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Validity and Reliability of the Balance Tracking System™ During Static Stance

Cody L. Grotewold

VALIDTY AND RELIABILITY OF THE BALANCE TRACKING SYSTEM™ DURING STATIC STANCE

by

CODY GROTEWOLD

(Under the Direction of Barry Munkasy)

ABSTRACT

Introduction: The Balance Tracking System™ (BTrackS™) is a balance board designed to quickly analyze postural control through center of pressure (COP) analysis.

Purpose: Examine concurrent validity and test-retest reliability of the BTrackS™ during static stance.

Methods: A convenience sample of 51 healthy collegiate students between 18 - 25 years old (21.8 ± 3.1 years) completed four, 20 second (s) trials of feet together static stance during both eyes open and closed trials. Data was simultaneously collected on the BTrackS™ and a laboratory force plate to establish concurrent validity. A second testing session was administered 48 - 72 hours later to establish test-retest reliability. Independent variables were device (BTrackS™/force plate) and time (Time Point 1/Time Point 2). Dependent variables were anterior-posterior (AP) and medial-lateral (ML) COP excursion. Eight Pearson's Product Correlations were used to compare the relationship of dependent variables between the BTrackS™ and laboratory force plate. Four Intra-Class Correlations (ICC) were used to compare the relationship of dependent variables between Time Point 1 and Time Point 2 measured by the BTrackS™. Four 2 x 2 (device x time) repeated measures ANOVA's were used to determine the magnitude of differences within independent variables.

Results: Pearson Product Correlations showed an excellent relationship ($r = 0.867 – 0.968$) between the BTrackS™ and laboratory force plate. However, the 2 x 2 repeated measures

ANOVA's showed a significant difference between devices during both eyes open and closed conditions for all dependent variables ($p < 0.001$). Intra-Class Correlations showed an excellent relationship (ICC = 0.859 – 0.984) between time points for the BTrackS™. The 2 x 2 repeated measures ANOVA's showed no significant differences between time points for the BTrackS™ during eyes open and closed conditions for all dependent variables ($p = 0.185 – 0.976$).

Conclusion: Findings suggest that the BTrackS™ is strongly correlated with a laboratory force plate, but is significantly different. The BTrackS™ is strongly correlated and not significantly different within 48 - 72 hours. Additional research regarding an acceptable difference between the BTrackS™ and a laboratory force plate is warranted before it can be used clinically.

INDEX WORDS: Postural control, Balance tracking system, Validity, Reliability

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CODY GROTEWOLD

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CODY GROTEWOLD

Major Professor:	Barry Munkasy
Committee:	Nicholas Murray
	Tamerah Hunt

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CHAPTER 1

INTRODUCTION

Balance is the ability to maintain the center of mass, which is the point of equal mass distribution within the body, inside the base of support to maintain upright stance.[1, 2] Postural control is a continuous process that requires the central nervous system to utilize this sensory information and employ an appropriate motor response to effectively maintain upright stance.[1] Sensory information is obtained by the visual, vestibular, and somatosensory systems.[1] The visual system utilizes sensory information to plan how one maintains upright stance.[1] The vestibular system uses the inner ear to sense accelerations of the body.[1] The somatosensory system uses position and velocity information regarding body segments.[1] An effective integration of these sensory systems results in optimal postural control.[1]

Postural control is commonly assessed with a laboratory force plate, which is often considered the gold standard for identifying impairments associated with neurological and musculoskeletal pathologies.[1, 3] However, a laboratory force plate may be difficult to use in a clinical setting because it is expensive and immobile.[2, 4-6] The Balance Tracking System™ (Balance Tracking System Inc. San Diego, CA, USA) is a balance board which was designed as an alternative postural control assessment tool for sport-related concussions because it is portable, relatively inexpensive, and provides immediate feedback.[7-9] The Balance Tracking System™ (BTrackS™) contains voltage sensors that are configured similarly to a laboratory force plate. The BTrackS™ and laboratory force plate measure ground reaction forces, which are used to analyze center of pressure (COP) for postural control assessment.[1, 3] COP is a weighted average of all the forces exerted over the surface area in contact with the plate.[1, 3] The BTrackS™ system analyzes COP excursion, which is the total displacement, independent of direction, throughout static stance.[10] According to the manufacturer, the magnitude of COP excursion

(centimeters) is averaged across three 20 second (s) trials during eyes closed double leg static stance.[9] The COP analysis provided by the BTrackS™ may help identify subtle changes in postural control to track recovery of impairments.[11] However, before the BTrackS™ can be used as an alternative postural control assessment tool, it must be both valid and reliable.

Validity ensures an instrument provides accurate measurements.[12] Concurrent validity, a type of criterion validity, seeks to determine the accuracy between two instruments that are administered simultaneously.[12] In order for an instrument to be considered valid, it also must be reliable.[12] A reliable instrument will produce consistent, dependable, and repeatable measurements.[12] Reliability determines the degree to which an instrument is free of measurement errors that may derive from testing procedures or the subjects.[12] Test-retest reliability evaluates these errors when using an instrument on two different testing sessions.[13]

Validity and reliability of the BTrackS™ has been previously established using a computerized numerical control (CNC) machine.[14] The CNC machine precisely applied pressure to an 11 x 11 grid of points on the BTrackS™ board.[14] A Pearson Product Correlation was used to determine the validity between the known location of the machine and the location produced by BTrackS™.[14] Pearson product correlation coefficients were greater than r = 0.99 in both AP and ML directions between the CNC machine and BTrackS™.[14] The CNC machine also established reliability of the BTrackS™ by applying 5 equal pressures, at 21 separate points.[14] Results showed that COP measurements from the BTrackS™ differed by an average of $1/10^{th}$ of a millimeter at each of the 21 points.[14] Despite valid and reliable findings, due to the dynamic nature of human posture,[1] validity and reliability also needs to be established during static stance.[15]

The BTrackS™ has been validated, during static stance, by examining the sensitivity rate of identifying postural control impairments associated with sport-related concussions.[9] Sensitivity provides validity to a diagnostic instrument by determining the proportion of true positives correctly identified.[16] Results suggest that the BTrackS™ had a moderate sensitivity rate (0.64) for identifying concussed individuals with postural control impairments.[9] Although the reported sensitivity rates provided some validity to the BTrackS™ as a diagnostic tool, during static stance, concurrent validity has yet to be examined with the gold standard in postural control assessment, the laboratory force plate, during static stance.

Test-retest reliability of the BTrackS™ has only been established, during static stance, between two testing sessions separated by approximately 7 days.[14] Results of this pilot study suggest that the BTrackS™ had moderate test-retest reliability (r = 0.80) when administered twice approximately 7 days apart.[14] Despite reliable findings, postural control assessment may also occur within a shorter period of time. However, test-retest reliability of the BTrackS™ has yet to be examined during a shorter follow-up period.

As previously discussed, the BTrackS™ was designed as an alternative postural control assessment tool for sport-related concussions and may be used within a relatively short period of time to track recovery of impairments.[9, 14] The postural control impairments associated with sport-related concussions typically resolve within 3 - 10 days post-injury.[17-22] Due to the transient nature of these impairments, postural control may be re-assessed within a relatively short period of time to track the recovery. Therefore, postural control may be re-assessed at 48 - 72 hours, as previous literature suggests that re-assessment be avoided within 24 hours to prevent learning effects.[23-25] Establishing reliability within this timeframe will ensure that the BTrackS™

will obtain reliable data for tracking the recovery of postural control impairments associated with a sport-related concussion.

Research has yet to use feet together stance when examining the validity and reliability of the BTrackS™, despite being included in the standard BTrackS™ postural control assessment. Static postural control assessment is often performed during feet together stance because of the narrow base of support that it creates, which results in increased COP excursion magnitudes. [1, 26-28] Feet together stance creates an inverted pendulum which forms hinges at the ankle and hip joints.[1] Postural control strategies at these joints can be represented by analyzing COP excursion in the anterior-posterior (AP) and medial-lateral (ML) directions.[1] During feet together stance, COP excursion in the AP direction is due to plantarflexion and dorsiflexion at the ankle joint, whereas COP excursion in the ML direction is the result of abduction and adduction at the hip joint.[1] COP excursions can be analyzed in the AP and ML directions separately, rather than total excursion, to provide a more in-depth analysis regarding subjects' postural control strategies. Therefore, feet together stance may be used to ensure an instrument can accurately measures AP and ML COP excursions.[12]

Standard BTrackS™ administration utilizes eyes closed stance despite examining its reliability. Static postural control assessment is often performed during eyes open and eyes closed stance to evaluate individuals' reliance on visual sensory information.[1] During eyes closed static stance, postural control is decreased as a result of limited sensory feedback available to the central nervous system, resulting in a less precise motor response.[29-33] As a result, eyes closed stance results in increased AP and ML COP excursion than eyes open stance.[29-33]

The purpose of our study was to examine the concurrent validity of the BTrackS™ with a laboratory force plate during static stance. This study hypothesized that AP and ML COP

excursion measured by the BTrackS™ would be strongly correlated and not significantly different from a laboratory force plate during static stance assessment. The purpose of our study was also to examine the test-retest reliability of the BTrackS™ between Time Point 1 and Time Point 2, separated by 48 - 72 hours. This study hypothesized that AP and ML COP excursion measured by BTrackS™ would be strongly correlated and not significantly different between Time Point 1 and Time Point 2, separated by 48 - 72 hours.

