

Balance Performance in Adolescents Following a Concussion

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Abstract

A concussion can result in a wide range of signs and symptoms including physical, cognitive, emotional and sleep-related symptoms. While a concussion can occur at any age, children and adolescents are at an increased risk of experiencing a concussion. Important physical consequences of concussion are balance deficits which affect approximately one in three cases. Balance is essential to perform many postures and activities and therefore it is important to accurately identify these deficits at the time of injury and during the recovery process in order to avoid potential further injury. A review of the literature regarding the different clinical and laboratory measures used to assess balance following a concussion was completed and identified several gaps in the literature. The four studies in this thesis were tailored to address these gaps in knowledge.

The first study addressed the sensitivity of a gold standard clinical measure and laboratory measures of standing balance in terms of identifying balance deficits in adolescents at 1-month post-concussion. Performance on the Balance Error Scoring System (BESS) and COP measures from single and dual-task balance conditions were compared between a group of adolescents at one-month post-concussion and a group of non-injured adolescents. The results demonstrated that COP measures from single and dual-task conditions identified balance deficits in the concussed group that were not captured by the BESS.

The second study addressed whether self-reported balance problems are a suitable alternative to COP measures to identify balance deficits in concussed adolescents. A secondary analysis of the data from study 1 was conducted to compare COP measures from the single and dual-task

conditions between concussed adolescents self-reporting balance problems, concussed adolescents self-reporting no balance problems and a group of non-injured adolescents. The results from this analysis showed that the concussed adolescents demonstrated balance deficits regardless of whether they self-reported balance problems.

There is significant clinical interest that lies in the ability to predict which adolescents presenting in the emergency department with concussion will be affected with ongoing balance deficits. The third study addressed the predictive ability of a set of COP variables recorded within the first 10 days following injury in a group of concussed adolescents to predict balance performance on a dual-task condition at one-month post-injury. Seven COP variables were identified as significant predictors. A secondary objective of this study was to compare performance on the COP measures between the concussed adolescents and a group of non-injured adolescents during the first session within the first 10 days following injury and during the second session at one-month post-injury and to compare performance between sessions within each group. The between session comparisons showed that performance remained relatively stable across sessions within both groups. In contrast, the between group comparisons revealed several significant differences in COP measures between the concussed and non-injured groups.

The fourth study in this thesis addressed the association between balance and saccadic eye movements in concussed adolescents. Impaired saccadic eye movements are an important consequence of concussion and may be associated with balance deficits since both processes are dependent on several of the same cortical structures and brainstem areas. In this study,

concussed and non-injured adolescents performed three different dual-task balance conditions involving either a high cognitive load, a low cognitive load and a gaze shifting component or a high cognitive load and a gaze shifting component. The results demonstrated that the concussed adolescents swayed over larger 95% ellipse areas while performing the two dual-tasks with the gaze shifting component, but these larger amounts of sway were not associated with an increase in saccades.

Taken together, these four studies extend the current knowledge regarding balance performance in concussed adolescents and provide results that can be applied to balance assessments for concussion.

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List of Abbreviations

A/P: Anterior-posterior

BESS: Balance Error Scoring System

COP: Center of Pressure

DT: Dual-task

EC: Eyes closed

ED: Emergency Department

EEG: electroencephalography

EO: Eyes open

ICC: intra-class correlation

M/L: medial-lateral

MRCP: Movement-related cortical potentials

PCCR: Pupil center corneal reflection

PCSI: Post-Concussion Symptoms Inventory

SCAT: Sport Concussion Assessment Tool

SOT: Sensory Organization Test

SWARII: Sliding window average with relevant interval interpolation

WBB: Wii Balance Board

Chapter 1: General Introduction and Review of Literature

Introduction

Concussions are a major public health concern. Canada's Federal Government currently recognizes that a substantial number of individuals experience a concussion during sport and recreational activities, with some individuals experiencing severe consequences. As a result, the Ministry of Health and the Ministry of Sport and Persons with Disabilities have been assigned with a mandate to collaborate with key stakeholders across different sectors to establish a Pan-Canadian Concussion Strategy to aid in the prevention and management of concussions (Government of Canada, 2018).

A concussion can be defined as "a traumatic brain injury induced by biomechanical forces" and is caused by either a direct blow to the head, face, or neck or by a blow elsewhere on the body with an impulsive force transmitted to the head. A concussion can result in an extensive range of clinical signs and symptoms, which may or may not include loss of consciousness. The clinical signs and symptoms represent a functional disturbance rather than a structural injury. Therefore, although a concussion can result in neuropathological changes, no abnormalities are shown on standard structural neuroimaging (McCroy et al., 2016).

Sixty percent of Canadian children who were treated for injuries in Emergency Departments between 2011 and 2014 experienced their injury through sports or recreational activities. Among these injuries, concussions were one of the most common and while a concussion can occur at any age, children report the highest incidence of concussion (Barlow, Crawford & Stevenson, 2010). Furthermore, in comparison to other types of injuries, head injuries in youth experienced during football, soccer and hockey have increased by 40% between 2005 and 2014 (Government of Canada, 2016). In addition to being particularly vulnerable to concussion, children may also experience more prolonged recoveries. Although the majority of children recover from their concussion within the first couple of weeks following

their injury, an estimated 30% of cases experience symptoms and impairments that can last for weeks, months and even years (Zemek, Farion, Sampson & McGahern, 2013).

A concussion can lead to a wide array of signs and symptoms including somatic, cognitive and emotional symptoms, physical signs, balance impairments, behavioural changes, cognitive impairments, and sleep/wake disturbances (McCrory et al., 2017). Though many of these signs and symptoms affect varying proportions of individuals, motor deficits including balance impairments and visual problems, such as impaired saccadic eye movements, are two important consequence both affecting approximately 1/3 of cases (Kontos et al., 2012; Murray, Salvatore, Powell & Reed-Jones, 2014). The abilities to efficiently control one's balance and efficiently scan the environment with saccadic eye movements are essential prerequisites for many postures and activities. As a result, it is important to accurately identify these impairments in individuals with concussion in order to avoid further injury.

1.2 Balance

Definitions

In order to execute everyday tasks and activities, individuals are required to control their posture. Postural control can be described as the ability to control the body's position in space in order to maintain orientation and stability. Orientation refers to the ability to maintain an efficient relationship between one's body segments and the environment and stability refers to the ability to control the position of the center of mass in relation to the base of support (Shumway-Cook & Woolacott, 2007). Postural control allows one to maintain their balance which can be defined as a condition in which all the forces and torques acting on the body are in equilibrium in order to maintain one's center of mass within one's limits of stability (Woolacott & Shumway-Cook, 1990). There are two types of balance, static and dynamic

balance. Static balance refers to the ability to maintaining one's balance during quiet upright standing or sitting (Yim-Chiplis & Talbot, 2000), while dynamic balance refers to the ability to maintaining one's balance while performing a movement or a task during which the center of mass and the base of support are in continuous motion (Bressel, Yonker, Kras, & Heath, 2007)

Static balance

In order to maintain an upright standing position, one must maintain their center of mass within their base of support (Winter, 1995), which refers to the area of contact between the feet and the supporting surface (Horak, 2006). In static conditions, small deviations from a perfect upright standing position result in a torque produced by gravity that accelerates the body even further away from an ideal upright position, moving the center of mass closer to the limits of the base of support. These deviations are known as postural sway and are corrected with postural adjustments intended to bring the center of mass back towards the middle of the base of support. These postural adjustments are modulated by the central nervous system in response to feedback from three different sensory systems (Peterka, 2002).

Sensory systems

To maintain static balance, the postural control system integrates information from the visual, somatosensory and vestibular systems. This information is monitored and processed by the central nervous system to generate the motor outputs that are required to control postural sway (Peterka, 2002).

The vestibular system contributes to maintaining balance by establishing a vertical reference to provide information on the head's position with respect to gravity and with respect to accelerations of the head. The peripheral vestibular system includes two types of receptors that are located inside the inner ear, the otolith organs and semicircular canals. These

receptors sense different types of acceleration. The otolith organs, the utricle and the saccule, sense linear accelerations, whereas the three semicircular canals sense rotational movements (Day & Fitzpatrick, 2005). The central components of the vestibular system, known as the vestibular nuclei, are involved in three important categories of reflexes. The vestibulo-ocular reflex (VOR) produces eye movements in the opposite direction of head movement to allow one to maintain visual fixation while the head is moving. The vestibulo-cervical reflex (VCR) allows for postural adjustments of the head and the vestibulo-spinal reflex allows for postural adjustments of the body (Purves et al., 2011).

The visual system provides information about the movement of objects in the environment and the individual's movement within the environment to establish an internal spatial representation of the external world (Bove, Fenoglio, Tacchino, Pelosin & Schieppati, 2009; Jancova, 2008). Visual information is also used to control the position of the head and trunk in space (Buchanan & Horak, 1999).

The somatosensory system provides information about proprioception which is known as our sense of body motion. It is comprised of two subsystems, one to provide information on mechanical stimuli such as light touch, vibration, pressure and cutaneous sensation, and one to detect pain and temperature (Purves et al., 2011). In regard to proprioception, several types of receptors are found in our joints, muscles, tendons and skin. These receptors provide information about changes in muscle length, muscle tension, vibration, and joint extremes (Batson, 2009).

Once the information from all three sensory systems reaches the central nervous system, this information must then be processed and organized to generate the appropriate

postural adjustments. Different theories have been proposed to explain how sensory information is integrated to achieve postural control. However, the sensory reweighting hypothesis is the theory that is most accepted and that has been validated in several studies (Mergner, Schweigart, Fennell & Maurer, 2009; Nashner and Berthoz, 1978; Nashner, 1982; Tremblay, Mireault, Dessureault, Manning & Sveistrup, 2005). This model postulates that sensory feedback is organized by attributing different weights to the vestibular, visual and somatosensory feedback depending on the availability and/or accuracy of the information provided by each system. A reweighting can also occur following changes in environmental conditions that alter the availability and/or accuracy of the information from one or several of the sensory system(s) (Peterka, 2002). Several studies have shown that healthy adults are able to attribute different weights to each source of sensory information to maintain postural stability in conditions for which sensory information is either unavailable and/or inaccurate for one or multiple sensory systems (Mergner, Schweigart, Fennell & Maurer, 2009; Nashner and Berthoz, 1978; Nashner, 1982; Tremblay, Mireault, Dessureault, Manning & Sveistrup, 2005). In contrast, although children can also reweight sensory information to maintain postural stability in conditions that remove and/or alter sensory information, they are unable to do so as efficiently as adults until later in adolescence (Hirabayashi & Iwasaki, 1995; Peterson, Christou & Rosengren, 2006; Stendl, Kunz, Schrott-Fischer & Scholtz, 2006).

1.3 Center of pressure

Relationship between COP and COM

In upright quiet standing, the goal is to maintain the vertical projection of the COM within the base of support in order to achieve balance. When standing with feet side by side, this is attained by movements of flexion and dorsiflexion at the ankles and movements of

abduction and adduction at the hips (Winter, Prince, Stergiou & Powell, 1993). Movements at the ankle are known as the ankle strategy and the movements at the hip are known as the hip strategy. Both strategies control the movement of the center of pressure (COP) under the feet in order to maintain the COM within the base of support. The COP refers to the center of the distribution of the total force applied to a supporting surface and it is the variable that represents the neuromuscular control of the COM to maintain balance. As a result, measuring the displacement of the COP is considered to be a valid method to describe static balance. The movement of the COP is measured in the anterior-posterior (A/P) and medial-lateral (M/L) directions. When standing with feet side by side, A/P displacement of the COP reflects movement at the ankles and M/L displacement of the COP reflects movement at the hips (Winter, Prince, Frank, Powell & Zabjek, 1996).

Measuring COP: force plates

Force plates are generally used in laboratory settings to record the displacement of the COP. A force plate measures and records ground reaction forces and moments (Benda, Riley & Krebs, 1994), which are used to compute the location of the COP in both the M/L and A/P directions at each time point in a given time series (Leach, Mancini, Peterka, Hayes & Horak, 2014). As such, a trajectory of the displacement of the COP is obtained and several variables can be calculated to provide different types of information about the movement of the COP.

COP variables can be categorized into two distinct categories: linear and non-linear. Linear COP variables characterize balance in terms of postural steadiness and measure the amplitude of COP oscillations (Cavanaugh et al., 2005). Linear measures of COP often include the velocity, the variability represented by the root mean square and standard deviation, the sway area, sway path length, and sway frequency (Lafond, Corriveau, Hébert & Prince, 2004).

While there are exceptions, it is generally understood that higher values reflect less efficient balance control (Chaudhry, Bukiet, Zhiming & Findley, 2011; Palmieri, Ingersoll, Stone & Krause, 2002). Many factors such as age (Peterka & Black, 1989), fatigue (Bisson, McEwen, Lajoie & Bilodeau, 2011), stance condition (Riley & Clark, 2003) and stance position (Tarantolaa, Nardonea, Tacchinia & Schieppatib, 1997) can lead to less efficient control reflected by higher values. Several pathologies and injuries can also lead to less efficient balance control. Examples of these pathologies and injuries include Parkinson's disease (Stylianou, McVey, Lyons, Pahwa & Luchies, 2011), multiple sclerosis (Daley & Swank, 1981), and concussion (Powers, Kalmar & Cinelli, 2014).

In contrast to linear COP variables, non-linear variables characterize postural stability as patterns of COP oscillations that emerge in time. These patterns can range from very structured and predictable to disordered and random (Cavanaugh et al., 2005). Similar to linear variables, there are also several non-linear variables that can be computed. However, entropy, a regularity statistic from non-linear dynamics (Cavanaugh et al., 2005), has been commonly used to investigate non-linearities in postural control associated with different pathologies and injuries, such as Parkinson's Disease (Morrison, Kerr, Newell & Silburn, 2008; Schmit et al., 2006), cerebral palsy (Donker, Ledebt, Roerdink, Savelsbergh & Beek, 2007), stroke (Roerdink, Haart, Daffertshofer, Donker, Geurts & Beek, 2006), and concussion (Cavanaugh et al., 2005; Sosnoff, Broglio, Shin & Ferrara, 2011; De Beaumont et al., 2011; Gao, Hu, Buckley, White & Hass, 2011). While different methods can be used to compute entropy, these measures reflect the degree of randomness of COP oscillations and are represented by a value between 0 and 2 for which higher values reflect more random and unpredictable patterns and lower values

reflect less random and more predictable patterns. Normal balance in healthy individuals is characterized by random patterns, whereas more predictable patterns are generally a sign of pathology or injury that affects balance control. It has been suggested that in a state of normal balance, in conditions where the postural control system is free to function with minimal constraints, the location of the COP fluctuates in a random manner to reflect the readiness of the system to respond to perturbations. In contrast, in a state of pathology or injury, normal interconnections among the components of the postural control system may be compromised thus reducing the complexity of the system. This in turn can lead to a postural control system that is more constrained resulting in more regular and predictable COP patterns (Cavanaugh et al., 2005).

Different study designs have been used to characterize static balance through COP characteristics. Studies differ in terms of the frequency of data acquisition, the length of data acquisition, stance position (e.g., feet shoulder width apart or together, single-leg stance, or tandem stance), and the use of different COP variables. In order to address the lack of standardization across studies, in 2012 a committee was appointed by the International Society for Posture and Gait Research to address these issues (Scoppa, Capra, Gallamini & Shiffer, 2012). The following table summarizes their recommendation regarding different parameters:

Parameter	Recommendations
Frequency of data acquisition	A frequency of at least 50Hz is needed to obtain steady and reliable standard COP variable such as sway path, sway area and confidence ellipse area
Length of data acquisition	At least 30 seconds of data acquisition is required to obtain stable and reliable COP variables for sway path, sway area and confidence ellipse area
Stance position	No conclusion could be reached with regard to recommendations for stance position

While the recommendations established by the committee did not address different COP variables, a systematic review by Ruhe, Fejer & Walker (2010) concluded that no single COP variable appears to be significantly more reliable.

An alternative to force plates: Wii Balance Board

Although measures of the COP recorded with a force plate are considered to be the gold standard to characterize static balance (Huurnink, Fransz, Kingma & Van Diën, 2013), the cost and lack of portability of force plates limits their application in clinics and on the sidelines in sports. Conversely, the Nintendo® Wii Balance Board (WBB) is a low-cost and portable device instrumented with four pressure transducers from which the resultant movement of the COP can be computed. A study by Weaver, Ma & Laing (2017) measured different technical specifications of the WBB, including drift, linearity, hysteresis, mass accuracy, uniformity and

COP accuracy. The definition of each measurement and their corresponding values are outlined in the table below:

Measurement	Measurement definition	Results Mean (SD)
Drift	The mean percent difference between the WBB mass output at 0 minutes, compared to 30, 60, and 120 minutes	-0.02% (0.02)
Linearity	Expressed as a coefficient of determination value from a linear regression between the load output and the input of each sensor (10 increments between 0 kg and 150 kg)	0.999 (0.001)
Hysteresis	The mean percent difference between the areas under the curve between the loading and unloading phases for different masses ranging between 0 kg and 150 kg	0.28% (0.16)
Mass accuracy	The mean percent difference between the mass measured by the WBB and the known mass measured from a force plate	0.20% (0.23)
Uniformity	The mean percent error over each of the four corners relative to the center of the WBB using a mass of 20 kg	0.61% (0.17)
COP accuracy	The difference between each known COP location and the calculated COP position at different locations on the board	8 of 30 calculated A/P and M/L COP positions fell within 3mm of the known location

Altogether these results demonstrate that the WBB exhibits minimal drift and low hysteresis, as well as high linearity, uniformity, and mass accuracy. In regard to the COP accuracy, the accuracy was high in the center of the board but decreased at the periphery.

Several studies have been conducted to determine the validity and the reliability of the WBB. Clark, Mentiplay, Pua & Bower (2017) conducted a systematic review to summarize these findings. Twelve studies included in this review assessed the test retest reliability of different COP variables computed from data recorded with a WBB. Intra-class correlation coefficient (ICC) was the most common statistical test used to identify reliability. ICC's for the studies ranged from 0.27 to 0.997 with the majority of studies reporting moderate to excellent reliability. Five studies consistently reported excellent reliability ranging from 0.76 to 0.94 for all calculated variables and these studies had higher quality ratings (76%) compared to the rest of the reliability studies (68%) included in the review. Methodological issues, such as the amount of time between trials, may have led to the lower ICC's reported in certain studies. Four studies also assessed the reliability of COP variables calculated from COP values recorded with a force plate and identified similar values to those obtained with the WBB.

Twenty-one studies assessed the criterion validity of the WBB and used different force plate systems as the reference criterion. Eight of the studies recorded data from both the force plate and the WBB simultaneously by placing the WBB on top of the force plate, whereas ten of the studies recorded data from both devices during separate trials and three studies did not specify if the data were recorded simultaneously or separately. Validity was often identified with correlation analyses including Pearson's correlations and ICC's. These correlations analyses identified values ranging from 0.003 to 0.90 for studies collecting data separately and values

between 0.82 and 1.00 for studies collecting data simultaneously. It is important to note that collecting data with both devices simultaneously is likely a better approach to determining the criterion validity of the WBB. Collecting data from both devices during separate trials is more likely to lead to different COP outputs due to variability between the trials.

While lower COP accuracy has been identified towards the periphery of the WBB (Weaver, Ma & Laing, 2017), studies that assessed the criterion validity of the WBB by collecting data from both a WBB and a force plate simultaneously (Bonnechere, Jansen, Omelina, Sholukha & Van Sint Jan, 2016; Chang, Levy, Seay & Goble, 2014; Huurnink, Fransz, Kingma & Van Diën, 2013; Pavan, Cardaioli, Ferril, Gobbi & Carraro, 2015; Scaglioni-Solano & Aragón-Vargas, 2014; Tweed, Williams, Williams & Dingley, 2014; Weaver, Ma, Laing, 2017), have shown excellent criterion validity between COP values recorded with a WBB and a force plate. Therefore, the lower accuracy obtained at the periphery of the board likely does not affect the validity of COP values and variables derived from a WBB. This may be because in quiet standing, the location of the COP is more likely to remain towards the center of the board.

Dual-task paradigms

The COP can be recorded under different paradigms including single-tasks and dual-tasks. In single-task paradigms, an individual stands on a force plate and holds a specific position such as standing on two feet, on one foot, or in tandem. These types of conditions are known as single-tasks since balance is the only behaviour involved. Conversely, in a dual-task paradigm an individual stands on a force plate and holds a specific stance while simultaneously completing a secondary task that is often a cognitive task. These types of conditions are known as dual-tasks since two behaviours, the balance and the secondary task, are involved.

Early research using dual-task paradigms established that contrary to what was previously thought, maintaining balance requires some degree of attention (Lajoie, Teasdale & Bard, 1993). Dual-task paradigms have since been used to investigate the attentional demands involved in the performance of a motor task or to investigate the effects of performing a secondary task on a motor task (Huang & Stemmons, 2001). Different models have been proposed to account for the behaviour(s) observed in dual-task conditions.

The capacity sharing model of dual-task postulates that the concurrent performance of two tasks is dependent on an attentional resource pool that allows simultaneous performance of both tasks. In situations during which the attentional demands of performing both tasks concurrently exceed the attentional resource pool, decrements in the performance of one or both tasks are observed. This model also assumes that when performing two tasks concurrently, it is possible to allocate priority to one task leading to decrements in the performance of the second task and in some cases both (Fraizer and Mitra, 2008). While the capacity sharing model suggests that attention is drawn from one general resource pool, the multiple-resource model suggests that there are multiple resource pools (Yogev-Seligmann, Hausdorff & Giladi, 2008). According to the multiple-resource model, interference between the concurrent performance of two tasks will only occur when there is competition for the same resources (Fraizer and Mitra, 2008).

In contrast to the capacity sharing and multiple-resource models, the bottleneck model postulates that interference between the performance of two concurrent tasks only occurs when the two tasks depend on the same neural processors or neural networks, creating a bottleneck in the processing of information (Yogev-Seligmann, Hausdorff & Giladi, 2008). When

a bottleneck arises, the processing of the second task is postponed until the first task is processed, which can result in decrements in the performance of the second task (Fraizer and Mitra, 2008). Therefore, according to this model, interference is less likely to arise from performing a cognitive and a motor task concurrently and more likely to arise from the concurrent performance of two motor tasks.

Dual-task paradigms have been used in several studies to further explore the nature of balance deficits in populations known to have difficulties controlling their balance such as in patients with Parkinson's disease (Marchese, Bove & Abbruzzese, 2002), cerebral palsy (Reiley, Woollacott, Donkelaar & Saavedra, 2007), multiple sclerosis (Jacobs & Kasser, 2012) and concussive head injuries (Dorman et al., 2015; Walters-Stewart, Rochefort, Longtin, Zemek & Sveistrup, 2018). Dual-task paradigms are especially relevant to the assessment of concussions because they assess two domains that are often affected following a concussion, balance and cognitive abilities. In addition, dual-tasks involving a balance and a cognitive task are more representative of everyday tasks and activities and have the potential to better identify how an individual affected with a concussion will perform in their everyday tasks (Howell, Osternig & Chou, 2013). Therefore, the cognitive tasks used in a dual-task paradigm should engage the types of cognitive processes that best represent those used in everyday motor tasks.

Although cognitive functioning involves several sub-processes, executive function represents "those abilities that enable an individual to engage successfully in autonomous, purposive, self-serving behavior" (Moering, Schinka, & Mortimer, 2003). Thus, simultaneously performing a balance task with a cognitive task that elicits executive function could provide useful information as to how a concussed individual will perform in their everyday tasks and

activities (Howell, Osternig & Chou, 2013). A test that is commonly used to measure executive function is the Stroop color-word test. The classic version involves naming the colour of the ink of colored words printed in an incongruent colour, e.g. the word red printed in yellow ink (Leon-Carrion, Garcia-Orza, & Perez-Santamaria, 2004). The Stroop color-word test can be easily completed while simultaneously performing a static balance task.

1.4 Balance Following a concussion

Overview

A concussion is characterized as an injury that leads to widespread physiological disruption in the brain rather than an injury affecting only specific structures or pathways (Giza & Hovda, 2014). Considering that several structures and pathways in the brain are involved in the process of maintaining balance (Takakusaki, 2017), it is not surprising that at least 30% of cases are affected with balance deficits following a concussion (Murray, Salvatore, Powell & Reed-Jones, 2014). While the mechanisms that lead to balance deficits following a concussion are not fully understood, two hypotheses have been proposed. First, it has been suggested that a concussion could result in damage to the peripheral receptors of the vestibular system, the otolith organs and semicircular canals, altering the accuracy of the information sensed by these receptors. Conversely, since a concussion leads to widespread disruption of the brain's physiology, it has also been suggested that a concussion could affect the functioning of the central components of the vestibular system leading to an inability to correctly integrate sensory information (Murray, Salvatore, Powell & Reed-Jones, 2014). It is currently unknown if balance deficits are due to one or a combination of both of these mechanisms. Nevertheless, balance deficits are an important marker of concussion and it is recommended to include a

balance evaluation in a concussion assessment (McCrory et al., 2017). Several methods are currently available to assess balance in individuals who have experienced a concussion.

Clinical balance measures used in the assessment of individuals with concussion

Self-Report

Following a concussion, balance deficits are often identified with symptom checklists and scales for which patients are asked to rate the presence or absence of specific post-concussion symptoms and are also asked to rate the severity of present symptoms. Several different versions of these ratings scales exist such as the symptom checklist included in the 5th edition of the Sport Concussion Assessment Tool (SCAT 5) (McCrory et al., 2017), the Postconcussion Scale (Lovell & Collins, 1998), and the Post-Concussion Symptoms Inventory (PCSI) (Sady, Vaughan & Gioia, 2014). While these rating scales differ slightly, they include aspects that evaluate many of the same symptoms. One item is a balance specific question where patients are asked to identify if they have a balance problem and, if yes, to rate the degree of severity of their balance problem. Previous studies have characterized the recovery of balance in concussed individuals using COP measures and have also used symptom scales to monitor recovery (Dorman et al., 2015; Fazio, Lovell, Pardini & Collins, 2007; Powers, Kalmar & Cinelli, 2014). While these studies report information on symptoms, these studies identify the number of reported symptoms and do not isolate balance problems specifically. Therefore, it is difficult to determine if individuals are reporting balance problems. In addition, athletes have been known to avoid disclosing their symptoms in order to prevent removal from sport participation and to return to play sooner (Chrisman, Quitiquit & Rivara, 2012; Reddy, Collins & Gioia, 2008). As a result, using symptom rating scales may not be the most reliable method to identify balance deficits following a concussion.

Balance Error Scoring System (BESS)

The Balance Error Scoring System (BESS), a clinical balance test specifically designed to assess static balance, is the most commonly used balance assessment tool for concussion (Furman et al., 2013). The test consists of holding a double-leg stance with feet together, a tandem stance with the non-dominant leg in the back, and a single-leg stance on the non-dominant leg, on both firm and foam surfaces for 20-seconds with eyes closed. While the participant performs the test, an observer records errors, which can include opening the eyes, moving the hands off the hips, taking a step, stumbling or falling, abducting or flexing the hip beyond 30 degrees, lifting the foot or heel off the testing surface, and remaining out of the testing position for more than 5 seconds. A maximum of 10 errors can be obtained for each condition and the number of errors for each of the six conditions is totaled to obtain a BESS total score (Guskiewicz, Ross & Marshall, 2001). The modified BESS, which includes the three stances performed on the firm surface only, is a component in the fifth edition of the Sports Concussion Assessment Tool (SCAT 5) (McCrory et al., 2017).

Studies that have used the BESS to assess balance in individuals who have experienced a concussion have shown that individuals make significantly more errors compared to their baseline scores within the first 24 hours following injury (Guskiewicz, Ross & Marshall, 2001; Guskiewicz, 2011; McCrea et al., 2003; McCrea et al., 2005) and performance generally returns to baseline scores within 3 to 5 days post-injury (McCrea et al., 2003; McCrea et al., 2005). While the BESS has the advantages of being low-cost and portable, the rapid recovery of balance identified with the BESS may be related to the gross level of assessment. In addition, learning effects have been shown to be associated with repeated administration of the BESS (McLeod, Perrin, Guskiewicz, Shultz, Diamond & Gansneder, 2004; Valovich, Perrin &

Gansneder, 2003). The BESS has also been shown to have varying levels of reliability with ICC's ranging from 0.6 to 0.92 for BESS total score and ranging from 0.57 to 0.96 for scores on individual stances (Bell, Guskiewicz, Clark & Padua, 2011). A minimum ICC of 0.75 is recommended for clinical tests (Portney & Watkins, 2000) and several studies have reported values below this level.

Sensory Organization Test (SOT)

The Sensory Organization Test (SOT) is another clinical test that has been used to assess balance in individuals affected with a concussion. Although not specifically designed as a balance assessment for concussion, the SOT was developed to evaluate an individual's ability to integrate and organize sensory information in the context of standing balance. The test consists of six conditions that are designed to alter the accuracy of the visual and/or somatosensory information and to alter the availability of visual information (Nashner, Black & Wall, 1982). The test includes the following six conditions: 1. Standing on fixed surface with eyes open, 2. Standing on fixed surface with eyes closed, 3. Standing on fixed surface with sway-referenced vision, 4. Standing on sway-referenced surface with eyes open, 5. Standing on sway-referenced surface with eyes closed, 6. Standing on sway-referenced surface with sway-referenced vision. Sway referencing refers to an anterior-posterior rotation of either the platform, visual surround or both, that is modulated by the individual's postural sway. Sway-referencing leads to unreliable information from the ankle joints (sway-referenced surface) or vision (sway-referenced vision) (Sosnoff, Broglio, Shin & Ferrara, 2011). Performance on the test is generally evaluated with equilibrium scores that reflect how much an individual sways in the anterior-posterior direction in relation to their limits of stability. Based on the equilibrium scores obtained in each of the six conditions, a composite score is computed. Vestibular, visual, and

somatosensory ratios are also calculated by comparing the relative difference between equilibrium scores from specific conditions (Guskiewicz, 2011).

Studies that have used the SOT to assess balance in individuals who have experienced a concussion have shown that balance deficits are present at an average of 1-day post-injury (Broglia, Macciocchi & Ferrara, 2007; Guskiewicz, Riemann, Perrin & Nashner, 1997; Guskiewicz, Ross & Marshall, 2001; Peterson, Ferrara, Mrazik, Piland & Elliott, 2003; Riemann & Guskiewicz 2000; Register-Mihalik, Mihalik & Guskiewicz, 2008; Sosnoff, Broglia & Ferrara, 2008). However, these studies show varying results in regard to the number of days post-concussion at which balance recovers. Certain studies have shown that balance recovers by day 3 post-injury (Guskiewicz, Riemann, Perrin & Nashner, 1997; Riemann & Guskiewicz 2000), whereas others have shown that participants had still not recovered on day 5 post-injury (Guskiewicz, Ross & Marshall, 2001), day 10 post-injury (Peterson, Ferrara, Mrazik, Piland & Elliott, 2003), and at an average of 44.3 months post-injury (Sosnoff, Broglia, Shin & Ferrara, 2011). Given the variability in these results, the SOT may not be the most reliable tool to assess balance following a concussion. Performance on the SOT is also based on equilibrium scores which are computed based on A/P sway only. Therefore, results from the SOT may not provide the most accurate representation of balance performance in concussed individuals since they do not reflect balance performance in the M/L direction.

Non-clinical balance measures used in the assessment of individuals with concussion: COP measures

Linear COP measures used to describe balance in concussion

Studies have used linear analysis of COP measures from single-task balance conditions in concussed individuals to monitor the recovery of balance and characterize balance deficits.

Although the studies have used different instrumentation including force plates and the WBB, much of the focus has been on identifying changes in the center of pressure.

Rhine, Byczkowski, Clark & Babcock (2016) evaluated static balance with a WBB in thirteen concussed children and twenty-six non-injured children. Participants with concussion completed the protocol at the time of injury when they presented to the Emergency Department following injury. Participants completed four different conditions: single-leg stance on the dominant leg with eyes open, single-leg stance on the dominant leg with eyes closed, double-leg stance with eyes closed, and double-leg stance with eyes open. Single-leg conditions consisted of 30-second trials and double-leg conditions consisted of 60-second trials. The COP path length was calculated for each condition. The results showed that the participants with concussion performed the double-leg stance with eyes open with larger path lengths. No other significant group differences were identified for the other conditions. These results demonstrate that at the time of injury, the participants with concussion showed balance deficits while standing on two feet with their eyes open.

Powers, Kalmar, & Cinelli (2014) reported the COP in nine athletes during the acute phase (1 to 13 days post-injury, $m = 5.33 \pm 4.33$) of their injury and at return to play (10 to 48 days post-injury, $m = 26.44 \pm 14.03$). Nine teammates who had not experienced a concussion throughout the season served as control participants and completed the testing protocol once. During the testing sessions, the participants stood on a force plate with feet shoulder width apart and completed three 60-second trials with their eyes open and three trials with their eyes closed. Four COP variables were computed: A/P and M/L displacement and A/P and M/L velocity. During the acute phase, the concussed group performed the eyes closed condition with significantly larger A/P displacement and faster A/P velocity compared to the control

group. At return to play, the concussed group performed both the eyes open and the eyes closed conditions with significantly faster A/P and M/L velocity. This study demonstrated that the athletes with concussion still showed balance deficits due to increase in COP velocity at the time they were cleared to return to play at an average of 26 days post-injury.

Thompson, Sebastianelli & Slobounov (2005) reported the COP in twelve concussed athletes and in twelve healthy control participants. The participants with concussion participated in the study between 70 and 131 days ($m=89.4$) post-injury. Participants were asked to stand on a force plate on two feet and to complete three 30-second trials with their eyes open and with their eyes closed. A 95% ellipse area was calculated for each condition. The results showed that compared to the control group, the participant with concussion swayed over a larger COP area with their eyes closed. These results suggest that the participants with concussion were affected with balance deficits at an average of 89 days post-injury.

Slobounov, Sebastianelli & Moss (2005) conducted a study measuring electroencephalography (EEG) and COP in static and dynamic balance tasks in eight concussed student athletes. Although the purpose of the study was to characterize movement-related cortical potentials (MRCP) in association with postural responses, this study also provided information on COP balance control. The participants completed the protocol prior to having suffered their concussion, i.e. at baseline, and repeated the protocol on days 3, 10 and 30 following their injury. For the static balance conditions, participants stood on two feet on a force plate with their eyes open and with their eyes closed for 30-seconds each. A 95% ellipse area was calculated for both conditions. The results showed that compared to their baseline performance, participants with concussion swayed over a larger COP area on day 3 post-injury

with their eyes open and closed and on day 10 post-injury with their eyes closed only. These results demonstrate that the participants' balance recovered by day 30 post-injury.

Slobounov, Cao, Sebastianelli, Slobounov & Newell (2006) also conducted a study to measure the COP in static and dynamic balance tasks in twelve student athletes prior to their concussion, i.e. at baseline, and at 30 days following their concussion. Participants completed three 30-second trials while standing on two feet on a force plate with their eyes open and with their eyes closed. Three COP variables were calculated for each condition: standard deviation, velocity and 90% ellipse area. In agreement with the results from one of their previous studies, no significant differences were identified for any of the COP variables between baseline performance and 30 days post-injury.

While the majority of studies that have measured linear COP variables in a concussed population have done so with single-task balance conditions, one study by Dorman and colleagues (2015) measured the COP with both single and dual-task conditions in adolescents following a concussion. Eighteen adolescents with a diagnosed concussion and twenty-six non-injured adolescents participated in the study. Participants with concussion completed four sessions. The first session took place within 10 days following the injury, the second session at an average of 15 days following the first session, the third session at an average of 24 days following the second session, and the fourth session at an average of 29 days following the third session. Participants in the control group completed two sessions separated by a week. Participants stood on a force plate and completed two 20-second single-task conditions consisting of standing shoulder width apart with eyes open and closed and two dual-tasks consisting of standing shoulder width apart with eyes open and closed while reciting the

months of the year in reverse order. Two COP variables were calculated for each condition: the 95% ellipse area and the velocity. The results demonstrated that during the first session, the concussion group showed larger COP areas and faster measures of velocity compared to the control group while performing all four conditions. During the second session, the concussion group showed larger COP areas compared to the control group while performing the two dual-task conditions only. The results from this study clearly demonstrate that the concussion group showed deficits on the two dual-task conditions for a longer period of time following their injury compared to the two static balance tasks.

Altogether these studies demonstrate variable results. Some studies show that balance deficits can persist for several weeks (Dorman et al., 2015; Powers, Kalmar, & Cinelli, 2014) and even months (Thomposon, Sebastianelli & Slobounov, 2005) following a concussion, whereas others show that these deficits have recovered by 30 days post-injury (Slobounov, Sebastianelli & Mossm, 2005; Slobounov, cao, Sebastianelli, Slobounov & Newell, 2005). The variability in these results could be due to different factors such as sample size, whether participants were compared to a control group or to their own baseline measures, the duration of the trials and the different COP variables that were used. In addition, the differences in results could also be due to the heterogeneous nature of concussion. There are different subtypes of concussion and each subtype is characterized by common symptoms and deficits (Maruta, Lumba-Brown & Ghajar, 2018). The studies identifying longer recovery periods for balance may have included more participants affected with a balance deficit. In contrast, the studies showing a quick recovery of balance may have included less participants affected with a balance deficit resulting in the group differences for balance being washed out by those not affected with a balance deficit. However, regardless of the variability in the results, these studies show that balance

deficits persist beyond the typical 3 to 5 day recovery period identified with the BESS. In addition, while measures of the SOT may show more prolonged recoveries in some cases, COP measures offer additional value by providing information on both A/P and M/L balance control. Different variables reflecting different aspects of postural sway can also be computed.

