UNIVERSITY of STIRLING

Inter-Day Reliability and Feasibility of an In-Shoe Plantar Pressure System for the Measurement of Balance Variability in Healthy, Non-Concussed Athletes

by

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For my Mother,

because without her this Master's Degree

would not have been possible.

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Abstract

Introduction: Sport-related concussion research has gained traction, as college and university athletes make up 1/3 of reported concussions. Nearly 50% of reported concussions are diagnosed in American football players. Current diagnostic and monitoring tools in place include undergoing expensive brain scans, or completing the Sport Concussion Assessment Tool-5 (SCAT5). The SCAT5 tool is universally utilised for recognizing and monitoring the symptomatology of concussions, but currently lacks a sensitive, objective measure of balance disturbances.

Purpose: The aim of this study was to investigate in-shoe plantar pressure systems as a reliable, feasible, and objective measure of balance disturbance. Additionally the study sought to determine relationships between in-shoe plantar pressure systems measurements and SCAT5 symptom evaluations.

Methods: Healthy, non-concussed participants (N = 17) from the University of Stirling American football team (23 ± 6 years old) were recruited to the lab for two visits, 1 week apart. To test inter-day reliability and repeatability of in-shoe plantar pressure systems' measurements, each participant completed SCAT5 and a balance test on both visits, using the Pedar-X® system. The balance test consisted of 4 stances: stances 1 and 3 were bilateral, and stances 2 and 4 were unilateral. In addition, stances 1 and 2 were completed with eyes open, whereas stances 3 and 4 were completed with eyes closed.

Results: Symptom count (visit 1: 3±4; visit 2: 4±5) and severity (visit 1: 5±7; visit 2: 6±7) reported from SCAT5. Balance measurements, in millimeters, from visit 1 (stance 1: 3.6±4.0; stance 2: 7.1±5.0; stance 3: 4.0±4.9; stance 4: 16.1±10.8) and visit 2 (stance 1: 4.7±6.1; stance 2: 7.6±7.6; stance 3: 5.7±7.7; stance 4: 14.8±10.0) recorded by Pedar-X®. Pedar-X® had moderately acceptable CVs (18-24%) for stances 1, 2 and 4, and had excellent inter-day repeatability for stances 2 and 4 (ICC: 0.854, 0.857; $p<0.05$). There was no significant difference between visit 1 and visit 2 Pedar-X® balance measurements (t-test: $p>0.05$). Pedar-X® had a strong correlation (PCC - r-value: 0.605-0.787, $p<0.05$ and Linear Regression - r-value: 0.27-0.40, $p<0.05$) with SCAT5 evaluated symptomatology.

Conclusion: This study has shown that Pedar-X® has moderate inter-day, intra-participant reliability, and excellent inter-day repeatability. Specifically stance 4 measurements have a strong correlation with SCAT5 symptom evaluations and have a positive linear correlation, indicating the ability to detect naturally occurring balance variance among participants.

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List of Abbreviations

ADHD – Attention Deficit Hyperactivity Disorder

CI – Confidence Interval

CNS – Central Nervous System

COP – Centre of Pressure

CT – Computerised Tomography

CTE – Chronic Traumatic Encephalopathy

CV – Coefficient of Variance

EMG – Electromyography

ICC – Intraclass Correlation Coefficient

LL – Lower Limit

mBESS – Modified Balance Error Scoring System

MRI – Magnetic Resonance Imaging

mTBI – Mild Traumatic Brain Injury

NFL – National Football League

PCC – Pearson Correlation Coefficient

SAC – Standardised Assessment of Concussion

SCAT5 – Sport Concussion Assessment Tool-5

SD – Standard Deviation

SEM – Standard Error of the Mean

UL – Upper Limit

1. Introduction

1.1 Concussions, American Football & Symptoms

Interest in concussions has consistently gained traction through recent years due to their direct relation to chronic traumatic encephalopathy (CTE), a disease that can cause mental illness and early onset dementia, often resulting in premature deaths in many athletes (Mannix et al., 2016; Stein et al., 2015). Annually in the United States, sport-related traumatic brain injuries occur an estimated 300 000 times, a majority of which are concussions (Gessel et al., 2017). The majority of sport-related concussions come from contact sport athletes, and 1/3 of all reported concussions arise from injury sustained during college and university athletics (Marar et al.,2012; Slobounov et al., 2007; Ryan et al., 2003). Sport-related concussion is becoming a major health concern for student athletes, especially those playing rugby or American football (Johnston, 2017). In the National Football League (NFL) in America, concussions are rated as the 5th most common sport-related injury (Lawrence et al. 2015). According to Meehan et al., (2011) 47.2% of reported concussions are received by American football players. These, perhaps shocking, figures indicate that innovative research into methods to prevent, diagnose, and ultimately treat concussions is necessary.

Concussions, also known as mild traumatic brain injuries (mTBI), are the outcome of the brain undergoing a large and sudden change in acceleration, usually caused by a trauma. This change in acceleration leads to the brain rotating, causing subsequent shear strain (Stillman et al., 2017). This can be a result of external forces acting directly on the head or the entire body (McKee 2009), such as a tackle during American football.

Common symptoms of concussion include headaches, difficulty concentrating, sensitivity to light, dizziness, disorientation, and balance disturbances. Due to the large array of possible symptoms, no two concussions are necessarily alike, making it hard to assess and manage them (McCrory et al., 2013). In 75.6% of concussions, dizziness is reported as a symptom, and in 30% balance disturbances are reported. Balance disturbance is diagnosed when a patient is unable to stand upright without deviating from, or swaying outside of, their base of support (Marar et al,. 2012).

When an athlete suffers a concussion, the resulting injury can affect the central nervous system (CNS) and its ability to integrate sensory information. The CNS encompasses the brain and spinal cord, which regularly receive vestibular, visual, and proprioceptive information and is routed through the cerebellum, cerebral cortex and brain stem. The outcomes of this input include motor impulses and the vestibule-ocular reflex which result in balance (Figure 1). When the brain undergoes an mTBI, it results in an impairment of integration of sensory input, causing a cascading effect on the body's ability to balance (Hanes and McCollum, 2009; Shumway-Cook et al., 2001; Broglio et al., 2016).

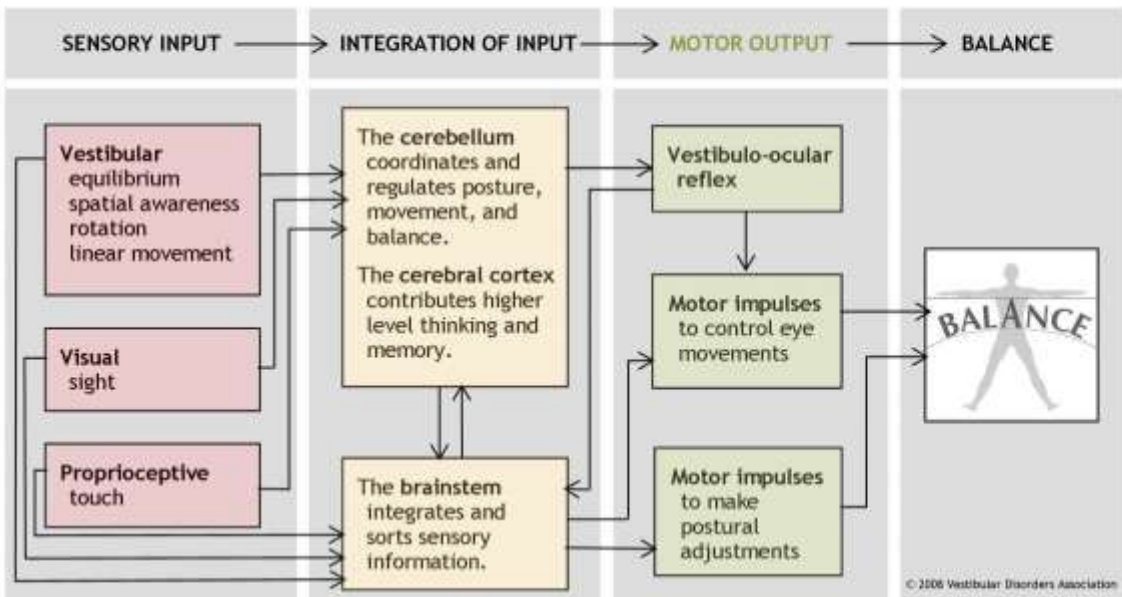

Figure 1. Flow of sensory information to the brain, its integration and output that result in balance (Watson et al., 2016).

Concussions are commonly received by athletes in contact sports, and the way in which athletes are trained to both give and take a hard hit has affected the way that these concussions are received (Tokish et al., 2017; Schussler et al., 2018). It is 6.5 times more likely for an American football player to receive an impact to the top of the head than to the sides (Guskiewicz et al., 2007). Crisco et al., (2010) found that American football players received around 40% of impacts to the head from the front of the helmet, and another 25% to the back of the helmet, whereas the quarterback is the only player to receive more impacts to the back of the helmet than the front. The common front and top impact on the brain could lead to a lowered ability to process vestibular, visual, somatosensory, and proprioceptive information in the cerebellum and cerebral cortex (Peterson et al., 2003). If sensory input is not able to be properly processed, balance disturbances can occur. This disturbance can stem from a concussion of any kind leading to a metabolic cascade, which has the potential to impact the entire brain (McCrea 2008). Concussion can lead to ionic changes, unusual energy demands, decreased cerebral blood flow and impaired neurotransmission (Blennow and Hardy, 2012). A common outcome of front of helmet impacts, affecting the anterior and posterior of the head, is an impairment of the cerebellum and cerebral cortex, affecting the processing of visual, somatosensory, vestibular and postural information (Giza and Hovda, 2014). These impairments negatively affect the integration of sensory input, causing a cascading effect on the body's ability to balance (Hanes and McCollum, 2009; Shumway-Cook et al., 2001; Broglio et al., 2016)

1.2 Current Concussion Diagnoses & Monitoring: SCAT5

Currently, concussion is diagnosed and monitored in hospital via magnetic resonance imaging (MRI) or a computerised tomography (CT) scan, along with a symptom evaluation (Stillman et al., 2017). Recently, the Food and Drug Administration, FDA, approved a blood serum biomarker test to evaluate mTBI by measuring the levels of proteins released by the brain within 12 hours of injury (FDA, 2018; Asken et al., 2018). Presently, on the sideline of a sporting event, a concussion is diagnosed and monitored using SCAT. Created by Echemendia et al., (2017), the most current edition, SCAT5, is recommended for on-field assessment and off-field baseline collection and monitoring (McCrory et al., 2017). The SCAT5 on-field assessment includes red flags, observable signs, memory assessment using Maddocks' questions (Maddocks et al., 1995), Glasgow Coma Scale assessment, and a cervical spine assessment. The off-field assessment includes athlete background information collection, symptom evaluation, cognitive screening using standardised assessment of concussion (SAC) (McCrea, 2001), concentration assessments, neurological screening including a Modified Balance Error Scoring System (mBESS) test (Guskiewicz, 2003), and a delayed recall assessment (Davis et al., 2017).

McCrory et al., (2005) and other concussion experts came to the consensus that concussion-related balance disturbances resolve within 72 hours of initial injury. However, when using objective data collection such as motion capture and force plates, rather than the more subjective human-rated mBESS, balance disturbances can be observed up to 30 days after the initial injury (Slobounov et al., 2007), suggesting that balance disturbances can surpass the earlier proposed 72 hour recovery period. This inconsistency in range for the symptomatology indicated within these studies may imply that the current mBESS test is not sensitive enough for long-term monitoring of concussion. The disruption caused to athletes' livelihoods by long-term balance disturbance highlights the need for an objective diagnostic test that is sensitive to slight changes in symptomatology over a larger timescale.

1.3 Modified Balance Error Scoring System

Both physicians and the off-field component of SCAT5 use mBESS to monitor balance disturbances. The mBESS has participants maintain a double leg, single leg, and tandem stance for 20 seconds; all stances are performed barefoot, with eyes closed, and hands on hips. Throughout each 20 second balance test, the SCAT5 assessor monitors the participant for errors, each error results in an error point to a maximum of 10 error points per stance (Guskiewicz, 2003).

Waddington et al., (2015) recruited athletes to complete SCAT2 on two separate occasions. They found a strong correlation between the two SCAT2 assessments for the symptom score and the total number of symptoms reported, but not a significant correlation between mBESS scores. Downey et al., (2018) determined that SCAT3 was only useful for assessing concussion symptoms with or without baseline data, within 3-5 days post-injury. They also went on to suggest that SCAT3 and similarly SCAT5 should be implemented alongside other comprehensive evaluations. Chin et al. (2016) found that symptom scores had the largest effect size at 24 hours, decreasing at 8 days, and no longer significant at and after 15 days. The mBESS score effect sizes were small to moderate at 24 hours, and become non-significant at and after day 8. This shows a limitation of SCAT and mBESS scoring as indices for concussion recovery and monitoring (Chin et al., 2016). Additionally, Houston et al., (2018) noted that MobileMat™ mBESS scores correlated with linear measures of balance, such as area and sway. They collected mBESS data objectively using the MobileMat™ and compared it to the subjective human-rated scores. This resulted in fewer mBESS error points being reported by the objectively quantified MobileMat™ measurements versus the subjective human-rated measurements. This further supports the need for objective measurements when monitoring concussion-related balance disturbances (Houston et al., 2018). Bell et al., (2011) completed a systematic review of 29 relevant studies and found that although mBESS is largely accepted as the gold standard for non-laboratory evaluation of balance disturbances, limitations remain. They found that overall the mBESS has a low sensitivity statistic (0.34); the inability to detect balance disturbances 1 week post-injury; and, due to the fact that mBESS greatly relies on the assessor's subjective interpretation, low inter-rater reliability.