CHAPTER 2
LITERATURE REVIEW
Introduction

Balance is the ability to maintain the center of gravity, within the base of support to maintain upright posture.[1, 2] Center of gravity is a vertical projection of the body's center of mass, which is the point of equal mass distribution within the entire body.[1] Upright posture is maintained through postural control, which is a continuous process that requires the central nervous system to integrate sensory information from the visual, vestibular, and somatosensory systems and employ an appropriate musculoskeletal response.[2] The central nervous system uses a hierarchy of three different levels in response to sensory information.[34, 35] The highest level includes the cerebral cortex, which is responsible for concentration, attention, memory, and emotion.[34, 35] The middle and lowest levels include the cerebellum, brain stem, and spinal cord which forms a reflex arc that receives and integrates sensory information from the eyes, vestibular apparatus, and proprioceptors to coordinate a response by adjusting muscle tension and joint angles.[34, 35]

A laboratory force plate is considered the gold standard in postural control assessment, and has been able to identify impairments associated with neurological and musculoskeletal pathologies.[1] A laboratory force plates measures ground reaction forces, which are equal and opposite forces exerted by the body.[1] Vertical ground reaction forces are used to calculate center of pressure (COP) which is a vertical representation of the average of all pressures over the surface area in contact with the ground.[1] For example, during double leg static stance, a COP weighted average is present underneath each foot, which produces a COP_{net} that falls somewhere between the left and right feet.[1]

Utilizing a laboratory force plate to assess postural control requires an understanding of the relationship between COP and COM.[1] COP and COM are independent of one another, however, throughout static stance, COP sway magnitude is greater than COM in both AP and ML directions in order to maintain upright posture.[1] If at any point during static stance, COM sway magnitude exceeds COP, a fall or false step will occur.[1] The direction of COP and COM sway magnitude has a strong inverse relationship to COM horizontal accelerations.[1] Horizontal COM accelerations move the COM back towards the center of the base of support in a more stable position.[1]

Laboratory force plate analysis may be used to identify postural control strategies used to maintain upright stance by analyzing COP movement in both the AP and ML directions.[1] Double leg stance can be represented by the inverted pendulum that creates a hinge at the ankle joint, which is capable of moving in the anterior-posterior (AP) and medial-lateral (ML) directions.[1] A majority of the COP movement in the AP direction is due to plantarflexion and dorsiflexion at the ankle joint, which is the result of a synchronized movement between the left and right ankles.[1] COP movement in the ML direction is the result of abduction and adduction at the hip joint, which occurs after a desynchronization between ankles resulting in a loading-unloading mechanism at the hip joint.[1] The desynchronization between limbs in the ML direction may be caused by the anatomical structure of the foot.[1] A smaller foot width allows for greater movement in the ML direction, which causes hip movement to become involved.[1] Greater movement is available in the AP direction due to a greater range of motion with dorsiflexion and plantarflexion at the ankle joint compared to inversion and eversion in the ML direction.[1]

Excursion is a simple linear metric that represents the magnitude of COP sway throughout static stance by measuring its displacement, which is independent of direction.[10] The

magnitude of COP movement occurs in response to a continually moving COM within the base of support.[36] The postural control sensory systems continuously provide positional information regarding the body's COM.[33] Generally, optimal postural control is represented by minimal COP sway magnitude.[36] Decreased COP sway is believed to be the result of a better ability to utilize the postural control system to minimize COM movement.[36] COP excursion has been used to identify postural control impairments associated with various neurological and musculoskeletal pathologies.[1, 11, 37-39] Postural control impairments were represented by increased COP excursion.[1, 11, 37-39] However, some literature contradicts these findings, showing that healthy elite athletes may exhibit greater COP sway magnitudes, although no impairment exists.[40] Therefore, when using COP excursion analysis, postural control of elite athletes need to be considered when being compared to recreational athletes and sedentary individuals.

Validity and Reliability

Although a laboratory force plate is considered the gold standard in postural control assessment, errors that may affect validity and reliability of testing administration need to be considered. Validity refers to the accuracy between two instruments and that it is measuring what it is supposed to.[12, 13] Many forms of validity exist, including: logical, content, criterion, and construct.[12] Criterion validity determines how well a test corresponds with a particular criterion.[13] Concurrent validity, a type of criterion validity, seeks to determine accuracy between 2 tests or instruments that are administered simultaneously.[12]

Validity may be affected by instrument errors occurring during data analysis.[12] Instrumentation errors that occur during data analysis may be controlled by selecting proper sampling and cut-off frequencies for data filtering. According to the Nyquist Theorem, static stance requires a minimum of 6 Hz sampling frequency, however, the ideal range is between 15 -

30 Hz.[41] Based on a previous systematic review, a minimum cut-off frequency of 10 Hz will ensure that the power of unwanted noise is controlled.[10,42]

Validity may also be affected by testing and instrumentation errors occurring throughout data collection.[12] Uncalibrated equipment may result in an inaccurate representation of COP analysis. [12] Standardized procedures should limit the instrumentation errors related to uncalibrated equipment. Testing errors may also occur during data collection, which may be the result of inexperienced testing administrators.[12] For example, subjects may fail to begin testing when instructed or they may finish testing early before instructed. These testing errors may be controlled by identifying errors during data collection and re-administering trials. In addition, testing administrators may also identify these errors by thoroughly reviewing data for any discrepancies.

An instrument cannot be considered valid without also being reliable.[12] Reliability refers to an instrument that produces consistent, dependable, and repeatable measurements.[12] Also, reliability is able to determine the degree to which an instrument is free of measurement errors.[13] Test-retest reliability is used to evaluate the magnitude of these errors between two separate testing sessions.[13] Reliability may be affected by errors from the subject, test, or instrument.[12]

Reliability of laboratory force plate assessment is largely dependent on the COP metric chosen for analysis.[43] No single metric to represents the whole postural control system, however, many COP metrics are available for analysis and have different levels of reliability.[44] The duration and number of trials were identified, by a systematic review, as significant factors for obtaining reliable data.[10] A systematic review suggests that between 90 - 120 s trials will meet acceptable reliability (ICC > 0.75) for a majority of COP metrics.[10] An additional study had suggests that approximately 7 trials were needed to reach acceptable reliability (ICC > 0.75) for a

majority of COP metrics.[43] Figure 2 includes the number of trials that are required to reach acceptable reliability for various COP metrics (Figure 1) during eyes open and eyes closed trials.[43] Reliability may also be improved by using an average between multiple testing session, when available which would decrease the number of intra-sessions trials.[43] Results of this study also showed that, in general, eyes closed trials had higher reliability than eyes open trials.[43] Regardless of the COP metrics selected, adjusting the duration and number of trials will ensure reliable data is obtained. [10, 43]

Figure 1

COP Summary Measure Abbreviations

Table 1
List of abbreviations (alphabetical order) used to describe the COP summary measures

COP summary measure	Description (units)
Area_CC	95% Confidence circle area (mm^2)
Area_CE	95% Confidence ellipse area (mm^2)
Area_SW	Sway area (mm^2/s)
CFREQ[a]	Centroidal frequency (Hz)
FD	Fractal dimension (unitless)
FD_CC	Fractal dimension based on the 95% confidence circle (unitless)
FD_CE	Fractal dimension based on the 95% confidence ellipse (unitless)
FREQD[a]	Frequency dispersion (unitless)
M_95[a]	95% Power frequency (Hz)
MDIST[a]	Mean distance (mm)
MPF[a]	50% Power frequency or Median power frequency (Hz)
MFREQ[a]	Mean frequency (Hz)
MVELO[a]	Mean velocity (mm/s)
POWER[a]	Total power (unitless)
RANGE[a]	Maximum distance between any two points (mm)
RDIST[a]	RMS distance (mm)

[a] These measures are computed based on the resultant distance (RD) time series (i.e., the vector distance from the mean COP to each pair of points in the AP and ML time series). Measures are also computed based on the AP time series, and similarly the ML time series.

Table 1: COP summary measures abbreviations. Reprinted from "Reliability of COP Summary Measures of Postural Steadiness in Healthy Young Adults," by B.R. Santos, 2008, *Gait and Posture,* 27(3), 409.

