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USE OF WEARABLE TECHNOLOGY TO DETECT AND ALTER SUBTLE GAIT ASYMMETRIES FOLLOWING ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

by

Alexander M. Morgan

A Dissertation Submitted in

Partial Fulfillment of the

Requirements for the Degree of

Doctor of Philosophy

in Kinesiology

at

The University of Wisconsin-Milwaukee

August 2020

ABSTRACT

USE OF WEARABLE TECHNOLOGY TO DETECT AND ALTER SUBTLE GAIT ASYMMETRIES FOLLOWING ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

by

Alexander M. Morgan

The University of Wisconsin-Milwaukee, 2020 Under the Supervision of Professor Kristian M. O'Connor

Knee osteoarthritis is a significant problem post-anterior cruciate ligament (ACL) reconstruction. Knee osteoarthritis can develop due to subtle changes in knee mechanics that affect loading on knee joint cartilage. Gait deficits during the loading phase have been observed up to four years post-surgery. However, changes in peak shank angular velocity have not been established long-term post-surgery. Peak shank angular velocity could be increased via an inertial measurement unit (IMU) based-biofeedback protocol to ultimately improve knee mechanics. Therefore, the objective of this project was to understand gait characteristics one to four years post-ACL reconstruction and to examine the effect of an IMU-based biofeedback protocol.

Twenty healthy participants and seven participants one to four years post-ACL reconstruction walked over-ground at 1.4 m/s while an IMU measured angular velocity of the shank and a three-dimensional motion capture system measured traditional gait kinematics and kinetics. Comparisons were made between groups and between limbs within the ACL-reconstructed group. Correlations were assessed between peak shank angular velocity traditionally measured kinematics and kinetics. Six participants in the ACL-reconstructed group

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then participated in a biofeedback session on a treadmill intended to increase peak shank angular velocity. Gait mechanics were assessed pre- and post-biofeedback for over-ground walking.

Peak shank angular velocity was significantly decreased in both ACL-reconstructed limbs compared to the healthy group. Knee range of motion and peak internal knee extension moment, two primary risk factors for developing knee osteoarthritis in this population, did not differ from the healthy group. Hip and ankle kinematics and kinetics did differ between groups. Only knee flexion at initial contact was different between ACL-reconstructed limbs. Additionally, peak shank angular velocity was moderately correlated with knee and hip range of motion, and peak internal knee extension moment. Post-biofeedback, peak shank angular velocity increased in both limbs. Changes were primarily observed in hip mechanics and stance time, rather than at the knee. However, asymmetries were present post-biofeedback in peak shank angular velocity, knee flexion at initial contact, and peak knee flexion during the loading phase. This work demonstrates that an inexpensive and portable device can detect abnormal gait patterns long-term post-ACL reconstruction and has the potential to be used in a biofeedback protocol to alter gait parameters that may reduce the risk of knee osteoarthritis for individuals post-ACL reconstruction.

© Copyright by Alexander M. Morgan, 2020 All Rights Reserved To Christine, my parents, and my sister. Thank you all.

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Chapter 1: Introduction

Knee osteoarthritis (OA) is a common degenerative joint disease that negatively affects the cartilage at the medial aspect of the tibiofemoral joint (Cicuttini, Wluka, & Stuckey, 2001). This can result from a cyclical loading of the medial compartment of the knee that is significantly greater than in the lateral compartment (Andriacchi & Mündermann, 2006; Mündermann, Dyrby, & Andriacchi, 2005), which can lead to significant pain and limitation in performing activities of daily living such as walking and running (Hurwitz et al., 2000; Lohmander, Östenberg, Englund, & Roos, 2004). While there is a high prevalence of knee OA in elderly individuals (Dillon, Rasch, Gu, & Hirsch, 2006), early onset knee OA is also becoming more prevalent in younger individuals (Lohmander et al., 2004). Regardless, knee OA can become a significant financial burden, particularly because total knee joint replacement surgery is becoming more common as a treatment option (Buckwalter, Saltzman, & Brown, 2004; Murphy & Helmick, 2012). Early onset knee OA is particularly prevalent among athletes who incur an anterior cruciate ligament (ACL) injury that requires surgery to reconstruct the ligament (Buller, Best, Baraga, & Kaplan, 2015). In fact, knee OA is between 3 and 4 times more likely to occur in ACL-reconstructed, or affected, knees as compared to contralateral unaffected knees (Ajuied et al., 2014; Lohmander, Englund, Dahl, & Roos, 2007).

The ACL is a structure within the knee joint that is connected on the posterior aspect of the lateral femoral condyle and the anterior aspect of the proximal tibia (Duthon et al., 2006). The role of the ACL is to stabilize the knee joint by resisting anterior translation of the tibia in relation to the femur, by resisting internal and external rotation of the tibia relative to the femur, and by resisting adduction and abduction of the knee in the frontal plane (Beynnon, Fleming, Churchill, & Brown, 2003; Butler, Noyes, & Grood, 1980). The ACL provides about 85% of the

total resistance to anterior translation of the tibia relative to the femur (Butler et al., 1980). ACL injuries that require reconstruction commonly occur as tears to the ligament due to excess anterior translation, rotation, or frontal plane movement, which can result from both neuromechanical and anatomical risk factors (Shultz et al., 2015). Both basketball and soccer remain the sports with the highest incidence of ACL injury (Prodromos, Han, Rogowski, Joyce, & Shi, 2007; Sanders et al., 2016).

Following an ACL injury, there are both conservative and surgical treatment options to attempt to return an individual to their previous level of activity. While conservative treatments allow individuals to avoid surgery and the costs associated with surgery, this option does not always ensure that an individual will be able to return to their previous level of activity, and patients may experience greater instability at the knee joint (Kessler et al., 2008; Strehl & Eggli, 2007). Thus, surgical treatment to reconstruct the ACL is often chosen, particularly when an athlete wishes to return to their sport or activity (Lynch et al., 2015). Reconstruction involves connecting a graft between the proximal tibia and the distal femur to recreate the anatomy and kinematics of the original ACL (Markatos, Kaseta, Lallos, Korres, & Efstathopoulos, 2013). ACL reconstructions have significantly increased from 1994 to 2006 in the United States, particularly in individuals under the age of 20 years old (Mall et al., 2014). As a result, any negative effects of an ACL injury that requires reconstruction, such as developing knee OA, may occur while an individual is younger and persist throughout their life.

