DETECTING GAIT IMBALANCE FOLLOWING CONCUSSION USING AN INERTIAL MEASUREMENT UNIT

by

Will Pitt

A DISSERTATION

Presented to the Department of Human Physiology
and the Graduate School of the University of Oregon
in partial fulfillment of the requirements
for the degree of
Doctor of Philosophy

September 2019

DISSERTATION APPROVAL PAGE

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Title: Detecting Gait Imbalance following Concussion using an Inertial Measurement Unit

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Degree awarded September 2019.

DISSERTATION ABSTRACT

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Concussion injury is shown to result in acutely impaired dynamic balance control. This impairment can last as long as two months post injury as evidenced by biomechanical metrics derived from data collected during dual-task (DT) gait using camera-based motion capture system. However, clinical application of such DT gait balance control with advanced kinematic analysis is yet limited. To advance the clinical translation of the laboratory findings to clinical practice, four studies were conducted to assess the utility of an inertial measurement unit (IMU) to detect gait imbalance following concussion. In the first study, a highly consistent and reliable DT assessment was developed using off the shelf hardware and software. Acceleration based kinematic markers collected from a single IMU placed over the fifth lumbar vertebra (L5) demonstrated potential for detecting subtle changes in gait balance control at a university sport medicine facility. In the second study the DT gait balance control of individuals sustaining an acute concussion was analyzed with the assessment and compared to that of healthy matched controls over a two month post injury period. Multiple-gait event specific accelerations and angular velocities collected from the L5 sensor were capable of detecting impaired gait balance control. In the third study, logistic regression models

including groups of between three and six kinematic and neurocognitive metrics collected from both straight and turning gait were shown to have high sensitivity (Sn) and specificity (Sp) in distinguishing acutely concussed from healthy individuals. Furthermore, these models maintained moderate Sn and Sp throughout the two month post injury period suggesting they are capable of identifying individuals with lingering balance control deficits. In the fourth study, the utility of dual-task cost (DTC) metrics derived from the kinematic and neurocognitive measures was assessed for post-concussion gait imbalance detection. It was determined that due to high levels of variability inherent to the metrics in this application, their utility in gait imbalance detection is limited, and are similarly unable to be used to describe differences or changes in task prioritization.

This dissertation includes co-authored work either previously published or unpublished.

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Pitt W. & Chou L.S. (2019). Gait Balance Control in Veterans with Chronic Symptoms Following mTBI. *Gait & Posture.* (In Review).

Pitt W. & Chou L.S. (2019). Reliability and Practical Clinical Application of an Accelerometer-Based Dual-Task Gait Balance Control Assessment. *Gait & Posture. 71,* 279-283.

Fino P.C., Parrington L, Pitt W., Martini D.N., Chesnutt J.C., Chou L.S., & King L.A. (2018). Detecting Gait Abnormalities after Concussion of Mild Traumatic Brain Injury: A Systematic Review of Single-Task, Dual-Task, and Complex Gait. *Gait & Posture. 62*,157-166.

Teyhen D.S., Pitt W.J., Bujak B.K., Miller C.N., Sela K.M., Moore J.H. (2008). Morphometry of the Vastus Medialis Muscle in Subjects with Patellofemoral Pain Syndrome using Ultrasound Imaging. *Journal of Orthopedic and Sports Physical Therapy, 38(1),* A41.

ACKNOWLEDGEMENTS

Completion of this degree program marks the culmination and highlight of my profession and educational careers to this point and by no means was it accomplished without assistance. I would like to take this opportunity to thank the many people who assisted and inspired me along this decade's long journey. First and foremost I would like to thank my parents, Kim and Tassoula Pitt, who instilled in me at an early age the importance of education and supported me as I first entered higher education.

During my first stint in graduate education at the Army/Baylor University Physical Therapy Program, I was greatly influenced by two faculty members. Colonel Joseph Molloy, my advisor, had a contagious geniality and optimism, while Colonel Deydre Teyhen provided mentorship as a junior researcher and guidance in my long path toward this degree.

I also owe much to my doctoral advisor, Dr. Li-Shan Chou, who gladly accepted me into his lab and accommodate the many demands of my military directed training guidelines. His assistance in all stages of my research was immense and his collaborative efforts will continue to benefit me for years to come. Other members of the Motion Analysis Laboratory were also of great assistance. Many thanks to the undergraduate research assistants, Emma Silverman, Haley Segelke, Ravahn Enayati, and Spencer Smith, as well as the graduate students Michael Utter, Quinn Peterson, JJ Hannigan, and Frankie Qu. I would like to offer particular thanks to graduate student colleague, Teresa Chen, as she acted as my nearly daily sounding board and statistical mentor.

I would also like to thank the members of my dissertation committee, Dr. Anita

Christie, Dr. Craig Davidson, Dr. Louis Osternig, and Dr. Paul Dassonville for their assistance and guidance with this project.

Beyond the lab and University, there are countless friends that supported me along the way. But one who has always been in my corner and continues to support me is my former partner Katie Pitt. Her unwavering support in the face of numerous hardships and trials was and continues to be inspiring. Furthermore, her selfless dedication to the care of our children is unmatched and allowed me to focus on my graduate studies. Our two children, Lily and Brysen are the inspiration and love of my life, and I can truly say I would not be here today without them.

Finally, I was financially supported in this endeavor by the United States Army Medical Department Long Term Health Education Training Fellowship. This investigation was also supported in part by the Department of Defense (AMEDD Advanced Medical Technologies Initiative Award No. W911QY-16-A-0014-0016), the American College of Sports Medicine (ACSM Foundation Doctoral Research Fellowship), the Eugene and Clarissa Evonuk Memorial Graduate Fellowship, the Shapiro Family Scholarship, and the Jan Broekhoff Graduate Scholarship.

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CHAPTER I

INTRODUCTION

Some material presented in this chapter was published in volume 62, of the journal *Gait & Posture* in 2018. Peter Fino, Lucy Parrington, and Will Pitt are co-primary authors. Douglas Martini, James Chesnutt, Li-Shan Chou, and Laurie King are additional co-authors. Dr. Peter Fino, Dr. Lucy Parrington, and Will Pitt all contributed to the concept, review of literature, grading of relevant articles, and preparation of the manuscript. Dr. Douglas Martini, Dr. James Chesnutt, Dr. Li-Shan Chou, and Dr. Laurie King contributed to the concept, editorial support, and review/revision of the manuscript. Citation:

Fino PC, Parrington L, Pitt W, et al. Detecting Gait Abnormalities after Concussion of Mild Traumatic Brain Injury: A Systematic Review of Single-Task, Dual-Task, and Complex Gait. *Gait & Posture*. 2018; 62:157-166.

Background and Significance

Concussion, often referred to as mild traumatic brain injury (mTBI), continues to occur at high rates in athletics and military service. In the United States, nearly 20,000[1] injures occur in military service and as many as 300,000 in contact-sports[2] annually. The high incidence is concerning as the injury can lead to adverse sequela such as second impact syndrome[3], musculoskeletal injury[4], subsequent concussive injury[5], chronic symptom development[6–9], and degenerative neurologic disorders[10]. In the military it may further lead to reduced operational readiness through a reduction in perceived readiness[11], increased occupational mishaps[12], and substance abuse comorbidities[9]. The breadth and

severity of post-injury consequences highlight the need for readily available objective clinical assessment tools to ensure accurate and timely detection, proper rehabilitation management, and objectively informed return to activity (RTA) decision making.

Although evaluation methods continue to improve, there remain significant limitations in many of the most commonly employed testing instruments. The Military Acute Concussion Assessment (MACE) loses sensitivity if not applied within 12 hours of injury and has mediocre diagnostic accuracy with sensitivity and specificity of .66 and .61 respectively[13]. The Automated Neuropsychological Assessment Metric (ANAM) has a similar temporal loss of diagnostic utility if administered more than 10 days post injury[14]. The Immediate Post-Concussion Assessment Tool (ImPACT), widely considered the standard in computerized neurocognitive assessments, may be susceptible to invalid baseline assessments[15], attentional and learning difficulties[16] and sandbagging[17]. Furthermore, computer based neurocognitive assessments are highly time and equipment intensive and tend to normalize within a week post injury. Arguably the most widely used assessment in athletics, the Standardized Concussion Assessment Tool (SCAT5) relies on a subjective symptom self-report and simple static balance metrics, both of which are shown to resolve within one to two weeks[18,19].

As a result of the limitations in available clinical assessments most injured athletes and military Service Members (SMs) return to full unrestricted activity within two weeks of injury. However, recent evidence indicates acutely concussed individuals continue to display gait balance impairments when performing a concurrent cognitive task (dual-task [DT]) as long as two months after injury[20,21]. Furthermore, the balance deficit worsens immediately after RTA suggesting incomplete recovery of dynamic gait

balance control[22,23], which may lead to delayed recovery, increased risk for further injury, long-term impairments, and disability.

Dual-Task Paradigm

Developed over the past 15 to 20 years, assessment of dynamic gait balance control while executing a concurrent cognitive task was initially applied to elderly fall risk prevention research. The paradigm is based on the limited capacity[24] and/or the bottleneck[25] cognitive processing theories. The limited capacity theory describes an individual's attentional, or information processing capacity as finite. Multiple cognitive processes are therefore unable to proceed simultaneously due to a limitation in processing resources. The bottleneck theory, suggests components of multiple cognitive processes utilize the same processing pathways, forcing tasks to wait on each other to complete their transit through a particular pathway before being allowed to proceed.

Simple steady-state gait is often considered a largely automated process, controlled through subcortical locomotor processing with little executive control in healthy individuals[26]. Despite this automaticity, higher level cognitive processes involved in sensory perception and integration are required to continuously fine tune the motor plan. According to the theories of cognitive processing, the combination of a cognitive task with dynamic locomotion either exceeds available attentional resources, or the two tasks become bottlenecked as they compete for the same pathways. Individuals with impaired balance or cognition may thus experience performance decrements in one or both tasks[27]. Some evidence suggests healthy individuals are able to selectively allocate attentional resources without sacrificing postural control, indicating a possible hierarchy

in attentional tasks with postural control being prioritized[28]. However, in multiple studies involving elderly individuals, both cognitive task performance and balance control were affected suggesting this ability is diminished in individuals with impaired neuromuscular control[27,29,30]. As individuals sustaining a concussion report symptoms in both cognitive and balance domains, it is reasonable to suggest a DT paradigm may help illuminate dynamic gait balance impairments.

There is mounting evidence for the utility of DT testing in concussion management[31]. As a method for detecting subtle neurological impairments following injury[32], it may provide insight into the ability to multitask in everyday activities and prove to be a more reliable assessment for determining RTA readiness. The utility of the DT paradigm is also gaining increased attention among Department of Defense (DoD) researchers as evidenced by a recent push to develop functional RTA assessment batteries including DT activities[33]. Extensive virtual reality systems have been used to present real-life, duty-specific testing scenarios[33]. A functional assessment battery, the Assessment of Military Multitasking Performance (AMMP) is also being developed[34]. The battery includes numerous military occupational specialty specific tasks, many of which combine motor and cognitive tasks: patrol-exertion, charge of quarters duty, run-roll-aim, ISAW-GRID (DT), Illinois agility-packing list (DT), load magazine-radio chatter (DT). The assessment is promising and highly functional but is time intensive, task specific, and has yet undetermined construct validity.

Various secondary cognitive tasks are utilized in DT gait research including the visual and auditory Stroop, various question and answer (Q&A) batteries, the Brooks mental task, verbal fluency tests, and simple reaction time tests[35]. Originally designed in

the 1930's[36], the Stroop test consists of the words red, blue, green, brown, and purple printed in rows and columns. Each word appears twice in each column and row, no word succeeds itself in row or column, and no word appears in the color ink it named. Subjects are instructed to report the color rather than the word on the sheet as fast as possible and told to correct errors as they are made. The test is categorized as a selective attention task based on the flanker effect[25] where the irrelevant color-word information slows down the correct naming of the color. The application of a visual Stroop test in gait analysis is impractical as vision is heavily employed by healthy individuals to maintain dynamic balance control during walking. Occupying this sensory system with a visual cognitive task would in itself produce an altered gait pattern.

Fortunately, an auditory version was created by Morgan and Brandt[37], providing a feasible secondary task for use in a DT gait paradigm. The test consists of four stimuli, the words "High" and "Low" spoken in a high or a low pitch (Table 1.1). Stimuli are either congruent (word matches the pitch spoken) or incongruent (word does not match the pitch spoken).

Table 1.1. Four stimuli utilized in the auditory Stroop task, listed by word spoken, in which pitch it was spoken, and whether or not the meaning of the word and pitch spoken were congruent.

Word Spoken	Pitch Spoken	Congruency
High	Low	No
High	High	Yes
Low	Low	Yes
Low	High	No

Subjects are required to identify the pitch spoken rather than the meaning of the word. Morgan and Brandt found a similar "Stroop" effect to the visual version, and

determined there was no effect of ear of presentation suggesting the dominant linguistic hemisphere does not result in a difference in processing time. As such, protocols using this assessment may be standardized to a single ear. Metrics commonly collected during this task include reaction time and accuracy. Dual-task cost (DTC) may also be calculated as the difference in reaction time and/or accuracy between single- and DT conditions.

Another task demonstrating utility in the DT gait paradigm is a series of Q&As. Questions commonly used include spelling a five letter word backward, counting backward from a give number by sixes or sevens, or reciting the months of the year in reverse order. Many studies utilizing these tasks have demonstrated a greater effect in DTC than the auditory Stroop, believed to be due to the increased complexity of the task. fMRI studies indicate these tasks are more complex, requiring the coordination of multiple brain regions[38,39]. The increased complexity of arithmetic and spelling tasks have also been correlated with decreased gait balance control[40]. Outcome variables collected for this task include test accuracy and DTC in accuracy.

Gait Balance Assessment with Whole Body Center of Mass Kinematics

Best-practice statements recommend balance testing as a critical component in the clinical examination of concussion[41,42]. As such gait balance assessments have been explored for use in concussion diagnosis and management. Numerous studies report gait abnormalities in both simple and complex gait[35]. Altered gait characteristics include gait velocity, stride length, stride width, stride time, and double support time, all of which can be assessed with currently available clinical instruments. While impairments in temporal distance gait metrics are consistently identified in acutely injured individuals, the metrics

lack sensitively to prolonged gait balance control deficits as they tend to normalize within 10 days[21,43–50].

In previous prospective, longitudinal studies of various whole body center of mass (COM) kinematic measures were used to identify persistent gait balance control deficits in concussed subjects despite earlier resolution of temporal distance gait parameters[20,22,23,40,48]. Whole body COM metrics are traditionally derived from camera-based motion capture using a full-body reflective marker set[20]. The position of the COM is then calculated as the weighted sum of a multi-segment linked system using anthropometric data[51]. COM metrics include total Medial-Lateral (M-L) displacement, peak M-L velocity, Anterior-Posterior (A-P) peak velocity, and maximum horizontal separation between the COM and center of pressure (COP) in the A-P and M-L directions[20,40,43,44,47,48,52,53]. In one study peak anterior velocity, peak M-L velocity, and total M-L displacement distinguished acutely concussed from healthy subjects[20]. Furthermore, the metrics continued to be sensitive to lingering deficits in dynamic control over a two month post injury period. The differences noted in COM position and velocity may be due to poor momentum control resulting from deficits in regulating COM acceleration, which may compromise an individual's ability to successfully perform physical activities efficiently and accurately. A previous study showing COM acceleration differences between individuals with and without functional limitations[54] supports this conclusion and suggests measurement of COM acceleration may help to illuminate balance control mechanisms during daily activities, and facilitate detection of balance impairments.

Wearable Sensor Technology - Inertial Measurement Units

Until recently clinical biomechanical analysis was not feasible due to exorbitant costs associated with equipment and extensive expertise required to both perform assessments and analyze results. Although there are recent applications of clinically directed gait analysis instruments, they are not ubiquitous and largely offer only basic temporal distance metrics. Fortunately, recent advances in wearable sensor technology have led to numerous wearable sensor options that coupled with convenient clinical software packages offer basic biomechanical analysis at an accessible price. Many of these devices incorporate multiple sensors such as tri-axial accelerometers, gyroscopes and magnetometers and are broadly described as inertial measurement units (IMU). As a relatively new technology, software packages focus primarily on basic gait parameters such as gait velocity, cadence, step length, step width, and step count. As previously described, these metrics lack the sensitivity to detect persistent changes in gait balance control.

A recent study utilizing a single wearable accelerometer examined side-to-side and front-to-back acceleration characteristics from a single accelerometer placed over the L5 vertebrae as a proxy for the whole body COM[21]. Concussed individuals were examined during DT walking over the course of five testing times from 72 hours to two months post injury. The results revealed concussed subjects displayed less side-to-side acceleration than controls during the transition from the single- to double-support phases of the gait cycle (**Figure 1.1**; Peak Acceleration 3) throughout the two month post-injury period. This suggests concussion may affect the ability to regulate side-to-side COM momentum control. The findings also showed peak acceleration 3 data effectively

discriminated concussion participants from controls within 72 hours and at two weeks post-injury and demonstrated potential for using accelerometry as an efficient and accurate tool for clinicians to monitor gait balance control following concussion. The study also demonstrated data obtained from a wearable accelerometer are comparable to camera-based systems for detecting gait imbalance in concussion patients.

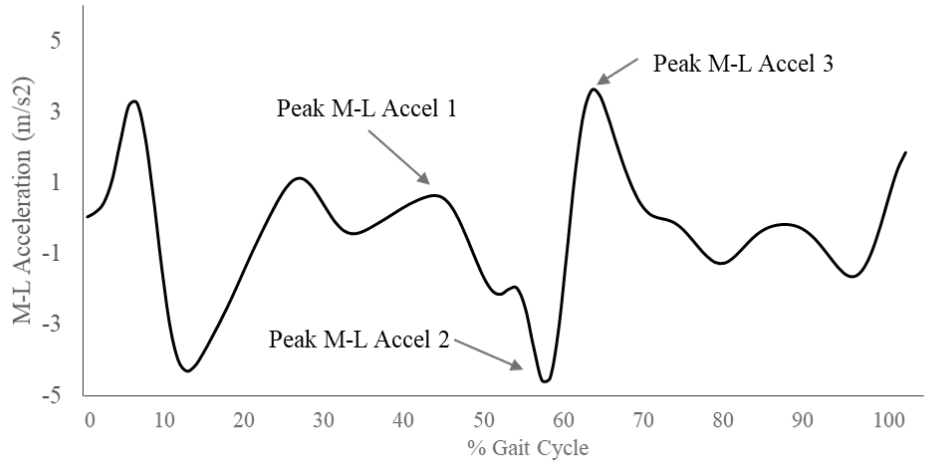

Figure 1.1. Exemplary profile for medial-lateral center of mass acceleration across a single gait cycle.

Knowledge Gaps

A comprehensive review of the current literature in post-concussion gait assessment was performed in a recently published systematic review[35]. Out of 233 studies involving concussion gait analysis, only 38 contained an objective post-concussion gait analysis using a control group or pre-concussion comparative measures. These 38 studies covered four gait/task conditions: simple gait, simple DT gait, complex gait, and complex DT gait. Near complete agreement among studies of abnormalities in gait temporal distance parameters support the conclusion that gait is abnormal in the acute post injury period. However, temporal distance characteristics normalized within one to two weeks

post injury when tested under a ST paradigm with equivocal results into the subacute (11-90 days), intermediate (91days to one year) and chronic (> one year) periods under both ST and DT conditions. More advanced biomechanical metrics such as analysis of COM movement, inter-joint coordination, and trunk stability/fluidity, particularly when measured under a DT paradigm, often identified persistent gait balance control deficits into the subacute and intermediate periods. However, inconsistent findings between studies and methodological limitations prevent definitive conclusion of gait balance control deficits persisting past the acute post injury period. The lack of consensus on the duration of dynamic gait balance deficits following concussion illustrates the need for additional longitudinal studies of post-concussion gait balance control assessment. Additionally, the dearth in studies employing advanced biomechanical markers of gait balance control suggest future investigations should include these biomechanical markers in a DT paradigm to better describe the complete recovery profile of dynamic gait balance control following concussion.

The application of sophisticated biomechanical markers of dynamic gait balance control to clinical environments remains challenging with currently utilized camera-based motion capture systems. However, the use of IMUs as a translational technology between laboratory-based research and clinical assessment is promising. Already numerous reliability studies have addressed instrumentation of commonly used clinical assessments (timed up and go, balance error scoring system, and static postural balance control) or analyzing basic gait temporal distance parameters. A recent review identified as many as 78 studies in which IMUs were used to assess gait quality in populations with various neurologic disorders[55]. Despite the proliferation in studies, the authors concluded the use

of IMUs has yet to affect clinical practice. While they suggest there are great prospects for IMU usage, they cautioned a lack of standardization and homogeneity in protocols and limited descriptions of gait perturbations as measured by IMUs, limits their utility and broad implementation.

A handful of studies seek to address these limitations through development of advanced biomechanical metrics. One investigation of acutely concussed individuals utilized single IMUs placed over the sternum and head in a six week longitudinal study, and calculated stride time variability and local dynamic stability during normal gait in both ST and DT conditions[46]. Both metrics were able to distinguish concussed subjects from healthy controls throughout a six week post injury period when tested in the DT condition. Another study of individuals with chronic symptoms following mTBI employed a five sensor protocol (one on each foot, lumbar spine, sternum, and forehead) and assessed different types of turns[56]. A metric called "peak velocity timing" was calculated in which the difference in time between peak velocities of the head and pelvis and head and trunk were identified respectively. Individuals with chronic symptoms had increased variability in both metrics compared to healthy controls.