Figure 2

COP Summary Measure Reliability

Table 3
Number of trials needed to reach excellent reliability (>0.75) with corresponding ϕ and %SEM values

	Eyes open (EO)						Eyes closed (EC)					
	1 Day			2 Days			1 Day			2 Days		
	# Trials	ϕ	%SEM	# Trials	ϕ	%SEM	# Trials	ϕ	%SEM	# Trials	ϕ	%SEM
Time-domain measures												
MDIST_AP	>10	–	*17.8*	10	0.75	12.9	4	0.77	15.8	2	0.77	15.7
MDIST_ML	6	0.75	17.5	3	0.79	15.7	7	0.75	15.4	3	0.75	15.3
RDIST_AP	>10	–	*16.1*	5	0.75	13.2	4	0.75	16.8	2	0.77	16.1
RDIST_ML	6	0.75	17.0	3	0.79	14.9	6	0.77	14.9	3	0.79	14.1
RANGE_AP	4	0.77	14.6	2	0.79	13.7	>10	–	*27.3*	8	0.75	21.2
RANGE_ML	5	0.75	13.8	2	0.75	13.5	7	0.76	15.5	3	0.76	15.5
MVELO_AP	7	0.75	5.6	3	0.79	5.0	>10	–	*6.0*	5	0.76	5.4
MVELO_ML	>10	–	*8.1*	5	0.75	6.4	5	0.77	6.7	3	0.81	6.1
AREA_CC	>10	–	*39.5*	9	0.75	28.3	6	0.75	29.5	3	0.77	28.0
AREA_CE	>10	–	*38.9*	8	0.75	28.1	4	0.76	30.0	2	0.76	30.0
AREA_SW	3	0.75	17.5	2	0.81	14.6	5	0.75	17.1	3	0.79	15.6
MFREQ_AP	>10	–	*14.5*	6	0.75	11.7	4	0.75	13.3	2	0.77	12.3
MFREQ_ML	7	0.75	12.8	3	0.77	12.1	3	0.78	12.9	2	0.79	12.3
FD	>10	–	*2.6*	5	0.76	2.1	6	0.77	2.3	3	0.77	2.3
FD_CC	>10	–	*2.9*	3	0.76	2.4	3	0.77	2.5	3	0.86	1.9
FD_CE	>10	–	*2.7*	3	0.77	2.3	2	0.75	2.7	3	0.87	1.7
Frequency-domain measures												
POWER_AP	>10	–	*21.0*	>10	–	*15.7*	>10	–	*18.0*	>10	–	*12.8*
POWER_ML	>10	–	*27.4*	>10	–	*19.4*	>10	–	*21.7*	>10	–	*15.5*
MPF_AP	6	0.76	9.3	2	0.75	9.6	4	0.76	10.2	3	0.81	9.0
MPF_ML	3	0.77	10.9	2	0.82	9.4	4	0.77	11.5	2	0.78	11.2
M_95_AP	4	0.76	7.4	2	0.80	6.7	7	0.77	8.6	4	0.79	8.1
M_95_ML	1	0.75	11.4	1	0.85	8.2	4	0.77	10.3	2	0.78	10.2
CFREQ_AP	2	0.80	7.3	1	0.82	6.8	4	0.76	8.5	2	0.76	8.5
CFREQ_ML	1	0.75	10.4	1	0.86	7.4	2	0.82	8.6	1	0.83	8.3
FREQD_AP	>10	–	*2.9*	3	0.76	2.5	6	0.75	8.5	4	0.78	8.5
FREQD_ML	4	0.78	2.5	2	0.79	2.4	9	0.75	2.7	4	0.76	2.7

Numbers in *italic* represent the corresponding %SEM when 10 trials are averaged (either on 1 day or 2 days).

Table 3: Number of trials required to reach excellent reliability. Reprinted from "Reliability of COP Summary Measures of Postural Steadiness in Healthy Young Adults," by B.R. Santos, 2008, *Gait and Posture*, 27(3), 412. © 2007 Elsevier B.V. All right reserved.

Reliability of laboratory force plate assessment may also be affected by subject errors which may be related to mood, motivation, fatigue, health, or learning effects.[12] It is difficult to control the effects of subjects' mood and motivation, however, testing administrator experience and efficient testing sessions may mitigate these potential effects.[12] Fatigue may be more easily managed by providing adequate rest between trials. However, research has shown that fatigue does not have a significant effect on reliability in healthy young adults, even when no rest period

was provided between trials.[43] Subjects' health status may be controlled to by providing strict inclusion/exclusion criteria prior to testing to ensure subjects are free of any pre-existing pathology that may affect postural control. Musculoskeletal and neurological conditions that have been shown to affect postural control may include: lower extremity musculoskeletal injury,[1] lower extremity surgical procedures within the last year,[1] chronic ankle instability,[45] sport-related concussions,[11, 17, 18, 20] attention deficit disorder/attention deficit hyperactivity disorder,[46] and learning disorders.[47, 48] Learning effects may controlled by providing practice trials and allowing adequate time between testing sessions.[12] Although some studies have reported low reliability between sessions during double leg static stance, this was attributed to random effects rather than a learning effect.[23-25, 43] Literature suggests avoiding testing on consecutive days to limit potential learning effects between sessions.[23-25] In addition, practice trials may also limit potential learning effects within a testing session. Testing administrators should adjust testing parameters to control subject errors related to fatigue, learning effects, and health to improve reliability.[12] Although mood and motivation are difficult to control, testing administrators should also be aware of their effects.[12]

Although a laboratory force plate is considered the gold standard in postural control assessment, they are large and expensive, which may be difficult to use in a clinical setting.[2, 4-6] Mobile force plates have been designed to improve portability of laboratory assessment,[49] however, extensive data analysis is still required also making it difficult to use in a clinical setting. Therefore, a portable, inexpensive, and user-friendly postural control assessment tool may be better suited to a clinical setting. These instruments need to be both valid and reliable in order to be used for postural control assessment. This review of literature will evaluate the

validity and reliability of alternative postural control assessments tools, specifically the Balance Tracking System™, and discuss the advantages of utilizing this particular device.

Balance Tracking System

The Balance Tracking System™ (Balance Tracking System Inc., San Diego, CA, USA) is a balance board that was designed to quickly analyze postural control following a sport-related concussion.[9] The Balance Tracking System™ (BTrackS™) contains voltage sensors that are configured similarly to a laboratory force plate. The BTrackS™ and laboratory force plate measure ground reaction forces, which are used to analyze COP for postural control assessment.[1, 3] The BTrackS™ may be beneficial in a clinical setting because they are more portable, affordable, and user-friendly than laboratory force plates.

The BTrackS™ can be administered through USB port via computer or tablet loaded with the BTrackS™ software.[9] The BTrackS™ system analyzes COP excursion (centimeters), which is averaged across 3 experimental trials of double leg static stance, which is completed for 20 s with the subject's eyes closed.[9] Three experimental trials was selected by BTrackS™ based upon previous literature which produced reliable measurements ($r > 0.70$).[50, 51] An additional trial is provided during the first testing session to familiarize the subject with the test in which no data is collected.[9] Standard BTrackS™ administration also suggests providing 10 s rest between trials.[9] Before the BTrackS™ can be used as an alternative postural control assessment tool, it must be both valid and reliable.

A computerized numerical control (CNC) machine has been used to establish validity and reliability of the BTrackS™.[14] The CNC machine established validity by precisely applying pressure to an 11 x 11 grid of points to establish whether the BTrackS™.[14] A Pearson product

correlation was used to determine the validity between the known location of the machine and the location produced by BTrackS™.[14] The Pearson product correlation coefficients greater than r = 0.99 in both AP and ML directions between the CNC machine and BTrackS™.[14]

The CNC machine was also used to establish the reliability of the BTrackS™.[14] The CNC machine applied 5 equal pressures, at 21 separate points, to establish reliability.[14] Results showed that COP measurements from the BTrackS™ differed by an average of 1/10th of a millimeter at each of the 21 points.[14] Although validity and reliability has been established with a CNC machine,[14] due to the dynamic nature of human posture,[15] it also needs to be established during static stance.

