You have completed all measures at least once as part of Georgia Southern Athletics' baseline concussion assessment. By signing below, you understand that medical care is available in the event of injury resulting from research but that neither financial compensation nor free medical treatment is provided. You also understand that you are not waiving any rights that you may have against the University for injury resulting from negligence of the University or investigators. Should medical care be required, you may contact Health Services at 912-478-5641.
5. You will likely receive no direct benefit from participating in this study. The results will be used to demonstrate the specificity of a multifaceted concussion assessment. Upon completion of the study, you may request your results if you so wish.
6. Duration/Time required from the participant: <90 minutes.
7. All data collected concerning your participation will be kept confidential. All information will be handled in a confidential matter and be kept secure and confidential with Caitlynn Hellwig as allowable by Georgia state law. The Georgia Southern Biomechanics lab will be a secure location to store coded information.
8. Right to Ask Questions: You have the right to ask questions and have those questions answered. If you have questions about this study, please contact the researcher named above or the researcher's faculty advisor, whose contact information is located at the end of the informed consent. For questions concerning your rights as a research participant, contact Georgia Southern University Office of Research Services and Sponsored Programs at 912-478-0843.
9. You will not receive any form of compensation for your participation in this study.
10. All participation is voluntary and participants have the right to end their participation at any time by informing the primary investigator or electing to not complete any of the assessments.

If Yes, please describe: _____

- 7) Please indicate any exertional activity in the past 3 hours:

Practice Game Weights Conditioning None

Other: _____

Please rate intensity of the activity using the scale located below:

Perceived	Description
0	Nothing at all
0.5	Extremely weak
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat Strong
5	Strong (Heavy)
6	
7	Very Strong
8	
9	
10	Extremely Strong
*	Maximal

Question #3 Addendum

Following a hit to the head, have you ever experienced: (mark Yes or No for each one)

Loss of Consciousness	Yes	No
Disorientation	Yes	No
Feeling Dazed/Confused	Yes	No
Headache	Yes	No
Dizziness	Yes	No
Balance Problems	Yes	No
Memory Difficulties	Yes	No
Blurred/Abnormal Vision	Yes	No
Nausea	Yes	No
Trouble Concentrating	Yes	No
Ringing in the Ears	Yes	No
Bothered by loud noises	Yes	No
Feeling slowed down or fatigued	Yes	No
Feeling in a "Fog"	Yes	No
Becoming Emotional or Irritable	Yes	No
Blacking Out	Yes	No
Trouble returning to activity	Yes	No
Sleep Problems	Yes	No
Problems with Coordination/Skills	Yes	No

BORG 10 Scale of Perceived Exercise

1) Please indicate any exertional activity in the past 3 hours:

Practice Game Weights Conditioning None

Other: _____

Please rate intensity of the activity using the scale located below:

Perceived	Description
0	Nothing at all
0.5	Extremely weak
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat Strong
5	Strong (Heavy)
6	
7	Very Strong
8	
9	
10	Extremely Strong
*	Maximal

BESS**BESS Test**

Footwear (shoes, barefoot, braces, tape, etc.) _____

Modified Balance Error Scoring System (BESS) testing³

Which foot was tested (i.e. which is the non-dominant foot)

Left : Right

Testing surface (hard floor, field, etc.) _____

Condition - On Firm Surface

Double leg stance: _____ Errors

Single leg stance (non-dominant foot): _____ Errors

Tandem stance (non-dominant foot at back): _____ Errors

Condition - On Foam (Airex) Pad

Double leg stance: _____ Errors

Single leg stance (non-dominant foot): _____ Errors

Tandem stance (non-dominant foot at back): _____ Errors

Total score: _____ Baseline score: _____

Types of Errors

1. Hands lifted off iliac crest
2. Opening eyes
3. Step, stumble, or fall
4. Moving hips into >30 degrees abduction
5. Lifting forefoot or heel
6. Remaining out of test position >5 sec

The BESS is calculated by adding one error point for each error during the six (6) 20-second tests.

Multiple errors count as one.

Date Completed _____

SAC

Cognitive assessment

Standardized Assessment of Concussion (SAC)

Orientation (1 point for each correct answer)

What month is it?	0	1
What is the date today?	0	1
What is the day of the week?	0	1
What year is it?	0	1
What time is it right now? (within 1 hour)	0	1

Orientation score of 5

Immediate memory

"I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order."

Trials 2 & 3:

"I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before."

Complete all 3 trials regardless of score on trial 1 & 2. Read the words at a rate of one per second. Score 1 pt. for each correct response. Total score equals sum across all 3 trials. Do not inform the athlete that delayed recall will be tested.

List	Trial 1	Trial 2	Trial 3	Alternative word list
elbow	0 1	0 1	0 1	candle baby finger
apple	0 1	0 1	0 1	paper monkey penny
carpet	0 1	0 1	0 1	sugar perfume blanket
saddle	0 1	0 1	0 1	sandwich sunset lemon
bubble	0 1	0 1	0 1	wagon iron insect
Total				

Immediate memory score of 15

Concentration**Digits Backward:**

"I am going to read you a string of numbers and when I am done, you repeat them back to me backwards, in reverse order of how I read them to you. For example, if I say 7-1-9, you would say 9-1-7."

If correct, go to next string length. If incorrect, read trial 2. One point possible for each string length. Stop after incorrect on both trials. The digits should be read at the rate of one per second.