It has been suggested that a major reason for the increase in knee OA following ACL injury and reconstruction may be subtle but clinically significant changes that an individual makes to their gait pattern to avoid putting stress on the reconstructed ACL (Herrington, Alarifi, & Jones, 2017; Lin, P., 2018; Lin, P. E. & Sigward, 2018; Lin, P. E. & Sigward, 2019; Milandri

et al., 2017; Roewer, Di Stasi, & Snyder-Mackler, 2011). The critical changes occur during the loading phase of the gait cycle, which is the period shortly after the foot contacts the ground. During normal gait, the knee will display about 15 to 20 degrees of flexion directly following heel strike, during the first 15% of the gait cycle (Neumann, 2009). This, combined with a large internal knee extension moment, allows the lower extremity to accept the body's weight and promote forward movement of the tibia over the foot (Neumann, 2009). Peak sagittal plane angular velocity can be used to measure forward progression of the tibia over the foot, with normal gait displaying angular velocities between 180 to 200 degrees per second (Lin, P. E. & Sigward, 2018; Sigward, Chan, & Lin, 2016). Studies have suggested that during gait, individuals who have undergone an ACL reconstruction will walk with significant reductions of between 2 and 5 degrees in knee flexion range of motion (ROM) and between 15% and 35% reductions in internal knee extension moment in the affected knee as compared to the unaffected knee and as compared to healthy controls (Herrington et al., 2017; Lin, P., 2018; Lin, P. E. & Sigward, 2018; Lin, P. E. & Sigward, 2019; Milandri et al., 2017; Roewer et al., 2011). Furthermore, significant reductions in peak shank angular velocity of at least 20 degrees per second have been observed in the affected limb three to four months post-surgery (Lin, P. E. & Sigward, 2018; Patterson, Delahunt, Sweeney, & Caulfield, 2014; Sigward et al., 2016). Gait mechanics in individuals post-ACL reconstruction are expected to normalize two to three months following surgery (van Grinsven et al., 2010). However, significant decreases in knee flexion ROM and internal knee extension moment during walking following surgery and extending out to four years post-surgery have been observed (Hart et al., 2016; Roewer et al., 2011). These reductions are observed without significant temporal differences in the gait patterns between limbs or between groups, suggesting that individuals post-ACL reconstruction may be attempting

to make up for these reductions in other aspects of their gait pattern, in order to keep their gait as normal as possible while minimizing strain on the ACL (Lin, P. E. & Sigward, 2019; Patterson et al., 2014).

In addition to changes in joint and segment kinematics and kinetics, increased impact forces and loading rates have been shown during gait in individuals with an ACL reconstruction as compared to healthy controls (Noehren, Wilson, Miller, & Lattermann, 2013). As such, this suggests that individuals with ACL reconstructions will tend to land stiffer and with more loading on the affected limb as compared to the unaffected limb and when compared to healthy controls. These abnormal kinetic measurements may help to further explain the increased risk of developing knee OA in this population. Landing with decreased knee flexion and internal knee extension moment may change the location and size of the cartilage contact area in the medial compartment of the affected knee, while increasing impact forces and loading rates may increase the loads onto these areas of cartilage that typically do not accommodate these forces (Kaur, Ribeiro, Theis, Webster, & Sole, 2016; Tashman, Thorhauer, Fu, & Irrgang, 2016). These changes in cartilage contact area have been observed in vivo, and have been suggested as a potential factor in explaining the early softening of the cartilage that may lead to the development of knee OA (Kaur et al., 2016; Tashman et al., 2016).

It has been suggested that the observed decreases in internal knee extension moment may be a result of decreases in quadriceps strength due to surgery and graft choice (Herrington et al., 2017; Keays, Newcombe, Bullock-Saxton, Bullock, & Keays, 2010; Milandri et al., 2017). However, quadriceps strength has been shown to return to normal levels six months post-surgery while gait deviations remain (Roewer et al., 2011; White, Logerstedt, & Snyder-Mackler, 2013). The return of quadriceps strength to normal levels is also a marker for an athlete to return to

play. However, these athletes that regain strength and return to play still retain these abnormal gait patterns that can lead to decreased internal knee extension moments (Roewer et al., 2011; White et al., 2013). This suggests that quadriceps strength alone may not fully explain these gait deviations, and that it is likely due to differences in kinematics and ground reaction forces.

While significant differences in gait parameters, such as knee flexion angle and peak shank angular velocity, have been shown in the affected knee, these deficits are subtle enough that they are difficult to detect clinically. It is important to target these subtle changes so that the gait pattern can be restored to normal (Lin, P., 2018). Typically, gait patterns are assessed in either a laboratory setting that requires a costly three-dimensional motion capture system or through observational gait analysis. Three-dimensional motion capture systems are often considered the gold standard for assessing kinematics and kinetics. However, this system is not easily accessible for clinical use. Observational gait analysis can be easily implemented in the clinical setting, however, there are inherent issues with subjectivity and a decreased ability to detect subtle changes to the gait pattern (Skaggs et al., 2000). Wearable technology, however, is a portable option for tracking movement that could be used in a clinical setting to detect these subtle changes (Cardinale & Varley, 2016). The use of inertial measurement units (IMUs) in research as a substitute for three-dimensional motion capture has increased recently (Crowell, Milner, Hamill, & Davis, 2010; Dowling, Ariel V., Favre, & Andriacchi, 2011; Willy et al., 2016). IMUs are small, relatively inexpensive sensors that contain accelerometers, gyroscopes, and magnetometers to measure kinematics and may prove easier for clinicians and the general population to use. IMUs have been previously used to measure lower limb three-dimensional kinematics during different walking conditions, and these findings have shown strong associations with kinematics measured from a three-dimensional motion capture system (Zhang,

Novak, Brouwer, & Li, 2013). This suggests that IMUs are valid devices for tracking movement. However, a single IMU cannot directly measure joint angle, and as such there is a need to determine whether movement of the lower limb segment as measured by a single IMU is correlated with knee joint angle as measured via three-dimensional motion capture.