These investigations demonstrate promise for applying advanced biomechanical analysis with IMUs to gait balance control assessment in concussed individuals. However, few studies assess the utility of IMUs as proxies for description of whole body COM kinematics. Esser and colleagues performed a validation of a COM proxy IMU for vertical COM displacement[57] and Myklebust's group validated use of the COM proxy in ski skating COM displacements on three axes[58]. While beneficial, the use of IMU derived position data requires the critical analysis of the integration methods utilized and do not

focus simply on raw sensor outputs. Consequently, there remains an absence of reliability or validation literature of directly measured accelerations from a COM proxy, particularly as they relate to gait events. The feasibility of such clinical IMU-based kinematic gait balance control assessments utilizing advanced biomechanical metrics is also yet to be established.

Current literature of clinical DT assessments employ manually administered cognitive tasks resulting in a lack of standardization and reliability. Additionally, investigations of the application of an IMU-based DT gait balance control assessment by clinicians such as athletic trainers, medics, and rehabilitation providers in existing medical treatment facilities is lacking. Also of great consideration in determining clinical applicability is assessment duration. Evaluation and follow-up appointment times are limited with even greater time constraints in competitive athletic environments, therefore the temporal feasibility of instrumented gait balance control assessments must be established.

While feasibility of clinical application is an important first step to applying advanced biomechanical metrics to gait balance control assessment, it alone cannot ensure the meaningful utility of such an assessment. Numerous metrics from a single IMU paired with a DT paradigm can be collected including cadence, gait velocity, gait event specific peak accelerations and angular velocities along three orthogonal axes, turning kinematics, reaction time and accuracy of concurrent cognitive tasks, and dual-task cost. A thorough investigation of these outcome measures in acutely concussed individuals throughout the post injury recovery period is necessary to enable clinical interpretation of their magnitudes and changes over time. Identifying distinct factors

among these variables may also allow for their grouping into different domains, thus providing additional insight into patient specific impairments. Furthermore, identification of a set of variables that together can differentiate concussed from healthy individuals with high sensitivity and specificity may provide a powerful tool for assisting clinicians in return to activity decision making.

A final consideration in determining the clinical validity and utility of an IMU-based DT gait assessment is understanding how individuals prioritized the applied motor and cognitive tasks. Of the 38 research studies identified in the systematic review of gait following concussion, 20 applied protocols with a DT component. Of those, 18 studies did not offer any prioritization instruction, while in one study subjects were instructed to "not" prioritize either task, and in the other study subjects were instructed to prioritize "both" tasks equally. Prioritization of tasks is a complex topic in DT gait assessment. The simple cue to "not" prioritize one task over the other, or "both" tasks equally may result in unintended prioritization effects. As the vast majority of concussion related DT gait assessments offer no prioritization instruction, it is important to understand how injured individuals prioritized tasks compared to those who are uninjured. The extent to which individuals prioritize one task over the other can have a large effect on the interpretation of balance control and cognitive outcome measures. Furthermore, identification of shifts in prioritization may offer additional insight into neurocognitive recovery and prove to be a valuable metric in and of itself.

Objectives and Specific Aims

The overall objective of this research is to investigate gait balance control impairment with a clinically feasible motion analysis system in young adults sustaining an acute concussion. To accomplish this objective a cohort of acutely concussed young adults and a cohort of healthy matched controls were assessed over a two-month post injury period with a novel dual-task gait balance control protocol employing off the shelf IMU technology. Four specific aims were identified and four studies were conducted to accomplish each aim, respectively.

Aim 1: To develop a portable dual-task gait balance control assessment from commercially available hardware and software and establish its reliability and clinical feasibility.

Aim 2: To identify IMU based kinematic metrics sensitive to changes in gait balance control in concussed individuals**.**

Aim 3: To identify the group of metrics from an L5 place IMU that provide the best predictive ability of concussion**.**

Aim 4: To explore the utility of DTC metrics for detection of post-concussion gait imbalance and description of task prioritization

Hypotheses

Hypothesis 2.1: Multiple gait-event related, temporal distance, linear acceleration, and angular velocity metrics collected during straight and turning gait are capable of identifying acutely concussed individuals when compared to healthy matched controls

Hypothesis 2.2: Composite scores on the symptom survey for concussed individuals will normalize (return to a level equal to healthy controls) prior to IMU-based gait balance control metrics.

Hypothesis 3.1: A principal component analysis can be applied to determine the set of factors that describe the concussion related Dual-Task gait balance control deficit construct

Hypothesis 3.2: A logistical regression model can be derived to accurately predict injury status (concussed or healthy)

Hypothesis 4.1: One or more DTC metrics could differentiate acutely concussed from healthy individuals

Hypothesis 4.2: Acutely concussed individuals will more heavily prioritize gait balance control than cognitive task response time and accuracy acutely following injury

Flow of Dissertation

This dissertation will follow a journal style format. Portions of the introductory Chapter (Chapter I) and Chapters II through V contain material previously published, submitted for review, or in preparation for submission to scientific journals.

Chapter I provides a brief introduction of gait balance control assessment in concussion. It broadly outlines the DT paradigm, emerging IMU technology, and whole body COM kinematic outcomes measures. Portions of this chapter are published in *Gait & Posture*. Peter Fino and Lucy Parrington are co-primary authors while Douglas Martini, James Chesnutt, Li-Shan Chou, and Laurie King are additional co-authors.

Chapter II demonstrates the internal consistency of a novel DT gait balance

control assessment and clinical protocol using off the shelf equipment and software. Consistency in a non-laboratory environment, across time, and between different raters was evaluated. Furthermore, a practical clinical application was performed in D1 female athletes in a collegiate sports medicine clinic. This work has been accepted for publication in *Gait & Posture*. Li-Shan Chou is a co-author.

Chapter III describes a longitudinal study of concussed subjects and healthy matched controls applying the previously validated IMU-based DT clinical protocol. Multiple outcome measures are identified capable of distinguishing injured from healthy subjects. The work is currently in preparation for submission to *Journal of Biomechanics*. Li-Shan Chou, and Szu-Hua Chen are co-authors.

Chapter IV examines the distinct factors identified in all of the possible outcome measures from the clinical assessment. The factor analysis is used to describe different domains of concussion related gait balance control impairment, and identify a subgroup of factors offering the highest sensitivity and specificity to detection of injury. This work is currently in preparation to the *Journal of Head Trauma and Rehabilitation.* Li-Shan Chou, Szu-Hua Chen, Craig Davidson, and Christian Stowell are co-authors

Chapter V is an exploration of DTC based metrics for identifying gait balance control impairment following concussion and determining task prioritization in the absence of prioritization instruction. The work is prepared according to University Graduate School format guidelines. Determination for publication is yet to be addressed.

Chapter VI offers a conclusion of findings and describes recommendations for future research.

CHAPTER II

RELIABILITY AND PRACTICAL CLINICAL APPLICATION OF AN ACCELEROMETER-BASED DUAL-TASK GAIT BALANCE CONTROL ASSESSMENT

This work has been accepted for publication in the journal *Gait & Posture*. Will Pitt and Li-Shan Chou are the authors. Will Pitt contributed to the concept and design, recruited subjects, collected data, wrote custom analysis software, analyzed data, and prepared the initial manuscript. Dr. Li-Shan Chou contributed to the concept and design, interpreted findings, provided editorial support, and assisted with revision of the manuscript.

Citation:

Pitt W and Chou LS. Reliability and Practical Clinical Application of an Accelerometer-Based Dual-Task Gait Balance Control Assessment. *Gait & Posture*. 2019. https://doi.org/10.1016/j.gaitpost.2019.05.014. (In Press).

Introduction

Assessment of dynamic gait balance control is increasingly important in concussion evaluation for diagnosing injury, evaluating rehabilitation progress, and informing return to activity (RTA) decision making [23,42,59]. Concussion induced gait balance impairments persisting as long as two months post-injury have been detected in laboratory studies using sensitive biomechanical markers obtained by sophisticated camera-based motion analysis systems [20,21,48,49]. This suggests that despite earlier resolution of subjective symptoms, static balance, and neurocognitive function, used in

current RTA guidelines, recovery may not be complete prior to RTA.

Many studies reporting prolonged deficits in gait balance control in acutely concussed individuals employ a dual-task (DT) assessment paradigm [47,60,61]. The paradigm pairs a gait task with a concurrent cognitive task, more closely resembling the demands of athletic, occupational, and daily activities [27,62]. It is particularly sensitive to prolonged gait imbalance as it requires simultaneous allocation of attentional resources to sensory processing for sensory-motor integration and cognitive task completion. This challenge to attentional function creates a competition for limited processing resources resulting in a reduction in cognitive and/or motor performance [63]. Often utilized cognitive tasks include the auditory Stroop test [37] and a more complex Question and Answer (Q&A) battery [38,39].

Many whole body center of mass (COM) kinematic measures, including the total medial-lateral (M-L) displacement, peak M-L velocity, and maximum M-L horizontal separation between the COM and center of pressure (COP) [20,47,64], were identified as capable of detecting persistent gait balance control deficits in concussed individuals despite earlier normalization of temporal distance gait parameters. This altered COM position and velocity may be the result of poor momentum control due to deficits in regulating COM acceleration, ultimately compromising an individual's ability to successfully execute the physical demands of daily and sport-related activities. A recent study comparing individuals with and without functional limitations found differences in COM accelerations [54], supporting this conclusion and suggesting measurement of COM acceleration may help illuminate balance control strategies during various activities.

Whole body COM is traditionally calculated as a weighted sum of linked rigid

body segments captured with a whole body reflective marker set and camera-based motion analysis equipment. Fortunately, recent advances in wearable motion sensor technologies offer an opportunity to translate previous laboratory findings that employed whole body video motion capture into the clinical environment with closely related measures of gait balance control. These inertial measurement units (IMU) combine accelerometers, gyroscopes, and magnetometers into a single sensor. As an emerging technology, the use of wearable sensors to identify gait and balance impairments has grown rapidly. Many studies demonstrated reliability and utility in assessing static balance control [65–67] and estimating gait temporal distance parameters [66,68,69] in both healthy and neurologically impaired (concussion and Parkinson's) individuals; while others used a low back placed sensor to estimate COM kinematics [58,70]. Given the close proximity between the fifth lumbar vertebra (L5) and the whole body COM during level walking, it could serve as a feasible location for IMU placement [71]. In a recent investigation using a single accelerometer placed on L5, the peak M-L acceleration occurring during the transition from single- to double-support was able to differentiate concussed from healthy subjects up to two weeks post injury. This suggests directly measured accelerations from the L5 may have a similar sensitivity to persistent gait imbalance as whole body COM kinematics [21].

While promising, measures of gait balance control using directly measured accelerations from a single IMU over the L5 vertebra are not well established or validated. Furthermore, sensitivity to changes in gait balance control and the consistency outside of the laboratory and across time of these measures is unknown. Without such investigations, the application of an IMU-based gait balance control assessment tool for

use in rehabilitation clinics, athletic training rooms, or austere field environments cannot be accomplished.

Therefore, the purposes of this study were to 1) determine the consistency of a DT wearable sensor gait balance assessment protocol in a non-laboratory setting and across time, 2) determine the assessment's inter-rater reliability, and 3) demonstrate its ability to be practically administered in a Division One (D1) collegiate sports medicine clinic. It was hypothesized that 1) acceleration-based kinematic metrics collected from a single sensor placed over the L5 vertebra would have high internal consistency in single- and dual-task walking conditions measured on two different testing days, in a laboratory and non-laboratory environment, and by two different raters, and 2) that it would have high inter-rater reliability. It was further hypothesized that 3) the assessment protocol could be practically administered in a real-world Division One (D1) sports medicine clinic in minimal time by sports medicine personnel.

Methods

Study participants consisted of healthy non-athlete young adults and D1 female soccer players from the University community. Participants were healthy, able to walk over level ground without an assistive device, and did not report hearing deficits. Individuals with lower extremity deficiencies, an injury affecting normal gait, a history of cognitive deficiencies such as permanent memory loss or concentration abnormalities, attention deficit hyperactivity disorder, three or more previous concussions, or a concussion within the past year were excluded. The study was approved by the Institutional Review Board and all participants provided written informed consent prior

to enrollment.

The testing apparatus consisted of a single laptop, a three-sensor OPAL motion analysis system operated by Motion Studio software (APDM, Inc., Portland, OR, USA), a single ear Bluetooth synced wireless headset and boom microphone (Blue Tiger USA, Stafford, TX, USA), and Superlab 5 software (Cedrus Corp., San Pedro, CA, USA). Sensors were attached with elastic straps over both lateral ankles for gait event detection and over the L5 vertebrae on the back [21]. The axes of the L5 sensor were oriented such that the positive vertical (Vert) axis pointed inferiorly, the positive medial-lateral (M-L) axis pointed to the right, and the positive anterior-posterior (A-P) axis pointed posteriorly **(Fig. 2.1)**. The DT assessment protocol was automated in a custom Superlab 5 program. All verbal commands were administered through the wireless headset.

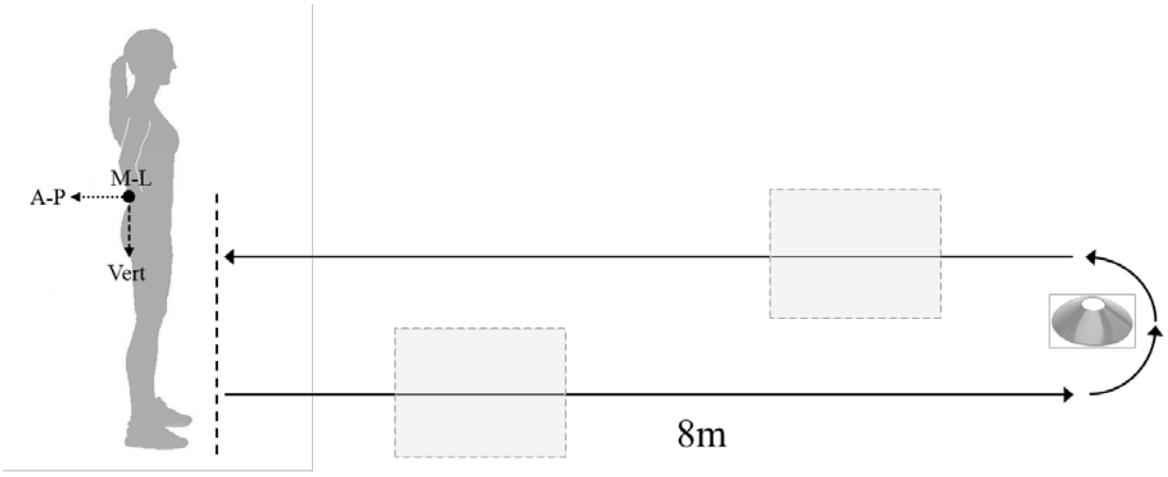

Figure 2.1: Placement of the L5 sensor and orientation of the three orthogonal axes and graphical illustration of the walking task. The task includes straight level walking along an 8m path, a 180 degree counter clockwise turn around a cone, and a return straight line walk. Shadowed boxes represent the two gait cycles trimmed for analysis.

Participants were instructed to walk at a self-selected comfortable pace from a feet together standing position over an eight meter level path, perform a 180 degree counter clockwise turn around a cone, and return to a stop at the start position. Trials

were initiated with an automated verbal command instructing participants to look straight ahead, followed by an auditory beep. The two concurrent cognitive tasks utilized during DT walking were the auditory Stroop test and a Q&A task. The auditory Stroop test consisted of four auditory stimuli, the words “high” or “low” spoken in either a high or a low pitch [37]. The stimuli were either congruent (pitch of the voice matched the meaning of the word) or incongruent (pitch of the voice did not match the meaning of the word). Participants were instructed to correctly identify the pitch of the voice rather than the word spoken. Three randomly presented stimuli were triggered manually by the rater to begin on the third heel strike during the walkout, one step prior to the 180 degree turn, and on the third heel strike during the return walk **(Fig. 2.1)**. The Q&A consisted of either spelling a five letter word backwards or subtracting from a given number by sixes or sevens. The first question was queued immediately upon walking initiation and participants responded continuously throughout the trial.

This study consisted of data collections from two separate cohorts of participants. The first cohort included 20 male and female healthy, young-adult, non-athletes (10 females; age 22.2 ± 2.8 yrs.; height 175.8 ± 8.1 cm; weight 71.0 ± 12.0 kg). They were assessed at two data collection sessions separated by one to two weeks, in two different environments, and by two different raters for the purpose of examining the reliability of the assessment. At each session participants completed four trials in a single-task (ST) and two DT walking conditions: ST (walking only), DT Stroop (walking while performing a concurrent auditory Stroop), and DT Q&A (walking while responding to Q&A). The three walking conditions were repeated in two different environments and by two different raters. The testing environments were a quiet laboratory and a hallway in an

adjacent building. Occasional visual and auditory distractions occurred in the hallway, similar to those expected in a medical clinic. Raters consisted of the primary author and an undergraduate student research assistant, minimally trained in biomechanical analysis. The order of environment, rater, and walking condition was randomized for each individual at each session. Participants performed four trials of the Stroop and Q&A tasks in a seated position prior to initiating the walking trials. Participants wore normal athletic clothing including a t-shirt, shorts (or tight fitting exercise pants), and athletic shoes.

The second cohort of 14 female athletes from the University D1 female soccer team (age 19.3 ± 1.3 yrs.; height 168.4 ± 7.1 cm; weight 64.6 ± 4.0 kg) was included for the purpose of assessing the practical clinical application of the assessment. Data were collected in this cohort during a separate session and examined independent of the first cohort. Athletes performed a single assessment with three trials in each of the three randomly presented walking conditions. The assessment was performed in a quiet workout recovery room in the university athletic medicine facility. The walls of the room were transparent glass allowing for occasional visual distractions. Participants completed the same walking task, received the same verbal instructions, and wore the same apparel as participants in the first cohort. Prior to completion of the three walking conditions, three trials of the Stroop and Q&A tasks were performed in a seated position, followed by two familiarization ST walking trials. A certified athletic trainer minimally trained in biomechanical analysis performed all athlete assessments. Total assessment time, including sensor placement was also recorded.

IMU sensor data were sampled at 128 Hz and streamed in real-time to a wireless hub. Raw data was filtered with a 2nd order low-pass Butterworth filter with a 12 Hz

cutoff frequency and analyzed with a custom Labview program (National Instruments, Austin, TX, USA). Ankle pitch angular velocity collected from the two ankle IMUs was used to identify heel strikes for trimming individual gait cycles. In this study, data from straight line walking were examined. Two gait cycles were analyzed in each trial; the gait cycles beginning on the fifth heel strike during the walk out and walk back. Acceleration measures from the L5 sensor were referenced to a single left heel strike initiation gait cycle. A tilt correction was performed to obtain acceleration values with respect to the anatomic frame of reference. Eight peak accelerations corresponding to specific gait events along the M-L, A-P, and Vertical axes were identified and obtained for analysis **(Fig. 2.2)**. Gait events included right terminal swing (M-L acceleration 1), left terminal

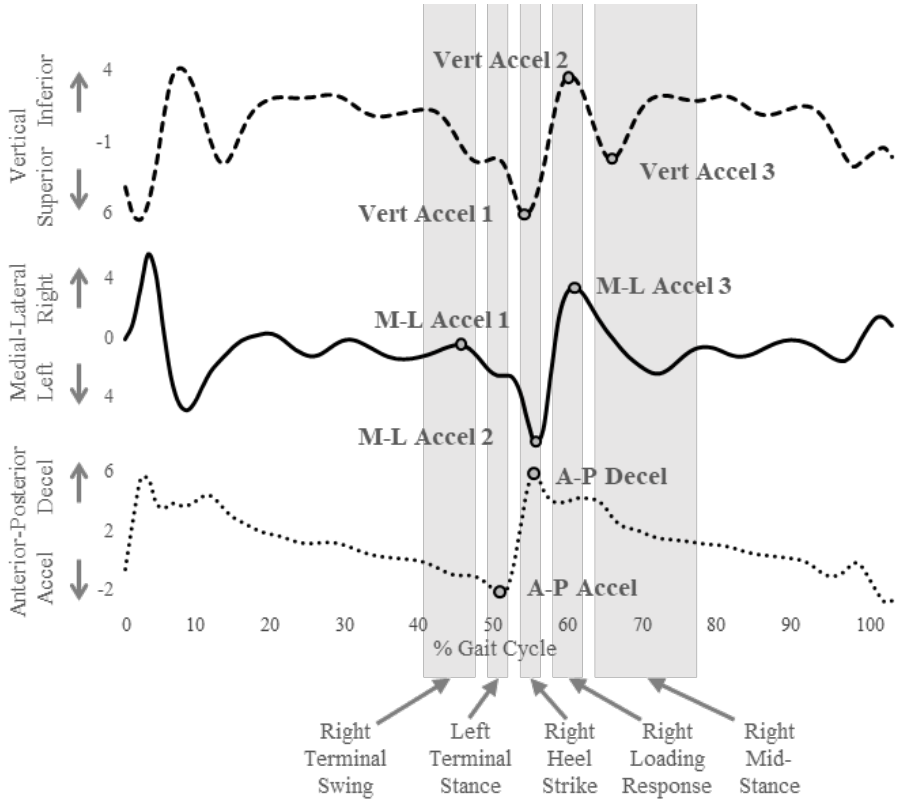

Figure 2.2: Representative acceleration profiles for vertical, medial-lateral, and anterior-posterior accelerations (m/s^2) and selected acceleration peaks. Gait events corresponding to peak accelerations are listed below and highlighted with gray vertical bars.

stance (A-P acceleration), right heel strike (Vertical acceleration 1, M-L acceleration 2, and A-P deceleration), right loading response (M-L acceleration 3 and Vertical acceleration 2), and right mid-stance (Vertical acceleration 3).