1.4 Single Leg Balance Testing, Compensatory Affects & Trial Duration

The heightened challenge of performing a single leg test, rather than a bilateral stance, can better reveal balance disturbances, especially for well-trained athletes (Riemann et al., 2017). The challenge for subjects is that a single leg acting as a base of support requires a reorganization of postural control over a far smaller base. In addition, single leg stances decrease the amount of sensory input that may serve to compensate for balance deficiencies (Ageberg et al., 2003; Riemann and Schmitz, 2012; Kouvelioti et al., 2015; Muehlbauer et al., 2014). A major drawback of single leg testing is the occurrence of compensatory events, also known within mBESS as errors. Naturally, participants use their upper extremities to shift their balance or touch down their other leg to correct it; these types of compensation are easily detected by surface measurements obtained by force plates and Wii® Boards. To avoid compensation affecting surface measurements, it is best to reduce trial length, while maintaining appropriate duration to allow for reliable measurements to be taken. Riemann et al., (2017) determined the best trial length during single leg stance by measuring 5 second incremented trial durations and maximum trial durations without compensatory affects. When the best trial lengths were repeated, they found that the intraclass correlation coefficient (ICC) values were good and excellent, suggesting an optimal trial duration of between 15 and 20 seconds for sufficient measures and minimal compensatory effect (Riemann et al., 2017).

1.5 Wii® Boards & Wii® Fit Balance Tests

Use of Wii® Boards (Nintendo®, Kyoto, Japan) to assess balance is becoming more popular, whereas using Wii® Fit software metrics to asses balance ability has become less popular due to its lack of reliability. While in recent years more researchers are opting to use Wii® Boards to collect surface measurement data, they are doing so using customized software in place of the Wii® Board's own (Goble et al., 2014). Wikstrom (2012) determined that Wii® Fit balance activity scores had poor correlation to single leg stance and Star Excursion Balance Test scores. Additionally Wii® Fit balance activity scores had poor reliability both from the intra-sessional and inter-sessional perspective (Wikstom, 2012). In a systematic review of 28 relevant articles, Murray et al. (2014) found that there were no reliable or valid data to support the use of Wii® Fit activities for detecting concussion-related balance disturbances.

Although Wii® Fit lacks reliability and validity for use detecting balance disturbances, the Wii® Board itself is still widely accepted as an inexpensive alternative to force plates due to its validity (Holmes et al., 2012). Clark et al., (2018) investigated the reliability and validity of Wii® Boards for standing balance assessments by reviewing 25 relevant studies. They found that reliability results were consistently stated as moderate to excellent, validity as mostly excellent, and both were comparable to results using force plates. The literature supports the continued use of Wii® Boards to assess balance disturbances, but considers them most appropriate when used with software other than Wii® Fit.

1.6 A Novel Approach: In-shoe Plantar Pressure System

A novel approach for a sensitive, objective measure of balance disturbance related to concussion could come from an in-shoe plantar pressure system. These systems are already commonly used for studies related to gait (Turcato et al., 2016), centre of pressure (COP) movement in Alpine skiing (Nakazato et al., 2013), elderly in-shoe foot comfort (Lane et al., 2014), and even improved balance in Tai Chi (Mao et al., 2006). This pressure measuring system fits a wide range of shoe sizes, is less than 2mm thick, and has 85-99 pressure sensors that can sense 15-1200kPa. These sensors relay information to computer software via Bluetooth® technology, allowing for mobile and flexible movement of participants (Novel.de, 2018). This system has the ability to measure each foot's COP, which is a point on the bottom of the foot that is the average location of all the pressures simultaneously acting on that foot (DeLisa, 1998).

In 2010, Ramanathan et al., (2010) published works testing the repeatability of the Pedar-X® insole measuring system. 160 parameters were statistically analysed for coefficient of variance (CV), using *CV=(SEM/mean)100*. Of those 93.1% had a CV of less than 25%; the remaining 6.9% of CVs fell largely within 25-50%, with few above 50%. When the normal variations in pressure from gait are taken into account, these values are considered acceptably repeatable results (Ramanathan et al., 2010). However, Ramanathan et al., (2010) calculated CV using standard error of the mean (SEM) values rather than standard deviation (SD). They calculated SEM using $SEM=Diff_{SD}/\sqrt{N}$, where $Diff_{SD}$ is the standard deviation of the differences between repeated measurement and N=2. By using SEM values and N=2 (ie. Visits) rather than the correct N=27 (ie. Participants), the resulting CV is approximately 70% what it would have been, had it been calculated using $CV=(SD/mean)100$. Their reported acceptable CV values of <25%, when recalculated correctly using SD, are more accurately <35%. Surprisingly, most noted studies use <10% as acceptable for CV, far lower than Ramanathan et al., (2010)'s reported 25% acceptability (Menz et al., 2004; Winter, 1999; Clark et al., 2015). Many studies have previously used, and currently use, the Pedar-X® in-shoe pressure measuring system to study a wide range topics (Turcato et al., 2016; Nakazato et al., 2013; Lane et al., 2014; Mao et al., 2006). However, regardless of its popularity in research, normal values and its reliability in balance studies have yet to be published.

1.7 Purpose & Aim of Study

The purpose of this study is to investigate whether in-shoe plantar pressure systems are a feasible and reliable method for balance measurement, with the required sensitivity to detect normal balance variances. This is necessary to first determine, in order to possibly develop a tool which will permit better monitoring and management of concussion-related balance disturbances. This is the first study to examine the reliability of balance measurements collected using a pressure-sensing insole and relate it to each healthy, non-concussed participant's associated symptomatology data collected from SCAT5.

The main aim of this study is to investigate the intra-day and inter-subject reliability and intra-day repeatability of in-shoe plantar pressure systems by using the Pedar-X® system. An additional aim of the study is to investigate the correlation between the current mBESS test and SCAT5 symptom evaluation, and the correlation of Pedar-X® measurements with the SCAT5 symptom evaluation.

1.8 Hypothesis

In summary, previous studies have shown that the current balance assessment included in SCAT5, mBESS, is limited due to its low inter-rater reliability as a result of subjectivity and human-rater error. Additionally, Wii® Boards are appropriate to use to assess balance disturbances, but not if used in conjunction with unreliable Wii® Fit activities, rather than customized software. Furthermore, Pedar-X® has the potential to be a novel approach to measuring balance disturbances, as it has far more numerous pressure sensors and is therefore more sensitive than Wii® Boards.

The hypothesis of this study is that the in-shoe plantar pressure system will feasibly provide a reliable and repeatable method of balance measurement. Additionally, this objective measurement will be better-associated with SCAT5 symptomatology than the current subjectively limited mBESS, when using healthy, non-concussed participants.

2. Methodology

2.1 Participants

This study recruited 18 healthy, non-concussed, male American football players from the University of Stirling, through communication with the coach and team. One participant was excluded from analysis as they were unable to undergo the second visit testing due to an unrelated knee injury. Therefore, the baseline cohort had 17 participants in total (mean ± SD: 23 ± 6 years old, mass: 98 ± 21.1 kg, stature: 182.2 ± 6.41 cm, experience playing American football: 68.1 ± 65.6 months) (Table 4). The participants were asked to attend the lab twice, a week apart, to collect repeated measures. Participants maintained their normal diet and daily routine throughout the study.

2.2 Ethical Approval

Approval of the study was granted by the local research ethics committee. The study followed the set guidelines of the Helsinki Declaration (World Medical Association, 2013) and all participants provided informed consent prior to the start if testing.

2.3 Process of Study

The participants were first introduced to the study through a presentation (Appendix A). The presentation explained the potential benefits of the study, how the study would be conducted, and that their participation may enhance our understanding of sport-related head injuries. After the presentation, the athletes were given an information sheet reiterating what was stated in the presentation, and an informed consent form (Appendix B). Participants were then asked to read the information sheet and, if they chose to participate, sign the consent form. The consent form would not be accepted prior to 48 hours after the presentation, to allow the potential participant time to process the information and make an informed decision. After the 48 hour period, the signed consent forms were collected and participants were contacted via email and asked to sign up online for a trial time slot that would fit in their schedule for two consecutive weeks, allowing for reliability testing. The athletes attended 2 lab sessions, each scheduled 7 days apart at the same time of day (Figure 2).

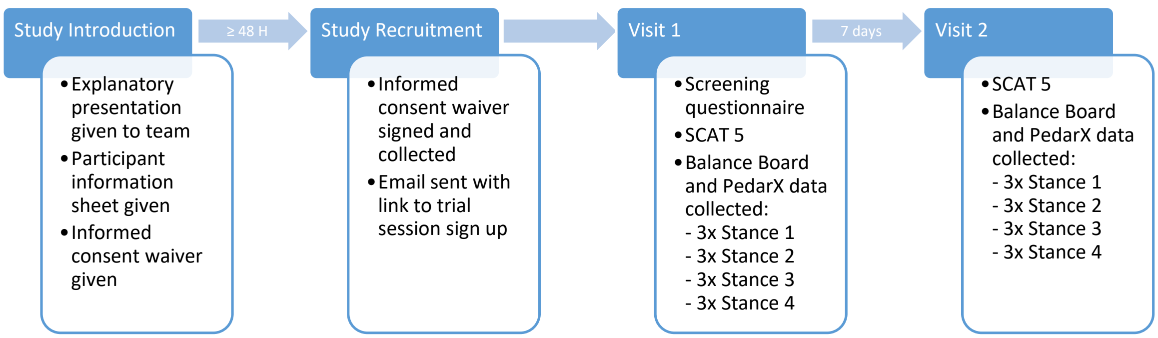

Figure 2. Timeline of study process from initial contact with American football team to the final laboratory visit of the participating athletes.

2.4 Study Design

2.4.1 Initial Participant Data Collection

Participants' stature (cm), mass (kg), age (years), and American football experience (months) were recorded in an Excel workbook, and on the Pedar-X® program when creating each participant's profile. Their weight was collected from a scale and their height from a stadiometer.

2.4.2 Sport Concussion Assessment Tool-5 (SCAT5)

SCAT5 is the most current version of the SCAT, and is recommended for assessing sport-related concussion both on and off of the field (McCrory et al., 2017). The SCAT5 off-field section contains the following assessments: symptom evaluation using the post-concussion symptom scale, cognitive screening using the SAC, concentration tests, neurological screening and balance examination using the mBESS, and a delayed recall test. Throughout the study, the assessment tool was completed following the instructions outlined on page 7 of the SCAT5 document (Appendix B).

2.4.2.1 Symptom Evaluation using Post-Concussion Symptom Scale

A list of 22 symptoms related to concussion were to be rated on severity on a 0-6 Likert scale. The total number of symptoms was restricted at 22, and the severity of those symptoms was restricted at 132 (Appendix B).

2.4.2.2 Cognitive Screening & Concentration

Using the SAC, cognitive screening was completed through assessing orientation and immediate memory (McCrea, 2001). To assess orientation, 5 basic questions are asked; each correct answer received 1 point, up to a total of 5 points. To assess immediate memory, a list of 5 words was read at the rate of one word per seconds. The participant was asked to repeat the list of words back in any order, with the goal of remembering all 5 words. This was repeated 3 times, with each correct word recalled receiving 1 point, for a possible total of 15 points. Secondly, the same test was given but with an additional 5 words appended. This list of 10 words was given at a rate of one word per second. Each correct word recalled earned the participant 1 point. This was repeated 3 times, for a total possible score of 30.

Concentration was initially evaluated using two tests: digits backwards and months in reverse. The digits backwards test was assessed using a string of numbers: the first string contained 3 numbers, the second contained 4, the third 5, and the final string 6. The list was read at the rate of one digit per second, after which the participant had to repeat the string of numbers in reverse order. If the participant was correct they would move onto the next, longer, string of numbers. If the participant was incorrect they were given a second chance with a new string of numbers of the same length. This was continued until the participant correctly repeated the final string of numbers, or the participant could not correctly repeat the initial trial or the second attempt trial. If unable to repeat a string for either trial, the assessment was concluded. For each correct attempt 1 point was awarded, up to a total of 4. The months in reverse test was assessed by listing the months of the year in reverse, starting from December. If done correctly, 1 point was awarded. The maximum possible score for concentration was 5 points.

Concentration was evaluated again at the end of SCAT5 using a delayed recall test. This test is recommended to be conducted after 5 minutes following the conclusion of the immediate recall test. The participant was asked to recall as many words as possible from the list of 10 words given earlier. Each correct word recalled received 1 point, for a possible total of 10 points (Davis et al., 2017).

2.4.2.3 Neurological Screen & Balance Examination

The neurological screen included the participant's ability to read aloud, movement of the eyes side-to-side and up-and-down, a finger-to-nose coordination test, a heel-to-toe gait test along a 3 metre line, and passive cervical spine movements (Figure 3).