In addition to detecting and analyzing the subtle changes to knee and shank mechanics, there is also the need to target and change these mechanics to reduce the risk for knee OA. One non-invasive treatment option to change an individual's gait pattern is the use of biofeedback. Biofeedback is a type of feedback in which information regarding body functions is provided to an individual with the goal of either changing a behavior or maintaining a behavior at a target goal (Giggins, Persson, & Caulfield, 2013; Tate & Milner, 2010; Van Gelder, Barnes, Wheat, & Heller, 2018). Biofeedback can be provided following the performance of a task or in real-time. Three of the common forms of biofeedback involve providing information to the user visually, audibly, or via a tactile sensation. As technology has advanced, so too has the use of biofeedback in gait retraining studies (Tate & Milner, 2010; Van Gelder et al., 2018). Due to the novelty of biofeedback technology, the majority of studies have focused on single sessions within a laboratory setting (Van Gelder et al., 2018). While not as generalizable as testing biofeedback in the field, it is important to test the validity of using biofeedback to promote short-term changes first. Additionally, the long-term retention of gait pattern changes has not been as widely studied, according to one review, about 70% of studies have shown beneficial short-term changes to gait patterns (Van Gelder et al., 2018). Finally, while several studies have utilized IMUs (Crowell & Davis, 2011; Dowling, A. V., Fisher, & Andriacchi, 2010; Wood & Kipp, 2014) and other three dimensional technologies (Ericksen et al., 2016; Ford, K. R., DiCesare,

Myer, & Hewett, 2015) to provide gait biofeedback, no study has focused on shank angular velocity during weight acceptance of walking.

Statement of Purpose

The ability to both detect subtle gait deviations in a clinical setting and to provide patients with immediate feedback on those gait deviations has the potential to dramatically improve rehabilitation of patients and to reduce the risk of developing knee OA. An IMU has potential as a relatively inexpensive and easily usable device in a clinical setting to achieve both goals. Therefore, the purpose of the proposed study is to assess the use of a single IMU as a proxy for measuring knee joint kinematics and as a means of providing real-time biofeedback during gait to alter shank segment and knee joint mechanics in individuals with a prior ACL reconstruction. The ultimate goal is to increase knee flexion and internal knee extension moment during the landing phase of gait via the use of real-time biofeedback provided by an IMU that targets peak shank angular velocity.

Specific Aims and Hypotheses

Aim 1: To determine if abnormal gait parameters in individuals with a prior ACL reconstruction exist one to four years post-surgery. It is hypothesized that abnormal changes in gait parameters will be present one to four years post-surgery as compared to a group of healthy individuals.

Aim 2: To examine the relationship between traditional- and IMU-based gait parameters in healthy individuals and individuals with an ACL reconstruction that occurred one to four years ago. It is hypothesized that shank angular velocity will significantly correlate with gait parameters that have been linked to risk of knee osteoarthritis.

Aim 3: To assess the feasibility of using an IMU to provide real-time biofeedback to increase peak shank angular velocity, sagittal plane knee range of motion, and peak internal knee extension moment in individuals with abnormal gait mechanics. It is hypothesized that individuals with a prior ACL reconstruction who exhibit an inhibited loading response will walk with increased peak shank angular velocity, sagittal plane knee range of motion following initial contact, and peak internal knee extension moment following initial contact with the use of real-time biofeedback.

Delimitations of the Study

- Data will be collected solely on females between the ages of 18 to 29. As such, generalizations are limited to this population.
- This study will examine walking at a set speed, limiting generalizations to walking at 1.4 m/s.

Assumptions of the Study

1. Participants will honestly answer all questions on the health history and physical activity questionnaire.

- 2. Healthy individuals will have normal ranges of motion.
- 3. Healthy individuals will display normal gait and go through the typical phases of the gait cycle.
- 4. All lower-extremity segments are rigid bodies.

Significance of the Study

Knee osteoarthritis development occurs at a higher rate in individuals with a prior ACL injury and reconstruction as compared to healthy individuals. Knee osteoarthritis can lead to significant pain and limitations in performing activities of daily living. Therefore, it is important to reduce this risk of knee osteoarthritis through early rehabilitation techniques. It has been suggested that a reason for the increase in knee osteoarthritis following ACL injury and reconstruction may be subtle but clinically significant gait asymmetries. These asymmetries likely are a result of individuals changing their gait pattern, particularly for the affected limb, to avoid putting stress on the reconstructed ACL. The literature suggests that changes in the sagittal plane occur just after initial contact and include decreased knee flexion, internal knee extension moment, peak posterior ground reaction force, and peak shank angular velocity. These changes are likely not observable without technology.

An IMU has the potential to detect subtle gait deviations in peak shank angular velocity, as single IMU can directly measure segmental angular velocity. As the IMU is relatively inexpensive and portable it can be easy to use in a clinical setting to detect these changes. Furthermore, the literature shows that an IMU can be used to provide feedback in real-time to adjust gait patterns. This suggests that an IMU could be used to provide real-time biofeedback to alter shank segment mechanics. The results of this study may provide additional information as to how shank angular velocity data from an IMU relates to other gait parameters in both healthy

and ACL-reconstructed populations. Furthermore, this study may inform future rehabilitation programs aimed at achieving gait symmetry and reducing the risk of knee osteoarthritis development in the ACL-reconstructed population post-surgery.