Non-linear COP measures used to describe balance in concussion

Studies have used non-linear analysis of COP measures from single-task balance conditions to characterize the degree of randomness of postural sway associated with concussion. Some studies have combined analysis of postural entropy and clinical measures, such as the BESS or the SOT, when determining difference from age-matched controls or change over time post-injury.

Cavanaugh and colleagues (2005) analyzed COP data from twenty-seven concussed athletes and thirty control participants who performed the conditions of the SOT. Concussed participants completed the SOT prior to their injury, i.e. at baseline, and within 48 hours following their injury. Control participants also completed the SOT on two separate occasions. In addition to analyzing the results from the SOT, values of approximate entropy in the A/P and M/L directions were also computed for each condition of the SOT. Based on the equilibrium scores from the SOT, within 48 hours following their injury, all concussed participants showed normal balance compared to their baseline values. In regard to the entropy values, a 3-way analysis of variance (group x day x SOT condition) revealed a significant three-way interaction between group, day, and SOT condition for A/P entropy and a significant interaction between group and day for M/L entropy. Instead of performing a post hoc analysis of main effects, the authors described the magnitude of difference in entropy values across days for each SOT condition. For A/P entropy, this demonstrated that in comparison to their baseline scores and to the control group, the concussed group showed a substantial loss of randomness of COP

oscillations, i.e. declines in entropy values were approximately three times larger than the standard error of the mean, for two of the SOT conditions. For M/L entropy, this demonstrated that in comparison to their baseline scores, the concussed participants showed a substantial loss of randomness in COP oscillations across all SOT conditions. Overall these results demonstrated that while concussed participants showed normal balance on the traditional measures of the SOT, they still showed altered balance strategies marked by more regular COP oscillations.

Cavanaugh and colleagues (2006) conducted a similar follow-up study for which twenty-nine concussed athletes completed the SOT prior to their injury (i.e. at baseline), and again within 48 hours post-injury and between 48 and 96 hours post-injury. Participants were divided into steady and unsteady groups based on their equilibrium scores within 48 hours post-injury. In terms of equilibrium scores, the results revealed a significant three-way interaction between group, day and SOT condition. For the participants in the unsteady group, their scores within 48 hours following their injury were substantially lower, i.e. declines were greater than 4 times the standard error of the mean, for all SOT conditions, whereas scores for the participants in the steady group were relatively unchanged in comparison to baseline. Between 48 and 96 hours post-injury, equilibrium scores for participants in the unsteady group returned within 1 to 2 standard errors of the mean of baseline values. For A/P entropy, values were lower at 48 hours post-injury compared to baseline and a significant day x condition interaction was obtained. The results demonstrated that for both groups combined, the changes in entropy values between baseline and within 48 hours post-injury was much larger, i.e. declines in entropy values were at least 3 times larger than the standard error of the mean, for two of the of the SOT conditions compared to all other conditions. For M/L entropy, values were lower at 48

hours post-injury compared to baseline and continued to be lower between 48 and 96 hours post-injury. Significant main effects were obtained for day and condition, but there were no significant interactions. These results demonstrated that for both groups combined, the declines in entropy values between baseline and 48 hours post-injury and between baseline and 48 to 96 hours post-injury were approximately 3 to 4 times larger than the standard error of the mean. In agreement with the results from the previous study, this study demonstrates that concussed participants continued to show altered balance strategies despite showing normal balance on SOT equilibrium scores.

Sosnoff, Broglio, Shin & Ferrara (2011) also conducted a study to assess balance in a group of concussed athletes with the SOT and computed values of entropy for each condition. A group of 224 athletes completed the SOT as part of an ongoing investigation of sport-related concussion and 62 of these athletes had experienced at least one concussion. The time since their injury ranged from 6.4 to 150.9 months ($m = 44.3$ months). In regard to the scores on the SOT, the athletes with previous concussion had greater visual ratio scores indicating a reduced ability to use visual information to maintain balance compared to the non-concussed athletes. In terms of A/P entropy, the previously concussed athletes had lower entropy values compared to the non-concussed athletes for conditions 1 through 4 (i.e., standing on fixed surface with (1) eyes open, (2) eyes closed and with (3) sway-referenced vision and standing on sway-referenced surface with (4) eyes open) and greater entropy values for conditions 5 and 6 (i.e., standing on sway-referenced surface with (5) eyes closed and with (6) sway-referenced vision). In terms of M/L entropy, the results demonstrated that in comparison to non-concussed athletes, previously concussed athletes showed higher entropy values in conditions 1 through 3 and lower entropy values in conditions 5 and 6. Altogether, these results demonstrate that for

the easier conditions, the previously concussed athletes exhibited more regular A/P COP patterns and more random M/L patterns. In contrast, for the more difficult conditions, the previously concussed athletes exhibited more random A/P COP patterns and more regular M/L COP patterns. Therefore, the previously concussed athletes performed the conditions of the SOT with different balance strategies compared to the non-concussed athletes.

Quatman-Yates and colleagues (2015) conducted a study to assess balance in concussed children with the BESS and with linear and non-linear COP measures. Twenty concussed children between 4 and 250 days ($m = 48.70 \pm 64.85$) post-injury and twenty control participants completed the BESS and two-minute trials with eyes open and with eyes closed while standing on a force plate. Four linear COP variables, area, path length, A/P standard deviation, and M/L standard deviation, were computed for both conditions. A/P and M/L sample entropy as well as Reni entropy, a value of entropy that reflects the spatial variability of a 2-dimensional COP trajectory, were also calculated from the COP trajectories obtained for both conditions. In regard to performance on the BESS, there were no significant group differences for scores for any of the six conditions and for BESS total score. In terms of the linear COP measures, the participants with concussion demonstrated shorter COP path lengths compared to the control participants. In terms of the non-linear COP measures, for both A/P and M/L sample entropy as well as Reni entropy, the participants with concussion showed lower values demonstrating more regular COP patterns compared to the control participants. Overall, these results demonstrate that while the participants with concussion did not perform the BESS with more errors than the control participants, they still demonstrated altered balance strategies as shown by shorter COP path lengths and more regular COP patterns.

In summary, the results from these studies demonstrate that non-linear COP measures identify balance deficits that are not identified with clinical tests such as the SOT and the BESS. Two of the studies that measured balance beyond the first couple of days post-injury (Quatman-Yates et al., 2015; Sosnoff, Broglio, Shin & Ferrara, 2011) have also shown that balance deficits can persist well beyond the typical 3 to 5 day recovery period identified with the BESS. Furthermore, in terms of comparing linear and non-linear COP measures to identify balance deficits following a concussion, Quatman-Yates and colleagues (2015) showed that the participants with concussion in their study performed similar to control participants for three of the four linear COP measures but showed different balance strategies in comparison to the control participants for all three non-linear COP measures. Therefore, non-linear COP measures such as entropy may identify prolonged balance deficits not identified with linear COP measures. Non-linear COP measures also provide a different type of information regarding balance control not captured by linear COP measures.

Predicting balance recovery following a concussion

Several studies have identified that balance deficits can persist for weeks and even months following a concussion. Given that balance is an essential component of everyday tasks and activities, it is important to accurately monitor these deficits to avoid potential further injury. Improvements in balance control have been shown in concussed individuals involved in vestibular training (Alsalaheen et al., 2010; Prangle, Aggerholm & Cinelli, 2017). Therefore, it would be useful to identify individuals who are at risk of developing persistent balance problems at the time of injury in order to offer them the appropriate care and rehabilitation programs as soon as possible. Some studies have focused on identifying predictors for persistent concussive symptoms (Zemek, Farion, Sampson & McGarhen, 2013; Zemek et al.,

2016), but no studies have focused on identifying predictors for persistent balance problems specifically.

1.5 Saccadic eye movements

Measuring saccadic eye movements

Saccades are rapid, ballistic eye movements used when rapidly changing the point of gaze. These movements can range from small movements, such as during reading, or larger movements used to scan the environment (Purves et al., 2011). Eye trackers can be used to measure and characterize different features of saccades. Eye trackers range from screen-based systems that require an individual to keep the head in a fixed position in front of a screen to wearable eye trackers that allow an individual to move freely within their environment. While different techniques can be used to track eye movements, the most commonly used technique is pupil center corneal reflection (PCCR). This technique consists of using a light source to illuminate the eye to produce visible reflections that are then captured with a camera. The image captured with the camera is used to identify the reflection of the light on the cornea and in the pupil. This information is used to calculate a vector formed by the angle between the cornea and the pupil's reflections. The eye's gaze direction is then calculated based on the direction of the vector and additional geometrical properties (Tobiipro, n.d.)

Saccadic eye movements following a concussion

Visual deficits, including impaired saccadic eye movements, affect approximately 30% of individuals who experience a concussion (Kontos et al., 2012). Several cortical and sub-cortical areas are involved in the execution of saccades (Leigh & Zee, 2015). Thus, it has been suggested that the diffuse nature of concussion could affect these areas leading to deficits in saccadic eye movements (Thiagarajan & Ciuffreda, 2014). Several parameters exist to measure various features of saccades and these parameters can be measured to identify impairments in saccadic

eye movements. In regard to concussions, studies have demonstrated that individuals who have experienced a concussion show impairments on measures of saccadic latency, saccadic gain, and saccadic ratio.

Saccadic latency refers to the amount of time between a change in target position and the time at which an individual executes a saccade to shift their point of gaze towards the new target position. Individuals with concussion have been shown to demonstrate longer saccadic latencies compared to a group of control participants when tracking a moving target. However, this measure has been shown to be impaired shortly after the injury and to recover within a couple of weeks (Pearson, Armitage & Horner, 2007).

The saccadic gain refers to the ratio between the amplitude of the first saccade executed towards a target that has been displaced or towards a new target and the amplitude of that target (Cifu, Wares, Hoke, Wetzel, Gitchel & Carne, 2015). In other words, the saccadic gain indicates whether an individual overshoots or undershoots the target's position. The mean amplitude of any additional corrective saccades that are executed following the first primary saccade is referred to as positional error. Studies have shown that concussed individuals tend to perform the first primary saccade towards a new target with smaller amplitude and perform corrective saccades with increased positional error (Cifu, Wares, Hoke, Wetzel, Gitchel & Carne, 2015; Heitger, Anderson & Jones, 2002).

A saccadic ratio refers to the ratio of "the total number of saccades executed to the total number of target displacements." Therefore, a ratio of 1 indicates that a single saccade was used to shift the point of gaze to a change in target position or towards a new target, whereas a higher saccadic ratio indicates that unnecessary saccades were executed to accomplish either of these goals. Studies have demonstrated that individuals who have

experienced a concussion demonstrate elevated saccadic ratios up to at least 1-year post-injury (Ciuffreda, Han, Kapoor & Ficarra, 2006; Thiagarajan & Ciuffreda, 2014).

Generating saccadic eye movements and maintaining balance are dependent on several of the same areas in the brain. Namely, the frontal lobe, the basal ganglia and the cerebellum, play important roles in producing eye movements and maintaining balance (Purves et al., 2011). Due to the interrelationship between these two processes, one could hypothesize that there could be an association between deficits in eye movements and balance deficits in concussed individuals.

1.6 Aim of Dissertation

Several important points regarding balance following a concussion can be summarized from this literature review:

- Self-reported rating scales may not be the most reliable method to identify balance deficits following a concussion.
- The BESS shows a quick recovery of balance taking place within 3 to 5 days post-concussion.
- Studies that have used the SOT to assess balance in concussed individuals have shown variable results with some studies showing a quick recovery of balance and others showing a more prolonged recovery.
- The majority of studies that have used linear and non-linear COP measures to assess balance beyond the first couple of days post-concussion have shown that balance deficits can persist for weeks and in some cases months. Studies have shown that linear and non-linear COP measures identify balance deficits that are not identified with clinical tests such as the SOT and the BESS.

- One study showed that COP dual-task conditions identified a more prolonged recovery of balance compared to COP single-task conditions.
- Non-linear COP measures may identify more prolonged balance deficits compared to linear COP measures.

This literature review also identified certain gaps in knowledge regarding balance following a concussion:

- It is unclear if there are differences in the sensitivity of the BESS, COP measures from single-task and dual-task conditions to identify persistent balance deficits following a concussion.
- It is unclear if self-reported balance problems are an adequate proxy for COP measures to identify balance deficits following a concussion.
- No previous studies have explored the association between balance performance close to the time of injury and long-term balance performance in a concussed population.
- No previous studies have explored the association between balance and saccadic eye movements in a concussed population.

The following series of studies were designed to provide clarity regarding the sensitivity of different methods to identify balance problems in concussed adolescents, to determine if there is an association between early balance problems and persistent balance problems in concussed adolescents, and to explore the association between balance performance and saccadic eye movements in concussed adolescents.

Study 1: Comparison of BESS scores and COP single and dual-task conditions between concussed and non-injured adolescents.

The objective of this study was to explore the sensitivity of the BESS and COP in single and dual-task conditions to identify balance deficits in adolescents at 1-month post-concussion. COP measures recorded during single and dual-task conditions and scores from the BESS were compared between adolescents at 1-month post-concussion and non-injured adolescents. It was hypothesized that the concussed adolescents would show significant differences compared to the non-injured adolescents for the COP measures collected during the single and dual-task conditions, but not for the scores from the BESS. The results from this study confirmed whether COP measures from single and dual-task conditions were better at identifying persistent balance problems in concussed adolescents compared to scores from the BESS.

Study 2: Comparison of COP measures during single and dual-task conditions amongst concussed adolescents self-reporting balance problems, concussed adolescents self-reporting no balance problems, and non-injured adolescents.

The objective of this study was to conduct a secondary analysis of the data in study 1 to explore the relationship between self-reported balance problems and COP measures from single and dual-task conditions. The purpose was to determine if self-reported balance problems are an adequate proxy for COP measures to identify balance deficits following a concussion. COP measures recorded from single and dual-task conditions were compared amongst concussed adolescents self-reporting balance problems, concussed adolescents self-reporting no balance problems and non-injured adolescents. The hypothesis was that the concussed adolescents reporting balance problems would show significant differences on the COP measures compared

to the non-injured adolescents, but that the concussed adolescents self-reporting no balance problems would perform similar to the non-injured adolescents. The results from this study confirmed whether self-reporting of balance problems is as effective as COP measures to identify balance deficits following a concussion.

Study 3: Predictors of Balance Performance at 1-Month Post-Injury in Concussed Adolescents

The primary objective of this study was to determine if there is an association between balance performance within the first ten days following a concussion and balance performance at 1-month post-concussion in adolescents. The secondary objective was to compare balance performance on linear and non-linear COP measures between concussed and non-injured adolescents within the first ten days following injury and at 1-month post-concussion and to compare performance between sessions within each group. It was hypothesized that a set of COP variables collected within the first 10 days would be good predictors of balance performance at 1-month post-concussion. It was also hypothesized that compared to the non-injured adolescents, the concussed adolescents would show significant differences on both linear and non-linear COP measures recorded during the single and dual-task conditions within the first 10 days and at 1-month post-concussion. The results from this study were used to determine if there is a relationship between balance performance close to the time of injury and balance performance at 1-month following a concussion. The results from this study were also used to demonstrate whether non-linear COP measures showed a more prolonged recovery of balance compared to linear COP measures.

Study 4: Association between balance and saccadic eye movements in concussed adolescents.

This study was designed to explore the relationship between balance and saccadic eye

movements in concussed adolescents as they performed different dual-task conditions. COP measures and saccadic eye movements were compared between concussed adolescents and non-injured adolescents while they completed three different dual-task balance conditions involving either a high cognitive load, a low cognitive load and a gaze shifting component, or a high cognitive load and a gaze shifting component. The hypothesis was that compared to the non-injured adolescents, the concussed adolescents would perform the dual-task with the low cognitive load and the gaze shifting component and the dual-task with the high cognitive load and the gaze shifting component with more COP displacement and velocity and also complete more saccades while performing these conditions. The results from this study were used to determine if there is an association between balance deficits and deficits in saccadic eye movements in concussed adolescents.

Chapters 2,3,4 and 5 have been submitted to peer-reviewed journals and are formatted according to the individual journal's submission requirements. All studies were approved by the Children's Hospital of Eastern Ontario Research Ethics Board and the University of Ottawa Health Sciences and Sciences Research Ethics Board.

Chapter 2: Balance Markers in Adolescents at One-Month Post-Concussion

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Balance Markers in Adolescents at One-Month Post-Concussion

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2.1 Abstract

Background: The Balance Error Scoring System (BESS) shows that balance tends to recover within days following a concussion, whereas measures of the movement of the center of pressure (COP) show that balance deficits can persist up to at one month following a concussion. While approximately 30% of adolescents suffering concussion have functional consequences including balance deficits, evidence of the use of different balance assessments for concussion is limited within this population.

Purpose: To compare performance on a series of balance assessments between adolescents with a diagnosed concussion at 1-month post-injury and non-injured control participants within the same age distribution.

Study design: Cohort study.

Methods: Thirty-three adolescents one-month post-concussion and thirty-three control participants completed the BESS followed by two 2-minute trials standing on a Nintendo Wii Balance Board™ (WBB) during which the center of pressure (COP) under their feet was recorded: i) double-leg stance, eyes open (EO); ii) double-leg stance, eyes closed (EC). Participants then completed a dual-task condition (DT) with eyes open combining a double-leg stance and a Stroop Colour-word test while standing on the WBB. Three commonly used COP variables, anterior-posterior (A/P) and medio-lateral (M/L) velocity, and 95% ellipse, were computed for each condition performed on the WBB.

Results: Participants post-concussion swayed over a significantly larger ellipse area compared to the control group in the EO ($p=0.008$), EC ($p=0.002$), and DT ($p=0.003$) conditions, and also performed the DT condition with faster COP velocity in the M/L direction ($p=0.007$). No significant group difference was identified for BESS total score.

Conclusions: At 1 month post-concussion, participants continued to demonstrate balance deficits in COP control despite scoring similar to controls on the BESS. Simple COP measures of balance may identify subtle impairments not captured by BESS.

2.2 Introduction

A concussion can result in a wide range of physical, cognitive, emotional, and sleep-related symptoms (Bartlett, Ting & Bingham, 2014). While adolescents are among those most at risk for experiencing a concussion, most will recover from these acute symptoms within a couple of weeks (Kirkwood, Yeates & Wilson, 2006). However, 30% of cases will experience symptoms that can last for months or even years postinjury (Zemek, Farion, Sampson & McGahern, 2013). These persistent symptoms can include residual balance deficits, which may affect one's ability to safely resume physical activity and further increase risk of reinjury (Lynal, Mauntel, Padua & Mihalik, 2015; Pietrosimone, Golightly, Mihalik & Guskiewicz, 2015).

The Balance Error Scoring System (BESS) is the most commonly used balance assessment tool for concussion (Furman et al., 2013). The subject performing the test stands on 2 feet, 1 foot, and with feet in tandem for 20 seconds with eyes closed on firm and foam surfaces while an observer records errors such as opening the eyes, stepping, or stumbling (Guskiewicz, Ross & Marshall, 2001). A modified version, with the firm surface only, is part of the third edition of the Sport Concussion Assessment Tool (SCAT3) (McCrory et al., 2012). Studies that have used the BESS with collegiate athletes who have sustained a concussion have shown that balance tends to recover within 3 to 5 days postinjury (Guskiewicz, Ross & Marshall, 2001; Riemann & Guskiewicz, 2000). However, the rapid recovery of balance identified with the BESS may simply be due the subjective scoring of the test. It has also been suggested that the same examiner score performance on the BESS during repeated testing due to the wide range of reliability reported for the BESS. Though this may be possible in a research environment, this is not a practical approach for sport and clinical settings (Bell, Guskiewicz, Clark & Padula, 2011).

Objective assessments of balance are performed by measuring the movement of the center of pressure (COP) under the feet as an individual stands on a force plate. COP measures are considered to be the gold standard to evaluate static balance (Huurnink, Fransz, Kingma & Dieen, 2013) and may identify subtle changes not identified using subjective balance assessments (Quatman-Yates, et al., 2015). By incorporating COP measures, balance deficits have been identified in collegiate athletes who sustained concussions up to 15 days postinjury (Slobounov, Sebastianelli & Hallett, 2012). Balance deficits have also been identified in a group of collegiate football players at the time that they obtained clearance to return to play at approximately 4 weeks postinjury (Powers, Kalmar & Cinelli, 2014). These periods of balance impairment extend beyond the 3- to 5-day recovery period typically identified with the BESS.

Although considered to be the gold standard to assess static balance, the cost and lack of portability of force plates limits their widespread application in clinics and on sports sidelines. In contrast, the Nintendo Wii Balance Board (WBB) (Nintendo) is a low-cost and portable device instrumented with 4 pressure transducers from which the resultant movement of the COP can be computed. Studies that have compared COP values collected with a force plate and with a WBB have demonstrated that COP values recorded with a WBB are both valid and reliable (Bartlett, Ting & Bingham, 2014; Chang, Levy, Seay & Goble, 2014; Clark et al., 2010; Huurnink, Fransz, Kingma & Dieën, 2013; Pavan, Cardajoli, Ferri & Gobbi, 2015). Recent studies have used the WBB to assess balance in children who have experienced a concussion (Rhine, Quatman-Yates & Clark, 2015; Rhine, Byczkowski, Clark & Babcock, 2016).

While objective measures including COP are valuable elements of a balance assessment, tasks and activities of everyday living including sports participation require the simultaneous

integration of cognitive functions and balance abilities (Broglio, Tomporowsk & Ferrara, 2005).

The postural control system is not totally autonomous, and dual-task investigations strongly suggest that posture control and higher level cognition have common resource requirements.

Therefore, completing conditions that involve balance only, such as standing on 2 feet with eyes open or closed, may not be sufficient to identify postural deficits associated with concussions.

In a key study by Dorman et al (2015), the movement of the COP was recorded while adolescents with concussion completed 2 simple balance conditions and 2 dual-task conditions (eg, completing a balance task while simultaneously completing a cognitive task). While the participants with concussion showed deficits on all 4 conditions within 10 days postinjury, at an average of 25 days postinjury, participants with concussion only showed deficits on dual-task conditions. This suggests that measures of balance recorded during dual-tasks may identify more complex functional deficits reflecting the interaction between cognition and balance that would otherwise be overlooked by assessing balance alone.

Previous studies that have assessed balance in individuals postconcussion have included either COP measures from both single- and dual-task balance conditions (Dorman et al., 2015) or COP measures from single-task balance conditions and scores from the BESS (Quatman-Yates et al., 2015). To date, no study has directly compared performance on the BESS and COP measures recorded during the performance of single- and dual-task balance assessments within the same group of individuals who have experienced a concussion. This makes it difficult to conclude whether one method is more sensitive than the others at identifying balance deficits after concussion.

The purpose of this study was to compare balance performance in adolescents diagnosed with a concussion at 1 month postinjury compared with a group of control participants within the same age distribution. We were specifically interested in scores on the BESS and COP measures recorded during 2 single-task balance conditions and a dual-task balance condition. It was hypothesized that there would be significant group differences in COP measures during the single-task balance conditions as well as during the dual-task balance condition but that there would be no significant group differences on the measures from the BESS.

2.3 Methods

Participants

Two groups of participants participated in this study. The first group, the concussion group, consisted of adolescents aged between 12 and 17 years who had been diagnosed with a concussion by a physician in the emergency department (ED) at a regional tertiary hospital. Participants were recruited through a larger study designed to derive a clinical prediction rule for postconcussion syndrome (Zemek et al., 2016). Participants were diagnosed with a concussion if they met the criteria for concussion defined by the Zurich consensus statement (McCrory et al., 2013), which includes a direct blow to the head, face, neck, or elsewhere on the body with an impulsive force transmitted to the head, resulting in 1 or more symptoms in 1 or more clinical domains (which may or may not have involved loss of consciousness):

- Somatic symptoms (eg, headache, nausea, loss of balance, dizziness, sensitivity to light or noise, visual problems, and clumsiness)
- Cognitive symptoms (eg, feeling like in a fog, difficulty concentrating or remembering,

answering questions more slowly, and confused with directions/tasks)

- Emotional/behavioral symptoms (eg, irritable, sad, nervous, and emotional lability)
- Sleep disturbance (eg, sleeping more, fatigue, drowsiness, and insomnia)

Participants were excluded from the study if the ED Glasgow Coma Scale was less than 14, abnormalities were observed on neuroimaging (if performed), operative intervention or procedural sedation was required, or if they presented with multisystem injuries requiring admission.

The control group consisted of 33 noninjured adolescents within the same age distribution who reported no concussive symptoms and who had not suffered any head trauma within the past year. Participants in this group completed the protocol once. All participants and their parents provided written informed consent.

Experimental Protocol

Participants completed a series of balance conditions, during which they were given a rest of 30 to 60 seconds between each trial. Participants completed 2-minute trials with their feet shoulder width apart with eyes open (EO) and then with their eyes closed (EC) while standing on the WBB. Two-minute trials were chosen because the International Society for Posture and Gait Research recommends using trials of at least 30 seconds to obtain stable COP values (Scoppa, Capra, Gallamini & Shiffer, 2013). Participants also completed a single-leg condition with eyes open while standing on the WBB, but the data from this condition were removed from analysis since approximately one-third of participants in both the concussion ($n = 11$) and control ($n = 9$) groups were unable to successfully complete the trial. For the EO condition, participants were instructed to fixate on a dot on a board placed at eye level at a

distance of 1 m and to focus on standing as still as possible. In the EC condition, participants fixated on the dot and then closed their eyes.

Participants completed a dual-task condition (DT) consisting of standing on the WBB with their feet shoulder width apart while simultaneously completing a Stroop color and word test (Stroop, 1935). The Stroop color and word test was presented on a single board placed at eye level at a distance 1 m in front of the participant. The board contained a 10 X 10 matrix of the words “red,” “blue,” “yellow,” and “green” in a random order written in an incongruent ink color. Following the procedures of the classic Stroop test, the participants were instructed to name the color of the ink of each word as quickly and as accurately as possible, and the number of correct responses was recorded for each participant. Participants were also instructed to stand as still as possible while completing the DT condition.

Each participant then completed the BESS, as outlined by Guskiewicz et al. (2001). Participants completed six, 20-second balance conditions with their eyes closed, consisting of 3 stances on both firm and foam surfaces: double-leg stance with feet together, a single-leg stance on the nondominant leg, and a tandem stance with the nondominant leg in the back. The number of errors defined as moving the hands off the iliac crest(s); opening the eyes; stepping, stumbling, or falling; abducting or flexing the hip beyond 30°; lifting the foot or heel off the testing surface; and remaining out of the testing position for more than 5 seconds were recorded, with a maximum number of 10 errors per condition. A total BESS score was obtained by adding the number of errors during each of the 6 conditions.

Participants in the concussion group completed the validated Post-Concussion Symptoms Inventory (PCSI) (Sady, Vaughan & Gioa, 2014) at the time of ED presentation and at

1 month postinjury. The PCSI consists of a list of concussion-related symptoms for which participants are asked to rate their preinjury as well as postinjury degree of symptoms to calculate a direct index of difference of a patient's perceived difference from their own norms. The 12-year old participants completed the 8-to 12-year-old age version (17 symptoms, 3-point graded scale) and participants aged 13 years or older completed the adolescent version (20 symptoms, 7-point graded scale).

Material and Data Processing

The WBB raw pressure data were recorded at a sampling frequency of 30 Hz. The WBB was connected to a laptop computer via a Bluetooth device. The raw pressure data were transformed to the COP using Matlab (The Mathworks Inc). The COP data were filtered using a second order low-pass Butterworth filter with a cutoff frequency of 12 Hz. The velocity of the COP in the medio-lateral (M/L) and anterior-posterior (A/P) directions and the COP 95% ellipse were calculated for each of the 3 balance tasks (EO, EC, DT) for each participant. The velocity was characterized as the mean absolute speed of the COP displacements and was calculated using the following equations (Duarte & Freitas, 2010):

$$\text{A/P velocity} = \text{sum} (\text{absolute difference (COP A/P)} * \text{frequency/length (COP A/P)})$$

$$\text{M/L velocity} = \text{sum} (\text{absolute difference (COP M/L)} * \text{frequency/length (COP M/L)})$$

The 95% ellipse consisted of an ellipse that covered 95% of the participant's COP trajectory and was calculated using the following equation (Duarte & Freitas, 2010):

$$[\text{vec}, \text{val}] = \text{eig}(\text{cov}(\text{COP A/P}, \text{COP M/L}))$$

$$\text{95\% ellipse} = \pi * \text{prod} (2.4478 * \text{sqrt} (\text{svd}(\text{val})))$$

An example of an ellipse of a participant in the concussion group and a participant in the control group is shown in Figure 1.

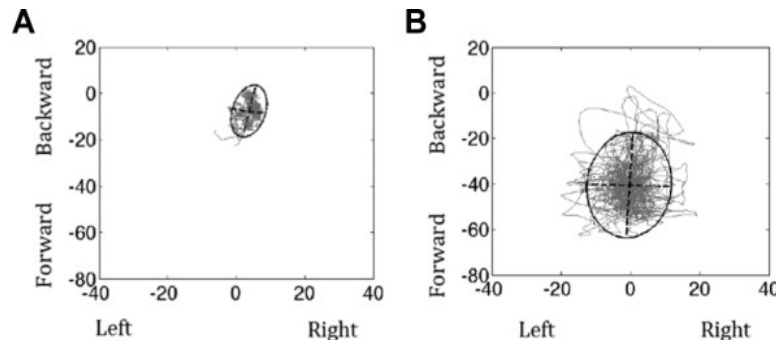


Figure 1. Example of a 95% ellipse for a participant in the (A) control group and (B) concussion group.

Statistical Analysis

Separate 2-way (condition X group) repeated-measures analyses of variance were used to determine differences between conditions (within-subjects factor) and groups (between-subjects factor) for each COP variable. Post hoc comparisons were performed using independent-samples t tests to identify the conditions for which there was a significant difference between the concussion and control groups. For the independent-samples t tests, the level of significance was adjusted to .017 to correct for multiple comparisons. A Mann-Whitney U test was used to determine whether there was a significant difference for the number of correct responses on the Stroop color and word test between the concussion and control groups. A Mann-Whitney U test was also used to determine whether there was a significant difference for BESS total score between the concussion and control groups.

Finally, correlations between the 3 dependent variables with 95% CIs were calculated to determine whether any of the variables were correlated within each condition. All analyses were completed using IBM SPSS Statistics version 23 (IBM Corp).

2.4 Results

Thirty-three participants with concussion (mean age, 14.2 ± 1.5 years; 21 females, 12 males) completed the protocol between 28 and 40 days postinjury (mean, 32 ± 3 days). Thirty-three noninjured participants within the same age distribution (mean age, 15.0 ± 1.5 years; 24 females, 9 males) completed testing once. Baseline characteristics for participants in the concussion group are summarized in Table 1. The incidence for specific postconcussion symptoms at the time of the ED visit and at 1 month are summarized in Table 2.

Table 1. Baseline Characteristics for Participants in the Concussion Group

Characteristic	n (%)
Age, y, median (IQR)	14.09 (13.36-16.05)
8-12	2 (6.1)
13-18	31 (93.9)
Female	20 (60.6)
History	
Hours between ED visit and injury, median (IQR)	15.15 (2.92 – 23.39)
Previous number of concussions	
0	22 (66.7)
1	8 (24.2)
2	2 (6.1)
3+	1 (3.0)
Longest symptom duration of previous concussion	
<1 wk	6 (18.2)
1-4 wk	2 (6.1)
5+ wk	3 (9.1)
Migraine	7 (21.2)
Learning disabilities	3 (9.1)
ADD/ADHD	3 (9.1)
Other developmental disorder	3 (9.1)
Anxiety	4 (12.1)
Depression	2 (6.1)
Loss of consciousness	4 (12.1)
Duration, min, mean (SD)	0.30 (0.39)
Seizure	1 (3.0)
Mechanism of injury	
Sports/recreational play	22 (66.7)
Soccer	4 (12.1)
Recreational play (gym, recess)	4 (12.1)
Hockey	3 (9.1)
Football	1 (3.0)
Ski/snowboarding	1 (3.0)
Bicycling	1 (3.0)
Trampoline	1 (3.0)
Nonsport-related injury/fall	8 (24.2)
Motor vehicle collision	1 (3.0)
Assault	2 (6.1)

Helmet use	5 (15.2)
Mouth guard use	6 (18.2)

ADD, attention deficit disorder; ADHD, attention deficit hyperactivity disorder; ED, emergency department; IQR, interquartile range.

Table 2. Percentage of Participants in the Concussion Group Reporting Specific Symptoms at the Time of Injury and 1 Month Postinjury

Symptom	Time of Injury, n (%)	1 Month Postinjury, n (%)
Headache	32 (96.7)	16 (48.5)
Nausea	25 (75.8)	12 (36.4)
Balance problems	26 (78.8)	12 (36.4)
Dizziness	30 (90.9)	11 (33.3)
Fatigue	32 (97.0)	17 (51.5)
Drowsiness	29 (87.9)	11 (33.3)
Sensitivity to light	28 (84.8)	12 (36.4)
Sensitivity to noise	20 (60.6)	11 (33.3)
Irritability	18 (54.5)	7 (21.2)
Sadness	11 (33.3)	4 (12.1)
Nervousness	12 (36.4)	8 (24.2)
Feeling slowed down	30 (90.9)	10 (30.3)
Difficulty concentrating	23 (69.7)	11 (33.3)
Difficulty remembering	15 (45.5)	7 (21.2)
Visual problems	19 (57.6)	3 (9.09)

Significant group effects were obtained for the 95% ellipse ($F = 13.0$, $P = 0.001$), A/P velocity ($F = 5.83$, $P = 0.02$), and M/L velocity ($F = 9.67$, $P = 0.003$). These significant group effects show that, regardless of the balance condition, the concussion group swayed over a larger area and also swayed faster in both A/P and M/L directions compared with the control group. Significant group X condition interactions were also obtained for the 95% ellipse ($F = 5.74$, $P = 0.005$) and M/L velocity ($F = 4.27$, $P = 0.02$) (Figure 2). For the 95% ellipse, post hoc

comparisons showed that the participants in the concussion group swayed over a larger area compared with the control group for the EO ($P = 0.008$), EC ($P = 0.002$), and DT ($P = 0.003$) conditions (Figure 2A). For M/L velocity, post hoc comparisons showed that the concussion group completed the DT condition with greater M/L velocity compared with the control group ($P = 0.007$) (Figure 2B).

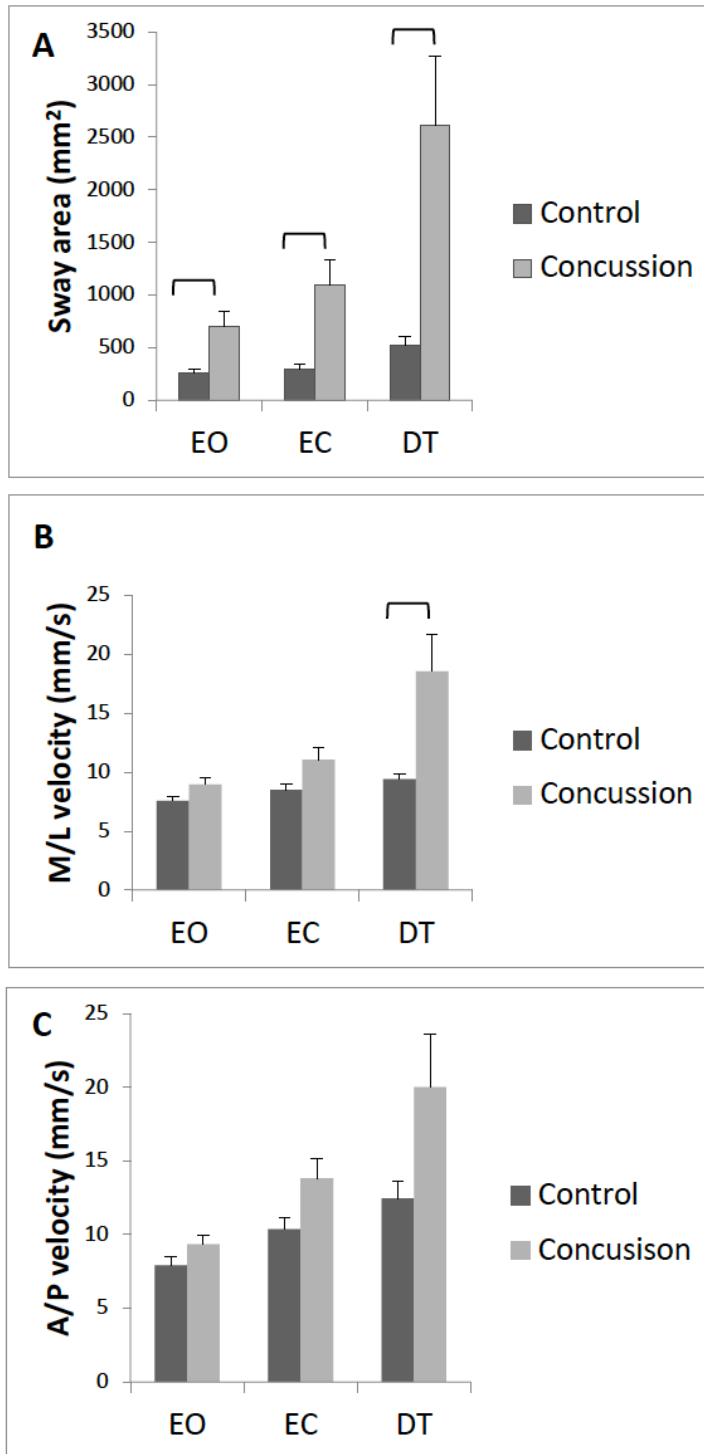


Figure 2. Data (mean + standard error) regarding the 3 balance conditions for the control and concussion groups: (A) 95% ellipse, (B) medio-lateral (M/L) velocity, and (C) anterior-posterior (A/P) velocity. Significant differences ($P < .017$) between groups are identified with brackets. DT, dualtask; EC, eyes closed; EO, eyes open.