Only two studies have established validity and reliability of the BTrackS™ during static stance.[9, 14] Test-retest reliability was established during static stance in 100 healthy subjects standing with their eyes open and feet apart between two testing sessions separated by a week.[14] Intra-class correlation coefficients showed excellent reliability (r = 0.80) between both testing sessions.[14]

Validity was established by using the BTrackS™ to identify postural control deficits in subjects that had sustained a sport-related concussion.[9] Subjects completed BTrackS™ standard protocol during pre-season baseline assessment.[9] Subjects diagnosed with a concussion and were tested again within 48 hours post-injury.[9] Sensitivity is the proportion of true positives that are correctly identified by a test.[16] Sensitivity was determined by the percentage of athletes showing a decline in postural control in follow-up testing.[9] BTrackS™ defined a decline in postural control as an increase in COP excursion by 5 centimeters, which was established by analyzing minimum detectable change at the 90% confidence interval.[9] Results showed that approximately 64% of subjects were identified as exhibiting a decline in postural control from baseline

performance.[9] All subjects showed an average increase in COP excursion of 18.8 centimeters.[9] Subjects identified as impaired showed an average increase of 30 centimeters during follow-up testing.[9]

The established sensitivity of the BTrackS™ (0.64) for sport-related concussions is higher than previous reports of the BESS (0.30).[52] The sensitivity of the BTrackS™ is also comparable to the Sensory Organization Test (0.62).[53] However, specificity of the BTrackS™ was not reported. Specificity is the proportion of true negatives correctly identified by a test.[16] Therefore, the proportion of healthy individuals correctly identified was not determined. A valid diagnostic test needs to report both sensitivity and specificity values. In summary, the BTrackS™ balance board may be beneficial in a clinical setting because it is relatively inexpensive, portable, and can provide immediate feedback regarding postural control.[9] However, before the BTrackS™ can be used clinically, it needs additional validation with a laboratory force plate during static stance, as well as, establish test-retest reliability during a more clinically relevant postural control assessment.

Conclusion

In conclusion, the BTrackS™ may be a suitable alternative a laboratory force plate because it is more user-friendly, affordable, and portable.[4, 6, 54] Criterion validity of the BTrackS™ has only been established using a computerized numerical control machine. However, due to the dynamic nature of human posture, validity and reliability needs to be established during static stance. The only study that has validated the BTrackS™ during static stance examined the sensitivity rate (0.64) of identifying postural control impairments associated with sport-related concussions.[9] Although this provided some validity of the BTrackS™ as a diagnostic tool during static stance, concurrent validity has yet to be examined with the gold

standard in postural control assessment, a laboratory force plate, during a static stance assessment.

Test-retest reliability of the BTrackS™ has only been established within 7 days, and has yet to be examined during a shorter follow-up period. The BTrackS™ was designed as an alternative postural control assessment tool for sport-related concussions and may be used within a relatively short period of time to track recovery of impairments.[9, 14] The postural control impairments associated with sport-related concussions typically resolve within 3 - 10 days post-injury.[17-22] Therefore, due to the transient nature of these impairments, postural control may be re-assessed within a relatively short period of time to track the recovery.

CHAPTER 3
METHODS
Study Design

A cross-sectional study design of healthy collegiate aged students was used to examine the concurrent validity and test-retest reliability of the BTrackS™. Concurrent validity was established by collecting COP data from the BTrackS™ simultaneously with an in-ground strain gauge force plate (AMTI OR6 Series, Watertown, MA, USA). Test-retest reliability of the BTrackS™ was established by comparing COP data collected between Time Point 1 and Time Point 2, which were separated by 48 - 72 hours.

Subjects

A convenience sample of healthy collegiate students (18 - 25 years old) at a single Division I university were recruited through undergraduate and graduate classes in the School of Health and Kinesiology. A medical history questionnaire and informed consent were completed prior to the first testing session. The medical history questionnaire was used to determine whether or not subjects met inclusion/exclusion criteria.

Exclusion criteria was based on various conditions that could potentially affect subjects' postural control. The following criteria excluded subjects from participation: current lower extremity musculoskeletal injury at the time of testing[1], participation in a neuromuscular training program for greater than 6 weeks[55], lower extremity surgical procedures within the last year[1], history of neurological disorder that would affect postural control[1], history of a concussion within the last year[11, 17, 18, 20], history of seizures, a diagnosis of attention deficit disorder or attention deficit hyperactivity disorder[46], or diagnosis of a learning disorder.[47, 48]

Instrumentation

The BTrackS™ balance board and AMTI in-ground strain gauge force plate were used to analyze COP excursion. A preliminary study has previously established validity and reliability of the BTrackS™ using a CNC machine.[14] However, limited research is available regarding the validity and reliability of the BTrackS™ during static stance. In this study, the BTrackS™ was directly compared to a laboratory force plate to examine the concurrent validity of the BTrackS™. The laboratory force plate is considered the gold standard in COP analysis and has previously established validity and reliability under various conditions during static stance.[10, 56]

The laboratory force plate was calibrated by laboratory research assistants at the beginning of each day. The laboratory force plate was zeroed at the beginning of each testing session. The BTrackS™ balance board was then placed directly on top of a single force plate to collect data simultaneously. The laboratory force plate was once again zeroed when the BTrackS™ balance board was in place. The BTrackS™ software performed an automatic self-calibration of its sensors at the beginning of each testing session.

Procedures

Research procedures were approved by the University's Institutional Review Board before testing began. Subjects completed a medical history questionnaire and provided written informed consent prior to the first testing session. All testing was completed in the University's Biomechanics Laboratory and administered by the principle investigator and one laboratory research assistant. Visual and auditory distractions were controlled by only allowing the subject and the testing administrators in the laboratory during testing. Subjects were asked to wear comfortable clothing and remove socks and shoes for testing.

Subjects stood with their feet together on the BTrackS™ balance board, which was placed directly on top of a single laboratory force plate. Subjects stood with either their eyes open or closed while their feet were together for 20 s. Data collection began and concluded with an auditory tone provided by the BTrackS™ software.[9] Subjects were provided with instructions regarding the auditory tones prior to each testing session. Subjects were instructed to "stand as still as possible" until they heard the second auditory tone.

The number and duration of the trials used in this study were set forth by the BTrackS™ software and were not altered in order to replicate a standard BTrackS™ administration.[9] Subjects completed a total of 8 trials (4 eyes open and 4 eyes closed) during each testing session. A single familiarization trial was provided at the beginning of each set of 4 trials in which no data was collected.[9] Approximately 10 s of rest was provided between trials, based on suggestions provided by BTrackS™.[9] A second testing session was administered 48 - 72 hours later to establish test-retest reliability of the BTrackS™.

Data Analysis

Raw force plate data was sampled at 1000 Hz and raw BTrackS™ data was sampled at 25 Hz. Force plate data was then processed as a .csv file, whereas, BTrackS™ data was processed as a .txt file. Data from both devices were then processed using a MATLAB® code (Mathworks; Natick, MA) to analyze AP and ML COP excursions. Raw data from both devices were filtered using a 4th order low-pass Butterworth filter with a 20 Hz cutoff frequency. Fundamental frequency analysis, using the Fast Fourier Transformation in MATLAB®, suggests that the given cutoff frequency (20 Hz) did not affect the COP data and controlled unwanted noise. In addition, a previous systematic review suggests that a minimum cut-off frequency of 10 Hz will control the power of unwanted noise.[10,42]

Independent variables for this study were device (BTrackS™ and force plate) and time (Time Point 1 and Time Point 2). Dependent variables for this study were AP and ML COP excursion. COP excursion was selected as the metric used to analyze postural control because it is a simple linear metric that represents the magnitude of COP sway throughout static stance by measuring its displacement, which is independent of direction.[10] COP excursions were further analyzed by separating into AP and ML directions, rather than total excursion, to distinguish the BTrackS™ ability to measure each individually. Previous literature suggests that AP and ML COP excursion reflect differences in hip and ankle postural control strategies.[1]

Once all data had been processed, an average value was obtained across 3 experimental trials for each dependent variable for statistical analysis. Obtaining an average value across multiple trials has shown better reliability than analyzing a single trial.[10, 43] Males and females were not separated for analysis as previous literature has shown no significant differences in postural control between genders.[10] Skewness and kurtosis analysis, using Statistical Package for Social Sciences (SPSS), was run on each dataset prior to statistical analysis to determine the normal distribution of the data. Presence of either skewness or kurtosis was established by values greater than 2.0. In the event of skewness or kurtosis, the data set was analyzed for outliers, which are unrepresentative scores that fall outside of 2 standard deviations of the mean.[12] Outliers were identified in order to account for pre-existing conditions that may not have been reported, which could have affected postural control. In addition, raw data from individual trials further analyzed to identify potential testing errors, which were then excluded from analysis. Once the data was completely analyzed, it was then exported to SPSS for statistical analysis.

