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### RELIABILITY AND VALIDITY OF THE GWALK FOR USE IN POSTURAL CONTROL

#### by

#### MEGAN ELIZABETH EVELYN MORMILE

(Under the Direction of Nicholas Gerald Murray)

#### ABSTRACT

Introduction: Clinical examinations are highly subjective when compared to the more sensitive and robust measures observed with force platform assessment. Currently, few methods exist to quantify objective postural control deficits in an easier and more accessible way for clinicians. *Purpose:* The purpose of this study was to examine the reliability and validity of a wireless inertial sensing device, the BTS GWalk, during postural control assessment. *Methods*: Fifty-six participants (27 male,  $22 \pm 1.9$  years, 29 female,  $21 \pm 0.9$  years) performed three trials each of quiet standing with eyes open (EO) and eyes closed (EC) on a force platform (FP). Participants were fitted with the BTS GWalk, which was placed on the lower back. To establish reliability, trials were administered over two time points approximately 48-72 hours apart. Raw center of pressure (COP) data from the FP and GWalk were exported and further analyzed using Excursion  $(Exc_{MI}/Exc_{AP})$  in the mediolateral and anteroposterior directions. Reliability of both devices was determined using a repeated measures ANOVA and corresponding ICC values. Criterion validity was determined using Pearson's correlations in SPSS v 23.0 *Results:* Repeated measures ANOVAs showed no significance for time or device. In the EO condition, the GWalk demonstrated excellent reliability in the ExcML (ICC=.929) and ExcAP (ICC=.791) directions. In the EC condition, the GWalk showed excellent reliability in Exc<sub>ML</sub> and AP (ICC=.909, .781). However, the repeated measures ANOVA

showed significant differences for device (p < .001 for EO and EC, respectively). Pearson's correlations showed strong likeliness across each variable for both eyes open and closed conditions (Exc<sub>ML</sub> (EO r = .703, EC r = .703), Exc<sub>AP</sub> (EO r = .732, EC r = .736). *Discussion:* Results of the current study indicate the GWalk is a reliable and moderately valid measurement of postural control in healthy populations, but currently is not recommended for comparison against COP parameters. Further research should examine the use of the GWalk against a measure of center of mass, to potentially provide an objective postural control assessment in clinical settings.

INDEX WORDS: Postural control, Balance assessment, Reliability, Validity, GWalk

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by

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B.S., State University of New York at Brockport, 2014

M.S., Georgia Southern University, 2017

A Thesis Submitted to the Graduate Faculty of Georgia Southern University in Partial Fulfillment of the Requirements for the Degree

MASTER OF SCIENCE

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Electronic Version Approved: May 2017

#### DEDICATION

I dedicate this document to my parents, who have never faltered in their love and support for me and this journey. Thank you for everything you have done for me, and continue to do.

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This project would not be possible without the caring and support of my mentor, Dr. Nicholas Murray. You have taught me so much about this process and I cannot thank you enough.

To my classmates: thank you for being my family, and always giving me a shoulder to cry on- literally. I love you all and I am so grateful for you!

To my professors and faculty in the Health and Kinesiology Department: I am so fortunate to have been a part of this department and experienced the professionalism and caring you provide every day. I'm lucky to have met each and every one of you, and thank you for everything that you do.

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#### CHAPTER 1. INTRODUCTION

Postural control is defined as the ability to maintain a postural orientation in response to external or volitional perturbations.<sup>1</sup> Postural control is largely based on innate neural mechanisms,<sup>2</sup> which attain afferent information from three main sensory systems (visual, vestibular, and somatosensory) and execute efferent responses in the form of muscular contractions.<sup>3,4</sup> The visual system is used primarily for movement planning and avoiding obstacles. The vestibular system obtains information about acceleration, balance, and coordination. Lastly, the somatosensory system senses kinesthetic information, highly useful for determining individual motor outputs to navigate in an environment. A marked deficiency in any one of these mechanistic properties may interfere with the nervous systems' ability to process and integrate sensory information, thus affecting balance.<sup>2,5</sup> The theory of postural control is complex, and many methods of assessment have arisen over time to determine the source and trajectories of sway in both healthy and pathological populations. These assessments have taken the form of both accessible and user-friendly clinical assessments, as well as more advanced laboratory assessments.

Many current clinical balance assessment methods have high levels of subjectivity. Though commonly used, these assessments typically lack the objectivity and sensitivity of more refined laboratory assessments, and have thus shown to be incapable of measuring more longterm balance deficits, especially with regards to pathology.<sup>6</sup> Clinical balance assessments such as the Balance Error Scoring System (BESS) test have shown a noteworthy discrepancy between the scoring systems used in comparison to more sophisticated laboratory assessments<sup>6</sup>. The BESS test involves three stances (feet together, single leg non-dominant, and tandem) on both a firm and a compliant surface. If a participant steps out of static stance, takes their hands off their hips, opens their eyes, or performs any other gross motor movement, it is counted as an error. The number of errors made by the participant are counted to provide an overall score, which is used as a hallmark to determine the overall effectiveness of the postural control system. Though commonly used, the BESS test has shown inconsistent intrarater reliability.<sup>7</sup> Administration with multiple raters increases the variability in scoring, which may change how the results are interpreted. This misinterpretation can be a genuine issue when making clinical decisions, as return to play decisions are based on scoring. Additionally, the BESS has also shown a significant learning effect when used at multiple time points, which can also affect interpretation of results.<sup>8,9</sup>

Contrastingly, laboratory assessments can identify postural control deficits by way of center of pressure data. Center of pressure (COP) is defined as the point location of the vertical ground reaction force vector, or a weighted average of the pressure over surface area in contact with the ground.<sup>10</sup> Center of pressure is an extremely sensitive measure, using pressurized sensors that identify even the slightest of movements. Usage of the center of pressure metric may prove useful in that subtle movements indicative of pathology may be unnoticed by the clinicians' eye. The parameters derived from center of pressure data have shown to be a powerful measure of postural control, as they are able to track subtle movements previously unidentified by clinical assessments.<sup>6</sup> Due to this high sensitivity, force platforms are considered to be the gold standard of postural control assessment. Variables such as excursion provide information regarding the amount of movement occurring over a time course during assessments such as quiet standing.<sup>11</sup>

Excursion is highly utilized in the literature to quantify the total amount of COP movement throughout static stance. Total excursion is defined as the total distance the center of pressure travels over the duration of the trial. Excursion can also be delineated into both anteroposterior and mediolateral directions, which is calculated as the sum of distances between consecutive points in the COP time series.<sup>12,13</sup> Excursion is often analyzed to determine the deficits in pathological populations because it is a simplistic measure of the total movement throughout a time series. The interpretation of excursion pertaining to stability is relatively simple: a larger excursion value will typically indicate lesser stability of the postural control system, while smaller excursion values would indicate less movement and therefore more stability.

In short, center of pressure data has shown to be a valuable indicator of the acute and lingering scarcities following pathology and neural dysfunction, as well as data pertaining to healthy individuals.<sup>6</sup> However, though the utilization of center of pressure data is advantageous, it is also a very costly method of assessment that requires great depth of understanding in postural control biomechanics. Currently, the use of this method proves neither a cost-effective or clinically feasible option in a clinical setting.

Recently, portable and cost effective inertial sensor devices have been developed to measure spatial-temporal parameters to quantify acceleration information during locomotion. These walking spatial-temporal parameters include time, speed/velocity, and distance, which have been previously validated in healthy populations.<sup>14,15</sup>

Usage of these devices provide a cordless and portable option to collect acceleration data, thus increasing potential clinical applicability for postural stability assessment. Inertial sensor devices contain a single accelerometer located at the L4-L5 joint space to collect data in the mediolateral and anteroposterior axes. The use of these accelerometer-based devices may help to bridge the gap between more objective laboratory measures and subjective clinical measures, as they provide a less expensive way to obtain quantitative information outside the laboratory.

The BTS GWalk (BTS Bioengineering, Brooklyn, NY) is a relatively new piece of technology that utilizes a small rectangular device containing a wireless network of inertial sensors designed to analyze human movement.<sup>15</sup> The sensor contains a 3-axis accelerometer, gyroscope, and magnetometer sampling at 100Hz to determine planes and axes of movement along with relative angles. To accurately represent acceleration data, the sensor is attached to an elastic belt placed across the subject's lower back at the L4-L5 intervertebral disk space. The data resultant from the GWalk is assessed in terms of acceleration in the anteroposterior and mediolateral axes, which exists in the same theoretical construct as acceleration from ground reaction forces. Thus, excursion data obtained from the GWalk should presume to be similar to force platform assessment, which would identify postural stability changes. <sup>16,17</sup> However, reliability and validity of the GWalk has not been established during postural stability assessment, particularly static stance.

Validity is defined as "the degree to which the test in question measures what it is supposed to measure", also referred to as the soundness of the interpretation of scores. <sup>18</sup> Multiple types of validity exist in the literature; for the purposes of this study, criterion validity and concurrent validity will be discussed. Criterion validity is defined as the degree to which scores on a testing measure are related to some organized standard or criterion.<sup>18</sup> Concurrent validity, a subset of criterion validity, is defined as the validity measurement of a device that is being measured simultaneously with its criterion. Establishing validity evidence in a testing environment is essential to ensure a testing measure is psychometrically sound.<sup>18</sup> Reliability is an integral part of validity testing, and measures the extent of which a testing measure is consistent and repeatable. A type of reliability testing is test-retest reliability, which involves validation of an assessment over multiple time points.<sup>18</sup> Reliability can be calculated as the ratio of a true score variance to an observed score variance.<sup>18</sup> Reliability is often expressed using a correlation coefficient, which ranges from 0-1.<sup>18</sup> The closer the coefficient is to 1, the more reliable a testing measure is considered to be, implying that the true score is assessed with little error variance. Sources of measurement error include participant, testing, scoring, and instrumentation.<sup>18</sup> However, these errors can be minimized as much as possible through careful methodological considerations and scorer expertise.<sup>18</sup>

Few clinical measures are able to identify initial or lasting deficits of the human postural control system in an inexpensive and objective manner. Technology such as the BTS GWalk ® may be able to provide clinicians with postural control information in a clinically applicable fashion. However, the GWalk needs to establish validity and reliability during static stance postural stability assessment before it can be used clinically. Therefore, the purpose of this study is to examine the test-retest reliability of the BTS GWalk as well as examine its criterion validity with the COP data measured by laboratory force platform. It is the aim of this research to determine if the GWalk can be used as an objective and inexpensive alternative to more traditional laboratory measures.

#### **CHAPTER 2**

#### **METHODS**

#### 2.1 Study Design

This study was a cross-sectional design using a healthy collegiate cohort.

#### 2.2 Research Setting

All research for the current study was conducted in the biomechanics laboratory of a single university. The biomechanics laboratory is a spacious, multi-purpose area that provides room for a multitude of varied testing and projects taking place at the university.

#### 2.3 Participants

Fifty-six healthy individuals (27 male,  $22 \pm 1.9$  years,  $180.48 \pm 5.48$  cm,  $85.43 \pm 17.82$  kg, 29 female,  $21 \pm 0.9$  years,  $165.45 \pm 7.37$  cm,  $67.44 \pm 12.56$  kg) enrolled in classes at the university participated in this study. To determine the most accurate reliability and validity data, a healthy cohort of individuals were used in lieu of pathological participants.