	0	1	Alternative digit lists
4-9-3	0	1	6-2-9 5-2-6 4-1-5
3-8-1-4	0	1	3-2-7-9 1-7-9-5 4-9-6-8
6-2-9-7-1	0	1	1-5-2-8-6 3-8-5-2-7 6-1-8-4-3
7-1-8-4-6-2	0	1	5-3-9-1-4-8 8-3-1-9-6-4 7-2-4-8-5-6

Months in Reverse Order:

"Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say December, November ... Go ahead!"

1 pt. for entire sequence correct

Dec-Nov-Oct-Sept-Aug-Jul-Jun-May-Apr-Mar-Feb-Jan 0 1

Concentration score of 5

Delayed recall

"Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order."

Circle each word correctly recalled. Total score equals number of words recalled.

List	Alternative word list
elbow	candle baby finger
apple	paper monkey penny
carpet	sugar perfume blanket
saddle	sandwich sunset lemon
bubble	wagon iron insect

Delayed recall score of 5

ImPACT

The ImPACT instrument is a computer-based program used to assess neurocognitive function and concussion symptoms. It consists of 6 test modules that evaluate attention, working memory, and processing speed, yielding composite scores on the areas of verbal memory, visual memory, processing speed, reaction time, and impulse control. ImPACT breaks down their test in the following manner: “Module 1: Word Discrimination evaluates attentional processes and verbal recognition memory utilizing a word discrimination paradigm. Module 2: Design Memory evaluates attentional processes and visual recognition memory using a design discrimination paradigm. Module 3: X's and O's measures visual working memory as well as visual processing speed and consists of a visual memory paradigm with a distractor task that measures response speed. Module 4: Symbol Matching Evaluates gauges visual processing speed, learning and memory. Module 5: Color Match represents a choice reaction time task and also measures impulse control and response inhibition. Module 6: Three Letter Memory measures working memory and visual-motor response speed.” Additional information can be found on the official ImPACT website <https://www.impacttest.com/about/?The-ImPACT-Test-4>.

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Tables

Table 1. Participant demographic information.

Demographics		n (%)
Gender	Female	70.8
	Male	29.2
Age		19.81 (SD 1.21)
Ethnicity	White	40 (83.3)
	African American	8 (16.7)
Year in School	Freshman	10 (20.8)
	Sophomore	17 (35.4)
	Junior	12 (25)
	Senior	9 (18.8)
Current Orthopedic Injury	None	30 (62.5)
	Upper Body	9 (18.8)
	Lower Body	9 (18.8)

Table 2. Participants by sport.

Sport	n (%)
Cheerleading	16 (33.3)
Volleyball	7 (14.6)
American Football	4 (8.3)
Softball	4 (8.3)
Swim	4 (8.3)
Women's Soccer	4 (8.3)
Track	3 (6.3)
Men's Basketball	3 (6.3)
Baseball	1 (2.1)
Dive	1 (2.1)
Men's Tennis	1 (2.1)

Table 3. Number of assessments by time elapsed from baseline.

	SAC	BESS	ImPACT
0-12 mo	16	17	14
13-24 mo	16	17	18
25-36 mo	9	8	9
37-48 mo	7	6	7
Total	48	48	48

Table 4. Scores and false positive rate by assessment.

Test Measure	Baseline	Assessment	False Positive n (%)
SAC	27.17 (1.53)	27.63 (1.54)	13 (27.1)
BESS	12.73 (5.91)	15.35 (7.02)	30 (62.5)
ImPACT			16 (33.3)
Battery Total			39 (81.3)
SAC and ImPACT Combined			26 (54.2)

Table 5. Scores and false positive rate by ImPACT composite score.

ImPACT Composite	Baseline	Assessment	False Positive n (%)
-Verbal Memory	87.33 (8.84)	88.31 (9.01)	7 (14.6)
-Visual Memory	78.50 (13.77)	77.23 (10.92)	6 (12.5)
-Processing Speed	40.97 (6.12)	41.65 (6.09)	3 (6.3)
-Reaction Time	.586 (.587)	.580 (.064)	5 (10.4)
ImPACT Total Score			16 (33.3)

Table 6. Symptom report

	GSC	PCSS Baseline	PCSS pre ImPACT	PCSS post ImPACT
Mean Symptoms	2.27	3.27	5.44	4.08
Range	0-14	0-31	0-58	0-43
0 Symptoms n(%)	20 (41.6)	26 (54.2)	26 (54.2)	28 (58.3)
1-2 Symptoms n(%)	12 (25)	16 (33.3)	5 (10.4)	8 (16.6)
3+ Symptoms n(%)	16 (33.3)	6 (12.5)	17 (35.4)	12 (25)

Table 7. History of concussion

	#	n (%)
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Self-report Diagnosed Concussions	0	31 (64.4)
	1	12 (25.0)
	2	4 (8.3)
	3+	1 (2.1)
-LOC	0	45 (93.8)
	1	3 (6.3)
-PTA	0	47 (97.9)
	1	1 (2.1)
-Unrecognized	0	41 (85.4)
	1	4 (8.3)
	2	1 (2.1)
	5+	2 (4.2)

Table 8. Frequency of clinical testing after baseline.

Participant #	ImPACT	SAC	BESS
1	4	1	2
2	2	2	3
3	1	1	1
4	1	2	2
5	3	3	3
6	3	3	3
7	1	2	5