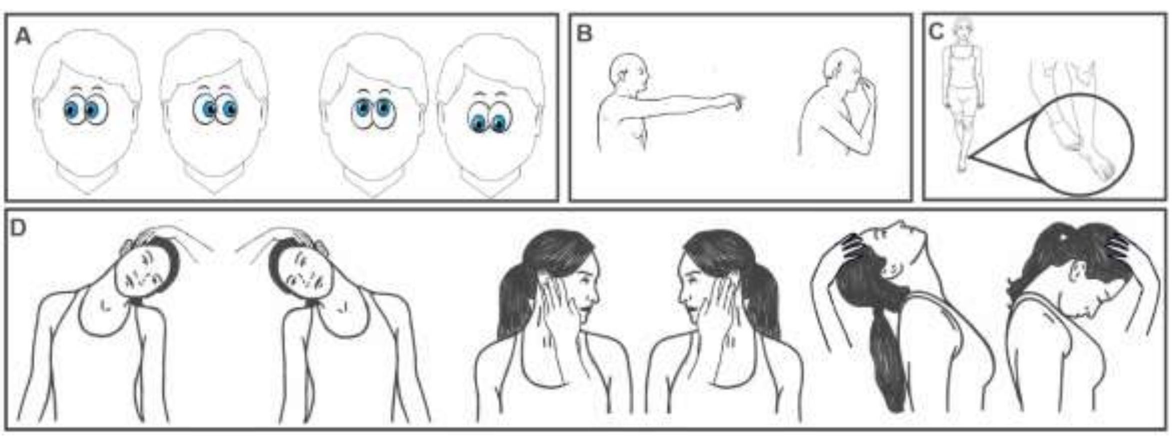

Figure 3. Neurological screening test from SCAT5: A) eyes movements: side-to-side and up-and-down; B) finger-to-nose coordination test; C) heel-to-toe gait test; D) passive cervical spine movements.

The mBESS test had participants maintain balance for 3 trials (Guskiewicz, 2003). All trials were completed barefoot, on hard floor, and lasted 20 seconds. The first trial was a double leg stance, which required the participant to stand with their feet together, hands on their hips, and eyes closed (Figure 4.A). The second trial was a single leg stance, which required the participant to stand on their non-dominant foot, with their dominant leg undergoing a 30° hip flexion and a 45° knee flexion, their hands on their hips, and eyes closed (Figure 4.B). The final trial was a tandem stance, which required the participant to stand heel-to-toe with the non-dominant foot posterior, their hands on their hips, and eyes closed (Figure 4.C).

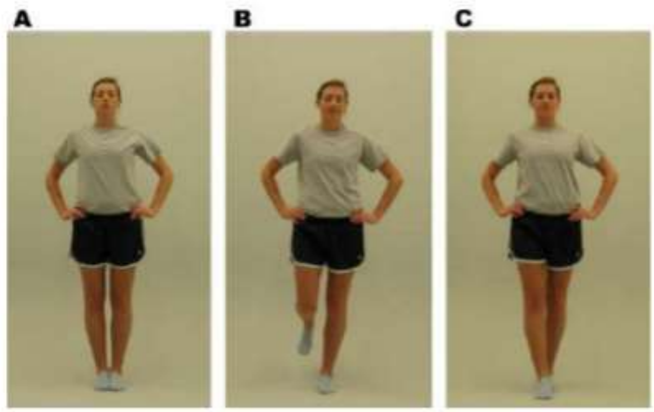

Figure 4. Illustration of mBESS stances taken for SCAT5. A) Double leg stance; B) single leg stance on non-dominant foot; C) tandem heel-to-toe stance with non-dominant foot at the back (Sulapas, 2018).

The 20 second timer was started when the participant was in the proper stance, with hands on hips and eyes closed. During the 20 seconds trials it was noted how many times the participant made an error. Possible errors include: hands lifted off of hips, a step, a stumble, a fall, lifting the forefoot or heel, opening eyes, move hip into >30° abduction, or remaining out of the proper test position for more than 5 seconds. Each of these errors received 1 point, towards a maximum of 10 points per stance. Multiple errors committed simultaneously only earned 1 point, contributing to the possible maximum score of the mBESS test of 30 points.

2.4.3 Balance Trials

Each participant completed 4 different stances. The first stance involved placing both feet shoulder width apart, hands on hips and eyes open. The second stance involved standing on the non-dominant foot, dominant leg undergoing a 30° hip flexion and a 45° knee flexion (Guskiewicz et al., 2003), hands on hips, and eyes open. The third stance involved feet shoulder width apart, hands on hips and eyes closed. The final stance involved standing on the non-dominant foot, dominant leg undergoing a 30° hip flexion and a 45° knee flexion (Guskiewicz et al., 2003), hands on hips and eyes closed. Each stance was maintained for 20 seconds, and each stance was attempted 3 times. Between each attempt and stance the participant was given a 20 second break (Table 1). The participant wore Pedar-X® (Novel GmbH, Munich, Germany) insoles in their shoes, and stood on a Wii® Board (Nintendo®, Kyoto, Japan) for all 4 stances (Figure 5 and Figure 6).

Table 1. Description of the 4 balance trial stances, how long they should be held for, length of breaks taken, how many times each stance should be repeated, and the proper file name to save it under on Pedar-X®.

Stance	Hands	Eyes	Footing	Hold (sec)	Break (sec)	Attempts
1	On hips	Open	Both feet, shoulder width apart	20	20	3
2	On hips	Open	One foot, non-dominant	20	20	3
3	On hips	Closed	Both feet, shoulder width apart	20	20	3
4	On hips	Closed	One foot, non-dominant	20	20	3

During stances 1 and 3, the participant had one foot on each panel of the Wii® board (Figure 5.C), whereas during stance 2 and 4, they stood on the non-dominant foot panel only (Figure 5.B).

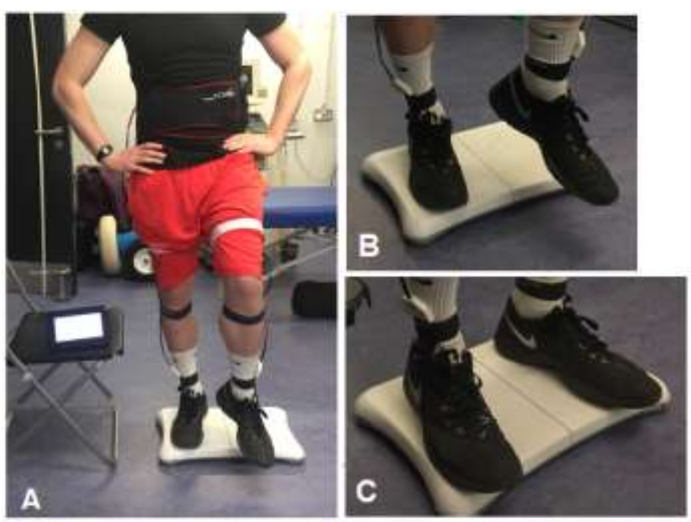

Figure 5. A) Participant doing stance 2 on Wii® board, wearing Pedar-X®; B) footing on Wii® board for stance 2 and 4; C) footing on Wii® board for stance 1 and 3.

2.4.3.1 Wii® Balance Board and Raspberry Pi

A Wii® Board (Figure 6) was used to measure the participant's overall COP, for all 4 balance trials. The Wii® Board has 4 pressure sensors, and it transmits pressure data via Bluetooth® to Raspberry Pi (Figure 6). Raspberry Pi plotted the X and Y coordinates of the COP throughout the trials at a sampling rate of 10Hz.

Figure 6. Left) Wii® board; Right) screen of Raspberry Pi.

2.4.3.2 Pedar-X®

Pedar-X® was Bluetooth® connected to a laptop, and data were collected using the Pedar-X® program. Pedar-X® insoles were placed into the participant's shoes, and the participant wore a waist belt containing the Pedar-X® Bluetooth® connected pack which sent COP information to the laptop. Prior to balance trials starting, each insole was calibrated according to the manufacturer's instructions.

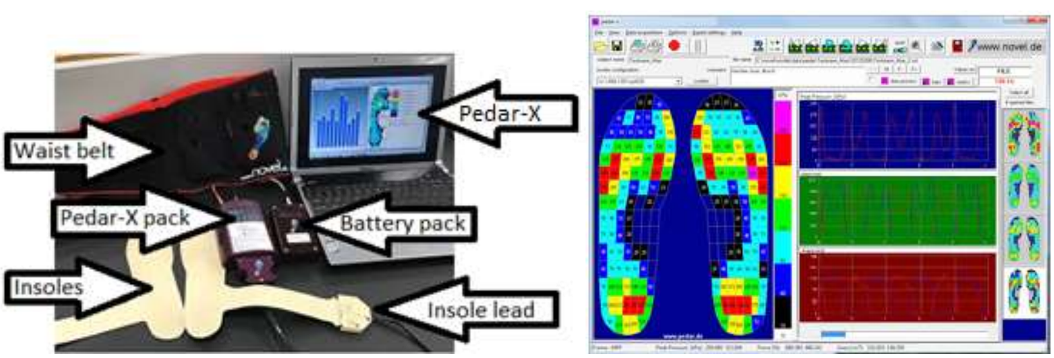

Figure 7. Left) Pedar-X® equipment used for balance trials; Right) screenshot of Pedar-X® on laptop.

Each Pedar-X® insole had 99 pressure sensors measuring up to 1200kPa of pressure. Using the change in pressure across the sensors, Pedar-X® computed two separate COPs, specific for each foot and insole. Pedar-X® sampled at a rate of 50Hz; incoming measurements were recorded and appeared live on the laptop (Figure 7).

2.5 Data and Statistical Analysis

Raw data were first run through Excel 2013 to create organized data sets. IBM SPSS Statistics 23 was used to calculate statistical data, whereas Graph Pad Prism 18 was used for statistical analysis and the production of figures. Using Excel, raw data points from Pedar-X® and the Wii® Board were organized and calculated into sets of SD. Each SD was used as an index of participants' balance, as SD is an indication of the deviation from the mean, indicating sway. These SD data sets were used for further statistical analysis of each participant.

Intra-day, intra-participant (Appendix C.1) reliability was analysed using CV for both visits 1 and 2, and calculated from the overall average SD of each stance's 3 trials. Additionally inter-day, intra-participant CV was analysed comparing the average SD of all 3 trials (mean), and the trial with the lowest SD (best). CV was calculated using $(\sigma/\mu)*100$, where σ is the SD and μ is the mean of a sample. CV was calculated for Wii® Board-collected data and Pedar-X®-collected data for both visits 1 and 2. If CVs indicated a learning effect, mean trial SD was used for further analyses, whereas if learning effect is not indicated, best trial SD was used for further analyses. Acceptable variability of a CV is defined as <10% (Menz et al., 2004; Winter, 1999; Clark et al., 2015), but other studies described CV values as acceptable up to 12%, and moderately acceptable up to 20% (Clark et al,. 2015). However, Ramanathan et al., (2010) allows moderate acceptability up to 25% using CV calculated from SEM (N=2), or 35% using a CV calculated from SD. Clark et al., (2015)'s acceptable CV values were calculated correctly using SD and advise this study to enforce a lower CV range for moderate acceptability, however those CV values are related to electromyography (EMG), rather than the more variable measurement of balance or Pedar-X®. As a result of past studies, this study will use a combination of reported acceptable CV ranges. For this study a CV of <10% will be considered acceptable (Menz et al., 2004; Winter, 1999; Clark et al., 2015), between 10-25% as moderately acceptable (Ramanathan et al., 2010), and >25% as unacceptable.

Participants' best trials were identified through the index of balance: SD. The average overall SD was calculated for all attempts at each stance. The lowest average SD indicated the least sway or balance disturbance throughout an attempt, therefore the lowest SD indicated which attempt was the best.

Inter-day reliability analysis of the Wii® Board and Pedar-X® balance tests were conducted using two-way mixed intraclass correlation coefficient (ICC) to compare the rank of visit 1 SDs to visit 2 SDs. ICC is *(V-v)/V*, where *V* is the averaged between-subject variances over the two visits, and *v* is the square of the SEM within a subject (Ditroilo et al., 2013). All ICC values had an associated 95% lower and upper bound confidence interval (CI) and p-value; p was significant if $p<0.05$. The reproducibility of an ICC value has been previously outlined by Cicchetti (1994) and more recently by Koo and Li (2016) as (Table 2):

Table 2. Grading scale of ICC values from poor to excellent.

ICC Value	ICC Rating
≤ 0.39	Poor
≥ 0.40 and ≤ 0.59	Fair
≥ 0.60 and ≤ 0.74	Good
≤ 0.75 and ≥ 1.00	Excellent

Paired-sample t-tests were used to analyse the intra-day repeatability of Pedar-X®. P-values were determined for all 4 stances of visit 1 and visit 2's balance indices, and a p-value was considered not significantly different if $p>0.05$.

Using Shapiro-Wilks was used to establish the normality of symptom count, symptom severity score, mBESS score, and balance index distribution for stance 2 and 4 measurements from visit 1 and visit 2. The data was considered not normally distributed, if it was found that $p<0.05$. Data were then log-transformed before completing Pearson correlations, and values of 0 were given a value of 0.1 as to not lose them in the logarithmic function (Feng et al., 2014; O'Hara and Kotze, 2010; Ekwaru and Veugelers, 2016). Stances with the highest associated ICC and lowest t-value were further analysed using Pearson correlation coefficients. Pearson correlation was completed for symptom count, symptom severity score and mBESS score in comparison to stance 2 and stance 4 on visit 1 and visit 2. Pearson correlation was also completed for symptom count and symptom severity score in comparison to mBESS score from stance 3 and stance 4 on visit 1 and visit 2. Associated p-values were recorded, and $p>0.05$ was considered not significant. Outlined by Cohen (1988), the grading scale for r-values is (Table 3):

Table 3. Grading scale of r-values values from zero to strong correlation.