All participants were screened using a medical history form (Appendix B) to exclude muscular and neurological pathologies that would hinder performance on a postural sway assessment. Participants who met criteria for inclusion (Table 1) were healthy individuals, ages 18-25 that did not participate in intercollegiate or varsity sports at the university.

Inclusion	Exclusion
Healthy as determined by self-report	Lower extremity musculoskeletal injury
College-age (18-25 years of age)	Surgery within the past year
	Neuromuscular injury
	Traumatic brain injury (within past year)
	Psychiatric illness
	History of seizures
	History of Attention deficit disorder (ADD)
	History of Attention deficit hyperactivity disorder
	(ADHD)
	History of Learning Disorder

Table 1. Criteria for Inclusion and Exclusion of Healthy Participants for the Current Study

Participants that met inclusion criteria were enrolled in the study. The primary researcher recruited participants through both undergraduate and graduate classes within the department, and provided an in-depth explanation of the study including methods of data collection, expectations of participants, and inclusion/exclusion criteria. All methods were approved by the Institutional Review Board at the university prior to all data collection.

#### 2.4 Instrumentation

#### Center of Pressure

Ground reaction forces were investigated using an in-ground strain gauge AMTI force platform (1000 Hz, AMTI OR6 Series, Watertown, MA, USA) measuring 20 in (length) x 18.25 in (width). Center of Pressure (COP) data was calculated from the ground reaction forces recorded from the force platform.

#### Acceleration

Acceleration data was collected using an inertial wireless sensing device (100 Hz, BTS GWalk BTS Bioengineering Corporation, Brooklyn, NY, USA). The GWalk was placed at the approximate L4-L5 intervertebral space, palpated mid-way between the posterior superior iliac spines (PSIS) to ensure accurate placement. Acceleration in the anteroposterior (AP) and mediolateral (ML) axes was then determined from signals sent via Bluetooth to a corresponding computer software program (G-Studio, BTS Bioengineering).

#### 2.5 Variables

Variables examined included excursion and root mean square in the AP and ML directions. All variables were derived from both raw COP data from the force platform as well as acceleration information from the GWalk. A custom code was used within the MATLAB software to further analyze these variables.

Excursion in the AP and ML directions ( $Exc_{AP}$  and  $Exc_{ML}$ ) was defined as the sum of the distances between consecutive points in the AP or ML COP time series (Figure 1).<sup>12</sup>

ExcML = 
$$\sum_{n=1}^{N-1} |ML[n+1] - ML[n]|$$

Figure 1. Mediolateral Excursion Equation

For the purposes of this study, excursion was chosen as a way to quantify the total movement of the individual being tested in multiple directions. Thus, differences in hip and ankle postural stability strategies would be defined by the GWalk and force platform.

#### 2.6 Procedures

Upon arrival at the first test session, participants filled out an informed consent and medical history form (Appendix B) that included demographic information such as height (cm), weight (kg), and age, as well as questions determining inclusion/exclusion criteria for the study.

After completion of the paperwork, participants then performed six trials of quiet standing. Participants were asked to stand as still as possible for thirty seconds with their bare feet placed together in the middle of the force platform. Keeping the feet together decreases the base of support, thereby allowing more movement to occur. Currently, there is no recommendation for the most reliable foot position; however, it is suggested that trials are standardized.<sup>19</sup> Previous literature has determined that a sampling duration of 90 seconds can be expected to yield good reliability for traditional COP measures; however, due to time constrictions and scheduling, a sampling duration of 30 seconds was used. Thirty seconds has shown to yield acceptable reliability when combined with multiple trials.<sup>19</sup> A successful trial was characterized by the participant completing the thirty seconds on the force platform without any voluntary or involuntary movement. Gross movements such as movement of the extremities, chewing gum, sneezing, or moving the head deemed the trial unsuccessful, and thus was repeated and overwritten.

Participants performed three trials each of eyes open and eyes closed quiet standing. Previous literature has determined three trials to be sufficient in trials of less than one minute, and yield acceptable reliability for most center of pressure parameters when averaged.<sup>19</sup> Use of both eyes open and eyes closed trials are a way to challenge the integration of visual and proprioceptive input.<sup>19</sup> Participants were tested a second time with approximately 48-72 hours (average 52.82 hours) between time points. Retest with longer periods of time in between is able to determine variability within trials, and may reflect stability of COP parameters.<sup>18</sup>

#### 2.7 Data Analysis

Raw COP data from the force platform and acceleration data from the GWalk were both filtered using a fourth order, zero phase Butterworth low-pass filter with a cutoff frequency of 12Hz. To compare likeliness of values for both COP and GWalk data, EXC<sub>ML</sub> and EXC<sub>AP</sub> were further analyzed using a custom code in MATLAB software (MathWorks® Inc, USA). Excursion was chosen as the primary variable, due to it being one of the most commonly used and reliable COP parameters<sup>19</sup>

Independent	Dependent
Time Point #1 (Initial Assessment)	Variables Calculated from GWalk and COP Data
Time Point #2 (24-48 Hours Post Initial Assessment)	$Exc_{ML}/Exc_{AP}$
	Condition
	Eyes Open
	Eyes Closed
Note: COP-center of pressure $E_{XC}$ and $T_{A}$ - Mediolateral Excursi	on ExcAP- Anteroposterior Excursion

Table 2. Independent and Dependent Variables

Note: COP=center of pressure,  $Exc_{ML}$ = Mediolateral Excursion, ExcAP= Anteroposterior Excursion

#### 2.8 Statistical Analysis

Reliability was established using multiple 2x2 repeated measures ANOVAs to determine the presence of significant main effects at two separate time points  $(T_1 \& T_2)$  during the eyes open (EO) and eyes closed (EC) conditions. Additionally, intraclass correlations (ICCs) were run to quantify the relative reliability of each variable. ICC values were adhered to as follows: poor (0.0-0.39), fair (0.40-0.59) good (0.60-0.74) and excellent (0.75-1.0).<sup>20</sup> These values are highly utilized in the literature, and thus were chose as a measure of consistency. To establish criterion

validity, Pearson's correlations were run to determine similarity of excursion values between COP and GW in the AP and ML directions. A Pearson's *r* value > 0.75 indicated good reliability (> 0.90 excellent), *r*=0.50 to 0.75 moderate to good validity, and < 0.50 poor validity.<sup>21,22</sup> Alpha level was set at *p* < .05 *a priori*. All statistical analyses were conducted using SPSS version 23.0 (IBM, Chicago, IL, USA).

#### CHAPTER 3.

#### RESULTS

#### 3.1 Eyes Open Condition

Results from the repeated measures ANOVA determined no significant differences for time using the force platform in the EO condition (EO Exc<sub>ML</sub> (F(1,55)=.259, p=.613), EO Exc<sub>AP</sub> (F(1,55)=.001, p=.981). Results from the GWalk determined similar findings, with no significant differences for time in the eyes open condition (EO Exc<sub>ML</sub> (F(1,55)=.259, p=.613), EO Exc<sub>AP</sub> (F(1,55)=.001, p=.981). When measured between devices, the repeated measures ANOVA determined significant differences between GW and FP in the eyes open condition (EO Exc<sub>ML</sub> (F(1,55)=646.32, p <.001), EO Exc<sub>AP</sub> (F(1,55)=611.24, p <.001), with the FP showing significantly more movement in both directions compared to GW (Figure 2). Means and standard deviations for all variables for both conditions and time points can be found in Table 3.

#### 3.2 Eyes Closed Condition

Results from the repeated measures ANOVA determined no significant differences for time using the force platform in the EC condition (EC  $\text{Exc}_{ML}(F(1,55)=.152, p=.698)$ ), EC  $\text{Exc}_{AP}(F(1,55)=.176, p=.677)$ ). Results from the GWalk determined no significant differences for time in the eyes closed condition (EC  $\text{Exc}_{ML}(F(1,55)=.152, p=.698)$ ), EC  $\text{Exc}_{AP}(F(1,55)=.176, p=.677)$ ). When measured between devices, the repeated measures ANOVA determined significant differences between GW and FP in the eyes closed condition (EC  $\text{Exc}_{ML}(F(1,55)=481.32, p <.001)$ ), EO  $\text{Exc}_{AP}(F(1,55)=402.51, p <.001)$ , with the FP showing significantly more movement in both directions compared to GW (Figure 3). Means and standard deviations for all variables for both conditions and time points can be found in Table 3.

Table 3. Means, Standard Deviations, and Significance Values for GWalk and Force			
Platform in Eyes Open and Eyes Closed Conditions			
	Gwalk	Force Platform	p-value
Eyes Open	Mean (SD) (m)	Mean (SD) (m)	
Exc <sub>ML</sub>	.0013 (.0003)	.1669 (.0516)	.001
Exc <sub>AP</sub>	.0013 (.0003)	.1659 (.0521)	.001
	Gwalk	Force Platform	
Eyes Closed	Mean (SD) (m)	Mean (SD) (m)	
Exc <sub>ML</sub>	.0014 (.0003)	.1821 (.0587)	.001
Exc <sub>AP</sub>	.0013 (.0003)	.1798 (.0586)	.001

Note:  $Exc_{ML}$ = Mediolateral Excursion,  $Exc_{AP}$ = Anteroposterior Excursion. All values derived from Repeated Measures ANOVAs in EC and EO conditions.



#### Means and Standard Deviations of Force Platform vs GWalk (Eyes Open, AP/ML Directions)

Note: FP= Force Platform, GW= GWalk, AP= anteroposterior direction, ML= mediolateral direction



Means and Standard Deviations of Force Platform vs GWalk (Eyes Closed, AP/ML Directions)

Note: FP= Force Platform, GW= GWalk, AP= anteroposterior direction, ML= mediolateral direction

#### 3.3 Intraclass Correlations (ICCs)

Force platform variables for the eyes closed condition consistently demonstrated excellent reliability across variables in the EO ( $Exc_{ML}$  (ICC=0.904),  $Exc_{AP}$  (ICC=0.915)) and EC ( $Exc_{ML}$ : ICC=0.945,  $Exc_{AP}$ : ICC=0.951) conditions (Table 4). Additionally, the GWalk showed excellent reliability in the EO condition for both  $Exc_{ML}$  (ICC=0.937) and  $Exc_{AP}$  (ICC=0.817). In the EC condition, the GWalk showed excellent reliability in  $Exc_{ML}$  (ICC=0.909) and  $Exc_{AP}$ (ICC=0.781) (Table 4).

in Lyes open and Lyes closed conditions		
Eyes Open	Gwalk	Force Platform
Exc <sub>ML</sub>	0.937	0.904
Exc <sub>AP</sub>	0.817	0.915
Eyes Closed	Gwalk	Force Platform
Exc <sub>ML</sub>	0.909	0.936
Exc <sub>AP</sub>	0.781	0.945

Table 4. Intraclass Correlation Coefficient (ICC) Values (Time) for Excursion Variables in Eyes Open and Eyes Closed Conditions

Note: Exc<sub>ML</sub>= Mediolateral Excursion, Exc<sub>AP</sub>= Anteroposterior Excursion

#### 3.3 Pearson's Product Correlations

Pearson's correlations revealed a moderate to good correlation between GWalk and force platform for both Exc AP and ML during both conditions (Table 3). In the EO condition, Pearson's correlations showed moderate to good correlations between GWalk and force platform in Exc<sub>ML</sub> and Exc<sub>AP</sub> directions (r= 0.703, r= 0.751). Similar values were observed during EC conditions for Exc<sub>ML</sub> and Exc<sub>AP</sub> (r= 0.722, r=0.752).