Statistical Analysis

Eight Pearson's Product Correlations were used to establish concurrent validity by analyzing the relationships between the BTrackS™ and force plate. Four Intra-Class Correlations (ICC) were used to establish test-retest reliability by analyzing the relationships between Time Point 1 and Time Point 2 on the BTrackS™. No comparisons were made between visual conditions or directions for either correlation, as previous literature has already examined differences between eyes open and closed conditions[29-33], as well as, differences between AP and ML COP excursion.[1] Pearson's Product Correlations and Intra-Class Correlations were considered to have a strong relationship when correlation coefficients were greater than 0.70.[12]

Four 2 x 2 (device x time) repeated measures ANOVA's were also used to establish concurrent validity and test-retest reliability by determining whether dependent variables were significantly different between devices and time. Each independent variable (device and time) included 2 levels (BTrackS™/force plate; Time Point 1/Time Point 2). Comparisons between devices utilized pooled data from Time Point 1 and Time Point 2 for analysis. Comparisons between Time Point 1 and Time Point 2 was only analyzed on the BTrackS™. No comparisons were made between visual conditions (eyes open/eyes closed) or directions (AP/ML). The repeated measures ANOVA's were included in the statistical analysis to determine the magnitude of the differences between devices and time. In addition, the repeated measures ANOVA's eliminate the amount of error that occurs between subjects, which is often a great source of error.[12] The repeated measures ANOVA's established significant differences between devices and time points using p-values less than 0.05 and F-ratios greater than 4.03. Partial eta-squared (η^2) was also used in the statistical analysis to determine the meaningfulness of the

differences.[12] Therefore, η^2 values less than 0.01 had a small effect size, η^2 values of 0.09 had a moderate effect size, and η^2 values greater than 0.25 had a large effect size.[12]

CHAPTER 4

RESULTS

A total of 59 subjects (21.8 ± 3.1 years old) met inclusion/exclusion criteria and agreed to participate in this study. Two subjects were lost to follow-up testing and were excluded from analysis. In addition, two other subjects were excluded because the time elapsed between Time Point 1 and Time Point 2 exceeded 72 hours. Three subjects were also excluded from analysis because they were identified outside of two standard deviations across all dependent variables, which was believed to be an indication that they had failed to report or were unaware of a pre-existing condition that would have affected their postural control. Another subject was excluded from analysis because of an instrumentation error during data collection. A total of 51 subjects were included in the final analysis. Average time elapsed between Time Point 1 and Time Point 2 for the subjects included in the analysis was 52.8 (±27.1) hours. All means and standard deviations are reported in Table 1.

Results of the Pearson Product Correlations showed excellent relationships (r = 0.867 – 0.968) between the BTrackS™ and laboratory force plate for all dependent variables, which are reported in Table 2. Results of the 2 x 2 (device x time) repeated measures ANOVA's showed a significant difference between devices for AP COP excursion during both eyes open $F(1,50) = 61.088$, $p < 0.001$, $\eta^2 = 0.55$ and eyes closed conditions $F(1,50) = 11.926$, $p = 0.001$, $\eta^2 = 0.193$. In addition, a significant difference also existed between devices for ML COP excursion during eyes open $F(1,50) = 156.866$, $p = < 0.001$, $\eta^2 = 0.758$ and eyes closed conditions $F(1,50) = 58.76$, $p < 0.001$, $\eta^2 = 0.54$. All p-values, F-ratios, and η^2 values for each of the 2 x 2 (device x time) repeated measures ANOVA's are included in Figure 3.

Results of the Intra-Class Correlations showed excellent relationships (ICC = 0.859 – 0.984) between Time Point 1 and Time Point 2 on the BTrackS™ for all dependent variables, which are reported in Table 3. Results of the 2 x 2 (device x time) repeated measures ANOVA's showed that AP COP excursion measured by the BTrackS™ was not significantly different between Time Point 1 and Time Point 2 for both eyes open $F(1,50) = 1.807$, $p = 0.185$, $\eta^2 = 0.035$ and eyes closed conditions $F(1,50) = 1.431$, $p = 0.237$, $\eta^2 = 0.028$. In addition, ML COP excursion measured by BTrackS™ was not significantly different between Time Point 1 and Time Point 2 for eyes open $F(1,50) = 0.001$, $p = 0.976$, $\eta^2 = 0.001$ and eyes closed conditions $F(1,50) = 0.56$, $p = 0.458$, $\eta^2 = 0.011$. All p-values, F-ratios, and η^2 values for each of the 2 x 2 (device x time) repeated measures ANOVA's are included in Figure 4.

Table 1

Means and Standard Deviations

AVG ± SD	EO1 AP (cm)	EO2 AP (cm)	EO1 ML (cm)	EO2 ML (cm)	EC1 AP (cm)	EC2 AP (cm)	EC1 ML (cm)	EC2 ML (cm)
FP	16.75 ± 4.21	16.22 ± 4.24	15.56 ± 3.70	15.33 ± 3.40	24.50 ± 6.73	23.90 ± 6.32	22.24 ± 5.87	21.89 ± 5.21
BT	15.47 ± 3.42	15.00 ± 3.78	13.01 ± 2.72	13.26 ± 2.73	23.61 ± 6.61	22.97 ± 5.99	20.31 ± 5.15	20.07 ± 4.73

*** FP = force plates, BT = BTrackS™, EO = eyes open, EC = eyes closed, 1 = time point 1, 2 = time point 2, AP = anterior – posterior direction, ML = medial – lateral direction, m = meters.

Table 2

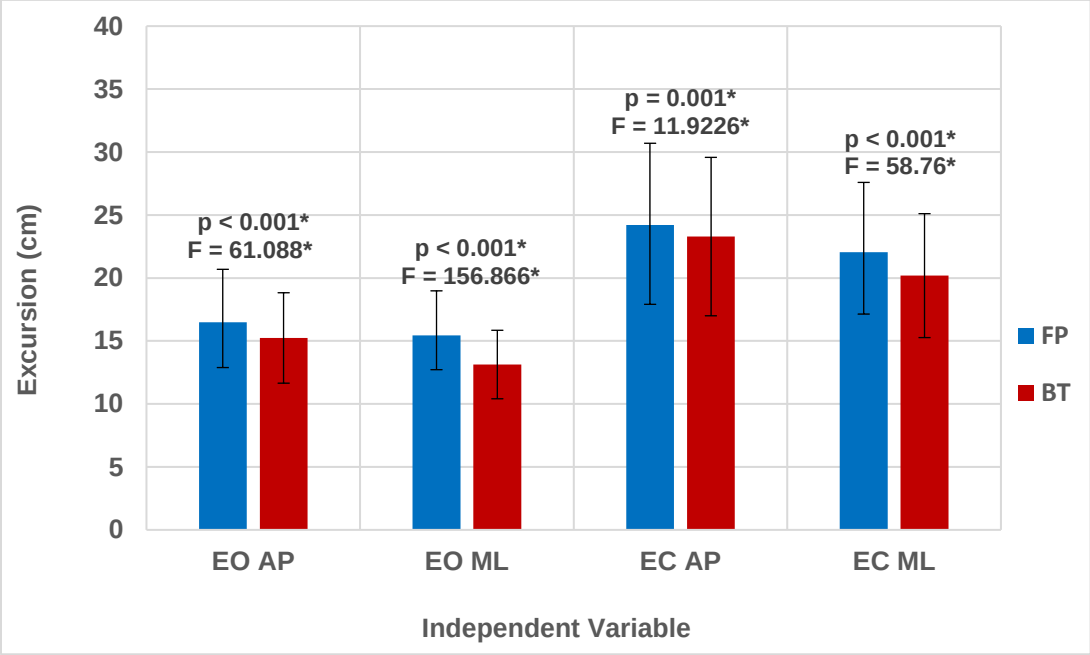
Pearson's Product Correlations

	EO1 AP	EO2 AP	EO1 ML	EO2 ML	EC1 AP	EC2 AP	EC1 ML	EC1 ML
(r)	0.949	0.928	0.876	0.867	0.932	0.968	0.913	0.966

EO = eyes open, EC = eyes closed, AP = anterior – posterior direction, ML = medial – lateral direction

Figure 3

Repeated Measures ANOVA's (Device)



EO = eyes open, EC = eyes closed, AP = anterior – posterior direction, ML = medial – lateral direction

Table 3

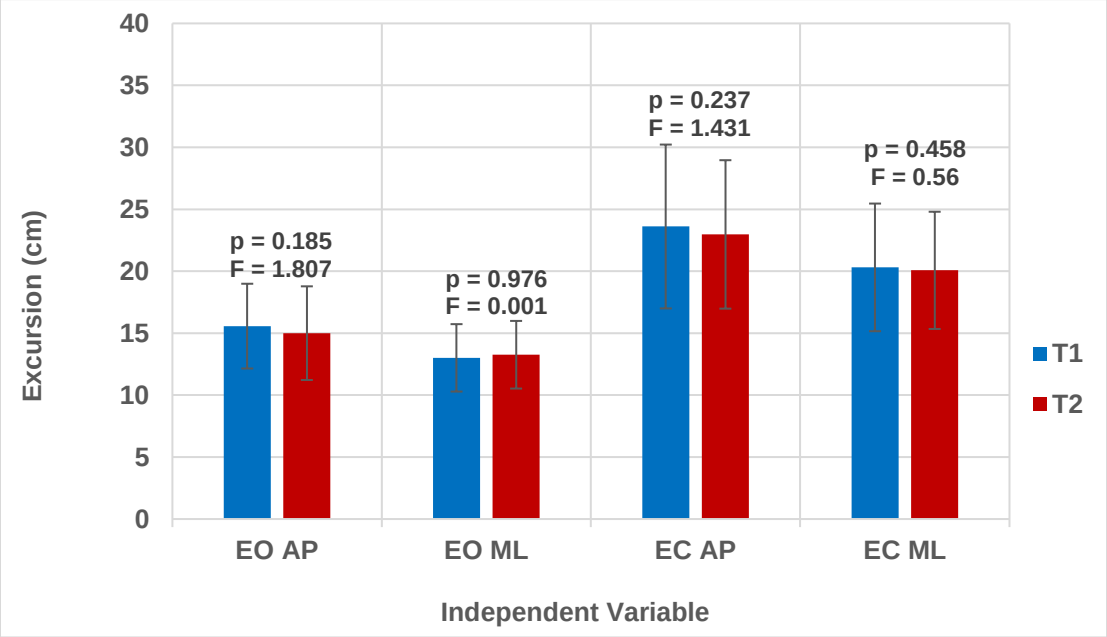
BTrackS™ Intra-class Correlation Coefficients (ICC)