R - Value	R - Value Rating
$\lvert r \rvert \geq 0.09$	Zero/no correlation
$0.10 \leq \lvert r \rvert \geq 0.29$	Small/weak correlation
$0.30 \leq \lvert r \rvert \geq 0.49$	Medium/moderate correlation
$0.50 \leq \lvert r \rvert$	Large/strong correlation

Finally, after determining the stance with the best PCCs (stance 4) linear regression was used to find any linear correlation between balance indices and symptom severity, and balance indices and symptom count for both visit 1 and visit 2. Associated R^2 values, and 95% upper, lower CI of the slope were recorded, along with p-values. A p-value was considered significant if $p<0.05$.

3. Results

3.1 Participant Data and SCAT5 Scores

Table 4. Mean ± SD of the age, mass, stature, and experience playing American football of all 17 participants. SD = standard deviation

Age (years)	23 ± 6
Mass (kg)	98.0 ± 21.1
Stature (cm)	182.2 ± 6.4
Experience Playing American Football (months)	68.1 ± 65.6

Mean ± SD for symptom count and severity score were lower during visit 1 than visit 2, whereas mBESS scores were high on visit 1 than visit 2 (Table 5).

Table 5. Mean ± SD of participants' symptom count, severity score, and mBESS score for visit 1 and 2. SD = standard deviation

	Visit 1	Visit 2
Symptom Count	3 ± 4	4 ± 5
Severity Score	5 ± 6	6 ± 7
mBESS Score	4 ± 4	3 ± 5

3.2 Inter-day, Intra-Participant Reliability

Mean ± SD was lower in bilateral stances 1 and 3 for Pedar-X®, whereas it was lower in eyes open stances 1 and 2 for Wii® Board. CVs were high for all measurements, indicating moderately-acceptable or not acceptable reliability between the 3 attempts of each stance. CVs were lower in unilateral stances 2 and 4 during visit 1 and 2 for both Pedar-X® and Wii® Board (Table 6).

Table 6. Mean ± SD of balance indices of visit 1 and visit 2 for all 3 stance attempts during the 4 stances. 95% CI with UL and LL, and inter-subject CV reported. SD = standard deviation, CV = coefficient of variance, CI = confidence interval, UL = upper limit, LL = lower limit.

	Pedar-X®					**Wii® Board**				
	Visit 1		**Visit 2**			**Visit 1**		**Visit 2**		
Stance	Mean ± SD	CV (%)	Mean ± SD	CV (%)	CI for Mean (95%) LL, UL	Mean ± SD	CV (%)	Mean ± SD	CV (%)	CI for Mean (95%) LL, UL
1	3.60 ± 4.02	35 ± 20	4.73 ± 6.09	36 ± 17	0.968, 1.188	6.94 ± 4.37	27 ± 18	5.36 ± 2.94	28 ± 15	1.275, 1.645
2	7.08 ± 4.96	21 ± 13	7.64 ± 7.57	27 ± 22	1.013, 1.255	8.18 ± 3.86	22 ± 17	8.01 ± 4.66	21 ± 13	1.021, 1.522
3	3.98 ± 4.85	35 ± 23	5.72 ± 7.74	33 ± 21	0.904, 1.116	8.47 ± 6.54	24 ± 13	8.51 ± 7.33	31 ± 18	1.146, 1.936
4	16.05 ± 10.78	21 ± 19	14.75 ± 9.99	24 ± 33	1.034, 2.611	16.21 ± 6.75	17 ± 11	16.70 ± 5.88	19 ± 10	0.916, 1.340

CVs were high for all measurements, indicating moderately-acceptable or not acceptable reliability for all 4 stances. CVs were lower for all stances using the mean SD for Wii® Board, but were variable for Pedar-X®. A learning effect was not indicated as CVs were not consistently lower during mean versus best trials. Both Pedar-X® and Wii® Board show the lowest level of CV during stances 2 and 4, which are single leg stances (Table 7).

Table 7. CVs comparing visit 1 and 2 for best trial, and average of all 3 trials. CV = coefficient of variance

	Pedar-X®		**Wii® Board**	
	Best	Mean	Best	Mean
Stance	CV (%)	CV (%)	CV (%)	CV (%)
1	24 ± 23	22 ± 26	30 ± 22	22 ± 19
2	20 ± 17	28 ± 23	20 ± 12	15 ± 14
3	32 ± 25	34 ± 24	20 ± 17	16 ± 17
4	18 ± 30	15 ± 10	15 ± 13	14 ± 14

3.3 Inter-day Repeatability

The ICC analysis showed Pedar-X® data for stance 1 (ICC = 0.209) to be unreliable, whereas stances 2 (ICC = 0.854), 3 (ICC = 0.688), and 4 (ICC = 0.857) were shown to be reliable and repeatable (Table 8).

Table 8. Single measure ICC, p-values, and 95% CIs with UL and LL reported between visit 1 and visit 2. ICC = intraclass correlation coefficient, CI =confidence interval, UL = upper limit, LL = lower limit.

	Pedar-X®		
Stance	ICC	CI (95%) LL, UL	p-value
1	0.209	-0.287, 0.617	0.202
2	0.854	0.643, 0.945	0.000003
3	0.688	0.325, 0.875	0.000791
4	0.857	0.649, 0.946	0.000003

The t-test showed stances 1 ($p = 0.44$), 2 ($p = 0.64$), 3 ($p= 0.0502$), and 4 ($p = 0.29$) had no significant difference of balance indices between visit 1 and 2 ($p>0.05$)(Table 9).

Table 9. T-values and p-values between visit 1 and visit 2 for all 4 stances from Pedar-X®.

Pedar-X®		
Stance	t-value	p-value
1	0.80	0.44
2	0.47	0.64
3	2.12	0.0502
4	1.10	0.29

3.4 SCAT5 Correlation

Although stances 2 and 4 had similar ICC values (stance 2: ICC = 0.854; stance 4: ICC = 0.857) (Table 9), stance 4 had a closer correlation between symptom count (Visit 1: r-value = 0.632, *p = 0.007*; Visit 2: r-value = 0.520, *p = 0.032*) and symptom severity score (Visit 1: r-value = 0.605, *p = 0.010*; Visit 2: r-value = 0.532, *p = 0.028*) (Table 10).

Table 10. R- and p-values for stance 2 and 4. Data from individual participant SD from visit 1 and visit 2 correlated to symptom count, symptom severity score and mBESS score. SD = standard deviation, mBESS = modified balance error scoring system.

	Visit 1				**Visit 2**			
	Stance 2		**Stance 4**		**Stance 2**		**Stance 4**	
Variables Compared	r-value	p-value	r-value	p-value	r-value	p-value	r-value	p-value
Symptom Count	0.355	0.213	0.632	0.007	0.071	0.787	0.520	0.032
Symptom Severity Score	0.381	0.179	0.605	0.010	0.111	0.671	0.532	0.028
mBESS score	0.121	0.643	0.180	0.491	0.393	0.119	-0.057	0.828

The mBESS r-values were not significant (*p>0.05*) (Table 11), whereas Pedar-X® stance 4 r-values were significant (*p<0.05*) (Table 10). There was less of a correlation between symptom count and severity when correlated with mBESS (Visit 1: r-value = 0.158, 0.132; Visit 2: r-value = 0.263, 0.254) scores (Table 11), than when correlated with Pedar-X® balance indices (Visit 1: r-value = 0.632, 0.605; Visit 2: r-value = 0.520, 0.532) (Table 10).

Table 11. R- and p-values from visit 1 and visit 2. Symptom count and symptom severity score correlated to mBESS test score. mBESS = modified balance error scoring system.

	Visit 1		**Visit 2**	
	r-value	p-value	r-value	p-value
Symptom Count	0.158	0.546	0.263	0.308
Symptom Severity Score	0.132	0.613	0.254	0.324

A positive linear correlation was determined between symptom severity score and stance 4 balance indices from visit 1 (r = 0.40, *p = 0.007*, CI of slope = 0.933, 4.904) and 2 (r = 0.29, *p = 0.028*, CI of slope = 0.175, 2.576) (Figure 8A.1 and 8A.2). Also, a positive linear correlation was determined between symptom score and stance 4 balance indices from visit 1 (r = 0.36, *p = 0.011*, CI of slope = 0.676, 4.355) and visit 2 (r = 0.27, *p= 0.032*, CI of slope = 0.123, 2.393) (Figure 8B.1 and 8B.2).

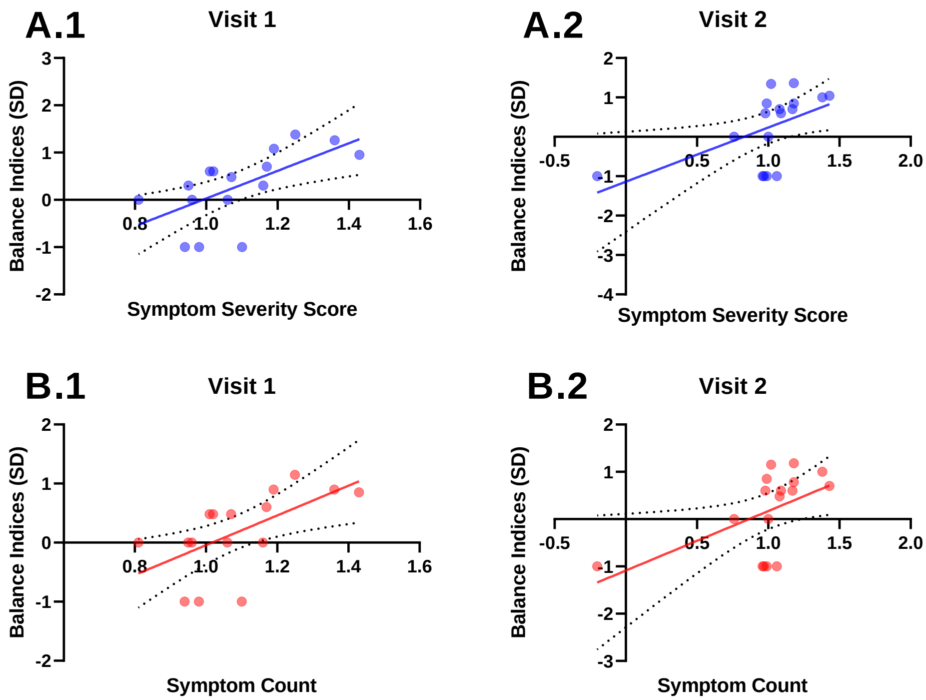

Figure 8. Linear regression of individual participant's log-transformed values of the correlation between A.1) visit 1 balance indices (SD) and symptom severity score, A.2) visit 2 balance indices (SD) and symptom severity score, B.1) visit 1 balance indices (SD) and symptom count, and B.2) visit 2 balance indices (SD) and symptom count of stance 4. Black dotted lines represent the 95% confidence intervals of the associated slope (line of best fit), blue and red solid line represent the line of best fit.

4. Discussion

This study found that inter-day repeatability was good and excellent for stances 2 through 4 (Table 8). Additionally, although there was the possibility of a learning effect the inter-day mean CV values were consistently less than the best CV counterpart, indicating no learning effect to be present (Table 7). The Between visit intra-participant reliability of Pedar-X® and Wii® Board measurements showed mostly that the Wii® Board had a lower dispersion around the mean, this was likely due the fact that Pedar-X® collects two separate COPs from each foot, whereas the Wii® Board collects one COP for both feet (Table 7). Furthermore, intra-day repeatability of Pedar-X® showed no significant differences between visits 1 and 2, emphasising the repeatability of the testing methodology (Table 9). Finally, stance 4 had the best correlation with both symptom count and symptom severity scores of SCAT5 (Table 10), and also had a positive linear regression with the SCAT5 symptom evaluation (Figure 8).

The Pedar-X® system demonstrates its inter-day repeatability (ICC), showing good and excellent values for all stances except for the first (Table 8). The Pedar-X® ICC values (Table 8) for stances 2 and 4 were better or similar to that of other balance and postural stability studies using force plates and Wii Board® measurements (Holmes et al., 2012; Muehlbauer et al., 2011), whereas stances 1 and 3 had lower ICCs. This may be due to the ease of the stance, as it is well-supported that the challenge of a single leg test results in a more true balance assessment (Ageberg et al., 2003; Riemann and Schmitz, 2012; Kouvelioti et al., 2015; Muehlbauer et al., 2014). Inter-day repeatability of Pedar-X® improves as the available sensory input decreases, regardless of the stance being harder to maintain according to Muehlbauer et al., (2014). By removing visual input but maintaining the somatosensory input and bilateral base, there is a noticeable increase in the reliability of the measure; this can be seen in the improvement of ICC values between stance 1 and 3 (Table 8) . The repeatability further increases when we maintain visual input, but decrease somatosensory input and the bilateral base to unilateral; this is observed as a greater improvement from stance 1 to 2 (Table 8). The most reliable stance, stance 4, removes visual input and decreases somatosensory input and changes the bilateral base to unilateral. By decreasing sensory inputs, which could compensate for deficiencies, we can assess the reliability of a participant's inherent ability to balance rather than their ability to integrate and respond to sensory input. The improvement of ICC as the challenge of a stance increases supports Pedar-X®'s ability to measure repeated balance indices over multiple visits, and additionally provides evidence that not all stances are the same in regards to the quality of data that can be ascertained from them.