An eight item Cronbach's α was calculated on data collected from the first cohort for each of the eight peak accelerations in each of the three walking conditions to establish the internal consistency of the assessment across two testing sessions, two environments, and two raters. An Intra-class Correlation Coefficient (ICC) with a 95% Confidence Interval (CI) was also calculated to determine inter-rater reliability. Cronbach's α values greater than .9 and ICC values greater than .75 were considered to indicate very high internal consistency and excellent interrater reliability.

A one-way, repeated-measures, Analysis of Variance (ANOVA) with an alpha level of .05 was performed on peak acceleration data collected from the second cohort (D1 athletes) to determine if there were differences in peak acceleration values between the three walking conditions. Total assessment time was also recorded. Data from the first and second cohorts were not compared to one another. All analyses were performed on Statistical Product and Service Solutions (SPSS version 24) software.

Results

The two testing sessions from cohort one were separated by 8.7 ± 1.7 days. Cronbach's α values for all eight metrics in each of the three walking conditions had a range of .839 to .989 **(Table 2.1)** indicating high to very high internal consistency. Inter-rater reliability was excellent as demonstrated by ICC values of .935 to .989 **(Table 2.1)**.

Total assessment time for the second cohort of female athletes including sensor

Table 2.1: Cronbach's α values for each of the eight acceleration metrics for all three walking conditions calculated. The eight items of the Cronbach's α consisted of all combinations of the levels of the three independent variables, environment, time, and rater. **Inter-rater reliability determined by an Intraclass Correlation Coefficient and 95% Confidence Interval calculated for each of the eight metrics.**

	Cronbach's α			ICC	95% CI
	ST	Stroop	Q&A		
Vert Accel 1	.967	.975	.974	.989	.984±.012
Vert Accel 2	.954	.975	.966	.988	.983±.012
Vert Accel 3	.946	.959	.944	.983	.975±.018
M-L Accel 1	.932	.942	.965	.964	.950±.036
M-L Accel 2	.955	.961	.961	.975	.964±.026
M-L Accel 3	.900	.910	.948	.935	.909±.049
A-P Decel	.940	.932	.929	.987	.982±.013
A-P Accel	.859	.839	.871	.966	.952±.025

placement and verbal instructions was 8.50±0.58 minutes. Significant differences between the three walking conditions for Vert Accel 1 ($p < 0.01$, $\eta_p^2 = 0.49$), Vert Accel 2 ($p = 0.01$, $\eta_p^2 = 0.30$), and A-P Accel ($p < 0.01$, $\eta_p^2 = 0.49$) were identified with the repeated-measures ANOVA **(Fig. 2.3)**. While not reaching a significant level,

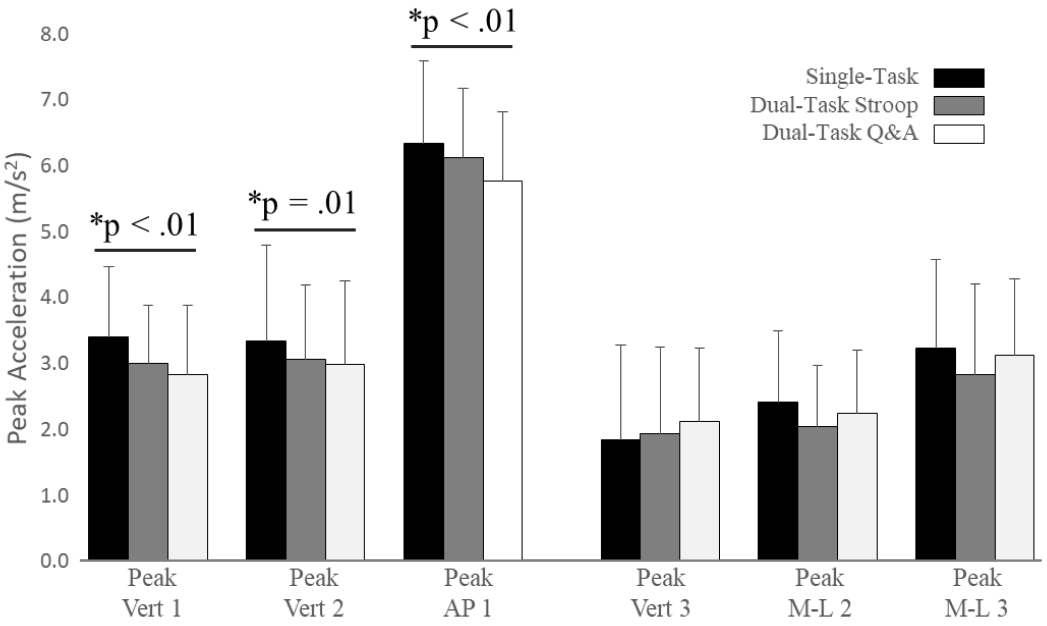

Figure 2.3: Vertical, anterior-posterior, and medial-lateral axis peak acceleration metrics in each of the three walking conditions for female D1 soccer players presented as mean ± SD. * indicates $p \leq 0.01$.

Vert Accel 3, M-L Accel 2, and M-L Accel 3, demonstrated potential to differentiate between walking conditions with p-values of 0.12, 0.14, and 0.06, respectively.

Discussion

This study established the reliability of a DT gait balance control assessment utilizing multiple peak accelerations recorded from a single IMU placed over the L5 vertebra. Our high Cronbach's α values, a statistic utilized for its ability to measure both the correlation and agreement among multiple measures, demonstrate the reproducibility of the kinematic measures in a non-laboratory environment. They further established the temporal consistency of the outcome measures in repeated assessments separated by one to two weeks inferring a minimal learning effect. High ICC values further suggest the test may be reliably performed by different, minimally trained raters.

We also demonstrated the ability to perform the assessment in a D1 collegiate sports medicine clinical environment. Our average assessment time of 8.50 minutes indicates it may be performed within a reasonable time with minimal impact to athlete training schedules. The assessment was also conducted by a team athletic trainer, untrained in biomechanical analysis, in a preexisting space in the athletic medicine facility. The length, ease of administration, and ability to perform the assessment in preexisting clinical space, suggest it may be practically applied in this setting. Furthermore, analysis of athlete data revealed multiple peak accelerations capable of differentiating between different walking conditions, indicating their sensitivity to subtle changes in gait balance control.

Traditionally, whole body COM is computed from a full body reflective marker

set captured with sophisticated camera-based motion analysis systems. A previous study using this method identified whole body COM kinematic variables (total M-L displacement and peak M-L velocity) capable of distinguishing healthy and concussed individuals across a two month post injury period with large effect sizes[20]. Recent advancements in wearable IMU technology offer an opportunity to translate these findings into a clinical biomechanical assessment by using a single IMU placed over the low back. A recent pilot investigation using a similar single IMU method identified an acceleration metric (peak M-L acceleration during the transition from single- to double-support) also capable of differentiating concussed from healthy individuals with a similarly large effect size for up to two weeks post injury[21]. Low power likely contributed to the reduced temporal sensitivity, however, the comparison of camera and IMU measures suggest the IMU-based technique may be a viable alternative for application of these measures in clinical environments.

In this study eight gait event specific peak accelerations along three orthogonal axes were investigated, the most consistent of which occurred at (in order of occurrence) terminal swing, terminal stance, heel strike, the loading response during the transition into single-support, and mid-stance. During the propulsive phase at terminal stance the COM is propelled forward and medially away from the base of support. A change in acceleration magnitude in the A-P or M-L directions may indicate adoption of a conservative gait strategy or excessive force output. Conversely, at heel strike the COM is moving toward the heel striking foot, requiring the neuromuscular system to attenuate the body's momentum. This continues into the early phase of single support where the entire momentum of the body is loaded onto the single limb and must be controlled or

risk breaching the base of support. Intuitively, changes in acceleration magnitudes during these gait events may denote altered gait balance control capability.

This study was not without limitations. The generalizability of our testing protocol may be affected by our relatively homogenous samples. Possible confounding variables present in athletic populations such as motivation (shamming), peer pressure, and other psychosocial variables may affect these results as well as the high level of dynamic balance control of elite athletes compared to non-athletes. There is also a high degree of between subjects variability in peak acceleration values, however, it is similar in magnitude to whole body COM position and velocity data obtained from video motion capture. Additionally, all facilities may not have the required space to perform such assessments nor be capable of accommodating the additional time required to add it to their existing assessment protocol. Finally, the small sample size of the D1 athlete group limited the ability to identify peak accelerations capable of detecting changes in balance control as evidenced by an observed power between .40 and .55 for the three metrics demonstrating non-significant trends.

Conclusion

Our results indicate analysis of accelerations collected with a wearable IMU over L5 under a DT testing paradigm, is a reliable measure of gait balance control during normal gait outside of the laboratory, is consistent over different testing days, and may be conducted by minimally trained individuals. Furthermore, it is able to detect subtle differences in DT gait balance control and can be performed in a reasonably short time by sports medicine staff in preexisting clinical facilities, supporting its practical application

in a D1 sports medicine environment. It is therefore reasonable to expect our clinical assessment may be successfully applied to acutely concussed individuals to accurately and rapidly measure deficits in dynamic gait balance control. It may further be capable of detecting improvements in balance control over the post-injury recovery period resulting in a better informed RTA decision.

Bridge

Chapter II described the development of a dual-task gait balance control assessment utilizing off the shelf technology. The reliability of the assessment was established in a non-laboratory environment, on different assessment days, and by different raters. It further demonstrated the practical clinical application of the assessment in a D1 athletics program. In the next chapter, the assessment is employed to assess acutely concussed individuals to identify distinct gait event specific accelerations and angular velocities capable of identifying gait balance control deficits across a two month post injury period.

CHAPTER III

USING IMU-BASED BIOMECHANICAL MARKERS TO MONITOR GAIT BALANCE CONTROL RECOVERY IN ACUTELY CONCUSSED INDIVIDUALS

This work is in preparation for submission to the *Journal of Biomechanics*. Will Pitt, Szu-Hua Chen, and Li-Shan Chou are the authors. Will Pitt contributed to the concept and design, recruited subjects, collected data, wrote custom analysis software, analyzed data, and prepared the initial manuscript. Szu-Hua Chen contributed to the design, data analysis, and statistical analysis. Dr. Li-Shan Chou contributed to the concept and design, interpreted findings, provided editorial support, and assisted with revision of the manuscript.

Introduction

Best-practice statements recommend the addition of gait and balance testing to current clinical examinations of concussion[41,42] leading to a growing body of literature addressing post injury gait balance control. Many studies reported concussed individuals demonstrate altered gait temporal-distance behaviors, such as velocity and step length, in both simple and complex gait[35]. Gait temporal-distance metrics could be assessed with currently available clinical instruments, however, they might lack sensitivity to detect prolonged gait deficit, especially subtle gait imbalance, and tend to normalize within 10 days post-injury[44–49,52].

Recent prospective, longitudinal studies employed various whole body center of mass (COM) kinematic measures in an attempt to improve sensitivity to subtle persistent impairment in gait balance control. These metrics are traditionally derived from camera-

based motion capture using a full-body reflective marker set[20] where COM is calculated as the weighted sum of a multi-segment linked rigid body system. Total medial-lateral (ML) displacement, peak ML velocity, anterior-posterior (AP) peak velocity of the COM, and maximum horizontal separation of the COM and center of pressure (COP) demonstrated sensitivity to changes in gait balance control in concussed individuals[20,40,43,44,47,48,52,53]. In multiple studies these metrics were able to detect gait imbalance as long as two months post injury despite earlier normalization of temporal-distance parameters[20,22,23,40,48].

Post-concussion changes in COM position and velocity may be due to poor momentum control associated with an inability to regulate COM acceleration, and may lead to diminished ability to perform physical activities efficiently and accurately. A study demonstrating COM acceleration differences between individuals with and without functional limitations[54] supports this conclusion and suggests measurement of COM acceleration may both illuminate balance control mechanisms during daily activities and facilitate detection of balance impairments. However, clinical biomechanical analysis of COM acceleration is not yet feasible due to exorbitant equipment costs and expertise requirements. To overcome such limitations, recent development of clinical gait analysis has focused on the use of wearable sensors commonly referred to as inertial measurement units (IMU). Combining tri-axial accelerometers, gyroscopes, and magnetometers, IMUs are coupled with convenient clinical software, yet are still limited to basic temporal distance gait parameters.

Recent studies sought to identify IMU based biomechanical metrics for use in gait assessment in acute and chronically concussed individuals. Metrics such as segmental

rotational timing variability[56], stride time variability, and local dynamic stability in a dual-task (DT) walking condition[46] were found to distinguish concussed from healthy individuals. Other studies investigated the utility of an IMU placed over the low back to estimate whole body COM kinematics. In one study an IMU placed over the sacrum (S1), a position resembling the COM, was validated for estimates of tri-axial displacements of the COM in ski skaters[58]. Another study validated estimates of vertical displacement of the COM from a single sensor placed over the fourth lumbar vertebra[57]. In addition, our preliminary investigation explored the use of accelerations measured from an IMU placed over the fifth lumbar vertebra (L5), due to its close proximity to the whole body COM, to distinguish concussed from healthy individuals in a DT walking condition[21]. Concussed individuals were found to display a smaller ML acceleration than controls during the transition from the single- to double-support at 72 hours and two weeks post injury. Furthermore, a recent study established the reliability of this peak ML acceleration metric, along with additional gait event specific peak accelerations along the ML, AP, and vertical axes[72]. These studies demonstrate the potential of using directly measured accelerations as an effective method to clinically assess gait balance control following concussion.

Given the close proximity of the L5 vertebra to the whole body COM during level walking, it would serve as a feasible location for IMU placement[71]. To increase the utility of IMUs in clinical gait assessment, a complete description of acceleration and angular velocity profiles collected from an L5 place IMU is necessary. Analysis of gait event specific accelerations and velocities may yield additional metrics for detecting gait

imbalance with a clinically feasible instrument and offer insight into changes in momentum control strategies employed by concussed individuals.

The purpose of this study was to provide an objective description of acceleration and angular velocity profiles along three orthogonal axes of a single IMU placed over the L5 vertebra; and to demonstrate that detectable differences could be identified in IMU based metrics for distinguishing individuals with concussion from healthy matched controls during straight gait in both ST and DT conditions. It was hypothesized that individuals with concussion would demonstrate differences in peak accelerations and angular velocities at various gait events when compared to healthy controls, and these detectable differences would be capable of distinguishing between concussed individuals and healthy matched controls across a two month post injury period.

Methods

Physicians at a University Student Health Clinic recruited young adults between 18-30 years of age diagnosed with acute concussion (within 72 hours of injury). Individuals expressing interest completed a release of contact form and were subsequently met by the investigator at the clinic where enrollment and the first of five post injury assessments were completed. Each concussed participant was matched to a healthy control by sex, age, height, and weight. Individuals with an injury affecting normal gait, a history of permanent memory loss or concentration abnormalities, or had impaired hearing were excluded. Potential control participants sustaining a concussion within the past year were also excluded. The study was approved by the Institutional Review Board and all participants provided written informed consent prior to enrollment.

Concussed participants completed a gait balance control assessment consisting of both single- and dual-task walking at five post injury time points: within 72 hours of injury (72hrs), at one week (1wk), two weeks (2wks), one month (1mo), and two months (2mos). Healthy participants were assessed at similar intervals from the initial testing. Gait assessment was performed during a walking task consisting of a seven meter walk over a straight level path at a comfortable self-selected pace, a 180 degree counter clockwise turn around a cone, and return to the start position (**Fig. 2.1**). The assessment protocol was automated with a custom Superlab 5 software program (Cedrus Corp., San Pedro, CA, USA) in which verbal commands and an auditory Stroop task were administered through a single ear Bluetooth wireless headset with boom microphone (Blue Tiger USA, Stafford, TX, USA). Motion analysis was performed with a three-sensor OPAL motion analysis system operated by Motion Studio software (APDM, Inc., Portland, OR, USA). Sensors were attached with elastic straps over both lateral ankles for gait event detection and over the low back at the level of the L5 vertebrae as a proxy for the whole body COM[21]. The L5 sensor axes were oriented such that the vertical (Vert) axis pointed down, the ML axis to the right, and the AP axis to the rear. All software and hardware were controlled from a single laptop.

The Stroop task consists of four auditory stimuli, the words “high” or “low” spoken in either a high or a low pitch[37], where the meaning of the word either matches the pitch in which it is spoken (congruent) or does not (incongruent). Subjects received auditory instructions on Stroop task performance then performed two practice trials of three stimuli each in a seated position. Next, four recorded trials of three stimuli each were performed (also while seated) and served as their ST baseline. Participants then

stood and a 15 seconds quiet standing trial was recorded. Following auditory instructions on walking task performance, two single-task practice walking trials were completed followed by eight recorded trials, half under ST and half under DT conditions, the order of which was randomized. Walking trials were initiated with an automated verbal command instructing participants to look straight ahead, followed by an auditory beep. During DT trials a single randomly presented stimulus was triggered on the third heel strike during the walkout and one step prior to the 180 degree turn. Assessments were performed in a hallway approximately 2.7 meters wide by 12 meters long, with minimal visual or auditory distractions.

IMU data were sampled at 128 Hz and streamed to a wireless hub. Raw signals were filtered with a 2nd order, zero-lag, low-pass Butterworth filter with a 12 Hz cutoff frequency. Individual gait cycles during straight walking were trimmed using ankle sensor pitch angular velocity local maxima occurring just prior to heel strike [73]. Three consecutive gait cycles beginning with the 3rd, 4th and 5th heel strikes during the walk out were processed for each trial. Accelerations and angular velocities collected from the L5 sensor were referenced to a left foot initiated gait cycle. A tilt correction using data collected from static stance was performed to obtain accelerations with respect to the anatomic frame of reference. All data processing was performed with a custom Labview program (National Instruments, Austin, TX, USA)

Demographic data were analyzed with individual independent samples t-tests. Participants also completed the Post-Concussion Symptom Score (PCSS) at each assessment. PCSS scores and reaction times (baseline, straight gait, and turning gait) were analyzed with two-way, repeated-measures, Analyses of Variance (ANOVA).

Independent variables were group (concussed vs. healthy) and time (72hrs, 1wk, 2wks, 1mo, and 2mos). All IMU measures were analyzed with a three-way ANOVA with group (concussed vs. healthy), condition (ST vs. DT), and time (72hrs, 1wk, 2wks, 1mo, and 2mos) as independent variables. An alpha level of .05 was used for all omnibus tests, while follow-up pairwise comparisons were performed using the Tukey's Honest Significant Difference method to control for family-wise type I error. All analyses were performed using the open access software environment for statistical computing program R.

Results

Fourteen participants with an acute concussion were recruited for the study. Three voluntarily withdrew prior to completion of all five assessments and were excluded from the analysis. The final analysis included 11 participants with acute concussion (7F/4M, age 20.1±1.3 years, height 171.3±8.2 cm, and weight 71.4±16.4 kg) and 11 healthy matched controls (7F/4M, age 20.6±1.9 years, height 172.0±9.9 cm, and weight 70.0±11.2 kg). There were no between groups differences for age, height, or weight. Concussed participants were assessed at 1.8±0.6, 6.2±1.2, 15.3±3.3, 26.2±3.6, and 56.6±9.9 days post injury.

A group by time interaction was identified for PCSS scores ($p < .001$, $\eta^2 = .24$; **Table 3.1**). PCSS scores for concussed participants at 72hrs were greater than their scores at 1wk, 2wks, 1mo, and 2mos ($p < .001$ for all comparisons) and at all five time points for controls ($p < .001$ for all comparisons). Concussed participants' scores at 1wk were greater than their scores at 1mo and 2mos ($p = .02$ and $p < .001$ respectively) and were greater than healthy participant scores at all five time periods ($p \leq .002$ for all

comparisons).

Table 3.1: Post Concussion Symptom Inventory composite scores for both groups at five assessments presented as mean (SD).

	Injured	Control
72hrs	47.9 (27.0)	0.6 (1.5)
1wk	27.9 (22.3)	0.5 (1.5)
2wks	16.7 (17.3)	0.4 (0.7)
1mo	11.3 (28.0)	0.0 (0.0)
2mos	1.1 (1.8)	0.1 (0.4)

A group by time interaction ($p = .04$) was identified for gait velocity (**Fig. 3.1**). Main effects of time ($p = .001$) and condition ($p = .02$) indicate both groups walked slower under the DT condition and walking velocity increased over the five assessments. Concussed participants walked slower at the 72hr assessment than they did at 2wks, 1mo and 2mos ($p < .001$ for all pairwise comparisons) and slower than healthy participants at 2wks and 1mo ($p = .04$ and $p = .02$ respectively).