Chapter 2: Identifying Gait Parameter Changes Related to Prior Anterior Cruciate Ligament Reconstruction

Introduction

The Anterior Cruciate Ligament (ACL) is a structure within the knee joint composed of collagen fibers running obliquely from the femur to the tibia (Duthon et al., 2006). The primary role of the ACL is to stabilize the knee joint by resisting anterior translation of the tibia relative to the femur (Butler et al., 1980). The annual incidence of ACL injuries from 2010, when adjusted for both age and sex, was approximately 68 per 100,000 person-years (Sanders et al., 2016). Surgical treatment of an ACL injury is often chosen as a means to prevent instability at the knee and return to sport or activity (Lynch et al., 2015). Surgical treatment involves a reconstruction of the ACL within the knee joint, which is done by connecting a graft between the proximal tibia and the distal femur (Markatos et al., 2013). ACL reconstructions have significantly increased from 1994 to 2006 in the United States (Mall et al., 2014).

Early onset knee osteoarthritis, a degenerative joint disease that negatively affects the cartilage in the tibiofemoral joint, is particularly prevalent among athletes who incur an anterior cruciate ligament (ACL) injury that requires surgery to reconstruct the ligament (Buller et al., 2015). In fact, knee osteoarthritis is between 3 and 4 times more likely to occur in ACL-reconstructed knees as compared to contralateral uninjured knees (Ajuied et al., 2014; Lohmander et al., 2007). Knee osteoarthritis causes limited mobility and significant pain at the tibiofemoral joint, leading to a decrease in ability or inability to perform activities of daily living (Fautrel et al., 2005; Hurwitz et al., 2000; Lohmander et al., 2004). Additionally, knee

surgery becomes more common as a treatment option (Buckwalter et al., 2004; Murphy & Helmick, 2012).

It has been suggested that a major reason for the increase in knee OA following ACL injury and reconstruction may be subtle but clinically significant changes that an individual makes to their gait pattern to avoid putting stress on the reconstructed ACL (Herrington et al., 2017; Lin, P., 2018; Lin, P. E. & Sigward, 2018; Lin, P. E. & Sigward, 2019; Milandri et al., 2017; Roewer et al., 2011). The critical changes occur during the loading phase of the gait cycle, which is the period shortly after the foot contacts the ground. During normal gait, the knee will display about 15 to 20 degrees of flexion directly following heel strike, during the first 15% of the gait cycle (Neumann, 2009). This, combined with a large internal knee extension moment, allows the lower extremity to accept the body's weight and promote forward movement of the tibia over the foot (Neumann, 2009). Peak sagittal plane angular velocity, as measured by an Inertial Measurement Unit, can be used to assess forward progression of the tibia over the foot, with normal gait displaying angular velocities between 180 to 200 degrees per second (Lin, P. E. & Sigward, 2018; Sigward et al., 2016).

Studies have suggested that during gait, individuals who have undergone an ACL reconstruction will walk with significant reductions of between 2 and 5 degrees in knee flexion range of motion (ROM) and between 15% and 35% reductions in internal knee extension moment in the affected knee as compared to the unaffected knee and as compared to healthy controls (Herrington et al., 2017; Lin, P., 2018; Lin, P. E. & Sigward, 2018; Lin, P. E. & Sigward, 2019; Milandri et al., 2017; Roewer et al., 2011). Furthermore, significant reductions in peak shank angular velocity of at least 20 degrees per second have been observed in the affected limb three to four months post-surgery (Lin, P. E. & Sigward, 2018; Patterson et al., 2014;

Sigward et al., 2016). Finally, increases in impact forces and loading rates have been shown during gait in individuals with an ACL reconstruction as compared to healthy controls (Noehren et al., 2013). This gait pattern may change the location and size of the cartilage contact area in the medial compartment of the ACL reconstruction knee, while increasing impact forces and loading rates may increase the loads onto these areas of cartilage that typically do not accommodate these forces (Kaur et al., 2016; Tashman et al., 2016). Gait mechanics in individuals post-ACL reconstruction are expected to normalize two to three months following surgery (van Grinsven et al., 2010). However, significant decreases in knee flexion ROM and internal knee extension moment during walking extending out to four years post-surgery have been observed (Hart et al., 2016; Roewer et al., 2011). These reductions are observed without significant temporal differences in the gait patterns between limbs or between groups, suggesting that individuals with ACL reconstructions may be attempting to make up for these reductions in other aspects of their gait pattern, in order to keep their gait as normal as possible while minimizing strain on the ACL (Lin, P. E. & Sigward, 2019; Patterson et al., 2014).

The purpose of this study was to determine if abnormal gait parameters in individuals with a prior ACL reconstruction exist one to four years post-surgery. Traditional and IMU-based measures of gait were compared between limbs for individuals with a prior ACL reconstruction on a single limb, and between healthy controls and both limbs for the ACL reconstructed sample. It was expected that abnormal changes in gait parameters would be present at one to four years post-surgery. A better understanding of gait parameter changes that occur well after ACL reconstruction, particularly as measured by an IMU, will provide insight on what parameters need to be targeted to decrease the risk for knee osteoarthritis development in this population.

Methods

Participants. Twenty healthy, recreationally active individuals and seven individuals with an ACL reconstruction one year to four years prior to participation in this study were recruited, as prior literature has suggested that, for athletes, return to sport typically occurs six to nine months post-surgery (Harris et al., 2014). Based on prior literature (Lin, P. E. & Sigward, 2018; Patterson et al., 2014; Sigward et al., 2016) a power analysis indicated that a minimum of 17 participants per group were necessary to detect a significant difference in peak shank angular velocity after providing auditory feedback with eighty percent power. Additionally, a minimum of 16 participants per group were necessary to detect significant correlations between peak shank angular velocity and knee flexion angle (G*Power 3.1.9.2). However, due to a disruption to human subjects research resulting from COVID-19, the study was limited to the aforementioned twenty-seven total participants. The participants were recruited from the University of Wisconsin-Milwaukee student population and surrounding areas through word of mouth and flyers posted on campus. Participants were females between the ages of 18-29 years old, as it has been suggested that 29 years of age is, on average, the earliest age of onset for knee osteoarthritis following ACL injury (Lohmander et al., 2004; Roos, Adalberth, Dahlberg, & Lohmander, 1995; Roos, Ornell, Gärdsell, Lohmander, & Lindstrand, 1995). Recreational activity was be defined as individuals participating in at least thirty minutes of physical activity three or more times per week. Participant information is included in Table 1. Individual subject information for the ACLreconstructed group is presented in Table 2.