No significant group differences were obtained for any of the conditions for A/P velocity (Figure 2C), the number of correct responses on the Stroop color and word test ($P = 0.5$; data not shown), and BESS total score ($P = 0.2$). The median number of errors and the interquartile ranges for each condition of the BESS and BESS total score are shown in Table 3.

Correlations between the dependent variables are shown in Table 4. The correlations between A/P velocity and the 95% ellipse were high for the EO ($r = 0.81$) and EC ($r = 0.82$) conditions but lower for the DT ($r = 0.63$) condition. Similar trends were obtained for the correlations between A/P and M/L velocity: correlations were high for the EO ($r = 0.78$) and EC ($r = 0.90$) conditions and again lower for the DT condition ($r = 0.45$). In contrast, the correlation between M/L velocity and the 95% ellipse was high for the DT condition ($r = 0.87$) and lower for the EC ($r = 0.79$) and EO conditions ($r = 0.69$). These results demonstrate that the participants' 95% ellipses were related to A/P sway velocity for the EO and EC conditions but related to M/L velocity for the DT condition.

Table 3. Median number of errors and the interquartile ranges for each condition of the BESS and BESS total score for both the Control and Concussion groups.

	Double-leg firm	Tandem firm	Single firm	Double-leg foam	Tandem foam	Single foam	BESS total
Control	0 (0-0)	1 (0-1)	2 (1-3.5)	0 (0-0)	2 (1-2.5)	4 (2.5-6)	8 (6-12.5)
Concussion	0 (0-0)	1 (0-2)	2 (1-4)	0 (0-0)	3 (1-4)	4 (3-7)	11 (6.5-15)

Table 4. Correlations between all three dependent variables within each condition performed on the WBB with 95% confidence intervals

	Eyes open			Eyes closed			Dual Task		
	Estimate	Lower 95	Upper 95	Estimate	Lower 95	Upper 95	Estimate	Lower 95	Upper 95
95% ellipse & AP velocity	0.81	0.70	0.88	0.82	0.72	0.88	0.63	0.46	0.76
95% ellipse & ML velocity	0.69	0.54	0.79	0.79	0.68	0.87	0.87	0.80	0.92
AP velocity & ML velocity	0.78	0.67	0.86	0.90	0.84	0.94	0.45	0.23	0.62

2.5 Discussion

In this study, we compared balance characteristics between adolescents at 1 month postconcussion and control participants within the same age distribution. The concussed group demonstrated increased area of sway compared with the control group while standing on 2 feet with eyes open, eyes closed, and while completing the dual-task condition. Participants with concussion also completed the dual-task condition with greater M/L velocity compared with control participants. Both groups made a similar number of errors on the Stroop color and word test. Therefore, the differences in balance characteristics seen in the concussed participants are likely due to impaired balance rather than to prioritizing the cognitive task. In contrast to COP measures, the BESS was not sensitive in detecting residual balance deficits in the concussed adolescents as both groups performed similarly.

To our knowledge, this is the first study to have measured both COP measures during single- and dual-task static balance conditions and scores from the BESS in the same group of concussed individuals and to have compared their performance with a group of control participants. Previous studies that have used only the BESS have identified that balance

recovers within 3 to 5 days postconcussion (Guskiewicz, Ross & Marshall, 2001) and although it is likely that a subset of these individuals would have continued to show balance deficits based on COP measures, this assumption could not be made without using both methods to assess balance in the same group of individuals. This study also differs from previous studies that have measured the COP in individuals who have experienced a concussion in the sense that the COP was recorded using a WBB as opposed to a standard force plate. Since the WBB is a low-cost and portable device, it would be much easier to implement the protocol used in this study in clinical and sport settings.

Dorman et al. (2015) conducted a study for which 18 adolescents with concussion and 26 adolescents without concussion completed 4 conditions during which the movement of their COP was recorded. The conditions included a double-leg stance performed with eyes open and with eyes closed and a dual-task performed with eyes open and eyes closed that involved maintaining balance in a double-leg stance while simultaneously reciting the months of the year in reverse. Two COP variables were measured: 95% ellipse and the velocity combining both A/P and M/L directions into 1 resultant measure. During the first session, which took place within 10 days postinjury, participants with concussion showed significant differences compared with control participants for both variables on all 4 conditions. However, during the second session, which took place at an average 15 days after the first session, the concussed group had significantly greater 95% ellipses than the control group in the 2 DT conditions only. In contrast to the study by Dorman et al. (2015), the current study also showed significant group differences for the 95% ellipse for the double-leg stance with eyes open and eyes closed at approximately 1 month postinjury. These inconsistencies may be due to differences in the

duration of the trials. In the current study, the COP was recorded for a total of 2 minutes for the EO and EC conditions, whereas in Dorman's study, the COP was recorded for 20 seconds. The International Society for Posture and Gait Research recommends using trials of at least 30 seconds to obtain stable COP values (Scoppa, Capra, Gallamini & Shiffer, 2013).

Unexpected observations were obtained while some participants in the concussion group performed the DT condition. Specifically, we observed that a subgroup of participants appeared to stabilize their head on their trunk and to shift their body from side to side while completing this condition. This side-to-side motion is also mirrored in the COP data since the correlations demonstrated that the participants' 95% ellipses were related to A/P sway velocity for the EO and EC conditions and related to M/L velocity for the DT condition. This inverse relationship obtained for the DT condition could be due to the participants shifting their body from side to side while completing this condition. It is possible that certain participants in the concussion group adopted this type of motion necessary to successfully shift their point of gaze toward the new target position (Thiagarajan & Ciuffreda, 2014). Thus, it is possible that some of the participants in the concussion group struggled to track the words of the Stoop color and word test with their eye movements, forcing them to shift their body from side to side to successfully track the words. These observations require further examination by measuring both saccadic eye movement parameters and COP parameters while participants with concussion complete the DT condition.

One limitation of this study is that not all participants in the concussion group were tested within the same number of days postinjury. Since the purpose of this study was to compare balance characteristics between adolescents at 1 month postconcussion and

noninjured control participants, it was essential that each participant in the concussion group complete the protocol as close as possible to 28 days postinjury. However, due to time constraints, some participants completed the protocol after 28 days postinjury. Yet, to keep the sample of participants as uniform as possible with regard to the time at which they completed the protocol, we ensured that all participants completed the protocol by 40 days postinjury at the latest. A second limitation is that no preinjury data were obtained for participants in the concussion group. Although it is possible that some participants in the concussion group performed poorly on the balance tasks due to pre-existing balance issues related to factors other than their head injury, including control participants within the same age distribution suggests this was not the case.

The results from this study clearly highlight the importance of assessing balance with more objective measures since the BESS failed to differentiate balance performance between the concussion and control groups whereas measures of the COP identified several significant differences between the 2 groups. The BESS involves 20-second trials, and it is possible that these trials are not long enough to identify balance impairments in individuals who have experienced a concussion. However, the BESS may also only be sensitive enough to identify balance deficits at the time of injury when individuals show more severe balance impairments. Yet, as individuals recover and show more subtle deficits, the BESS no longer identifies these deficits. Although no studies have explicitly shown that subtle balance deficits increase the risk for reinjury in individuals who have experienced a concussion, studies have shown that increased COP displacement is associated with an increased risk for falls in older adults (Pirtola & Era, 2006) and associated with a risk for ankle sprains in young basketball players (McGuine,

Greene, Best & Levenson, 2000). As a result, it is likely that subtle balance deficits could also lead to functional consequences in adolescents who have suffered a concussion and could place them at risk for a second concussion if not fully recovered.

2.6 Conclusion

We demonstrated that adolescents continued to show balance deficits for both easy (EO, EC) and more difficult (DT) balance tasks at 1 month postconcussion despite scoring similar to control participants on the BESS. Measures of the COP recorded with a WBB may identify subtle postural impairments not captured by the BESS. Future research should focus on developing objective and sensitive balance assessments for concussion that can be used in clinics and on the sidelines in sport.

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Conflicts of Interest

There are no conflicts of interest to disclose.

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Chapter 3: Self-Reported Balance Status is not a Reliable Indicator of Balance Performance in Adolescents at One-Month Post-Concussion

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Self-Reported Balance Status is not a Reliable Indicator of Balance Performance in Adolescents at One-Month Post-Concussion

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3.1 Abstract

Objectives: To determine if self-reported balance symptoms can be used as a proxy for measures of the center of pressure (COP) to identify balance deficits in a group of concussed adolescents.

Design: Case-control.

Methods: Thirteen adolescents 1-month post-concussion who reported ongoing balance problems (Balance+), 20 adolescent 1-month post-concussion who reported no balance problems (Balance-), and 30 non-injured adolescents (control) completed a series of balance tests. Participants completed two 2-min trials standing on a Nintendo Wii Balance Board™ during which the COP under their feet was recorded: i) double-leg stance, eyes open; ii) double-leg stance, eyes closed. Participants also completed a dual-task condition combining a double-leg stance and a Stroop Colour-word test.

Results: Participants in both the Balance+ and Balance- group swayed over a larger ellipse area compared to the control group while completing the Eyes Closed (Balance+, $p = 0.002$; Balance-, $p = 0.002$) and Dual-Task (Balance+, $p = 0.001$; Balance-, $p = 0.004$) conditions and performed the Dual-Task condition with faster medio-lateral velocity (Balance+, $p = 0.003$; Balance-, $p = 0.009$). The participants in the Balance- group also swayed over a larger ellipse area compared to the control group while completing the Eyes Open condition ($p = 0.005$). No significant differences were identified between the Balance+ and Balance- groups.

Conclusions: At 1-month post-concussion, adolescents demonstrated balance deficits compared to non-injured adolescents regardless of whether they reported balance problems. These results suggest that self-reported balance status might not be an accurate reflection of balance performance following a concussion in adolescents

3.2 Introduction

A concussion can be a significant event in the life of an adolescent and can lead to acute symptoms as well as long-term consequences. In contrast to most other injuries, no simple test can be administered to diagnose a concussion (Covassin & Elbin, 2005), thus clinicians rely largely on symptoms for diagnosis and management (McLeod & Leach, 2012). Balance problems are an important marker of concussion presenting in approximately 30% of concussion cases (Murray, Salvatore, Powell & Reed-Jones, 2014) and affecting up to 50% of adolescents with a sports-related concussion (Lau, Kontos, Collins & Mucha, 2011). Balance problems, specifically the inability to control the position of the center of gravity during tandem stance, in conjunction with other variables measured within 48 hours post-concussion, have been shown to be a moderate predictor for persistent symptoms lasting up to at least 28 days post-injury in children and adolescents (Zemek et al., 2016).

Balance is defined as the ability to maintain the vertical projection of one's center of mass within the base of support (Yim-Chiplis & Talbot, 2000). During quiet upright standing, small deviations from a perfect upright position continuously occur (Peterka & Loughlin, 2004). The postural control system coordinates and integrates information from multiple sensory systems to generate the appropriate motor outputs in order to correct for these postural deviations (Guskiewicz, 2011). These motor outputs, often the dorsi- and plantarflexors at the ankle, directly reflect the neural control of the ankle musculature and resulting movement of the center of pressure (COP) under the feet. Thus, the trajectory of the center of pressure ensures the appropriate acceleration and deceleration of the center of mass for stability (Winter, 1995).

Balance problems are often clinically identified with symptom checklists and scales for which the patient is asked to indicate the presence or absence of specific concussive symptoms and is usually required to rate the severity of present symptoms. However, some athletes who have experienced a concussion may not fully disclose their symptoms in order to prevent removal from sport participation or to return to play sooner (Reddy, Collins & Gioia, 2008). As a result, caution should be taken when making clinical decisions based on self-reported symptoms. In addition, although several symptom checklists and scales are available to aid in the assessment of concussions, the psychometric properties of most of these scales and checklists are not known (McLeod & Leach, 2012).

It has been suggested that objective assessments be used in addition to self-reported symptoms in order to increase the sensitivity of a concussion assessment (Broglia, Macciocchi & Ferrara, 2007). While most concussive symptoms cannot be objectively quantified, balance can be measured objectively by recording anterior-posterior (A/P) and medio-lateral (M/L) movements of the center of pressure (COP). Including such measures in a concussion assessment would likely increase the likelihood of identifying balance deficits in individuals who have experienced a concussion compared to focusing solely on self-reported symptoms. However, there is a paucity of studies examining the association between self-reported balance symptoms and balance performance on COP measures in individuals with concussion.

The lack of agreement between self-report and objective measures of balance has been proposed in a previous study (Rhine, Byczkowski, Clark & Babcock, 2016). Children and adolescents within 6 h post-concussion had larger COP displacements during quiet standing than control participants suggesting impaired balance. The results also revealed that self-

reported balance symptoms were not predictive of standing balance performance in concussed adolescents, suggesting that self-reported symptoms are not associated with COP measures following a concussion. Yet, it is not clear if this lack of association is due to lack of reporting (e.g., the adolescents identified as having impaired balance on the COP measures did not disclose balance related symptoms) or due to lack of fidelity of the assessment to detect deficits (e.g., quiet standing does not have adequate sensitivity to detect impaired balance in those adolescents reporting balance-related symptoms).

The purpose of this study was to further explore the relationship between self-reported balance problems and objectively measured balance performance in adolescents who have experienced a concussion to determine whether self-reported balance status is an adequate proxy for objective measures of balance. COP velocity and displacement values were compared between adolescents at 1-month post-concussion who reported ongoing balance problems, adolescents at 1-month post-concussion who reported no balance problems, and non-injured age-matched control participants. It was hypothesized that the group of concussed adolescents reporting balance problems would show significant differences on the COP measures compared to the control group, but that there would be no significant group differences between the group of concussed adolescents reporting no balance problems and the control group.

3.3 Methods

Participants

Adolescents (aged 12–17 years) diagnosed with a concussion by a physician in the emergency department (ED) at a regional tertiary hospital were recruited through a larger study (Zemek et al., 2016). The adolescents were recruited in the ED and contacted by phone to

schedule an appointment to complete the protocol for the current study. The diagnosis of concussion used for the larger study was based on the criteria from the Zurich consensus statement (McCrory et al., 2013):

A direct blow to the head, face, neck or elsewhere on the body with an impulsive force transmitted to the head, resulting in one or more symptoms in one or more of the following clinical domains (which may or may not have involved loss of consciousness):

- Somatic symptoms (e.g., headache, nausea, loss of balance, dizziness, sensitivity to light or noise, visual problems and clumsiness).
- Cognitive symptoms (e.g., feeling like in a fog, difficulty concentrating or remembering, answering questions more slowly and confused with directions/tasks).
- Emotional/behavioural symptoms (e.g., irritable, sad, nervous and emotional lability).
- Sleep disturbance (e.g., sleeping more, fatigue, drowsiness and insomnia).

Exclusion criteria were Glasgow Coma Scale (Teasdale & Jennett, 1974) less than 14, abnormalities observed on neuroimaging (if performed), operative intervention or procedural sedation required, or presentation with multisystem injuries requiring admission.

Participants with concussion were divided into two groups based on whether their self-reported balance status at 1-month post-injury was as good as/better than before their injury (Balance– group) or worse than before their injury (Balance+ group). A third group of participants (control group) consisted of adolescents between the same ages who reported no concussive symptoms and who had not suffered any head trauma within the last year. These participants were recruited from the community at large.

Self-reported balance status was determined based on the participant's response to the balance-related item on the Post-Concussion Symptoms Inventory (PCSI) (Sady, Vaughan & Gioia, 2014). Participants completed the PCSI when they completed the protocol for the current study at approximately 1-month post-injury. Participants used a 6 point scale to rate their balance problems pre- and post-injury with "0" indicating no problem, "3" indicating a moderate problem and "6" indicating a severe problem. Participants reporting a 1-point or more increase in balance problems between their post-injury rating and their pre-injury rating were placed in the Balance+ group. Participants who reported no change or a decrease in balance problems between their post- and pre-injury rating were placed in the Balance- group.

Experimental protocol

Prior to participating in the study, all participants and their parent provided written informed consent. This study was approved by the institution's ethics research board (Children's Hospital of Eastern Ontario Research Ethics Board). All participants completed the balance testing protocol once. Participants with concussion completed the protocol between 28 and 40 days post-injury. Participants completed a series of balance tasks while standing on a Nintendo Wii Balance Board. The Wii Balance Board has been shown to be a valid alternative to a force plate to collect the COP. The error between COP trajectories recorded with a Wii Balance Board and a force plate has been shown to be minimal: 0.33 mm–0.58 mm in the medio-lateral direction and 0.31 mm–0.63 mm in the anterior-posterior direction (Huurnink, Fransz, Kingma & Dieën, 2013). In addition, very strong correlations ranging from 0.99 to 1.00 have been reported between COP trajectories recorded with both devices and variables

computed from these trajectories (Huurnink, Fransz, Kingma & Dieën, 2013; Chang, Levy, Seay & Goble, 2014).

Participants first stood with their feet shoulder width apart and held this position for two minutes with their eyes open (Eyes Open) and then with their eyes closed (Eyes Closed). For both conditions, participants were instructed to focus on standing as still as possible for the entire trial. Participants then completed a dual-task condition (Dual-Task), which consisted of standing on the Wii Balance Board with their feet shoulder width apart while completing a Stroop Colour-word test (Stroop, 1935). The Stroop Colour-word test was presented on a board placed at eye-level at a distance of one meter from the participant. The board contained 20 rows of 5 words consisting of a random series of the words “red”, “blue”, “yellow” and “green” written in incongruent ink. Participants were asked to name the colour of the ink of each word as quickly and as accurately as possible. Participants were also asked to stand as still as possible while completing this condition. The number of correct responses was recorded for each participant to calculate a percentage of accuracy by dividing the number of correct responses by the number of total responses. The purpose of the Stroop colour-word test was to evaluate the effects of adding a cognitive load on balance performance since everyday tasks and activities require the simultaneous integration of cognitive functions and balance abilities.

Material and Data Processing

The Wii Balance Board raw pressure data were recorded to a laptop computer via a Bluetooth device at a sampling frequency of 30 Hz. A custom Matlab (The Mathworks Inc., Natick, MA, USA) script was used to transform raw pressure data to COP values in the anterior-posterior and medio-lateral directions. The COP data were filtered using a second order low-

pass Butterworth filter with a cut-off frequency of 12 Hz. The velocity of the COP in the medio-lateral and anterior-posterior directions and the COP 95% ellipse were calculated for each of the three balance tasks (Eyes Open, Eyes Closed, Dual-Task) for each participant. The velocity was characterized as the mean absolute speed of the COP displacement. The 95% ellipse consisted of an ellipse that covered 95% of the participant's COP trajectory. An example of an ellipse of a control participant, a participant in the Balance+ group and a participant in the Balance- group are shown in Figure 1.

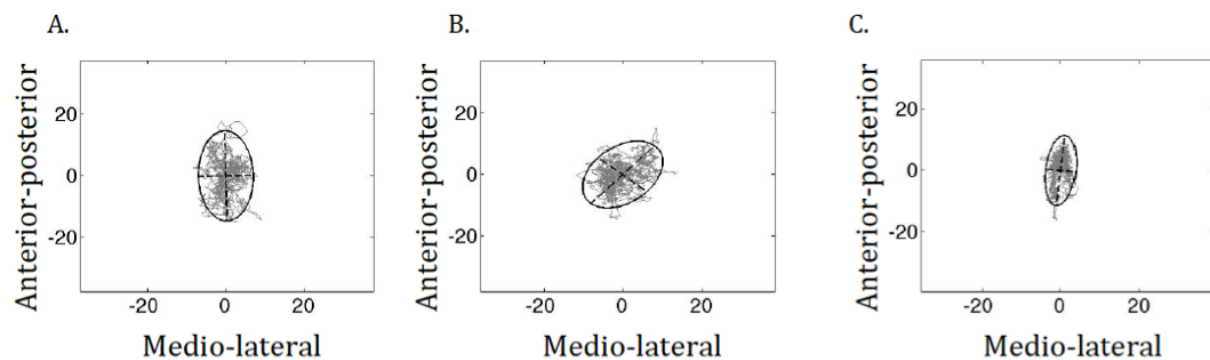


Figure 1. The light grey line in each panel shows the COP trace during 2 min of quiet standing with eyes open for a single subject in each group. The dark oval shows the area incorporated in the 95% ellipse for a control participant (A), a participant in the Balance+ group (B), and a participant in the Balance- group (C).

Statistical Analysis

For each COP dependent variable, separate 2-way (condition X group) repeated measures ANOVA were used to test for differences between conditions (within-subjects factor) and groups (between subjects factor). A one-way ANOVA (group) was used to test for differences between groups for the percent accuracy on the Stroop Colour-word test. When a significant main effect was obtained for group, post-hoc comparisons were performed using independent samples t-tests to identify the conditions for which there was a significant

difference between the three groups. Significance levels were adjusted to 0.017 to correct for multiple comparisons. All analyses were completed using IBM SPSS Statistics version 23 (SPSS Inc., Chicago, IL, USA).

3.4 Results

Thirteen participants in the Balance+ group (mean age = 14.7 ± 1.6 , 12 females and 1 male) and twenty participants in the Balance- group (mean age = 13.8 ± 1.3 , 9 females and 11 male) completed the protocol once (mean number of days post-concussion = 32 ± 3). Thirty non-injured participants with similar age distribution (mean age = 15.0 ± 1.5 , 19 females and 11 males) completed testing once. Baseline characteristics for the participants in the Balance+, Balance- and control groups are summarized in Table 1.

Table 1. Baseline characteristics for participants in the Balance-, Balance+ and Control groups

Characteristic	Balance- (n = 20)	Balance+ (n = 13)	Control (n = 30)	p Value
Age (%)				0.34
12–14	14 (70.0)	6 (46.2)	16 (53.3)	
15–17	6 (30.0)	7 (53.8)	14 (46.7)	
Female (%)	8 (40.0)	12 (92.3)	19 (63.3)	0.01
History (%)				
Hours between ED visit and injury (median, IQR)	6.4 (2.2–2.8)	21.9 (10.6–27.1)		
Previous number of concussions				0.19
0	11 (55.0)	11 (84.5)		
1	7 (35.0)	1 (7.7)		
2	1 (5.0)	1 (7.7)		
3+	1 (5.0)	0 (0.0)		
Longest duration of previous concussion				0.18
Less than 1 week	6 (30.0)	0 (0.0)		
1–4 weeks	1 (5.0)	1 (7.7)		
5+ weeks	2 (10.0)	1 (7.7)		
Migraine	5 (25.0)	2 (15.4)		0.68
Learning disabilities	2 (10.0)	1 (7.7)		1.00
ADD/ADHD	3 (30.0)	0 (0.0)		0.26
Other developmental disorder	3 (30.0)	0 (0.0)		0.26
Anxiety	4 (20.0)	0 (0.0)		0.14
Depression	2 (10.0)	0 (0.0)		0.51
Loss of consciousness	2 (10.0)	2 (15.4)		1.00
Seizure	1 (5.0)	0 (0.0)		1.00

Mechanism of injury (%)			0.70
Sports/recreational play	12 (60.0)	10 (76.9)	
Non-sport related injury/fall	5 (25.0)	3 (23.1)	
Motor vehicle collision	1 (5.0)	0 (0.0)	
Assault	2 (10.0)	0 (0.0)	

For anterior-posterior velocity, there was a significant main effect for condition ($F = 29.1$, $p < 0.001$), but no significant main effect of group ($F = 2.47$, $p = 0.093$) or significant interaction between group and condition ($F = 1.13$, $p = 0.34$) (see Figure 2A). There was also no significant main effect of group ($F = 0.275$, $p = 0.76$) for the percentage of accuracy on the Stroop Colour-word test meaning that all three groups performed the task with similar percentages of accuracy (data not shown).

For the 95% ellipse, a two-way ANOVA (group $\times$ condition) with repeated measures on the second factor revealed a significant main effect for group ($F = 5.97$, $p = 0.004$) and condition ($F = 13.6$, $p < 0.001$) and a significant interaction between group and condition ($F = 3.84$, $p = 0.02$). Post-hoc comparisons showed that the Balance+ group swayed over a significantly larger area compared to the control group while performing the Eyes Closed ($p = 0.002$) and Dual-Task ($p = 0.001$) conditions (Figure 2B). Post-hoc comparisons also showed that the Balance- group swayed over a significantly larger area compared to the control group while performing the Eyes Open ($p = 0.005$), Eyes Closed ($p = 0.002$) and Dual-Task ($p = 0.004$) conditions (Figure 2B). Regardless of self-reported balance status (Balance+ vs Balance-), the area of COP displacement was not significantly different for any of the conditions.

For medio-lateral velocity, a two-way ANOVA (group $\times$ condition) with repeated measures on the second factor revealed significant main effects for group ($F = 4.52$, $p = 0.02$) and condition ($F = 13.2$, $p < 0.001$) and a significant interaction between group and condition ($F = 3.63$, $p = 0.02$). Post-hoc comparisons showed that both the Balance+ and Balance- groups swayed significantly faster than the control group during the Dual-Task condition (Balance+, $p = 0.003$; Balance-, $p = 0.009$), but not for the other conditions (Figure 2C). Again, no significant group differences were identified between the Balance+ and Balance- groups for any of the conditions.

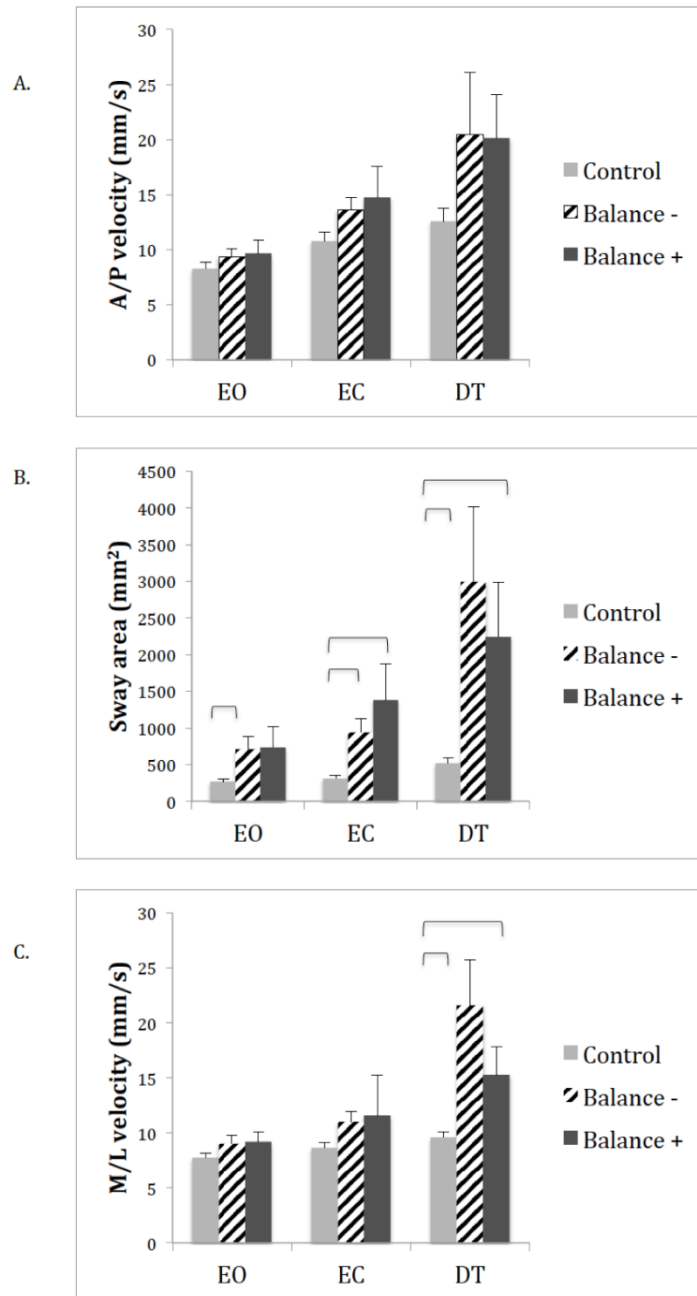


Figure 2. Data (mean + standard error) are shown for Eyes Open (EO), Eyes closed (EC) and Dual-Task (DT) conditions for the Control, Balance- and Balance+ groups. Top panel (A): Anterior-Posterior (A/P) velocity; Middle panel (B): 95% ellipse; Bottom panel (C): Medio-Lateral (M/L) velocity. Significant differences ($p < 0.017$) between groups are identified with brackets.

3.5 Discussion

In this study, we compared COP measures between adolescents at 1-month post-concussion who reported balance problems, adolescents at 1-month post-concussion who reported no balance problems, and control participants within the same age distribution while they completed a series of balance tasks. Both the Balance+ and Balance– groups showed balance deficits compared to the control group as demonstrated by increased area of sway while completing the Eyes Closed and Dual-Task conditions and increased medio-lateral velocity while completing the Dual-Task condition. The Balance– group also showed balance deficits compared to the control group as demonstrated by increased area of sway while completing the Eyes Open condition. Importantly, the Balance+ and Balance– groups performed similarly on all balance tasks. These results demonstrate that the participants with concussion showed balance deficits on the COP measures regardless of whether they self-reported balance problems.

Balance deficits post-concussion may be more evident under certain conditions or in specific movement directions. A previous study (Broglia, Sosnoff & Ferrara, 2009) completed pre-season baseline testing including the Sensory Organization Test, a balance assessment designed to alter the presence and accuracy of sensory information, in 36 collegiate athletes. Athletes who experienced a concussion during the season repeated the testing protocol within 48 h post-injury. The results showed that almost 50% of participants reported balance-related symptoms (46%), whereas less than one-fifth of participants (19%) showed post-injury declines on their scores from the Sensory Organization Test. In contrast, our data report that regardless of self-reported balance problems, participants post-concussion showed balance deficits compared to the control group. Specifically, more participants were identified as having a

balance problem on objective balance testing compared to the number of participants who self-reported balance problems.

The discrepancies between the results from these two studies may be due to the COP measures obtained. Performance on the Sensory Organization Test is evaluated with equilibrium scores, which reflect how much an individual's COP moves in the anterior-posterior direction in relation to their limits of stability. However, movement of the COP in both the anterior-posterior and medio-lateral directions are involved in maintaining balance and reflect two distinct control mechanisms. In a quiet stance position with feet shoulder width apart, anterior-posterior sway reflects activity at the ankles and medio-lateral sway represents the loading and unloading mechanisms of the hips (Winter, Prince, Frank & Powell, 1996). Previous studies have shown that individuals with concussion show balance deficits in COP measures in both anterior-posterior and medio-lateral directions (Powers, Kalmar & Cinelli, 2014) and therefore simply relying on values that only take anterior-posterior sway into account may fail to identify balance problems post-concussion.

To our knowledge, this is one of a limited number of studies that have performed a comparison between self-reported balance symptoms and objective measures of balance in a concussed population. Though other studies have reported performance on objective measures of balance as well as the number or severity of self-reported concussive symptoms (Powers, Kalmar & Cinelli, 2014; Dorman et al., 2015), the results from these studies do not specify if the participants with concussion reported balance problems. This makes it difficult to draw conclusions as to whether an objective balance assessment can increase the sensitivity of identifying balance deficits post-concussion. In addition, while a previous study showed that

self-reported symptoms related to balance were not predictive of balance performance on COP measures in concussed adolescents at the time of injury (Rhine, Byczkowski, Clark & Babcock, 2016), the reason for this lack of association was not clear. Specifically, it was not clear if the participants demonstrating balance deficits on the COP measures were not reporting balance-related symptoms or if participants reporting balance-related symptoms were not identified as having balance problems on the COP measures. The current study adds to the existing literature by demonstrating that participants with concussion were identified as having balance problems on the COP measures regardless of whether they reported balance problems.

It was difficult to ensure that all participants with concussion accurately self-reported whether they had balance problems. Certain participants with balance problems may have been placed in the Balance– group if they hid or masked their balance problems. However, some participants may learn to adapt to their balance problems making them unaware of these problems. A second limitation of this study includes the fact that the Balance+ group was heavily skewed towards females (12 females, 1 male) compared to the Balance– group (8 females, 12 males). Previous studies have shown that females tend to report more post-concussive symptoms compared to males (Lovell et al., 2006; Broshek, Kaushik, Freeman & Erlanger, 2005). Therefore, the uneven distribution of females in the Balance+ group is likely due to this tendency and further demonstrates the drawbacks associated with using self-reported symptoms to identify balance problems.

From a clinical perspective, the results from this study clearly highlight the importance of including objective measures of balance in addition to subjective reports of balance symptoms in a concussion assessment. This is supported by the fact that both concussion

groups performed worse than the control group on two or three of the balance tasks, but were not different from each other. As mentioned previously, factors such as unwillingness to report symptoms or compensating for and remaining unaware of underlying balance problems challenge the use of self-reported symptoms to identify balance problems post-concussion. Clinicians are encouraged to include objective measures of balance in a concussion assessment.

3.6 Conclusion

We demonstrated that adolescents at 1-month post-concussion continued to demonstrate balance deficits compared to a group of control participants regardless of whether they self-reported ongoing balance problems. Objective measures of balance obtained easily with a Wii Balance Board may identify balance deficits that would otherwise be overlooked if clinicians focus solely on self-reported symptoms.

3.7 References

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Chapter 4: Predictors of Balance Performance at 1-Month Post-Injury in Concussed Adolescents

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Predictors of Balance Performance at 1-Month Post-Injury in Concussed Adolescents

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4.1 Abstract

Background: Balance deficits affect approximately 30% of individuals who experience a concussion and can persist up to at least 1-month post-injury. While balance deficits may increase risk of re-injury, there are currently no methods to determine which individuals are at risk of developing persistent balance problems following a concussion. Our objective was to explore the relationship between balance performance within the first 10-days post-injury and at 1-month post-injury in a group of concussed adolescents. Secondary aims were to compare balance performance within the concussion group and a control group of non-injured adolescents, and between groups over time.

Methods: Concussed adolescents aged 11 to 16 years of age (n=30) and non-injured adolescents within the same ages (n=37) completed a balance protocol twice. Participants in the concussion group completed the first session within the first 10-days following their injury and the second session at approximately 1-month post-injury. Non-injured adolescents completed both sessions at approximately three-week intervals. During both sessions, participants completed two-minute trials of standing on a Nintendo Wii Balance Board (WBB) with their eyes open and closed. Participants also stood on the WBB while simultaneously completing a Stroop colour-word test (“dual-task” condition). Pressure data from the WBB were used to compute five COP variables including the anterior-posterior (A/P) and medial-lateral (M/L) velocity, A/P and M/L entropy and a 95% ellipse area for each condition. To examine the relationship in balance performance between sessions, the five COP variables measured during each balance condition during the first session were used as predictor variables for the 95% ellipse area measured during the dual-task condition during the second session in the concussion group.

Results: The following variables measured during the first session were significant predictors for the 95% ellipse area measured during the dual-task during the second session: M/L velocity – dual-task ($R^2 = 0.48$; $p < 0.001$), 95% ellipse area – dual-task ($R^2 = 0.253$; $p = 0.013$), M/L velocity – eyes open ($R^2 = 0.253$; $p = 0.012$), A/P velocity – eyes open ($R^2 = 0.198$; $p = 0.037$), M/L velocity – eyes closed ($R^2 = 0.197$; $p = 0.037$), 95% ellipse area – eye open ($R^2 = 0.195$; $p = 0.039$) and A/P velocity – dual-task ($R^2 = 0.186$; $p = 0.046$). Between session comparisons showed that the control group performed the eyes open condition with lower M/L entropy values ($p < 0.001$) during the second session compared to the first session. Between group comparisons showed that during the first session the concussion group swayed over a larger 95% ellipse area ($p = 0.004$). In addition, during the second session, the concussion group performed the dual-task condition with a larger 95% ellipse area ($p < 0.001$), faster M/L velocity ($p = 0.006$) and lower A/P entropy ($p < 0.001$) and also performed the eyes closed condition with lower A/P entropy ($p = 0.002$).