	Table 5. Pearson's Correlations for GWalk and Force Platform Variables.		
	EO ( <i>r</i> )	EC ( <i>r</i> )	
$Exc_{ML}$	0.703	0.722	
ExcAP	0.751	0.752	

Note:  $Exc_{ML}$  = Mediolateral Excursion,  $Exc_{AP}$  = Anteroposterior Excursion, r = Pearson's product correlation

## CHAPTER 4. DISCUSSION

#### 4.1 Overview

The purpose of this study was to examine the test-retest reliability of the BTS GWalk as well as examine its criterion validity with the COP data measured by laboratory force platform. Previous literature has shown usage of the laboratory force platform to be the gold standard in postural stability assessment. The hypothesis for this study was partially met, as the GWalk and force platform collected similar movement patterns as shown by moderate to excellent ICC values but did not output similar results. Previous literature regarding inertial sensors has determined that the technology may offer accurate and reliable methods to assess human motion; however, the degree of accuracy is highly dependent on the site of contact and task at hand.<sup>15</sup> Overall, the GWalk showed moderate to excellent reliability in both eyes closed and eyes open conditions with regards to parameters commonly used in the assessment of postural control. Pearson's correlations showed moderate correlations between the GWalk and force platforms; however, when analyzed between devices, the GWalk and FP were significantly different. Therefore, though the GWalk was shown to be reliable within device, it may not be the most reliable method when compared to typical COP parameters.

#### 4.2 Reliability: Force Platform

For the current study, reliability values were determined from force plate variables  $Exc_{ML}$ and  $Exc_{AP}$  in both eyes open and eyes closed conditions. In eyes open quiet stance, reliability of the excursion variables in the ML and AP directions were found to be within the excellent range, with ICCs of .904 and .916, respectively. These numbers are consistent with previous literature,<sup>22</sup> which has demonstrated ICCs for excursion in the excellent range (Santos et al.: 0.75-0.79, Li et al. 0.79-0.81).<sup>22,23</sup> This finding further affirms that the force platform is an excellent and reliable tool for postural control assessment.

In the eyes closed condition, ICC values for excursion demonstrated excellent reliability. Similar to eyes open stance, values for Exc<sub>ML</sub> and Exc<sub>AP</sub> (Table 4) were consistent with Santos et al., who reported excursion values of 0.77 and 0.75 over 2-3 trials.<sup>23</sup> The absence of a main sensory system may play a role in the consistency of trials; in the eyes closed condition, there may be less external distraction playing a part into the ability to maintain postural orientation. Thus, trials across time may display higher reliability. The numbers found in the current study closely resemble those determined by Santos et al., who over 2-3 trials observed ICC values of 0.79 and 0.77 in ExcML and ExcAP in the eyes closed condition.<sup>23</sup> Results from the current study suggest that excursion variables show to be consistently reliable across time; though already commonly used, the eyes closed condition is one that should continue to be utilized as a determinant of fluctuations in the postural control system.

Reliability values obtained from force platform data in the current study were higher in eyes closed quiet standing than eyes open stance, which contradicts previous literature.<sup>23</sup> Previous findings of lower reliability during eyes closed conditions in certain conditions has been attributed to the role the visual system plays in the maintenance of optimal postural control. Absence of visual cues along with lack of distractions in the testing setting during eyes closed stance may play a role in the consistently excellent reliability values observed in this condition. Additionally, the movement strategies displayed in the eyes closed condition may be similar across the sample population, as humans do not typically observe their surrounding environment deprived of a major sensory system. Therefore, it is understandable to see more consistent reliability values across parameters in the eyes closed condition.

#### 4.3 Reliability: GWalk

Results determined from a repeated measures ANOVA found no significant differences for time using the GWalk; however, the degree of reliability varied slightly regarding excursion variables in both eyes open and eyes closed conditions. Overall, the GWalk demonstrated excellent reliability regarding excursion in eyes open and eyes closed quiet stance. ICC values presented similarly between visual conditions (Table 4).

Though there are few studies outlining the reliability of the GWalk in particular, recent studies have explored the reliability of other types of wireless inertial sensing devices.<sup>24</sup> In a study by Sankarpandi et al., the Mobility Lab System was used to assess patients with vestibular disorders. The Mobility Lab System contains a three-axis accelerometer, gyroscope, and magnetometer, much like the GWalk. Results from the study determined excellent reliability in AP/ML path length (ICC=0.87 and 0.92 respectively).<sup>24</sup> These results are similar to the findings of the current study, and thus affirm that the GWalk is a reliable device over time. With regards to trial number and duration, the methodology used by Sankarpandi et al. similarly reflected the methodology of the current study, with three trials each on the iSway balance assessment tool.<sup>24</sup> Lower reliability demonstrated in iSway parameters compared to the gait analysis in Sankarpandi's research was attributed to the shorter trial duration of the test, which was set at thirty seconds.<sup>24</sup> Previous literature has determined that for acceptable reliability, quiet standing trials should be set at 60-90 seconds<sup>19</sup>. It is possible that the ICC values obtained within the current research may change with a higher trial frequency and duration, and is an inherent limitation of the current study that should be explored in the future.

Results comparing the amount of movement between GWalk and FP may be attributed to the movement strategies displayed in quiet upright stance; during quiet standing, there are more degrees of freedom (DOF) in the AP direction than in the ML direction due to increased range of motion at the ankle joint. Typical postural control strategies displayed at the ankle joint may translate to lesser movement in the ML direction at the trunk, as shown by the smaller means and standard deviations observed by the GWalk (Table 3). This may be a direct reflection of the miniscule amounts of overall movement observed at the trunk during both eyes open and eyes closed quiet standing, as the movement itself may not be enough for accurate recording.

When considering for condition, reliability values determined from force platform data were higher in eyes closed quiet standing than eyes open stance. However, this finding was the opposite when considering reliability of the GWalk. Previous literature<sup>23</sup> has attributed higher reliability in certain conditions to the role the visual system plays in the maintenance of optimal postural control. Santos et al discovered lower ICC values in the eyes closed condition during quiet stance on a force platform, suggesting that the strategies used to compensate for a lack of visual information in eyes closed stance may account for such differences. However, the results of the current study determined the opposite. Higher ICC values in the eyes closed condition may be attributed to equality of an eyes closed environment across all participants; conversely, movement strategies while in the eyes open condition may differ with each participant and thus determine more or less movement and greater variability between time points, as suggested by the findings of the current study.

#### 4.4 Between Device Repeated Measures ANOVAs and Pearson's Correlations

Results of current study found significant differences between devices using a repeated measures ANOVA. This finding suggests that though the GWalk and FP both show reliable data

across multiple time points, the data measured itself is significantly different. This conclusion is highly dependent upon the amount of movement observed between devices; as shown when placed at the trunk, the GWalk exhibited significantly less movement than COP, which was collected at the ground. Values derived from the raw data showed the signals between both devices to be similar; however, due to massive difference in amount of movement a fair comparison was unable to be made.

Location of the GWalk itself during data collection may play a significant role in the results observed, as well as explain the discrepancy in amount of movement seen in the means and standard deviations across device metrics. The GWalk is placed at the participant's lower back, emulating the theoretical center of mass. Therefore, data from the GWalk regarding acceleration may be a truer comparison to center of mass (COM) than to COP. Models of postural control in the literature have suggested that the body works as an inverted pendulum, with the axis of motion below the center of mass.<sup>25</sup> In quiet stance, this translates to increased motion at the ankle joint, with lesser motion at the hip and trunk. Though comparisons were able to be made using identical parameters derived from raw data, results were consistent with the aforementioned model. This finding is reasonable when considering the relationship between COM and COP. Humans account for sway in multiple directions by activating lower extremity musculature to keep the body's center of mass within the base of support.<sup>26</sup> This results in the COP revolving around the COM, much like a sheepdog herding sheep. Therefore, it is understandable that higher means with COP were discovered when compared to means from GWalk. However, COP has been found to be proportional to the acceleration of the COM, which may explain the similarity in raw signals between devices despite significant differences in means.<sup>27</sup>

Though the means and standard deviations of the variables measured by each device varied by amount of movement over time, Pearson's correlations run for each condition between devices showed moderate correlations for Exc<sub>ML</sub> and Exc<sub>AP</sub>. Table 5 delineates the results observed with Pearson's correlations across devices. These correlations may be ascribed to the similarity of data during simultaneous collection, but do not take into consideration the magnitude of difference. Therefore, though moderate to good correlations were observed between the two devices, results displaying significant differences between devices should be taken into consideration.

#### 4.5 Limitations

Though the current study partially met the hypotheses set, it is not without limitations. The location of the GWalk presents a potential for increased noise during data collection, due to the layers of clothing separating the device from the patient's skin. Accurate placement of the GWalk at the L4-L5 intervertebral space along with tightening the elastic band as snug as possible aimed to combat this limitation. Further research using the GWalk may take this into consideration, to obtain a sensitive measurement of acceleration data.

All testing of participants took place in the Biomechanics Laboratory at Georgia Southern University. The laboratory is a large, multidisciplinary space used for a variety of projects taking place at the university. Though the primary researchers of the current study attempted to minimize distractions during quiet stance assessment, it was impossible to provide a completely silent and distraction-free environment. Future studies should aim to eliminate distractions that may affect the quality of postural control assessment.

#### 4.6 Conclusion

Wireless inertial sensing devices provide a portable yet quantifiable way to determine deficits in both gait and postural control due to a multitude of factors. However, more research should be done to help irrevocably determine the validity of such devices so that they may have a steadfast role in clinical settings. The current study found that within certain parameters, the use of a wireless inertial sensing device was a reliable and moderately valid device for use in postural control. Assessments that require lesser amounts of trials with a shorter trial duration, root mean square may not be the most accurate or identifying parameter. However, excursion showed to be a valid and reliable parameter for use in quiet stance with eyes open and eyes closed.

Future work regarding the use of this type of device in postural control assessment should aim for validation against a full body marker set, to more accurately measure acceleration information at the trunk and center of mass. Though results reasonably defined accurate reliability and validity values, the current study found significantly lesser amounts of movement at the trunk as compared to ankle strategies on a force platform. Therefore, future studies should take into consideration these factors if using a wireless inertial sensing device for use in postural control.