Table 1

Participant Characteristics by Group

| | Healthy | ACL-Reconstructed | | |
|-----------------------------|-------------|-------------------|--|--|
| Ν | 20 | 7 | | |
| Age (SD), year | 23.0 (2.8) | 20.1 (2.1) | | |
| Height (SD), m | 1.64 (0.07) | 1.68 (0.08) | | |
| Weight (SD), kg | 66.3 (12.8) | 70.3 (12.7) | | |
| Affected Limb | | 4 L; 3R | | |
| Time since surgery (SD), mo | | 35.9 (10.0) | | |
| Tampa Score (SD) | | 33.3 (6.8) | | |
| | | | | |

Note. SD = Standard Deviation

Table 2Individual Subject Characteristics for the ACL-Reconstructed Group

| | Age (vr) | Age (vr) Height (m) Mass (kg) At | Affected Limb | Time Since Surgery (mo) | ry (mo) Tampa Score | Affected | Unaffected | |
|-----------|----------|----------------------------------|---------------|-------------------------|---------------------|----------|------------|-----------|
| | 8- () / | 0 () | (8) | 11110000 2000 | | | Q-H ratio | Q-H ratio |
| Subject 1 | 19 | 1.6002 | 81.9 | L | 29 | 33 | 1.45 | 1.28 |
| Subject 2 | 18 | 1.7272 | 72.7 | R | 23 | 41 | 1.25 | 1.49 |
| Subject 3 | 20 | 1.651 | 57.5 | L | 27 | 28 | 1.09 | 1.26 |
| Subject 4 | 19 | 1.8034 | 89.7 | L | 45 | 37 | 0.81 | 1.62 |
| Subject 5 | 22 | 1.7018 | 57.5 | L | 46 | 30 | 1.62 | 0.88 |
| Subject 6 | 24 | 1.5748 | 59.4 | R | 47 | 23 | 1.78 | 1.71 |
| Subject 7 | 19 | 1.7018 | 73.3 | R | 34 | 41 | 1.83 | 1.59 |

Potential participants for this study were excluded if they had experienced an injury to the lower back, hips, legs, or feet within the six months prior to the study that prevented them from engaging in physical activity at that time, or if they were currently experiencing any pain during gait. Participants were also excluded if they were pregnant. Additionally, participants were excluded if they had surgery on the lower extremities within the past year. Participants for the ACL-reconstructed group were excluded if their ACL reconstruction had occurred less than one year prior to data collection. Finally, participants for the ACL-reconstructed group were excluded if any graft other than a bone-patellar tendon-bone graft was used during surgery, as this is the most common graft choice and controlled for the effect of graft type on gait mechanics (Kraeutler, Bravman, & McCarty, 2013).

Experimental setup. A single session was used to collect data on these participants. Testing occurred in the Neuromechanics Laboratory at the University of Wisconsin-Milwaukee. Threedimensional kinematic data of the lower extremity were collected using a three-dimensional motion capture system at 256 Hz (Motion Analysis, Inc., Sana Rosa, CA). Reflective markers were placed on the pelvis, thighs, lower legs, and feet. Kinetic data were collected using a Bertec 4060 force plate at 1280 Hz (Bertec Inc., Columbus, OH). Inertial Measurement Units (IMUs) were worn on anteromedial aspect of the tibia of both limbs for the ACL reconstructed group, and only the right tibia for healthy individuals, to collect angular velocity of the lower leg in the sagittal plane at 256 Hz (Shimmer3 IMU Unit, Shimmer, Boston, MA). Noraxon accelerometers were worn directly next to the Shimmer3 IMU Unit to synchronize events between the IMU and the motion capture system (Noraxon, Scottsdale, AZ). Timing gates were used to monitor gait speed when walking over-ground (Timer model 54035A, Lafayette Instrument Company,

Lafayette, IN). While not a primary goal of the study, muscle strength was assessed in order to relate the characteristics of the ACL-reconstructed group to those in previous studies. Therefore, a handheld dynamometer was used to measure maximal voluntary isometric contractions (MVIC) of the quadriceps and hamstrings (Manual muscle tester model 01165, Lafayette Instrument Company, Lafayette, IN). Saucony Jazz shoes were provided to all participants for this study to standardize footwear (Saucony, Lexington, MA).

Experimental protocol. All participants first completed an informed consent form that was approved by the UWM Institutional Review board. Demographic, health history and physical activity questionnaires were then completed to ensure that participants met the inclusion criteria for the study. For healthy participants, these questionnaires included questions about injury history and current activity level. For participants with a prior ACL reconstruction, these questionnaires included questions about the type of ACL injury participants had experienced, the affected leg, duration since injury, duration since surgery, injury history, activity level prior to ACL injury and activity level currently. Additionally, participants filled out the Tampa Scale to assess kinesiophobia (Miller, Kori, & Todd, 1991). The Visual Analog Scale was used to assess knee pain prior to and following gait analysis (AHCPR, 1994).