It is vital to mention that inter-day, intra-participant CV values are moderately acceptable for stances 1, 2 and 4, but inter-day ICC values for stances 2 and 4 are excellent, and stance 3 is good (Table 7; Table 8). This disparity is due the fundamental difference between the dynamics of CV and ICC. ICC describes how closely the values of visit 1 track the values of visit 2, from participant to participant, giving the repeatability, and it represents how rank order is replicated between visits 1 and 2 (Albertus, 2008; Hopkins, 2000). CV, in contrast, describes intra-participant variability which gives the reliability of measurements and portrays the consistency, dependability and error free nature of them (Albertus, 2008; Hopkins, 2000). Additionally, ICC values describe the trend of repeatability within a group of participants, whereas CV describes the trend of reliability within an individual participant's measurements. Metaphorically and graphically speaking, CVs would be represented as separate points on a graph, one for each participant, whereas ICC would be represented as a single line of best fit. Although the individual points on the graph may not be positioned linearly, the line of best fit informs us otherwise. In this study, CV values mostly are moderately acceptable, as there is a moderate amount of variability (Table 7), but ICC values were good and excellent (Table 8). These outcomes mean that data collected from this study are not best used for a one-on-one study of concussion as there is too much noise relative to signal, indicated by CV, for a proper assessment. This is a similar outcome to studies using serum as a biomarker for concussion in student athletes (Asken et al., 2018). Although concussion could very well effect balance, using CV and this study to indicate concussion would not be advisable, as this study looks at balance variance of healthy athletes.

Equally important to note, concerns can arise within reliability testing when a participant repeats a stance multiple times, as this can lead to the possibility of a learning effect taking place. As the inter-day mean CVs were not consistently lower than the best CVs, there does not appear to be a learning effect (Table 4). Further proof of this is seen where participant's best trial is shown to vary between stances (Appendix D.1). In light of this, the importance of thorough baseline testing, prior to assessing injured athletes on the side-line, becomes apparent. The proper baseline sampling of each participant allows contemporary measurements to be tested against their predetermined range of balance abilities in a non-concussed situation. This is especially crucial as athletes' balance abilities vary greatly between one another. This range can be due to athleticism, family history of mental health, the presence of mental illness, attention deficit hyperactivity disorder (ADHD), and being diagnosed with a learning disability, which negatively influences the ability to balance (Downey et al., 2018; Chin et al., 2016). As balance baseline form a constantly-evolving metric for deviation from an athletes' normal ability, it is imperative that there is a robust and reliable system available to quantify balance disturbances both on- and off-field.

It is valuable to demonstrate whether measurements taken from Pedar-X® are comparably reliable to current devices used, such as the Wii® Board. Between visit intra-participant reliability (CV) of Pedar-X® and Wii® Board balance measurements found that the Wii® Board does have lower dispersion around the mean for all stances and visits except for stance 1 (Table 7). Pedar-X® likely showed greater dispersion as it was collecting two separate COPs from each foot, whereas the Wii® Board collects one COP for both feet. This is further supported by the best CVs results being significantly more consistent between Pedar-X® and

Wii® Board measurements during single leg stances 2 and 4 (Table 7). It is important to state that Wii® Board and Pedar-X® CV values were higher in this study than other studies that used the Wii® Board, force plates, and Pedar-X® (Jorgensen et al,. 2014; Ramanathan et al., 2012). The disparity between Wii® Board CV values could be related to the contrast in type of balance test: static vs dynamic, the data collected being a score within a set range, and the difference in test length (Jorgensen et al., 2014). Ramanathan et al., (2012) stated CV values are much lower than those in Table 7 due to the nature of their calculation. Had the values been calculated using the standard *(σ/μ)*100*, where σ is the SD and μ is the mean of a sample, the values would be much more comparable. The difference between the Wii® Board and force plate could be due to a lack of sensitivity as the Wii® Board has less sensors and a lower frequency than a standard force plate (Huurnink et al., 2013; Bartlett et al., 2014). However, as Wii® Boards are widely used as a robust methodology for recording balance measurements, the marginal disparity between this study's Pedar-X® and Wii® Board collected CVs could indicate that Pedar-X® is similarly reliable.

It is clear that Pedar-X® has proven its capability to measure balance indices, and that it has the potential to be useful for future large-scale studies. But first, it is essential to establish its ability as a successful balance assessor over time, as this system would ultimately be used throughout an entire season of athleticism – not just during one game. Likewise, it is important to confirm the quality of information collected from each stance, as we have already noted that not all stances are created equally valuable for our purpose. Looking at the intra-day repeatability (t-test) of Pedar-X® data showed the difference to not be significant (p>0.05) between visit 1 and visit 2 measurements, although values could still be considerably different, as variance increases it lowers the likelihood of a difference between trials being analysed as significant (Table 9). Although all p-values indicated no significant difference, the best repeatability comes from the stances with the highest ICC values (Table 8), stances 2 and 4, the unilateral balance tests. This further supports that a single leg balance test results in more robust assessment of balance, and additionally that the quality of measurements taken from all 4 stances is not equal (Ageberg et al., 2003; Riemann and Schmitz, 2012; Kouvelioti et al., 2015; Muehlbauer et al., 2014).

To provide evidence that Pedar-X® can be feasibly used for future studies relating to concussion management, it is imperative to demonstrate that it can be used successfully in conjunction with the widely-used SCAT5. Due to the outcome of inter- and intra-day repeatability tests of stances 2 and 4, correlation was analysed between these stances and SCAT5 symptom evaluations and mBESS scores (Table 10). Stance 4, similarly to the ICC results (Table 8), had the best correlational outcomes, as it correlated well with both symptom count and symptom severity scores of SCAT5. Although stance 2 had a great ICC (Table 8), it had a poor correlational relationship with SCAT5 evaluations (Table 10), possibly due to the availability of visual sensory input compensating for balance deficiencies (Ageberg et al., 2003; Riemann and Schmitz, 2012; Kouvelioti et al., 2015; Muehlbauer et al., 2014). The only functional difference between stances 2 and 4 is the availability and loss of visual sensory input, respectively. The strong correlation between symptom evaluations and stance 4 confirms that Pedar-X® can work effectively with part of the current SCAT5. However, both stances 2 and 4 had a generally weak correlation with SCAT5 mBESS scores. This is an indication that the current subjective balance test scoring system used for SCAT5 may not be the best, particularly when compared to data from stance 4 using Pedar-X®. For this reason, the current SCAT5 balance test scoring system, mBESS, was correlated with the same symptom evaluations as stances 2 and 4 (Table 11). When correlating SCAT5 mBESS scores to symptom evaluations, there was no significant correlation. This demonstrates that the current set-up for balance testing scoring within SCAT5 is not the best option for assessing concussion-related balance disturbances, and that Pedar-X® is a more accurate objective measurement system, notably when paired with stance 4. To further support the success of stance 4 Pedar-X® measurements in conjunction with SCAT5 symptom evaluations, Figure 9 shows a positive linear correlation for both visits. This validates the feasibility of using Pedar-X® measurements in conjunction with SCAT5 to obtain a more accurate measurement of balance variance.

As noted previously, the major drawback to using mBESS is the subjectivity of the scoring system (Houston et al., 2018; Bell et al., 2011). Although mBESS is still considered the gold standard for non-laboratory evaluation of balance disturbances, it can still be improved upon to be less subjective. The stances used during mBESS are still consistently used in research for monitoring and managing concussion (Houston et al., 2018). This is due to heightened challenge of the stances resulting in better exposing balance disturbances, especially for well-trained athletes (Riemann et al., 2017). In addition, the difficulty of the stances and the decrease of visual input and sometimes sensory input serve to reduce the compensation of balance deficiencies (Ageberg et al., 2003; Riemann and Schmitz, 2012; Kouvelioti et al., 2015; Muehlbauer et al., 2014). In this study the best stance used was unilateral with eyes closed, which is an exact copy of a stance from the mBESS, further indicting that the issue is not with the balance test, but rather the subjective scoring system.

Many but not all university and collegiate sport programs enforce a baseline testing protocol for all high risk sports teams. The enforced baseline protocols vary amongst schools, but can include SCAT5, balance and eye tracking tests (Parachute 2018). But as a specific baseline protocol is not internationally enforced, many athlete's injuries will go unnoticed. It is important to create a robust testing method for both baseline, and post-injury assessment. The assessment used during baseline testing should be easily repeated post-injury, wherever that injury may occur. The repeatability of an assessment is important as it removes the delay of needing injured athletes to only test in a specific laboratory environment, due to the type of measurement devices used. This study proposes the possibility of using a portable device that is not constricted by the use of Wi-Fi or electrical sockets. If in future testing this device and stance 4 assessment prove to be capable of noting a balance disturbance difference from normal balance variance as a result of concussion, it could prove to be a very powerful monitoring and management tool.

Wii® Boards are an affordable and effective off-field alternative to force plates, but they are not as feasible as Pedar-X® insoles for the future of side-line assessment of athletes. During a game, between plays, athletes do not have the time to leave the field to stand on a Wii® Board to be assessed. With Pedar-X® insoles, players can wear them constantly throughout the game. Due to the success of stance 4 at measuring normal balance variance in healthy, non-concussed individuals, after further research into its ability to detect balance disturbance in regards to concussion, players suspected of receiving a concussion can quickly be connected to the Pedar-X® pack transmitter and battery, and promptly assume stance 4. This can be done anywhere along the side-line, and in inclement weather this can be done under an umbrella, whereas the Wii® Board would require a weather protected area and a socket for the Raspberry Pi® peripheral. Pedar-X® does not need a socket to transmit, collect, or analyse data, and it would be Bluetooth® transmitted to the Pedar-X® software on a laptop, where it can be immediately analysed for any indication of balance disturbances. Wii® Boards are mass produced which leads to many technical limitations, calling into questions the validity of measurements (Clark et al., 2018). In the future, Pedar-X® could possibly be used to detect concussion-related balance disturbances during games; after further research regarding its ability to detect balance disturbances outside the normal caused by concussion, once tabletor iPad®-compatible software is developed, and when the insoles do not need to be attached to the battery and Pedar-X® pack to transmit data. With the aforementioned improvements, Pedar-X® has the potential to become a standard protocol for responsible management of players' health, able to monitor them regardless of whether a player is at the far end of the field.

The positive relationship between SCAT5 symptom evaluations and Pedar-X® measurements is significant, because it had been noted that the mBESS is not the most accurate balance test scoring system (Waddington et al., 2015; Downey et al., 2018; Chin et al., 2016; Houston et al., 2018). The correlation between SCAT5 and Pedar-X® indicates that there is a more accurate, objective test than what is currently offered through SCAT5. When it comes to the health and wellbeing of athletes, it is important that they do not slip through the cracks, due to an inaccurate measurement system. This system will potentially lead to future studies that can better detect changes in balance ability of athletes, and therefore better detect sport-related concussion.

4.1 Future Directions

In future, the study could be repeated with a much larger sample size, to create normative values for baseline and injury comparison, as this study was limited by the availability of appropriate athletes. Assessing over two visits limited this study's ability to map repeatability, and future studies should include more iterated visits to better-discern the long-term capacity of Pedar-X® to monitor balance disturbances. An additional limitation was that non-concussed athletes were studied, which questions whether these measurements would have been sensitive enough to detect change related to concussion. Moreover, participants' measurements were taken a week apart - during which time practices and games took place. Although such events were not recorded or controlled for, large impacts potentially leaving participants sub-concussed (Pearce, 2016; Di Virgilio et al., 2016) and adding to the variability of measurements could have occurred. In the future potential sub-concussive events should be recorded, or participants should be controlled to avoid such events. It would be beneficial to see future studies determine the values for concussed versus non-concussed participants and contact sport versus non-contact sport participants, for both males and females. Furthermore, with the responsiveness of Pedar-X®, the patterns and direction of balance disturbances could be analysed in conjunction with SCAT5 symptom evaluations for correlation. This novel idea has the ability to also impact the research surrounding strokes and the elderly, as current research localizes around a change in gait, but this study indicates that the repeatability of Pedar-X® may be able to one day indicate resultant changes in balance.

4.2 Conclusion

This study was the first of its kind to use Pedar-X® as a measurement of balance index, in conjunction with SCAT5 evaluations. It built on existing research to determine if there was a need for a more comprehensive measure of balance disturbances, to be used alongside SCAT5. Balance measurements taken using the Pedar-X® in-shoe plantar pressure measurement system were similar to Wii® Board intra-participant reliability measurements. When further analysed, Pedar-X® proved to be moderately-reliable for inter-day measurements, but only for the harder to maintain stances 2 through 4. Most stances had good or excellent inter-day repeatability, showing no significant differences between visits 1 and 2. When the two stances with the best repeatability, stances 2 and 4, were evaluated for their correlation with SCAT5, stance 4 had the strongest and only significant correlation. Stance 4 correlated closely with the SCAT5 symptom evaluations, but poorly with mBESS scores. When mBESS scores were correlated to SCAT5 symptom evaluations, there was no significant correlation computed. Pedar-X® measurements from stance 4 had a positive linear correlation with SCAT5 symptom scores and severity for both visits. Until such a time as this promising technology is further developed, it is recommended that it be used for baseline data collection and further research into its possible ability to detect balance disturbance outside of the normal related to concussion. This research could serve as a basis for future large-scale studies as inter- and intra-repeatability values are acceptable, leading to a future where athletes are safer in contact sport. Overall, Pedar-X® was moderately reliable and had excellent repeatability measurements of balance, and this study could be feasibly used in conjunction with SCAT5 to aid in future research.