#### APPENDIX A.

#### LITERATURE REVIEW

#### A.1 Introduction

Postural control has previously been defined as "the ability to maintain a desired postural orientation in response to external or volitional perturbations".<sup>1</sup> An activity largely based upon innate neural mechanisms,<sup>2</sup> the body must take afferent information from three main sensory systems and execute efferent responses in the form of muscular contractions.<sup>3,4</sup> The visual system is used primarily for movement planning and avoiding obstacles, while taking in a multitude of information from the outside world. The vestibular system senses linear and angular accelerations, and uses this information to stay stable. Lastly, the somatosensory system senses kinesthetic information, or where the body is in space.<sup>4</sup> Possessing good postural control is necessary for athletic activity; deficiencies in these sensory or motor mechanisms may interfere with the nervous systems' ability to process and integrate sensory information, thus affecting balance.<sup>2,5</sup> The theory of postural control is complex, and many methods of assessment have risen to determine the source and trajectories of sway in both healthy and pathological outcomes. General assessments of postural stability are implemented throughout varied populations, such as older adults, individuals with Parkinsons' Disease, Multiple Sclerosis (MS), and athletes who have sustained a concussion.<sup>6,7</sup>

#### A.2 Neuroanatomy

Four important components of the central nervous system play into the process of postural control.<sup>28</sup> Descending motor pathways, spinal motor circuits, basal ganglia, and the cerebellum are all major contributors that play into maintaining posture through movement of the

limb and trunk muscles.<sup>28</sup> Descending motor pathways utilize information from regions of the cerebral cortex and brainstem to send efferent signals to initiate both rapid postural adjustments and finite motor control, respectively.<sup>28</sup> Spinal motor circuits comprise of motor neurons and interneurons, receiving signals from descending motor pathways as well as acting independently through reflexive motor actions.<sup>28</sup> Spinal motor circuits are most commonly known for their role in reflexes, in which motor pathways synapse directly onto motor neurons and activate motor units to produce active muscular contraction.<sup>28</sup> Reflexive movement is an important component of postural control, as seen with feed-forward and feedback control mechanisms. Both spinal motor circuits and the cerebellum associate with extensive signal processing in the form of feed-forward and feedback control mechanism, the brain evaluates incoming sensory information and makes anticipatory adjustments to accomplish a desired output.<sup>29</sup> In contrast, a feedback control mechanism produces postural adjustments in response to volitional or external stimuli. Both mechanisms of feed-forward and feedback control collaborate in the central nervous system to produce optimal human posture.<sup>29</sup>

The cerebellum, located posteriorly in the brain, accounts for 10% of the volume of the brain and accounts for over 50% of the total number of neurons in the brain.<sup>29</sup> The cerebellum is primarily responsible for motor learning and maintenance of balance and posture, coordinating voluntary movements by modifying afferent signals from the central nervous system to refine human movements.<sup>29</sup> Together, the cerebellum and basal ganglia regulate motor behavior by acting on descending brain stem pathways and cortical pathways.<sup>28</sup> Damage to the cerebellum results in impaired postural and motor control, as demonstrated by altered postural strategies in order to compensate.<sup>29</sup>
In humans, the thalamus is a functional center responsible for both sensory and motor functions, and is a critical component of balance.<sup>29</sup> Though proprioceptive ability has been shown to relate to postural stability deficits,<sup>30</sup> the integrity of the structural connectivity of proprioceptive pathways has not been studied in healthy or clinical populations.<sup>30</sup> However, deficits in transmission and processing of sensory feedback have been estimated to result from damaged white matter pathways.<sup>31</sup> Impaired vestibular and visual input to the central nervous system (CNS) due to injury or disorder may reflect increased measures of center of pressure displacement and velocity in aforementioned populations. Assessments that detect this finding may possibly indicate diminished postural control and loss of balance. Studies have shown neural components of proprioception to include activity in the primary sensorimotor cortex, thalamus, and basal ganglia, as determined by functional magnetic resonance imaging (fMRI).<sup>30,31</sup> Disruption to white matter in the brain has recently been identified in the literature by way of diffusion tensor imaging (DTI), a form of magnetic resonance imaging (MRI) that measures changes in the directionality of water diffusion.<sup>31</sup> Results from DTI are analyzed with a variable known as fractional anisotropy (FA), which ranges from 0-1 and indicates more or less stable directionality, magnitude and thus a possibility of white matter injury, respectively.<sup>31</sup> Studies in populations with multiple sclerosis have found correlations between white matter integrity and overall balance performance, indicating that damage to white matter pathways in the brain may lead to decreased postural control.<sup>32</sup>

## A.3 Postural Control

Though commonly used interchangeably, balance and postural control are defined in different ways. Balance is defined as the ability to maintain and control the position and motion

of the body's center of mass (CoM) relative to the base of support (BOS); in contrast, postural control requires coordination and integration of multiple sensory systems to maintain equilibrium, given the constant state of instability in bipedal stance.<sup>11</sup> Trajectory of the center of mass is an essential part of modeling the postural control system,<sup>11</sup> as instability of the body and often falls will occur if the center of mass deviates from the base of support.<sup>6</sup> Over time, postural control models have been theorized regarding how the body adjusts and changes in response to its environment using feed-forward and feedback mechanisms. These models have allowed researchers to estimate internal joint forces, so that the kinematics influencing postural control can be measured in human subjects.<sup>33</sup>

A long withstanding theory, the inverted pendulum model has been introduced in the literature to give researchers an understanding of how human movement occurs in upright stance.<sup>25</sup> In the inverted pendulum model, both internal and external forces cause the body to pivot around the ankle joint to account for natural sway caused by the upper body's two-thirds of total body mass (Figure 1).<sup>25</sup> In quiet standing, humans account for sway in multiple directions by activating lower extremity muscles to keep the body's center of pressure within range of the center of gravity. Loram and colleagues (2005) found that during forward sway, the lower extremity muscles contract eccentrically to increase tendon length and resist forward motion via series elasticity.<sup>26</sup> These movements occur in both the anteroposterior and mediolateral direction and require a larger amount of range covered by the center of pressure, as it must control for changes in center of gravity to negate loss of balance.<sup>25</sup> Using the inverted pendulum model, center of pressure and center of mass have been found to be proportional to the horizontal acceleration of the center of mass.<sup>25</sup> However, the inverted pendulum model does not account for

central nervous system involvement with regards to postural control,<sup>6</sup> and is thus a more simple approximation of the mechanism.



**Figure 1.** A subject swaying back and forth while standing quietly on a force platform. Five different points in time are described, showing the centre of gravity (g) and the centre of pressure (p) locations along with the associated angular accelerations ( $\alpha$ ) and angular velocities ( $\omega$ ). See text for detailed description.

When considering multisystem integration, the sensorimotor model of postural control has been theorized to explain how the visual, proprioceptive, and vestibular systems synchronize with regards to their role in postural control. Additionally, the sensorimotor model explains how the brain regulates postural control through direct interaction with sensory systems.<sup>6</sup>

To maintain upright stance, as

described in the inverted pendulum model, the body must counter destabilizing forces with corrective ones. This is often thought to be the result of a feedback control system,<sup>26</sup> as corrective torque is generated through sensory transduction, transmission, processing, and then to muscle activation.<sup>26</sup> During the feed-forward postural control mechanism, depolarization of neurons and subsequent action potentials help to produce movement, uniting the control of posture and movement into a single scheme.<sup>27</sup> Individuals with sensory loss have been found to demonstrate increased muscular stiffness and consequently lower center of pressure excursion in quiet stance, as compared to a healthy population.<sup>34</sup> Integration of the visual, somatosensory, and vestibular systems are essential for posture, as they drive the proper feedback signals. Unavailability of feedback cues may result in increased reliance on the visual and somatosensory

systems, lessening the efficiency of the postural control system and increasing vulnerability to loss of balance and possible falls.<sup>34</sup>

Though the sensorimotor model provides an explanation for how the central nervous system regulates the postural control system, it does not consider for anticipatory postural adjustments (APAs). Anticipatory and early postural adjustments have been qualitatively measured, indicating that different neural mechanisms are involved in postural control.<sup>34</sup> Anticipatory postural adjustments are changes in activation levels of postural muscles that may be seen 100 milliseconds prior to initiation of action.<sup>34</sup> These small contractions are controlled by the cerebral cortex, and are independent of voluntary motion.<sup>3</sup> With regards to postural stability, APAs have found a purpose in the generation of forces to combat internal and external perturbations.<sup>34</sup> For example, when the body prepares to take a step, the center of pressure shifts backwards from both feet to the supporting foot to avoid loss of balance when initiation occurs.<sup>34</sup> Anticipatory postural adjustments use feed-forward control to anticipate an event occurring, while using feedback signals to adjust to movements as they occur. Research has discovered that control of equilibrium may be based on predicted displacement of the center of mass that is learned, using integration of sensory information to predict future activity.<sup>3,26</sup> APAs are heavily dependent on the task at hand, support provided by surroundings, and neurological status.<sup>3</sup> This model incorporates both the pendulum model with sensorimotor regulation to explain how postural control in humans is regulated both physiologically and neurologically in response to environmental stimuli. In individuals with neurological dysfunction or pathology, these interruptions in feedback mechanisms may show deficits in postural control during post-injury assessment.

# A.4 Static Assessment: Clinical Balance Measures

As isolating the source of balance deficits due to pathology may prove challenging, many assessments have been developed over the course of the past decade with the intention of providing both sideline-friendly and objective measurements. Unfortunately, clinicians often do not have access to instrumented balance assessment techniques, and are forced to rely on more subjective measures to determine postural deficits post injury. A practical method developed in 1853 for clinical balance assessment is the Romberg test.<sup>35</sup> The Romberg test is a static balance assessment that aims to evaluate sensory impairment in individuals by inhibiting the visual system. Since its introduction, there have been many modifications to the test, mostly with varying foot positions to alter the patient's base of support. In a study by Steffen in 2008, the Romberg test showed test-retest intraclass correlations of .84 and .86 in individuals with Parkinson's disease during reduced-vision and normal-vision conditions, respectively.<sup>36</sup> This indicates high reliability of the Romberg, with regards to identifying balance deficits in individuals with Parkinson's. Sensitivity and specificity values of the Romberg are found to be slightly lower, showing that the test accurately identified balance deficits in individuals with vestibular dysfunction 60% of the time.<sup>36</sup>

Another assessment, arguably one of the most common and cost-effective measures used clinically today, is the Balance Error Scoring System (BESS) test. Adapted originally from the Romberg Test, the BESS test consists of three stances (double leg, single leg, and tandem) on a firm surface and a foam surface. Participants are instructed to stand as still as possible with their hands on their hips and eyes closed for 20 seconds. Any errors in stance are recorded and compiled into a composite score. The BESS test is typically used in a baseline assessment battery

and as a post-injury assessment at multiple time points post-concussion, to determine an athletes' recovery time to their baseline measure.<sup>7</sup>

Though the BESS is widely used by clinicians nationwide, recent studies have determined that it may not be the most accurate assessment to identify more long-term deficits due to pathology.<sup>35</sup> A 2010 study by Burk and colleagues looked at BESS scores at the pre and post season; the findings determined a significant improvement (p=.003) between the two time points, indicating that the BESS test provides a significant learning effect.<sup>9</sup> Many studies have looked at inter and intra-relater reliability within the BESS test, along with sensitivity and specificity values.<sup>35,37</sup> Finnoff et al. found the BESS test to be inadequate when using multiple scorers, as determined by a wide range of ICC values ranging from .50-.88.<sup>37,38</sup> Sensitivity values in individuals with concussion were found to be around .34. Overall reliability of the BESS ranges anywhere from unacceptable clinical levels (below .75) to excellent (.96).<sup>35</sup> These findings indicate that when considering administration of the BESS test, there are multiple factors to consider; firstly, reliability of the test is dependent on clinician consistency, as use of multiple clinicians may alter the scores collected over a period of time. Secondly, the BESS has shown to have a learned practice effect; when used repeatedly over the course of up to 30 days, scores may decrease and stabilize even though more subtle deficits may still exist.<sup>7</sup> In 2001, a validation study of the BESS by Guskiewicz and colleagues determined that when compared to the Sensory Organization Test (SOT), concussed athletes returned to baseline scores quicker than by use of the force platform.<sup>7</sup> Additionally, a prospective study by McCrea and colleagues (2003) examined scores over a recovery period from concussion; similar to results from Guskiewicz, concussed athletes returned to baseline scores three to five days after injury.<sup>37</sup> As

shown by these studies, the BESS has shown an inability to detect balance dysfunction past day 7 post-injury,<sup>35</sup> and may not be a truly sensitive measure for long-term postural deficits.