Conclusion: We identified seven COP variables measured within the first 10 days following injury that were significant predictors for the 95% ellipse area measured during a dual-task at 1-month post-injury in a group of concussed adolescents. The results from this study also demonstrated that concussed adolescents showed balance deficits at 1-month post-concussion that were not present within the first 10 days following their injury. These results suggest that changes in the characteristics of balance deficits may take place during the recovery period following a concussion.

4.2 Introduction

Concussions are a common injury in children with an estimated 700,000 emergency department visits for pediatric concussion each year in the United States (National Center for Injury Prevention and Control, 2010). While children can experience many different symptoms following a concussion, balance problems are an important consequence affecting approximately one-third of cases (Murray, Salvatore & Powell, 2014). These deficits may have important implications for the safe practice of sports and other activities with physical and cognitive demands.

Balance deficits following a concussion have been shown to persist longer than what was previously established. Balance measured with clinical evaluations, such as the Balance Error Scoring System (BESS), has been shown to recover within 3 to 5 days post-injury (Guskiewicz, Ross & Marshall, 2001; Riemann & Guskiewicz, 2000). However, more recent studies incorporating measures of the center of pressure (COP) have shown that balance problems can persist up to at least 1-month post-injury in concussed children and adolescents (Dorman et al. 2015; Rhine, Quatman-Yates & Clark, 2015; Rochefort et al., 2017a; Walters-Stewart, Rochefort, Longtin, Zemek & Sveistrup, 2018). Balance protocols incorporating measures of the COP have also identified balance deficits in concussed adolescents regardless of whether they self-reported balance problems (Rochefort et al., 2017b). This suggests that concussed adolescents may choose not to disclose their balance problems or may be unaware of them.

Persistent balance problems may place concussed individuals at risk for further injury. Studies have shown that athletes with a history of concussion had a higher odds ratio of sustaining a lower extremity injury during a 90-day period (Brooks, Peterson, Biese, Sanfilippo &

Heiderscheit, 2016; Herman et al., 2017) and up to 1 year (Lynall, Mauntel, Padua & Mihalik, 2015) after return to play compared to control athletes who had not experienced a concussion. It has been suggested that alterations in the control of balance following a concussion could lead to an increased risk for lower extremity injuries (Brooks, Peterson, Biese, Sanfilippo & Heiderscheit, 2016; Herman et al., 2017; Lynall, Mauntel, Padua & Mihalik, 2015). In addition, while no studies have shown that increased COP displacements are associated with a risk for further injury in individuals with concussion, studies have shown that increased COP displacements are associated with a risk for falls in older adults (Piirtola & Era, 2006) and associated with a risk for ankle sprains in young basketball players (McGuine, Greene, Best & Levenson, 2000). As a result, it is likely that similar mechanisms occur in individuals who have experienced a concussion placing those with balance deficits at risk for further injury.

It is recommended to include a balance examination in a standard concussion assessment to aid in the diagnosis of an acute concussion (McCrory et al., 2016). While balance testing at the time of injury can identify patients affected with balance deficits, these results provide no indication as to whether these patients' balance will recover quickly or become a persistent problem. Vestibular rehabilitation programs have been shown to be an effective approach to improve balance in individuals affected with post-concussion syndrome (Prangley, Aggerholm & Cinelli, 2017) and in individuals affected with persistent dizziness and balance problems following a concussion (Alsalaheen et al., 2010). Yet, concussed individuals with balance deficits likely do not benefit from these programs until they have been affected with these problems for an extended period of time.

Several studies have focused on identifying predictors for persistent postconcussion symptoms in children (Morgan et al., 2015; Miller, 2017; Zemek et al., 2016). While these studies have identified predictors to identify children who are at risk of experiencing a delayed recovery, there is a paucity of studies investigating predictors for specific persistent symptoms such as prolonged balance problems. Given that balance problems affect at least 1/3 of individuals with concussion and may increase the risk for further injury, it is important to identify individuals at risk for long-term balance problems at the time of injury in order to provide them with the appropriate care.

The primary objective of this study was to examine the relationship between balance performance within the first ten days and at 1-month post-injury in a group of concussed adolescents. Center of pressure displacement, velocity and entropy values recorded during a set of balance tasks completed within the first 10 days were used as predictor variables for the COP 95% ellipse area measured during a dual-task balance condition completed at 1-month post-injury. The secondary objective was to compare balance performance between the two sessions within the concussion group and within a group of non-injured adolescents. The third objective was to compare balance performance between both groups during each session. Center of pressure displacement, velocity and entropy values were compared between both sessions with the concussion and non-injured groups and compared between groups during the first and second sessions.

4.3 Methods

Participants

Two groups of participants participated in this study. The concussion group consisted of adolescents aged 11 to 16 years diagnosed with a concussion by a physician in the emergency department (ED) at a regional hospital. The control group consisted of non-injured adolescents within the same ages who reported no concussive symptoms or head trauma within the past year. Participants in both groups completed the protocol twice. Participants in the concussion group completed the first session within the first 10 days following their injury and completed the second session between 28 and 40 days post-injury. Participants in the control group completed both sessions separated by approximately three weeks. Prior to participating in the study, all participants and their parent provided written informed consent. This study was approved by the institution's ethics research board.

Experimental Protocol

During both sessions, participants completed three different balance tasks while standing shoulder width apart on a Nintendo Wii Balance Board that recorded the movement of the COP under their feet.

Participants completed a two-minute trial with their eyes open and with their eyes closed. For the eyes open condition, participants were instructed to fixate on a dot placed at eye level at a distance of 60cm. For the eyes closed condition, participants were instructed to fixate on the dot and then to close their eyes. For both conditions, participants were instructed to focus on standing as still as possible. Participants also performed a dual-task condition consisting of completing a Stroop colour-word test while standing shoulder width apart on the Wii Balance Board. The Stroop colour-word test was presented on a board placed 60cm in front

of the participant. The board contained a 20x5 matrix of a random series of the words “red”, “yellow”, “blue”, and “green” written in an incongruent ink colour, e.g. “red” printed in blue. Participants were instructed to name the colour of the ink of each word from left to right beginning with the first row. The number of correct responses was recorded for each participant and the percentage of accuracy was calculated by dividing the number of correct responses by the number of total responses and multiplying by 100.

Participants in the concussion group also completed the validated Post-Concussion Symptoms Inventory (PCSI) (Sady, Vaughan & Gioia, 2014) at each session. The PCSI consists of a list of concussive symptoms for which participants are asked to rate their pre-injury and post-injury degree of symptoms. The 11 and 12 year old participants completed the version for children 8-12 years of age (17 symptoms, 3-point graded scale) and participants between 13 and 16 years of age completed the version for adolescents 13-18 years of age (20 symptoms, 7-point graded scale).

Material and Data Processing

The Wii Balance Board raw pressure data were recorded to a laptop computer via a Bluetooth device. The raw pressure data were transformed to the COP in the lateral and anterior-posterior directions using a custom Matlab (The Mathworks Inc.) script. The COP data were resampled at a frequency of 30Hz using a sliding window average with relevant interval interpolation (SWARII) (Audiffren & Contal, 2016). Three linear COP measures, the velocity of the COP in the medial-lateral (M/L) and anterior-posterior (A/P) directions and the 95% ellipse area, were calculated for each of the three balance tasks performed during both sessions for each participant. Two non-linear COP measures, the approximate entropy in the A/P and M/L

directions, were also calculated for each balance task for each participant. Approximate entropy reflects the degree of randomness of COP oscillations and is presented as a value between 0 and 2 for which higher values reflect more random and unpredictable patterns and lower values reflect less random and more predictable patterns. Random and unpredictable patterns of COP oscillations are typical of normal balance, whereas more predictable and less random patterns are generally a sign of pathology (Cavanaugh et al., 2005). When calculating measures of approximate entropy, it is recommended to use the same number of data points for each participant (Pincus, 1991). Therefore, for the eyes open and eyes closed conditions, the first 3,500 data points were used to calculate the entropy measures. For the dual-task condition, the first 2,000 data points were used to calculate the entropy measures since the time to complete the dual-task condition varied among participants.

Statistical analysis

To address the primary objective of examining the relationship between balance performance within the first 10 days following injury and at 1-month post-injury, each of the COP variables measured during the three balance conditions during the first session in the concussion group were used to predict the 95% ellipse area measured during the dual-task during the second session in the concussion group. The 95% ellipse area measured during the dual-task was chosen as the outcome variable since it is a global measure that takes both A/P and M/L COP movement into account and has been shown to be sensitive to the effects that concussions have on postural balance under dual-task conditions (Dorman et al., 2015; Rochefort et al., 2017). Separate ordinary least square regressions were used to model the relationships between each predictor variable and the outcome variable. Restricted cubic

splines with 3 knots were applied to each model to allow for non-linearity in the relationships. Statistical significance for the predictors was set at $p < 0.05$.

Separate generalized least squares were used to examine the second and third objectives of comparing balance performance between sessions within the concussion and control groups and to compare the two groups during both sessions. A model for each of the five COP variables was established to identify the relationship between the COP variable and the three predictors of testing session, balance condition and group specified in a three-way interaction. To compare the percentage of response accuracy for the Stroop task between sessions within each group and to compare the two groups during both sessions, generalized least squares were used to model the relationship between the percentage of response accuracy and the two predictors of testing session and group. For each model, Wald's test was used to determine if each predictor was a significant contributor to the model and to determine if any significant interactions were present between the predictors.

Contrasts were extracted from each model to compare performance between the first and second sessions within the concussion and control groups for each balance condition and the percentage of accuracy on the Stroop task. Contrasts were also extracted from each model to compare the control and concussion groups under all three balance conditions and for the percentage of response accuracy on the Stroop task during the first session and the second sessions. Cohen's d effect sizes were calculated for each comparison between the concussion and control groups and for the comparisons between sessions within each group. For the model contrasts pertaining to the COP variables, the threshold for significance was set to $p < 0.008$ to adjust for the six comparisons extracted from each model, i.e. comparing performance

between both sessions for the three balance conditions within each group or comparing both groups on each balance condition during each session. For the model contrasts pertaining to the percentage of response accuracy on the Stroop task, the threshold for significance was set to $p < 0.025$ to adjust for the two comparisons extracted from the model, i.e. comparing performance between both sessions within each group or comparing the two groups during each session.

4.4 Results

Participants

Thirty participants with concussion (mean age = 13.4 ± 1.96 , 17 males and 13 females) completed the first session between 2 and 9 days post-injury (mean = 5.8 ± 2.0) and completed the second session between 28 and 40 days post-injury (mean = 34.2 ± 3.8). Thirty-seven non-injured participants with similar age and sex distributions (mean age = 12.9 ± 1.49 , 22 males and 15 females) completed the two sessions separated by an average of 21.02 ± 5.85 days. Baseline characteristics for the participants in the concussion and control groups are summarized in Table 1. There were no significant group differences in terms of age, sex and number of previous concussions. The incidence for specific post-concussion symptoms during the first and second sessions are summarized in Table 2.

Table 1. Baseline characteristics for study participants

Characteristic	Concussion (n=30)	Control (n=37)	p value
Age, y, median (IQR)	14 (11 - 15)	13 (11.5 - 14)	0.7
11-13 n (%)	14 (46.6)	21 (60)	
14-16 n (%)	16 (53.3)	14 (40)	
Female (%)	13 (43.3)	15 (40.5)	1.0
Previous number of concussions n (%)			0.5
0	23 (76.7)	31 (83.8)	
1	2 (6.67)	4 (10.8)	
2	3 (10)	2 (5.41)	
3	1 (3.33)	0 (0)	
4+	1 (3.33)	0 (0)	
Mechanisms of injury n (%)			
Sport/recreational play	20 (66.7)		
Soccer	4 (20)		
Karate	1 (5)		
Football	1 (5)		
Basketball	2 (10)		
Cheerleading	1 (5)		
Ball hockey	1 (5)		
Gymnastics	1 (5)		
Ice hockey	4 (20)		
Volley ball	2 (10)		
Skiing	1 (5)		
Rugby	2 (10)		
Nonsport-related injury/fall	8 (26.7)		
Motor vehicle collision	1 (3.33)		
Assault	1 (3.33)		

Table 2. Percentage of participants in the concussion group reporting specific symptoms at the time they completed the first and second balance testing sessions.

Symptom	Session 1 n (%)	Session 2 n (%)
Headache	19 (63.3)	8 (26.7)
Nausea	14 (46.7)	3 (10)
Balance problems	15 (50)	4 (13.3)
Dizziness	15 (50)	6 (20)
Fatigue	16 (53.3)	6 (20)
Drowsiness	14 (46.7)	4 (13.3)
Sensitivity to light	22 (73.3)	5 (16.7)
Sensitivity to noise	14 (46.7)	5 (16.7)
Irritability	12 (40)	3 (10)
Sadness	7 (17.5)	3 (10)
Nervousness	5 (16.7)	0 (0)
Feeling slowed down	15 (50)	3 (10)
Difficulty concentrating	16 (53.3)	6 (20)
Difficulty remembering	11 (36.7)	4 (13.3)
Visual problems	13 (4.77)	1 (3.3)

Primary objective

For the primary objective, R^2 values and p values from the regression analysis between each predictor variable and the outcome variable (95% ellipse) are shown in Table 3. Seven of the fifteen predictors were significant: M/L velocity from the dual-task condition ($p<0.001$; $R^2=0.48$), 95% ellipse area from the dual-task condition ($p=0.013$; $R^2=0.253$), M/L velocity from the eyes open condition ($p=0.012$; $R^2=0.253$), A/P velocity from the eyes open condition ($p=0.037$; $R^2=0.198$), M/L velocity from the eyes closed condition ($p=0.037$; $R^2=0.197$), 95% ellipse area from the eye open condition ($p=0.039$; $R^2=0.195$) and A/P velocity from the dual-task condition ($p=0.046$; $R^2=0.186$) (Figure 1).

Table 3. p values and R² values associated with the relationship between each predictor variable and the outcome variable (95% ellipse). Values in bold represent significant predictors (p<0.05).

Variable and condition	P	R²
95% ellipse eyes open	0.039	0.195
95% ellipse eyes closed	0.112	0.136
95% ellipse dual-task	0.013	0.253
A/P velocity eyes open	0.037	0.198
A/P velocity eyes closed	0.099	0.143
A/P velocity dual-task	0.046	0.186
M/L velocity eyes open	0.012	0.253
M/L velocity eyes closed	0.037	0.197
M/L velocity dual-task	<0.001	0.48
A/P entropy eyes open	0.459	0.051
A/P entropy eyes closed	0.512	0.044
A/P entropy dual-task	0.984	0.001
M/L entropy eyes open	0.052	0.179
M/L entropy eyes closed	0.216	0.097
M/L entropy dual-task	0.755	0.019

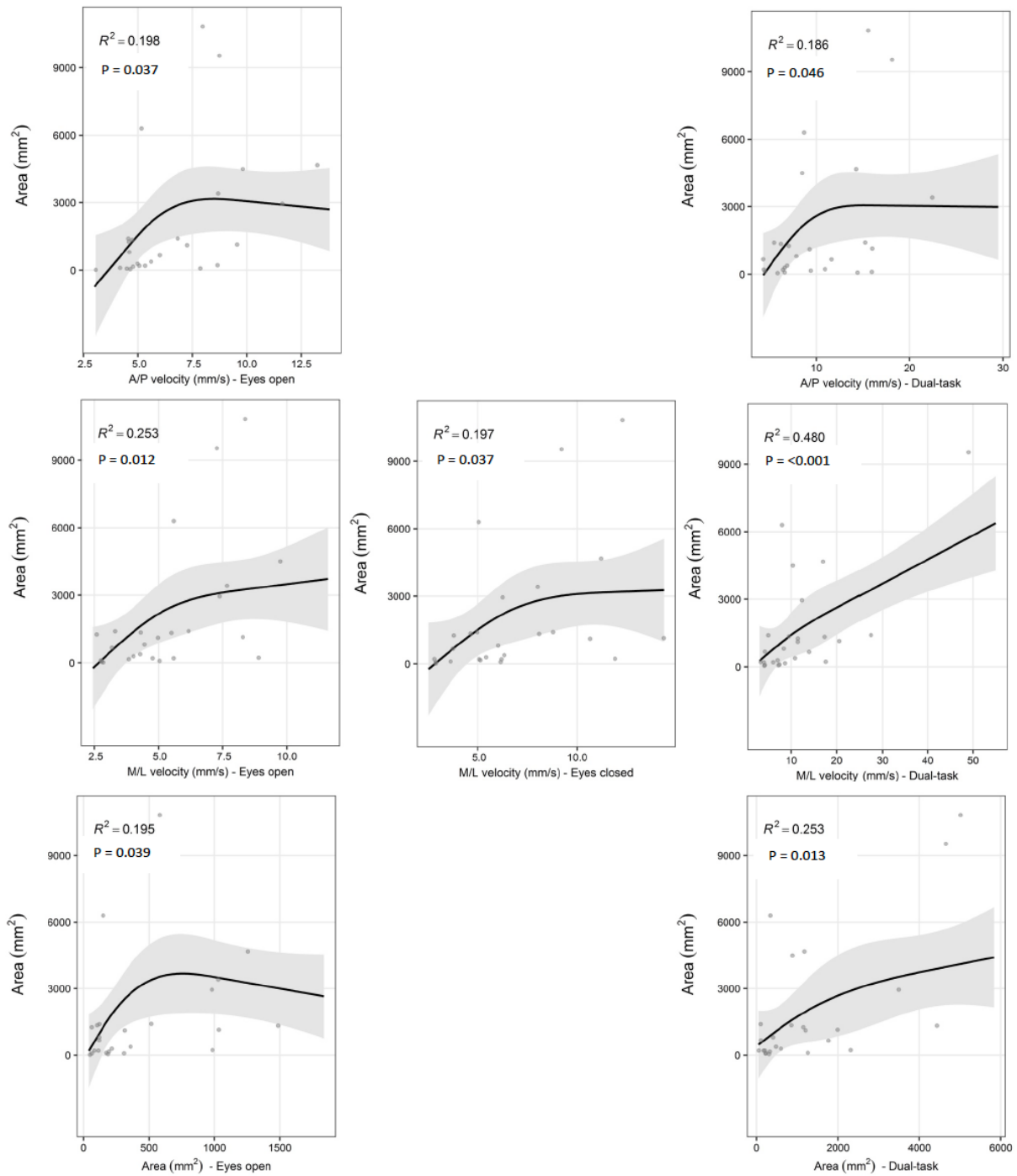


Figure 1. Plots of relationships between significant predictor variables and the outcome variable. The relationships are plotted over the 5th to 95th percentile of each predictor variable.

Secondary and third objectives

Significant predictors and interactions

Condition was identified as a significant predictor for the models of A/P entropy ($p < 0.001$), A/P velocity ($p < 0.001$), M/L velocity ($p < 0.001$) and the 95% ellipse area ($p < 0.001$). Group was identified as a significant predictor for the models of A/P entropy ($p < 0.001$), M/L velocity ($p = 0.02$) and the 95% ellipse area ($p = 0.005$). A condition X group interaction was identified as a significant predictor for the models of M/L velocity ($p = 0.011$) and the 95% ellipse area ($p = 0.034$). Testing session was identified as a significant predictor for the models of M/L entropy ($p < 0.001$) and the percentage of accuracy on the Stroop task ($p < 0.001$).

Secondary objective: Comparing performance between both sessions within each group

Effect sizes and p values for the contrasts comparing performance between the first and second sessions within the concussion and control groups are presented in Table 4. For M/L entropy, model contrasts showed that the control group demonstrated more predictable patterns of sway shown by significantly lower values while performing the eyes open condition during the second session compared to the first session ($p < 0.001$) (Figure 2B). For the percentage of accuracy on the Stroop task, model contrasts showed that both the concussion and control groups performed the task with a higher percentage of accuracy during the second session compared to the first session (control, $p = 0.002$; concussion, $p < 0.001$).

Table 4. p values and effect sizes for the model contrasts comparing performance between the first and second sessions within the concussion and control groups. Values in bold represent significant differences between the two sessions ($p < 0.008$ for COP variables; $p < 0.025$ for response accuracy).

		Concussion			Control		
		eyes open	eyes closed	dual-task	eyes open	eyes closed	dual-task
A/P velocity	p value	0.510	0.722	0.202	0.904	0.425	0.423
	Effect size	0.114	0.056	0.128	0.050	0.169	0.169
M/L velocity	p value	0.889	0.874	0.550	0.781	0.673	0.798
	Effect size	0.066	0.062	0.056	0.164	0.159	0.058
A/P entropy	p value	0.888	0.752	0.018	0.501	0.407	0.949
	Effect size	0.041	0.085	0.508	0.137	0.146	0.012
M/L entropy	p value	0.478	0.091	0.640	<0.001	0.010	0.425
	Effect size	0.155	0.461	0.114	0.639	0.502	0.184
95% ellipse	p value	0.251	0.582	0.318	0.647	0.287	0.970
	Effect size	0.211	0.093	0.106	0.245	0.420	0.013
Response accuracy	p value			<0.001			0.002
	Effect size			0.252			0.731

Third objective: Comparing performance between the two groups during each session

Effect sizes and p values for the contrasts comparing the concussion and control groups for each condition during both sessions are presented in Table 5. During the first session, model contrasts showed that the concussion group swayed over a significantly larger 95% ellipse area compared to the control group in the dual-task condition ($p = 0.004$) (Figure 2E). During the second session, model contrasts showed that the concussion group demonstrated more predictable patterns of sway in the anterior-posterior direction shown by significantly lower A/P entropy values compared to the control group for the eyes closed condition ($p = 0.002$) and the dual-task condition ($p < 0.001$) (Figure 2A). During the second session, model contrasts also showed that in comparison to the control group, the participants in the concussion group

performed the dual-task condition with significantly faster M/L velocity ($p=0.006$) (Figure 2D)

and larger 95% ellipse areas ($p<0.001$) (Figure 2E).

Table 5. p values and effect sizes for the model contrasts comparing the concussion and control groups during the first and second sessions. Values in bold represent significant differences between groups ($p<0.008$ for COP variables, $p<0.025$ for response accuracy).

		Session 1			Session 2		
		eyes open	eyes closed	dual-task	eyes open	eyes closed	dual-task
A/P velocity	p value	0.563	0.363	0.118	0.334	0.877	0.242
	Effect size	0.2	0.264	0.259	0.297	0.0374	0.248
M/L velocity	p value	0.998	0.759	0.014	0.739	0.881	0.006
	Effect size	0.00128	0.159	0.371	0.212	0.0664	2.18
A/P entropy	p value	0.042	0.028	0.035	0.109	0.002	<0.001
	Effect size	0.537	0.552	0.425	0.461	0.75	1.194
M/L entropy	p value	0.014	0.954	0.634	0.913	0.333	0.908
	Effect size	0.481	0.109	0.259	0.0156	0.0346	0.0324
95% ellipse	p value	0.395	0.025	0.004	0.148	0.303	<0.001
	Effect size	0.478	0.678	0.611	0.342	0.263	0.581
Response accuracy	p value			0.16			0.259
	Effect size			0.309			0.283

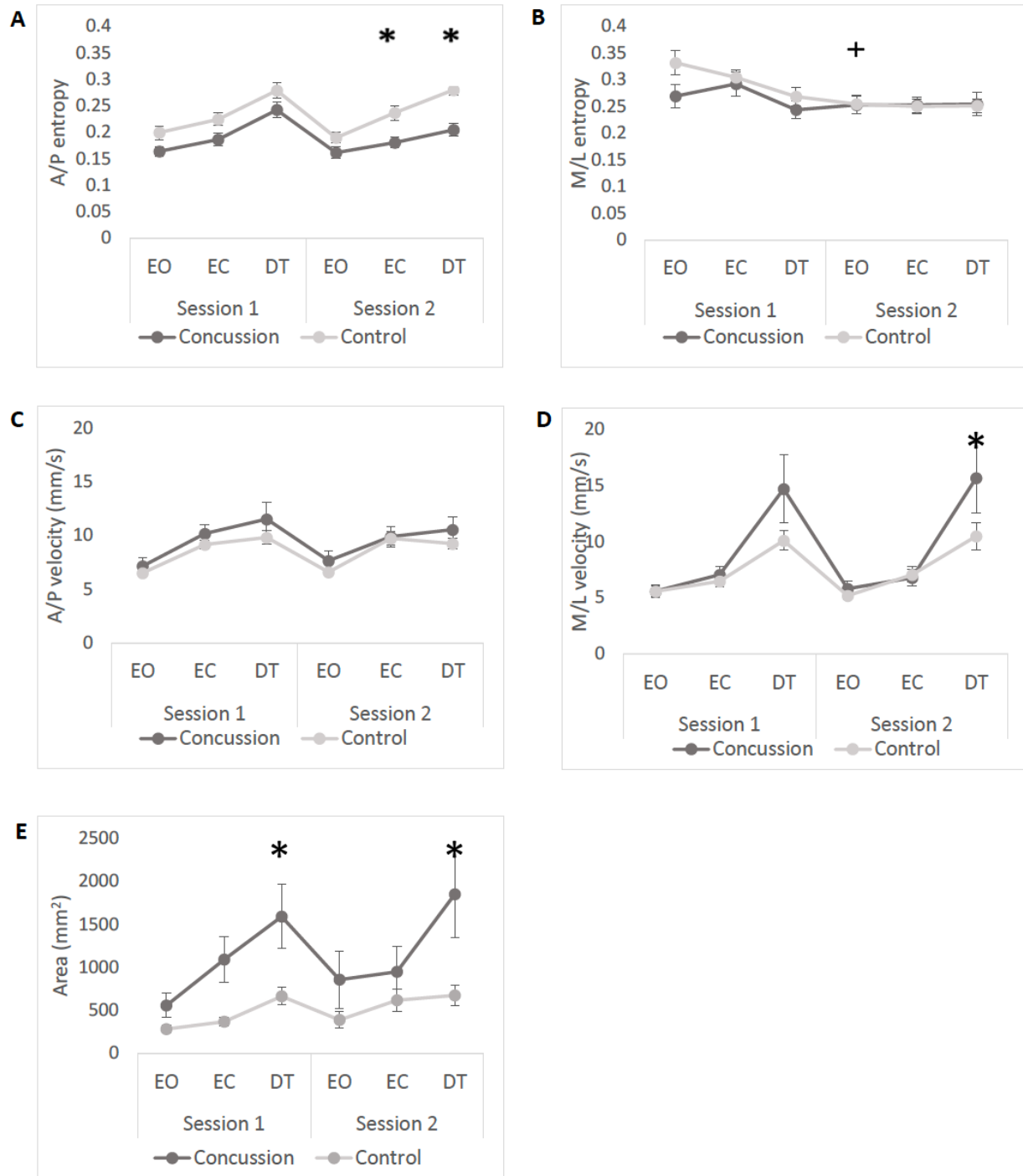


Figure 2. Data (mean $\pm$ standard error) regarding the three balance conditions during the first and second sessions for the control and concussion groups: (A) A/P entropy, (B) M/L entropy, (C) A/P velocity, (D) M/L velocity, and (E) 95% ellipse area. * indicates a significant group difference ($p < 0.008$). + indicates a significant difference ($p < 0.008$) between the first and second session within the control group.

4.5 Discussion

The primary purpose of this study was to examine the relationship between balance performance within the first 10-days following injury and at 1-month post-injury in a group of concussed adolescents. Seven COP balance variables measured within the first 10 days following injury were significant predictors for the 95% ellipse area measured during the dual-task at 1-month post-concussion. The M/L velocity measured during the dual-task was the most significant predictor. The secondary purpose was to compare balance performance between the two separate sessions within the concussed group and a group of non-injured adolescents and the third objective was to compare performance between the groups during each session. In terms of between session comparisons, there was only one significant difference for balance for which the control group performed the eyes open condition with more predictable patterns of M/L COP oscillations during the second session compared to the first session. In terms of between group comparisons, within the first 10 days post-concussion, the concussed participants swayed over larger 95% ellipse areas while performing the dual-task condition only. At 1-month post-concussion, the number of differences between groups increased with the concussed participants performing the dual-task condition with larger 95% ellipse areas, greater M/L velocity and more predictable A/P COP oscillations and also performing the eyes closed condition with more predictable A/P COP oscillations.

Predicting balance at 1-month post-concussion

The M/L velocity measured during the dual-task condition within the first 10 days post-concussion may be the best predictor for the 95% ellipse area measured during the dual-task at 1-month post-concussion due to the potential relationship between these two variables. In a previous study conducted by our group (Rocheffort et al., 2017), concussed and control

participants completed a similar balance protocol at 1-month post-concussion. The COP A/P and M/L velocity and the COP 95% ellipse area were calculated for each condition. Correlations between the COP variables within each balance condition were reported in the study and showed that the 95% ellipse area and the M/L velocity were highly correlated for the dual-task condition and less correlated for the eyes open and eyes closed conditions. The opposite was shown for A/P velocity which was highly correlated with the 95% ellipse area for the eyes open and eyes closed conditions and less correlated for the dual-task condition. This relationship may explain why in the current study the M/L velocity measured during the dual-task within the first 10 days following injury was the best predictor for the 95% ellipse area measured during the dual-task at 1-month post-concussion.

Comparison of performance between both sessions within each group

In terms of balance performance, only one significant difference between the two sessions was identified in the control group. The control participants performed the eyes open condition with more predictable patterns of M/L COP oscillations shown by significantly lower M/L entropy values during the second session compared to the first session. In contrast to the differences in balance performance between the sessions, both the concussion and control groups performed the Stroop task with significantly less errors during the second session compared to the first session. These results demonstrate that overall there is no learning effect in terms of balance performance associated with completing the current balance protocol on two separate occasions. These results are in line with previous studies that show that COP measures tend to remain relatively stable between trials in quiet stance conditions (Ruhe, Fejer & Walker, 2010). On the other hand, there may be a learning effect in terms of cognitive

performance associated with repeated administration of the Stroop colour-word test. These results are consistent with previous studies showing that with practice individuals can learn to respond faster and make less errors on a Stroop task (Dulaney & Rogers, 1994; McLeod, 1988; McLeod & Dunbar, 1988). Therefore, the COP measures used in this study may be used to monitor the recovery of balance in concussed individuals, while caution should be taken when using a similar Stroop task to monitor cognitive recovery.

Group differences in balance performance during each session – Comparison with the concussion literature

A similar balance protocol was used in a previous study conducted by our group (Rocheffort et al., 2017). In our earlier study, participants completed the protocol once with the concussed participants completing the protocol at approximately 1-month post-injury. In agreement with the 1-month results in the current study, participants with concussion swayed over a larger 95% ellipse area while performing the dual-task condition and also performed this condition with faster M/L sway velocity. Yet, in contrast to the current study, the concussed participants in the previous study also swayed over a larger 95% ellipse area while performing the eyes open and eyes closed conditions. Dorman and colleagues (2015) also conducted a similar study for which concussed and non-injured adolescents completed a balance protocol consisting of standing on two feet with their eyes open and closed and while completing a dual-task with eyes open and eyes closed. In agreement with the results from the current study, the results showed that within the first 10 days following injury and during the second session taking place at an average of 15 days following the first session, the concussed participants swayed over larger 95% ellipse areas while completing the two dual-task conditions. However,

in contrast to the results from the current study, during the first session in Dorman's study (2015) the concussed participants also swayed over larger 95% ellipse areas in the eyes open and eyes closed conditions and performed all four conditions with faster velocity.

The differences in the results reported in the three studies discussed above may be related to various factors. First, balance problems affect approximately 30% of individuals who experience a concussion (Murray, Salvatore & Powell, 2014). Therefore, different proportions of concussed participants may have been affected with a balance problem in these three studies leading to more significant group differences emerging in one study relative to the others. Second, while all three studies used similar COP variables including a 95% ellipse area and measures of velocity, the two studies conducted by our group measured the velocity in both the A/P and M/L directions, whereas Dorman's study computed a measure of velocity combining both A/P and M/L velocity into one resultant measure. In both studies conducted by our group, the concussion group swayed faster in the M/L direction while completing the dual-task at 1-month post-concussion, whereas Dorman's study did not identify a significant group difference for the velocity during the second session. However, Dorman's study did identify significant group differences for the velocity within the first 10 days following injury, whereas the current study did not. Therefore, in order to capture the full extent of balance impairments in concussed individuals, it may be necessary to measure velocity separately for both directions and with a measure that combines both directions together.

Shift in the characteristics of balance deficits

Unexpected differences were obtained in the results at 1-month post-injury in comparison to those obtained within the first 10 days following injury. During the first session

within 10 days post-injury, only one significant group difference was identified for which the concussion group swayed over a larger 95% ellipse area compared to the control group in the dual-task condition. On the other hand, during the second session at 1-month post-injury, four significant group differences were identified. The concussion group swayed over a larger 95% ellipse area in the dual-task condition in addition to performing this condition with faster M/L velocity and more predictable A/P COP oscillations. The concussion group also performed the eyes closed condition with more predictable A/P COP oscillations compared to the control group. It is important to note that given the small sample size, some caution should be taken when interpreting these results. A larger sample size may have been better powered to detect more significant group differences within the first 10 days post-injury. Nonetheless, more group differences with smaller p values and larger effect sizes were still identified at one-month post-injury compared to within the first 10 days. While several studies have shown that balance tends to recover and improve over time in a concussed population (Dorman et al., 2015; Powers Kalmar & Cinelli, 2014; Rhine, Quatman-Yates & Clark, 2015), two studies have shown that balance can in contrast regress over time (Howell, Osternig & Chou, 2015; Parker, Osternig, Van Donkelaar & Chou, 2006).

A study conducted by Parker and colleagues (2006) demonstrated that a group of concussed college students that returned to activity within 14 days following their injury performed dual-task walking with significantly greater center of mass M/L displacement compared to a control group on days 2, 5 and 28 post-injury, but not on day 14. In addition, a study conducted by Howell and colleagues (2015) demonstrated that adolescents post-concussion performed a dual-task walking condition with a significantly greater percentage of

change in center of mass M/L displacement compared to a control group following return to activity, whereas no significant group difference was identified prior to returning to activity. To explain their results, Howell and colleagues (2015) referenced studies that demonstrated that the current methods used to determine return to activity may not be sensitive enough to identify concussion-related changes that persist beyond symptom and clinical recovery (Prichet, McCrea, Barr, Powell & Chabot, 2013; Teel, Ray, Geronimo & Slobounov, 2014). They therefore suggested that concussed individuals may be returning to activity before they have completely recovered which could lead to a regression in balance. Although return to activity was not documented in the current study, the concussion group may have shown more significant group differences at 1-month post-injury compared to within the first 10 days following injury due to a premature return to activity.

Limitations

One limitation of this study was that due to the small sample size we did not examine the relationship between any of the predictor variables in terms of using a set of these variables to perform a multivariate analysis to predict balance performance at 1-month post-concussion. We also did not address the predictive ability of other non-balance variables, such as sex, age, and number previous concussions. Despite these limitations, this study was able to identify preliminary COP variables that could be used in a larger study designed to establish a model to predict persistent balance problems in concussed adolescents. A second limitation includes that the participants in the concussion group completed the first and second sessions at a varying number of days following their injury. Since a secondary objective of this study was to characterize balance performance in concussed adolescents at two different time points, it

would have been ideal to have all participants complete the two sessions on the same number of days post-injury. While this was not possible due to time constraints, the results from this study still provide some valuable insight regarding the concussed group's balance performance close to the time of injury and around 1-month post-injury.

Clinical implications

The results from this study identified COP balance variables that may be used in a future model designed to predict persistent balance problems in concussed adolescents. The results from this study also highlight that there may be a shift in the characteristics of balance deficits that occurs during the recovery period following a concussion. This was supported by the fact that within the first 10 days following injury the concussed participants performed similar to control participants for all balance conditions and variables with the exception of the 95% ellipse area measured during the dual-task condition. In contrast, at 1-month post-injury, the concussed participants performed significantly different than the control participants for the 95% ellipse area, the M/L velocity and the A/P entropy measured during the dual-task condition and the A/P entropy measured during the eyes closed condition. Therefore, the concussed participants showed balance deficits for certain COP variables and balance conditions at 1-month post-injury that were not present within the first 10 days following their injury. These results have important implications for the safe return to activity since an incomplete recovery of balance could lead to further injury. Stepwise return to sport protocols, such as the graduated return-to-sport strategy outlined in the 5th consensus statement on concussion in sport (McCrory et al., 2017), should consider adding that athletes complete an objective balance assessment prior to obtaining clearance to return to sports.

4.6 Conclusion

We identified seven COP variables measured within the first 10 days following injury that were significant predictors for the 95% ellipse area measured during a dual-task at 1-month post-injury in a group of concussed adolescents. Future studies should focus on using these variables to develop a prediction model for persistent balance problems in concussed adolescents. We also demonstrated that concussed adolescents showed more balance deficits at 1-month post-injury compared to within the first 10 days following their injury. More research is needed to better understand the mechanisms that are responsible for the shift in the characteristics of balance deficits that occurs during the recovery period following a concussion.