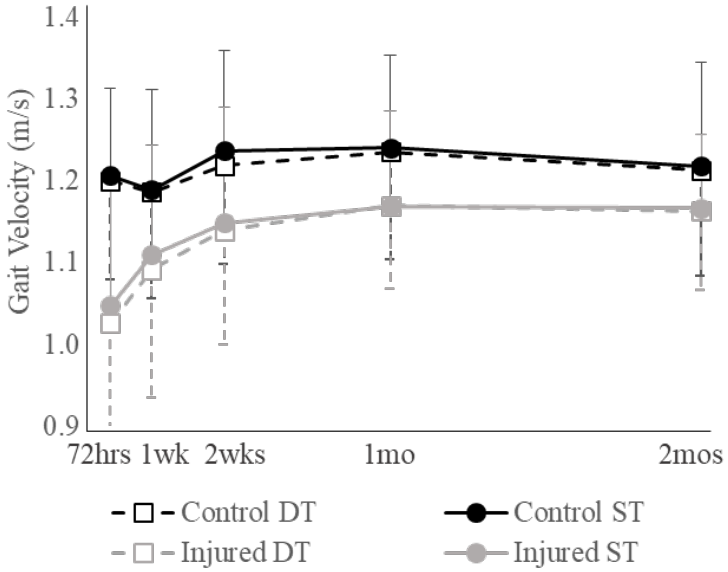

Figure 3.1: Gait velocity for both groups in both walking conditions (dual-task [DT] and single-task [ST]) across the five post injury assessments (mean±SD).

Eight consistent gait event specific peak accelerations along the ML, AP, and Vert axes and six peak angular velocities about the AP (roll) and Vert (yaw) axes were identified. All accelerations and angular velocities are referenced to a left heel strike to left heel strike gait cycle, and occurred during the following gait events: right terminal swing, left terminal stance, right heel strike, right single- to double-support transition (loading response), and right mid-stance (**Fig. 3.2**). Across the ML axis a peak acceleration to the right occurred at right terminal swing (ML 1), followed by a peak to the left at right heel strike (ML 2), and a second peak to the right during right loading response (ML 3). Two peak accelerations occurred along the AP axis, one represented the peak forward acceleration during left terminal stance (AP 1), while the other was directed toward the rear and occurred during the right heel strike to loading response interval (AP 2). The peak AP 2 acceleration had a characteristic double peak where the first peak could be larger or smaller in magnitude than the second. Along the vertical axis an upwardly peak acceleration occurred at right heel strike (Vert 1), followed by a downward acceleration during right loading response (Vert 2), and a second upward peak during early right stance (Vert 3). Three peak angular velocities about the vertical axis (rotation in the horizontal plane) were identified (**Fig. 3.2b**). The first, a clockwise angular velocity, coincided with right terminal swing (Yaw 1), followed by a counterclockwise peak at right heel strike (Yaw 2), and a third, clockwise peak, during right mid-stance (Yaw 3). There were also three peak angular velocities about the AP axis (frontal plane rotation). The first represented a rotation to the right occurring at left terminal stance, the second a left rotation arose at right heel strike, and the last right rotation occurred during right mid-stance.

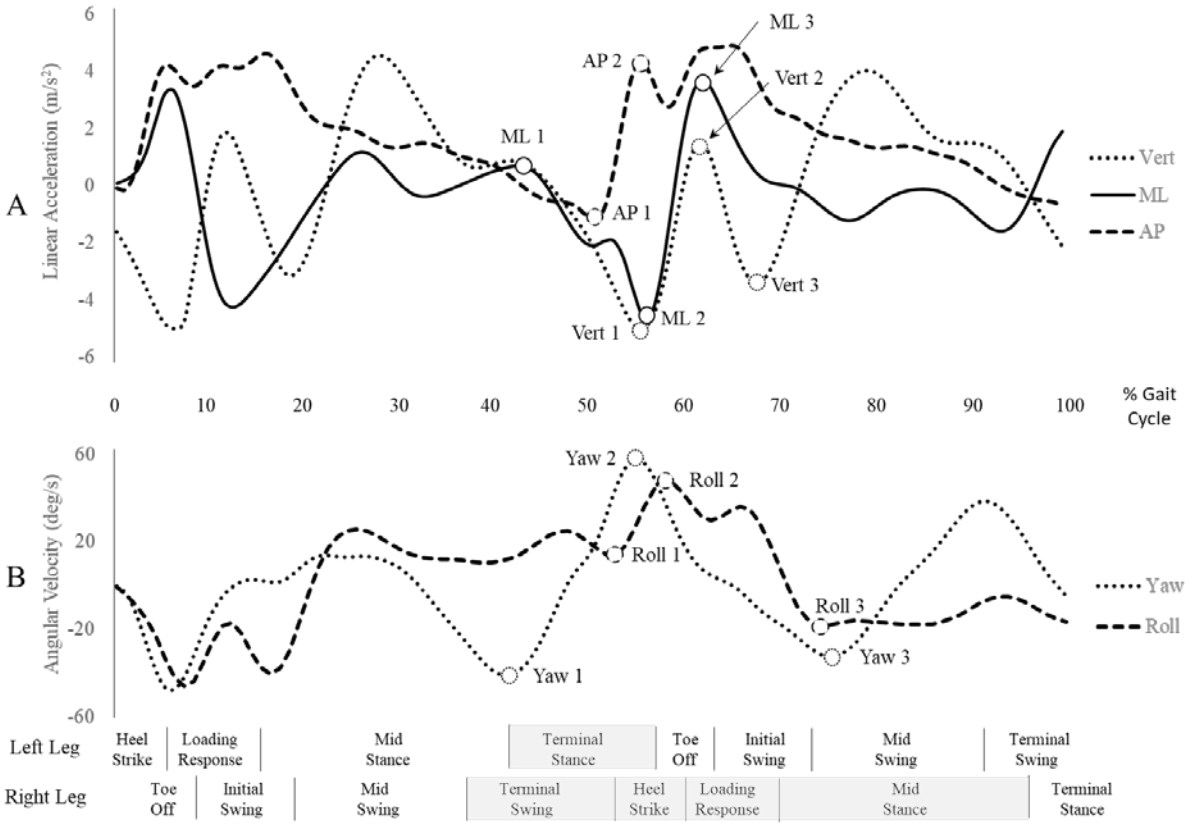

Figure 3.2: (A) Vertical, Medial-Lateral (ML), and Anterior-Posterior (AP) acceleration profiles. Gravitational acceleration is removed from the vertical axis for illustrative purposes. **(B) Yaw and Roll angular velocity profiles.** All profiles are referenced to a single left heel strike to left heel strike gait cycle.

A group by condition by time interaction effect ($p = .04$) was identified for Vert 2 indicating healthy individuals produced a greater downward acceleration during the loading response, and that it increased over time in both groups (**Fig. 3.3a**). Concussed participants had a smaller upward acceleration at the end of terminal stance than healthy participants (main effect of group, $p = .02$; **Fig. 3.3b**).

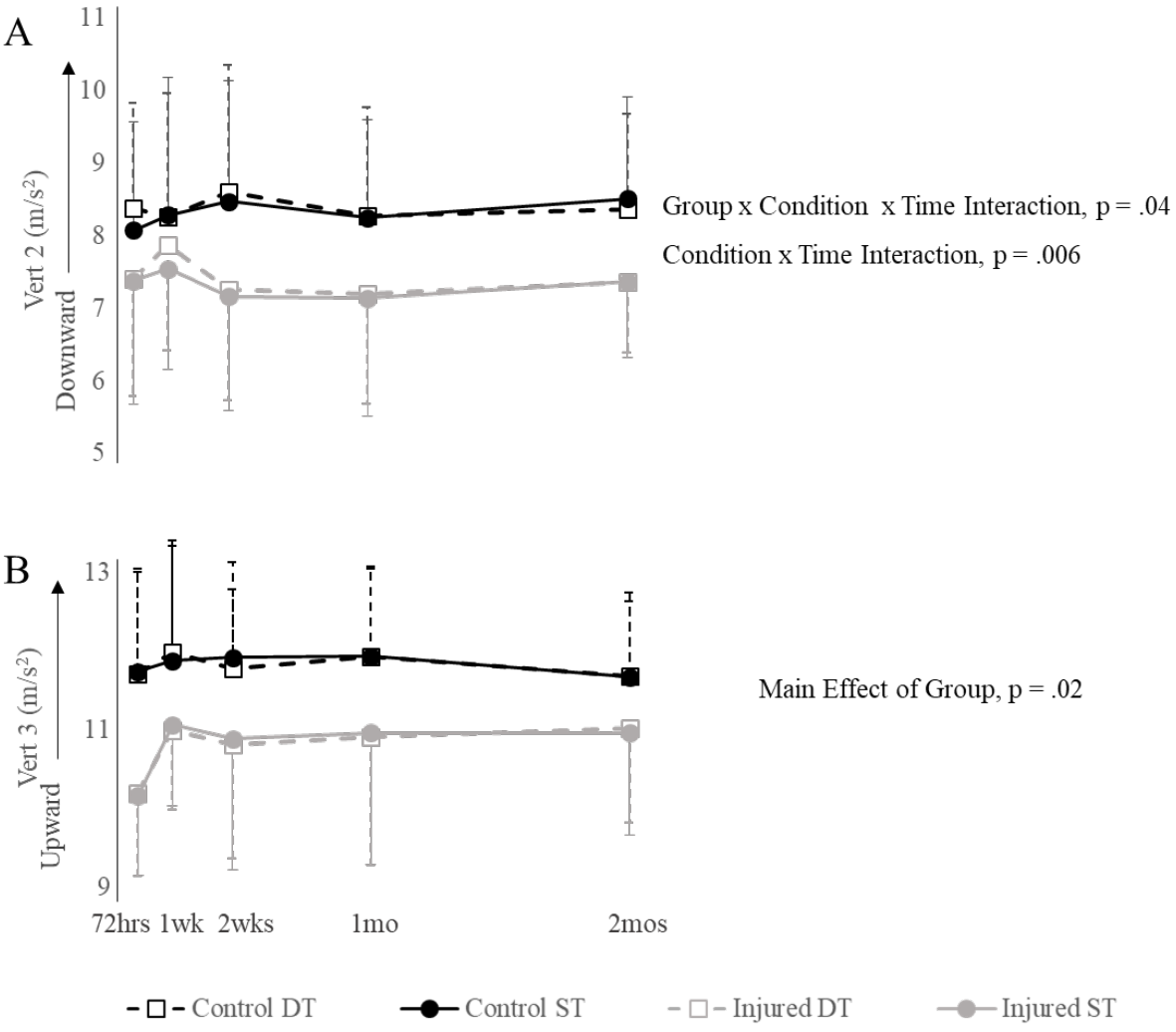

Figure 3.3: (A) Peak vertical acceleration 2 (Vert 2) and (B) peak vertical acceleration 3 (Vert 3) presented for both groups in under both conditions (dual-task [DT] and single-task [ST]) at all five assessments times (mean±SD). Acceleration referenced to a left heel strike to left heel strike gait cycle. Significant interaction and main effects are presented.

Concussed participants also showed non-significant trends of smaller peak ML (ML 2, p = .06; **Fig. 3.4a**) accelerations toward the left at right heel strike and to the right during loading response (ML 3, p = .06; **Fig. 3.4b**), and a greater peak minimal AP acceleration (AP 2, p = .07; **Fig. 3.4c**) from right heel strike through loading response.

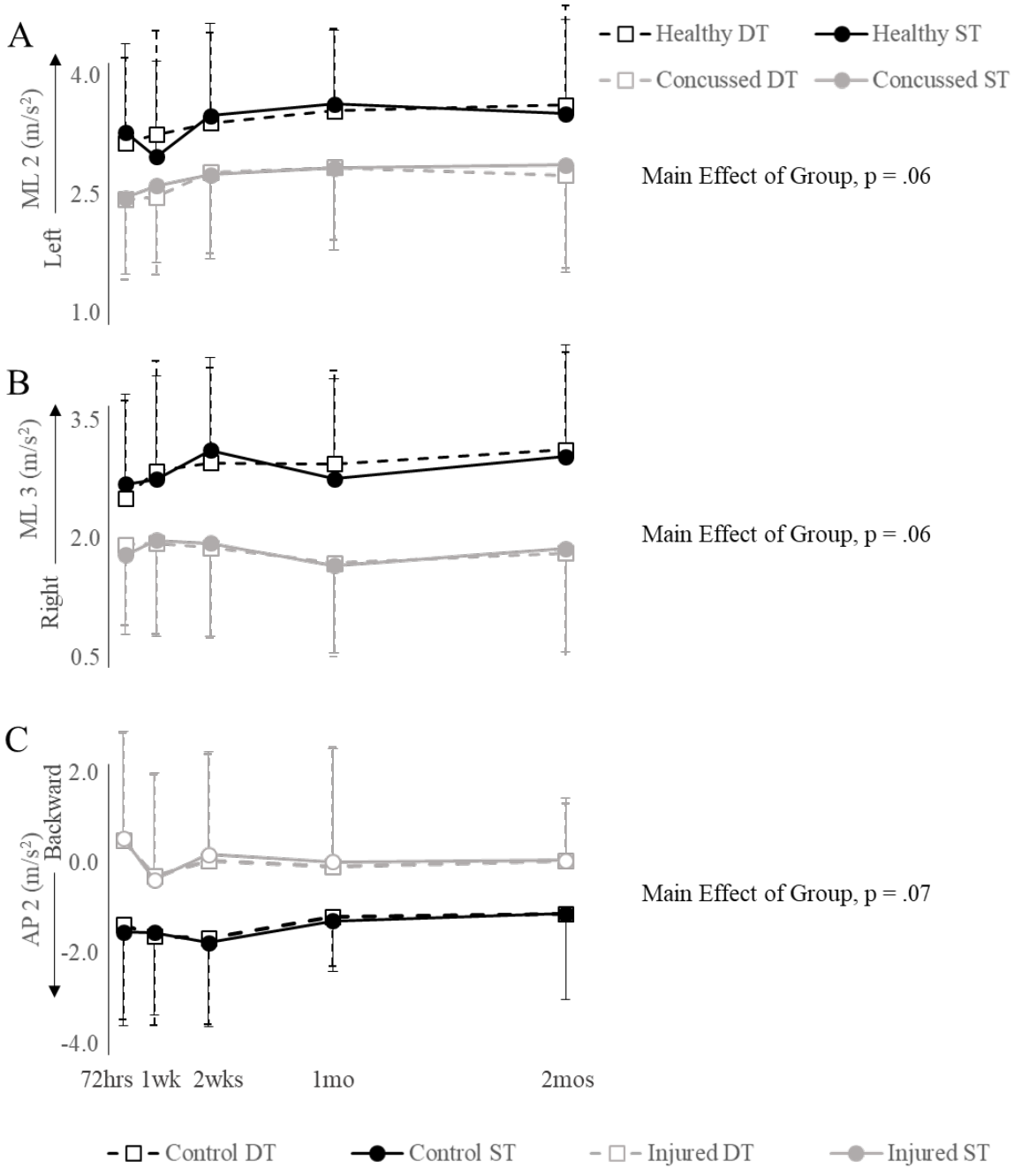

Figure 3.4: (A) Peak ML acceleration 2 (ML 2), (B) ML acceleration 3 (ML 3), and (C) AP acceleration 2 (AP 2) presented for both groups in both conditions (dual-task [DT] and single-task [ST]) at all five assessments times (mean±SD). Accelerations referenced to a left heel strike to left heel strike gait cycle. P-values for main effects of group are presented.

Concussed participants demonstrated a slower transverse plane clockwise rotational velocity during right heel strike than concussed participants, which increased over the five assessments as indicated by a three-way interaction effect for Yaw 2 ($p < .001$; **Fig. 3.5**).

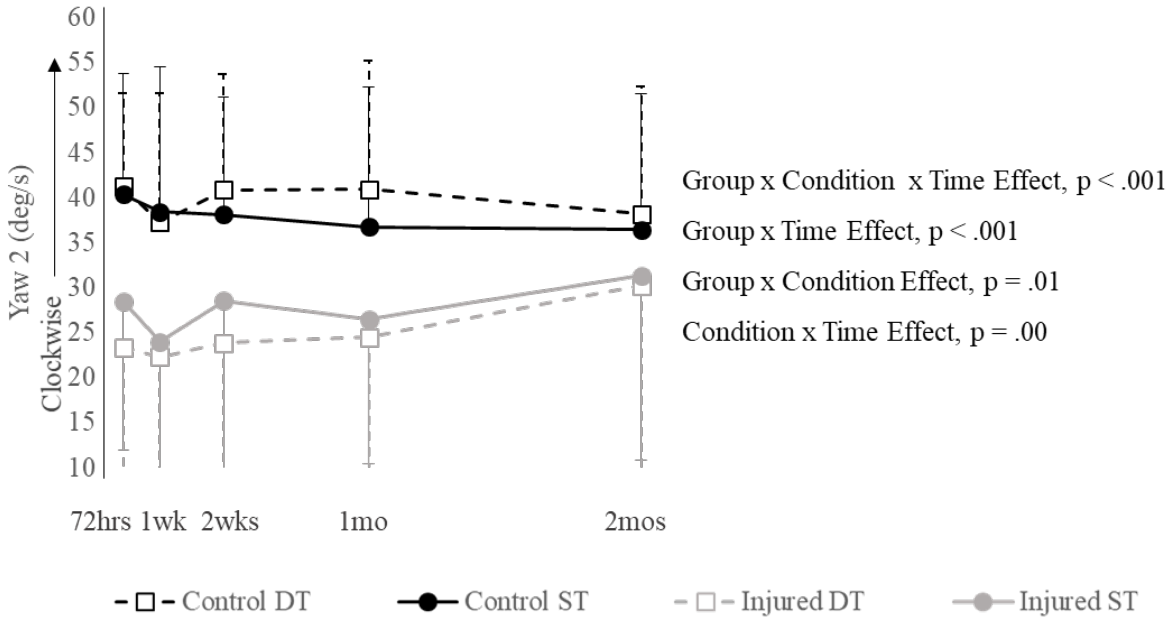

Figure 3.5: Peak yaw angular velocity 2 (Yaw 2) presented for both groups in both conditions (dual-task [DT] and single-task [ST]) at all five assessments times (mean±SD). Angular velocities referenced to a left heel strike to left heel strike gait cycle. Significant interaction effects are presented.

During the DT condition, participants experienced a slower roll velocity to the right at left terminal stance (Roll 1; main effect of condition, $p = .02$; **Fig. 3.6a**) and to the left during right loading response (Roll 2; main effect of condition, $p = .04$; **Fig. 3.6b**). Roll 2 velocity also increased over the course of the five assessments (main effect of time, $p < .001$) as did roll velocity to the right during mid-stance (Roll 3; Main effect of time, $p = .02$; **Fig. 3.6c**).

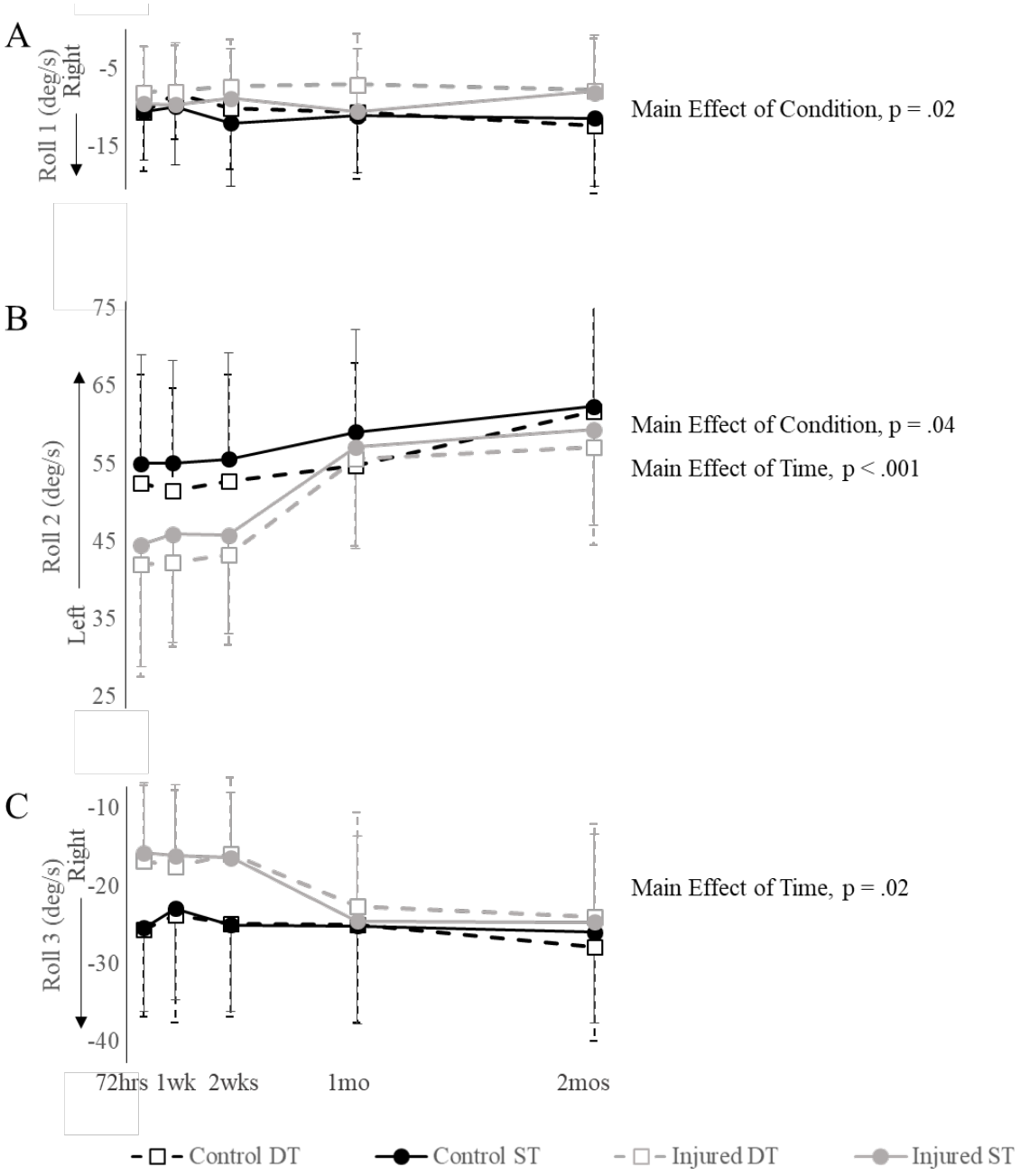

Figure 3.6: (A) Peak roll angular velocity 1 (Roll 1), (B) roll angular velocity 2 (Roll 2), and (C) roll angular velocity 3 (Roll 3) presented for both groups in both conditions (dual-task [DT] and single-task [ST]) at all five assessments times (mean±SD). Angular velocities referenced to a left heel strike to left heel strike gait cycle. Significant main effects are presented.