# A.5 Dynamic Assessment

Though typical measures of postural stability with regards to pathology have primarily focused on static stance, this type of assessment lacks the impulsive environmental stimulus that stresses the functional capacity of the postural control system.<sup>6</sup> A dynamic assessment has the ability to target each the visual, vestibular, and somatosensory systems individually, by way of stressing the feedback and feed-forward mechanisms of postural control. This investigates the possibility of determining deficits not previously identified using traditional methods of static assessment.<sup>6</sup> Interruptions in neurometabolic brain function, as described above, may be measured more finitely using dynamic methods.

Studying post-injury changes in the gait cycle has been studied for many years in various populations. Previous research has indicated that center of mass trajectory may provide a better insight into the dynamic balance control mechanism.<sup>39</sup> This theory has been tested by using dynamic gait stability, or the ability to properly coordinate lower body segments with proper displacement and speed while maintaining upright stance.<sup>40</sup> Dynamic gait stability, like static stance, involves maintaining the center of mass within the limits of support to avoid abnormal sway. Similar to static stance, if the center of mass falls outside the limits of stability, balance dysfunction and falls may occur.

Literature regarding pathology effecting postural control has previously employed a dualtask paradigm, in which participants walk while simultaneously performing a cognitive task.<sup>39,41</sup> Incorporation of a cognitive task tends to alter gait stability, forcing individuals to adopt a more conservative strategy in order to negate loss of balance.<sup>42</sup> In a sample of 28 young adults, Cantena and colleagues (2008) collected CoM displacement data and peak velocity in the A/P and M/L directions along with gait parameters such as velocity, stride length, and stride time in both single and dual-task conditions. Results found that the concussed group elicited significantly slower gait velocities during all tasks (p=.003) than the control group, and significantly slower (p=.007) peak anterior velocities than controls in each task.<sup>39</sup>

Incorporating a dual-task paradigm within concussed populations has also shown differences in time to complete as compared to single-task level walking (p<.001). Concussed athletes demonstrated a significantly smaller CoM-CoP separation distance (p=.038) in the anterior direction as compared to controls, and showed significantly greater sway in the coronal plane during the Q&A task (p=.045).<sup>39</sup> Though this study found significance in acutely concussed populations, it did not further explore changes in gait stability over a recovery period from concussion.<sup>39</sup> In 2008, a study by Parker and colleagues looked to determine long-term motor deficits in a sample of 28 concussed individuals. All subjects were tested within 48 hours of injury, and again at 5, 14, and 28 days after injury. Testing included both single-task and dualtask conditions along a 10m walkway and force plates, while simultaneously measuring average gait velocity, maximum separation of CoM and CoP, and CoM displacement and peak velocity in the M/L direction. Repeated-measures ANOVAs found that in both concussed and nonconcussed individuals, dual-task walking resulted in significantly slower gait velocity and higher sway as compared to single-task (p=.003 and p=.002, respectively) for up to 28 days post-injury. Center of mass peak sway velocity in the M/L direction was also significantly greater in the dualtask condition (p=.001), and concussed individuals demonstrated smaller CoM-CoP separation distance as compared to normal controls.<sup>41</sup> The results from these studies implicate that a

dynamic attention test may be a more sensitive measure to determine postural deficits due to pathology.

# A.6 Center of Pressure and Assessment Methods

Center of pressure is defined as the point location of the vertical ground reaction force vector, or a weighted average of the pressure over surface area.<sup>43</sup> Collection of center of pressure data involves measurement of ground reaction forces using a force platform collecting at a base number of Hertz (Hz) per second.<sup>6,17,44</sup> Raw CoP coordinates are typically analyzed and filtered using custom codes that determine variables such as excursion, mean and peak excursion velocity and root mean square.<sup>6,45</sup> Over time, assessments utilizing force plate technology have been developed to measure and quantify changes in balance control and identify fluctuations in the body's CoP excursions.<sup>27</sup> In more recent literature, it has been suggested that center of pressure trajectories may be a more sensitive and powerful measure of postural control impairments.<sup>46</sup> Thus, theoretical models from non-linear dynamics focusing on patterns of CoP oscillation have recently emerged as an alternative assessment of postural control. Information obtained from CoP data, though not immediately applicable to clinicians in a sports setting, may be a valuable tool in tracking subjects with impaired postural stability.

The measurement of Peak Excursion Velocity suggests a link between the neural and the motor mechanisms of postural control, and may be attributed to the sensory receptors related to the postural control system.<sup>11</sup> These sensory receptors typically favor rate information rather than positional information.<sup>11</sup> Though information about body position and subsequent changes results from the proprioceptive system, these small changes may not play a noticeable enough role in the obtainment of velocity information.<sup>11</sup> Previous literature has suggested that the central

nervous system utilizes a velocity-dependent strategy reliant on multisensory integration to maintain postural control.<sup>47</sup> Velocity provides an indication of direction and magnitude in a time series, and thus provides useful information regarding anticipatory movement and displacement of the postural control system.<sup>47</sup> Some studies have utilized velocity information in aging populations, but it is a novel concept and requires more research.<sup>47</sup>

Excursion is a variable highly utilized in the literature to quantify the total amount of movement of the postural control system over the duration of a single trial. Total excursion is defined as the total distance the center of pressure travels over the duration of the trial; additionally, excursion can be quantified into both anteroposterior and mediolateral directions, calculated as the sum of distances between consecutive points in the COP time series.<sup>12,13</sup> Being a more simplistic way to measure the total movement of the time series, excursion is not often used to determine the more subtle deficits in pathological populations. The interpretation of excursion pertaining to stability is relatively simple: a larger excursion value will typically indicate less stability of the postural control system, while smaller excursion values would indicate less movement and therefore more stability. However, recent literature<sup>12</sup> has indicated that the size of the excursions may not be the best way to define the "wellness" of the postural control system; rather, different training strategies adopted in athletics and extracurricular may influence the plasticity and fluidity of the neural networks, leading to the possibility of a large excursion and a more stable system, and vice versa.

Due to this inequity, it is reasonable to use multiple variables to ensure a correct and comprehensible assessment. Root Mean Square is a value that represents the average absolute displacement around the average COP, and can be quantified into both anteroposterior and mediolateral directions.<sup>12,13</sup> A lower RMS value indicates higher stability, whereas a higher value

indicates decreased stability. Root Mean Square can be used along with excursion as a more sensitive measure, and may provide a helpful determinant of validity and reliability information. Force plates measure vertical ground reaction forces within a fixed base of support produced by the body's center of gravity.<sup>42,48</sup> Typical postural assessment using force plates includes measurement of quiet stance, recording net center of pressure in the anteroposterior (AP) and mediolateral (ML) directions.<sup>25,49</sup> An assessment technique called the Sensory Organization Test (SOT) has been used in many studies to determine differences in balance control post-injury. The SOT uses dual-force plates to alter orientation information while simultaneously measuring patients' ability to stand quietly, assessing the integrity of the postural control system.<sup>7,50</sup> It has shown to be a valid and reliable tool, with relatively high sensitivity and specificity (.128, .949) respectively, 1.077 combined)<sup>50</sup> values for measuring balance deficits after concussion.<sup>7</sup> A study by Guskiewicz and colleagues (2001) found significant differences (p < .01) in SOT composite scores in a population of 36 Division I collegiate athletes with concussions on days 1, 3, and 5 post-injury as compared to controls.<sup>48</sup> In a 2000 study, Reimann and Guskiewicz evaluated both concussed and non-concussed groups using the BESS and the SOT over a ten-day period postinjury.<sup>51</sup> Findings found that scores for both measures were significantly different between days one and three post-injury, indicating that balance in both studies tends to improve over the course of 3-5 days. These findings described above implicate that postural stability deficits due to concussion typically resolve within five days, and are consistent with previous findings revealed with clinical balance tests.<sup>51</sup> Unfortunately, though the SOT has shown validity and reliability for measuring postural control deficits, these values have been largely determined in healthy individuals.<sup>6</sup> Additionally, it is an extremely expensive assessment (>\$75,000) and is not a feasible option for clinical assessments.<sup>6</sup>

# A.7 Center of Mass, Displacement, and Acceleration

Postural sway is typically measured in terms of distance and area, and is defined as the movement of the CoM in a standing position.<sup>52</sup> Postural sway velocity is defined by the average horizontal area (in both anteroposterior and mediolateral directions) covered by the center of pressure per second.<sup>52</sup> Though increased postural sway may not be definitively associated with poor balance,<sup>52</sup> both postural sway and sway velocity have been found to be higher in populations with balance deficits, indicating lesser postural control.<sup>52</sup>

Recent literature has introduced the reasoning that body CoM may be a better indicator of body sway, rather than measurements of CoP.<sup>25,27</sup> Center of mass references a point equivalent of total body mass in the global reference system, or space where movement occurs.<sup>25</sup> It is typically imagined to be located just above the umbilical, and adjusts for all movement of the body. It has been found that the trajectory of the CoM provides an important measure of stability when considering the postural control system;<sup>10</sup> thus, uncharacteristic trajectories of the CoM outside the normal base of support may lead to impaired balance and possible falls.<sup>10</sup>

Several different methods of data collection have been proposed and attempted in the literature to propose an estimate of one's center of mass. One such method is the usage of center of mass acceleration, which has been used in some postural control studies.<sup>17,44,53</sup> Measurement of acceleration has previously been shown as an effective means of assessing standing balance, as it denotes the horizontal position of the CoM over the base of support and is theoretically proportional to the CoP-CoM position using an inverted pendulum model.<sup>17,44,53</sup> This measure has been previously obtained in literature by using CoP data derived from a force platform and dividing horizontal ground reaction force by body mass.<sup>16</sup> The dynamic response of CoM

acceleration serves as a whole body measure<sup>16</sup> that is extremely sensitive to movement, along with age and disease-related postural changes.<sup>16,53</sup> While keeping coordination and dynamic interaction among joints, the center of mass is able to facilitate action to correct for both volitional and subliminal perturbations should significant changes in posture occur.<sup>16,17</sup>

Because center of mass of the human body is not a fixed measurement, another method of estimation has utilized reflective markers on bony landmarks of the body. This model uses linked segment models (LSMs) to model the body as a chain of rigid body segments connected by joints.<sup>54</sup> Much of human movement analysis that has been previously explored in the literature has primarily utilized a two-dimensional markup. However, this method may miss certain aspects of general movement, as the human body moves in three different planes and axes. Now referred to as the statically equivalent serial chain (SESC), the LSM model method produces three-dimensional movement via a motion capture system,<sup>17,27,41,44</sup> and estimates of position, magnitude, and mass distribution contribute to an estimation of center of mass.<sup>27</sup> Previous studies using this method have found use of reflective markers to be a reliable method of assessing gait parameters, with the highest values (>.8) in the sagittal plane and lowest values (<.72) in the transverse plane.<sup>55</sup> Unfortunately, this method of data collection is both costly and clinically restrictive, due to the necessity of equipment and trained personnel.<sup>10,27</sup>

More recently, inertial sensor devices using spatial-temporal parameters have arisen in an attempt to quantify displacement in individuals based on pelvic movement during walking.<sup>14,15</sup> Wireless inertial sensing devices have recently gained popularity due to the ease of accessing spatial-temporal parameters in open and untethered environments.<sup>14</sup> The use of these inertial sensing devices may also bridge a gap between more objective laboratory measures and subjective clinical measures, as they provide quantitative information in a more clinical setting.