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Chapter 5: Balance Markers and Saccadic Eye Movement Parameters in Adolescents with Concussion

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Balance Markers and Saccadic Eye Movement Parameters in Adolescents with Concussion

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5.1 Abstract

Context: Deficits in balance and oculomotor function, including impairments of saccadic eye movements, are both observed in approximately 30% of cases post-concussion. While balance and saccadic eye movements are routinely assessed separately, there is growing evidence suggesting that they should be assessed concurrently.

Objective: To explore the relationship between balance and saccadic eye movements in adolescents with concussion.

Design: Case-control study.

Setting: Concussion clinic and two private schools.

Patients or Other Participants: Twenty-five adolescents (15 females, median age = 14; IQR = 11.5-16) between one and three months post-concussion (median number of days since injury = 39.5; IQR = 30 – 56.75) and thirty-five non-injured adolescents (16 females, median age = 13, IQR = 11.5-14).

Main Outcome Measure(s): Number of saccades and center of pressure (COP) 95% ellipse area and medial-lateral and anterior-posterior velocity in dual-task balance conditions including a high cognitive load (Cognitive condition), a low cognitive load and a gaze shifting component (Visual condition), or both a high cognitive load and a gaze shifting component (Combined condition).

Results: Participants with concussion swayed over larger COP ellipse areas in the Combined ($p=0.005$) and Visual ($p=0.015$) conditions, but not in the Cognitive condition. No significant group differences were identified for anterior-posterior and medial-lateral velocity.

Participants with concussion also did not perform more saccades than the control participants.

Conclusions: Performing dual-task balance conditions for which the secondary task involves a gaze shifting component or both a gaze shifting component and a high cognitive load result in greater sway amplitude in adolescents with concussion. However, these larger amounts of postural sway were not associated with increased saccadic eye movements.

5.2 Introduction

Concussions are a major health concern among children and adolescents. Children and adolescents report the highest incidence of concussion (Barlow et al., 2010) and may also experience more prolonged recoveries (McCrory et al., 2017). While several acute symptoms can follow a concussion, balance deficits and deficits in oculomotor function including problems performing saccades are two common impairments. Both the processes of maintaining balance and performing saccades are dependent on several of the same cortical structures and brainstem areas (Ouchi, Yoshikawa, Nobezawa & Futatsubashi, 1999; Tse et al., 2013). Yet despite this interrelationship, balance and saccades are routinely assessed separately following a concussion and no studies have explored the potential association between balance and saccadic eye movements in individuals with concussion.

Balance deficits affect approximately 30% of individuals who experience a concussion (Murray, Salvatore, Powell & Reed-Jones, 2014). Common clinical assessments, such as the Balance Error Scoring System (BESS), show a quick recovery of balance occurring within the first few days following injury (Guskiewicz, Ross & Marshall, 2001; Riemann & Guskiewicz, 2000), whereas assessments incorporating measures of the movement of the center of pressure (COP) show that these deficits can persist up to at least 1-month post-injury (Dorman et al., 2015; Rochefort et al., 2017; Walters-Stewart, Rochefort, Longtin, Zemek & Sveistrup, 2018). The COP can be measured while an individual holds a position (i.e., single-task condition) or while an individual holds a position while simultaneously performing a secondary task often in the form of a cognitive task (i.e., dual-task condition). Dual-task balance conditions have been found to be more sensitive in detecting post-concussion balance deficits showing more prolonged times

to recovery than single-task balance conditions (Dorman et al., 2015) and describing impairments not identified with single-task balance conditions (Rochefort et al., 2017).

Similar to balance deficits, approximately 30% of individuals with concussion report visual problems including impaired saccadic eye movements (Kontos et al., 2012). Studies have shown that compared to control participants, individuals post-concussion have a tendency to perform saccades with smaller amplitudes when instructed to shift their point of gaze towards a target that has changed position and to perform more corrective saccades with increased positional error (Cifu et al., 2015; Heitger, Anderson & Jones, 2002). Individuals with concussion have also been shown to perform more saccades than necessary when shifting their point of gaze from one target to the next (Ciuffreda, Han, Kapoor & Ficarra, 2006; Thiagarajan & Ciuffreda, 2014).

Previous studies have shown that performing saccades while completing a balance task leads to improvements in balance in healthy children relative to conditions during which children were instructed to fixate on a central target (Lions, Bui-Quoc & Bucci, 2013; Ajrezo, Wiener-Vacher & Bucci, 2013). In contrast, the effects of performing saccades on balance in children with concussion are unclear. In a previous study conducted by our group (Rochefort et al., 2017), healthy adolescents as well as adolescents 1-month post-concussion were asked to stand on a Nintendo Wii Balance Board that recorded the movement of the COP with their eyes open, with their eyes closed, and also while completing a cognitive task, i.e. dual-task balance condition. The cognitive task used in the dual-task involved a Stroop colour-word test for which the participants were required to name the colour of the ink of words printed in an incongruent ink colour, e.g. “red” printed in blue, displayed in rows on a board. While the results showed

that the participants with concussion swayed over larger COP ellipse areas while performing all three conditions, the participants with concussion only swayed faster in the lateral direction while performing the dual-task condition. The Stroop task involves shifting one's gaze from one word to the next and involves an increase in cognitive load, yet it is unclear if the participants with concussion completed the task with more lateral COP velocity due to the inability to shift their gaze with saccades, the increased cognitive load, or both.

The present study sought to determine the effects of saccadic eye movements and cognitive load on balance performance in adolescents with concussion. Balance performance and saccadic eye movement parameters were compared between adolescents with concussion and healthy non-injured adolescents while they completed three different dual-task balance conditions. Each dual-task included a secondary task that involved either a high cognitive load ("Cognitive" condition), a low cognitive load and a gaze shifting component ("Visual" condition), or both a high cognitive load and a gaze shifting component ("Combined" condition). It was hypothesized that compared to the control participants, the participants with concussion would perform more saccades, sway over larger COP ellipse areas and show greater lateral sway velocity while completing the Visual and Combined conditions. It was also hypothesized that the participants with concussion would sway over larger COP ellipse areas while completing the Cognitive condition, but that there would be no group differences in the number of saccades completed and in the amount of lateral sway velocity during the performance of this condition.

5.3 Methods

Participants

Two groups of participants were recruited to participate in this study. The concussion group consisted of adolescents between 11 and 16 years of age receiving care for post-concussion syndrome at a regional concussion clinic. Participants were diagnosed with post-concussion syndrome if they experienced one or more symptoms for a period of at least four weeks in one or more of the following clinical domains outlined in the 5th consensus statement on concussion in sport (McCrory et al., 2017):

- Symptoms: somatic (e.g., headache), cognitive (e.g., feeling like in a fog) and/or emotional symptoms (e.g., lability)
- Physical signs (e.g., loss of consciousness, amnesia, neurological deficit)
- Balance impairment (e.g., gait unsteadiness)
- Behavioural changes (e.g. irritability)
- Cognitive impairment (e.g., slowed reaction times)
- Sleep/wake disturbance (e.g., somnolence, drowsiness)

Participants were between one and three months post-concussion at the time of participation. The control group consisted of adolescents between the same ages who reported no concussive symptoms and had not suffered any head trauma within the past year. Control participants were recruited from two local private schools. To be included in the study, participants in both groups were required to be able to read text on a board or tablet placed at a distance of 60 cm in front of them without prescription glasses. Corrective contact lenses

were permitted. Prior to participating in the study, all participants and their parent provided written informed consent. This study was approved by the institution's research ethics board.

Experimental Protocol

Participants completed three different dual-task balance conditions while standing on a Nintendo Wii Balance Board that recorded the movement of the COP under their feet. While completing these conditions, participants were also fitted with a pair of Tobii Pro Glasses 2 (Tobii Pro, Stockholm, Sweden) that recorded their eye movements. For each of the three dual-task balance conditions, the secondary task consisted of a different version of a Stroop task designed to include primarily a cognitive component ("Cognitive" condition), primarily a gaze shifting component ("Visual" condition), or both cognitive and gaze shifting components ("Combined condition"). See Figure 1 for experimental set-up.

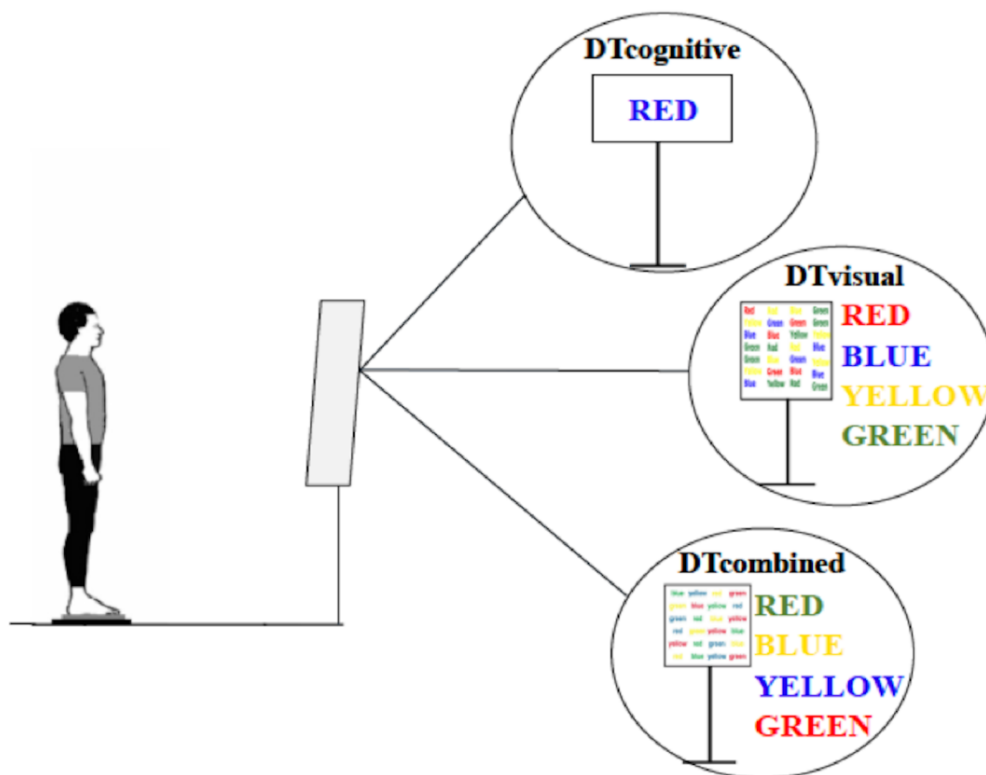


Figure 1. Experimental set-up.

For the Cognitive condition, a visual Stroop task was displayed on a tablet placed at eye level at a distance of 60 cm in front of the participant. One hundred words were presented one at a time in the center of the participant's visual field. The words consisted of the words "red", "yellow", "blue" and "green" presented in a random order and written in an incongruent ink colour, e.g. "red" printed in blue. Participants were instructed to name the colour of the ink when the word appeared on the tablet.

For the Visual condition, the Stroop task was displayed on a board placed at a distance of 60 cm in front of the participant. The board contained 20 rows of five words consisting of a random series of the words "red", "yellow", "blue" and "green" written in a congruent ink colour, e.g. "red" printed in red. Participants were instructed to read the words from left to right beginning with the first row.

For the Combined condition, the Stroop task was displayed on a board placed at a distance of 60 cm in front of the participant. The board contained 20 rows of five words consisting of a random series of the words "red", "yellow", "blue" and "green" written in an incongruent ink colour, e.g. "red" printed in blue. Participants were instructed to name the colour of the ink of each word from left to right beginning with the first row.

The board used for the Visual and Combined conditions was 40 cm wide which translates to a visual range of 23.5 degrees when placed 60 cm in front of the participant. For all three conditions, participants were stopped at 3 minutes regardless of whether the task was completed. For the Cognitive and Combined conditions, the number of correct responses was recorded to allow for the calculation of a percentage of accuracy obtained by dividing the number of correct responses by the number of total responses and multiplying by 100.

The Visual and Combined conditions included a gaze shifting component since the participants were required to shift their point of gaze from one word to the next. The Cognitive condition did not include a gaze shifting component since the words were presented in the center of the participant's visual field. In contrast to the Visual condition for which the participants were simply required to read the words displayed on the board, the Cognitive and Combined conditions included an increase in cognitive load since the participants were required to inhibit the meaning of the word while naming the colour of the ink.

Participants in the concussion group also completed the Post-Concussion Symptoms Inventory (PCSI) prior to completing the balance protocol (Sady, Vaughan & Gioia, 2014). The PCSI consists of a list of concussive symptoms for which participants are asked to rate their pre-injury and post-injury degree of symptoms. The 11 and 12 year old participants completed the version for children 8-12 years of age (17 symptoms, 3-point graded scale) and participants between 13 and 16 years of age completed the version for adolescents 13-18 years of age (20 symptoms, 7-point graded scale).

Material and data processing

Wii Balance Board

The Wii Balance Board raw pressure data were directly recorded on a laptop computer via a Bluetooth device. The raw pressure data were transformed to the COP in the lateral and anterior-posterior (A/P) directions using a custom Matlab (The Mathworks Inc.) script. The COP data were resampled to a frequency of 60Hz using a sliding window average with relevant interval interpolation (SWARII) (Audiffren & Contal, 2016). The velocity of the COP in the A/P

and medial-lateral (M/L) directions and a COP 95% ellipse area were calculated for each of the three dual-task balance conditions (Cognitive, Visual, Combined) for each participant.

Tobii Pro Glasses 2

The Tobii Pro Glasses 2 consist of a binocular eye tracking system. Eye movements were captured with the eye tracker at a frequency of 100 Hz. Data recorded with the eye tracker were imported in the Tobii Pro analysis software and the data were segmented into fixations and saccades using a velocity threshold identification classification algorithm. The number of saccades completed by each participant during each of the three balance conditions was identified. The number of saccades completed was expressed as the number of saccades completed divided by the number of words completed in the condition.

Statistical analysis

A sample size was calculated based on a two-tailed analysis with an alpha level set at 0.05 and power set at 80%. The sample size was calculated using data from a previous study measuring balance with COP measures in a concussed adolescent population (Rocheffort et al., 2017). A sample size of 22 participants in each group was identified to detect statistically significant group differences in COP measures.

For each COP dependent variable and for the number of saccades completed, separate 2-way (condition X group) repeated measures ANOVA were used to test for differences between conditions (within-subject factor) and groups (between-subjects factor). When a significant main effect was obtained for group, post hoc comparisons were performed using independent samples t tests to identify the conditions for which there was a significant difference between the concussion and control groups. For the independent samples t tests,

the threshold for significance was adjusted to 0.017 to adjust for multiple comparisons.

Independent samples t tests were also used to determine if there were significant differences between the percentages of accuracy on the Stroop task between the concussion and controls group for both the Cognitive and Combined conditions. All analyses were completed using IBM SPSS statistics version 25 (IBM Corp.).

5.4 Results

Twenty-five participants with concussion (median age =14, IQR=11.5-16, 15 females and 10 males) completed the protocol between 28 and 90 days post-injury (median=39.5, IQR=30 – 56.75). Thirty-five non-injured participants within the same age distribution (median age=13, IQR=11.5-14, 16 females and 19 males) completed the protocol once. Baseline characteristics for participants in the concussion and control groups are summarized in Table 1. The participants in the concussion group were significantly older than those in the control group ($p=0.03$). The participants in the concussion group also experienced a larger number of previous concussions compared to the control group ($p=0.001$). The incidence for specific post-concussion symptoms at the time the participants in the concussion group completed the protocol are summarized in Table 2.

Table 1. Baseline characteristics for participants in the concussion and control groups.

Characteristic	Concussion (n=25)	Control (n=35)	p value
Age, y, median (IQR)	14 (11.5-16)	13 (11.5 – 14)	0.03
11-13 (%)	9 (36)	22 (62.9)	
14-16 (%)	16 (64)	13 (37.1)	
Female (%)	15 (60)	16 (45.7)	0.3
Previous number of concussions (%)			0.001
0	10 (40)	30 (85.7)	
1	5 (20)	3 (8.6)	
2	7 (28)	2 (5.7)	
3	3 (12)	0 (0)	
Mechanism of injury (%)			
Sport/recreational play	13 (52)		
Soccer	5 (20)		
Football	2 (8)		
Cheerleading	1 (4)		
Ball hockey	1 (4)		
Gymnastics	1 (4)		
Hockey	1 (4)		
Horseback riding	1 (4)		
Rugby	1 (4)		
Nonsport-related injury/fall	10 (40)		
Motor vehicle collision	1 (4)		
Assault	1 (4)		

IQR, inter-quartile range

Table 2. Percentage of participants in the concussion group reporting specific symptoms at the time they completed the balance protocol.

Symptom	n (%)
Headache	22 (88)
Nausea	16 (64)
Balance problems	16 (64)
Dizziness	22 (88)
Fatigue	21 (84)
Drowsiness	17 (68)
Sensitivity to light	22 (88)
Sensitivity to noise	18 (72)
Irritability	17 (68)
Sadness	15 (60)
Nervousness	9 (36)
Feeling slowed down	17 (68)
Difficulty concentrating	21 (84)
Difficulty remembering	17 (68)
Visual problems	12 (48)

A significant main effect of condition was obtained for M/L velocity ($F=12.1$, $p<0.001$), the 95% ellipse area ($F=7.25$, $p=0.001$) and the number of saccades completed ($F=25.03$, $p<0.001$). No significant main effect of condition was obtained for A/P velocity ($F=1.39$, $p=0.3$). A significant main effect of group was identified for the 95% ellipse area ($F=12.5$, $p=0.001$). Post hoc comparisons showed that the participants in the concussion group swayed over a larger ellipse area compared to the control group for the Visual ($p=0.015$) and Combined ($p=0.005$) conditions, but not for the Cognitive condition ($p=0.07$) (Figure 2A). No significant main effect

of group was obtained for A/P velocity ($F=2.57$, $p=0.1$) (Figure 2B), M/L velocity ($F=0.157$, $p=0.7$) (Figure 2C) and the number of saccades completed ($F=2.04$, $p=0.2$) (Table 3). No significant group difference was obtained for the percentages of accuracy on the Stroop task for both the Cognitive ($p=0.07$) and Combined ($p=0.4$) conditions (Table 3).

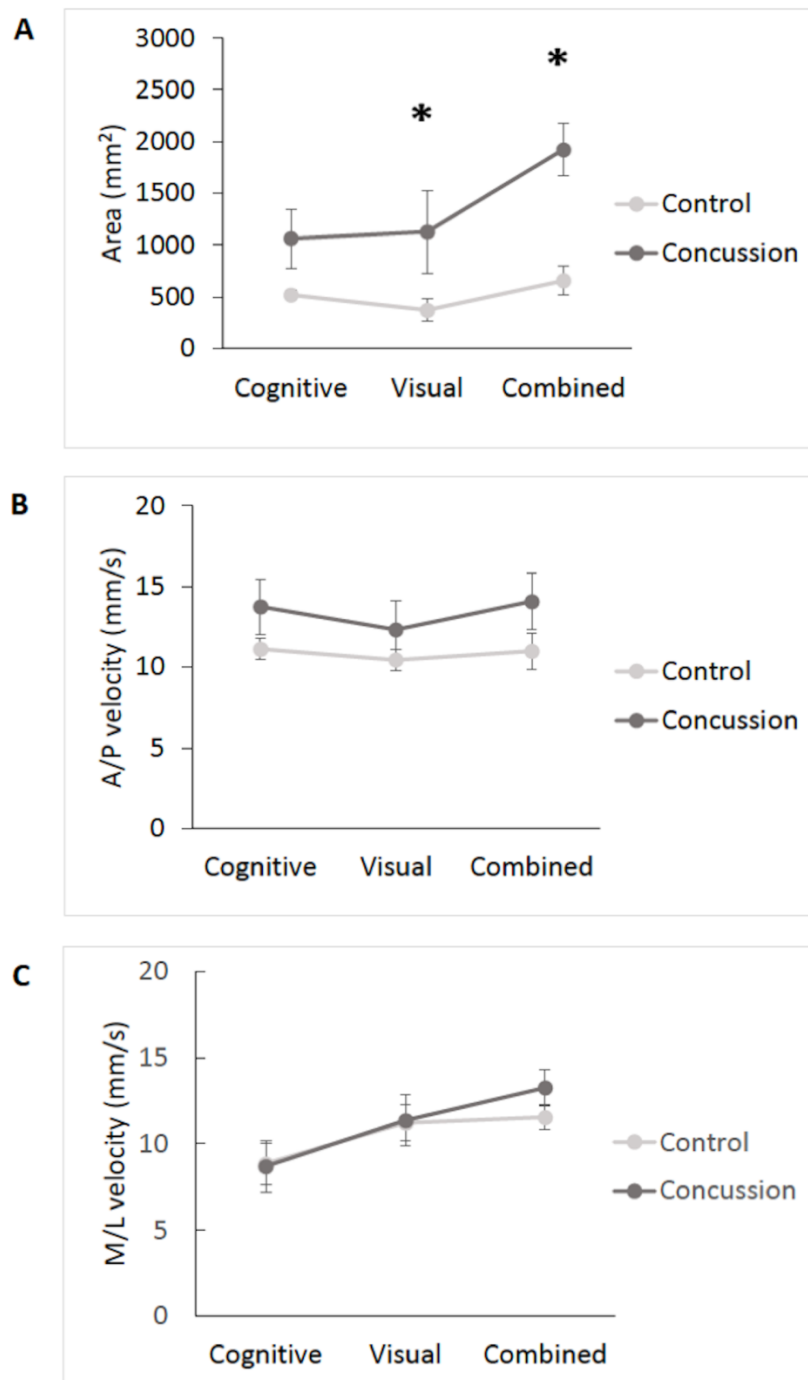


Figure 2. COP data ($\pm$ mean standard error) for the three dual-task conditions for the control and concussion groups: (A) 95% ellipse, (B) anterior-posterior velocity, (C) medial-lateral velocity. Significant differences ($P<0.017$) between groups are identified with an asterisk.

Table 3. Number of saccades completed for each balance condition and the percentage of accuracy for the Stroop task in the Cognitive and Combined conditions. Data are presented as means (standard deviation).

	Control			Concussion		
	Cognitive	Visual	Combined	Cognitive	Visual	Combined
Number of saccades	2.25 (2.36)	2.53 (1.45)	4.77 (3.8)	1.83 (1.07)	2.15 (0.674)	3.52 (1.45)
% of accuracy	96.2 (3.68)		96.3 (2.84)	98 (1.73)		97.2 (3.39)

5.5 Discussion

The purpose of this study was to compare balance measures and saccades between adolescents one to three months post-concussion and healthy non-injured adolescents while they completed three different dual-task balance conditions involving primarily a cognitive component, primarily a gaze shifting component or both cognitive and gaze shifting components. In agreement with our initial hypothesis, the participants with concussion swayed over a larger COP ellipse area compared to the control participants while performing the Visual and Combined condition. However, in contrast to our hypothesis, the participants with concussion did not sway over a larger COP ellipse area while performing the Cognitive condition. The participants with concussion also did not perform the Visual and Combined conditions with greater COP M/L velocity and did not perform more saccades while completing these conditions. These results demonstrate that the Visual and Combined conditions elicited greater amounts of sway in the group with concussion, but these larger amounts of sway are not associated with an increase in saccades.

Previous studies have shown that individuals with concussion perform more saccades than necessary when completing an eye tracking task (Ciuffreda, Han & Kapoor, 2006;

Thiagarajan & Ciuffreda, 2014). In these studies, participants with concussion were asked to complete a simulated reading task for which they were required to complete saccades to track a dot that moved from left to right on a screen. Although participants were instructed to complete a single saccade to shift their point of gaze towards the dot's new position, the results showed that participants completed an excessive number of saccades to accomplish this task. In the current study, participants with concussion did not complete more saccades than the control participants while completing any of the dual-task balance conditions even though the Visual and Combined conditions required that the participants shift their point of gaze from one word to the next. These diverging results may be related to the presentation of the eye movement task. In the current study, the words were separated by an even distance, whereas in the simulated reading task used in the previous studies (Ciuffreda, Han & Kapoor, 2006; Thiagarajan & Ciuffreda, 2014), the dot moved across the screen and the distance between the dot's displacements varied. As a result, it is possible that the participants with concussion in the current study quickly learned to adjust the amplitude of their saccades given that the distance remained consistent and that all of the words were visible at the start of the trial. In addition, in the previous studies (Ciuffreda, Han & Kapoor, 2006; Thiagarajan & Ciuffreda, 2014), the participant's head was fixed while they completed the simulated reading tasks, whereas in the current study participants were free to move their head while performing the Visual and Combined conditions. Therefore, the participants with concussion in the current study may have compensated with head rotation to shift their point of gaze from one word to the next as opposed to relying on saccades to accomplish the task.

The participants with concussion did not complete more saccades or sway faster in the M/L direction compared to the control participants while performing the dual-task balance conditions; yet, they swayed over larger COP ellipse areas while performing the Visual and Combined conditions. In addition, although the participants with concussion did not sway over larger COP ellipse areas while completing the cognitive condition, they showed a trend towards larger ellipse areas in this condition. A larger sample size might have been better powered to detect a group difference for this variable and condition. Altogether, these results demonstrate that completing a secondary task that involved a gaze shifting component and a minimal cognitive load affected the concussed participants' balance to a greater extent than completing a secondary task that did not require the participants to shift their point of gaze but included a much higher cognitive load.

According to the capacity-sharing model of dual-task, the concurrent performance of a cognitive and motor task is dependent on a general attentional resource pool that allows simultaneous performance of both tasks (Fraizer & Mitra, 2008). In situations during which the attentional demands of performing both tasks concurrently exceed the attentional resource pool, decrements in the performance of one or both tasks are observed (Lacour, Bernard-Demanze & Dumitrescu, 2008). Previous studies have identified changes in dynamic balance in individuals with concussion while they simultaneously performed a gait and a cognitive task, and it has been suggested that these changes are due to a decrease in attentional resources (Catena, Van Donkelaar & Chou, 2007a; Catena, Van Donkelaar, Chou, 2007b). Yet, the results from the current study challenge this hypothesis since the Cognitive condition used in this study should have engaged more attentional resources relative to the Visual condition.

The Stroop task in the Visual and Combined conditions may have interfered with the concussed participants' balance to a greater extent due to the possible head rotation involved in the task. The board used to display the Stroop task in these conditions included a visual range of 23.5 degrees which falls outside of the five degrees of central vision that individuals use to focus on words while reading (Rayner, 2009). Thus, participants were required to shift their point of gaze from one word to the next either by executing saccades and/or rotating their head. Though these differences are not statistically significant, on average the participants with concussion executed less saccades compared to the control participants in all three dual-task conditions. This suggests that when given the option, concussed participants may choose to compensate with head rotation in order to avoid executing saccades. In addition, since the vestibular system is sensitive to rotational accelerations of the head (Purves et al., 2011), the potential head rotation involved in the Visual and Combined tasks would have increased the amount of vestibular information to be processed and integrated by the central nervous system. It has been suggested that balance deficits following a concussion are due to the inability to efficiently organize and integrate sensory information (Murray, Salvatore, Powell & Reed-Jones, 2014). Therefore, the possible head rotation involved in the Visual and Combined conditions may have increased the amount of vestibular information to be processed leading to less efficient balance control in the participants with concussion. Furthermore, the larger group difference observed in the Combined condition relative to the Visual condition may reflect the combined effects of an increase in vestibular feedback and cognitive load.

A limitation of this study is that the concussed and control participants were not matched based on age, sex and other co-variates such as the number of previous concussions

and baseline levels of physical activity. The concussed and control participants were recruited simultaneously and therefore it was not possible to match the participants based on these characteristics. A second limitation of this study may be that not all participants with concussion had a prolonged balance impairment following their concussion. Thus, potential group differences in the COP velocity variables could have been washed out due to this limitation. Despite these limitations, the results from this study highlight important information regarding dual-task balance testing for concussion.

To our knowledge, this study is one of a few studies to have measured both balance and saccades simultaneously in a concussed population. The finding that no differences were identified in the number of saccades completed between the concussed and control groups, may be explained by the concussed participants possible preference in using head rotation as opposed to eye movements to shift their point of gaze. These results have important implications for the safe practice of sports as well as participation in everyday activities since sports and other common activities often require the simultaneous integration of balance, saccades, head rotation and cognitive abilities.

5.6 Conclusion

Performing dual-task balance conditions for which the secondary task involves a gaze shifting component (i.e., Visual condition) or both a gaze shifting component and a high cognitive load (i.e., Combined condition) result in greater sway amplitude in adolescents with concussion relative to healthy non-injured adolescents. However, these larger amounts of postural sway observed in the adolescents with concussion were not associated with increased

saccadic eye movements. Future studies should focus on discerning the effects of executing saccades from the effects of head rotation on balance performance in a concussed population.

5.7 References

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Chapter 6: General Discussion

6.1 Summary of the main findings

This thesis extends current knowledge regarding the assessment and recovery of balance following a concussion in adolescents. The first study compared balance performance between adolescents at one-month post-concussion and non-injured adolescents on scores from the BESS and COP measures from single and dual-task balance conditions. In study 2, a secondary analysis of the data in Study 1 was conducted to compare COP balance measures between adolescents at one-month post-concussion who self-reported balance problems, adolescents at one-month post-concussion who self-reported no balance problems and non-injured adolescents. The primary objective of the third study was to determine the ability of a set of COP variables collected within the first 10 days following a concussion to predict balance performance on a dual-task in adolescents at one-month post-concussion. A secondary objective of this study was to compare COP measures between the group of concussed adolescents and a group of non-injured adolescents within the first 10 days following injury and at one-month post-injury and to compare performance between sessions within each group. The objective of the fourth study was to explore the relationship between balance and saccadic eye movements in adolescents with concussion. The results associated with each of these objectives have been discussed in detail in the four manuscripts presented in this thesis. Therefore, the goal of this discussion is to summarise the main findings of each manuscript and to integrate these findings to discuss the results across the four manuscripts.

Comparison of BESS scores and COP measures from single and dual-task conditions between adolescents at one-month post-concussion and non-injured adolescents (Study 1)

The results from this study indicated that the adolescents at one-month post-concussion and the non-injured adolescents performed the BESS with similar amounts of errors. In contrast, there were several significant group differences for the COP variables from the single and dual-task conditions. The concussed adolescents swayed over larger 95% ellipse areas and swayed faster in the medial-lateral direction while performing the dual-task condition in comparison to the control group. The concussed adolescents also swayed over larger 95% ellipse areas while performing the eyes open and eyes closed single-task conditions. These results demonstrate that COP measures from single and dual-task conditions can identify balance deficits not identified with the BESS in adolescents at one-month post-concussion. The BESS may fail to identify balance deficits in concussed individuals due to the possible lack of sensitivity. Different factors have been identified to affect the sensitivity of the BESS including learning (Broglia, Zhu, Sapienza & Park, 2009; Mulligan, Boland & McIlhenny, 2013) practice (Valovich, Perrin & Gansseder, 2003) and fatigue effects (Wilkins, McLeod, Perrin & Gansseder, 2004).

No previous studies have used both the BESS and COP measures from single and dual-task conditions to characterize balance in a concussed population. However, the results from this study are in line with previous studies showing a quick recovery of balance on the BESS (Guskiewicz, Ross & Marshall, 2001; Guskiewicz, 2011; McCrea et al., 2003; McCrea et al., 2005) and a more prolonged recovery with COP measures from single (Powers, Kalmar, & Cinelli, 2014; Thompson, Sebastianelli & Slobounov, 2005) and dual-task conditions (Dorman et al.,

2015). In addition, a study conducted by Quatman-Yates and colleagues (2015) demonstrated that adolescents at an average of 48 days post-concussion showed significant differences compared to a group of non-injured adolescents in COP measures recorded during two single-task conditions, but that no significant group differences were identified for performance on the BESS.

Comparisons of COP measures amongst concussed adolescents self-reporting balance problems, concussed adolescents self-reporting no balance problems and non-injured adolescents (Study 2)

In this study, several significant differences were identified for the COP variables from the single and dual-task conditions between the control group and the group of adolescents self-reporting balance problems (Balance+) and the group of adolescents self-reporting no balance problems (Balance-). Both the Balance+ and Balance- group swayed over a larger 95% ellipse area compared to the control group while performing the eyes closed and dual-task conditions and performed the dual-task condition with faster medial-lateral velocity. The participants in the Balance- group also swayed over a larger 95% ellipse area compared to the control group while performing the eyes open condition. In contrast, no significant group differences were identified between both groups of concussed adolescents. These results indicate that the concussed adolescents showed balance deficits compared to the control group regardless of whether they self-reported balance problems. Studies have shown that concussed individuals can at times underreport concussive symptoms (Lovell & Solomon, 2013; Meier, Brummel, Singh, Nerio, Polanski & Bellgowan, 2015; Van Kampen, Lovell, Pardini, Collins & Freddie, 2006). These results emphasize the risk of relying on self-reported symptoms to make

decisions regarding return to activity and highlight the importance of incorporating objective measures in a concussion assessment.

Few studies have investigated the association between self-reported balance problems and performance on objective measures of balance in a concussed population. A study by Broglio, Sosnoff & Ferrara (2009) showed that 46% of concussed participants in their study reported balance-related symptoms, whereas only 19% showed post-injury declines on their scores from the Sensory Organization Test compared to their pre-injury scores. In contrast, the results from the current study demonstrate that concussed adolescents showed balance deficits compared to the control group regardless of whether they self-reported balance problems. The differences between these two studies may be due to the measures used. The current study recorded COP measures with a Wii Balance Board, whereas Broglio, Sosnoff & Ferrara used the SOT. Performance on the SOT is determined with equilibrium scores, which are based on A/P movement of the COP only. Therefore, measuring the COP in both the A/P and M/L directions may be necessary in order to capture the full extent of balance deficits associated with concussions.

A study by Rhine, Byczkowski, Clark and Babcock (2015) indicated that self-reported balance problems may not be associated with balance performance on COP measures. In their study, they showed that self-reported balance symptoms were not related to balance performance on COP measures in concussed adolescents. However, based on their results, it was not clear if the adolescents reporting balance problems were not identified as having a balance problem on the COP measures or if the adolescents identified as having a balance problem on the COP measures were not reporting balance problems. Therefore, the results

from the current study add clarity to this question by demonstrating that adolescents with concussion showed balance deficits regardless of whether they self-reported balance problems.

Predictive ability of a set of COP variables collected within the first 10 days post-concussion to predict balance performance at one-month post-concussion in adolescents (Study 3 – Primary objective)

Seven COP variables measured within the first 10 days following injury were significant predictors for the 95% ellipse area measured during a dual-task at one-month post-concussion in the group of adolescents. These variables could be used to establish a model to predict persistent balance performance in concussed adolescents. This could eventually provide a method to identify adolescents who are at risk of developing persistent balance problems at the time of injury in order to provide them with the appropriate interventions as soon as possible.

The medial-lateral velocity measured during the dual-task was the most significant predictor. This may be due to the relationship between the medial-lateral velocity and the 95% ellipse. In study 1, correlations between each of the three dependent variables (A/P velocity, M/L velocity and 95% ellipse area) were reported for each condition (eyes open, eyes closed and dual-task). These showed that the 95% ellipse area and the medial-lateral velocity were highly correlated for the dual-task condition and less correlated for the eyes open and eyes closed conditions. This relationship may explain why in the current study the medial-lateral velocity measured during the dual-task within the first 10 days post-injury was the most significant predictor for the 95% ellipse measured during the dual-task at one-month post-concussion.

Comparing balance performance between the concussed and control groups within the first 10 days following injury and at one-month post-injury as well as comparing performance across sessions within each group (Study 3 - Secondary objectives)

For COP measures, only one significant between session difference was identified within the control group. The participants performed the eyes open condition with more predictable patterns of M/L COP oscillations during the second session compared to the first session. In contrast, for the cognitive measures, both the concussed and control groups performed the Stroop task with less errors during the second session compared to the first session. These results indicate that the majority of COP measures remain consistent across sessions, but that learning effects may be associated with repeated administration of the Stroop task. In terms of comparing performance between groups during each session, several significant group differences were identified. During the first session that took place within the first 10 days following injury, the concussed group swayed over larger 95% ellipse areas while performing the dual-task condition. During the second session at one-month post-concussion, the concussed group performed the dual-task condition with larger 95% ellipse areas, greater M/L velocity and more predictable patterns of A/P COP oscillations. During the second session, the concussed group also performed the eyes closed condition with more predictable patterns of A/P COP oscillations. These results suggest that the concussed group demonstrated balance deficits at one-month post-concussion that were not present within the first 10 days post-injury.

The shift in the presentation of balance deficits between the two sessions in the group of concussed adolescents are in line with previous studies that have identified changes in

balance deficits that occur over time in a concussed population. Both Parker and colleagues (2006) and Howell and colleagues (2015) identified balance deficits in a group of concussed athletes that were not present closer to the time of injury. Therefore, there may be factors associated with a shift in the way that balance deficits present themselves in individuals who have experienced a concussion. Howell and colleagues (2015) suggested that concussed individuals may be returning to activity before they have fully recovered and that this may interfere with the recovery of balance.