Discussion

In this study we investigated the use of a single IMU placed over the low back (L5) to identify gait balance control deviations following acute concussion. Straight, steady-state gait balance control was described using gait event specific accelerations and angular velocities. Three peak angular velocities and accelerations were able to identify differences in gait balance control between concussed and healthy participants across a two month post injury period (Yaw 2, Vert 2, and Vert 3), while three additional accelerations (AP 2, ML 2, and ML 3) showed promise. These metrics occurred during the middle section of the gait cycle beginning just prior to right heel strike, extending through right mid-stance. This period is associated with maximum propulsion followed by a contralateral loading response as weight is shifted from one limb to the other. Diminished control of the body's momentum during this transition may result in objectively measured imbalance. The gait event specific accelerations and angular velocities identified in this study appear to provide additional insight into dynamic balance control.

At approximately 35-45% of the gait cycle, the left limb is in mid-stance as the right limb enters terminal swing generating a counterclockwise angular momentum in the transverse plane (Yaw 1) and a peak ML acceleration toward the right limb (ML 1). Shortly thereafter the left limb enters terminal stance, propelling the body forward and laterally (toward the right limb). This is expressed as the maximum anterior acceleration (AP 1) along the AP axis and as Roll 1 along the ML axis. As angular and linear velocity are related ($v_t = r\omega$, where v_t is the tangential velocity, r the distance to the axis of rotation, and ω the angular velocity), this peak roll velocity represents an increase in frontal plane momentum toward the right. The anterolateral momentum created during this

phase must be effectively controlled in the ensuing gait phases to prevent loss of balance.

At right heel strike (approximately 55% of the gait cycle) a peak ML acceleration (ML 2) toward the left limb indicates an initial lateral deceleration of the body's momentum. Transverse plane rotational momentum is also arrested and reversed (Yaw 2). As the right loading response begins, a third ML peak acceleration (ML 3) oriented to the right is generated, indicating the body's momentum continues to accelerate laterally following heel strike. The increased frontal plane lateral momentum is further illustrated by a second peak roll velocity to the right (Roll 2) and is likely the result of the terminal propulsive force occurring at toe off.

At the same time, along the AP axis, a minimum acceleration (AP 2) or AP deceleration occurs. This characteristically double-peaked profile occurring from right heel strike through loading response represents "braking", which is used to control anterior momentum. Simultaneously two vertical accelerations occur in quick succession, one directed inferiorly (Vert 2) and one directed upward (Vert 3). The Vert 2 acceleration represents the body's momentum "dropping" during the single- to double-support transition followed by an upwardly direct peak serving to decelerate the downward momentum and prevent the COM from collapsing to the ground. Taken together, the peaks from the three orthogonal axes illuminate a balance control mechanism in which anterolateral momentum is controlled by shifting some of the anteriorly directed energy both downward and laterally toward the limb being loaded. Healthy individuals are able to shift more momentum away from the AP axis (AP 2) and into the ML (ML 3) and vertical (Vert 2) axes. The resultant shift in momentum is then effectively dispersed throughout the remainder of the loading response phase into mid-stance.

By the end of mid-stance, momentum in the anterior, lateral (toward the right limb), and inferior directions has been appropriately managed and momentum is then generated in the opposite directions to continue propagation of the gait cycle. Two peak angular velocities are associated with this transition, Yaw 3 and Roll 3. Yaw 3 represents the generation of counter clockwise angular momentum in the transverse plane while Roll 3 indicates frontal plane momentum directed away from the stance foot toward the left.

This collective examination of peak accelerations and angular velocities suggest balance control strategies may differ between healthy and concussed individuals. During straight gait, a healthy individual generates more angular and linear momentum toward the heel striking foot as evidenced by increased yaw velocity at terminal swing and increased roll velocity at terminal stance. To control this momentum, a greater braking acceleration is generated in the AP direction, causing a shift in energy from the AP axis into the ML and Vert axes (laterally and inferiorly respectively). This shift is expressed as a larger peak lateral ML acceleration (ML 3; oriented to the right) and inferior vertical acceleration (Vert 2; deceleration of the falling COM).

These changes in accelerations and angular velocities do not appear to be entirely gait velocity dependent. Rather they suggest gait balance control is achieved with off axis shifts of momentum that can be effectively attenuated throughout the early to mid-stance phases. While injured individuals appear to generate less rotational and linear momentum prior to these events, it is still to be determined whether they are incapable of doing so, or if they are intentionally limited due to an inability to attenuate the large ML and Vertical momentum shifts. Regardless, the noted change in momentum control suggests the adoption of a more conservative gait balance control strategy and offers a promising

method for identifying individuals with impaired dynamic gait balance control.

Our results support previous findings of increased whole body COM displacements and velocities in the M-L direction in acutely concussed compared to healthy individuals persisting for an extended post injury period[20,48]. While our results demonstrate faster frontal plane velocities and generally higher peak accelerations in concussed individuals along all three axes, they are specific to gait events and are better understood in the context of dynamic balance control strategy. Still, results from the two perspectives can be reconciled. The larger total M-L displacement of the whole body COM and increased peak velocity across the entire gait cycle identified in concussed individuals may be a result of diminished capacity to redirect, rapidly generate, and attenuate the body's momentum.

A key contribution of this study is the identification of biomechanical markers of gait imbalance directly obtained from a single IMU placed over the L5 vertebra applied in a short (10 minutes or less) DT protocol. This offers a promising foundation for development of a clinical gait assessment providing clinicians with both a quantification of imbalance and insight in to altered balance control strategies. Additional investigation is needed to identify the group of metrics best suited to detect concussion related gait imbalance with high sensitivity and specificity, then package them into an automated algorithm for real-time results. Furthermore, the results of this study suggest we did not fully exploit the potential of the DT paradigm in revealing balance control deficits. The limited effect of walking condition noted in our results may be due to the simple cognitive task selected. Future investigation using more complex tasks such as a continuous auditory Stroop, spelling and arithmetic tasks, or working memory tasks such as the n-back may

reveal greater group differences. Future studies should also include larger samples as our results are likely impacted by the relatively small sample and between subjects variability.

Despite these limitations this study provides the first objective description of gait event specific accelerations and angular velocities collected from a single IMU placed over the L5 vertebrae. Multiple peak accelerations and angular velocities were identified and demonstrated potential to differentiate concussed from healthy individuals across a two month post injury period. Furthermore, the collective analysis of peak accelerations and angular velocities during specific gait events offers insight into altered momentum control strategies exhibited in acutely concussed individuals.

Bridge

Chapter III described acceleration and angular velocity profiles collected from an L5 placed IMU. Multiple peak accelerations and angular velocities were shown to be sensitive to changes in gait balance control in acutely concussed individuals across a two month post injury period. In the next chapter a group of IMU-based kinematic variables are identified capable of detecting gait balance control impairments in acutely concussed individuals with high sensitivity and specificity.

CHAPTER IV

SENSITIVITY AND SPECIFICITY OF USING IMU MEASURES TO DISTINGUISH INDIVIDUALS FOLLOWING CONCUSSION IN DUAL-TASK WALKING

This work is in preparation for submission to the *Journal of Head Trauma and Rehabilitation*. Will Pitt, Szu-Hua Chen, Craig Davidson, Christian Stowell, and Li-Shan Chou are the authors. Will Pitt contributed to the concept and design, recruited subjects, collected data, wrote custom analysis software, analyzed data, and prepared the initial manuscript. Szu-Hua Chen contributed to the design, data analysis, and statistical analysis. Dr. Craig Davidson and Dr. Christian Stowell contributed to the concept, recruited subjects, and managed the medical care for acutely injured subjects. Dr. Li-Shan Chou contributed to the concept and design, interpreted findings, provided editorial support, and assisted with revision of the manuscript.

Introduction

Divided attention gait balance control has gained increased consideration in post-concussion assessment as a construct more accurately representing the demands of daily and sport related physical activities. Two recent systematic reviews of post-concussion gait analysis identified 24 studies employing a form of dual-task (DT) assessment[35,74]. Outcome measures ranged from typical gait temporal distance metrics (e.g. gait speed, step length/width, stride time, etc.) to processing intensive whole body center of mass (COM) kinematic measures (e.g. medial-lateral and anterior-posterior displacements and

velocities). The results of the reviews clearly indicate gait is impaired acutely following concussion. However, temporal distance metrics and ST gait tended to normalized within five days, while persistent gait imbalance was detected with DT simple and complex gait protocols using whole body COM measures through the subacute period (11-90 days)[35]. Both reviews conclude that future investigation should focus on translation of these results into clinically feasible objectively quantifiable DT gait assessments.

The clinical application of sophisticated biomechanical markers of gait balance control is challenging due to equipment and processing intensive laboratory methods currently utilized. Fortunately, advancements in inertial measurement units (IMU) technology offer a promise for translation of laboratory-based research to clinical assessments. Already numerous studies have addressed instrumentation of commonly used clinical assessments (timed up and go, balance error scoring system, and static postural balance control) for analyzing basic gait temporal distance and static balance parameters. A recent review identified as many as 78 studies in which IMUs were used to assess gait quality in populations with various neurologic disorders[55]. However, the authors noted many challenges and considerations for successful implementation of devices in clinical gait assessments.

Step detection/segmentation, cognitive task complexity, sensor quantity and placement, and outcome measure selection must all be considered. Processing intensive algorithms associated with gait event detection and outcome measure calculations may limit clinical utility. Simple cognitive tasks may be easily automated and graded but are often limited in their ability to extract a meaningful dual-task cost (DTC) compared to complex tasks which may be impractical for standardization and automation. Increased

sensor quantity may provide increased resolution for whole body kinematic analysis but come with increased costs, processing time, and application complexity. And many currently employed clinical IMU based protocols are able to employ basic gait temporal distance metrics, but lack the ability to measure more sophisticated metrics previously shown to be sensitive to persistent gait balance control deficits.

There has been much effort to overcome many of these challenges. Already both single sensor[75] and multi-sensor[73] gait event detection algorithms have been validated. Efforts have been made to establish the utility of a single sensor placed over the low back to estimate COM displacement[57,58,70,76], however, processing time, acceleration signal integration drift, and the construct validity of the location as a proxy for the whole body COM kinematics may limit the utility of these metrics. Another study identified a peak medial-lateral (ML) acceleration occurring at the transition from single- to double-support as capable of detecting gait balance impairment up to a week post-concussion, illuminating the potential of directly measured gait event specific accelerations as metrics for describing gait balance control.

Despite all of this work, as yet, a clinical DT gait assessment employing sophisticated IMU based kinematic and neurocognitive metrics, capable of sensitively detecting acute and persistent gait balance control impairment, does not exist. The purpose of this study is therefore to determine if a group of kinematic and neurocognitive metrics collected from a single IMU placed over the fifth lumbar (L5) vertebra in a DT gait protocol are capable of identifying DT gait balance control impairment in acutely concussed individuals. To address this purpose, participants suffering an acute concussion and healthy matched controls underwent a previously developed clinical DT gait analysis

protocol where straight and turning gait were assessed with a single L5 placed IMU.

It was hypothesized that a group of kinematic and DT neurocognitive metrics collected in the assessment could determine group identification with high sensitivity and specificity within 72 hours of injury. We further hypothesized that the model would retain moderate predictive capability throughout a two month post injury period.

Methods

Acutely concussed participants between 18-30 years of age, and diagnosed with an acute concussion (within 72 hours of injury) were recruited from the University Student Health Clinic. Each concussed participant was matched to a healthy control participant by sex, age, height, and weight. Prospective participants were excluded who had an injury affecting normal gait, a history of permanent memory loss or concentration abnormalities, or impaired hearing. Control participants were also excluded who sustained a concussion within the past one year. The study was approved by the Institutional Review Board and all participants provided written informed consent prior to enrollment.

Concussed participants performed a DT gait balance control assessment at five post injury time points: within 72 hours of injury (72hrs), at one week (1wk), two weeks (2wks), one month (1mo), and two months (2mos). Healthy participants completed the same assessment at similar intervals from the initial testing. The walking task consisted of a seven meter walk over a straight level path at a comfortable self-selected pace, a 180 degree counter clockwise turn around a cone, and returned to the start position (**Fig. 2.1**). The concurrent cognitive task consisted of an auditory Stroop task consisting of four auditory stimuli, the words “high” or “low” spoken in either a high or a low pitch [37], the

meaning of which either matched the pitch in which it was spoken (congruent) or did not (incongruent). One randomly selected stimulus was presented on the third heel strike during the walk out, and at one step prior to initiating the 180 degree turn.

Verbal commands and Stroop stimuli were presented through a single ear Bluetooth wireless headset with microphone (Blue Tiger USA, Stafford, TX, USA) and automated with a custom Superlab 5 software program (Cedrus Corp., San Pedro, CA, USA). Three IMUs were attached with elastic straps over each lateral ankle (gait event detection) and the L5 vertebra and were controlled with Motion Studio software (APDM, Inc., Portland, OR, USA). The L5 sensor axes were oriented such that the vertical (Vert) axis pointed down, the ML axis to the right, and the AP axis to the rear (**Fig. 2.1**). All software and hardware were controlled from a single laptop.

Two trials of three stimuli each were performed for Stroop task familiarization followed by four additional trials which were recorded as the participant's baseline measure. Participants then performed two ST familiarization walking trials followed by four recorded DT trials. All walking trials commenced with a verbal command to look straight ahead, followed by an auditory beep. The assessment was performed in a hallway measuring 2.7 meters wide by 12 meters long, with minimal visual or auditory distractions.

IMU data were sampled at 128 Hz. Raw data was filtered with a 2^{nd} order, zero-lag, low-pass Butterworth filter with a 12 Hz cutoff frequency. Ankle pitch angular velocity local maxima occurring just prior to heel strike were used to trim individual gait cycles. Three consecutive gait cycles beginning with the 3^{rd}, 4^{th} and 5^{th} heel strikes during the initial straight walk were processed for each trial. A tilt correction using data from a 15

second static stance was performed to obtain accelerations with respect to the anatomic frame of reference. All accelerations and angular velocities collected from the L5 sensor were referenced to a left foot initiated gait cycle. Eight consistent gait event specific linear accelerations and six angular velocities were recorded during straight gait cycles (**Fig. 3.2**). The 180 degree turn was trimmed for analysis by integrating L5 sensor angular velocity signal to yaw angle [77]. Total turn time, peak yaw and peak roll angular velocities were obtained during the turning event. Stroop task reaction time (RT) was also recorded for baseline, straight gait, and turning gait. Data was processed with a custom Labview program (National Instruments, Austin, TX, USA).

To screen variables with potential to distinguish healthy from concussed participants, independent samples t-tests ($\alpha = .20$) were performed on all 21 variables (gait velocity, eight peak accelerations and 6 peak angular velocities during straight gait, total turn time, peak turning yaw, peak turning roll, and RT during baseline, turning and straight gait) derived from data of 72hrs assessment.

A variable reduction was performed using a principle component analysis (PCA) on data from the 72hr assessment for concussed subjects. Components with eigenvalues of ≥ 1.00 were retained. A varimax rotation was applied to the PCA component matrix to identify collinear clusters of variables most closely associated with each component. Variables meeting the screening criteria were carried forward into a logistic regression model. If no variables in a given component met the screening criteria, the variable with the lowest p-value was carried forward. All combinations of variables carried forward (one from each component of the PCA) were analyzed using a binary stepwise logistic regression to identify the group of variables providing the highest predictive capability

(eq. 1).

$$Z = a + b_1X_1 + b_2X_2 + b_3X_3 + \ldots + b_{n+1}X_{n+1} \quad (1)$$

The model attaining the highest overall predictive capability was applied to all subject data for the remaining assessment days (1wk, 2wks, 1mo, and 2mos) to determine the sensitivity (Sn) and specificity (Sp) of the model to group status across the two month post injury period (cutoff value of ≥ 0.5; eq. 2).

$$\text{Probability} = \frac{e^z}{1+e^z} \quad (2)$$

A univariate binary logistic regression was also applied to the PCSS and gait velocity metrics individual for comparisons purposes. All statistical analyses were performed on Statistical Package for the Social Sciences (SPSS version 25) software.

Results

Fourteen participants with an acute concussion were recruited for the study and matched to 14 healthy control participants (**Table 4.1**). Data from the 14 matched pairs were included in the PCA and regression model construction. Three participants

Table 4.1: Participant demographic data (mean ± SD). 14 participants completed the first visit and were included in the logistic regression model. The model was applied to 11 subjects that completed all five assessments to determine predictive capability at each testing point.

Assessments Completed	Group	n	F/M	Age (yrs)	Ht (cm)	Wt (kg)
1st Assessment (72hr)	Injured	14	8F/6M	20.1 ± 1.2	172.2 ± 8.9	71.7 ± 16.9
	Control			20.7 ± 1.9	172.3 ± 10.2	69.9 ± 12.6
2^{nd}-5^{th} Assessments	Injured	11	7F/4M	20.1 ± 1.3	171.3 ± 8.2	71.4 ± 16.4
	Control			20.6 ± 1.9	172.0 ± 9.9	70.0 ± 11.2

voluntarily withdrew prior to completion of all five assessments, therefore data from the remaining matched pairs was used to determine the Sn and Sp of the regression models at the 1wk, 2wks, 1mo, and 2mos assessments. There were no significant differences between groups for age, height or weight. Concussed participants were first assessed at 1.8±0.6 days post injury.

The PCA yielded six components with eigenvalues greater than 1.0, accounting for 85.4% of the total variance **(Table 4.2)**. One variable from component 1, two from component 2, three from component 3, two from component 4, 1 from component 5, and one from component 6 were kept based on selection criteria. Each combination of one variable from each component (12 total combinations) were assessed using the binary logistic regression model.

Immediately after the injury, the six variables with the highest predictive capability were AP Min, ML 2, Turning RT, Turn Time, Vert 3, and ML 1 (**Table 4.3**). The stepwise regression revealed four models containing three to six variables. The six variable model had the highest explained variance with an R squared of .852 (Table 3) and had a Sensitivity (Sn) of 92.9 and Specificity (Sp) of 85.7. The remaining models maintained similar R squared, Sn and Sp values. The model with the highest combined Sn and Sp was the three variable model (Model 4) with Sn and Sp of 92.9.

Table 4.2: Principle component analysis component matrix following a varimax rotation. Variables are blocked according to the component for which they have the highest factor loading. * indicates variables carried forward into the logistic regression model.

	p-value	Component					
		1	2	3	4	5	6
Vert 2	.509	0.927	0.123	0.062	-0.238	-0.044	0.070
Peak Turn Roll	.633	0.858	0.424	0.085	0.080	-0.023	-0.089
AP Max	.387	0.850	-0.036	0.311	0.090	0.157	-0.010
AP Min*	.225	0.837	-0.180	0.314	-0.213	0.195	0.202
Yaw 3	.297	0.700	-0.057	0.220	0.448	0.182	0.325
Vert 1	.471	0.629	-0.242	-0.176	-0.298	0.435	-0.028
ML 3	.462	-0.251	0.944	-0.008	-0.054	0.061	0.103
Roll 2	.475	-0.001	0.855	-0.117	-0.018	-0.165	0.156
ML 2*	.017	-0.260	-0.830	0.032	-0.058	-0.069	0.099
Yaw 2*	.001	0.088	0.811	0.150	0.329	0.032	-0.194
Straight Gait RT*	.034	-0.142	-0.057	-0.847	-0.194	0.132	-0.034
Baseline RT*	.009	-0.116	-0.336	-0.844	-0.023	0.148	0.152
Yaw 1	.626	0.149	-0.292	0.656	-0.148	0.052	0.522
Roll 1	.900	0.255	-0.295	0.597	-0.060	0.229	-0.133
Turning RT*	.001	-0.222	0.396	-0.542	0.345	0.017	0.488
Turn Time*	.132	-0.089	-0.265	0.239	-0.875	-0.002	0.105
Peak Turn Yaw*	.130	-0.291	-0.055	0.284	0.832	-0.227	-0.108
Roll 3	.270	0.069	0.083	-0.110	-0.014	0.918	0.094
Vert 3*	.007	0.596	-0.101	0.117	-0.193	0.701	-0.134
ML 1*	.745	-0.255	-0.047	0.167	0.478	-0.028	-0.665

Table 4.3: Variables included in each of the models from the stepwise regression and PCSS and velocity univariate logistic regressions. Variance explained (R squared), Sensitive (Sn), and Specificity (Sp), Beta score, Standard Error (SE) and p-values are presented.