Three-dimensional displacements of the lower body may be derived by the body's center of mass trajectory. Amplitude and timing of this displacement has been correlated to spatial-temporal parameters as measured by these devices.

The BTS GWalk <sup>®</sup> (BTS Bioengineering, Brooklyn, NY) is a relatively new piece of technology that comprises of a small rectangular sensor that contains a wireless network of inertial sensors designed to analyze human movement.<sup>15</sup> The sensor contains a 3-axis accelerometer, gyroscope, and magnetometer to determine planes and axes of movement. To accurately record pelvic displacement, the sensor is attached to a semi-elastic belt placed across the subject's lower back, at the estimated L4-L5 intervertebral disk space. Pelvic acceleration and displacement in the anteroposterior and mediolateral axes is then determined from signals sent via Bluetooth to a corresponding computer software program.<sup>15</sup> Previous literature involving use of the GWalk is slight, and has primarily focused on reliability and validity measures concerning dynamic gait parameters.<sup>14</sup> These studies have shown the tool to be valid in a young and healthy population ages 20-35 years<sup>14</sup> in measures such as walking speed, cadence, bilateral symmetry, stride length, stance time, swing time, single and double support times in the sagittal, coronal, and transverse rotation planes.<sup>14</sup>

# A.8 Reliability and Validity

For a testing measure to be acceptable for use in research, it must be considered a reliable tool. Reliability is an integral part of validity testing, and measures the extent of which a testing measure is consistent and repeatable.<sup>18</sup> Reliability uses terms such as observed score, true score, and error score with the ultimate goal of removing error to observe a true score. Reliability can then be calculated as the ratio of a true score variance to an observed score variance.<sup>18</sup>

Reliability is often expressed using a correlation coefficient, which ranges from 0-1.<sup>18</sup> The closer the coefficient is to 1, the more reliable a testing measure is considered to be, implying that the true score is assessed with little error variance. Researchers often come to terms with different sources of measurement error, such as participant, testing, scoring, and instrumentation error.<sup>18</sup> These errors can be minimized as much as possible through careful methodological considerations and scorer expertise.<sup>18</sup>

Multiple methods of establishing reliability exist and have been used in the literature.<sup>18</sup> For the purposes of a using a test-retest method for establishing reliability, the coefficient of stability is used. This method is frequently used with motor performance measures and is a more severe test of consistency.<sup>18</sup> Using the coefficient of stability, the test or assessment is given on one day and then repeated within a day or so later.<sup>18</sup> The coefficient of stability is then calculated using intraclass correlations, to determine amount of variance between days of testing and other errors as mentioned above.<sup>18</sup>

A second method of establishing reliability is objectivity, or the degree to which the same or different testers can measure the same scores on the same subjects.<sup>18</sup> Objectivity is preferred in reliability testing, due to ease of statistical analysis and comprehension. When multiple testers are used, an intraclass correlation is taken to determine an intertester reliability coefficient.<sup>18</sup>

Lastly, reliability coefficients can be obtained by multiple methods grouped into a common definition known as internal consistency.<sup>18</sup> This method measures the consistency of parts of the measure, and will determine high or low consistency depending on which parts of the assessment measure the same idea.

These multiple methods of reliability are an important part of establishing validity, as a test cannot be considered valid if it is not reliable.<sup>18</sup> Validity refers to the degree to which a test

or assessment measures what it is supposed to measure.<sup>18</sup> As many assessments are different, multiple types of validity have been determined, such as construct validity, logical validity, content validity, and criterion validity.<sup>18</sup> Often, multiple tests or assessments are administered simultaneously to correlate a testing measure or instrument with a previously validated criterion; this method, called concurrent validity, helps to minimize error that may occur from multiple testing sessions and assessments.<sup>18</sup>

Construct validity determines the degree to which scores from a test measure a hypothetical construct, and is typically used to relate to a type of behavior. Construct validity may also be used when there is no universally accepted criterion for assessment, and the validity process itself establishes a criterion.<sup>18</sup> Logical validity, or face validity, is established when a testing measure is valid by definition. In other words, an assessment or measurement obviously measures what it is supposed to measure. For example, a test that involves vertical jump would be measured by height of jump. This method, used rarely in research studies, lacks more refined objective evidence for measurement validity.<sup>18</sup> Content validity is defined by how accurately a course or content matter applied to the testing measure.<sup>18</sup> Typically used in educational settings or attitude instruments, content validity is used to measure a relative degree of emphasis on course or content objectives that a testing measure delegates to. Lastly, criterion validity involves a type of assessment that is compared to a well-known and validated, or gold standard, criterion. Criterion validity incorporates two subsets of validity, concurrent and predictive. Predictive validity determines the degree to which scores of predictor variables can predict criterion scores accurately.<sup>18</sup>

# A.9 Conclusion

As aforementioned, reliability and validity measures for the BTS GWalk <sup>®</sup> have been explored predominantly with regards to gait analysis, and have not been explored in postural control assessments. The current aim of this study is to determine validity and reliability of the GWalk <sup>®</sup> with the intent of expanding clinical applicability in an area that has previously relied on subjective assessments of postural control. Usage of the GWalk in a clinical setting may provide an objective measurement of acceleration, with the intention of assisting clinicians with the identification of postural control deficits pertaining to certain pathologies. Current clinical methods of postural control assessment are severely limited to subjectivity and potential errors of the clinician with regards to inter- and intrarater reliability. The gap between these expensive laboratory measures and clinical assessments is substantial; therefore, validating a tool such as the BTS GWalk may potentially provide a relatively inexpensive bridge between clinical and laboratory measures of postural control.

# APPENDIX B.

# MEDICAL HISTORY FORM AND INSTITUTIONAL REVIEW BOARD DOCUMENTS

# B.1. Medical History Questionnaire

Subject	Date	
Gender:	r: Male Female Year in School: FR SO JR SR Grad	
DOB: _	Height: Weight:	
DI		
Please a	answer the following questions about your medical and injury history:	
1.	Have you suffered a traumatic brain injury within the past year? YES NO	
	If yes, please provide a short description of the incident(s):	
2.	Have you had any lower extremity injury (instability, strain, sprain, fracture, etc) within the past year t	hat
	would affect your performance on a standing balance assessment? YES NO	
	If yes, please provide a short description of the incident(s) (please include surgery):	
3.	Do you have any known balance, metabolic, or neurological disorders? YES NO	
	If ves, please explain:	
4	Do you have a history of seizures? VES     NO	

6.	Do you have a learning disorder? YES NO
	If yes, please explain:
7.	Are you currently participating in a balance training program? YES NO
Additio	onal Notes:

Primary Investigator: Megan Mormile, ATC

Secondary Investigators: Cody Grotewold, ATC, Nicholas Murray, PhD

# **B.2** Informed Consent Form



# COLLEGE OF HEALTH AND HUMAN SCIENCES

# DEPARTMENT OF HEALTH AND KINESIOLOGY

# CONSENT TO ACT AS A SUBJECT IN AN EXPERIMENTAL STUDY

1. Title of Project: Reliability and Validity of the BTS GWalk for Use in Postural Control Assessment

2. Title of Project: Validity and Reliability of the Balance Tracking System During Static Stance.

Investigator's Name:	Megan Mormile, ATC	Phone: (607) 351-4131
-	Cody Grotewold, ATC	Phone: (605) 413-5211

Participant's Name:

Date: \_\_\_\_\_

Data Collection Location: Biomechanics Laboratory, Georgia Southern University Campus

3. We are current masters' students at Georgia Southern University, developing this project in accordance with fulfilling the requirements for our masters' theses.

4. The purpose of the following studies is to determine the validity and reliability of the BTS GWalk <sup>®</sup> and BTrackS Balance Tracking System for use in clinical postural control assessment. The result of these studies may assist to bridge the gap between clinical and laboratory measures of assessing postural control.

5. You are being invited to participate in this study because you are a healthy, college-age control subject. Additionally, you have no muscular or neurological pathologies that may hinder performance on a postural control assessment, as well as no lower extremity musculoskeletal injury or surgery within the past year, neuromuscular injury, history of traumatic brain injury, psychiatric illness, history of seizures, attention deficit disorder, or learning disorder.

Should you agree to participate in this study, you will be asked to attend three individual testing sessions within two weeks, each lasting approximately 20 minutes. Each testing time point will include two separate assessments of postural control. The first assessment includes four 30 second trials of quiet standing on a force plate with eyes open and eyes closed. During this assessment, you will be wearing an elastic belt that contains an inertial sensing device. The second assessment includes six 20 second trials of quiet standing on a balance board with eyes open and eyes closed.

6. The risk assumed during this testing is no greater than you experience during normal daily activities. There is minimal risk of physical injury or mental discomfort while performing these assessments. Should there be a risk of falling during the balance trials, a member of the research team will be in close proximity. You understand that medical care is available in the event of injury resulting from this research but neither financial compensation, nor free medical treatment is provided. You also understand that you are not waiving any rights that you may have against the University for injury resulting from negligence of the University or investigators. Should medical care be required, you may contact Health Services at (912) 478-5641.

7. You will likely receive no direct benefit from participating in this study; however, you may be provided your results upon request. The results of this study may be used to better understand the clinical application of the instruments in question for use in postural control assessments.

8. You will be asked to attend three individual testing sessions over the span of two weeks. Each testing session will last approximately twenty minutes. Testing will comprise of two different assessments of postural control, including trials of quiet standing with eyes open and eyes closed. The first assessment will take place on a force plate using an inertial sensing device. The second assessment will take place on a balance board placed on a force plate.