The relationship between balance and saccadic eye movements in adolescents with concussion (Study 4)

Concussed adolescents and a group of non-injured adolescents performed three different dual-task conditions involving either a high cognitive load (Cognitive condition), a low cognitive load and a gaze shifting component (Visual condition) or a high cognitive load and a gaze shifting component (Combined condition). No significant differences were identified between the concussed and non-injured adolescents for the number of saccades completed, A/P and M/L velocity while performing all three of the dual-task conditions. However, the concussed adolescents did sway over larger 95% ellipse areas compared to the control group while performing the Visual and Combined conditions, but not the Cognitive condition. These results demonstrate that performing a dual-task condition with a low cognitive load and a gaze shifting component and a dual-task with a high cognitive load and a gaze shifting component result in greater sway amplitudes in concussed adolescents, but that these larger amounts of sway are not associated with increased saccadic eye movements.

These results differ from previous studies that have shown that concussed individuals perform more saccades than necessary when shifting their gaze from one target to the next (Ciuffreda, Han, Kapoor & Ficarra, 2006; Thiagarajan & Cieffreda, 2014). In these studies participants performed a simulated reading task for which they were instructed to track a dot that moved from left to right across a screen and the distance between the dot's displacements varied. In contrast, in the current study, participants could see all of the words displayed on the board at the beginning of the trial and the distance between the words did not vary. Therefore, the participants may have quickly learned to adjust the amplitude of their saccades. In addition, in the current study participants were free to move their head, whereas in the other studies, the participant's head was fixed. As a result, the participants in the current study may have compensated with head rotation to track the words on the board.

The COP results from this study challenge previous work that hypothesized that alterations in dynamic balance identified in concussed individuals as they performed a gait dual-task were due to decreased attentional resources (Catena, Van Donkelaar & Chou, 2006; Catena, Van Donkelaar & Chou, 2007; Yogev-Seligmann, Hausdorff & Giladi, 2008). The Cognitive condition used in this study should have engaged more attentional resources than the Visual condition, yet the concussed participants swayed over larger 95% ellipse areas in the Visual and Combined conditions only. The potential head rotation involved in the Visual and Combined conditions may have led to less efficient balance control in the concussed participants due to the increase in the amount of vestibular feedback to be processed and integrated by the postural control system. Thus, in a concussed population, head rotation may interfere with the control of balance to a greater extent than an increase in cognitive load.

6.2 Integration of findings

Comparing balance variables and conditions across studies

Similar balance conditions were used in all four studies and similar COP variables were extracted from the COP time series. These COP variables were compared across conditions and groups. In studies 1 and 2, concussed and non-injured adolescents completed two-minute trials of quiet standing with their feet shoulder width apart with their eyes open and closed. Participants also completed a dual-task consisting of standing shoulder width apart while simultaneously completing a Stroop Colour-word test. In study 3, concussed and non-injured participants completed the same quiet standing and dual-task conditions; the only difference being that the participants completed two sessions with the concussed group completing the first session within the first 10 days following their injury and the second session at approximately one-month post-injury. In study 4, concussed and non-injured adolescents completed three different dual-task conditions for which one condition, the Combined condition, was the same as the dual-task used in studies 1, 2 and 3. The table below outlines the results obtained for these conditions in the four studies. “Yes” indicates a significant group difference and “No” indicates that there was no significant group difference.

	Study 1	Study 2	Study 3 session 1	Study 3 Session 2	Study 4
A/P velocity – Eyes open	No	No	No	No	Did not complete
M/L velocity – Eyes open	No	No	No	No	Did not complete
95% ellipse – Eyes open	Yes	Yes for Balance- compared to Control group	No	No	Did not complete
A/P velocity – Eyes closed	No	No	No	No	Did not complete
M/L velocity – Eyes closed	No	No	No	No	Did not complete
95% ellipse – Eyes closed	Yes	Yes for Balance+ and Balance- compared to Control group	No	No	Did not complete
A/P velocity – Dual-task	No	No	No	No	No
M/L velocity – Dual-task	Yes	Yes for Balance+ and Balance- compared to Control group	No	Yes	No
95% ellipse – Dual-task	Yes	Yes for Balance+ and Balance- compared to Control group	Yes	Yes	Yes

Although similar COP variables and balance conditions were used in the four studies, as can be observed in the table above, the results are inconsistent across studies. The only variable and condition that remains significantly different between groups across all four studies is the 95% ellipse measured during the dual-task condition. In contrast, the 95% ellipse measured during the eyes open condition was significantly different between the control and

concussed group in study 1 and between the control and Balance- group in study 2, whereas no significant group difference was identified for this variable and condition during both sessions in study 3. Similarly, the 95% ellipse measured during the eyes closed condition was also significantly different between the control and concussed group in study 1 and between both concussed groups (Balance+ and Balance-) and the control group in study 2, whereas no significant group differences were identified for this variable and condition in study 3. Finally, the medial-lateral velocity measured during the dual-task was significantly different between the control and concussed groups in study 1, between both concussed groups (Balance+ and Balance-) and the control group in study 2 and between the concussed and control group in study 3 during the second session only. In contrast, no significant group difference was shown for this variable and condition during the first session in study 3 and in study 4.

The discrepancies in the results obtained in the four studies may be related to various factors. First, balance problems affect approximately 30% of individuals who experience a concussion (Murray, Salvatore, Powell & Reed-Jones, 2014). Therefore, it is possible that a greater proportion of adolescents were affected with a balance problem in one study relative to the others. In fact, 36% of concussed participants in study 1 fell two standard deviations above the control group's mean for the M/L velocity measured during the dual-task condition, compared to only 13% during the first session and 17% during the second session in study 3 and 8% in study 4. This could explain why more significant group differences were obtained for the same variables and conditions in studies 1 and 2 in comparison to studies 3 and 4. These differences could also be related to the amount of time post-injury at which the concussed participants completed the protocol in these studies. The concussed participants completed the

protocol at one-month post-injury in studies 1 and 2, within the first 10 days following injury and at one-month post-injury in study 3, and between one and three months post-injury in study 4. Therefore, in study 4, the concussed participants' balance may have recovered to a greater extent by the time they completed the protocol. This may explain why the concussed participants performed the dual-task condition with greater COP medial-lateral velocity at one-month post-injury in studies 1, 2 and 3, but not in study 4.

While some of the results from the four studies differ for the same variables and conditions, it is apparent that the dual-task condition consistently identifies balance deficits in the concussed group across the four studies. More specifically, the 95% ellipse measured during the dual-task remains significantly different between the concussed and control groups in all four studies. In addition, though not significant in every study, the medial-lateral velocity measured during the dual-task was also significantly different between groups in studies 1 and 2, and during session 2 in study 3. The dual-task condition is the only condition for which significant group differences were identified for this variable. It is clear from these results that dual-tasks may be better at identifying balance deficits associated with concussions. Concussed adolescents may have no issues maintaining their balance alone, whereas balance deficits may emerge when asked to maintain their balance while simultaneously completing a cognitive task. These results have important implications for the assessment of balance following a concussion since balance is generally evaluated alone and sports as well as every day activities require the simultaneous integration of balance and cognitive abilities.

6.3 Future research directions

While this thesis extends the current knowledge about balance deficits in concussed adolescents, there are many opportunities to extend the scope of this research. Outlined below

are a few research questions that will further our understanding of balance deficits in individuals with concussion.

Better understanding of the mechanisms that lead to balance deficits following a concussion

Studies 1 and 2 provide clarity regarding the sensitivity of different methods to identify balance deficits in concussed adolescents including the BESS, self-reported balance problems and COP measures from single and dual-task conditions. While these studies provide important information for the assessment of balance following a concussion, it was beyond the scope of this thesis to identify the mechanisms that lead to these deficits. In order to develop interventions for concussed individuals who are affected with balance deficits, it is essential that future studies focus on uncovering the mechanisms that lead to these deficits. In addition, the results from study 3 demonstrated that there may be a change in the way that balance deficits present themselves in concussed adolescents. More specifically, there were balance deficits identified at one-month post-injury that were not present within the first 10 days following injury. Previous studies have suggested that a premature return to activity could be responsible for these shifts in balance deficits. Future studies should focus on better understanding the effects that returning to activity has on the recovery of balance in a concussed population.

Developing a prediction model for persistent balance deficits

In study 3, seven COP variables were shown to significantly predict balance performance on a dual-task at one-month post-injury in a group of concussed adolescents. While it was essential to first identify which COP variables and balance conditions measured close to the time of injury are associated with balance performance at one-month post-concussion, future

studies should use these variables to develop a prediction model for persistent balance deficits in a concussed population. This will provide clinicians with a tool to flag concussed individuals who are at risk of developing persistent balance problems at the time of injury.

Deciphering the effects of head rotation from saccades on balance in a concussion population

In study 4, the concussed group performed two of the three dual-task conditions with larger 95% ellipse areas despite completing a similar number of saccades as the control participants. These results were unexpected since previous studies have shown that concussed individuals have a tendency of performing an excessive number of saccades when completing an eye tracking task. However, it was noted that the concussed participants in study 4 may have compensated with head rotation to shift their point of gaze as opposed to only relying on saccades. Therefore, although the increased COP displacements identified in this study were not associated with increased saccades, future studies should focus on designing an eye tracking task that prevents head rotation to further understand the effects of performing saccades on balance in a concussed population.

6.4 Conclusion

This thesis fills gaps in the literature regarding the sensitivity of balance assessments for concussion, the association between balance performance close to the time of injury and at one-month post-injury in concussed adolescents, and the association between balance performance and saccadic eye movements in concussed adolescents.

Studies 1 and 2 provide important information regarding balance assessments for concussion. Study 1 demonstrated that COP measures recorded from single and dual-task balance conditions identify balance deficits in concussed adolescents that are not identified

with the BESS. Study 2 demonstrated that concussed adolescents demonstrate balance deficits while performing single and dual-task balance conditions regardless of whether they self-report balance problems. As a result, clinicians should consider using more objective measures of balance in a concussion assessment. Study 3 identified seven COP variables that were significant predictors for balance performance on a dual-task condition at one-month post-injury in a group of concussed adolescents. These results provide the groundwork to develop a prediction model for persistent balance deficits associated with concussions. Study 3 also demonstrated that there may be a shift in the characteristics of balance deficits that takes place between the first 10 days following injury and one-month post-injury. These results highlight the importance of assessing balance prior to clearing concussed individuals to return to activity. Finally, study 4 demonstrated that performing a dual-task condition with a gaze shifting component and either a high or low cognitive load resulted in greater sway amplitude in concussed adolescents compared to non-injured adolescents, whereas performing a dual-task with a high cognitive load and no gaze shifting component did not. While the conditions with a gaze shifting component resulted in greater amounts of sway in the concussed adolescents, these were not associated with increased saccadic eye movements.

Addendum

The following tables were added to the thesis following the oral defense in response to comments from the examining committee. The tables outline the effect sizes for the comparisons between groups and the minimum sample size required to obtain a significant difference for each study.

Table 1. Effect size and minimum sample size required to obtain a significant difference for each comparison between the concussion and control group in study 1.

	EO		EC		DT	
	Effect size	Sample (n)	Effect size	Sample (n)	Effect size	Sample (n)
A/P velocity	0.42	99	0.56	52	0.49	58
M/L velocity	0.52	62	0.58	46	0.71	Significant
95% ellipse	0.7	Significant	0.83	Significant	0.79	Significant

Table 2. Effect size and minimum sample size required to obtain a significant difference for each comparison between the three groups (Control, Balance+ and Balance-) in study 2. Equal means indicates that the means between groups are equal and that no minimum sample size could be calculated.

		EO		EC		DT	
		Effect size	Sample (n)	Effect size	Sample (n)	Effect size	Sample (n)
A/P velocity	Control vs. Balance+	0.38	118	0.5	61	0.61	40
	Control vs. Balance-	0.35	140	0.59	50	0.44	67
	Balance+ vs. Balance-	0.094	Equal means	0.098	Equal means	0.016	Equal means
M/L velocity	Control vs. Balance+	0.5	64	0.52	53	0.84	Significant
	Control vs. Balance-	0.45	81	0.65	40	0.75	Significant
	Balance+ vs. Balance-	0.079	Equal means	0.12	Equal means	0.37	109
95% ellipse	Control vs. Balance+	0.63	31	0.83	Significant	0.91	Significant
	Control vs. Balance-	0.72	Significant	0.84	Significant	0.79	Significant
	Balance+ vs. Balance-	0.058	Equal means	0.32	155	0.21	391

Table 3. Effect size and minimum sample size required to obtain a significant difference for each comparison between the concussion and control group during the first session in study 3. Equal means indicates that the means between groups are equal and that no minimum sample size could be calculated.

	EO		EC		DT	
	Effect size	Sample (n)	Effect size	Sample (n)	Effect size	Sample (n)
A/P velocity	0.2	449	0.264	284	0.259	266
M/L velocity	0.00128	Equal means	0.159	826	0.371	121
A/P entropy	0.537	71	0.552	69	0.425	118
M/L entropy	0.481	91	0.109	Equal means	0.259	Equal means
95% ellipse	0.478	74	0.678	33	0.611	Significant

Table 4. Effect size and minimum sample size required to obtain a significant difference for each comparison between the concussion and control group during the second session in study 3. Equal means indicates that the means between groups are equal and that no minimum sample size could be calculated.

	EO		EC		DT	
	Effect size	Sample (n)	Effect size	Sample (n)	Effect size	Sample (n)
A/P velocity	0.297	197	0.0374	Equal means	0.248	304
M/L velocity	0.212	Equal means	0.0664	Equal means	2.18	Significant
A/P entropy	0.461	100	0.75	Significant	1.194	Significant
M/L entropy	0.0156	Equal means	0.0346	Equal means	0.0324	Equal means
95% ellipse	0.342	142	0.263	273	0.581	Significant

Table 5. Effect size and minimum sample size required to obtain a significant difference for each comparison between the concussion and control group in study 4. Equal means indicates that the means between groups are equal and that no minimum sample size could be calculated.

	Dtcognitive		Dtvisual		Dtcombined	
	Effect size	Sample (n)	Effect size	Sample (n)	Effect size	Sample (n)
A/P velocity	0.34	148	0.28	191	0.44	77
M/L velocity	0.034	Equal means	0.02	Equal means	0.25	274
95% ellipse	0.5	101	0.73	Significant	0.86	Significant

General references for introduction and discussion

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Annexed Information

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Appendix A – Rochefort, C., Cournoyer, J., Post, A., Hoshizaki, T.B., Zemek, R. & Sveistrup, H. (2017). Brain Tissue Strain and Balance Impairments in Children Following a Concussion: An exploratory study. *Submitted to the Journal of Concussion*.

Appendix B – Consent forms (English only)

Appendix C – Ethics approval certificates

APPENDIX A

Title: Brain Tissue Strain and Balance Impairments in Children Following a Concussion: An exploratory study

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Abstract

Background: Balance impairments present in approximately 30% of concussion cases. Biomechanical reconstructions model the degree and location of brain tissue strain associated with injury. The objective was to examine the relationship between the magnitude and location of brain tissue strain and balance impairment following a concussion.

Methods: Children 1-month post-concussion (n=33) and non-injured children (n=33) completed two balance conditions while standing on a Wii Balance Board that recorded the center of pressure during: i) double-leg stance with eyes closed (EC), ii) dual-task (DT) combining double-leg stance while completing a cognitive task. Injury reconstructions were performed for ten of the concussed participants. A 5th percentile Hybrid III headform was used to obtain linear and rotational acceleration time-curves of the head impact. These data were input in the University College Dublin Brain Trauma Model (UCDBTM) to calculate maximum principal strains (MPS) and cumulative strain damage values at 10% (CSDM-10) and 20% (CSDM-20) for different brain regions. Correlations between balance and reconstruction variables were calculated.

Results: For MPS values, correlations with balance variables ranged from -0.0190 to 0.265 for the DT condition and from -0.225 and 0.152 for the EC condition. For CSDM-10 values, correlations with balance variables ranged from 0.280 to 0.386 for the DT condition and from -0.103 to 0.252 for the EC condition. For CSDM-20 values, correlations with balance variables ranged from 0.0629 to 0.289 for the DT condition and from -0.353 to -0.155 for the EC condition.

Conclusions: No association was established between the presence of balance impairment and the magnitude and/or location of brain tissue strain. Maintaining balance is a complex process integrated into multiple subcortical regions, white matter tracts and cranial nerves, which were not represented in the brain model and as a result the UCDBTM may not be sensitive to damage in these areas.

Key words: Concussion, Center of Pressure, Biomechanics, Injury Reconstruction, Postural Balance, Youth

Introduction

Concussions are a growing public health concern among children. Youth report the highest incidence of concussion¹ and while most concussed children recover within a couple of weeks, 30% of cases experience symptoms that can last up to months or years post-injury². Balance impairment may affect approximately 30% of individuals who experience a concussion³ and have been shown to persist up to at least 1-month post-injury in adolescents^{4,5}. While balance deficits may occur as the result of a concussive impact, the relationship between how an individual is impacted, the resulting brain tissue deformation, and these signs of brain impairment is unknown.

Balance is defined as the ability to maintain one's center of mass within the base of support⁶. The process of maintaining balance is very complex and is dependent on specific structures within the brain, multiple subcortical regions, white matter tracts, cranial nerves and other neural tissue; all these structures may be vulnerable to impairment following an impact to the head. The process of maintaining balance is also inherently unstable. The body continuously produces small deviations from a perfect upright standing position⁷. In order to correct for these postural deviations, the brainstem integrates sensory information to obtain a sense of the body's position and orientation in space⁸ and the cerebellum coordinates the motor outputs that are required to reposition the body within the base of support⁹.

Biomechanically, concussion is often the result of a head impact that causes injurious strains to the brain tissues. The severity of the impact and the magnitude of strain incurred by the brain tissues are influenced by mechanical characteristics such as impact surface, the velocity at which the impact occurred, impact location and angle^{10,11}. These characteristics have been shown to influence the head's dynamic response following the impact in terms of linear and rotational accelerations and the resulting strain on the brain tissues^{12,13}. Changes in the dynamics of the

impact have also been shown to affect the amount of strain in different regions of the brain¹⁴, a phenomenon that may be pertinent to the presence of balance impairments from a concussion. Specific structures within the brain, namely the brainstem and the cerebellum, are involved in the process of maintaining balance, and the relationship between impact, strain on the tissues in these regions, and outcome measures for concussion is unknown.

The purpose of this exploratory study was to examine the relationship between the magnitude and location of brain tissue strain and resulting balance performance following a concussion. Biomechanical reconstructions of head injuries were performed in a group of concussed children for which a subset was affected with balance impairments to model the degree and location of brain tissue strain. It was hypothesized that the children affected with balance impairments would show greater values of tissue strain in the brainstem and cerebellum compared to the children with normal balance.

Methods

Participants

Concussion group

Participants with acute concussion (less than 48 hours) were recruited from the emergency department (ED) as part of a large, prospective multicentre study¹⁵. As part of the larger study, participants were diagnosed with a concussion by a physician based on the criteria from the Zurich consensus statement¹⁶. Thirty-three children between 9 and 17 years of age (mean age= 14.2 ± 1.5 , 12 males and 21 females) with a diagnosed concussion also completed a balance testing protocol as part of an *a priori*-planned substudy⁵. Only participants whose concussion resulted from a direct blow to the head were included in this reconstruction study.

Control group

Thirty-three non-injured children between the same ages (mean age = 15.0 ± 1.5 , 9 males and 24 females) also completed the balance testing protocol as part of the previous study⁵. These participants reported no concussive symptoms and had not suffered any head trauma within the last year. In the context of the current study, the control group data was used to establish a threshold for normal balance to determine if the concussed participants had normal or impaired balance.

Balance testing

Protocol

Prior to participating in this study, all participants and their parent provided written informed consent. This study was approved by the institution's ethics research board. Participants with concussion completed the balance testing protocol at approximately 1-month post-injury (mean number of days = 32 ± 3). Participants in the control group completed the protocol once.

Comprehensive methods are provided in a previously published paper⁵. Participants completed three different balance conditions while standing on a Nintendo Wii Balance Board (WBB) that recorded the movement of the center of pressure (COP) under their feet. Participants completed two-minute trials while standing on the WBB with their feet shoulder width apart with eyes open and then with eyes closed. Participants also completed a dual-task condition consisting of standing shoulder width apart on the WBB while simultaneously completing a Stroop-Colour word test. The Stroop-Colour word test was presented on a board placed in front of the participant and displayed 20 rows of 5 words consisting of a random series of the words "red",

“blue”, “yellow” and “green” written in an incongruent ink colour. Participants were asked to name the colour of the ink that each word was printed in.

Material and data processing for WBB data

The WBB raw pressure data were recorded to a laptop computer via a Bluetooth device at a sampling frequency of 30Hz. A custom Matlab (The Mathworks Inc., Natick, MA, USA) script was used to transform raw pressure data to COP values in the anterior/posterior and lateral directions. The COP data were filtered using a second order low-pass Butterworth filter with a cut-off frequency of 12Hz. The COP 95% ellipse was calculated for both the eyes closed and dual-task conditions for each participant.

Balance status concussion group

Participants with concussion were identified as having either impaired or normal balance on both the eyes closed and dual-task conditions. For both conditions, participants were identified as having impaired balance if they showed a value of at least 2 standard deviations above the control group’s mean for the 95% ellipse. For both conditions, participants were identified as having normal balance if they showed a value within 2 standard deviations from the control group’s mean for the 95% ellipse.

Injury reconstruction

Impact characteristics

A detailed description of the events surrounding each participant’s head injury was obtained during their visit to the ED through use of a standardized mechanism of injury report form^{17,15} and during a telephone follow-up. Nine of the ten cases included in this study were falls. The following information was needed to proceed with laboratory reconstructions to ensure the most accurate representation of the injury: height of the subject, falling height, age, gender,

impacting surface, the impact location on the head and the body part that made the first contact with the ground and general description of the event and the environment where the event occurred. The impact location was quantified by using the grid shown in **Figure 1**.

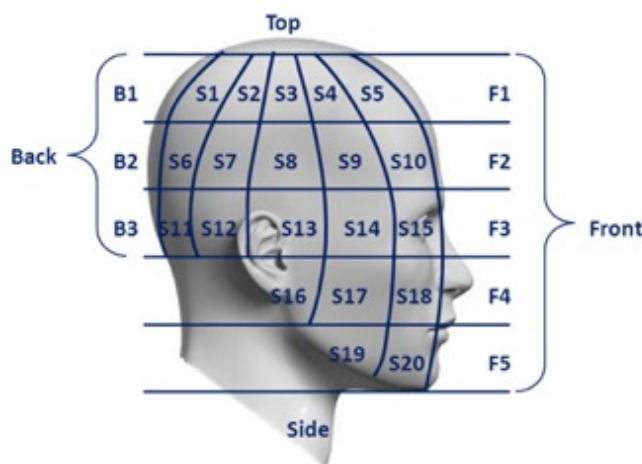


Figure 1. Grid used to quantify the impact location.

To determine falling head contact velocity, the information recorded was used as input for a Mathematical Dynamic Models (MADYMO) simulation¹⁸. To conduct this analysis a simulation was conducted using anthropometric ellipsoid dummy models that were closely matched to the dimensions of the subject. This dummy was placed in the virtual environment that closely matched that of the witness reports and was allowed to fall in a way similar to that of the subject. The simulation would then allow the ellipsoid dummy to fall with the kinematics and restrictions of a human fall, and produce a measurable output upon contact with the impact surface. In the case of this research the head impact velocity was the output. For the one collision case, additional details surrounding the event were necessary such as: the sport being played (in this case soccer); if the subject and striking player were immobile, jogging, or running at the time

of the event; and what body part made contact with the head. In this case, the impact velocity was determined using the literature describing running speed for a teenage soccer player¹⁹. These methods have been used for brain injury reconstruction for pediatric and adult cases and were found to be in close agreement with anatomical and animal research^{20,17}.

Reconstruction procedure

The laboratory reconstruction of the brain injury event used computational, physical and finite element models. For the falls, once the impact velocity was determined from MADYMO the Hybrid III headform was attached to the monorail drop rig and dropped from a height to attain the appropriate speed on impact. The headform was positioned to impact the same location reported on the standardized mechanism of injury report form. The impacted surface (anvil) was also of the same composition as the surface that the head impacted during the event. For the collisions, a pendulum impactor was used to simulate the event by impacting the headform at the impact location described in the standardized mechanism of injury report form. Three impacts were conducted for each injury case. From these impacts (falls and the collision) the linear and rotational acceleration times histories were recorded, and then used for analysis of strain in the brain tissues using the University College Dublin Brain Trauma Model (UCDBTM)²¹.

Equipment

Monorail

The monorail is a 4.7 m long vertical single rail to which a drop carriage was affixed via ball bushings. The headform was attached to the drop carriage by an unbiased neckform. The drop carriage was released by a pneumatic piston after which the drop carriage with the head and neckform attached would slide down and impact the anvil at the base. The anvil at the base of the monorail was comprised of concrete with a steel top with bolt holes to allow different surfaces to

be fixed to it. The impact velocity was measured within 0.02 m of the impact via a photoelectric timegate.

Pendulum

The pendulum was a 4 wire cylinder that was suspended from the ceiling. This pendulum was drawn back using a winch attached to a distal wall and released via an electromagnet. Upon release it would travel until it impacted the headform that was fixed on an impact table. This table allowed for the placement of the headform in 6 degrees of freedom so that the appropriate impact location could be contacted for the reconstruction. The mass of the impactor was 9.6 kg and determined from literature describing the effective mass of impact²². The impact velocity was determined 0.02 m prior to impact by Photron High Speed Camera (HSI Inc.).

Headform, neckform, and data acquisition

A Hybrid III 5th headform was used to conduct the physical reconstructions as this size headform closely matched the head size of the population. The headform was outfitted with a 3-2-2-2 accelerometer array for the measurement of linear and rotational acceleration in 6 degrees of freedom²³. The accelerometers used were nine Endevco 7264C-2KTZ-2-300 sensors (Irvine, CA, USA). The unbiased neckform was a series of alternating symmetrical aluminum and rubber butyl discs with the same dimensions as a Hybrid III neckform, but without the biased response that the Hybrid III would provide upon impact²⁴. The data was collected at 20 kHz, with a CFC 180 filter using DTS TDAS software (Seal Beach, CA, USA).

Finite element model

To determine the maximum principal strain values for the reconstructions of the concussion cases the University College Dublin Brain Trauma Model (UCDBTM) was used. This finite element model had geometry that was determined from medical imaging of the head

of a male cadaver that included: scalp, skull, pia, falx, tentorium, cerebrospinal fluid (CSF), grey and white matter, cerebellum, and the brainstem¹². In total, the UCDBTM includes approximately 26,000 hexahedral elements. The simulations were conducted using ABAQUS explicit software (Dassault Systèmes, MA, USA).

The material properties of the model²¹ were developed from tissue sample and anatomical testing. The tissues of the brain were modelled using a linearly viscoelastic model combined with large deformation theory. The brain tissue behaviour was characterized as viscoelastic in shear with a deviatoric stress rate dependent on the shear relaxation modulus²¹. The compression of the brain tissue was defined as elastic. The shear characteristic of the viscoelastic brain was expressed:

$$(1) \quad G(t) = G_{\infty} + (G_0 - G_{\infty})e^{-\beta t}$$

with G_{∞} representing the long term shear modulus, G_0 the short term modulus and β the decay factor. The brain skull interaction was defined as sliding with no separation between the pia and the CSF, with the CSF modelled with a bulk modulus of water with a low shear modulus²¹. The sliding interface had a coefficient of friction of 0.2²⁵.

Validation of the model was accomplished by comparing the UCDBTM's responses to cadaveric research^{26,27}. Further brain injury comparisons were conducted and achieved good agreement with the magnitudes of strain and stress in the literature for the target injury types^{18,20,28}.

There are newer and more complex finite element models than the UCDBTM that have been developed and have been used for brain injury research^{29,30,31}. While not as complex as these models, the UCDBTM has been used to process the largest dataset of brain injured, and non-injured cases, and may provide a better reference than these other models with which to interpret the magnitudes of response for the current research^{32,11,33,17,20}.

Scaling of the UCDBTM

Currently there is no agreed scientific consensus as to the proper representation of brain tissue for a youth population for a finite element model of the head and brain, with many researchers suggesting the material characteristics being within those of adults^{34,35,36}. As a result, the UCDBTM was scaled to represent the youth head geometry for this research, with the size matched to the anthropometrics of the population that was part of this research. This scaling reduced the size of the UCDBTM to 95% of the original size, which was based on MRI brain size data for this population³⁷. The fit of the model was concentrated on the anterior-posterior and inferior superior axes (within one standard deviation)¹⁷.

Biomechanical dependent variables

The biomechanical variables used to determine damage to the brain tissues were maximum principal strain (MPS) and cumulative strain damage measure (CSDM; 10% and 20%). The MPS was used as it has been identified through research to be correlated to the mechanisms of concussive injury^{38,12}. The CSDM is a measure that can be used to determine the amount of elements of the model that has incurred strain above a certain amount, in this case 10% and 20% strain^{39,29}. The 10% strain is commonly used in biomechanical analyses of impact induced injury and has been found to have some predictive capacity in terms of concussive and non-concussive events^{29,40}. The CSDM set to 20% is a measure that examines how much of the brain tissues passes 20% strain, which has been identified as the amount of deformation that may be associated with structural changes to the grey and white matter³⁸.

Statistical analysis

Correlations were calculated between the reconstruction variables including MPS, CSDM_{10%} and CSDM_{20%} values for each brain region and the 95% ellipse measured during both the eyes closed and dual-task conditions.

Results

Head injury reconstructions were completed for ten concussed participants that completed the balance testing protocol (mean age=12.8± 1.2, 6 males and 4 females) between 28 and 40 days post-injury (mean number of days = 31.9 ± 1.98). Participant demographics and their corresponding injury characteristics are summarized in **Table 1**. Out of the ten participants for which reconstructions were completed, six were identified as having impaired balance on the eyes closed condition and six were identified as having impaired balance on the dual-task condition.

Table 1. Participant characteristics for injury reconstructions

Case no.	Age	Gender	Mechanism of injury	Type of surface/object	Balance status Eyes closed	Balance status Dual-task
1	15	female	Fall	Grass	Impaired	Impaired
2	13	male	Fall	Concrete	Impaired	Normal
3	13	female	Fall	Ice with helmet	Normal	Normal
4	14	female	Fall	Concrete	Impaired	Normal
5	12	female	Fall	Steel	Normal	Impaired
6	12	male	Fall	Branch	Normal	Impaired
7	9	male	Fall	Sand	Impaired	Impaired
8	16	male	Collision	Shoulder	Normal	Normal
9	13	male	Fall	Ice with helmet	Impaired	Impaired
10	11	male	Fall	Ice with helmet	Impaired	Impaired

Mean MPS, CSDM_{10%} and CSDM_{20%} values for each brain region are presented in **Table**

2. Correlations between the 95% ellipse measured during the eyes closed condition and the MPS, CSDM_{10%} and CSDM_{20%} values are presented in **Table 3**. Correlations between the 95% ellipse measured during the dual-task condition and the MPS, CSDM_{10%} and CSDM_{20%} values are also presented in **Table 3**.

Table 2. MPS, CSDM_{10%}, and CSDM_{20%} values for different brain regions. Data are presented as means + standard deviations.

Brain region	MPS	CSDM-10	CSDM-20
Frontal lobe	0.351 ± 0.213	39.9 ± 29.3	6.72 ± 8.15
Temporal lobe	0.400 ± 0.159	47.1 ± 28.6	8.72 ± 8.81
Occipital lobe	0.299 ± 0.180	46.6 ± 35.7	7.57 ± 12.7
Parietal lobe	0.271 ± 0.177	37.8 ± 31.9	3.88 ± 6.90
Brainstem	0.796 ± 0.403		
Cerebellum	0.497 ± 0.252		

Table 3. Correlations between 95% ellipse measured during the eyes closed condition and MPS, CSDM_{10%}, and CSDM_{20%} values for different brain regions (left side) and correlations between 95% ellipse measured during the dual-task condition and MPS, CSDM_{10%}, and CSDM_{20%} values for different brain regions (right side).

Brain region	Eyes closed condition			Dual-task condition		
	MPS	CSDM-10	CSDM-20	MPS	CSDM-10	CSDM-20
Frontal lobe	-0.171	0.124	-0.289	0.174	0.321	0.163
Temporal lobe	0.152	0.252	-0.155	0.265	0.386	0.0911
Occipital lobe	-0.143	0.0572	-0.248	0.131	0.280	0.0629
Parietal lobe	-0.192	-0.103	-0.353	0.158	0.314	0.289
Brainstem	-0.225			-0.0190		
Cerebellum	-0.181			0.0476		

Correlations between the 95% ellipse measured during the eyes closed condition were weak for both the brainstem and cerebellum (**Figure 2A**) and for all other brain regions (**Figure 3**).

Correlations between the 95% ellipse measured during the dual-task condition and the MPS

values were also weak for both the brainstem and the cerebellum (**Figure 2B**) as well as for all other brain regions (**Figure 3**). These correlations demonstrate a lack of relationship between the amount of postural sway and the magnitude of the reconstruction variables.

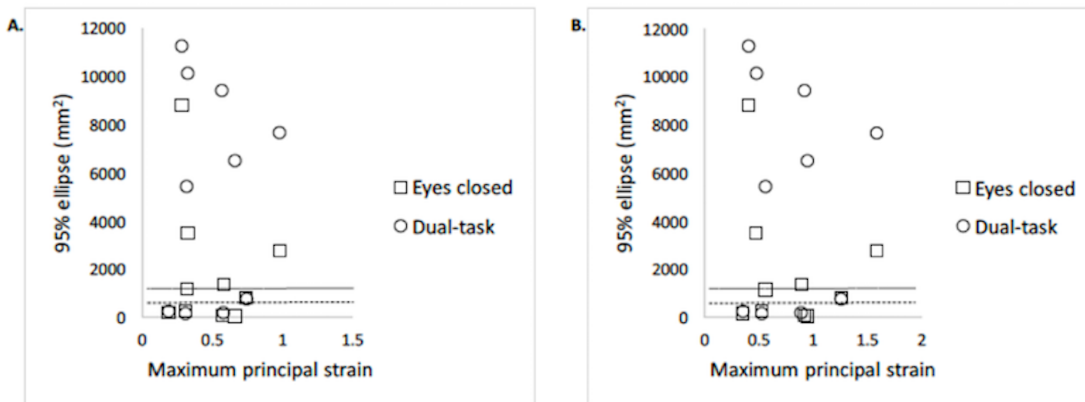


Figure 2. Association between maximum principal strain values and the 95% ellipse measured during the eyes closed (A) and dual-task (B) condition are shown for each participant. Dashed line represents threshold for normal balance. Normal balance is defined as 2 standard deviations within the control group's mean.

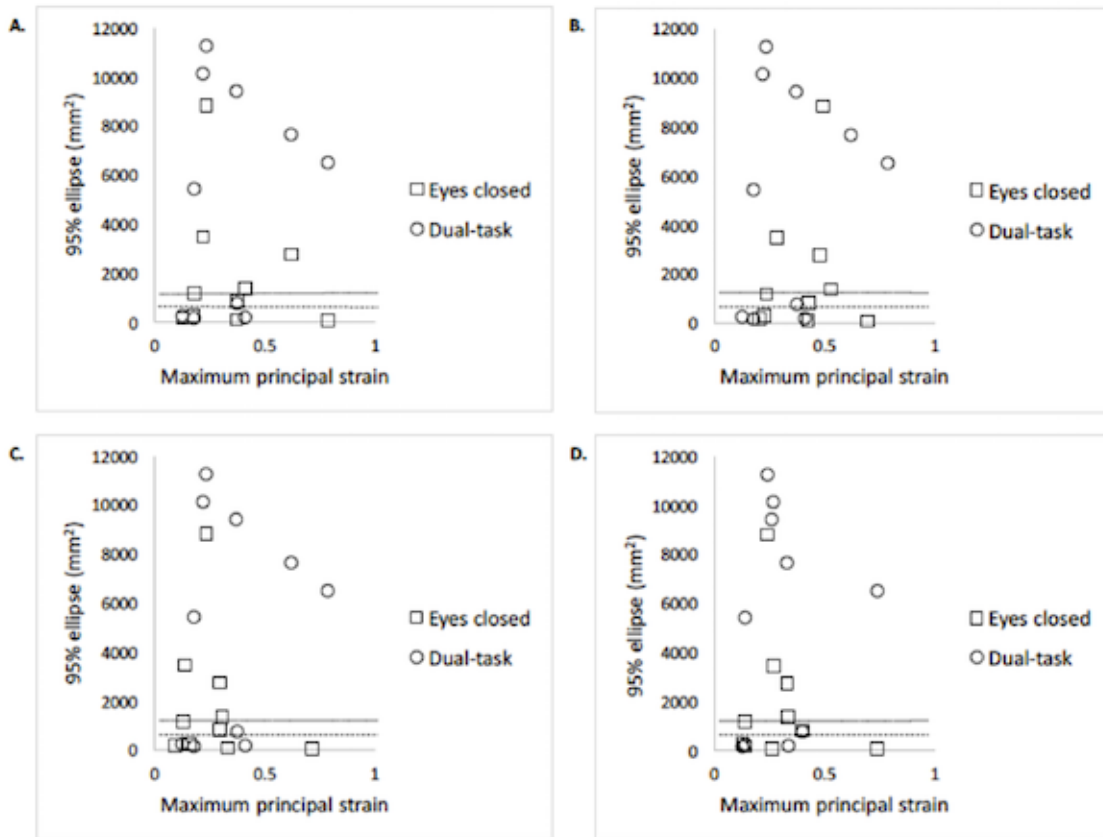


Figure 3. Association between 95% ellipse measured during the eyes closed and dual-task balance conditions and MPS values are shown for each participant for different brain regions: Frontal lobe (A), Temporal lobe (B), Parietal lobe (C), Occipital lobe (D). Dashed line represents threshold for normal balance for the eyes closed condition and solid line represents threshold for normal balance for the dual-task condition. Normal balance is defined as 2 standard deviations within the control group's mean.