	EO AP	EO ML	EC AP	EC ML
ICC	0.859	0.984	0.910	0.912

EO = eyes open, EC = eyes closed, AP = anterior – posterior direction, ML = medial – lateral direction

Figure 4

Repeated Measures ANOVA's (Time)



EO = eyes open, EC = eyes closed, AP = anterior – posterior direction, ML = medial – lateral direction

CHAPTER 5

DISCUSSION

This study hypothesized that AP and ML COP excursion measured by the BTrackS™ would be strongly correlated and not significantly different from a laboratory force plate during static stance assessment. Results of the Pearson Product Correlations showed an excellent relationship (r = 0.867 – 0.968) between the BTrackS™ and laboratory force plate for all dependent variables. Findings suggest that the AP and ML COP excursion measured by the BTrackS™ are strongly related to measurements of a laboratory force plate. However, results of the four 2 x 2 (device x time) repeated measures ANOVA's showed that the AP and ML COP excursion measured by the BTrackS™ was significantly different than the laboratory force plate during both eyes open and closed conditions. Based on the means for each device reported in Table 6, findings suggest that the BTrackS™ measured significantly less AP and ML COP excursions than the laboratory force plate during both visual conditions. Findings suggest that BTrackS™ and a laboratory force plate are strongly related for all dependent variables. However, significant differences were found between the BTrackS™ and a laboratory force plate for all dependent variables, which may limit its use as an alternative clinical assessment of postural control at this point.

This study also hypothesized that AP and ML COP excursion measured by BTrackS™ would be strongly correlated and not significantly different between Time Point 1 and Time Point 2, separated by 48 - 72 hours. Results of the Intra-Class Correlations showed excellent relationships (ICC = 0.859 – 0.984) between Time Point 1 and Time Point 2 on the BTrackS™. Findings suggest that the AP and ML COP excursion measured by the BTrackS™ between Time Point 1 and Time Point 2 are strongly related. Results of the four 2 x 2 (device x time) repeated measures ANOVA's showed that both AP and ML COP excursion measured on BTrackS™

between Time Point 1 and Time Point 2 were not significantly different during both eyes open and closed conditions. Findings suggest that the BTrackS™ is reliable between two testing sessions, separated by 48 – 72 hours, based on the strong relationship and non-significant differences reported between Time Point 1 and Time Point 2 for all dependent variables.

Our study cannot directly compare the means and standard deviations to similar literature, given the variation in testing administration (trial duration, COP metric, feet position, subject demographics, etc.). Although our study did not make direct comparisons between visual conditions, the differences in COP excursion between eyes open and closed stance can be justified with previous literature.[1] For example, static postural control assessment is often performed during eyes open and eyes closed stance to evaluate individuals' reliance on visual sensory information.[1] Our study, similar to existing literature, suggests that greater magnitudes of COP excursion occur during eyes closed stance than eyes open stance.[29-33] Increased COP excursion during eyes closed stance is the result of decreased postural control because of the limited sensory feedback available to the central nervous system, resulting in a less precise motor response.[29-33]

Although our study did not make direct comparisons between AP and ML COP excursion, the differences between directions can also be justified with previous literature.[1] Our study, similar to previous literature, suggests that AP COP excursions are greater than ML COP excursions during feet together static stance.[1] Differences in AP and ML COP excursions may be explained by the inverted pendulum model, which occurs during a narrow base of support.[1] The inverted pendulum model, created by feet together stance, suggests that COP excursions in the AP direction is the result of movement at the ankle joint, whereas COP excursion in the ML direction is the result of movement at the hip joint.[1] These postural control strategies suggest that

greater COP excursion magnitudes in the AP direction would be the result of a greater range of motion available at the ankle joint.[1]

Our study adds to the existing literature regarding the validity and reliability of the BTrackS™ by examining its concurrent validity with a laboratory force plate during static stance, as well as, examining its test-retest reliability within a short follow-up period (48 - 72 hours). Previous literature has established validity and reliability of the BTrackS™ using a CNC machine.[14] However, due to the dynamic nature of human posture,[1] validity and reliability also needed to be established during static stance before the BTrackS™ can be used for as a tool for postural control assessment.[15]

One previous study established validity of the BTrackS™ during static stance by examining the sensitivity rate of identifying postural control impairments associated with sport-related concussions (0.64).[9] The moderate sensitivity rates provided diagnostic validity to the BTrackS™ by determining its ability to correctly identify existing impairments in individuals that had sustained a sport-related concussion.[16] However, prior to our study, research had yet to examine the concurrent validity of the BTrackS™ with a laboratory force plate, during static stance.

One previous study established moderate test-retest reliability of the BTrackS™ during static stance.[14] Test-retest reliability was examined between two testing sessions separated by approximately 7 days.[14] However, postural control assessment may occur within a shorter period of time. Prior to our study, research had yet to examine test-retest reliability of the BTrackS™ during a shorter follow-up period.

Our study examined the test-retest reliability of the BTrackS™ within 48 – 72 since it was designed as an alternative postural control assessment tool for sport-related concussions, which is often used within a relatively short period of time to track recovery of impairments.[9, 14] These postural control impairments are transient in nature and typically resolve within 3 - 10 days.[17-22] Therefore, within this period of recovery, postural control may be re-assessed at 48 - 72 hours, as previous literature suggests that re-assessment be avoided within 24 hours to avoid learning effects.[23-25] Establishing reliability within this timeframe ensured that the BTrackS™ obtained reliable data for tracking the recovery of postural control impairments associated with a sport-related concussion within a short period of time.

Findings may be limited to healthy collegiate aged subjects. The results of the 2 x 2 (device x time) repeated measure ANOVA may have been limited by the number of subjects that had participated (51). The number of subjects that participated in this study was less than determined by the a priori (Cohen's d) power analysis (2,042 - 2,504) to detect significant differences. However, including 2,000 subjects would greatly increase the likelihood of Type I error, meaning a significant difference would be detected between devices or time when one did not exist. The repeated measures ANOVA's comparison between devices produced a moderate to large effect size (η^2 =0.193 - η^2 = 0.758). Therefore, the significant differences between devices may have been meaningful, suggesting that the sample size was sufficient for this particular comparison. The between time comparison for the repeated measures ANOVA's produced a small effect size (η^2 =0.001 - η^2 = 0.035). Therefore, the non-significant differences between Time Point 1 and Time Point 2 may not have been as meaningful, which would be the result of an insufficient sample size.

Additional limitations of this study may have included: testing errors, trial duration, number of trials, and experimental mortality. Testing errors could potentially affect the internal validity of our findings. Testing administrators were responsible for identifying testing errors during data collection. In the even a testing error occurred, it was excluded from analysis and a new trial was administered. Raw data was further analyzed to identify potential testing errors that were not recognized during data collection. Individual trials and one entire subject were identified as testing errors and were excluded from analysis.

Previous research identified the duration and number of trials as significant factors for obtaining reliable data.[10] Findings suggest that approximately 7 trials of between 90 - 120 s will meet acceptable reliability (ICC > 0.75) for a majority of COP metrics.[10, 43] However, the number (3) and duration (20 s) of experimental trials used in our study were not altered in order to replicate a standard BTrackS™ administration.[9]

Experimental mortality, which is the loss of subjects to follow up testing may also affect internal validity when using multiple testing sessions.[12] However, only two subjects had missed follow-up testing, which may have mitigated by a relatively short follow-up period, 48 - 72 hours, and efficient testing sessions. The two subjects that had missed follow-up testing were excluded from the final analysis.