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Appendix A

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Recovery After Sports-Related Concussion

Kathryn Schulze,
Zacharias Nikolaou

DAILY NEWS

NEW YORK'S HOMETOWN NEWSPAPER

This is your brain on football

SEE SPORTS

- NFL concussions up a stunning 58%
- Frightening figures just 'tip of iceberg'

WHITE HOUSE: HIL HAD TOP-SECRET EMAILS PAGES 6-7

Sport Concussion by the Numbers

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- In USA 152 cases of sport concussion per 100,000 A&E admissions (Coronado et al 2015)
- Two thirds of these cases occur <19 years old
- UK: Rugby Union report high prevalence of sport concussion 2.43 concussions/1000 player hours (Roberts et al 2017)
- Higher prevalence in youth players 3.35 concussions/1000 player hours (Kirkwood 2015)
- Prevalence likely higher due to under reporting (McCrory et al 2013)
- Concussion can = disability, memory impairment and poor life satisfaction (Whiteneck et al 2016)

Sport concussion is a public health issue

Why, Concussion Management?

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January 29, 2011
- "3 blows to the head"
- Sent back to the field each time
- Inadequate recovery time between blows; aka Second Impact Syndrome
- Later died in Hospital

Ben Robinson's rugby death is first of its kind in Northern Ireland

The first death in Northern Ireland due to second impact syndrome has been recorded at a 14-year-old boy's inquest.

The coroner at the hearing in Belfast said it was also "probably" the first such case in the UK.

Ben Robinson, from Carrickfergus, County Antrim, died after suffering concussion during a school rugby match.

The syndrome happens when a blow causes swelling to the brain before it has recovered fully from an earlier injury.

The schoolboy was in several heavy tackles before collapsing near the end of the game in January 2011.

Ensure adequate recovery to prevent second impact syndrome

When, Concussion Management?

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Identify and manage concussion safely:

- from the initial incident
- through the mandatory rest periods
- to the graduated return to play

How, Concussion Management?

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- Evidence for SCAT3 effectiveness is weak
- Likely to be improved if accompanied by objective tests (Thomas et al. 2016)
- SCAT5 is being introduced and may improve effectiveness

How, Concussion Management?

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MINIMUM RETURN TO PLAY INTERVALS WHEN FOLLOWING GRTP PROTOCOL

AGE GROUP	GRTP STAGE 1 MINIMUM REST PERIOD	CAUTION!	GRTP STAGES 2 to 5	CAUTION!	GRTP STAGE 6 MINIMUM RETURN TO PLAY INTERVAL
Children and Adolescents (aged 18 and under)	14 days	Return to play protocol should be started only if the player is symptom free and off medication that modifies symptoms of concussion	4 Stage GRTP Progression every 48 hours, if symptom free	Contact sport should be authorised only if the player is symptom free and off medication. MEDICAL CLEARANCE RECOMMENDED	14 day rest + 9 day GRTP = Day 23 post injury
Adults	7 days		4 Stage GRTP Progression every 24 hours, if symptom free		7 day rest + 4 day GRTP = Day 12 post injury

CAUTION! Any player with a second concussion within 12 months, a history of multiple concussions, players with unusual presentations or prolonged recovery should be assessed and managed by health care providers with experience in sports-related concussions.

Evidence for these time periods = √0 **Aka none**

Protocol, and How We Fit In

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GRTP PROTOCOL: EACH STAGE IS A MINIMUM OF 24 HOURS IN ADULTS, 48 HOURS IN THOSE AGED 18 AND UNDER

Test 1, Test 2, Test 3, Test 4, Test 5, Test 6, Test 7

Stage	Rehabilitation Stage	Exercise Allowed	% Max Heart rate	Duration	Objective
1	Minimum rest period	Complete body and brain rest			Recovery
2	Light exercise	Walking, light jogging, swimming, stationary cycling or equivalent. No resistance training, weight lifting, jumping or hard running	<70%	<15min	Increase heart rate
3	Sport-specific exercise	Simple movement activities e.g. running drills. Limit body and head movement. NO head impact activities	<80%	<45min	Add movement
4	Non-contact training	Progression to more complex training activities with increased intensity, coordination and attention e.g. passing. May start resistance training. NO head impact activities	<90%	<60min	Exercise, coordination and skills/tactics
5	Full Contact Practice	Normal training activities e.g. tackling			Restore confidence and assess functional skills by coaching staff
6	Return to Play	Player rehabilitated			Return to play

How, Concussion Management? In the Lab

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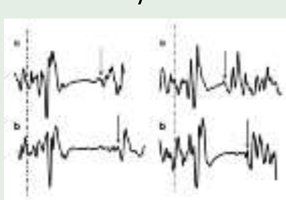
Transcranial Magnetic Stimulation (TMS)

- Magnetic field generator, or "coil", is placed upon head
- Magnetic current is induced upon specific area of the brain, causing inhibition of specific muscle group
- Tells us about your muscle's ability to regain strength



How, Concussion Management? In the Lab

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Pedar Insoles

- The insole is placed inside the patients shoe
- Using 85-99 sensors, measuring pressure and pressure changes on the bottom of foot
- Tells us about weight distribution, and balance



What We Want to Do

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Aim: To establish objective measures of concussion by harnessing TMS, blood biomarkers, motor control and balance to current clinical practice as advocated by the Scottish Concussion Guidelines.

Objective: To perform these measurements alongside existing clinical measurements following concussions from amateur youth and adult contact team sport players

Why Work Together?

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- Reduce amount of inactive rest before RTP
- Introduce graded return to play, based on Scottish Sports Concussion Guidance
- Complement graded return to play with objective measures
- Need your signed consent to participate


Appendix B

Participant Information Sheet

Title of Study: RECOVERY OF NEUROPSYCHOLOGICAL, NEUROMUSCULAR AND MOTOR FUNCTION DEFICITS FOLLOWING SPORTS-RELATED CONCUSSION

Investigators: Mr Zacharias Nicolaou, Ms Kathryn Schulze, Dr Magdalena Ietswaart, Prof Lindsay Wilson, Prof David Donaldson, Dr Willie Stewart (University of Glasgow) and Dr Angus Hunter

Before signing the written informed consent form, allowing you to take part in the study, it is important that you fully understand the tasks you will be required to perform for this project. I strongly encourage you to read this document carefully and if you have any doubts and/or questions do not hesitate to contact me. My contact information can be found at the end of this participant information sheet. I also would like to inform you that participation in this project is completely voluntary and should you wish to withdraw from it you will be able to do so without having to provide any explanation.

Aims of the Study:

The current test used by teams to inform the graded return to play after an athlete is concussed is Sport Concussion Assessment Tool (SCAT). ***Concussion*** is a temporary injury to the brain caused by a bump, blow or violent shake to the head.

In this study, we would like to see how well SCAT compares with: 1) the transcranial magnetic stimulation (TMS) method, 2) balance tests in athletes that are concussed. TMS method works by sending weak magnetic signals to specific areas of the brain (motor cortex), which control muscle contraction. So using the TMS method will allow us to test how well the signals travel from the brain to the muscles. TMS is widely used and completely safe.

We will carry out baseline tests on non-contact sports as well, using the above tests, to see whether these measures are sensitive and reliable in detecting subtle differences between concussed and non-concussed athletes.

Protocol:

The study wants to recruit athletes from contact sports (American Football, Rugby) for baseline tests (see ‘Aims of the study’). These athletes will be required to complete an informed consent form within 48 hours of receiving the participant information sheet.

The baseline tests are SCAT5, TMS and balance test. If you decide you want to participate in the study, you will need to attend the performance laboratories found in the Gannochy Sports Centre at the University of Stirling.

In addition, we ask that you **bring shorts** with you, so that we can perform the TMS measurements.

Day 1 (Baseline or 1st assessment 48 hours following concussion)

You will start by completing the Sport Concussion Assessment Tool.

We will show you how to complete a set of maximal voluntary contractions (MVCs – maximal force you can produce) on an Isokinetic Dynamometer (Kin-Com).
On this day you will also go through the TMS measurement for familiarization. First, we will shave and rough up the area of skin above the muscle of interest (Rectus Femoris, and Vastus lateralis – two of the four muscles of your thighs). Following placement of 2 electrodes on the shaved area of skin, a weak magnetic current will then be delivered to your brain via a handheld coil positioned above your scalp. This current will cause the brain to send signals to the muscles on the thigh to contract. Then the two electrodes attached to your leg will record this signal, via a technique known as electromyography.

On the same day, we will test your balance using a force platform (very similar to a Wii Board) and foot sensors (Pedar-X insoles), which will measure how much your centre of pressure changes in response to four different conditions. These conditions are: (i) Standing on two legs and eyes open, (ii) Standing on two legs and eyes closed; (iii) Standing on one leg and eyes open and (iv) Standing on one leg and eyes closed.

Day 2 (Reliability and Repeatability measurements)

Repeat of Day 1, please refer to Day 1 to see what will be done during this session.

TMS
TMS is very safe but you should be aware of hypothetical risks associated with using this method, mainly if you are currently taking certain types of medication.
For this reason, you will be asked to fill out some questionnaires, which will help us understand whether it is safe for you to go through the procedure. There are also certain conditions that are considered as high risk factors. Key conditions are listed below:

- If you have neurological conditions
- If you have suffered from epilepsy, seizures, fainting spells in the past (or if a member of family does)
- If you have any electrical devices fitted to your body (such as pacemakers, cochlear implant, medication pump, surgical clips, neurostimulator)
- If you have any metal implants in his/her brain
- If you have undergone any type of neurosurgery procedure (including eye surgery)

A minor side effect linked with the use of TMS is the possibility of a temporary change in hearing due to the noise produced when the TMS sends a magnetic signal, although it should go away within a few hours. We will also give you earplugs to protect your ears during the procedure.

Lastly, because of the need to shave and rough up the skin to ensure a good signal from the electrodes, there may be some mild-to-moderate irritation and, in very rare cases, it could result in an infection.

What are the possible benefits of taking part?

In the long term, the information we get can help to improve the current Scottish Sport Concussion Guidelines by providing objective evidence for more objective, therefore more accurate return to play timescale.

What if there is a problem?

If you are concerned about any aspect of this study, you can speak to myself on the contact details provided below, and I will endeavor to answer your questions. If I am unable to answer your concerns and you wish to complain formally, you can do this by contacting the Dean of the Faculty of Health Sciences and Sport Professor Jayne Donaldson on jayne.donaldson@stir.ac.uk.

Is there any Involvement of the General Practitioner/Family Doctor (GP)?

Your GP will not be informed of your participation of the study, however if questionable results are found that may be detrimental to your health, you will be informed and it will be recommended that you make an appointment to discuss such issues with your GP.

Will my taking part in the study be kept confidential?

All the data recorded will be stored on computers and paper files in accordance with the Data Protection Act, 1998. All your personal information will be compiled under a code known only to myself and members of the research team to ensure anonymity.

Should you have any concerns, or wish to speak to someone independent of the study, please contact Professor Jayne Donaldson, Dean of faculty, faculty of health sciences and sports at: jayne.donaldson@stir.ac.uk

If you have any further queries regarding this project do not hesitate to contact either me or the post-graduates:

Dr Angus Hunter,
Room 3A77,
University of Stirling,
Stirling,
FK82AW
Office: 01786 466497
Mobile: 07736071314

Mr Zacharias Nikolaou
Email: zacharias.nicolaou1@stir.ac.uk
Mobile: 07842220614
Facebook: Zacharias Nicolaou

Ms Kathryn Schulze
Email: kathryn.schulze1@stir.ac.uk

FOR 19 YEAR OLDS AND ABOVE:

CONSENT BY PATIENT/VOLUNTEER TO PARTICIPATE IN:

A study comparing the test currently used to assess concussion (SCAT 5) with three objective measures (Transcranial magnetic stimulation, postural stability, and blood samples).

Name of Patient/Volunteer: …..

Contact info (Email: …………………………………………………………………………

& Telephone Number): ……………………………………………………….

Name of Study: RECOVERY OF NEUROPSYCHOLOGICAL, NEUROMUSCULAR AND MOTOR FUNCTION DEFICITS FOLLOWING SPORTS-RELATED CONCUSSION.

Principal Investigator: ....

I have read the participant information sheet on the above study and have had the opportunity to discuss the details with either Dr. Angus Hunter, or Mr Zacharias Nikolaou, or Ms Kathryn Schulze, and ask questions. The principal investigator has explained to me the nature and purpose of the tests to be undertaken. I understand fully what is suggested to be done.

I have agreed to take part in the study as it has been outlined to me, but I understand that I am completely free to withdraw from the study or any part of the study at any time I wish. I understand and agree that my participation in the study is entirely at my own risk.

I understand that these trials are part of a research project designed to promote medical or scientific knowledge, which has been approved by the NHS, Invasive or Clinical Research (NICR) committee, and may be of no benefit to me personally. The Sports Studies Ethics Committee may wish to inspect the data collected at any time as part of its monitoring activities.

I also understand that is my responsibility to inform my General Practitioner that I have taken part in this study if any unusual or surprising observations are made.