9. You understand that all data concerning your assessment will be kept confidential and available only upon your written request to Megan Mormile, ATC or Cody Grotewold, ATC. You understand that any information about your records will be handled in a confidential manner consistent with medical records. Deidentified or coded data from this study may be placed in a publically available repository for study validation and further research. You will not be identified by name in the data set or any published research using information obtained from this study, and your confidentiality as a participant in this study will remain secure. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions.

10. Participants have the right to ask questions and have those questions answered. If you have questions about this study, please feel free to contact Megan Mormile at (607) 351-4131 or Cody Grotewold at (605) 413-5211. For questions concerning your rights as a research participant, please contact the IRB Coordinator at the Georgia Southern University Office of Research Services and Sponsored Programs at 912-478-5465.

11. You will not receive compensation for your participation in this project. You will not be responsible for any additional costs for your participation in this project.

12. You understand that your participation in this study is purely voluntary. You may end your participation and withdraw from this study at any time by contacting the primary investigators, Megan Mormile or Cody Grotewold.

13. You understand that you may terminate your participation in this study at any time without penalty or retribution. Owing to the scientific nature of the study, the investigators may in their absolute discretion terminate the procedures and/or investigation at any time.

14. You understand that there is no deception involved in this project.

15. You certify that you are 18 years of age or older and you have read the preceding information, it has been read to you, and you understand its contents. Any questions you have

regarding the research may be directed to the investigators listed at the beginning of this contact form.

You will be given a copy of this consent form to keep for your records. This project has been reviewed and approved by the GSU Institutional Review Board under tracking number H\_\_\_\_\_.

Title of Project: Validation of the BTS GWalk for Use In Postural Control Assessment

Principal Investigators: Megan Mormile, ATC Biomechanics Lab, Hanner Building (607) 351-4131 mm11789@georgiasouthern.edu nmurray@georgiasouthern.edu

Participant Signature

I, the undersigned, verify that the above informed consent procedure has been followed.

Investigator Signature

Title of Project: Validity and Reliability of the Balance Tracking System During Static Stance

<u>Principal Investigators:</u> Cody Grotewold, ATC Hanner Building Office 1207 (605) 413-5211 cg05473@georgiasouthern.edu bmunkasy@georgiasouthern.edu

Participant Signature

I, the undersigned, verify that the above informed consent procedure has been followed.

Investigator Signature

Date

Date

Secondary Investigator: Barry Munkasy, PhD 0107D Hollis Building (912) 478-0985

Secondary Investigator: Nicholas Murray, PhD 0107B Hollis Building (912) 478-5268

Date

Date

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# Research Compliance Combined Cover Page

Georgia Southern University

Application for Research Approval

Investigator Information:			
Name of Principal Investigator:	Phone: (607) 351-4	131	For Office Use Only:
Megan Elizabeth Evelyn Mormile			
Email: mm11789@georgiasouthern.edu	Faculty D	octoral 🗌 Specialist	Date Received:
	Masters U	ndergraduate	
(Note: Georgia Southern email addresses will be	Other:	C	Protocol ID
used for correspondance.)			-
Department Name and PO Box: Health and			
Kinesiology, PO Box 8076			
Nome(a) of Co. Investigators:	Dhome: (012) 479 (	0202	-
Name(s) of Co-investigators:	Phone: (912) 4/8-0	1205	
Dr. Nicholas Murray			
Dr. Porry Murkosy			
DI. Barry Mulikasy Katalyn Grimas, ATC			
Brian Szekely			
Email addresses			
Email addresses:			
rmurray@georgiasouthern.edu F		atoral: Spacialist: N	Masters 🗌 Undergraduate
hmunkasy@goorgiasouthern.edu F	(If multiplay identit	b by initial lotton bobind r	ama E a E for facultu)
kg03803@georgiasouthern edu M	(I) multiple: taeniij	y by inilial leller benina n	ame. E.g., F for faculty)
hs073/3@georgiasouthern edu M			
Department Name and BO Poy: Health and			
Kinesiology PO Box 8076			
Kinesiology, I O Dox 6070			
Personnel and/or Institutions Outside of Georg	ia Southern Universi	ty involved in this researc	h (Attach training certification)
N/A		ty mored in this researc	in (Attach training certification).
Project Information: (Note: funded project tit	les must match gran	t title)	
Title: Validity and Reliability of the GWalk for	r Use in Postural Co	ntrol	
Validity and Reliability of the Balance Trackin	g System During Sta	tic Stance	
Brief (less than 50 words) Project Summary: C	Current clinical meth	ods of balance and postura	al control are subjective and do
not provide optimal information about patholog	gies affecting the pos	stural control system. The	purpose of these studies is to
determine the validity and reliability of the Bal	ance Tracking Syste	m and BTS GWalk for us	e in postural control.
Compliance Information:			
Please indicate which of the following will be i	used in your research	1: (application may be sub	omitted simultaneously)
Human Subjects (Complete Section A: Hu	man Subjects below	)	
Care and Use of Vertebrate Animals (Com	plete Section B: Cal	re and Use of Vertebrate A	Animals below)
Biohazards (Complete Section C: Biohaza	urds below)	*	
Do you or any investigator on this project 1	have a financial inter	act in the subjects study	outcome or project spensor ()
disclosed conflict of interest will not preclude approval	n undisclosed conflict of	interest will result in disciplinar	v action )
Project Start Date: 09/2016 End Date:05/2017	(no more than 1	Check one	,
vear) Anticipated renewals vear 2 vear 3	(no more than 1	New submission	Resubmission #H17022
jem, inderpated tene warsyeur 2yeur 3			

Funding Source: Federal	State	Private	Internal GSU	Self-funded/non- funded
Funding Agency:			Not Applicable	

Section A: Human Subjects 🗌 Not Applicable				
Number of Subjects (Maximum) 200	Date of IRB education completion: 05/2016 (attach copy of completion			
	certificate)			
<ul> <li>Purpose of Research: (Check all that apply)</li> <li>New Publication/use in thesis/dissertation</li> <li>New Publication (journal, book, etc.)</li> <li>New Poster/presentation to a scientific audience</li> <li>New Completion of a class project</li> <li>New Presentation to GSU audience only</li> <li>New Presentation in outside of GSU</li> <li>New Results will not be published</li> <li>Other</li> </ul>	Please indicate if the following are included in the study (Check all that apply):         Human Subjects Incentives         Informed Consent Document         Greater than minimal risk         Research Involving Minors         Deception         Generalizable knowledge (results are intended to be published)         Survey Research         At Risk Populations (prisoners, children, pregnant women, etc)         Video or Audio Tapes         Medical Procedures, including exercise, administering drugs/dietary supplements, and other procedures			

Section B: Care and Use of Vertebrate Animals 🖾 Not Applicable				
Purpose of use/care of animals:Please indicate if the following are included in the study:				
Research	Physical intervention with vertebrate animals			
L Teaching	Housing of vertebrate animals			
Demo only	Euthanasia of vertebrate animals			
Student participation in faculty work	Use of sedation, analgesia, or anesthesia			
Class Project	Surgery			
Exhibition	Farm animals for biomedical research (e.g., diseases, organs, etc.)			
Display	Farm animals for agricultural research (e.g., food/fiber production,			
	etc.)			
	Observation of vertebrate animals in their natural setting			

Section C: Biological Research 🛛 Not Applicable 🗌 Submitted Separately				
Biosafety Level: Please indicate if the following are included in the study:				
<ul> <li>Exempt</li> <li>BSL 1</li> <li>BSL 2</li> <li>BSL 3</li> </ul>	<ul> <li>Use of rDNA</li> <li>Non native/invasive plant species</li> <li>Last EHS lab safety inspection date: _Attach Report</li> <li>Last IBC biosafety lab inspection date: _Attach Report</li> </ul>			

Signature of Applicant(s): (PI, CoPI)	Date: 07/26/2016
X	
If student project please complete research advisor's in before application will be reviewed.):	<b>iformation below</b> (note that advisor signature must be received
Research Advisor's Name: Dr. Nicholas Murray	Advisor's E-mail: nmurray@georgiasouthern.edu
Advisor's Phone: (912) 478-0203	Advisor's Department: Health and Kinesiology P.O. Box: 8076
If student project - Signature of faculty member who is res	sponsible for the student conducting research.
If faculty project – Signature of department head or chair.	

By signing this cover page I acknowledge that I have reviewed and approved this pr merit, rational and significance. I further acknowledge that I approve the ethical ba	ereviewed and approved this protocol for scientific edge that I approve the ethical basis for the study.	
Signature of Committee Chair/Research Advisor (if student) Department Chair(if faculty):	Date:	
v		

Please submit this protocol to IRB@georgiasouthern.edu in a single email; scanned signatures are accepted. Original signature pages may follow by mail or fax. Applications may also be submitted via mail to the Georgia Southern University Office of Research Integrity, P.O. Box 8005 or via fax to 912-478-0719.

The application should contain all required documents specific to the committee to which you are applying. Questions or comments can be directed to (912)478-5465 or <u>IRB@georgiasouthern.edu</u>.

#### GEORGIA SOUTHERN UNIVERSITY INSTITUTIONAL REVIEW BOARD PROPOSAL NARRATIVE

#### Personnel.

Megan Mormile, ATC: Graduate Student (Principal Investigator) Cody Grotewold, ATC: Graduate Student (Principal Investigator) Nicholas Murray, PhD: Director of Concussion Research, Georgia Southern University (Secondary Investigator) Barry Munkasy, PhD: Director of Biomechanics Lab, Georgia Southern University (Secondary Investigator) Katelyn Grimes, ATC: Graduate Student Brian Szekely, B.S: Graduate Student

#### Purpose.

The purpose of the following studies is to determine if the BTS GWalk and Balance Tracking System are valid and reliable tools that can be used for postural control assessment. We hypothesize that the GWalk and Balance Tracking System will provide a valid and reliable measurement of displacement and velocity in response to internal and external perturbations. Current clinical measures of postural assessment are highly subjective, and thus do not provide concrete evidence of long-term postural deficits due to pathology. The results from this study may assist in bridging the gap between clinical and laboratory measures, and provide a more objective measurement to identify potential deficits.

#### Literature Review.

Current clinical assessments of postural control, such as the Romberg Test and Balance Error Scoring System, can be administered quickly and require minimal equipment.<sup>1</sup> However, these assessments are scored subjectively and have shown variable reliability.<sup>2</sup> Due to their subjective nature and learning effects, it is often difficult to detect subtle or longer-lasting deficits in postural control as a result of pathology.<sup>3</sup>

The current gold standard with regards to postural control assessment is laboratory grade force plates, which are able to detect the subsequent muscular responses to internal and external forces acting upon the body. Force plate technology is expensive, and requires extensive training and resources to analyze raw center of pressure data. Center of pressure (CoP) is defined as the point location of the vertical ground reaction force vector, or a weighted average of the pressure over surface area.<sup>4</sup> Collection of center of pressure data involves measurement of ground reaction forces using force platforms collecting at a base number of Hertz (Hz) per second.<sup>5</sup> Raw CoP coordinates are typically analyzed and filtered using custom codes that determine common variables such as mean and peak velocity of sway<sup>5</sup> and approximate and sample entropy.<sup>5</sup>

The NeuroCom Sensory Organization Test (SOT) is a postural control assessment used in laboratory research that is able to objectively evaluate postural control. The SOT uses laboratory grade force plates to measure anterior-posterior center of gravity sway.<sup>6</sup> Postural sway is typically measured in terms of distance and area, and uses excursion values derived from raw center of pressure data. Though the SOT is a gold-standard assessment, it is difficult to use in clinical settings due to its size, expense, and extensive analysis that is required. <sup>1,7-10</sup> Therefore, a more inexpensive, portable, and user-friendly method is warranted for use in clinical settings.