Model	Metric	R Squared	Sn	Sp	Beta	SE	p-value
Model 1		0.852	92.9	85.7			.000
	AP Min				1.116	1.277	.382
	ML 2				2.840	2.279	.213
	Turning RT				0.033	0.021	.114
	Turn Time				3.056	2.472	.216
	Vert 3				2.007	1.106	.070
	ML 1				6.624	4.668	.156
Model 2		0.834	82.9	85.7			.000
	ML 2				1.583	1.248	.205
	Turning RT				0.023	0.013	.074
	Turn Time				2.719	2.079	.191
	Vert 3				1.761	0.878	.045
	ML 1				3.816	2.565	.137
Model 3		0.789	85.7	85.7			.000
	ML 2				1.477	0.915	.107
	Turning RT				0.015	0.006	.023
	Vert 3				1.543	0.723	.033
	ML 1				1.737	1.431	.225
Model 4		0.756	92.9	92.9			.000
	ML 2				1.190	0.779	.127
	Turning RT				0.013	0.005	.017
	Vert 3				1.289	0.601	.032
PCSS		1.000	100.0	100.0	2.906	378.826	.000
Velocity		0.388	78.6	71.4	-11.201	4.723	.002

The regression model for PCSS scores alone attained a perfect predictive capability and variance explained while the model for gait velocity along had low variance explained (R squared = .388) and moderate Sn (78.6) and Sp (71.4).

All six models were applied to data from 11 concussed participants and 11 healthy matched controls (**Table 4.1**) who completed all five post injury assessments (1.8±0.66.2±1.2, 15.3±3.4, 26.2±3.6, and 56.6±9.9 days post injury). Sn and Sp data for all four models along with gait velocity and PCSS are displayed in **Table 4.4**. Models 1-4 and PCSS had high or perfect Sp. Sp for gait velocity was moderate at 72hrs and 1wk, high at 2wks and 1mo, then moderate at 2mos. The Sn for PCSS scores was perfect initially, but experienced moderate drops at each subsequent assessment point, dropping to only 18% by 1mo and 0% at 2mos. Sn for gait velocity was moderate initially gradually dropping to 27% by 2mos. Model 1 had a marked drop in Sn at 1wk which continued through the remaining assessments, ending at 18%. Model 2 had a lower initial drop in Sn at 1wk, but also ended at 18%. Models 3 and 4 dropped to 73% and 64% at 1wk, 45% by 2wks, but generally maintained the 2wks Sn values through 2mos (36% and 45% respectively).

Table 4.4: Sensitivity (Sn) and Specificity (Sp) data displayed for the four IMU based models and the velocity and PCSS models for each of the five post injury assessments.

	Model 1		Model 2		Model 3		Model 4		Velocity		PCSS	
	Sn	Sp	Sn	Sp	Sn	Sp	Sn	Sp	Sn	Sp	Sn	Sp
72hr	93	86	93	86	86	86	93	93	77	73	100	100
1wk	55	100	73	100	73	100	64	91	55	64	82	100
2wks	45	100	55	100	45	91	45	82	45	91	64	100
1mo	18	100	36	100	45	100	45	100	27	91	18	100
2mos	18	100	18	100	36	82	45	82	27	73	0	100

Discussion

In this study we demonstrated the capability of kinematic metrics from a single L5 placed IMU and reaction times, collected during a DT gait assessment to accurately identify individuals sustaining an acute concussion. To our knowledge, this is the first study to demonstrate this capability in a clinical IMU-based DT gait assessment. The purpose of this study however, is not to replace currently utilized clinical assessments which include subjective symptom surveys, neurocognitive tests, and basic balance metrics. Rather, it offers an additional tool for assessing an important functional domain related to both daily and sport related activities; divided attention simple and complex gait.

These results build on and support the findings of previous laboratory investigations of post-concussion DT gait balance control. Multiple studies demonstrated that whole body COM kinematic measures are capable of identifying gait balance control deficits in concussed individuals which could persist as long as two months post injury[20,44,47]. These metrics, derived from camera-based motion capture, include total ML displacement, peak ML velocity, and peak AP velocity. While useful for alerting medical practitioners to possible persistent balance control deficits in this population, the equipment and processing intensive nature of the measures limit their clinical utility. Fortunately, wearable IMU technology provides an opportunity to translate this research into clinical practice.

Instrumentation of post-concussion balance control assessments is gaining increased popularity. Multiple researchers validated instrumented versions of the balance error scoring system (BESS), a subjective static balance assessment included in the SCAT

5[65,67]. Research progressed to dynamic gait assessment with a recent systematic review identifying as many as 78 studies utilizing IMUs in gait analysis of patients with neurologic disorders[55]. Studies largely employed traditional gait temporal distance parameters, but others explored more advanced metrics such as inter-joint coordination, symmetry, and stability measures. A few assessed accelerations of, and derived range of motions of, sensors placed over the low back. Prior research suggests the location on the low back around the L5 or S1 vertebra may provide a reasonable corollary to COM kinematics during normal walking[70,71].

One study utilized this methodology to determine if directly measured accelerations from a single IMU placed over the low back were similarly sensitive as COM velocity and displacement to identify gait impairments in concussed individuals[21]. In the study, the peak acceleration along the ML axis occurring during the transition from single- to double-support was able to differentiate concussed from healthy participants up to a week post injury. This finding supports the theory that altered COM displacement and velocity may be a result of poor momentum control due to an in ability to regular COM acceleration. Not surprisingly four of the six metrics identified in our regression models were accelerations (AP min, ML 1, ML 2, and Vert 3).

ML 1 represents an acceleration toward the contralateral limb just prior to heel strike during ipsilateral terminal stance. A greater peak acceleration may indicate an ability to attenuate increased laterally directed momentum in the ensuring gait phases. A greater ML 2, occurring at contralateral heel strike directed toward the ipsilateral limb, suggests a greater ability to attenuate contralaterally directed momentum at this phase. The AP min represents the braking force generated from heel strike through the initial loading

response phase. Greater values indicate an ability to attenuate forward momentum which is redirected down and toward the heel striking limb. This shift in momentum is then controlled both in the ML direction and along the vertical axis as indicated by Vert 3 which is the upward acceleration which occurs in loading response and prevents the COM from collapsing to the ground.

The two additional metrics included in the model relate to turning performance (Turn Time), and cognitive task function during the complex 180 degree turning gait task (Turning RT). Slower turn times may indicate an inability to generate and control rotational momentum, or the adoption of a conservative turning strategy. Combined with the RT during the turn a DT cost is illuminated in both turning and cognitive task performance and suggests acutely concussed individuals have neurocognitive impairments that diminish their ability to perform complex divided attention tasks.

While none of the four models achieved 100% Sn and Sp within 72 hours of injury, they all retained high Sp throughout the two month period. Furthermore, the four models all experienced drops in Sn over the two month period, but continued to identify injured subjects at one and two months post injury, where the PCSS model experienced a near complete loss of Sn after two weeks. The loss of Sn in the PCSS is not unexpected as subjective symptom reports tend to normalize within one to two weeks. The comparison of the PCSS and IMU based regression models is not intended to demonstrate superiority, rather it suggests they are capable of identifying individuals with persistent dynamic gait balance control impairment even after resolution of subjective symptoms.

Another interesting and potentially useful finding is that the two models with the fewest metrics (three and four metric models) appear to perform the best over time with a

Sn of 36% and 45% at the 2mos assessment. To maximize clinical utility, IMU based gait assessments must provide real-time or near real-time feedback to medical providers. A grading algorithm employing a minimal number of metrics greatly limits processing time and capacity requirements.

Conclusion

Divided attention simple and complex gait is an integral part of daily and sport related activities. It is well established that concussion injury results in an acute impairment of DT gait balance control that can persist in some individuals up to two months post injury. An inability to appropriately evaluate this functional capacity in the clinical environment may result in premature return to activity, possibly leading to adverse sequela. We demonstrated that impaired divided attention balance control can be assessed with as few as three IMU based metrics, and that a regression model employing the metrics remains sensitive to persistent gait balance control impairment.

Bridge

Chapter IV describes the sensitivity and specificity to acute and persistent gait balance control impairments of a group of kinematic and neurocognitive metrics collected from and IMU based DT gait assessment. A model with as few as three metrics demonstrated high acute sensitivity and specificity, and was able to identify individuals with persistent balance deficits for up to two months post injury. In the next chapter the utility of kinematic and neurocognitive dual-task cost metrics is assessed as both a measure of post-concussion gait balance control impairment, and method for determining

task prioritization.

CHAPTER V

DUAL-TASK COSTS: EXPLORATION FOR DETECTION OF POST-CONCUSSION GAIT IMBALANCE AND DESCRIPTION OF TASK PRIORITIZATION

Introduction

Dual-task (DT) gait analysis, in which a gait task is paired with a concurrent cognitive task, has gained increased popularity for its ability to illuminate subtle changes in balance control[32] or other motor deficits that may otherwise be undetectable. The paradigm, developed over the past 15 to 20 years, was initially applied to elderly fall risk prevention research but has since been widely applied to other neurologic conditions including mild traumatic brain injury (or concussion). The theoretical foundation of the paradigm is based on the limited capacity[24] and/or the bottleneck[25] cognitive processing theories. The limited capacity theory suggests an individual's attentional, or information processing capacity, are finite and therefore place a limit on concurrent execution of multiple cognitive processes. The bottleneck theory submits multiple cognitive processes utilize the same processing pathways forcing tasks to wait on each other to complete their transit through shared pathway. The result of this capacity limitation or pathway congestion could produce a measurable cost in gait and/or cognitive task performance.

Steady-state gait is often considered a largely automated process, controlled through subcortical locomotor processing with little executive control in healthy individuals[26]. Still, higher level cognitive processes involved in sensory perception and integration are necessary to continuously fine tune the motor plan. Combined with a concurrent cognitive task, the resultant processing demands may either exceed available

attentional resources or become bottlenecked as they compete for shared pathways. Individuals with conditions affecting balance or cognition may therefore experience a performance decrement in one or both tasks[27], often referred to as a dual-task cost (DTC). Intuitively, this metric can be derived from any biomechanical or neurocognitive outcome measure collected in a DT assessment. However, its utility in clinical gait assessment is dependent on multiple factors.

Cognitive task complexity is an important consideration necessitating some compromise between the desired cognitive effects and practical application. Many secondary cognitive tasks of varying complexity have been utilized in DT gait research. Such tasks include the visual and auditory Stroop, various question and answer (Q&A) batteries, the Brooks mental task, and the n-back[35], which assess various cognitive domains. For example, the Stroop task is relatively simple and categorized as a selective attention task based on the flanker effect[25]. Color-word combinations are presented that are either congruent (color matches the word displayed) or incongruent (color does not match the word displayed) and the irrelevant color-word information slows down the correct naming of the color. Although it is a relatively simple task, application of visual variations to gait assessment may yield different effects than an auditory variant as the visual system is the dominant sensory modality for dynamic balance control.

Worden and colleagues demonstrated this point in their study comparing the DTC in obstacle-crossing of a visual versus auditory Stroop task in a cohort of healthy young adults[78]. They reported greater accuracy and shorter response times for the visual version when performing the cognitive task alone. However, the DTC was greater during obstacle-crossing (DT), likely due to the added structural interference. While the added structural

interference may relate to various functional activities and produces a greater effect, application in clinical settings may be impractical as it is more equipment intensive.

Q&A tasks are also popular and often apply questions of simple spelling and arithmetic (e.g. spelling a five letter word backwards or counting backward from a starting number by a given value). fMRI studies indicated these tasks are more complex, requiring the coordination of multiple brain regions[38,39]. In an investigation of acutely concussed adolescents, three secondary tasks (single auditory Stroop, multiple auditory Stroop, and Q&A) were applied in the DT assessment of simple gait. The increase in task complexity from single-Stroop, to multiple-Stroop, to Q&A resulted in both decreased cognitive task accuracy rates, and decrease balance control as measured with various whole body center of mass (COM) kinematic metrics[40].

Another task with increased difficulty utilized in brain injury DT research is the n-back. Used to tax working memory it can be modulated to increase or decrease the working memory load. The test can be applied with numerals or letters, and in visual or auditory forms[79]. It generally consists of a string of alphanumeric characters presented at given intervals and requires individuals to indicate when a character is repeated a given number of stimuli in the past (e.g. 3-back, the individual responds when a character repeats itself after three successive stimuli). The Brooks mental task is also commonly used to assess working memory[80], but adds a visual-spatial component that may occupy neural pathways utilized for visual perception, resulting in an additional form of cognitive interference. Again, the utility of these assessments must be weighed against potential technical considerations associated with clinical application such as audiovisual equipment, automation, and assessment grading.

While cognitive task complexity must be critically examined, so too must the complexity of gait tasks and biomechanical outcome measures. Simple steady-state gait is often utilized for its ease and standardization but is limited in its generalizability. Turning, obstacle negotiation, and gait initiation/termination are ubiquitous to daily activity and should therefore be considered when designing a clinical DT gait assessment. They may also yield additional outcome measures for which potentially useful DTC metrics can be derived.

Traditionally, gait analysis is performed using sophisticated camera-based motion capture. However, these methods are limited in utility due to their equipment and time intensive nature. Already numerous clinical technologies assist in clinical gait analysis from instrumented walkways to wearable inertial measurement units (IMUs). They are capable of assessing simple gait temporal distance characteristics, however, increasing evidence suggests these metrics are not sensitive to lingering balance control impairments that can exist well into the subacute phases of post-concussion recovery. On the other hand, sophisticated biomechanical markers such as estimated whole body COM kinematics, inter-joint coordination, and variability may be computationally costly or have minimal effect sizes, potentially limiting the sensitivity of derived DTCs. A recent systematic review of post-concussion DT gait analysis highlights this fact as 11 articles were identified demonstrating significant differences between concussed and healthy individuals in total medial-lateral (ML) displacement of the COM[74]. The magnitude of difference was less than or equal to one centimeter.

A final consideration in the utility of DTC metrics is the division of cost between the cognitive and motor tasks. There is some evidence suggesting healthy individuals are

able to selectively allocate attentional resources without sacrificing postural control, indicating a possible postural control priority hierarchy[28]. However, in multiple studies involving elderly individuals, both cognitive task performance and balance control were affected suggesting this ability is diminished in individuals with impaired neuromuscular control[27,29,30]. Adding to the difficulty in assessing attentional allocation is prioritization instruction. In the previously mentioned systematic review, all but two studies did not offer any prioritization instruction, while one provided instructions to "not" prioritize either task, and in the other study subjects were instructed to prioritize "both" tasks equally. Prioritization of tasks is a complex topic in DT gait assessment. The simple cue to "not" prioritize one task over the other, or "both" tasks equally may result in unintended prioritization effects. The extent to which individuals prioritize one task over the other can have a large effect on the interpretation of balance control and cognitive outcome measures. As the vast majority of concussion related DT gait assessments offer no prioritization instruction, it is important to determine if individuals with and without injury prioritize tasks differently and if that difference can be quantified in clinical DT gait assessments. Furthermore, identification of shifts in prioritization may offer additional insight into neurocognitive recovery and prove to be a valuable metric in and of itself.

The purpose of this investigation was therefore to evaluate the utility of DTC metrics, derived from kinematic and neurocognitive outcome measures from an IMU based DT gait assessment, to differentiate concussed from healthy individuals. A secondary purpose is to determine if quantification of prioritization between the concurrent gait and cognitive tasks can be accomplished using this metric.

It was hypothesized that one or more DTC metrics could differentiate acutely

concussed from healthy individuals. It was also hypothesized that concussed individuals would more heavily prioritize gait balance control (i.e. greater DTC in kinematic versus neurocognitive measures) acutely post-concussion, and that this prioritization would more closely approximate that of healthy individuals over the course of a two month post injury period.

Methods

Individuals between the ages of 18-30 sustaining an acute concussion (within 72 hours of injury) were recruited by sports medicine physicians at the University Student Health Clinic and matched to healthy controls by sex, age, height, and weight. Individuals with an injury affecting normal gait, a history of permanent memory loss or concentration abnormalities, or had impaired hearing were excluded. Matched control participants sustaining a concussion within the past year were also excluded. The study was approved by the Institutional Review Board and all participants provided written informed consent prior to enrollment.

An IMU-based gait balance control assessment employing both single- and dual-task straight and turning gait was performed at five post injury time points: within 72 hours of injury (72hrs), at one week (1wk), two weeks (2wks), one month (1mo), and two months (2mos). Healthy participants were assessed at similar intervals from the initial testing. The assessment consisted of a seven meter straight walk at a self-selected steady-state pace, a 180 degree counter clockwise turn around a cone, and returned to the start position (**Fig. 2.1**). An auditory Stroop task consisting of four auditory stimuli, the words "high" or "low" spoken in either a high or a low pitch[37], was applied in DT gait trials.

Subjects first performed two practice ST auditory Stroop trials consisting of three stimuli each. Next four additional three stimuli ST trials were performed and recorded as their ST comparative measure.

Four ST and four DT walking trails with a randomized order were performed. Participants were provided automated instructions on Stroop task performance, however, they were not given any instructions to prioritize or not prioritize one task over the other. Each walking trial was initiated with an automated verbal command instructing participants to look straight ahead, followed by an auditory beep. During DT trials a single randomly presented stimulus was triggered on the third heel strike during the walkout and one step prior to the 180 degree turn. All verbal instruction and auditory stimuli were automated with a custom Superlab 5 software program (Cedrus Corp., San Pedro, CA, USA) administered through a single ear Bluetooth wireless headset with boom microphone (Blue Tiger USA, Stafford, TX, USA).

Straight gait metrics were collected during three consecutive gait cycles beginning with the 3rd, 4th and 5th heel strikes during the walk out referenced to a single left foot contact initiated gait cycle, while turning metrics were collected from the initiation to termination of the 180 degree turn. All kinematic outcome measures were recorded from a single IMU placed over the L5 vertebra (APDM, Inc., Portland, OR, USA). The sensor axes were oriented such that the vertical (Vert) axis pointed down, the ML axis to the right, and the AP axis to the rear. Sensor data was collected at 128 Hz and low-pass filtered with a second order, zero-lag Butterworth filter with a 12 Hz cutoff frequency. A tilt correction using data collected from static stance was performed to obtain accelerations with respect to the anatomic frame of reference.

Straight gait kinematic outcome measures included eight gait event specific peak accelerations (three along the ML axis, three along the vertical axis, and two along anterior-posterior [AP] axis) and six peak angular velocities (three about the vertical axis [Yaw] and three about the AP axis [Roll]). The 180 degree turn was trimmed for analysis by integrating L5 sensor angular velocity signal to yaw angle[77]. Total turn time, peak yaw and peak roll angular velocities were obtained during the turning event. Stroop task response time (RT) was also recorded for baseline, straight gait, and turning gait. DTC was calculated for all outcome measures (eq. 1) and presented as a percentage.

$$DTC = \frac{DT - ST}{ST} \quad (1)$$

Negative DTC values indicated a decrease in the given metric from ST to DT conditions. Individual values greater than three standard deviations from the mean for the given outcome measure, group and day were considered significant outliers and removed from the analysis[81].

All DTC metrics (eight peak accelerations, six peak angular velocities, turn time, peak turning yaw and roll, and turning and straight gait RTs) were analyze with two-way, repeated-measures, Analyses of Variance (ANOVA). Independent variables were group (concussed vs. healthy) and time (72hrs, 1wk, 2wks, 1mo, and 2mos). All analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 25.

Results

Eleven participants with acute concussion (7F/4M, age 20.1±1.3 years, height 171.3±8.2 cm, and weight 71.4±16.4 kg) and 11 healthy matched controls (7F/4M, age 20.6±1.9 years, height 172.0±9.9 cm, and weight 70.0±11.2 kg) completed all five

assessments. There were no between groups differences for age, height, or weight. Concussed participants were assessed at 1.8±0.6, 6.2±1.2, 15.3±3.3, 26.2±3.6, and 56.6±9.9 days post injury.

A group by time interaction effect was identified for ML 2 DTC ($p = .047$, $\eta_p^2 = .112$; **Fig. 5.1**). This peak ML acceleration occurring at heel strike and directed toward the contralateral limb was initially greater in the DT condition for concussed participants, but then demonstrated a minimal DTC throughout the remaining four assessments. However, healthy participants initially

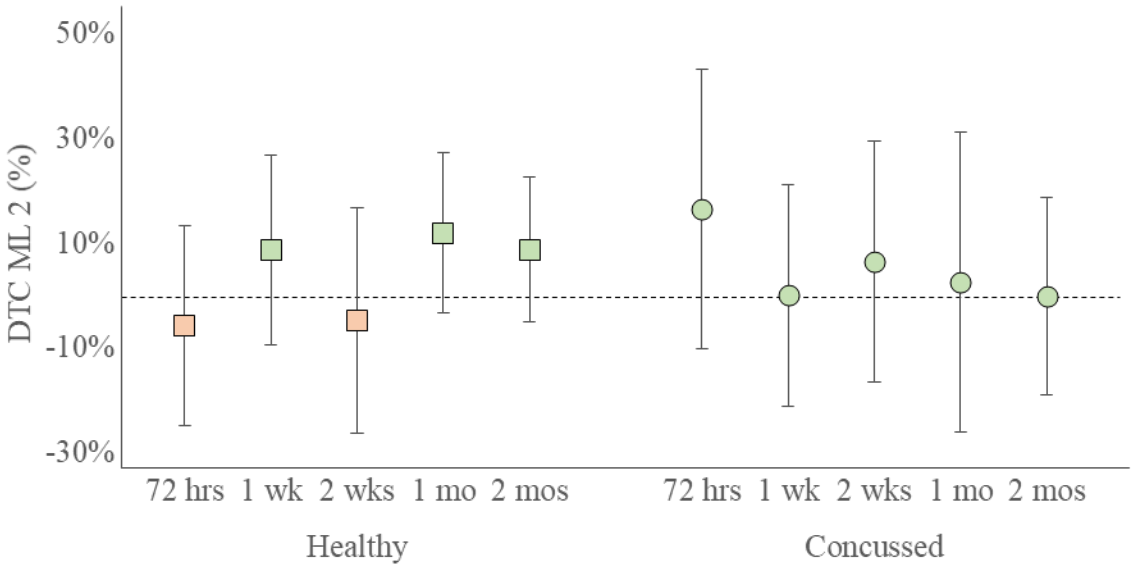

Figure 5.1: Dual-task cost (DTC) for peak medial-lateral (ML) acceleration 2 presented for all five assessments for both groups (mean±SD). Orange colored markers indicate negative DTC while green indicate positive values. A significant group by time interaction effect was identified, $p = .047$.

experienced a smaller peak acceleration in the DT condition, but that cost fluctuated between a negative and positive cost through the remaining assessments.