I hereby fully and freely consent to participate in the study, which has been fully explained to me.

(Please only print this consent form and once both of you have signed it please return it to room 3A72 to Zacharias Nikolaou or Kathryn Schulze).

Signature of Patient/Volunteer: ....

Date: ....

I (Investigator) confirm that I have explained to the patient/volunteer named above, the nature and purpose of the tests to be undertaken.

Signature of Investigator: ....

Date: ....

Appendix C

BJSM Online First, published on April 26, 2017 as 10.1136/bjsports-2017-097506SCAT5

To download a clean version of the SCAT tools please visit the journal online (http://dx.doi.org/10.1136/bjsports-2017-097506SCAT5)

SCAT5©

SPORT CONCUSSION ASSESSMENT TOOL — 5TH EDITION

DEVELOPED BY THE CONCUSSION IN SPORT GROUP

FOR USE BY MEDICAL PROFESSIONALS ONLY

supported by

FIFA FEI

Patient details

Name: ______________________________

DOB: ______________________________

Address: ______________________________

ID number: ______________________________

Examiner: ______________________________

Date of Injury: ____________________ Time: ____________________

WHAT IS THE SCAT5?

The SCAT5 is a standardized tool for evaluating concussions designed for use by physicians and licensed healthcare professionals[1]. The SCAT5 cannot be performed correctly in less than 10 minutes.

If you are not a physician or licensed healthcare professional, please use the Concussion Recognition Tool 5 (CRT5). The SCAT5 is to be used for evaluating athletes aged 13 years and older. For children aged 12 years or younger, please use the Child SCAT5.

Preseason SCAT5 baseline testing can be useful for interpreting post-injury test scores, but is not required for that purpose. Detailed instructions for use of the SCAT5 are provided on page 7. Please read through these instructions carefully before testing the athlete. Brief verbal instructions for each test are given in italics. The only equipment required for the tester is a watch or timer.

This tool may be freely copied in its current form for distribution to individuals, teams, groups and organizations. It should not be altered in any way, re-branded or sold for commercial gain. Any revision, translation or reproduction in a digital form requires specific approval by the Concussion in Sport Group.

Recognise and Remove

A head impact by either a direct blow or indirect transmission of force can be associated with a serious and potentially fatal brain injury. If there are significant concerns, including any of the red flags listed in Box 1, then activation of emergency procedures and urgent transport to the nearest hospital should be arranged.

Key points

- Any athlete with suspected concussion should be REMOVED FROM PLAY, medically assessed and monitored for deterioration. No athlete diagnosed with concussion should be returned to play on the day of injury.
- If an athlete is suspected of having a concussion and medical personnel are not immediately available, the athlete should be referred to a medical facility for urgent assessment.
- Athletes with suspected concussion should not drink alcohol, use recreational drugs and should not drive a motor vehicle until cleared to do so by a medical professional.
- Concussion signs and symptoms evolve over time and it is important to consider repeat evaluation in the assessment of concussion.
- The diagnosis of a concussion is a clinical judgment, made by a medical professional. The SCAT5 should NOT be used by itself to make, or exclude, the diagnosis of concussion. An athlete may have a concussion even if their SCAT5 is "normal".

Remember:

- The basic principles of first aid (danger, response, airway, breathing, circulation) should be followed.
- Do not attempt to move the athlete (other than that required for airway management) unless trained to do so.
- Assessment for a spinal cord injury is a critical part of the initial on-field assessment.
- Do not remove a helmet or any other equipment unless trained to do so safely.

1

IMMEDIATE OR ON-FIELD ASSESSMENT

The following elements should be assessed for all athletes who are suspected of having a concussion prior to proceeding to the neurocognitive assessment and ideally should be done on-field after the first first aid / emergency care priorities are completed.

If any of the "Red Flags" or observable signs are noted after a direct or indirect blow to the head, the athlete should be immediately and safely removed from participation and evaluated by a physician or licensed healthcare professional.

Consideration of transportation to a medical facility should be at the discretion of the physician or licensed healthcare professional.

The GCS is important as a standard measure for all patients and can be done serially if necessary in the event of deterioration in conscious state. The Maddocks questions and cervical spine exam are critical steps of the immediate assessment; however, these do not need to be done serially.

STEP 1: RED FLAGS

RED FLAGS:

- **Neck pain or tenderness**
- **Double vision**
- **Weakness or tingling/ burning in arms or legs**
- **Severe or increasing headache**
- **Seizure or convulsion**
- **Loss of consciousness**
- **Deteriorating conscious state**
- **Vomiting**
- **Increasingly restless, agitated or combative**

STEP 2: OBSERVABLE SIGNS

Witnessed ☐ Observed on Video ☐

Lying motionless on the playing surface	Y	N
Balance / gait difficulties / motor incoordination: stumbling, slow / laboured movements	Y	N
Disorientation or confusion, or an inability to respond appropriately to questions	Y	N
Blank or vacant look	Y	N
Facial injury after head trauma	Y	N

STEP 3: MEMORY ASSESSMENT MADDOCKS QUESTIONS[2]

"I am going to ask you a few questions, please listen carefully and give your best effort. First, tell me what happened?"

____

____

Mark Y for correct answer / N for incorrect

What venue are we at today?	Y	N
Which half is it now?	Y	N
Who scored last in this match?	Y	N
What team did you play last week / game?	Y	N
Did your team win the last game?	Y	N

Note: Appropriate sport-specific questions may be substituted.

Name: ______________________________

DOB: ______________________________

Address: ______________________________

ID number: ______________________________

Examiner: ______________________________

Date: ______________________________

STEP 4: EXAMINATION GLASGOW COMA SCALE (GCS)[3]

Time of assessment			
Date of assessment			
Best eye response (E)			
No eye opening	1	1	1
Eye opening in response to pain	2	2	2
Eye opening to speech	3	3	3
Eyes opening spontaneously	4	4	4
Best verbal response (V)			
No verbal response	1	1	1
Incomprehensible sounds	2	2	2
Inappropriate words	3	3	3
Confused	4	4	4
Oriented	5	5	5
Best motor response (M)			
No motor response	1	1	1
Extension to pain	2	2	2
Abnormal flexion to pain	3	3	3
Flexion / Withdrawal to pain	4	4	4
Localizes to pain	5	5	5
Obeys commands	6	6	6
Glasgow Coma score (E + V + M)			

CERVICAL SPINE ASSESSMENT

Does the athlete report that their neck is pain free at rest?	Y	N
If there is NO neck pain at rest, does the athlete have a full range of ACTIVE pain free movement?	Y	N
Is the limb strength and sensation normal?	Y	N

In a patient who is not lucid or fully conscious, a cervical spine injury should be assumed until proven otherwise.

OFFICE OR OFF-FIELD ASSESSMENT

Please note that the neurocognitive assessment should be done in a distraction-free environment with the athlete in a resting state.

STEP 1: ATHLETE BACKGROUND

Sport / team / school: ______________________

Date / time of injury: ______________________

Years of education completed: ______________________

Age: ______________________

Gender: M / F / Other

Dominant hand: left / neither / right

How many diagnosed concussions has the athlete had in the past?: ______________________

When was the most recent concussion?: ______________________

How long was the recovery (time to being cleared to play) from the most recent concussion?: ______________________ (days)

Has the athlete ever been:

Hospitalized for a head injury?	Yes	No
Diagnosed / treated for headache disorder or migraines?	Yes	No
Diagnosed with a learning disability / dyslexia?	Yes	No
Diagnosed with ADD / ADHD?	Yes	No
Diagnosed with depression, anxiety or other psychiatric disorder?	Yes	No

Current medications? If yes, please list:

____

____

____

____

____

Name: ______________________

DOB: ______________________

Address: ______________________

ID number: ______________________

Examiner: ______________________

Date: ______________________

2

STEP 2: SYMPTOM EVALUATION

The athlete should be given the symptom form and asked to read this instruction paragraph out loud then complete the symptom scale. For the baseline assessment, the athlete should rate his/her symptoms based on how he/she typically feels and for the post injury assessment the athlete should rate their symptoms at this point in time.

Please Check: ☐ **Baseline** ☐ **Post-Injury**

Please hand the form to the athlete

	none	mild		moderate		severe	
Headache	0	1	2	3	4	5	6
"Pressure in head"	0	1	2	3	4	5	6
Neck Pain	0	1	2	3	4	5	6
Nausea or vomiting	0	1	2	3	4	5	6
Dizziness	0	1	2	3	4	5	6
Blurred vision	0	1	2	3	4	5	6
Balance problems	0	1	2	3	4	5	6
Sensitivity to light	0	1	2	3	4	5	6
Sensitivity to noise	0	1	2	3	4	5	6
Feeling slowed down	0	1	2	3	4	5	6
Feeling like "in a fog"	0	1	2	3	4	5	6
"Don't feel right"	0	1	2	3	4	5	6
Difficulty concentrating	0	1	2	3	4	5	6
Difficulty remembering	0	1	2	3	4	5	6
Fatigue or low energy	0	1	2	3	4	5	6
Confusion	0	1	2	3	4	5	6
Drowsiness	0	1	2	3	4	5	6
More emotional	0	1	2	3	4	5	6
Irritability	0	1	2	3	4	5	6
Sadness	0	1	2	3	4	5	6
Nervous or Anxious	0	1	2	3	4	5	6
Trouble falling asleep (if applicable)	0	1	2	3	4	5	6

Total number of symptoms:	of 22
Symptom severity score:	of 132
Do your symptoms get worse with physical activity?	Y N
Do your symptoms get worse with mental activity?	Y N
If 100% is feeling perfectly normal, what percent of normal do you feel?	

If not 100%, why?

____

____

____

Please hand form back to examiner

3

Name:	
DOB:	
Address:	
ID number:	
Examiner:	
Date:	

STEP 3: COGNITIVE SCREENING

Standardised Assessment of Concussion (SAC)[4]

ORIENTATION

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

The Immediate Memory component can be completed using the traditional 5-word per trial list or optionally using 10-words per trial to minimise any ceiling effect. All 3 trials must be administered irrespective of the number correct on the first trial. Administer at the rate of one word per second.

Please choose EITHER the 5 or 10 word list groups and circle the specific word list chosen for this test.

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. For 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.

List	Alternate 5 word lists					Score (of 5) Trial 1	Trial 2	Trial 3
A	Finger	Penny	Blanket	Lemon	Insect			
B	Candle	Paper	Sugar	Sandwich	Wagon			
C	Baby	Monkey	Perfume	Sunset	Iron			
D	Elbow	Apple	Carpet	Saddle	Bubble			
E	Jacket	Arrow	Pepper	Cotton	Movie			
F	Dollar	Honey	Mirror	Saddle	Anchor			
					Immediate Memory Score			of 15
					Time that last trial was completed			

List	Alternate 10 word lists					Score (of 10) Trial 1	Trial 2	Trial 3
G	Finger	Penny	Blanket	Lemon	Insect			
	Candle	Paper	Sugar	Sandwich	Wagon			
H	Baby	Monkey	Perfume	Sunset	Iron			
	Elbow	Apple	Carpet	Saddle	Bubble			
I	Jacket	Arrow	Pepper	Cotton	Movie			
	Dollar	Honey	Mirror	Saddle	Anchor			
					Immediate Memory Score			of 30
					Time that last trial was completed			

CONCENTRATION

DIGITS BACKWARDS

Please circle the Digit list chosen (A, B, C, D, E, F). Administer at the rate of one digit per second reading DOWN the selected column.

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

Concentration Number Lists (circle one)					
List A	List B	List C			
4-9-3	5-2-6	1-4-2	Y	N	0
6-2-9	4-1-5	6-5-8	Y	N	1
3-8-1-4	1-7-9-5	6-8-3-1	Y	N	0
3-2-7-9	4-9-6-8	3-4-8-1	Y	N	1
6-2-9-7-1	4-8-5-2-7	4-9-1-5-3	Y	N	0
1-5-2-8-6	6-1-8-4-3	6-8-2-5-1	Y	N	1
7-1-8-4-6-2	8-3-1-9-6-4	3-7-6-5-1-9	Y	N	0
5-3-9-1-4-8	7-2-4-8-5-6	9-2-6-5-1-4	Y	N	1
List D	List E	List F			
7-8-2	3-8-2	2-7-1	Y	N	0
9-2-6	5-1-8	4-7-9	Y	N	1
4-1-8-3	2-7-9-3	1-6-8-3	Y	N	0
9-7-2-3	2-1-6-9	3-9-2-4	Y	N	1
1-7-9-2-6	4-1-8-6-9	2-4-7-5-8	Y	N	0
4-1-7-5-2	9-4-1-7-5	8-3-9-6-4	Y	N	1
2-6-4-8-1-7	6-9-7-3-8-2	5-8-6-2-4-9	Y	N	0
8-4-1-9-3-5	4-2-7-9-3-8	3-1-7-8-2-6	Y	N	1
		Digits Score:			of 4

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.

Dec - Nov - Oct - Sept - Aug - Jul - Jun - May - Apr - Mar - Feb - Jan	0 1
Months Score	of 1
Concentration Total Score (Digits + Months)	of 5

Davis GA, et al. Br J Sports Med 2017;0:1–8. doi:10.1136/bjsports-2017-097506SCAT5

4

STEP 4: NEUROLOGICAL SCREEN

See the instruction sheet (page 7) for details of test administration and scoring of the tests.