After completing the informed consent and questionnaire, participants changed into the Saucony Jazz shoes. Participants were allowed to wear their own athletic t-shirt and shorts. Participants then performed three MVICs of the quadriceps and the hamstrings for a period of five seconds each, with thirty second rests between each MVIC. MVIC strength was measured bilaterally for both the quadriceps and hamstrings. Measurement of the quadriceps' MVIC strength was performed with participants seated on a training table, with the lower leg hanging off the table and the hip and knee flexed to 90° as described by Douma and colleagues (Douma

et al., 2014). A seatbelt was strapped around the ankle, with the dynamometer placed between the seatbelt and the anterior portion of the lower leg. Participants were then given verbal instructions to maximally contract the quadriceps until instructed to stop at five seconds, while keeping the trunk upright and each hand placed on the opposite shoulder. Measurement of the hamstrings' MVIC strength was performed with participants seated on a training table, with the lower leg hanging off the table and the hip and knee flexed to 90° as described by Douma and colleagues (Douma, Soer, Krijnen, Reneman, & van der Schans, Cees P, 2014). The seatbelt was strapped about the ankle joint, with the dynamometer placed between the seatbelt and the posterior portion of the lower leg. Participants then followed the same instructions as presented for measuring quadriceps MVICs.

Following collection of quadriceps and hamstring MVICs, 44 reflective markers were placed on the participants' pelvis and lower extremities to track three-dimensional motion. These 44 markers were used for the standing calibration trial. Single markers were located bilaterally on the anterior and posterior iliac spines, iliac crests, greater trochanters, medial and lateral epicondyles of the knee, medial and lateral malleoli at the ankle, and the heads of the first and fifth metatarsals. Rigid plates containing four markers each were placed on the lateral aspect of the thigh and shank, and on the heel. The thigh and shank plates were attached via Velcro to elastic bands wrapped around the leg while the heel plates were attached to the shoe directly via Velcro. A five-second standing calibration trial was collected, after which sixteen of the calibration markers were removed from the iliac crests, greater trochanters, epicondyles of the knee, malleoli of the ankle, and metatarsal heads to leave 28 tracking markers. Additionally, Shimmer3 IMUs and Noraxon accelerometers were placed on the anteromedial aspect of the right tibia for healthy controls and both tibias for the ACL reconstructed group (Figure 1). These

sensors were placed at 25% of the distance from the medial epicondyle to the medial malleolus and were calibrated prior to beginning the study using the Shimmer3 IMU software. These sensors were stabilized with Velcro straps and athletic tape.



Figure 1. Experimental setup following standing calibration for an ACL reconstructed participant. 28 reflective markers were placed on the pelvis and lower extremities. IMUs and accelerometers were placed on the anteromedial aspect of each shank.

Participants were instructed to walk across a force plate embedded in a raised platform in the laboratory at 1.4 m/s, based on previous literature (Lin, P., 2018). Walking speed was monitored using timing gates located 6.65 meters apart. Participants were allowed practice trials to become accustomed to the walking speed. Participants were instructed to stomp on the ground three times with the foot of the limb that the IMU and accelerometer was attached to and then to walk across the force plate. The stomps were performed such that events could be synchronized between the Shimmer IMU and the motion capture system. Data from the Noraxon accelerometer was used to achieve this synchronization. For healthy controls, five walking trials in which the right foot completely contacted the force plate were collected. For the ACL reconstructed group, five walking trials in which the right foot completely contacted the force plate were collected. Gait speed was required to fall within a 10% range from the standardized gait speed of 1.4 m/s, based on previous literature (Lin, P., 2018).

Data reduction. Quadriceps and hamstrings strength data were averaged for each limb, and for each participant. Quadriceps to hamstrings ratios were calculated for the dominant and non-dominant limbs for healthy participants, and for the affected and unaffected limbs for ACL-reconstructed participants.

Three-dimensional kinematic and kinetic data from the motion capture system for the hip, knee, and ankle, sagittal plane shank angular velocity, vertical and posterior ground reaction

forces, and stance time were measured. Initial contact was defined as time at which the vertical ground reaction force is greater than 30 N.

Kinematic and kinetic data were processed using Visual3D (v6.00.15, C-Motion, Inc., Rockville, MD). Kinematic motion capture data were low-pass filtered at 6 Hz, and kinetic data were low-pass filtered at 50 Hz. The hip joint center was calculated as twenty-five percent of the linear distance between the greater trochanter markers. The knee joint center was determined as fifty percent of the linear distance between the lateral and medial femoral epicondyles. The ankle joint center was determined as fifty percent of the linear distance between the lateral and medial malleoli. All kinetic measurements were calculated via an inverse dynamics approach and were normalized to body mass. IMU and accelerometer data were not filtered.

Sagittal plane hip, knee, and ankle angle at initial contact were calculated (Figure 2B-D). Peak knee flexion and ankle plantarflexion were also calculated during the first thirty percent of stance (Figure 2C-D). Additionally, sagittal plane hip and knee range of motion from initial contact to the time of peak knee flexion during the loading portion of the stance phase, and sagittal plane ankle range of motion from the time of peak ankle plantarflexion to the time of peak knee flexion during the loading portion of the stance phase, were calculated (Figure 2B-D). Peak positive shank angular velocity (Figure 2A), peak internal knee extensor moment, peak internal hip extension moment, peak internal ankle dorsiflexion moment, peak vertical ground reaction force and peak posterior ground reaction force following initial contact within the first thirty-percent of the stance phase were calculated or extracted (Figure 3A-D).



Figure 2. Exemplary data for sagittal plane peak shank angular velocity (A), knee angle (B), hip angle (C), and ankle angle (D) during the stance phase. The asterisk indicates peak shank angular velocity. The brackets indicate the percentage of the stance phase used to calculate kinematic ranges of motion.


Figure 3. Exemplary data for vertical (solid line) and posterior ground reaction (dashed line) forces (A), knee moment (B), hip moment (C), and ankle moment (D) during the stance phase. The asterisks indicate the peak values extracted for analysis.