The correlations between the CSDM_{10%} values and the 95% ellipse measured during both the eyes closed and dual-task conditions (**Figure 4**) and the correlations between the CSDM_{20%} values and the 95% ellipse measured during both balance conditions (**Figure 5**) were also weak demonstrating again that there is no association between the balance measures and the reconstruction variables.

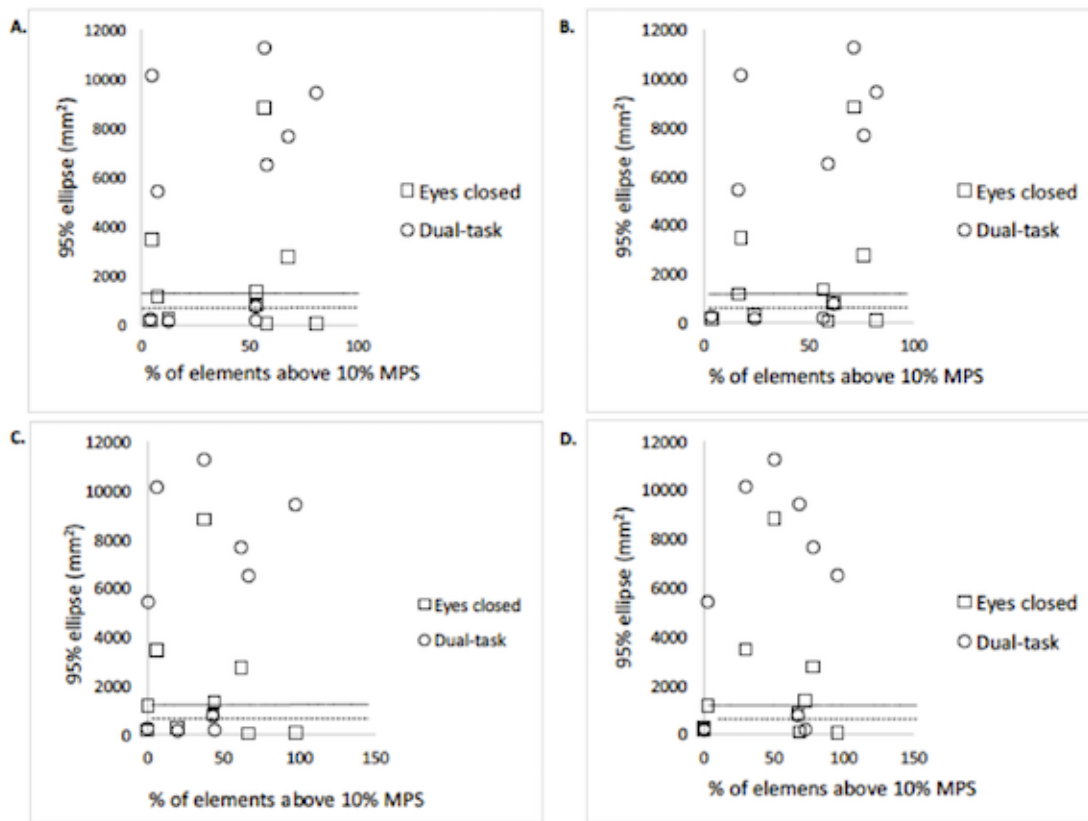


Figure 4. Association between 95% ellipse measured during the eyes closed and dual-task balance conditions and CSDM_{10%} values are shown for each participant for different brain regions: Frontal lobe (A), Temporal lobe (B), Parietal lobe (C), Occipital lobe (D). Dashed line represents threshold for normal balance for the eyes closed condition and solid line represents threshold for normal balance for the dual-task condition. Normal balance is defined as 2 standard deviations within the control group's mean.

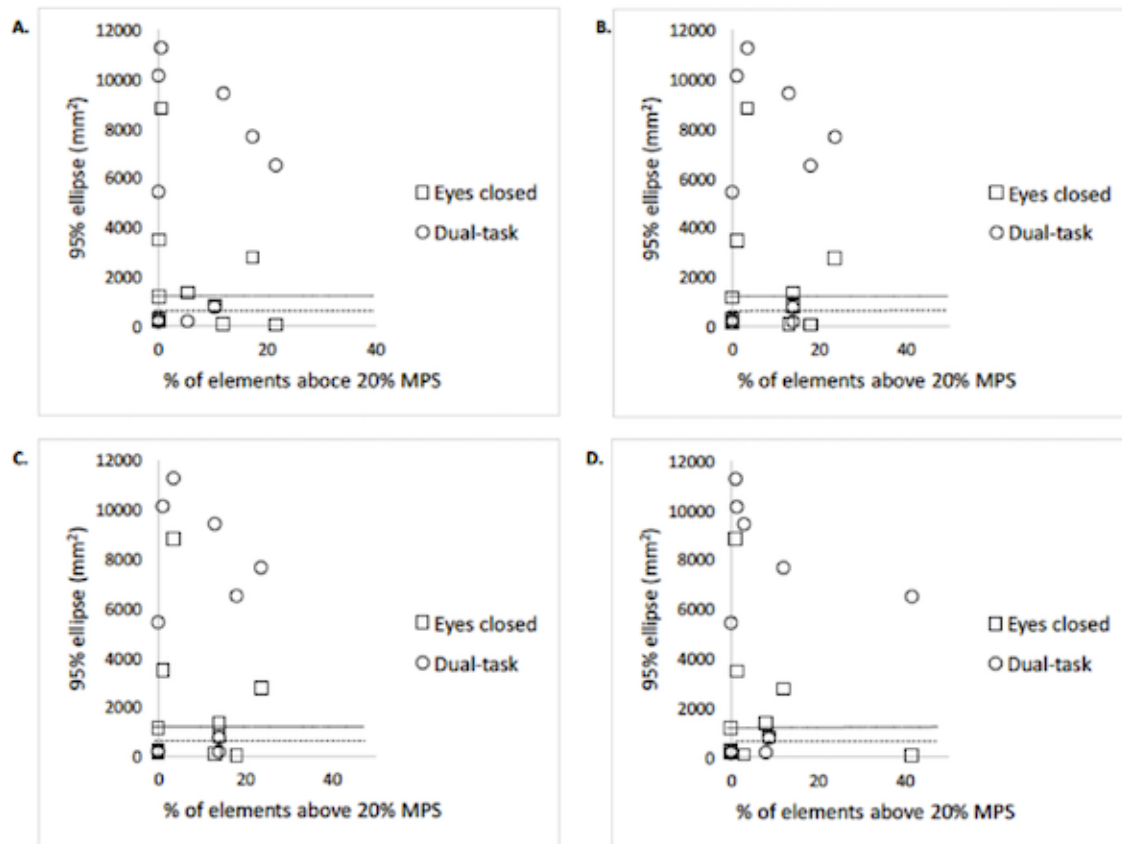


Figure 5. Association between 95% ellipse measured during the eyes closed and dual-task balance conditions and $CSDM_{20\%}$ values are shown for each participant for different brain regions: Frontal lobe (A), Temporal lobe (B), Parietal lobe (C), Occipital lobe (D). Dashed line represents threshold for normal balance for the eyes closed condition and solid line represents threshold for normal balance for the dual-task condition. Normal balance is defined as 2 standard deviations within the control group's mean.

Discussion

Association between biomechanics and balance measures

The goal of this study was to examine the relationship between the location and magnitude of brain tissue strain and balance performance at 1-month post-concussion in a group of concussed children. The correlations between the balance variables and the reconstruction

variables were low for all brain regions including the brainstem and the cerebellum demonstrating that there is little relationship between the location and amount of brain tissue strain and resulting balance performance. Considering that higher strain in the brain tissues have been postulated to result in more severe injury, these results suggest that the current methods and metrics of head injury reconstructions may not be sensitive to balance performance at 1-month following a concussion.

While this research identified that the biomechanics of impact do not predict long-term balance performance, there has been research in the past linking impact severity and magnitudes of strain in the brain to severity and duration of symptoms in animal models ^{41,42}. This lack of significant findings in the current study may be related to the time lapse between the biomechanics of the impact and the resulting measures. The impact biomechanics are related to the immediate structural effect of the event and may not reflect the subsequent pathophysiological cascades that occur over a 1-month period. Balance testing closer to the event may result in a different outcome in terms of the relationships between these variables.

While no relationship was identified in this present study between the biomechanics and balance measures, they both identify that an injurious event had occurred. Therefore, the lack of relationship may also be related to what each form of analysis represents. The biomechanical analyses are specific to brain tissue responses and may not be precise enough to target the areas within the brain that are involved in maintaining balance. Key structures such as the brainstem and cerebellum do play important roles in the process of maintaining balance, yet distinct areas within these structures, as opposed to the structures as a whole, accomplish specific functions to maintain balance⁴³. Obtaining measures of brain tissue strain within a cortical lobe or within the

brainstem or cerebellum as a whole may not be precise enough to identify a relationship between the magnitude of brain tissue strain and balance impairments.

The process of maintaining balance is also dependent on structures located inside and outside of the brain. The vestibular system is strongly involved in the process of maintaining balance and is comprised of a central component located within the brainstem and a peripheral component located inside the inner ear⁴⁴. The peripheral component includes two types of receptors that sense linear and rotational accelerations of the head and it has been suggested that damage to these receptors can lead to balance impairments in some individuals who have experienced a concussion³. Therefore, the lack of association identified between the amount of brain tissue strain and balance performance in this study could be due in part to some participants experiencing balance impairments due to damage located outside of the brain.

Limitations

A limitation of this study involves the small sample size. The limited number of participants included in this study may have influenced the correlations between the balance measures and the measures of brain tissue strain. Although weak correlations were identified between the majority of the balance and reconstruction variables, stronger correlations may emerge with a larger sample size. The finite element model is a representation of the structure and material properties of a human head and brain system. As a result, the magnitudes of response reported by the model is dependent upon the assumptions in material characteristics and boundary conditions that were used in its construction.

Conclusion

In this exploratory study, we demonstrated that values of brain tissue strain are not associated to balance performance at 1-month post-concussion in a group of children. The values

obtained from biomechanical reconstruction of head injuries may be useful in understanding the conditions that lead to concussion, but may not offer any predictive value in terms of balance performance following a concussion. This may be related to the complex nature of balance impairments and to some impairments resulting from injury to regions outside of the brain. This study should be repeated with a larger sample size in order to confirm these results.

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Conflict of Interest: The Author(s) declare(s) that there is no conflict of interest.

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APPENDIX B

Consent forms



How do teenagers with minor head injury keep their balance?

PRINCIPAL INVESTIGATOR:

We want to know how teenagers like you with a minor head injury keep their balance.

What you will do:

You will stand on a Wii Balance Board and a game will be placed on a poster in front of you. For the game, you will see words printed in different colors on the poster. You will have to name the color of the ink that the words are printed in. For example, you could see the word blue printed in red ink and you would have to say red. While you do this, there will be a headband placed around your head.

You will also be asked to hold your balance on two feet, one foot, and one foot in front of the other.

The session will take about 30 minutes of your time.

If you chose to participate, you will receive a 5\$ gift certificate from Chapters.

It's ok if you change your mind and don't want to participate anymore. You just have to let one of your parents or the researchers know. You can ask questions at any time.

Name of child participating
(In block letters)

Consent Signature

____/____/____
Date dd/mmm/yy

I have explained all of the pertinent aspects of this research project to the child and parent/guardian, and have answered their questions. I have indicated that participation is free and voluntary, and that they are free to withdraw from the study at any time.

**Name of Individual obtaining
consent (in block letters)**

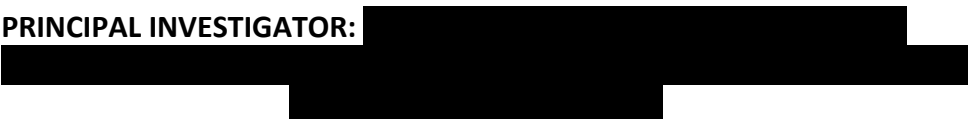
Signature

____/____/____
Date dd/mmm/yy



How do teenagers with minor head injury keep their balance?

PRINCIPAL INVESTIGATOR:



We want to know how teenagers with a minor head injury keep their balance. To do this, we also need to look at how teenagers like you, with no minor head injury, maintain their balance.

What you will do:

You will stand on a Wii Balance Board and a game will be placed on a poster in front of you. For the game, you will see words printed in different colors on the poster. You will have to name the color of the ink that the words are printed in. For example, you could see the word blue printed in red ink and you would have to say red. While you do this, there will be a headband placed around your head.

You will also be asked to hold your balance on two feet, one foot, and one foot in front of the other. You will do this with your eyes closed standing on the floor and on a foam surface.

The session will take about 30 minutes of your time.

If you chose to participate, you will receive a 5\$ gift certificate from Chapters.

It's ok if you change your mind and don't want to participate anymore. You just have to let one of your parents or the researchers know. You can ask questions at any time.

Name of child participating
(In block letters)

Consent Signature

____/____/____
Date dd/mmm/yy

I have explained all of the pertinent aspects of this research project to the child and parent/guardian, and have answered their questions. I have indicated that participation is free and voluntary, and that they are free to withdraw from the study at any time.

**Name of Individual obtaining
consent (in block letters)**

Signature

____/____/____
Date dd/mmm/yy



Balance Markers in Adolescents with Mild Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: [REDACTED]

WHY ARE WE DOING THIS?

We are doing a study on teenagers like you, who have experienced a minor head injury. We would like to learn more about how teenagers with minor head injuries maintain their balance.

WHAT DO I HAVE TO DO?

You will stand on a Wii Balance Board and a poster will be placed in front of you. On the poster, you will see words of colors printed in different colors. You will be asked to name the color of the ink that the word is printed in. For example, you could see the word blue printed in red ink and you would have to answer red. While you do this, there will be a headband placed around your head.

You will also be asked to hold your balance on two feet, one foot, and one foot in front of the other. You will do this with your eyes closed while standing on the floor and on a foam surface. The session will take about 30 minutes of your time.

WHAT ARE THE RISKS?

There is very little risk in participating in this study. At most, you may become tired while completing the balance tests. However, you may request to take a rest at anytime.

ARE THERE ANY BENEFITS?

You will not get any personal benefit from being part of this study

DO I HAVE TO DO THIS?

The decision to take part in this study is up to you. If you do or do not want to take part in this study, the doctors and nurses at the hospital will still take care of you and won't treat you any differently.

WILL MY RECORDS BE KEPT PRIVATE AND CONFIDENTIAL?

Your personal information will be kept strictly confidential. The data produced from this study will be stored in a secure, locked location, and only the members of the research team will have access to it. Published study results will not reveal your identity.

COMPENSATION

If you chose to participate, you will receive a 5\$ gift certificate from Chapters.

WHERE CAN I GET MORE INFORMATION?

The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different backgrounds. The Board reviews all research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at [REDACTED], although this person cannot provide any health-related information about the study.

QUESTIONS?

Please ask us any questions that you want. If you agree to participate, please write your name and sign below:

_____	_____	____/____/____
Name of child participating (In block letters)	Consent Signature	Date dd/mmm/yy

I have explained all of the pertinent aspects of this research project to the child and parent/guardian, and have answered their questions. I have indicated that participation is free and voluntary, and that they are free to withdraw from the study at any time.

_____	_____	____/____/____
Name of Individual obtaining consent (in block letters)	Signature	Date dd/mmm/yy



Balance Markers in Adolescents with Mild Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: [REDACTED]

WHY ARE WE DOING THIS?

We are doing a study to learn more about how teenagers with minor head injuries maintain their balance. To do this, we also need to look at how teenagers like you, with no minor head injury, maintain their balance.

WHAT DO I HAVE TO DO?

You will stand on a Wii Balance Board and a poster will be placed in front of you. On the poster, you will see words of colors printed in different colors. You will be asked to name the color of the ink that the word is printed in. For example, you could see the word blue printed in red ink and you would have to answer red. While you do this, there will be a headband placed around your head.

You will also be asked to hold your balance on two feet, one foot, and one foot in front of the other. You will do this with your eyes closed while standing on the floor and on a foam surface. The session will take about 30 minutes of your time.

WHAT ARE THE RISKS?

There is very little risk in participating in this study. At most, you may become tired while completing the balance tests. However, you may request to take a rest at anytime.

ARE THERE ANY BENEFITS?

You will not get any personal benefit from being part of this study.

DO I HAVE TO DO THIS?

The decision to take part in this study is up to you. If you do or do not want to take part in this study, there will be no negative consequences.

WILL MY RECORDS BE KEPT PRIVATE AND CONFIDENTIAL?

Your personal information will be kept strictly confidential. The data produced from this study will be stored in a secure, locked location, and only the members of the research team will have access to it. Published study results will not reveal your identity.

COMPENSATION

If you chose to participate, you will receive a 5\$ gift certificate from Chapters.

WHERE CAN I GET MORE INFORMATION?

The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different backgrounds. The Board reviews all research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at [REDACTED], although this person cannot provide any health-related information about the study.

QUESTIONS?

Please ask us any questions that you want. If you agree to participate, please write your name and sign below:

**Name of child participating
(In block letters)**

Consent Signature

____/____/____
Date dd/mmm/yy

I have explained all of the pertinent aspects of this research project to the child and parent/guardian, and have answered their questions. I have indicated that participation is free and voluntary, and that they are free to withdraw from the study at any time.

**Name of Individual obtaining
consent (in block letters)**

Signature

____/____/____
Date dd/mmm/yy



Balance Markers in Adolescents with Mild Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: [REDACTED]

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to compare three different measures of balance in adolescents who have experienced a minor head injury. This study will help determine if the measures that are commonly used in the emergency room and on the sidelines in sport settings are sensitive enough to identify balance impairments in adolescents who have experienced a minor head injury.

WHAT WILL MY CHILD BE ASKED TO DO?

Your child's participation will consist of one 30-minute session. For this session, you will be asked to either come to the motor control laboratory at the University of Ottawa or it can be arranged for a research assistant to come to your home. Your child will be asked to stand on a Wii Balance Board and to complete a cognitive task at the same time. A headband that measures accelerations will also be placed around your child's head while he/she completes this task. Your child will also be asked to complete a clinical test of balance for which he/she will hold three different positions with their eyes closed on a firm and a foam surface.

WHAT ARE THE RISKS?

There is very little risk in participating in this study. At most, your child may become tired while completing the balance tests. However, your child may request to take a rest at anytime.

ARE THERE ANY BENEFITS FOR MY CHILD?

Your child will not get any personal benefit from being part of this study.

IS MY CHILD OBLIGATED TO PARTICIPATE?

Your child is under no obligation to participate and if he/she chooses to participate, he/she can withdraw from the study at any time and there will be no penalty or consequences. If he/she chooses to withdraw, all data gathered until the time of withdrawal will be destroyed. Your decision to allow your child to participate or not in this study will not affect the care that he/she receives at CHEO.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE AND CONFIDENTIAL?

Your child's personal information will be kept strictly confidential. The data produced from this study will be stored in a secure, locked location, and only the members of the research team

will have access to it. The data from this study will be published and used in a graduate student's thesis. Your child's identity will not be revealed.

WILL MY CHILD BE COMPENSATED?

If your child participates, he/she will receive a 5\$ gift certificate for Chapters.

WHERE CAN I GET MORE INFORMATION?

The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different backgrounds. The Board reviews all research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at [REDACTED], although this person cannot provide any health-related information about the study.

Acceptance: I, _____ agree to allow my child _____ to participate in the research study described above.

There are two copies of this consent form provided – please keep one for your own records.

_____ Name of parent or guardian who gives consent (In block letters)	_____ Consent Signature	____/____/____ Date dd/mmm/yy
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I have explained all of the pertinent aspects of this research project to the child and parent/guardian, and have answered their questions. I have indicated that participation is free and voluntary, and that they are free to withdraw from the study at any time.

_____ Name of Individual obtaining consent (in block letters)	_____ Signature	____/____/____ Date dd/mmm/yy
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Balance Markers in Adolescents with Mild Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: [REDACTED]

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to compare three different measures of balance in adolescents who have experienced a minor head injury. This study will help determine if the measures that are commonly used in the emergency room and on the sidelines in sport settings are sensitive enough to identify balance impairments in adolescents who have experienced a minor head injury. In order to do this, we also need to look at how adolescents who have not experienced a minor head injury maintain their balance.

WHAT WILL MY CHILD BE ASKED TO DO?

Your child's participation will consist of one 30-minute session. For this session, you will be asked to either come to the motor control laboratory at the University of Ottawa or it can be arranged for a research assistant to come to your home. Your child will be asked to stand on a Wii Balance Board and to complete a cognitive task at the same time. A headband that measures accelerations will also be placed around your child's head while he/she completes this task. Your child will also be asked to complete a clinical balance test for which he/she will hold three different positions with their eyes closed on a firm and a foam surface.

WHAT ARE THE RISKS?

There is very little risk in participating in this study. At most, your child may become tired while completing the balance tests. However, your child may request to take a rest at anytime.

ARE THERE ANY BENEFITS FOR MY CHILD?

Your child will not get any personal benefit from being part of this study.

IS MY CHILD OBLIGATED TO PARTICIPATE?

Your child is under no obligation to participate and if he/she chooses to participate, he/she can withdraw from the study at any time and there will be no penalty or consequences. If he/she chooses to withdraw, all data gathered until the time of withdrawal will be destroyed.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE AND CONFIDENTIAL?

Your child's personal information will be kept strictly confidential. The data produced from this study will be stored in a secure, locked location, and only the members of the research team will have access to it. The data from this study will be published and used in a graduate student's thesis. Your child's identify will not be revealed.

WILL MY CHILD BE COMPENSATED?

If your child participates, he/she will receive a 5\$ gift certificate for Chapters.

WHERE CAN I GET MORE INFORMATION?

The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different backgrounds. The Board reviews all research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at (), although this person cannot provide any health-related information about the study.

Acceptance: I, _____ agree to allow my child _____ to participate in the research study described above.

There are two copies of this consent form provided – please keep one for your own records.

_____	_____	____/____/____
Name of parent or gardian	Consent Signature	Date dd/mmm/yy
who gives consent		
(In block letters)		

I have explained all of the pertinent aspects of this research project to the child and parent/guardian, and have answered their questions. I have indicated that participation is free and voluntary, and that they are free to withdraw from the study at any time.

_____	_____	____/____/____
Name of Individual obtaining	Signature	Date dd/mmm/yy
consent (in block letters)		



Protocol title: Prediction Model for Balance Performance at One-month Post-concussion in Children and Adolescents

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Telephone number: [REDACTED]

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better. In our study, we want to see how children like you, who have had a concussion, maintain their balance.

Who will take part?

Children seen at the CHEO are being asked to join this study. We expect to have 30 children who have had a concussion and 60 children who have not had a concussion join the study over the next 6 months.

What will happen during the study?

If you decide to participate in this study, you will be asked to complete two 15-minute balance testing sessions. You will be asked to do the first one today and the second one in about three weeks from now. These sessions will take place at your home during school hours, after school or on the weekend. During each session, we will first ask you to stand on the board for the game Wii Fit and to stand as still as you can for two minutes with your eyes open and with your eyes closed. After this, we will ask you to stand on the Wii Fit board again and we will ask you to complete a game at the same time. During each session, we will also ask you some questions about how you are feeling and about how your head injury occurred.

Are there good things that can happen from this study?

Sometimes good things can happen to people when they are in a study. These good things are called "benefits". This study will help us better understand children like you who have had a concussion. That is a benefit. There are no other benefits that we think will happen to you if you decide to join this study.

Are there bad things that can happen from this study?

We do not think that anything bad would happen if you decide to join this study.

What if something bad happens?

If something does go wrong, your doctor and the researchers will be there to take care of you.

Will I receive something for participating?

If you decide to participate, you will receive one 5\$ Tim Horton's gift card for each time that you do the balance measures.

What if there is new information?

Sometimes during a study, we learn new information. We will talk to your doctors about any new information that might be important to you.

Is this private?

We will keep your information private whether you decide to join this study or not. Any information that would indicate that you are being harmed or at risk of being harmed will be shared with your doctor.

Can I say no?

You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or your doctor if you want to stop being in the study, and they will tell the researchers. No one will be mad at you if you choose not to take part.

What if I have questions?

Please ask us and we will do anything we can to answer your questions.

Your parent may receive a summary of the results at the conclusion of the study if they wish so.

Assent form signatures

If you agree to participate in this research study, please sign the form.

I understand the information that was explained to me and I can ask any questions that I like about the study.

Signature of Participant

Name of Participant

Date



Protocol title: Prediction Model for Balance Performance at One-month Post-concussion in Children and Adolescents

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]
Telephone number: [REDACTED]

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better. In our study, we want to see how children and teenagers like you, who have experienced a concussion, maintain their balance.

Who will take part?

Children and teenagers seen at the CHEO are being asked to join this study. We expect to have 30 children and teenagers who have had a concussion and 60 children and teenagers who have not had a concussion join the study over the next 6 months.

What will happen during the study?

If you decide to participate in this study, you will be asked to complete two 15-minute balance testing sessions. You will be asked to do the first one today and the second one in about three weeks from now. These sessions will take place at your home during school hours, after school or on the weekend. During each session, you will first be asked to stand on the board for the game Wii Fit and to stand as still as you can for two minutes with your eyes open and with your eyes closed. After this, you will be asked to stand on the Wii Fit board again and we will ask you to complete a game at the same time. For this game, you will see the words “red”, “yellow”, “green” and “blue” written on a board in front of you. The words on the board will be printed in the incorrect colour. For example, you could see the word “red” printed in blue. We will ask you to name the colour of the ink that each word is printed in. During each session, we will also ask you some questions about how you are feeling and about how your head injury occurred.

Are there any benefits to participating?

You will not get any personal benefit from being part of this study; however this study will help us better understand children who have had a concussion.

Are there any risks to participating?

We do not think that anything bad would happen if you decide to join this study.

What if something bad happens?

If something does go wrong, your doctor and the researchers will be there to take care of you.

Will I be compensated for participating?

If you decide to participate, you will receive one 5\$ Tim Horton's gift card for each session that you complete in recognition of your time and effort.

What if there is new information?

Sometimes during a study, we learn new information. We will talk to your doctors about any new information that might be important to you.

Is this private?

We will keep your information private whether you decide to join this study or not. Any information that would indicate that you are being harmed or at risk of being harmed, will be shared with your doctor.

Can I say no?

You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or your doctor if you want to stop being in the study, and they will tell the researchers. No one will be mad at you if you choose not to take part.

What if I have questions?

Please ask us and we will do anything we can to answer your questions.

Your parent may receive a summary of the results at the conclusion of the study if they wish so.

Assent form signatures

If you agree to participate in this research study, please sign the form.

I understand the information that was explained to me and I can ask any questions that I like about the study.

Signature of Participant

Name of Participant

Date



Protocol title: Prediction Model for Balance Performance at One-month Post-concussion in Children and Adolescents

Principal investigator: [REDACTED]

Address: [REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Telephone number: [REDACTED]

You are being invited to join in a research study about the recovery of balance following a concussion. You are being invited to join this study because you have experienced a concussion. Before agreeing to take part in this study, it is important that you read and understand this document.

Taking part in this study is voluntary. Your decision to participate or not in this study will not affect the care you receive at CHEO. You are free to withdraw from the study at any time and there will be no penalty.

Why is this study being done?

The purpose of this study is to identify a method that can identify children and adolescents who are most likely to be affected with ongoing balance problems following a concussion. This will allow physicians to identify these children and adolescents at the time of injury in order to offer them the appropriate care as soon as possible.

How many children will participate?

We expect to have 30 children and adolescents who have had a concussion and 60 children and adolescents who have not had a concussion participate. We expect to invite children and adolescents to participate for 6 months. This study is expected to be active for 8 months.

What will I be asked to do?

If you decide to participate in this study, you will be asked to participate in two 15-minute balance testing sessions. The first session will take place at your home within the first week following the date of your head injury and the second testing session will take place at your home at approximately one month following the date of your head injury. These sessions will take place either during school hours, after school or on the weekend. We will require your address in order to complete the first and second balance testing sessions at your home.

During each session, you will first be asked to stand on a Nintendo Wii Balance Board and to focus on standing as still as possible for two minutes with your eyes open and with your eyes closed. You will then be asked to complete a cognitive task while standing on the Nintendo Wii Balance Board. For the cognitive task, you will be presented with a board containing a series of the words “red”, “yellow”, “green” and “blue” written in the incorrect colour. For example, the word “red” could be written in blue. You will be asked to name the colour of the ink that each word is printed in. During these sessions, you will also be asked to complete a questionnaire about your symptoms and you will also be asked a couple of questions related to how your head injury occurred.

Are there any risks to participating?

There is very little risk in participating in this study. At most, you may become tired while completing the balance tests. However, you may request to take a rest at any time.

Are there any benefits to participating?

You will not get any personal benefit from being part of this study; however, we hope to improve the way balance is assessed following a concussion to take better care of patients in the future.

Will I be compensated for participating?

If you decide to participate, you will receive one 5\$ Tim Horton’s gift card for each session that you complete in recognition of your time and effort.

What if I get injured?

In the event that you suffer an injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to you. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will I be told about new information?

We will inform you of any new information that might influence your decision to continue to participate in this research project. We will ask you again if you want to be in the study.

Will my records be kept private and confidential?

Your personal information will be kept strictly confidential. For this study we will be collecting gender and Date Of Birth (DOB) for the research purposes described in this consent form. Representatives from the CHEO research Ethics Board may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The data produced from this study will be stored in a secured locked location. Only members of the research team and the individuals described above will have access to the data. Following completion of the research study the data will be kept for 7 years after the last publication of this study. They will then be destroyed.

Signature of Participant

Name of Participant

Date

**Witness to Participant's
Signature**

Name of Witness

Date

**Signature of person
Obtaining Informed Consent**

**Name of Person Obtaining
Informed Consent**

Date



Protocol title: Prediction Model for Balance Performance at One-month Post-concussion in Children and Adolescents

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Telephone number: [REDACTED]

You are being invited to join in a research study about the recovery of balance following a concussion. You are being invited to join this study because your child has experienced a concussion. Before agreeing to take part in this study, it is important that you read and understand this document.

Taking part in this study is voluntary. Your decision to participate or not in this study will not affect the care you receive at CHEO. You are free to withdraw from the study at any time and there will be no penalty to you or your child.

Why is this study being done?

The purpose of this study is to identify a method that can identify children and adolescents who are most likely to be affected with ongoing balance problems following a concussion. This will allow physicians to identify these children and adolescents at the time of injury in order to offer them the appropriate care as soon as possible.

How many children will participate?

We expect to have 30 children and adolescents who have had a concussion and 60 children and adolescents who have not had a concussion participate. We expect to invite children and adolescents to participate for 6 months. This study is expected to be active for 8 months.

What will my child be asked to do?

If you decide to participate in this study, your child will be asked to participate in two 15-minute balance testing sessions. The first session will take place at your home within the first week following the date of your child's head injury and the second testing session will take place at your home at approximately one month following the date of your child's head injury. These

sessions will take place either during school hours, after school or on the weekend. We will require your address in order to complete the first and second balance testing sessions at your home.

During each session, your child will first be asked to stand on a Nintendo Wii Balance Board and to focus on standing as still as possible for two minutes with their eyes open and with their eyes closed. Your child will then be asked to complete a cognitive task while standing on the Nintendo Wii Balance Board. For the cognitive task, your child will be presented with a board containing a series of the words “red”, “yellow”, “green” and “blue” written in an incongruent ink colour. For example, the word “red” could be written in blue. Your child will be asked to name the colour of the ink that each word is printed in. During these sessions, your child will also be asked to complete a questionnaire related to his/her symptoms and will also be asked a couple of questions related to how his/her head injury occurred.

Are there any risks to participating?

There is very little risk in participating in this study. At most, your child may become tired while completing the balance tests. However, your child may request to take a rest at any time.

Are there any benefits to participating?

Your child will not get any personal benefit from being part of this study; however, we hope to improve the way balance is assessed following a concussion to take better care of patients in the future.

Will my child be compensated for participating?

If your child participates, he/she will receive one \$5 Tim Horton’s for each session that he/she completes in recognition of your time and effort.

What if my child gets injured?

In the event that your child suffers an injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to your child. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will I be told about new information?

We will inform you of any new information that might influence your decision to continue to participate in this research project. We will ask you again if you want to be in the study.

Will my child’s records be kept private and confidential?

Your child’s personal information will be kept strictly confidential. For this study we will be collecting gender and Date Of Birth (DOB) for the research purposes described in this consent form. Representatives from the CHEO research Ethics Board may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The data produced from this study will be stored in a secured locked location. Only members of the research team and the individuals described above will have access to the data. Following

completion of the research study the data will be kept for 7 years after the last publication of this study. They will then be destroyed.

Any information that would indicate that a child was being harmed or at risk of such harm, would not be kept confidential and instead be disclosed as appropriate to offset that risk.

Your child will not be identified in any publication or presentation of this study. A copy of the signed consent form will be provided to you.

Is the research team benefiting from the study?

The research team members are not benefiting personally, financially or in some other way from this study.

What if I have questions?

If you have any questions concerning participation in this study, or if at any time feel that you have experienced a study-related injury, contact:

[REDACTED]

This study has been reviewed and approved by the CHEO Research Ethics Board. The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different professional backgrounds. The Board reviews all human research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at [REDACTED], although this person cannot provide health-related information about the study.

A summary of the results will be provided to you at the conclusion of the study if you desire.

Consent form signatures

By signing this consent form I agree that:

- I am voluntarily agreeing to participate in this research study;
- I understand the information within this consent form;
- All of the risks and benefits of participation have been explained to me;
- All of my questions have been answered;
- I allow access to my child's medical records and/or personal information as described in this consent form, and;
- I do not give up my legal rights by signing this form.

Signature of Parent or
Guardian

Name of Parent or
Guardian

Date

Witness to Parent or
Guardian's Signature

Name of Witness

Date

Signature of person
Obtaining Informed Consent

Name of Person Obtaining
Informed Consent

Date



uOttawa



Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better. In our study, we want to see how children like you, who have had a concussion, maintain their balance. We also want to look at factors that could affect your recovery. This is why we will also ask you questions about anxiety and depression.

Who will take part?

Children seen at the CHEO concussion clinic and at the ActiveCare clinic in Kanata are being asked to join this study. We expect to have 30 children and teenagers who have had a concussion and 60 children and teenagers who have not had a concussion join the study over the next 6 months.

What will happen during the study?

If you want to do this study, we will measure your balance three times. Each time will take 30-minutes. You will be asked to do the first one today, the second one in two months from now and the third one in five months from now. It is up to you to decide if you want to participate just for today or if you want to come back one or two more times. You will complete these sessions at the CHEO concussion clinic between the hours of 8 am 4pm between Monday and Friday.

Each time, we will ask you to stand on the board for the game Wii Fit and to stand as still as you can for two minutes with your eyes open and with your eyes closed. After this, we will ask you to stand on the board again and we will ask you to complete three different games while you are standing. While you do this, there will be a headband placed around your head, a strap placed around your torso, and you will wear a pair of glasses.

We will also ask you to answer a couple of questions about how you are feeling and about any symptoms from your concussion.

Are there good things that can happen from this study?

Sometimes good things can happen to people when they are in a study. These good things are called “benefits”. This study will help us better understand children who have had a concussion. That is a benefit. There are no other benefits that we think will happen to you if you decide to join this study.

Are there bad things that can happen from this study?

We do not think that anything bad would happen if you decide to join this study.

What if something bad happens?

If something does go wrong, your doctor will be there to take care of you.

Will I receive something for participating?

If you decide to participate, you will receive one 5\$ Tim Horton’s gift card for each time that you do the balance measures.

What if there is new information?

Sometimes during a study, we learn new information. We will talk to your doctors about any new information that might be important to you.

Is this private?

We will keep your information private whether you decide to join this study or not. Any information that would indicate that you are being harmed or at risk of being harmed, will be shared with your doctor.

Can I say no?

You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or your doctor if you want to stop being in the study, and they will tell the researchers. No one will be mad at you if you choose not to take part.

What if I have questions?

Please ask us and we will do anything we can to answer your questions.

Your parent may receive a summary of the results at the conclusion of the study if they wish so.

Assent form signatures

If you agree to participate in this research study, please sign the form.

I understand the information that was explained to me and I can ask any questions that I like about the study.

Signature of Participant

Name of Participant

Date



Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better. In our study, we want to see how children and teenagers like you, who have experienced a concussion, maintain their balance. We also want to look at factors that could affect your recovery. This is why we will also ask you questions about anxiety and depression.

Who will take part?