Methods utilizing mobile technology have recently arisen to provide an alternative to more expensive laboratory measures, such as the SOT or traditional force plate assessment.<sup>8</sup> These methods are relatively user-friendly and inexpensive, with the ultimate goal of providing clinicians with limited resources a way to assess lingering deficits in postural control.<sup>8-9</sup>

The Balance Tracking System (BTrackS) is a FDA approved mobile device used to quickly evaluate postural control, utilizing the BTrackS Balance Board.<sup>11</sup> The BTrackS Balance Board includes four inertial sensors that measure raw center of pressure data.<sup>11</sup> This data is immediately sent to a computer or tablet loaded with the BTrackS software via USB drive.<sup>11</sup> Preliminary data has shown that the BTrackS can measure CoP with similar accuracy and reliability as laboratory-grade force plates.<sup>12</sup> Validity of an 11x11 grid of points revealed a Pearson's correlation coefficient greater than r=0.99 in both anteroposterior and mediolateral axes.<sup>12</sup> Reliability between five equal pressures at 21 points differed by an average 1/10<sup>th</sup> of a millimeter.<sup>12</sup> The Balance Tracking System is a relatively inexpensive, lightweight, commercially available, and portable mobile device.<sup>11</sup> However, concurrent validity nor test-retest reliability has not been established in healthy subjects.

More recently, inertial sensor devices using spatial-temporal parameters have arisen in an attempt to quantify displacement in individuals based on pelvic movement during walking.<sup>13-14</sup> Wireless inertial sensing devices have recently gained popularity due to the ease of accessing spatial-temporal parameters in open and untethered environments.<sup>14</sup> Three-dimensional displacements of the lower body may be determined by the body's trajectory, and this displacement has been correlated to spatial-temporal parameters as measured by these devices.<sup>14</sup>

The BTS GWalk ® (BTS Bioengineering, Brooklyn, NY) is a relatively new piece of technology that comprises of a small rectangular sensor that contains a wireless network of inertial sensors designed to analyze human movement.<sup>13-14</sup> The sensor contains a 3-axis accelerometer, gyroscope, and magnetometer to determine planes and axes of movement.<sup>14</sup> To accurately record pelvic center of mass, the sensor is attached to a semi-elastic belt placed across the subject's lower back, at the estimated L4-L5 intervertebral disk space.<sup>14</sup> Pelvic center of mass acceleration and displacement in the anteroposterior, mediolateral, and vertical axes is then determined from signals sent via Bluetooth to a corresponding computer software program.<sup>13</sup> Previous literature involving use of the GWalk have shown the tool to be valid in a young and healthy population ages 20-35 years<sup>14</sup> in measures such as walking speed, cadence, bilateral symmetry, stride length, stance time, swing time, single and double support times in the sagittal, coronal, and transverse rotation planes.<sup>14</sup> Thus, reliability and validity measures for the BTS GWalk ® have been explored predominantly with regards to gait analysis, and have not been explored in postural control assessments.

The current aims of these studies are to determine validity and reliability of the GWalk (a) and Balance Tracking Systems with the intent of expanding clinical applicability in an area that has previously relied on subjective assessments of postural control. Usage of these mobile assessments in clinical settings may provide an objective measurement to assist clinicians with the identification of postural control deficits pertaining to certain pathologies. There is a gap between standard clinical measures of balance and more refined and objective measures; therefore, validating tools such as the BTrackS and GWalk may potentially provide a relatively inexpensive bridge between clinical and laboratory measures of postural control.

The methodology and research procedures used in this study have been used before, primarily with regards to obtaining center of pressure data to identify postural control deficits in individuals with pathologies such as Parkinson's Disease and concussion. The current study is the first to validate usage of the BTrackS and GWalk ® for use in postural control. Due to validation purposes, this study will utilize a convenience sample of healthy control participants, and thus will not be generalizable to a pathologic population.

#### **Outcome.**

We expect to find that the GWalk and Balance Tracking System provide both a valid and reliable measure of postural control, comparable to that of more refined laboratory equipment. The results from this study may be used to provide clinicians with a more objective method of assessing postural control deficits.

#### Describe your subjects.

This study will require participation from a minimum of thirty healthy control subjects. Due to validation purposes, all participants will be screened using a medical history form to exclude muscular and neurological pathologies that would hinder performance on a postural sway assessment. Pathologies include lower extremity musculoskeletal injury or surgery within the past year, numbness or tingling in extremities, neuromuscular injury, traumatic brain injury within the past year, psychiatric illness, history of seizures, attention deficit disorder (ADD) or attention deficit hyperactivity disorder, or learning disorder. Participants must be 18 years of age or older, male or female.

#### **Recruitment and Incentives.**

Participants will be recruited from both graduate and undergraduate classes within the School of Health and Kinesiology at Georgia Southern University, including biomechanics, structural kinesiology, and exercise science. The primary researcher(s) will attend classes and provide an in-depth explanation of the study, including methods of data collection, expectations of participants, and inclusion/exclusion criteria along with a sign-up form. Emails will be sent to participants who indicate willing involvement in the study. All participation in this study will be voluntary; no reward or compensation will be given upon completion of the study.

#### **Research Procedures and Timeline.**

All data collection for this study will be done in the Biomechanics Laboratory at Georgia Southern University. This study will include a minimum of thirty college-age participants, both male and female, recruited as healthy controls to participate in a validation study. Data will be collected on each participant individually in the laboratory. Participants will be tested at three separate time points over the span of approximately two weeks in which they will perform a quiet standing task on a force plate and a balance board. Upon arrival at the first time point, participants will fill out an informed consent form and a medical history form that includes demographic information (height, weight, and age) as well as questions regarding inclusion/exclusion criteria for the study. After completing paperwork, participants will perform two trials of eyes open and eyes closed quiet standing on the force plate for 30 seconds and six trials of eyes open and eyes closed quite standing on a balance board for 20 seconds. During quiet standing, participants will stand barefoot with their feet placed together in the middle of the force plate and balance board with their hands by their sides. Participants will be instructed to stand as still as possible for each trial with eyes open, looking straight ahead at a single crosshair on a blank surface, or eyes closed. Any outside movement by the participants, such as chewing gum, sneezing, or moving the head, deems the trial unsuccessful. At the completion of each trial, participants will be given rest as needed before beginning the next trial. During all trials, participants will be fitted with the BTS GWalk to record displacement and subsequent excursion.

#### Data Analysis.

Raw data collected using both the GWalk and the Balance Tracking System will be run through a custom code using MATLAB and further inputted into a spreadsheet using Microsoft Excel. Statistical analysis will be conducted using Statistical Package for Social Sciences (SPSS) v23.0. Intra-class Correlation Coefficients will be used to determine test-retest reliability of the GWalk and Balance Tracking System at separate time points during a one-week period. To determine validity of the GWalk, separate Pearson's correlations will be run to determine likeness between excursion of the GWalk and force plate center of pressure data. To determine validity of the Balance Tracking System, separate Pearson's correlations will be run to determine likeness of center of pressure displacement and velocity between the Vicon force plate and Balance Tracking System balance plate. Results of this study will be handled in a confidential manner consistent with medical records. Deidentified or coded data from this study may be placed in a publically available repository for study validation and further research. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions.

#### **Special Conditions:**

**Risk**. The risk assumed during the testing is no greater than the risk of normal daily activities. There is minimal risk of physical injury, mental or social discomfort during this study. If at any time a participant feels unstable during data collection, a member of the research team will be within close distance to prevent falls.

**Research involving minors**. This study will not include minors.

Deception. This study does not involve deception.

Medical procedures. This study does not include medical procedures.

#### Literature Review Reference list:

1. Guskiewicz KM. Balance assessment in the management of sport-related concussion. *Clin Sports Med.* 2011;30(1): 89-102.

2. Finnoff JT, Peterson VJ, Hollman JH, et al. Intrarater and interrater reliability of the Balance Error Scoring System (BESS). *PM R*. 2009;1(1): 50-4.

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	Institutional Review Board (IRB)		
Phone: 912-478-5465		Veazey Hall 3000 PO Box 8005	
Fax: 912-478-0719	IRB@GeorgiaSouthern.edu	Statesboro, GA 30460	
To:	Mormile,Megan;		
	Grotewold, C.,		
	Murray, N.		
	Munkasy, B.		
	Szekely, B.		
From	Office of Research Services and Spor	nsored Programs	
	Administrative Support Office for Research Oversight Committees (IACUC/IBC/IRB)		
Initial Approval Date:	8/1 8/2016		
Expiration Date:	7/31/2017		
Subject: Status of Application for Approval to Utilize Human Subjects in Research Expedited			

After a review of your proposed research project numbered <u>HI 7022</u> and titled <u>"Validity and Reliability of the G Walk</u> for Use of Postural Control" it appears that (1) the research subjects are at minimal risk. (2) appropriate safeguards are planned, and (3) the research activities involve only procedures which are allowable. You are authorized to enroll up to a maximum of <u>200</u> subjects.

Therefore, as authorized in the Federal Policyfor the Protection of Human Subjects, I am pleased to notify you that the Institutional Review Board has approved your proposed research. Description: The purpose of these studies is to determine the validity and reliability of the Balance Tracking System and BTS G Walk for use in postural control.

If at the end of this approval period there have been no changes to the research protocol; you may' request an extension of the approval period. In the interim, please provide the IRB with any' information concerning any significant adverse event, whether or not it is believed to be related to the study, within five working days of the event. In addition, if a change or modification of the approved methodology' becomes necessary, you must notify the IRB Coordinator prior to initiating any such changes or modifications. At that time, an amended application for IRB approval may be submitted. Upon completion of your data collection, you are required to complete a Research Study ternination form to notify the IRB Coordinator, so your file may be closed.

Sincerely,

Haynes

Eleanor Haynes

# APPENDIX C.

# ADDITIONAL INFORMATION

# **Research Question**

The purpose of this study is to examine the test-retest reliability of the BTS GWalk as well as examine its criterion validity with the COP data measured by laboratory force platform. It is the aim of this research to determine if the GWalk can be used as an objective and inexpensive alternative to more traditional laboratory measures.

# Hypotheses

It was hypothesized that the GWalk would provide a reliable (ICC = >.75) and valid (r = >.75) measure of postural control as compared to the force platform when utilizing test-retest reliability.

# Assumptions

Data collection for the current study involved participants standing as still as possible on a force platform, following instructions provided by the testing administrators. It was assumed that all equipment was up to date and working properly, at the responsibility of the administrator. It was assumed that all participants were honest, provided an accurate medical history, and gave maximum effort on all testing sessions.

# **Delimitations**

The sample of individuals utilized in the current study were selected of convenience from a single university. Appropriate exclusion criteria was noted and ensured over the course of the study (see Table 1).

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