A group by time interaction effect was also identified for peak yaw angular velocity during the 180 degree turn ($p = .003$, $\eta_p^2 = .189$; **Fig. 5.2**). Overall concussed

participants experienced a negative DTC (slower peak yaw angular velocity) at all post-injury assessments with the exception of the 1mo assessment, while healthy participants had faster DT yaw

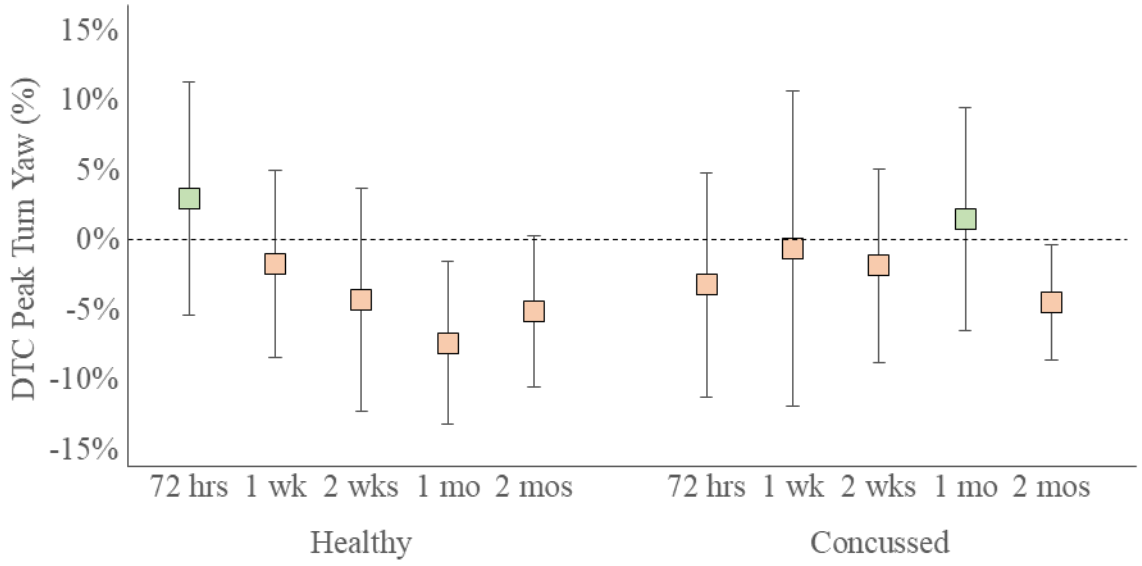

Figure 5.2: Dual-task cost (DTC) for peak yaw angular velocity during the 180 degree turn presented for all five assessments for both groups (mean±SD). Orange colored markers indicate negative DTC while green indicate positive values. A significant group by time interaction effect was identified, p = .003.

velocities (positive DTC) at the initial assessment, then slower DT yaw velocities for the remaining four assessments. At each of the four assessments from 1wk to 2mos, healthy participants demonstrated greater DTCs than concussed participants.

A main effect of time was identified for Vert 2 ($p = .006$, $\eta_p^2 = .163$; **Fig. 5.3**). This vertical acceleration is oriented downward and occurs during the transition from single- to double-support. While both groups had greater peak accelerations at the initial assessment (positive DTC), the increased DT acceleration magnitude generally decreased over time, ending as a lower DT acceleration (negative DTC) at the 2mos assessment.

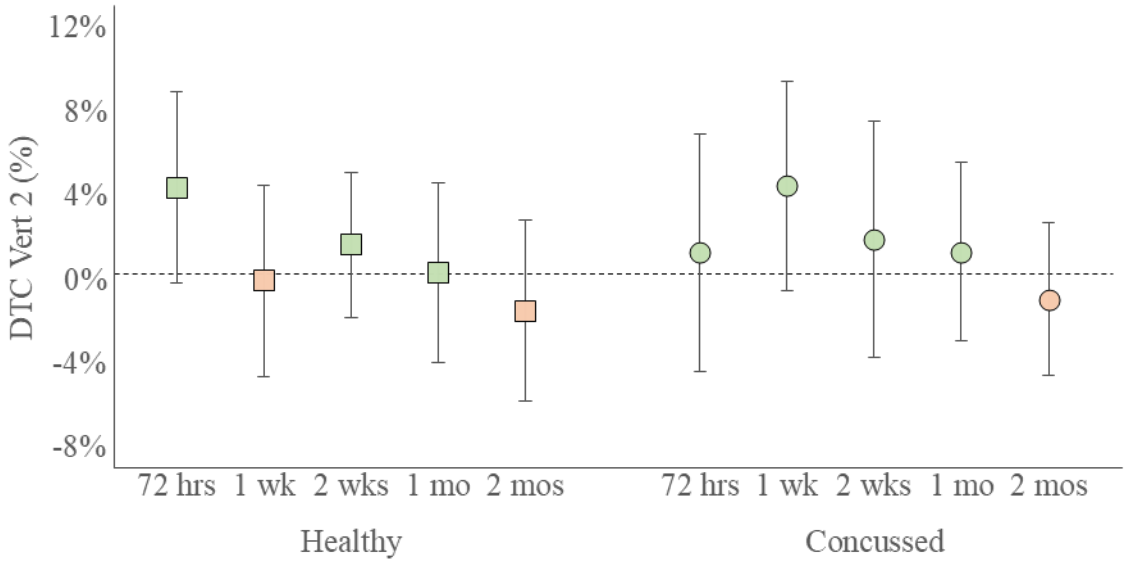

Figure 5.3: Dual-task cost (DTC) for peak vertical acceleration 2 presented for all five assessments for both groups (mean±SD). Orange colored markers indicate negative DTC while green indicate positive values. A significant main effect of time was identified, p = .006.

There were no other significant interaction or main effects. However, visual examination of the two response time DTCs (neurocognitive measure) indicate healthy participants exhibit very little change in RT between conditions in either turning or straight gait, while concussed participants had faster RTs (negative DTC) at the 72hrs assessment, but little difference between conditions thereafter (**Fig. 5.4**).

Comparison of neurocognitive to kinematic DTC metrics is difficult due to substantial variability across all metrics as illustrated by standard deviations that in almost all cases were greater than the mean cost, and in many cases as much to five or six times as great (**Table 5.1**). However, at the 1wk and 2mos assessments, healthy individuals tend to display larger magnitudes in straight gait kinematic variables in the DT condition (positive DTCs).

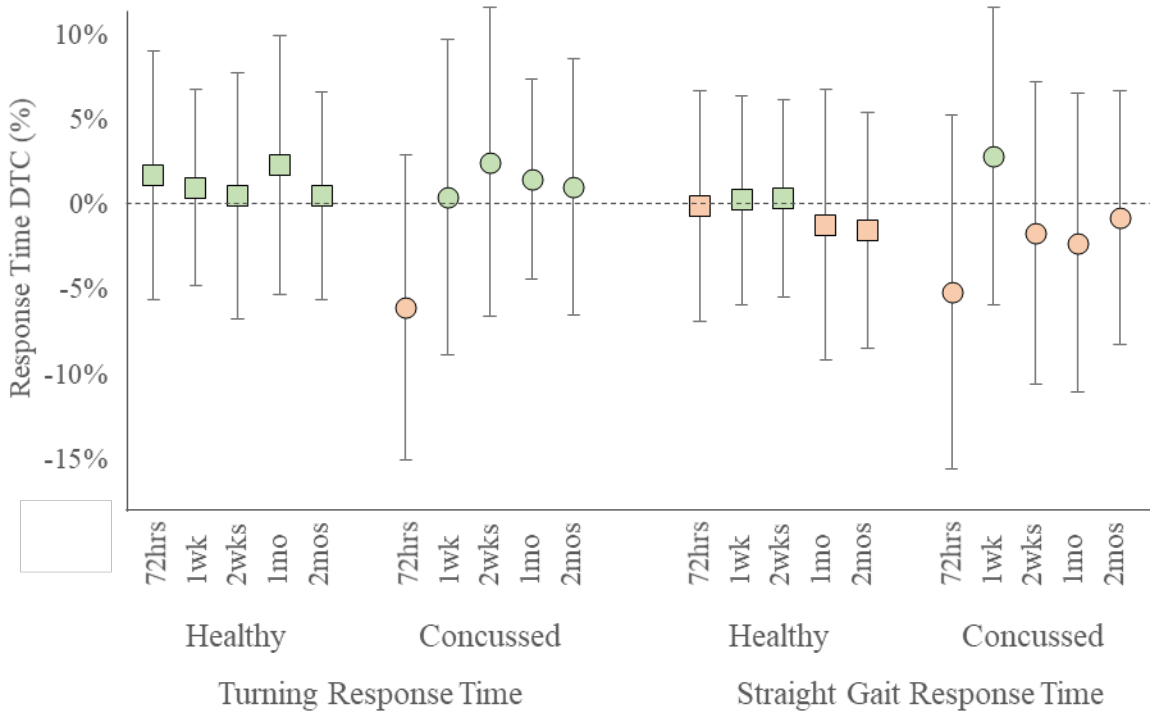

Figure 5.4: Dual-task cost (DTC) for response time during turning and straight gait presented for all five assessments for both groups (mean±SD). Orange colored markers indicate negative DTC while green indicate positive values.

Table 5.1: Dual-task costs (DTC) for all acceleration, angular velocity, turning, and reaction time outcome measures presented for all five assessments and both groups (mean±SD). Means are colored with red representing the greatest DTC (negative) through green which represents the most positive DTC. Green boxes highlight potential trends for increased magnitudes in straight gait kinematic metrics.

Outcome	Healthy					Concussed				
Measure	72hrs	1wk	2wks	1mo	2mos	72hrs	1wk	2wks	1mo	2mos
Vert 1	-1.8 (2.6)	-0.5 (3.2)	-0.3 (2.9)	0.7 (3.3)	-1.5 (3.9)	0.2 (2.3)	-2.1 (3.1)	-0.5 (3.3)	0.0 (2.8)	0.4 (1.8)
Vert 2	4.4 (4.7)	0.0 (4.6)	1.7 (3.4)	0.3 (4.3)	-1.5 (4.3)	1.3 (5.7)	4.5 (5.0)	1.9 (5.6)	1.3 (4.3)	-0.9 (3.7)
Vert 3	-0.2 (4.1)	1.2 (4.6)	-1.0 (2.2)	0.0 (2.5)	0.1 (2.3)	0.4 (2.4)	-0.6 (3.3)	-0.3 (3.4)	-0.3 (1.4)	0.8 (2.8)
ML 1	-0.5 (20.1)	16.7 (23.2)	-1.4 (14.6)	-1.4 (9.1)	6.9 (14.5)	2.2 (12.2)	-1.1 (19.2)	4.1 (12.0)	4.3 (8.2)	0.4 (9.0)
ML 2	-5.8 (19.1)	8.6 (18.1)	-4.7 (21.6)	11.9 (15.3)	8.8 (13.7)	16.6 (26.7)	0.0 (21.1)	6.6 (23.0)	2.6 (28.6)	-0.2 (18.8)
ML 3	6.2 (22.6)	14.9 (30.9)	0.2 (11.1)	1.9 (19.9)	6.9 (16.5)	10.5 (15.2)	3.9 (28.2)	1.0 (18.5)	24.0 (49.7)	4.6 (16.0)
AP 1	-2.6 (3.8)	0.5 (6.9)	-1.7 (3.5)	1.7 (4.5)	-2.0 (8.8)	2.7 (4.3)	0.1 (5.4)	2.3 (7.5)	-3.7 (16.2)	0.1 (3.1)
AP 2	-20.0 (32.3)	18.8 (25.3)	13.1 (37.2)	-5.4 (33.5)	-21.3 (50.5)	4.0 (22.0)	3.1 (35.9)	-4.2 (27.1)	-3.6 (31.0)	-5.9 (50.0)
Yaw 1	1.3 (34.2)	-0.7 (15.1)	4.9 (20.4)	0.6 (21.9)	-0.8 (14.3)	-0.4 (18.0)	2.2 (13.0)	4.8 (11.2)	1.9 (20.3)	-4.9 (13.2)
Yaw 2	12.7 (39.2)	-0.3 (19.0)	15.0 (26.9)	9.2 (13.7)	16.6 (53.4)	2.5 (49.3)	-7.5 (71.0)	-9.9 (26.2)	4.0 (44.5)	-7.5 (29.5)
Yaw 3	21.7 (73.5)	21.7 (61.0)	-22.8 (51.5)	-25.3 (78.5)	17.4 (100.5)	4.6 (67.4)	8.0 (62.0)	28.4 (63.6)	9.9 (62.9)	-26.0 (112.0)
Roll 1	-1.4 (40.1)	28.5 (101.6)	-2.5 (68.6)	-0.2 (50.0)	39.7 (69.4)	-21.4 (118.2)	20.0 (209.3)	-51.2 (73.3)	-47.1 (57.9)	5.7 (129.9)
Roll 2	-4.7 (14.0)	-6.5 (13.7)	-5.1 (12.7)	-7.0 (12.4)	-0.1 (9.2)	0.3 (16.8)	-3.8 (10.0)	-2.3 (11.1)	0.7 (14.5)	-1.2 (12.6)
Roll 3	9.8 (31.8)	17.7 (35.1)	8.3 (37.0)	11.6 (38.4)	11.5 (16.6)	6.0 (25.7)	6.9 (19.7)	-6.8 (18.3)	-5.0 (26.6)	13.0 (57.7)
Turn Time	4.9 (11.5)	5.8 (7.9)	6.0 (14.1)	7.1 (7.5)	6.3 (8.7)	8.2 (6.3)	3.6 (7.3)	1.9 (4.3)	-0.1 (5.9)	5.6 (6.0)
Turn Yaw	2.9 (8.4)	-1.8 (6.7)	-4.3 (7.9)	-7.4 (5.8)	-5.1 (5.4)	-3.2 (8.1)	-0.6 (11.2)	-1.8 (6.9)	1.5 (8.0)	-4.5 (4.1)
Turn Roll	-0.7 (22.2)	5.0 (11.5)	-1.7 (15.3)	2.3 (13.3)	-2.6 (8.1)	-3.3 (12.5)	-2.6 (9.9)	-0.6 13.0)	1.6 (7.4)	-2.1 (9.0)
Turning RT	1.77 (7.3)	1.02 (5.8)	0.53 (7.3)	2.33 (7.6)	0.56 (6.1)	-6.07 (9.0)	0.46 (9.3)	2.53 (9.1)	1.52 (5.9)	1.04 (7.6)
Straight RT	-0.05 (6.8)	0.28 (6.2)	0.39 (5.8)	-1.17 (8.0)	-1.50 (6.9)	-5.14 (10.4)	2.88 (8.7)	-1.66 (8.9)	-2.24 (8.8)	-0.76 (7.5)

Discussion

The result of this investigation reveal minimal utility of kinematic and neurocognitive DTC metrics, recorded during a DT IMU-based gait assessment, for identifying individuals sustaining an acute concussion. Only three kinematic metrics (Vert 2, ML 2, and peak turning yaw) demonstrated significant interaction effects. Further, these three metrics did not yield significant group effects, suggesting they were driven by changes over the course of the five post-injury assessments.

It is apparent that kinematic DTC metrics collected from the single IMU placed over the L5 vertebra, and the RT DTC metrics collected during a single auditory Stroop task, are subject to substantial variability. While, investigations using the magnitudes in these variables were capable of distinguishing concussed from healthy individuals throughout a two month post-injury period[21,82], the variability inherent to the DTC metrics appear to limit their utility.

Laboratory based investigations employing camera-based motion capture and whole body COM kinematic measures and similar DT gait assessments were able to demonstrate the utility of DTC metrics derived from these measures in the assessment of post-concussion gait imbalance[40,74,82]. This is likely due to high resolution of the laboratory-based methods in detecting minimal changes in these measures. The IMU-based kinematic corollaries collected over the low back, do not appear to have the same resolution, as expected. This is a consideration in the development of a clinically practical and useful biomechanical DT gait assessment. In this case, the resolution of biomechanical markers of gait balance control impairment is sacrificed for the practical utility of wearable sensors and appears to result in the diminished utility of DTC metrics.

Similarly, neurocognitive DTC metrics appear to be limited in their utility by the simplicity of the single auditory Stroop task. More complex tasks demonstrate consistently DTCs of greater magnitude[40,78], however, may not be easily lend themselves to automation in clinical assessments. The single auditory Stroop task utilized in this study, while resulting in limited DTC metric utility, is easily automated and graded.

The relatively equivocal utility of the DTC metrics in this study also affect the ability to determine task prioritization. Prioritization instruction is always a consideration in DT assessments, however, there is little agreement on the nature of those instructions. The vast majority of post-concussion DT assessments provide no prioritization instruction, while instructions to "not" prioritize either task, or to prioritize both tasks equally are also utilized. In this study no prioritization instruction was given based on the argument that any instruction has an inherent effect on task prioritization.

While no significant findings were identified, an interesting observation in RT data suggests concussed participants actually reduce RT in the DT condition at the 72hr assessment, suggesting they are prioritizing the cognitive task. This trend does not appear in healthy participants and is attenuated in concussed participants by the next assessment.

A second observation suggests a trend toward superior straight gait kinematic outcome measure values in DT over ST walking in healthy participants at the 1wk and 2mos assessments. These trends occur in the absence of a relevant DTC in Stroop RT suggesting the addition of the secondary cognitive task in healthy young adults may actually cause them to apply additional attentional resources to the gait task. This trend is not apparent in concussed participants, possibly due to a limitation in attentional capacity related to the injury.

Conclusion

This investigation concludes that kinematic and neurocognitive DTC metrics derived from a clinically practical DT gait balance control assessment may be limited in their utility to distinguish healthy from concussed individuals. This limitation is likely a result of the compromise between high laboratory resolution and clinical practicality. Furthermore, while speculations can be made regarding differences in task prioritization in this assessment, substantial variability in the DTC metrics limits definitive conclusions.

CHAPTER VI

CONCLUSION

Findings Summary

Utility of IMUs for the detection of post-concussion gait balance control impairment was investigated in this study. We sought to translate laboratory-based biomechanical markers collected under a DT paradigm, previously shown to be sensitive to persistent balance impairment, to a clinically practical application. To this end a simple DT gait balance control assessment was developed using off the shelf hardware and software. Directly measured kinematic measures from a single L5 place IMU were assessed for their consistency and reliability in a non-laboratory environment, across time, and by different raters. The assessment was then applied to acutely concussed individuals in a two month, longitudinal, matched control design, and kinematic biomechanical markers were evaluated for their ability to both describe dynamic balance control and detect impaired gait balance control. Groups of the kinematic and neurocognitive measures were then assessed for their ability to correctly identify concussed and healthy individuals across a two month post injury period. The work ends with an exploration of the utility of DTC metrics derived from the assessment both for detecting impaired balance control and for determining differences in prioritization between cognitive and motor tasks.

In the first study, a clinically practical gait assessment, consisting of both straight and turning gait, and paired with three concurrent auditory cognitive tasks was developed. Acceleration measures had high internal consistency in both laboratory and non-laboratory

environments, on multiple days separated by one to two weeks, and when collected by different raters. Furthermore, the assessment was successfully applied to 14 healthy athletes from a D1 women's soccer team, by sports medicine personnel, in a pre-existing rehabilitation space, and in a reasonably short time. Eight consistent acceleration-based kinematic metrics were identified with many capable of detecting small differences in balance control among the cohort of healthy athletes exhibited between the different walking conditions. Combined, these findings suggest the assessment can be reliability and practically applied in a clinical setting, and demonstrates the sensitivity of kinematic metrics collected from a single L5 placed sensor to subtle changes in gait balance control.

In the second study, the assessment was applied to young adults within 72 hours of sustaining an acute concussion, and uninjured healthy matched controls. A description of ML, AP, and Vertical acceleration, and Yaw and Roll angular velocity profiles were described during a single gait cycle. Eight peak accelerations and six peak angular velocities corresponding to specific gait events were identified and assessed for their ability to distinguish healthy from concussed individuals across the two month post-injury period. Peak Yaw 2, Vert 2, and Vert 3 were capable of distinguishing healthy from concussed individuals across the five post injury assessments, while three additional accelerations (AP 2, ML 2, and ML 3) showed promised. These peak accelerations and angular velocities occur primarily in the middle gait phases where maximum propulsion is followed by a contralateral loading response as weight is shifted from one limb to the other. The results of this study suggest healthy individuals may be able to generate more anterior and ML momentum (toward the heel striking limb). They are also better able control the increased momentum during the transition from single- to double-support by

shifting energy away from the AP axis, down and laterally toward the heel striking limb. This increase in vertical and ML energy is then better attenuating it in the ensuring loading response phase.