Can the patient read aloud (e.g. symptom check-list) and follow instructions without difficulty?	Y	N
Does the patient have a full range of pain-free PASSIVE cervical spine movement?	Y	N
Without moving their head or neck, can the patient look side-to-side and up-and-down without double vision?	Y	N
Can the patient perform the finger nose coordination test normally?	Y	N
Can the patient perform tandem gait normally?	Y	N

BALANCE EXAMINATION

Modified Balance Error Scoring System (mBESS) testing[5]

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

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

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

Condition	Errors
Double leg stance	of 10
Single leg stance (non-dominant foot)	of 10
Tandem stance (non-dominant foot at the back)	of 10
Total Errors	of 30

Name: ____________________

DOB: ____________________

Address: ____________________

ID number: ____________________

Examiner: ____________________

Date: ____________________

5

STEP 5: DELAYED RECALL:

The delayed recall should be performed after 5 minutes have elapsed since the end of the Immediate Recall section. Score 1 pt. for each correct response.

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.

Time Started ____

Please record each word correctly recalled. Total score equals number of words recalled.

____

____

____

Total number of words recalled accurately: of 5 or of 10

6

STEP 6: DECISION

Domain	Date & time of assessment:		
Symptom number (of 22)			
Symptom severity score (of 132)			
Orientation (of 5)			
Immediate memory	of 15 of 30	of 15 of 30	of 15 of 30
Concentration (of 5)			
Neuro exam	Normal Abnormal	Normal Abnormal	Normal Abnormal
Balance errors (of 30)			
Delayed Recall	of 5 of 10	of 5 of 10	of 5 of 10

Date and time of injury: ____________________

If the athlete is known to you prior to their injury, are they different from their usual self?
☐ **Yes** ☐ **No** ☐ **Unsure** ☐ **Not Applicable**
(If different, describe why in the clinical notes section)

Concussion Diagnosed?
☐ **Yes** ☐ **No** ☐ **Unsure** ☐ **Not Applicable**

If re-testing, has the athlete improved?
☐ **Yes** ☐ **No** ☐ **Unsure** ☐ **Not Applicable**

I am a physician or licensed healthcare professional and I have personally administered or supervised the administration of this SCAT5.

Signature: ____________________

Name: ____________________

Title: ____________________

Registration number (if applicable): ____________________

Date: ____________________

SCORING ON THE SCAT5 SHOULD NOT BE USED AS A STAND-ALONE METHOD TO DIAGNOSE CONCUSSION, MEASURE RECOVERY OR MAKE DECISIONS ABOUT AN ATHLETE'S READINESS TO RETURN TO COMPETITION AFTER CONCUSSION.

CLINICAL NOTES:

Name:

DOB:

Address:

ID number:

Examiner:

Date:

CONCUSSION INJURY ADVICE

(To be given to the person monitoring the concussed athlete)

This patient has received an injury to the head. A careful medical examination has been carried out and no sign of any serious complications has been found. Recovery time is variable across individuals and the patient will need monitoring for a further period by a responsible adult. Your treating physician will provide guidance as to this timeframe.

If you notice any change in behaviour, vomiting, worsening headache, double vision or excessive drowsiness, please telephone your doctor or the nearest hospital emergency department immediately.

Other important points:

Initial rest: Limit physical activity to routine daily activities (avoid exercise, training, sports) and limit activities such as school, work, and screen time to a level that does not worsen symptoms.

1) Avoid alcohol

2) Avoid prescription or non-prescription drugs without medical supervision. Specifically:

a) Avoid sleeping tablets

b) Do not use aspirin, anti-inflammatory medication or stronger pain medications such as narcotics

3) Do not drive until cleared by a healthcare professional.

4) Return to play/sport requires clearance by a healthcare professional.

Clinic phone number:

Patient's name:

Date / time of injury:

Date / time of medical review:

Healthcare Provider:

Contact details or stamp

Davis GA, *et al. Br J Sports Med* 2017;**0**:1–8. doi:10.1136/bjsports-2017-097506SCAT5

INSTRUCTIONS

Words in *Italics* throughout the SCAT5 are the instructions given to the athlete by the clinician

Symptom Scale

The time frame for symptoms should be based on the type of test being administered. At baseline it is advantageous to assess how an athlete "typically" feels whereas during the acute/post-acute stage it is best to ask how the athlete feels at the time of testing.

The symptom scale should be completed by the athlete, not by the examiner. In situations where the symptom scale is being completed after exercise, it should be done in a resting state, generally by approximating his/her resting heart rate.

For total number of symptoms, maximum possible is 22 except immediately post injury, if sleep item is omitted, which then creates a maximum of 21.

For Symptom severity score, add all scores in table, maximum possible is 22 x 6 = 132, except immediately post injury if sleep item is omitted, which then creates a maximum of 21x6=126.

Immediate Memory

The Immediate Memory component can be completed using the traditional 5-word per trial list or, optionally, using 10-words per trial. The literature suggests that the Immediate Memory has a notable ceiling effect when a 5-word list is used. In settings where this ceiling is prominent, the examiner may wish to make the task more difficult by incorporating two 5–word groups for a total of 10 words per trial. In this case, the maximum score per trial is 10 with a total trial maximum of 30.

Choose one of the word lists (either 5 or 10). Then perform 3 trials of immediate memory using this list.

Complete all 3 trials regardless of score on previous trials.

"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." The words must be read at a rate of one word per second.

Trials 2 & 3 MUST be completed regardless of score on trial 1 & 2.

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."

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.

Concentration

Digits backward

Choose one column of digits from lists A, B, C, D, E or F and administer those digits as follows:

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

Begin with first 3 digit string.

If correct, circle "Y" for correct and go to next string length. If incorrect, circle "N" for the first string length and read trial 2 in the same string length. One point possible for each string length. Stop after incorrect on both trials (2 N's) in a string length. The digits should be read at the rate of one per second.

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

Delayed Recall

The delayed recall should be performed after 5 minutes have elapsed since the end of the Immediate Recall section.

"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."

Score 1 pt. for each correct response

Modified Balance Error Scoring System (mBESS)[5] testing

This balance testing is based on a modified version of the Balance Error Scoring System (BESS)[4]. A timing device is required for this testing.

Each of 20-second trial/stance is scored by counting the number of errors. The examiner will begin counting errors only after the athlete has assumed the proper start position. The modified BESS is calculated by adding one error point for each error during the three 20-second tests. The maximum number of errors for any single condition is 10. If the athlete commits multiple errors simultaneously, only one error is recorded but the athlete should quickly return to the testing position, and counting should resume once the athlete is set. Athletes that are unable to maintain the testing procedure for a minimum of five seconds at the start are assigned the highest possible score, ten, for that testing condition.

OPTION: For further assessment, the same 3 stances can be performed on a surface of medium density foam (e.g., approximately 50cm x 40cm x 6cm).

Balance testing – types of errors

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

"I am now going to test your balance. Please take your shoes off (if applicable), roll up your pant legs above ankle (if applicable), and remove any ankle taping (if applicable). This test will consist of three twenty second tests with different stances."

(a) Double leg stance:

"The first stance is standing with your feet together with your hands on your hips and with your eyes closed. You should try to maintain stability in that position for 20 seconds. I will be counting the number of times you move out of this position. I will start timing when you are set and have closed your eyes."

(b) Single leg stance:

"If you were to kick a ball, which foot would you use? [This will be the dominant foot] *Now stand on your non-dominant foot. The dominant leg should be held in approximately 30 degrees of hip flexion and 45 degrees of knee flexion. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."*

(c) Tandem stance:

"Now stand heel-to-toe with your non-dominant foot in back. Your weight should be evenly distributed across both feet. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

Tandem Gait

Participants are instructed to stand with their feet together behind a starting line (the test is best done with footwear removed). Then, they walk in a forward direction as quickly and as accurately as possible along a 38mm wide (sports tape), 3 metre line with an alternate foot heel-to-toe gait ensuring that they approximate their heel and toe on each step. Once they cross the end of the 3m line, they turn 180 degrees and return to the starting point using the same gait. Athletes fail the test if they step off the line, have a separation between their heel and toe, or if they touch or grab the examiner or an object.

Finger to Nose

"I am going to test your coordination now. Please sit comfortably on the chair with your eyes open and your arm (either right or left) outstretched (shoulder flexed to 90 degrees and elbow and fingers extended), pointing in front of you. When I give a start signal, I would like you to perform five successive finger to nose repetitions using your index finger to touch the tip of the nose, and then return to the starting position, as quickly and as accurately as possible."

References

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3. Jennett, B., Bond, M. Assessment of outcome after severe brain damage: a practical scale. Lancet 1975; i: 480-484
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CONCUSSION INFORMATION

Any athlete suspected of having a concussion should be removed from play and seek medical evaluation.

Signs to watch for

Problems could arise over the first 24-48 hours. The athlete should not be left alone and must go to a hospital at once if they experience:

- Worsening headache
- Drowsiness or inability to be awakened
- Inability to recognize people or places
- Repeated vomiting
- Unusual behaviour or confusion or irritable
- Seizures (arms and legs jerk uncontrollably)
- Weakness or numbness in arms or legs
- Unsteadiness on their feet.
- Slurred speech

Consult your physician or licensed healthcare professional after a suspected concussion. Remember, it is better to be safe.

Rest & Rehabilitation

After a concussion, the athlete should have physical rest and relative cognitive rest for a few days to allow their symptoms to improve. In most cases, after no more than a few days of rest, the athlete should gradually increase their daily activity level as long as their symptoms do not worsen. Once the athlete is able to complete their usual daily activities without concussion-related symptoms, the second step of the return to play/sport progression can be started. The athlete should not return to play/sport until their concussion-related symptoms have resolved and the athlete has successfully returned to full school/learning activities.

When returning to play/sport, the athlete should follow a stepwise, **medically managed exercise progression, with increasing amounts of exercise.** For example:

Graduated Return to Sport Strategy

Exercise step	Functional exercise at each step	Goal of each step
1. Symptom-limited activity	Daily activities that do not provoke symptoms.	Gradual reintroduction of work/school activities.
2. Light aerobic exercise	Walking or stationary cycling at slow to medium pace. No resistance training.	Increase heart rate.
3. Sport-specific exercise	Running or skating drills. No head impact activities.	Add movement.
4. Non-contact training drills	Harder training drills, e.g., passing drills. May start progressive resistance training.	Exercise, coordination, and increased thinking.
5. Full contact practice	Following medical clearance, participate in normal training activities.	Restore confidence and assess functional skills by coaching staff.
6. Return to play/sport	Normal game play.	

In this example, it would be typical to have 24 hours (or longer) for each step of the progression. If any symptoms worsen while exercising, the athlete should go back to the previous step. Resistance training should be added only in the later stages (Stage 3 or 4 at the earliest).

Written clearance should be provided by a healthcare professional before return to play/sport as directed by local laws and regulations.

Graduated Return to School Strategy

Concussion may affect the ability to learn at school. The athlete may need to miss a few days of school after a concussion. When going back to school, some athletes may need to go back gradually and may need to have some changes made to their schedule so that concussion symptoms do not get worse. If a particular activity makes symptoms worse, then the athlete should stop that activity and rest until symptoms get better. To make sure that the athlete can get back to school without problems, it is important that the healthcare provider, parents, caregivers and teachers talk to each other so that everyone knows what the plan is for the athlete to go back to school.

Note: If mental activity does not cause any symptoms, the athlete may be able to skip step 2 and return to school part-time before doing school activities at home first.

Mental Activity	Activity at each step	Goal of each step
1. Daily activities that do not give the athlete symptoms	Typical activities that the athlete does during the day as long as they do not increase symptoms (e.g. reading, texting, screen time). Start with 5-15 minutes at a time and gradually build up.	Gradual return to typical activities.
2. School activities	Homework, reading or other cognitive activities outside of the classroom.	Increase tolerance to cognitive work.
3. Return to school part-time	Gradual introduction of schoolwork. May need to start with a partial school day or with increased breaks during the day.	Increase academic activities.
4. Return to school full-time	Gradually progress school activities until a full day can be tolerated.	Return to full academic activities and catch up on missed work.

If the athlete continues to have symptoms with mental activity, some other accomodations that can help with return to school may include:

- Starting school later, only going for half days, or going only to certain classes
- More time to finish assignments/tests
- Quiet room to finish assignments/tests
- Not going to noisy areas like the cafeteria, assembly halls, sporting events, music class, shop class, etc.
- Taking lots of breaks during class, homework, tests
- No more than one exam/day
- Shorter assignments
- Repetition/memory cues
- Use of a student helper/tutor
- Reassurance from teachers that the child will be supported while getting better

The athlete should not go back to sports until they are back to school/learning, without symptoms getting significantly worse and no longer needing any changes to their schedule.

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Notes

Appendix D

Table 1. Overall percentage (%) of attempts when considered the *best* trial for a participant, out of the 3 attempts. Percentage shown for all 4 stances for both visit 1 and visit 2.

	Visit 1				Visit 2			
Best Attempt	Stance 1	Stance 2	Stance 3	Stance 4	Stance 1	Stance 2	Stance 3	Stance 4
Attempt 1	35.3%	53.0%	41.2%	76.5%	29.4%	53%	17.6%	17.6%
Attempt 2	29.4%	23.5%	35.3%	5.9%	17.6%	29.4%	35.3%	29.4%
Attempt 3	35.3%	23.5%	23.5%	17.6%	53.0%	17.6%	47.1%	53.0%