Conclusion

The BTrackS™ contains voltage sensors that are configured similarly to a laboratory force plate and measure ground reaction forces to analyze COP movement for postural control assessment.[7-9] The BTrackS™ may be used as an alternative postural control assessment tool to the laboratory force plate because it is portable, relatively inexpensive, and provides immediate

feedback.[9] The purpose of our study was to examine the concurrent validity of the BTrackS™ with a laboratory force plate during static stance. Findings suggest that BTrackS™ and laboratory force plate are strongly related for all dependent variables. However, the BTrackS™ measured significantly less AP and ML COP excursion than the laboratory force plate, which suggests that the voltage sensors within BTrackS™ may not be able to precisely track COP excursions in the AP and ML directions. The significant differences between devices limits the BTrackS™ as an alternative clinical assessment of postural control at this point.

The purpose of our study was also to examine the test-retest reliability of the BTrackS™ between Time Point 1 and Time Point 2, separated by 48 - 72 hours. Findings suggest that AP and ML COP excursion measured by the BTrackS™ between Time Point 1 and Time Point 2, separated by 48 – 72 hours, are strongly related and not significantly different. Therefore, the BTrackS™ will produce reliable COP excursion measurements within 48 - 72 hours of testing administration, and that any postural control changes would be the result of impairment rather than an unreliable device.

Additional research regarding the significant differences between the BTrackS™ and a laboratory force plate is warranted before the BTrackS™ can be used clinically. Future research should determine whether an acceptable difference in AP and ML COP excursions, between the BTrackS™ and laboratory force plate, can be accounted for in order to be used clinically. Future research may also examine the validity and reliability of the BTrackS™ using additional COP metrics during static stance assessment. Finally, once validity and reliability of the BTrackS™ has been established with a wide range of COP metrics, future research may examine its sensitivity and specificity rates in clinical populations with known postural control impairments.

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APPENDIX A

Research Question

Will the BTrackS™ show concurrent validity to a laboratory force plate during static stance assessment? Will the BTrackS™ show test-retest reliability on testing sessions separated by 48 - 72 hours?

Hypotheses

This study hypothesized that AP and ML COP excursion measured by the BTrackS™ would be strongly correlated and not significantly different from a laboratory force plate during static stance assessment. This study also hypothesized that AP and ML COP excursion measured by BTrackS™ would be strongly correlated and not significantly different between Time Point 1 and Time Point 2, separated by 48 - 72 hours.

Assumptions

This study assumed that subjects provided an accurate medical history form to ensure that they did not have any pre-existing conditions that would affect postural control. This study also assumed that subjects understood and followed instructions provided by the testing administrators and performed with maximal effort in order to provide an accurate representation of each subject's postural control.

Repeated measures ANOVA statistical analysis assumes sphericity, which is uncorrelated and equal variance among independent variables.[12] Failure to establish sphericity will increase the risk for Type I error.[12] However, skewness and kurtosis analysis of the final data set revealed a normal distribution across all dependent variables.

Limitations

Findings may be limited to healthy collegiate aged subjects. The results of the 2 x 2 (device x time) repeated measure ANOVA may have been limited by the number of subjects that

had participated (51). The number of subjects that participated in this study was less than determined by the a priori (Cohen's d) power analysis (2,042 - 2,504) to detect significant differences. However, including 2,000 subjects would greatly increase the likelihood of Type I error, meaning a significant difference would be detected between devices or time when one did not exist. The repeated measures ANOVA's comparison between devices produced a moderate to large effect size (η^2 =0.193 - η^2 = 0.758). Therefore, the significant differences between devices may have been meaningful, suggesting that the sample size was sufficient for this particular comparison. The between time comparison for the repeated measures ANOVA's produced a small effect size (η^2 =0.001 - η^2 = 0.035). Therefore, the non-significant differences between Time Point 1 and Time Point 2 may not have been as meaningful, which would be the result of an insufficient sample size.

Additional limitations of this study may have included: testing errors, trial duration, number of trials, and experimental mortality. Testing errors could potentially affect the internal validity of our findings. Testing administrators were responsible for identifying testing errors during data collection. In the even a testing error occurred, it was excluded from analysis and a new trial was administered. Raw data was further analyzed to identify potential testing errors that were not recognized during data collection. Individual trials and one entire subject were identified as testing errors and were excluded from analysis.

Previous research identified the duration and number of trials as significant factors for obtaining reliable data.[10] Findings suggest that approximately 7 trials of between 90 - 120 s will meet acceptable reliability (ICC > 0.75) for a majority of COP metrics.[10, 43] However, the number (3) and duration (20 s) of experimental trials used in our study were not altered in order to replicate a standard BTrackS™ administration.[9]

Experimental mortality, which is the loss of subjects to follow up testing may also affect internal validity when using multiple testing sessions.[12] However, only two subjects had missed follow-up testing, which may have mitigated by a relatively short follow-up period, 48 - 72 hours, and efficient testing sessions. The two subjects that had missed follow-up testing were excluded from the final analysis.

Delimitations

Findings of this study may only be generalized to healthy collegiate age students between 18 - 25 years old. The sample was delimited to healthy subjects to ensure that subjects did not have any pre-existing conditions that would affect their postural control. As previously stated, the following criteria excluded subjects from participation: current lower extremity musculoskeletal injury at the time of testing[1], participation in a neuromuscular training program for greater than 6 weeks[55], surgical procedures within the last year[1], history of neurological disorder that would affect postural control[1], history of a concussion within the last year[11, 17, 18, 20], history of seizures, a diagnosis of attention deficit disorder or attention deficit hyperactivity disorder[46], or diagnosis of a learning disorder.[47, 48]

APPENDIX B

Research Compliance Combined Cover Page

Georgia Southern University

Application for Research Approval

Investigator Information:		
Name of Principal Investigator: Megan Elizabeth Evelyn Mormile	Phone: (607) 351-4131	**For Office Use Only:**
Email: mm11789@georgiasouthern.edu (Note: Georgia Southern email addresses will be used for correspondance.)	☐ Faculty ☐ Doctoral ☐ Specialist ☒ Masters ☐ Undergraduate ☐ Other:	Date Received:_____ **Protocol ID**
Department Name and PO Box: Health and Kinesiology, PO Box 8076		
Name(s) of Co-Investigators: Cody Lee Grotewold, ATC Dr. Nicholas Murray Dr. Barry Munkasy Katelyn Grimes, ATC Brian Szekely	Phone: (912) 478-0203	
Email addresses: cg05473@georgiasouthern.edu M nmurray@georgiasouthern.edu F bmunkasy@georgiasouthern.edu F kg03893@georgiasouthern.edu M bs07343@georgiasouthern.edu M	☒Faculty; ☐Doctoral; ☐Specialist; ☒Masters ☐ Undergraduate *(If multiple: identify by initial letter behind name. E.g., F for faculty)*	
Department Name and PO Box: Health and Kinesiology, PO Box 8076		

Personnel and/or Institutions Outside of Georgia Southern University involved in this research (Attach training certification): N/A

Project Information: (Note: funded project titles must match grant title)

Title: Validity and Reliability of the GWalk for Use in Postural Control

Validity and Reliability of the Balance Tracking System During Static Stance

Brief (less than 50 words) Project Summary: Current clinical methods of balance and postural control are subjective and do not provide optimal information about pathologies affecting the postural control system. The purpose of these studies is to determine the validity and reliability of the Balance Tracking System and BTS GWalk for use in postural control.

Compliance Information:

Please indicate which of the following will be used in your research: (application may be submitted simultaneously)

☒ Human Subjects (Complete *Section A: Human Subjects* below)
☐ Care and Use of Vertebrate Animals (Complete *Section B: Care and Use of Vertebrate Animals* below)

☐ Biohazards (Complete *Section C: Biohazards* below)

☐ Do you or any investigator on this project have a financial interest in the subjects, study outcome or project sponsor. (A disclosed conflict of interest will not preclude approval. An undisclosed conflict of interest will result in disciplinary action.).

Project Start Date: 09/2016 End Date:05/2017 (no more than 1 year) Anticipated renewals ☐ year 2 ☐ year 3	**Check one:** ☐ **New submission** ☒ **Resubmission #H17022**

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)**
Purpose of Research: (Check all that apply) ☒ Publication/use in thesis/dissertation ☒ Publication (journal, book, etc.) ☒ Poster/presentation to a scientific audience ☒ Completion of a class project ☒ Presentation to GSU audience only ☒ Presentation in outside of GSU ☐ Results will **not** be published ☐ Other	*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 ☐ Teaching ☐ Demo only ☐ Student participation in faculty work ☐ Class Project ☐ Exhibition ☐ Display	☐ Physical intervention with vertebrate animals ☐ Housing of vertebrate animals ☐ Euthanasia of vertebrate animals ☐ Use of sedation, analgesia, or anesthesia ☐ Surgery ☐ Farm animals for biomedical research (e.g., diseases, organs, etc.) ☐ 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: ☐ Exempt ☐ BSL 1 ☐ BSL 2 ☐ BSL 3	*Please indicate if the following are included in the study*: ☐ Use of rDNA ☐ Non native/invasive plant species ☐ Last EHS lab safety inspection date: _Attach Report_____ ☐ Last IBC biosafety lab inspection date: __Attach Report_____

Signature of Applicant(s): (PI, CoPI) Date: 07/26/2016 X	
If student project please complete research advisor's information below (note that advisor signature must be received before application will be reviewed.):	
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 responsible 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 protocol for scientific merit, rational and significance. I further acknowledge that I approve the ethical basis for the study.	
Signature of Committee Chair/Research Advisor (if student) Department Chair(if faculty): Date: X	

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 IRB@georgiasouthern.edu.