Children and teenagers seen at the CHEO concussion clinic and the ActiveCare clinic in Kanata are being asked to join this study. We expect to have 30 children and teenagers who have had a concussion and 60 children and teenagers who have not had a concussion join the study over the next 6 months.

What will happen during the study?

If you decide to participate in this study, you will be asked to complete up to three 30-minute sessions. You will be asked to do the first one today, the second one in two months from now and the third one in five months from now. It is up to you to decide if you want to participate just for today or if you want to come back one or two more times. You will complete these sessions at the CHEO concussion clinic between the hours of 8 am and 4 pm from Monday to Friday. During each session, you will first be asked to stand on the board for the game Wii Fit and to stand as still as you can for two minutes with your eyes open and with your eyes closed. After this, you will be asked to stand on the board again and we will ask you to complete three different games while you are standing. For these games, you will see the words "red", "yellow", "green" and "blue" on a screen or on a poster in front of you. Some of these words will be printed in the correct colour, like "red" printed in red. Other words will be printed in the incorrect colour, like "red" printed in blue. You will be asked to name the colour of the ink that the words are printed in or just to read the words. While you do this, there will be a headband placed around your head, a strap placed around your torso, and you will wear a pair of glasses.

We will also ask you to complete 5 short questionnaires. These questionnaires will ask you about how you are feeling and about any symptoms from your concussion.

Are there any benefits to participating?

You will not get any personal benefit from being part of this study; however this study will help us better understand children who have had a concussion.

Are there any risks to participating?

We do not think that anything bad would happen if you decide to join this study.

What if something bad happens?

If something does go wrong, your doctor will be there to take care of you.

Will I be compensated for participating?

If you decide to participate, you will receive one 5\$ Tim Horton's gift card for each session that you complete in recognition of your time and effort.

What if there is new information?

Sometimes during a study, we learn new information. We will talk to your doctors about any new information that might be important to you.

Is this private?

We will keep your information private whether you decide to join this study or not. Any information that would indicate that you are being harmed or at risk of being harmed, will be shared with your doctor.

Can I say no?

You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or your doctor if you want to stop being in the study, and they will tell the researchers. No one will be mad at you if you choose not to take part.

What if I have questions?

Please ask us and we will do anything we can to answer your questions.

Your parent may receive a summary of the results at the conclusion of the study if they wish so.

Assent form signatures

If you agree to participate in this research study, please sign the form.

I understand the information that was explained to me and I can ask any questions that I like about the study.

Signature of Participant

Name of Participant

Date



uOttawa



Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

You are being invited to join in a research study about the recovery of balance following a concussion. You are being invited to join this study because you have experienced a concussion. Before agreeing to take part in this study, it is important that you read and understand this document.

Taking part in this study is voluntary. Your decision to participate or not in this study will not affect the care you receive at CHEO, the CHEO concussion clinic and the ActiveCare clinic in Kanata. You are free to withdraw from the study at any time with no penalty.

Why is this study being done?

The purpose of our study is to learn more about balance problems and problems with eye movements following a concussion. This study will help determine if it is important to observe eye movements when testing balance. We are also interested in learning more about factors that are linked to recovery following a concussion. In order to do this we will collect information on anxiety and depression.

How many children will participate?

We expect to have 30 children and teenagers who have had a concussion and 60 children and teenagers who have not had a concussion participate. We expect to invite children and teenagers to participate for 6 months. This study is expected to be active for 8 months.

What will I be asked to do?

If you decide to participate in this study, you will be invited to do up to three 30-minute balance sessions. The first session will take place between 1 and 3 months following the date of your concussion, the second session at 2-months following the date of your first session and the third session at 5-months following the date of your first session. These sessions will take place

at the CHEO concussion clinic [REDACTED] and will be completed between the hours of 8 am and 4 pm from Monday to Friday.

During these sessions, you will first be asked to stand on a Nintendo Wii Balance Board and to focus on standing as still as possible for two minutes with your eyes open and with your eyes closed. You will then be asked to complete three different cognitive tasks while standing on the Nintendo Wii Balance Board. For these tasks, you will be presented with a series of the words “red”, “yellow”, “green” and “blue” printed in the correct or incorrect colour. For example, you could see the word “red” printed in red or printed in an incorrect colour like blue. You will be asked to either read the words or to name the colour of the ink that each word is printed in. While you complete these tasks, a headband that measures the accelerations of your head movements will be placed around your head, a strap that measures the accelerations of your torso will be placed around your torso, and you will be asked to wear a pair of glasses that records eye movements.

During these sessions, you will also be asked to complete five short questionnaires. These questionnaires will ask you about how you are feeling and about any symptoms from your concussion.

Are there any risks to participating?

There is very little risk in participating in this study. At most, you may become tired while completing the balance tests. However, you may request to take a rest at anytime.

Are there any benefits to participating?

You will not get any personal benefit from being part of this study; however we hope to improve the way balance is assessed following a concussion to take better care of patients in the future.

Will I be compensated for participating?

If you decide to participate, you will receive one 5\$ Tim Horton’s gift card for each session that you complete in recognition of your time and effort.

What if I get injured?

In the event that you suffer injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to you. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will I be told about new information?

We will inform you of any new information that might influence your decision to continue to participate in this research project. We will ask you again if you want to be in the study. If this study uncovers information that might be helpful to your current or future health, the investigator will provide this information to your most responsible physician for follow-up. In the event of a positive depression screen, the principle investigator will be notified. We will offer that you be seen at an emergency department and you will be provided with the phone number for a crisis line.

Will my records be kept private and confidential?

Your personal information will be kept strictly confidential. For this study we will be collecting gender and Date Of Birth (DOB) for the research purposes described in this consent form. Representatives from the CHEO research Ethics Board may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The data produced from this study will be stored in a secured locked location. Only members of the research team and the individuals described above will have access to the data. Following completion of the research study the data will be kept for 7 years after the last publication of this study. They will then be destroyed.

Any information that would indicate that you are being harmed or at risk of being harmed, will be shared with your doctor.

You will not be identified in any publication or presentation of this study.

A copy of the signed consent form will be provided to you.

Is the research team benefiting from the study?

The research team members are not benefiting personally, financially or in some other way from this study.

What if I have questions?

If you have any questions concerning participation in this study, or if at any time feel that you have experienced a study-related injury, contact:

This study have been reviewed and approved by the CHEO Research Ethics Board. The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different professional backgrounds. The Board reviews all human research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at [REDACTED], although this person cannot provide health-related information about the study.

A summary of the results of the study will be provided to you at the conclusion of the study if you desire.

Consent form signatures

By signing this consent form I agree that:

- I am voluntarily agreeing to participate in this research study;
- I understand the information within this consent form;
- All of the risks and benefits of participation have been explained to me;
- All of my questions have been answered;
- I allow access to my medical records and/or personal information as described in this consent form, and;
- I do not give up my legal rights by signing this form.

Signature of Participant

Name of Participant

Date

**Witness to Participant's
Signature**

Name of Witness

Date

**Signature of person
Obtaining Informed Consent**

**Name of Person Obtaining
Informed Consent**

Date

Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

You are being invited to join in a research study about the recovery of balance following a concussion. You are being invited to join this study because your child has experienced a concussion. Before agreeing to take part in this study, it is important that you read and understand this document.

Taking part in this study is voluntary. Your decision to participate or not in this study will not affect the care you receive at CHEO, the CHEO concussion clinic and the ActiveCare clinic in Kanata. You are free to withdraw from the study at any time and there will be no penalty to you or your child.

Why is this study being done?

The purpose of this study is to learn more about balance problems and problems with eye movements following a concussion. This study will help determine if it is important to observe eye movements when testing balance. We are also interested in learning more about factors that are linked to recovery following a concussion. In order to do this we will collect information on anxiety and depression.

How many children will participate?

We expect to have 30 children and adolescents who have had a concussion and 60 children and adolescents who have not had a concussion participate. We expect to invite children and adolescents to participate for 6 months. This study is expected to be active for 8 months.

What will my child be asked to do?

If you decide to participate in this study, we will ask you to participate in up to three 30-minute sessions. The first session will take place between 1 and 3 months following the date of your child's concussion, the second session at 2-months following the date of your child's first session and the third session at 5-months following the date of your child's first session. These

sessions will take place at the CHEO concussion clinic [REDACTED] and will be completed between the hours of 8 am and 4 pm from Monday to Friday.

During each session, your child will first be asked to stand on a Nintendo Wii Balance Board and to focus on standing as still as possible for two minutes with their eyes open and with their eyes closed. Your child will then be asked to complete three different cognitive tasks while standing on the Nintendo Wii Balance Board. For these tasks, your child will be presented with a series of the words “red”, “yellow”, “green” and “blue” printed in the correct or incorrect colour. For example, the word “red” could be printed in red or printed in an incorrect colour like blue. Your child will be asked to either read the words or to name the colour of the ink that each word is printed in. While your child completes these tasks, a headband that measures head accelerations will be placed around your child’s head, a strap that measures torso accelerations will be placed around your child’s torso, and your child will be asked to wear a pair of glasses that records eye movements.

During these sessions, your child will also be asked to complete five short questionnaires. These questionnaires will ask your child about how he/she is feeling and about symptoms related to his/her concussion.

Are there any risks to participating?

There is very little risk in participating in this study. At most, your child may become tired while completing the balance tests. However, your child may request to take a rest at anytime.

Are there any benefits to participating?

Your child will not get any personal benefit from being part of this study; however we hope to improve the way balance is assessed following a concussion to take better care of patients in the future.

Will my child be compensated for participating?

If your child participates, he/she will receive one \$5 Tim Horton’s gift card for each session that he/she completes in recognition of your time and effort.

What if my child gets injured?

In the event that your child suffers injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to your child. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will I be told about new information?

We will inform you of any new information that might influence your decision to continue to participate in this research project. We will ask you again if you want to be in the study. If this study uncovers information that might be helpful to your child’s current or future health, the investigator will provide this information to your child’s most responsible physician for follow-up. In the event of a positive depression screen, the principle investigator will be notified. We will offer that your child be seen at an emergency department and you will be provided with the phone number for a crisis line.

Will my child's records be kept private and confidential?

Your child's personal information will be kept strictly confidential. For this study we will be collecting gender and Date Of Birth (DOB) for the research purposes described in this consent form. Representatives from the CHEO research Ethics Board may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The data produced from this study will be stored in a secured locked location. Only members of the research team and the individuals described above will have access to the data. Following completion of the research study the data will be kept for 7 years after the last publication of this study. They will then be destroyed.

Any information that would indicate that a child was being harmed or at risk of such harm, would not be kept confidential and instead be disclosed as appropriate to offset that risk.

Your child will not be identified in any publication or presentation of this study.

A copy of the signed consent form will be provided to you.

Is the research team benefiting from the study?

The research team members are not benefiting personally, financially or in some other way from this study.

What if I have questions?

If you have any questions concerning participation in this study, or if at any time feel that your child has experienced a study-related injury, contact:

This study have been reviewed and approved by the CHEO Research Ethics Board. The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different professional backgrounds. The Board reviews all human research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at [REDACTED], although this person cannot provide health-related information about the study.

A summary of the results will be provided to you at the conclusion of the study if you desire.

Consent form signatures

By signing this consent form I agree that:

- I am voluntarily agreeing to participate in this research study;
- I understand the information within this consent form;
- All of the risks and benefits of participation have been explained to me;
- All of my questions have been answered;
- I allow access to my child's medical records and/or personal information as described in this consent form, and;
- I do not give up my legal rights by signing this form.

**Signature of Parent or
Guardian**

**Name of Parent or
Guardian**

Date

**Witness to Parent or
Guardian's Signature**

Name of Witness

Date

**Signature of person
Obtaining Informed Consent**

**Name of Person Obtaining
Informed Consent**

Date



Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better. In our study, we want to see how children and teenagers who had had a concussion maintain their balance. To do this, we also need to look at how children and teenagers like you, who have not had a concussion, maintain their balance.

Who will take part?

Children and teenagers who have had a concussion are being asked to join this study. Children and teenagers who have not had a concussion are also being asked to join this study. We expect to have 30 children and teenagers who have had a concussion and 60 children and teenagers who have not had a concussion to join the study over the next 6 months.

What will happen during the study?

If you decide to participate in this study, you will be asked to complete two 20-minute balance sessions. These sessions will take place at your school and will be completed three weeks apart. You will complete these sessions during school hours. During each session, you will first be asked to stand on the board for the game Wii Fit and to stand as still as you can for two minutes with your eyes open and with your eyes closed. After this, you will be asked to stand on the board again and we will ask you to complete three different games while you are standing. While you do this, there will be a headband placed around your head, a strap placed around your torso, and you will wear a pair of glasses.

Are there good things that can happen from this study?

Sometimes good things can happen to people when they are in a study. These good things are called "benefits". This study will help us better understand children who have had a head injury. That is a benefit. There are no other benefits that we think will happen to you if you decide to join this study.

Are there bad things that can happen from this study?

We do not think that anything bad would happen if you decide to join this study.

What if something bad happens?

If something does go wrong, the researchers will be there to take care of you.

Will I receive something for participating?

If you decide to participate, you will receive one 5\$ Tim Horton's gift card after completing the first session and you will receive a second 5\$ Tim Horton's gift card after you complete the second session.

Is this private?

We will keep your information private whether you decide to join this study or not.

Can I say no?

You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or the researchers if you no longer want to take part in this study. No one will be mad at you if you choose not to take part.

What if I have questions?

Please ask us and we will do anything we can to answer your questions.

Your parent may receive a summary of the results at the conclusion of the study if they wish so.

Assent form signatures

If you agree to participate in this research study, please sign the form.

I understand the information that was explained to me and I can ask any questions that I like about the study.

Signature of Participant

Name of Participant

Date

Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better. In our study, we want to see how children and teenagers who have experienced a concussion keep their balance. In order to complete our study, we also need to look at how children and teenagers like you, who have not experienced a concussion, maintain their balance.

Who will take part?

Children and teenagers who have and have not had a concussion are being asked to join this study. We expect to have 30 children and teenagers who have had a concussion and 60 children and teenagers who have not had a concussion participate in this study over the next 6 months.

What will happen during the study?

If you decide to participate in this study, you will be asked to complete two 20-minute sessions. These sessions will take place at your school and will be completed three weeks apart. You will complete these sessions during school hours. During each session, you will first be asked to stand as still as you can on the board for the game Wii Fit for two minutes with your eyes open and then with your eyes closed. After this, you will be asked to stand on the board again and we will ask you to complete three different games while you are standing. For these games, you will see the words “red”, “yellow”, “green” and “blue” on a screen or on a poster in front of you. Some of these words will be printed in the correct colour, like “red” printed in red. Other words will be printed in the incorrect colour, like “red” printed in blue. You will be asked to name the colour of the ink that the words are printed in or just to read the words. While you do this, there will be a headband placed around your head, a strap placed around your torso, and you will wear a pair of glasses.

Are there any benefits to participating?

You will not get any personal benefit from being part of this study; however this study will help us better understand children who have had a concussion.

Are there any risks to participating?

We do not think that anything bad would happen if you decide to join this study.

What if something bad happens?

If something does go wrong, the researchers will be there to take care of you.

Will I be compensated for participating?

If you decide to participate in this study, you will receive one 5\$ Tim Horton's gift card after completing the first balance testing session and you will receive a second 5\$ Time Horton's gift card after completing the second balance testing session.

Is this private?

We will keep your information private whether you decide to join this study or not.

Can I say no?

You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or the researchers if you no longer want to take part in this study. No one will be mad at you if you choose not to take part.

What if I have questions?

Please ask us and we will do anything we can to answer your questions.

Your parent may receive a summary of the results at the conclusion of the study if they wish so.

Assent form signatures

If you agree to participate in this research study, please sign the form.

I understand the information that was explained to me and I can ask any questions that I like about the study.

Signature of Participant

Name of Participant

Date



Protocol title: Balance Markers and Saccadic Eye Movement Parameters in Children and Adolescents with Concussion

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

You are being invited to join in a research study about the recovery of balance following a concussion. You are being invited to join this study because you have not had concussion in the last year. This will allow us to compare the maintenance of balance between children who have had a concussion and those that have not. Before agreeing to take part in this study, it is important that you read and understand this document.

Why is this study being done?

The purpose of our study is to learn more about balance problems and problems with eye movements following a concussion. This study will help determine if it is important to look at eye movements when testing balance.

How many children will participate?

We expect to have 30 children and adolescents with a diagnosed concussion and 60 children and adolescents who have not experienced a concussion participate. We expect to invite children and adolescents to participate for 6 months. This study is expected to be active for 8 months.

What will I be asked to do?

If you decide to participate in this study, you will be asked to complete two 20-minute sessions to be completed approximately 3 weeks apart. These sessions will take place at your school and will be completed during school hours. During these sessions, you will first be asked to stand on a Nintendo Wii Balance Board and to focus on standing as still as possible for two minutes with your eyes open and with your eyes closed. You will then be asked to stand on the Nintendo Wii Balance Board and to complete three different cognitive tasks. For these tasks, you will be presented with a series of the words "red", "yellow", "green" and "blue" printed in the correct or incorrect colour. For example, you could see the word "red" printed in red or printed in an incorrect colour like blue. You will be asked to either read the words or to name the colour of the ink that each word is printed in. While you complete these tasks, a headband that measures

the accelerations of your head movements will be placed around your head, a strap that measures the accelerations of the movements of your torso will be placed around your torso, and you will be asked to wear a pair of glasses that records eye movements.

Are there any risks to participating?

There is very little risk in participating in this study. At most, you may become tired while completing the balance tests. However, you may request to take a rest at anytime.

Are there any benefits to participating?

You will not get any personal benefit from being part of this study; however we hope to improve the way balance is assessed following a concussion to take better care of patients in the future.

Am I obligated to participate in this study?

You are under no obligation to participate and if you choose to participate, you can withdraw from the study at any time and there will be no penalty or consequences. If you choose to withdraw, all data gathered until the time of withdrawal will be destroyed.

Will I be compensated for participating?

If you decide to participate in this study, you will receive one 5\$ Tim Horton's gift card after completing the first balance testing session and you will receive a second 5\$ Time Horton's gift card after completing the second balance testing session.

What if I get injured?

In the event that you suffer injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to you. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will my records be kept private and confidential?

Your personal information will be kept strictly confidential. For this study we will be collecting gender and Date Of Birth (DOB) for the research purposes described in this consent form. Representatives from the CHEO research Ethics Board may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The data produced from this study will be stored in a secured locked location. Only members of the research team and the individuals described above will have access to the data. Following completion of the research study the data will be kept for 7 years after the last publication of this study. They will then be destroyed.

You will not be identified in any publication or presentation of this study.

A copy of the signed consent form will be provided to you.

The research team members are not benefiting personally, financially or in some other way from this study.

If you have any questions concerning participation in this study, or if at any time feel that you have experienced a study-related injury, contact:

A summary of the results will be provided to you at the conclusion of the study if you desire.

By signing this consent form I agree that:

- I am voluntarily agreeing to participate in this research study;
- I understand the information within this consent form;
- All of the risks and benefits of participation have been explained to me;
- All of my questions have been answered;
- I allow access to my personal information as described in this consent form, and;
- I do not give up my legal rights by signing this form.

We believe that the data gathered for this study are very important. We would like to continue doing further research to learn more about balance problems following a concussion. We would like to use the data collected for this study to answer additional research questions. We may collaborate with researchers at other sites for future studies; however, the data would not contain any information that could identify you. We would like your permission to use this data for future research studies.

 Yes, I agree to the use of my research data in future studies

☐ No, only use my research data for this study

Signature of Participant

Name of Participant

Date

**Witness to Participant's
Signature**

Name of Witness

Date

**Signature of person
Obtaining Informed Consent**

**Name of Person Obtaining
Informed Consent**

Date



uOttawa



Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

Principal investigator: [REDACTED]

Address: [REDACTED]
[REDACTED]

Telephone number: [REDACTED]

Primary University of Ottawa investigator: [REDACTED]

You are being invited to join in a research study about the recovery of balance following a concussion. You are being invited to join this study because your child has not had a concussion in the last year. This will allow us to compare the maintenance of balance between children who have had a concussion and those that have not. Before agreeing to take part in this study, it is important that you read and understand this document.

Why is this study being done?

The purpose of this study is to learn more about balance problems and problems with eye movements following a concussion. This study will help determine if it is important to look at eye movements when testing balance.

How many children will participate?

We expect to have 30 children and adolescents who have had a concussion and 60 children and adolescents who have not had a concussion to participate. We expect to invite children and adolescents to participate for 6 months. This study is expected to be active for 8 months.

What will my child be asked to do?

If you decide to participate in this study, your child will be asked to complete two 20-minute sessions to be completed approximately 3 weeks apart. These sessions will take place at your child's school and will be completed during school hours. During these sessions, your child will first be asked to stand on a Nintendo Wii Balance Board and to focus on standing as still as possible for two minutes with their eyes open and with their eyes closed. Your child will then be asked to stand on the Nintendo Wii Balance Board and to complete three different cognitive tasks. For these tasks, your child will be presented with a series of the words "red", "yellow", "green" and "blue" printed in the correct or incorrect colour. For example, the word "red" could be printed in red or printed in an incorrect colour like blue. Your child will be asked to either read the words or to name the colour of the ink that each word is printed in. While your child completes these tasks, a headband that measures head movement accelerations will be placed around your child's head, a strap that measures accelerations of the torso will be placed

around your child's torso, and your child will be asked to wear a pair of glasses that records eye movements.

Are there any risks to participating?

There is very little risk in participating in this study. At most, your child may become tired while completing the balance tests. However, your child may request to take a rest at anytime.

Are there any benefits to participating?

Your child will not get any personal benefit from being part of this study; however we hope to improve the way balance is assessed following a concussion to take better care of patients in the future.

Is my child obligated to participate?

Your child is under no obligation to participate and if he/she chooses to participate, he/she can withdraw from the study at any time and there will be no penalty or consequences. If he/she chooses to withdraw, all data gathered until the time of withdrawal will be destroyed.

Will my child be compensated for participating?

If your child participates, he/she will receive one 5\$ Tim Horton's gift card after completing the first balance testing session and will receive a second 5\$ Time Horton's gift card after completing the second balance testing session.

What if my child gets injured?

In the event that your child suffers injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to your child. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will my child's records be kept private and confidential?

Your child's personal information will be kept strictly confidential. For this study we will be collecting gender and Date Of Birth (DOB) for the research purposes described in this consent form. Representatives from the CHEO research Ethics Board may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The data produced from this study will be stored in a secured locked location. Only members of the research team and the individuals described above will have access to the data. Following completion of the research study the data will be kept for 7 years after the last publication of this study. They will then be destroyed.

Your child will not be identified in any publication or presentation of this study.

A copy of the signed consent form will be provided to you.

Is the research team benefiting from the study?

The research team members are not benefiting personally, financially or in some other way from this study.

What if I have questions?

If you have any questions concerning participation in this study, or if at any time feel that you have experienced a study-related injury, contact:

This study have been reviewed and approved by the CHEO Research Ethics Board. The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different professional backgrounds. The Board reviews all human research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board, for information regarding patient's rights in research studies at _____, although this person cannot provide health-related information about the study.

A summary of the results will be provided to you at the conclusion of the study if you desire.

Consent form signatures

By signing this consent form I agree that:

- I am voluntarily agreeing to participate in this research study;
- I understand the information within this consent form;
- All of the risks and benefits of participation have been explained to me;
- All of my questions have been answered;
- I allow access to my child's personal information as described in this consent form, and;
- I do not give up my legal rights by signing this form.

Acceptance: I, _____ agree to allow my child _____ to participate in the research study described above.

There are two copies of this consent form provided – please keep one for your own records.

We believe that the data gathered for this study are very important. We would like to continue doing further research to learn more about concussions. We would like to use the data collected for this study to answer additional research questions related to concussions. We may collaborate with researchers at other sites for future concussion research studies; however, the data would not contain any information that could identify you. We would like your permission to use this data for future concussions studies.

_____ **Yes, I agree to the use of my research data in future studies related to concussion**

_____ No, only use my research data for this study

Signature of Parent or
Guardian

Name of Parent or
Guardian

Date

Witness to Parent or
Guardian's Signature

Name of Witness

Date

Signature of person
Obtaining Informed Consent

Name of Person Obtaining
Informed Consent

Date

APPENDIX C

Ethics approval certificates

Principal Investigator: [REDACTED]
REB Protocol No: 13/94X
Romeo File No: 20130258
Project Title: CHEOREB#13/94X - Predicting Persistent Postconcussive Problems in Pediatrics: A Clinical Prediction Rule Derivation and Validation Study
Primary Affiliation: Clinical Research\Emergency
Protocol Status: Active

Date Modifications Approved: February 18, 2015

Documents Reviewed & Approved:

Document Name	Comments	Version Date
Assent Form	Assent form control group 8-11 years of age - Version date: December 9, 2014, Amendment #3	2014/12/09
Assent Form	Assent form mTBI group 8-11 years of age - Version date: December 9, 2014, Amendment #3	2014/12/09
Assent Form	sub-study assent control (12-15 years of age)	2014/12/09
Assent Form	sub-study assent mTBI (12-15 years of age)	2014/12/09
Consent Form	sub-study Parent consent control	2014/12/09
Consent Form	sub-study Parent consent mTBI	2014/12/09
Consent Form	study Participant consent control (16 and 17 years of age)	2014/12/09
Consent Form	study Participant consent mTBI (16 and 17 years of age)	2014/12/09
Consent Form	5P consent version 6	2014/12/09

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval for the modifications to the above named research study. The minor modification was reviewed and approved by the Chair, and would be ratified by the full Board at its subsequent meeting. In fulfilling its mandate, the CHEO REB is guided by: Tri-Council Policy Statement (TCPS); ICH Good Clinical Practice Practices: Consolidated Guideline; Applicable laws and regulations of Ontario and Canada (e.g., Health Canada Division 5 of the Food and Drug Regulations & the Food and Drugs Act - Medical Devices Regulations).

Approval is granted with the understanding that the investigator agrees to comply with the following requirements:

- 1 The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
- 2 The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB except where necessary to eliminate an immediate hazard to the research subject, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff). As soon as possible, however, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted to the Board for review.
- 3 The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.
- 4 For clinical drug or device trials, investigators must promptly report to the REB all adverse events that are both serious and unexpected (SAEs). For SAE reports on CHEO patients, the investigator must also comply with the hospital-wide Policy regarding, Procedures For Considering Medical Error In The Differential Diagnosis of Severe Adverse Events (SAE) Associated with the Drugs Administered in a Clinical Trial (see http://cheonet/data/1/rec_docs/3792_Medical%20Error%20Policy%20revised%20january%2020061.doc).
- 5 For all other research studies, investigators must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
- 6 Investigators must promptly report to the REB any new information regarding the safety of research subjects (e.g., changes to the product monograph or investigator's brochure for drug trials). Where available, any reports produced by Data Safety Monitoring Board should be submitted to the REB.
- 7 Investigators must notify the REB of any study closures (temporary, premature or permanent), in writing along with an explanation of the rationale for such action.
- 8 Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated on the final approval letter.
- 9 Investigators must submit a final report at the conclusion of the study.
- 10 Investigators must provide the Board with French version of the consent form, unless a waiver has been granted.

The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.

If you have any questions, pertaining to this letter, please contact Natalie

[REDACTED]

Regards,

[REDACTED]

Chair, Research Ethics Board
Présidente, Comité d'éthique de la recherche

4 [REDACTED]



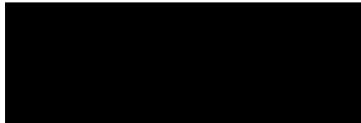
Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

Ethics Approval Notice

Health Sciences and Science REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

<u>First Name</u>	<u>Last Name</u>	<u>Affiliation</u>	<u>Role</u>
		Medicine / Medicine	Principal Investigator
		Health Sciences / Occupational Therapy	Co-investigator
		Health Sciences / Human Kinetics	Co-investigator

File Number: H03-14-23

Type of Project: Professor

Title: Predicting Persistent Postconcussive Problems in Pediatrics: A Clinical Prediction Rule Derivation and Validation Study

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
04/28/2014	04/27/2015	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:

N/A



Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

This is to confirm that the University of Ottawa Research Ethics Board identified above, which operates in accordance with the Tri-Council Policy Statement (2010) and other applicable laws and regulations in Ontario, has examined and approved the ethics application for the above named research project. Ethics approval is valid for the period indicated above and subject to the conditions listed in the section entitled "Special Conditions / Comments".

During the course of the project, the protocol may not be modified without prior written approval from the REB except when necessary to remove participants from immediate endangerment or when the modification(s) pertain to only administrative or logistical components of the project (e.g., change of telephone number). Investigators must also promptly alert the REB of any changes which increase the risk to participant(s), any changes which considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project and safety of the participant(s). Modifications to the project, including consent and recruitment documentation, should be submitted to the Ethics Office for approval using the "Modification to research project" form available at: <http://www.research.uottawa.ca/ethics/forms.html>.

Please submit an annual report to the Ethics Office four weeks before the above-referenced expiry date to request a renewal of this ethics approval. To close the file, a final report must be submitted. These documents can be found at: <http://www.research.uottawa.ca/ethics/forms.html>.

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5387 or by e-mail at: ethics@uOttawa.ca.

Signature:



Protocol Officer for Ethics in Research
For Daniel Lagarec, Chair of the Sciences and Health Sciences REB



RESEARCH INSTITUTE
INSTITUT DE RECHERCHE

CHEO Research Ethics Board Approval - Delegated Review

Principal Investigator: [REDACTED]

REB Protocol No: 16/173X

Romeo File No: 20160559^[L]_[SEP] **Project Title:** CHEOREB# 16/173X -
Prediction Model for Balance Performance at One-Month Post-
Concussion in Children and Adolescents

Primary Affiliation: Clinical Research\Emergency

Protocol Status: Active

Approval Date*: January 30, 2017

Valid Until:** January 15, 2018

Annual Renewal Submission Deadline: 15 December 2017

Documents Reviewed & Approved:

Document Name	Comments	Version Date
Assent Form	Assent form 12-15 years of age clean version	2017/01/18
Assent Form	Assent form 8-11 years of age clean version	2017/01/18
Consent Form	Parent consent form clean version	2017/01/18
Consent Form	Participant consent form clean version	2017/01/18
Other Document	Participant data sheet	2016/11/15
Protocol	Protocol clean version	2017/01/18
Questionnaire/Survey	Injury report clean version	2017/01/18
Questionnaire/Survey	Post-concussion symptom inventory 8-12 years of age	2017/01/18

Questionnaire/Survey	Impact location grid clean version	2017/01/18
Questionnaire/Survey	Post-concussion symptom inventory 13-18 years of age	Received 1/20/2017

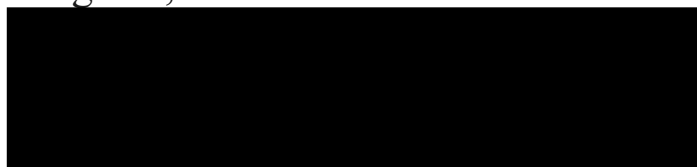
This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed under the delegated review stream, which is reserved for projects that involve no more than minimal risk to human subjects.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

- 11 The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
- 12 Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated above.
- 13 The investigator must not implement any deviation from, or changes to, the protocol, consents or assents without the approval of the REB.
- 14 The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.
- 15 Investigators must provide the Board with French versions of the consent form, unless a waiver has been granted. An interpreter should be offered to participants as required or at the request of the participant throughout the course of research.
- 16 The investigator must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
- 17 Investigators must notify the REB of any study closures (closed to accrual, temporary, premature or permanent).
- 18 Investigators must submit a final report at the conclusion of the study.

Should you have any questions or concerns, please do not hesitate to contact the Research Ethics Board Office at [613-737-7600](tel:613-737-7600) ext. 3350 or 2128.

Regards,



, PhD^[SEP]Chair, Research Ethics Board^[SEP]Président,
 Comité d'éthique de la recherche^[SEP]*The final approval date for initial
 delegated study applications approved with or without modifications
 will be the date the REB has determined that the conditions of approval
 have been satisfied.^[SEP]**The expiry date of REB approval for initial
 study application that required no modifications will be as follows:^[SEP]• If
 the date of review and approval was **on or before** the 15th of the month,
 the expiry date will be the 15th of the month prior to the date of review
 and approval by the Chair and/or delegate *in the following year*; ^[SEP]• If
 the date of review and approval was **after** the 15th the expiry date will
 be the 15th of the month in which the date of review and approval by the
 REB *in the following year*.^[SEP]The expiry date of REB approval for
 initial study applications that **require modifications** will be as
 follows:^[SEP]• If the initial feedback was sent **on or before** the 15th of the
 month, the expiry date will be the 15th of the month prior to the date the
 letter of REB feedback is issued to the investigator(s) *in the following*
year; ^[SEP]• If the initial feedback was sent **after** the 15th the expiry date
 will be the 15th of the month in which the feedback was sent *in the*
following year



RESEARCH INSTITUTE
INSTITUT DE RECHERCHE

[L]
[SEP]

CHEO Research Ethics Board Approval - Delegated Review

Principal Investigator: [REDACTED]

REB Protocol No: 16/132X

Romeo File No: 20160439 [L]
[SEP] **Project Title:** CHEOREB# 16/132X -

Balance markers and saccadic eye movement parameters in children and adolescents with concussion

Primary Affiliation: Clinical Research\Nursing

Protocol Status: Active

Approval Date*: December 15, 2016

Valid Until:** October 15, 2017

Annual Renewal Submission Deadline: 15 September

2017 [L]
[SEP] **Documents Reviewed & Approved:**

Document Name	Comments	Version Date
Assent Form	Assent 12-15 years of age Control group	2016/11/15
Assent Form	Assent 8-11 years of age Control group	2016/11/15
Assent Form	Assent Concussion group 12-15 years of age	2016/11/15
Assent Form	Assent Concussion group 8-11 years of age	2016/11/15
Consent Form	Parent consent form	2016/12

		/14
Consent Form	Participant consent form	2016/12/14
Consent Form	Parent consent Concussion group	2016/11/15
Consent Form	Participant consent Concussion group	2016/11/15
Other Document	Participant data sheet control group	2016/09/15
Other Document	Participant data sheet concussion group	2016/09/15
Protocol	Protocol	2016/11/15
Questionnaire /Survey	Injury report	2016/09/15
Questionnaire /Survey	Kutcher adolescent depression scale questionnaire	2016/09/15
Questionnaire /Survey	Impact location grid	2016/09/15
Questionnaire /Survey	Generalised anxiety disorder assessment questionnaire	2016/09/15
Questionnaire /Survey	Pediatric vestibular questionnaire	2016/09/15
Questionnaire /Survey	Post-Concussion Symptoms Inventory (13-18 years of age)	2016/09/15
Questionnaire /Survey	Post-Concussion Symptoms Inventory (8-12 years of age)	2016/09/15

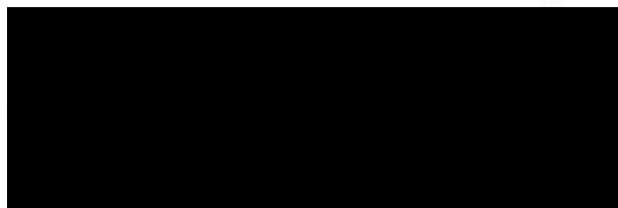
This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed under the delegated review stream, which is reserved for projects that involve no more than minimal risk to human subjects.

Final approval is granted for the above noted study, with the

understanding that the investigator agrees to comply with the following requirements:

- 19 The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
 - 20 Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated above.
 - 21 The investigator must not implement any deviation from, or changes to, the protocol, consents or assents without the approval of the REB.
 - 22 The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.
 - 23 Investigators must provide the Board with French versions of the consent form, unless a waiver has been granted. An interpreter should be offered to participants as required or at the request of the participant throughout the course of research.
 - 24 The investigator must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
 - 25 Investigators must notify the REB of any study closures (closed to accrual, temporary, premature or permanent).
 - 26 Investigators must submit a final report at the conclusion of the study.
- Should you have any questions or concerns, please do not hesitate to contact the Research Ethics Board Office at [613-737-7600 ext. 3350](tel:613-737-7600) or 2128.

Regards,



Ph.D. [LSEP] Interim Chair, CHEO Research Ethics

Board [LSEP]

[LSEP]*The final approval date for initial delegated study applications approved with or without modifications will be the date the REB has determined that the conditions of approval have been satisfied. [LSEP]*The expiry date of REB approval for initial study application that required no modifications

will be as follows:^[SEP]• If the date of review and approval was **on or before** the 15th of the month, the expiry date will be the 15th of the month prior to the date of review and approval by the Chair and/or delegate *in the following year*; ^[SEP]• If the date of review and approval was **after** the 15th the expiry date will be the 15th of the month in which the date of review and approval by the REB *in the following year*.^[SEP]^[SEP]The expiry date of REB approval for initial study applications that **require modifications** will be as follows:^[SEP]• If the initial feedback was sent **on or before** the 15th of the month, the expiry date will be the 15th of the month prior to the date the letter of REB feedback is issued to the investigator(s) *in the following year*; ^[SEP]• If the initial feedback was sent **after** the 15th the expiry date will be the 15th of the month in which the feedback was sent *in the following year*.