Statistical design & analysis. Tests for normality were performed prior to additional statistical tests. Three one-way MANOVAs were conducted. Dependent variables for each MANOVA included quadriceps to hamstring ratios, and all kinematic, kinetic, temporal measures. The independent variable for each MANOVA was the observed limb. The first MANOVA compared the healthy control limb to the affected limb of the ACL reconstructed group. The second MANOVA compared the healthy control limb to the affected limb to the intact limb of the ACL reconstructed group. The second MANOVA compared between limbs within the ACL reconstructed group. The MANOVAs were separated to account for between-subject versus within-subject comparisons. Effect sizes were also calculated for each comparison using Cohen's d. Ensemble averages for all kinematic and kinetic variables from initial contact to thirty percent of the stance phase were calculated and are presented in the results section. A significance level of $\alpha = 0.05$ was used for all statistical analyses. All statistical analyses were performed using SPSS (v19.0 SPSS Inc., Chicago, IL).

Results

All participants in the ACL-reconstructed group indicated no pain on the Visual Analog Scale, both before and after the walking session. The average TAMPA score to assess kinesiophobia was 33.3 ± 6.8 . This average indicates a mild to moderate level of kinesiophobia for these individuals. Time series displaying ensemble averages over the first thirty percent of the stance phase for each of the kinematic variables are presented in Figure 4. All three MANOVAs reported a significant limb main effect for kinematics and kinetics (Table 3). All kinematic summary data are presented in Table 4 and the different individual kinematic responses for the ACL-reconstructed subjects are presented in Figures 5 and 6.

Table 3.MANOVA Comparisons Between Conditions

| | F-ratio | p-value |
|---------------------|---------|---------|
| Healthy-Affected | 10.5 | < 0.001 |
| Healthy-Unaffected | 8.0 | < 0.001 |
| Affected-Unaffected | 2.4 | 0.012 |

Table 4Kinematic and Temporal Comparisons Between Conditions

Note. ^a indicates p < 0.05 for H vs. A; ^b indicates p < 0.05 for H vs. U; ^c indicates p < 0.05 for A vs. U.

| | Healthy (H) | Affected Limb (A) | Unaffected Limb (U) |
|-------------------------------------|--------------|---------------------------|---------------------------|
| Peak Shank Angular Velocity (°/s) | 170.6 (22.6) | 147.2 (17.7) ^a | 153.6 (19.0) ^b |
| Knee Flexion at Initial Contact (°) | 3.4 (4.1) | 5.9 (3.3) ^a | 3.7 (2.6) ^c |
| Peak Knee Flexion (°) | 20.3 (5.2) | 21.7 (2.0) | 20.7 (3.5) |
| Knee Range of Motion (°) | 16.9 (3.9) | 15.8 (3.1) | 17.1 (3.7) |
| Hip Angle at Initial Contact (°) | 27.4 (8.5) | 31.2 (6.9) ^a | 29.7 (6.2) |
| Hip Range of Motion (°) | 4.9 (2.2) | 6.6 (2.5) ^a | 5.7 (2.1) |
| Ankle Angle at Initial Contact (°) | 10.8 (3.6) | 13.4 (2.6) ^a | 12.8 (3.1) ^b |
| Peak Ankle Plantarflexion (°) | -6.9 (3.8) | -5.9 (1.9) | -6.5 (3.3) |
| Ankle Range of Motion (°) | 6.8 (2.7) | 5.5 (1.7) ^a | 6.8 (3.6) |
| Stance Time (s) | 0.61 (0.04) | 0.62 (0.03) | 0.62 (0.03) |



Figure 4. Ensemble averages over the first thirty percent of stance across limbs for shank angular velocity (A), hip angle (B), knee angle (C), and ankle angle (D). Solid lines indicate the healthy limb, dashed lines indicate the affected limb, and crosses indicate the unaffected limb. Positive angles indicate flexion for the hip and knee, and dorsiflexion for the ankle.

In comparing the healthy to the affected limb, the affected limb exhibited significantly less peak shank angular velocity (p < 0.001, ES: 1.15), greater knee flexion at initial contact (p = 0.002, ES: 0.67), greater hip flexion at initial contact (p = 0.019, ES: 0.49), greater hip range of motion (p = 0.001, ES: 0.72), greater ankle dorsiflexion at initial contact (p < 0.001, ES: 0.83), and greater ankle range of motion (p = 0.007, ES: 0.62). In comparing the healthy to the unaffected limb displayed significantly less peak shank angular velocity (p < 0.001, ES: 0.81) and greater ankle dorsiflexion at initial contact (p = 0.003, ES: 0.60). In comparing the affected to the unaffected limb, the affected limb the affected limb exhibited a significantly greater knee flexion angle at initial contact (p = 0.002, ES: 0.74) (Table 4).



Figure 5. Average values for peak shank angular velocity, knee kinematics and hip kinematics for each subject in the ACL-reconstructed group. White bars represent the affected limb. Black bars represent the unaffected limb. Error bars represent standard deviations.



Figure 6. Average values for ankle kinematics for each subject in the ACL-reconstructed group. White bars represent the affected limb. Black bars represent the unaffected limb. Error bars represent standard deviations.

All kinetic summary data are presented in Table 5. Time series displaying ensemble averages over the first thirty percent of the stance phase for each of the kinetic variables are presented in Figure 7. The different individual responses for the ACL-reconstructed subjects are presented in Figure 8.

Table 5

Kinetic Comparisons Between Conditions

| | Healthy (H) | Affected Limb (A) | Unaffected Limb (U) |
|---|--------------|---------------------------|---------------------------|
| Peak Internal Hip Extension Moment (Nm/kg) | -1.07 (0.23) | -1.49 (1.35) ^a | -1.16 (0.24) |
| Peak Internal Knee Extension Moment (Nm/kg) | 0.84 (0.24) | 0.85 (0.28) | 0.79 (0.22) |
| Peak Internal Ankle Dorsiflexion Moment (Nm/kg) | 0.39 (0.08) | 0.47 (0.09) ^a | 0.46 (0.12) ^b |
| Peak Vertical Ground Reaction Force (N/BW) | 1.17 (0.11) | 1.18 (0.10) | 1.21 (0.12) |
| Peak Posterior Ground Reaction Force (N/BW) | -0.26 (0.05) | -0.24 (0.06) | -0.23 (0.06) ^b |
| Q-H Ratio | 1.45 (0.35) | 1.40 (0.37) | 1.40 (0.29) |

Note. ^a indicates p < 0.05 for H vs. A; ^b indicates p < 0.05 for H vs. U.