GEORGIA SOUTHERN UNIVERSITY INSTITUTIONAL REVIEW BOARD

INSTRUCTIONS FOR PREPARATION OF PROPOSAL NARRATIVE

Instructions: *Please respond to the following as clearly as possible. The Narrative should include a step by step plan of how you will obtain your subjects, conduct the research and analyze the data. Make sure the narrative clearly explains aspects of the methodology that provide protections for your human subjects.* ***Your narrative should be written to be read and understood by a general audience who does not have prior knowledge of your research and by committee members who may not be expert in your specific field of research. Your reviewers will only have the information you provide in your application. Explain any technical terms, jargon or acronyms.*** *The narrative is a part of the complete application.*

The application may be submitted electronically at irb@georgisouthern.edu (email attachment) or sent to the Office of Research Integrity, at P O Box 8005, Statesboro, GA 30460, fax (912) 478-0719.

Personnel.

Megan Mormile, ATC: Graduate Student (Principal Investigator)

Cody Grotewold, ATC: Graduate Student (Secondary 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.[1] However, these assessments are scored subjectively and have shown variable reliability.[2] 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.[3]

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 denoted at center of pressure (CoP). Force plate technology is expensive, requires extensive training to operate, and resources to analyze the data. Center of pressure is defined as the point location of the vertical ground reaction force vector, or a weighted average of the pressure over the surface area.[4] 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.[5] Raw CoP coordinates are typically analyzed and filtered using custom codes that determine common variables such as mean and peak excursion velocity of sway[5] and approximate and sample entropy.[5]

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.[6] 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. [1, 7-10] 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.[8] 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.[8-9] Ultimately, commercially available mobile technology may be beneficial to clinicians with limited resources because they are unable objectively assess postural stability.[8] This allows clinicians to use objective measurements to track postural stability deficits and ensure complete recovery when making return to play decisions.[9] The BTrackS and GWalk are types of mobile technology that have been used to assess postural stability.

The Balance Tracking System (BTrackS) is a FDA approved mobile device used to quickly evaluate postural control, utilizing the BTrackS Balance Board.[11] The BTrackS Balance Board includes four inertial sensors that measure raw center of pressure data.[11] This data is immediately sent to a computer or tablet loaded with the BTrackS software via USB drive.[11] Preliminary data has shown that the BTrackS can measure CoP with similar accuracy and reliability as laboratory-grade force plates.[12] Validity of an 11x11 grid of points revealed a Pearson's correlation coefficient greater than r=0.99 in both anteroposterior and mediolateral axes.[12] Reliability between five equal pressures at 21 points differed by an average $1/10^{th}$ of a

millimeter.[12] The Balance Tracking System is a relatively inexpensive, lightweight, commercially available, and portable mobile device.[11] 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.[13-14] Wireless inertial sensing devices have recently gained popularity due to the ease of accessing spatial-temporal parameters in open and untethered environments.[14] 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.[14]

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.[13-14] The sensor contains a 3-axis accelerometer, gyroscope, and magnetometer to determine planes and axes of movement.[14] To accurately record pelvic center of mass, the sensor is placed in a semi-elastic belt, which is located on the subject's lower back, at the estimated L4-L5 intervertebral disk space.[14] 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.[13] Previous literature involving use of the GWalk have shown the tool to be valid in a young and healthy population ages 20-35 years[14] 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.[14] 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 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 CoP 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 two hundred 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.

Recruitment and Incentives.

Participants will be recruited from both graduate and undergraduate classes within the School of Health and Kinesiology at Georgia Southern University during the Fall 2016 semester, 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.

Participants will be tested at three separate time points over the span of approximately two weeks, each on a different day 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. Participants will be assigned a ID number to ensure confidentiality. After completing paperwork, participants will perform four thirty second trials of eyes open and eyes closed quiet standing on the force platform to record displacement and subsequent excursion. During the first trial, participants will be fitted with the BTS GWalk, a semi-elastic belt located at the L4-L5 intervertebral space. The belt is secured via Velcro around the patient's waist. Following the first assessment, participants will perform six twenty second trials of eyes open and eyes closed quiet

standing on a the BTrackS balance board, which will be placed on top of the force platform. 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. All data collected will be securely stored and archived for a minimum of three years.

Data Analysis.

Raw data collected using both the GWalk and the BTrackS will be run through a custom code using MATLAB and further inputted into a spreadsheet using Microsoft Excel. Peak excursion velocity in the anteroposterior and mediolateral directions will be derived from ground reaction force center of pressure data from both the force platform and the BTrackS balance board. Excursion velocity will also be calculated from raw GWalk data using a separate custom code. 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 BTrackS at separate time points during a two-week period. To determine validity of the GWalk, separate Pearson's correlations will be run to determine likeness between excursion velocity of the GWalk and force platform CoP 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 force platform and BTrackS balance plate. Variables will be analyzed to determine likeliness at multiple time points for the purpose of reliability. 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. All consent forms and likewise paperwork will be stored and securely filed in a locked filing cabinet. 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:

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16. Riemann BL, Guskiewicz KM. Effects of mild head injury on postural stability as measured through clinical balance testing. *J Athl Train*. 2000;35(1):19-25.

Cover page checklist. *Please provide additional information concerning risk elements checked on the cover page and not yet addressed in the narrative. If none, please state "none of the items listed on the cover page checklist apply." The cover page can be accessed from the IRB forms page. (Note – if a student, make sure your advisor has read your application and signed your cover page. (Your advisor is responsible for the research you undertake in the name of Georgia Southern.)*

Reminder: No research can be undertaken until your proposal has been approved by the IRB.

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 ® 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. 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 on a different day. 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. De-identified or coded data from this study may be placed in a publically available repository for study validation and further research. All data collected will be securely stored and archived for a minimum of three years. You will be assigned an ID number and 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 investigator (Megan Mormile) or secondary investigator (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 H17022.

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

Principal Investigator:

Megan Mormile, ATC

Biomechanics Lab, Hanner Building

(607) 351-4131

mm11789@georgiasouthern.edu

Faculty Advisor:

Nicholas Murray, PhD

0107B Hollis Building

(912) 478-5268

nmurray@georgiasouthern.edu

_____ _____

Participant Signature Date

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

_____ _____

Investigator Signature Date

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

Secondary Investigator:

Cody Grotewold, ATC

Hanner Building Office 1207

(605) 413-5211

cg05473@georgiasouthern.edu

Faculty Advisor:

Barry Munkasy, PhD

0107D Hollis Building

(912) 478-0985

bmunkasy@georgiasouthern.edu

_____ _____

Participant Signature Date

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

_____ _____

Investigator Signature Date

MEDICAL HISTORY QUESTIONNAIRE

Title of Project(s): Validity and Reliability of the GWalk for Use in Postural Control

Validity and Reliability of the Balance Tracking System During Static Stance

Subject ID _____ Date _____

Gender: Male ☐ Female ☐ Year in School: FR ☐ SO ☐ JR ☐ SR ☐ Grad ☐

DOB: _____ Height: _____ Weight: _____

Please 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 that 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 yes, please explain: _____

4. Do you have a history of seizures? YES ☐ NO ☐
5. Have you ever been diagnosed with Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD)? YES ☐ 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 ☐

Additional Notes:

_____

_____

_____

Primary Investigator: Megan Mormile, ATC

Secondary Investigators: Cody Grotewold, ATC, Nicholas Murray, PhD, Barry Munkasy, PhD, Katelyn Grimes, ATC, Brian Szekely, B.S

Georgia Southern University
Office of Research Services & Sponsored Programs

Institutional Review Board (IRB)

Phone: 912-478-5465
Fax: 912-478-0719
IRB@GeorgiaSouthern.edu
Veazey Hall 3000
PO Box 8005
Statesboro, GA 30460

To:	Mormile, Megan; Grotewold, C.; Murray, N.; Munkasy, B.; Grimes, K.; Szekely, B.
From:	Office of Research Services and Sponsored Programs Administrative Support Office for Research Oversight Committees (IACUC/IBC/IRB)
Initial Approval Date:	8/18/2016
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 **H17022** and titled **"Validity and Reliability of the GWalk 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 **200** subjects.

Therefore, as authorized in the Federal Policy for 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 GWalk 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 Termination* form to notify the IRB Coordinator, so your file may be closed.

Sincerely,

Ele Haynes (SS)

Eleanor Haynes
Compliance Officer