In the third study metrics collected during a 180 degree turn, along with neurocognitive metrics from the concurrent cognitive task were assessed together with the metrics from study two. The variables were reduced with a PCA, largely to remove collinearity among variables. Metrics with the greatest potential for differentiating concussed from healthy individuals were included in a binary stepwise logistic regression resulting in four models of three to six variables capable of accurately classifying study participants with high sensitivity and specificity. All of the models maintained some predictive capability throughout the two month post injury period, however, the three and four metric models maintain moderate Sn (36% and 45% respectively) and high Sp (82% for both) out to the two month assessment. This suggests that a logistic regression model with as few as three outcome measures (ML 2, Turning RT, and Vert 3) may be capable of identifying concussed individuals with lingering balance control impairments. The results further provide the foundation for development of automated clinical grading algorithms in IMU based gait analysis, potentially offering medical providers with an objective functional balance control measure to include in RTA decision making.

In the fourth study the utility of the DTC metric was investigated. DTC can be applied to nearly any outcome measure (motor or cognitive) collected in a DT gait assessment and has been shown in previous laboratory research to be a useful metric in post-concussion gait imbalance detection. However, our results suggest the compromises in metric resolution and cognitive task complexity required for clinical application, limit

the utility of these metrics to this assessment. Furthermore, the substantial variability in the DTC metrics limiting their capability to distinguish concussed from healthy individuals and the ability to conclusively identify task prioritization strategy.

Future Research

The desired end state of this research is the development of a readily available, highly sensitive, DT gait assessment capable of providing clinicians with an objective measure of functional balance control in real-time. To achieve this goal future research should first focus on building a robust database of concussed and healthy individuals sufficiently addressing factors such as age, sex, and sport/activity. Next, further refinement of the grading algorithms might be accomplished through the application of an artificial neural network employing a logistic transfer function. The network could be trained with the enhanced database to provide greater accuracy for a wide range of populations. The grading algorithm then needs to be packaged with other necessary algorithms (single sensor gait event detection, cognitive task automation and grading, and kinematic outcome measure analysis) to produce a clinical assessment capable of real-time or near real-time results generation. Finally, such an instrument requires multi-site, longitudinal, clinical investigations to determine added value of the objective balance control analysis on both immediate and long term outcomes.

APPENDIX A

INFORMED CONSENT FORM:

DUAL-TASK GAIT STABILITY ASSESSMENT UTILIZING A WEARABLE

MOTION ANALYSIS SENSOR: DIAGNOSIS AND MANAGEMENT OF MTBI

INTRODUCTION

You are being asked to be a research subject in a study of dual-task gait stability assessment, utilizing a wearable sensor system. You were selected as a possible participant because you are a healthy individual 18-40 years of age, are able to walk over level ground without any assistive devices, and have normal hearing. However, if you do not pass the screening test, you may be excluded from participation in this study. We ask that you read this form and ask any questions that you may have before agreeing to be in the study

PURPOSE OF THE STUDY

The purpose of this study is to compare gait stability measurements in two dual-task walking conditions and identify which metrics best identify gait stability impairments wearable motion sensor system will be used to capture the motion data, the validity of which is being assessed for possible use in the clinical setting

DESCRIPTION OF THE STUDY PROCEDURES (NON-ATHLETE HEALTH ADULTS)

If you agree to be in the study, we will ask you to do the following: Visit the motion analysis laboratory (B52 Gerlinger Annex) for two testing sessions spaced by one to two weeks. Each session will take no longer than 1 hour and 10 minutes.

<u>Screening Session</u>

At the beginning of the initial session you will be asked to complete this consent form and asked to complete a health history questionnaire. If you answer yes to any of the exclusion questions you will be excluded from participation in this study.

<u>Sensor Set Up</u>

Three small sensors will be applied to your body with elastic belts, one over the low back at the level of the fifth lumbar vertebra, and one over each lateral ankle. The Opal Wearable Motion Analysis Sensor system utilized in this study will only be used in the manner in which it was developed and intended for use by the manufacturer. Set up will take approximately 1-2 minutes.

<u>Practice Stroop and Question and Answer</u>

You will hear the words “high” and “low” each spoke in either a “high” or “low”

tone. You will be asked to correctly identify the pitch of the voice, regardless of if it matches the tone spoken in or not. You will be asked a series of questions and asked to correctly answer them.

Walking Task

You will be asked to complete a simple walking task without any cognitive test, while performing the auditory Stroop test, and while performing the Q&A. The walking task is performed wearing normal athletic shoes. It is initiated from a feet together standing position. You will be instructed to walk at a self-selected pace over a seven meter path, perform a 180 degree turn, and return to a stop at the original start position.

First Environment

You will begin testing in either the laboratory or a hallway similar to a medical clinic. You will perform the walking task as previous indicated approximately 6 times per condition. After completion, you will repeat the same tasks for a second evaluator.

Second Environment

You will be taken to the other environment and asked to complete the same three walking tasks for both evaluators.

Equipment Removal and Questions

All sensors will be removed and you will have the chance to ask any questions you may have.

DESCRIPTION OF THE STUDY PROCEDURES (COLLEGIATE ATHLETES)

If you agree to be in the study, we will ask you to do the following: All testing will be performed at the team movement screening sessions performed by the athletic medicine staff. The single testing session will take approximately 20 minutes.

Screening Session

At the beginning of the initial session you will be asked to complete this consent form and asked to complete a health history questionnaire. If you answer yes to any of the exclusion questions you will be excluded from participation in this study.

Sensor Set Up

Three small sensors will be applied to your body with elastic belts, one over the low back at the level of the fifth lumbar vertebra, and one over each lateral ankle. The Opal Wearable Motion Analysis Sensor system utilized in this study will only be used in the manner in which it was developed and intended for use by the manufacturer.

Practice Stroop and Question and Answer

You will hear the words “high” and “low” each spoke in either a “high” or “low” tone. You will be asked to correctly identify the pitch of the voice, regardless of if it matches the tone spoken in or not. You will be asked a series of questions and asked to correctly answer them.

Walking Task

You will be asked to complete a simple walking task without any cognitive test, while performing the auditory Stroop test, and while performing the Q&A. The walking task is performed wearing normal athletic shoes. It is initiated from a feet together standing position. You will be instructed to walk at a self-selected pace over a seven meter path, perform a 180 degree turn, and return to a stop at the original start position.
Equipment Removal and Questions: All sensors will be removed and you will have the chance to ask any questions you may have.

RISKS/DISCOMFORTS OF BEING IN THE STUDY

Possible Risk for the Loss of Confidentiality to Participants

There is a chance that coded data could be deciphered by outside parties, but no greater than would be encountered in daily life situations. To minimize the risk, all records will be archived in coded form and kept by the principal investigator in a locked filing cabinet in the security regulated Motion Analysis Laboratory (B52, Gerlinger Annex).

Possible Risks Associated with a Breach of Identifiable Information

Minimal risk exists for the intentional or negligent breach of identifiable information. To attenuate that risk only the principal investigator and co-investigator will have access to code sheets containing your personal identifiable information. The coded form will be kept in a locked filing cabinet in the security regulated Motion Analysis Laboratory (B52, Gerlinger Annex). Further, both individuals have completed and will maintain currency in the required CITI training.

Possible Psychological Risk/Discomforts to Participants

You will wear athletic attire consisting of shorts and a tee shirt of your choosing. No attire changes are required, nor will any clothing need to be removed for marker placement. However, you may feel embarrassed or nervous about performing the assessments while in the laboratory, a hallway similar to a medical clinic, or at team movement screening sessions (collegiate athletes only). To minimize this, you will be consistently asked about your condition and provided short breaks if necessary. The risk of becoming too nervous to perform the tasks will be minimized by fully explaining the tasks to you and giving you a series of practice trials for familiarization. If you become too embarrassed or nervous, the experiment will be stopped.

Possible Physical Risk/Discomforts to Participants

The three sensors will be applied using elastic straps. Care will be taken to ensure the straps are tight enough to prevent excessive motion between the sensor and the skin, but not so tight as to cause discomfort. You will be asked throughout the testing session if the sensor placement is uncomfortable. If you experience discomfort, the investigator will attempt to adjust the strap. If the discomfort is unable to be resolved, the experiment will be terminated. There is very little risk of physical injury to you as you are in good health and are performing a simple walking task. However, a remote chance of falling due to the dual-task protocol, particularly in the 180 degree turn may exist. You will be consistently asked about physical condition throughout the testing session. If you appear to be dizzy or unstable, the testing session will be halted and you will be allowed to rest until the

symptoms resolve. If you sustain an injury while participating in this study the researchers will assist you in obtaining appropriate medical treatment. All expenses related to that treatment will be covered by you and/or your insurance company. If you are a University of Oregon student or employee and are covered by a University of Oregon medical plan, the plan might have terms that apply to your injury.

BENEFITS OF BEING IN THE STUDY

There are no direct benefits to you from participation in this study. However, knowledge gained from this study will increase our understanding of kinematic characteristics that are most predictive of dual task gait impairments. Further, the employment of non-invasive, wearable motion analysis sensors may lead to a significant advancement in our ability to diagnoses these deficits in a timely manner in the clinical setting.

COMPENSATION

Non-Athlete Healthy Adults

You will be provided a check of $20 at the end of the second testing session as compensation for you participation. In any circumstance where you do not complete the study, you will receive a partial compensation of $10.

Collegiate Athletes

You will be provided a $10 gift card at the end of the testing session as compensation for your participation. In any circumstance where you do not complete the testing session once it begins, you will also receive the $10 gift card.

The difference in total compensation between non-athlete healthy adult subjects and collegiate athlete subjects is due to the difference in the total time commitment which is two, one hour and 10 minutes sessions versus a single 20 minute session respectively.

COST

There is no cost to you to participate in this research study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we may publish, we will not include any information that will make it possible to identify a participant. Your name will be replaced by code numbers. The code numbers matching particular data sets to individual subjects will be stored in a hard copy. The hard copy will be kept in a locked filing cabinet separate from the data itself and only the principal investigator, coinvestigators, and graduate students involved in this project will have access to it. All laboratory notes will be archived in coded form in a locked filing cabinet and security regulated Motion Analysis Laboratory (B52, Gerlinger Annex). No identifiable information other than name will be retained after data is gathered from you. At the completion of the study and after the results have been published, the list of participants' names will be destroyed. Access to the data, records and code numbers will be limited to the researchers; however, please note that the Institutional Review Board and internal University of Oregon auditors may review the research records.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University of Oregon. You are free to withdraw at any time, for whatever reason. There is no penalty or loss of benefits for not taking part or for stopping your participation. If you are a student of the University of Oregon, you do not jeopardize grades nor risk loss of present or future faculty/school/University relationships due to early withdrawal. Participation by collegiate athletes will not affect team status or medical clearance to play. Coaching staff will not be informed of your decision to participate in the study or decision to withdrawal should you do so.

DISMISSAL FROM THE STUDY

The investigator may withdraw you from the study at any time for the following reasons: 1) withdrawal is in your best interests (e.g. side effects or distress have resulted), or 2) you have failed to comply with the study requirements**.**

CONTACTS AND QUESTIONS

The researchers conducting this study are Will Pitt, Quinn Peterson. For questions or more information concerning this research you may contact them at 315-222-6194 or 541-346-
1033. Dr. Li-Shan Chou is the faculty advisor for this study and can be contacted at541-346-4311. If you believe you may have suffered a research related injury, contact Will Pitt at 315-222-6194 who will give you further instructions. If you have any questions about your rights as a research subject, you may contact: Research Compliance Services, University of Oregon at (541) 346-2510 or ResearchCompliance@uoregon.edu.

COPY OF CONSENT FORM

You will be given a copy of this form to keep for your records and future reference.

STATEMENT OF CONSENT

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form.

SIGNATURES/DATES

_____

Study Participant (Print Name)

_____

Participant or Legal Representative Signature

_____

Date

APPENDIX B

INFORMED CONSENT FORM

MONITORING RECOVERY FOLLOWING CONCUSSION WITH A

WEARABLE MOTION ANALYSIS SENSOR SYSTEM

INTRODUCTION

You are being asked to be a research subject in a study of gait imbalance evaluation and recovery utilizing a wearable sensor system. You were selected as a possible participant because you are a University of Oregon student who is 18-30 years of age and fall within one of two possible groups: Young adult student suffering an acute concussion within the past 72 hours and are not participating in club or Division I sports, or Young adult student who is healthy and has not suffered an acute concussion. Regardless of group, all potential subjects must be able to walk over level ground without any assistive devices, have normal hearing, and not have any permanent memory or concentration abnormalities. If you do not pass the screening questionnaire, you may be excluded from participation in this study. We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

PURPOSE OF THE STUDY

The purpose of this study is to assess concussed young adults and collegiate athletes with a wearable sensor system to identify metrics associated with gait instability and to track those metrics throughout the recovery period. We are also interested in describing the characteristics of head motion during gait in concussed young adults. The wearable sensor system is a new application of off the shelf technology and we hope to develop it into an assessment tool that can help improve clinical concussion diagnosis and management.

DESCRIPTION OF THE STUDY PROCEDURE

If you agree to be in the study, we will ask you to do the following: Location: will visit the motion analysis laboratory (B52 Gerlinger Annex) for five testing session at the following time points: within 72 hours of injury, at 1 week, 2 weeks, 1 month and 2 months post injury. Each session will take no longer than 40 minutes.

<u>Screening Session</u>

At the beginning of the initial session you will be asked to complete this consent form, an authorization for research disclosure of personal health information form, a concussion symptom inventory, and a health history questionnaire. If you answer yes to any of the exclusion questions on the health history questionnaire you will be excluded from participation in this study.

Sensor Set Up

Five small sensors will be applied to your body with elastic belts, one over the low back at the level of the fifth lumbar vertebra, one over each lateral ankle, one in a chest harness over your sternum, and one in a head band over the front of your head. The Opal Wearable Motion Analysis Sensor system utilized in this study will only be used in the manner in which it was developed and intended for use by the manufacturer.

Practice Stroop and Question and Answer

You will hear the words "high" and "low" each spoke in either a "high" or "low" tone. You will be asked to correctly identify the pitch of the voice, regardless of if it matches the tone spoken in or not. You will be asked a series of questions and asked to correctly answer them.

Walking Task

You will be asked to complete a simple walking task without any cognitive test, while performing the auditory Stroop test, and while performing the Q&A. The walking task is performed wearing normal athletic shoes. It is initiated from a feet together standing position. You will be instructed to walk at a self-selected pace over an eight meter path, perform a 180 counter clockwise turn around a cone, and return to a stop at the original start position.

Equipment Removal and Questions

All sensors will be removed and you will have the chance to ask any questions you may have.

Follow-Up Sessions

Testing sessions will be scheduled at approximately 1 week, 2 weeks, 1 month and 2 months post injury. The assessments performed on the first session will be repeated at each subsequent session.

RISKS/DISCOMFORTS OF BEING IN THE STUDY

Possible Risk for the Loss of Confidentiality to Participants

There is a chance that coded data could be deciphered by outside parties, but no greater than would be encountered in daily life situations. To minimize the risk, all records will be archived in coded form and kept by the principal investigator in a locked filing cabinet in the security regulated Motion Analysis Laboratory (B52, Gerlinger Annex).

Possible Risks Associated with a Beach of Identifiable Information

Minimal risk exists for the intentional or negligent breach of identifiable information. To attenuate that risk only the principal investigator and co-investigator will have access to code sheets containing your personal identifiable information. The coded form will be kept in a locked filing cabinet in the security regulated Motion Analysis Laboratory (B52, Gerlinger Annex). Further, both individuals have completed and will

maintain currency in the required CITI training.

Possible Psychological Risk/Discomforts to Participants

You will wear athletic attire consisting of shorts and a tee shirt of your choosing. No attire changes are required, nor will any clothing need to be removed. However, you may feel embarrassed or nervous about performing the assessments while in the laboratory or athletic medicine facility. To minimize this, you will be consistently asked about your condition and provided short breaks if necessary. The risk of becoming too nervous to perform the tasks will be minimized by fully explaining the tasks to you and giving you a series of practice trials for familiarization. If you become too embarrassed or nervous, the experiment will be stopped

Possible Physical Risk/Discomforts to Participants

The wearable sensors will be applied using elastic straps. Care will be taken to ensure the straps are tight enough to prevent excessive motion between the sensor and the skin, but not so tight as to cause discomfort. You will be asked throughout the testing session if the sensor placement is uncomfortable or you are feeling any skin irritation. If you experience discomfort from the wearable sensors, the investigator will attempt to adjust the strap. If the discomfort is unable to be resolved, the experiment will be terminated. There is very little risk of physical injury due to the simple walking task utilized. However, a remote chance of falling due to the dual-task protocol, particularly in the 180 degree turn may exist. You will be consistently asked about physical condition throughout the testing session. If you appear to be dizzy or unstable, the testing session will be halted and you will be allowed to rest until the symptoms resolve
If you sustain an injury while participating in this study the researchers will assist you in obtaining appropriate medical treatment. All expenses related to that treatment will be covered by you and/or your insurance company. If you are a University of Oregon student or employee and are covered by a University of Oregon medical plan, the plan might have terms that apply to your injury.

BENEFITS OF BEING IN THE STUDY

There are no direct benefits to you from this research study. However, knowledge gained from this study will increase our understanding of concussion recovery timelines, effects of previous concussion history on injury severity and recovery, and the effects of return to activity timing on symptom duration. Further, the employment of non-invasive, wearable motion analysis sensors may lead to a significant advancement in our ability to diagnoses these deficits in a timely manner in the clinical setting with the development of a reliable, low-cost, portable, and easy to implement tool

PAYMENTS

You will be provided a check of $10 at the end of each testing session as compensation for you participation. In any circumstance where you do not complete the study, you will receive a compensation of $10 for the last session initiated.

COSTS

There is no cost to you to participate in this research study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we may publish, we will not include any information that will make it possible to identify a participant. Your name will be replaced by code numbers. The code numbers matching particular data sets to individual subjects will be stored in a hard copy. The hard copy will be kept in a locked filing cabinet separate from the data itself and only the principal investigator, co-investigators, and graduate students involved in this project will have access to it. All laboratory notes will be archived in coded form in a locked filing cabinet and security regulated Motion Analysis Laboratory (B52, Gerlinger Annex). No identifiable information other than name will be retained after data is gathered from you. At the completion of the study and after the results have been published, the list of participants' names will be destroyed. Access to the data, records and code numbers will be limited to the researchers; however, please note that the Institutional Review Board and internal University of Oregon auditors may review the research records.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University of Oregon. You are free to withdraw at any time, for whatever reason. There is no penalty or loss of benefits for not taking part or for stopping your participation. If you are a student of the University of Oregon, you do not jeopardize grades nor risk loss of present or future faculty/school/University relationships due to early withdrawal

DISMISSAL FROM THE STUDY

The investigator may withdraw you from the study at any time for the following reasons: 1) withdrawal is in your best interests (e.g. side effects or distress have resulted), or 2) you have failed to comply with the study requirements.

CONTACTS AND QUESTIONS

The researchers conducting this study are Will Pitt, Michael Utter, and Dr. Greg Skaggs. For questions or more information concerning this research you may contact them at 315-222-6194 or 541-346-1033. Dr. Li-Shan Chou is the faculty advisor for this study and can be contacted at 541-346-4311. If you believe you may have suffered a research related injury, contact Will Pitt at 315-222-6194 who will give you further instructions. If you have any questions about your rights as a research subject, you may contact: Research Compliance Services, University of Oregon at (541) 346-2510 or ResearchCompliance@uoregon.edu.

COPY OF CONSENT FORM

You will be given a copy of this form to keep for your records and future reference.

STATEMENT OF CONSENT

I have read (or have had read to me) and understand the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form.

SIGNATURES/DATES

_____

Study Participant (Print Name)

_____

Participant or Legal Representative Signature

_____

Date

APPENDIX C

HIPPA AUTHORIZATION:

MONITORING RECOVERY FOLLOWING CONCUSSION WITH A

WEARABLE MOTION ANALYSIS SENSOR SYSTEM

AUTHORIZATION TO USE OR DISCLOSE (RELEASE) HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

- If you sign this document, you give permission to all healthcare providers at the University of Oregon Casanova Treatment Center and Student Health Center to use or disclose (release) your health information that identifies you for the research study described here:
"Monitoring Recovery Following Concussion with a Wearable Motion Analysis Sensor System"
A study using small wearable motion sensors to measure walking imbalance related to concussion injury and monitor recovery of walking balance control throughout a two month post-injury period.

- The health information that we may use or disclose (release) for this research includes:
Name, contact information (phone number and email), diagnosis of concussion, return to play date, return to play evaluation criteria, and past concussion history.

- The health information listed above may be used by and/or disclosed (released) to: Will Pitt, Michael Utter, Dr. Li-Shan Chou, or Dr. Greg Skaggs.

- The "covered components" of the University of Oregon are required by law to protect your health information. By signing this document, you authorize the covered components of the University of Oregon to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

- Please note that the covered components of the University of Oregon may not condition (withhold or refuse) treating you on whether you sign this Authorization.

- Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, Casanova Medical Center and UO Student Health Center healthcare providers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization. To revoke this Authorization, you must write to: Dr. Greg Skaggs (gskaggs@uoregon.edu) or UO Student Health Center Medical Records (uhcmedicalrecords@uoregon.edu).

- No publication or public presentation about the research described above will reveal your identity without another authorization from you.

- This Authorization does not have an expiration date.

Signature of participant Date

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