Figure 7. Ensemble averages over the first thirty percent of stance across limbs for vertical ground reaction force (A), posterior ground reaction force (B), hip moment (C), knee moment (D), and ankle moment (E). Solid lines indicate the healthy limb, dashed lines indicate the affected limb, and crosses indicate the unaffected limb. Positive moments indicate internal hip flexion moment, internal knee extension moment, and internal ankle dorsiflexion moment.

In comparing the healthy to the affected limb, the affected limb displayed a significantly greater peak internal hip extension moment (p = 0.003, ES: 0.43) and peak internal ankle dorsiflexion moment (p < 0.001, ES: 0.94). In comparing the healthy to the unaffected limb, the unaffected limb exhibited a significantly greater peak internal ankle dorsiflexion moment (p = 0.001, ES: 0.69) and a smaller peak posterior ground reaction force (p = 0.015, ES: 0.45) (Table 5).



Figure 8. Average values for hip, knee and ankle kinetics, and peak vertical and posterior ground reaction forces for each subject in the ACL-reconstructed group. White bars represent the affected limb. Black bars represent the unaffected limb. Error bars represent standard deviations.

Discussion

This study primarily examined gait mechanics as measured by both an IMU and a traditional three-dimensional motion capture system for healthy individuals and individuals who have had a prior ACL-reconstruction. The ACL-reconstructions occurred between one and four years prior to the study. The main finding was that significant differences in gait mechanics were present between the healthy group and both limbs of the ACL-reconstructed group, as well as between the affected and unaffected limbs of the ACL-reconstructed individuals. These differences were present without significant between-limb differences in strength as measured by quadriceps to hamstrings ratios and in stance time. However, only knee angle at initial contact displayed a significant difference between the affected and unaffected limbs of the ACLreconstructed group. This suggests that these individuals, on average, may not display many between limb gait asymmetries up to four years post reconstruction. This contradicts previous work suggesting asymmetrical gait patterns both within six months of surgery (Alshehri et al., 2020; Roewer et al., 2011; Sigward et al., 2016) and up to four years post reconstruction (Noehren et al., 2013; Roewer et al., 2011). However, given the small sample size of participants in the ACL-reconstructed group, it is possible that a larger sample size may indicate asymmetries between affected and unaffected limb.

The first objective was to examine peak shank angular velocity in the sagittal plane during the first thirty percent of the stance phase as measured by an IMU during gait. Peak shank angular velocity values in the affected limb were similar to values previously established by Sigward and colleagues, however values in the unaffected limb were much lower than what has been published previously (Alshehri et al., 2020; Lin, P. E. & Sigward, 2018; Sigward et al., 2016). Peak shank angular velocity was significantly lower in the affected limb of the ACL-

reconstructed group as compared to healthy individuals. This supports one of the primary hypotheses for this study and suggests that individuals that may be as far as four years post-ACL reconstruction may still exhibit abnormal gait patterns in the affected limb. A gait pattern with a lower peak shank angular velocity shows that the individual, after initial contact, rotates their lower leg over their ankle at a slower rate. This also suggests that they may flex their knee at a slower rate and thus land more stiffly. A novel finding of this study is that the unaffected limb also displayed significantly less peak shank angular velocity compared to the healthy group, while displaying no significant difference compared to the affected limb. While the lack of asymmetry differs from previous work (Alshehri et al., 2020; Lin, P. E. & Sigward, 2018), it is possible that individuals with decreased peak shank angular velocity in the affected limb adapt long-term to walk with the same peak shank angular velocity in the unaffected limb and thus maintain the appearance of gait symmetry. Only two of the seven individuals in the ACL-reconstructed group displayed peak shank angular velocities in the unaffected limb far above that of the affected limb, which suggests that the lack of asymmetry may not be a sample size issue.

A second objective of this study was to identify between subject and between limb differences in gait kinematics and kinetics. Previous studies have displayed decreased knee range of motion in the affected limb (Lin, P. E. & Sigward, 2018; Milandri et al., 2017; Webster, Kate E., Feller, & Wittwer, 2012), particularly in combination with decreased peak shank angular velocity (Lin, P. E. & Sigward, 2018). However, in the current study, no significant differences were found for average knee range of motion compared to healthy controls. Examining individual knee ranges of motion for the affected limb indicated that only two individuals displayed decreased values similar to what has been previously published for the affected limb (Lin, P. E. & Sigward, 2018; Milandri et al., 2017; Webster, Kate E. et al., 2012). It is, however,

possible that these knee ranges of motion are decreased as a result of the far larger values for knee flexion at initial contact that these two individuals displayed. Additionally, five individuals appeared to display greater knee range of motion for the unaffected limb compared to the affected limb, similar to that of previous literature (Lin, P. E. & Sigward, 2018; Roewer et al., 2011; Webster, Kate E. et al., 2012). It should be noted that time since surgery did not appear to be a factor in identifying individuals with smaller affected limb knee ranges of motion or between limb asymmetries in this variable. However, it is possible that, with a larger sample size, significant asymmetries in knee range of motion may be identified. If true, this could suggest that, because peak shank angular velocities do not differ much between limbs, different kinematic and kinetic strategies may be employed individually between limbs to achieve the symmetry in peak shank angular velocity.

In addition to knee range of motion, it was hypothesized that a decrease in peak internal knee extension moment would be observed in the affected limb, which would indicate a stiffer landing pattern. However, the results did not support this hypothesis as the average peak internal knee extension moment for the affected limb did not differ from the healthy controls, nor the unaffected limb. Five individuals displayed peak internal knee extension moment values for both limbs of the ACL-reconstructed group that were far more similar to those values identified for the unaffected limb in previous literature (Lin, P. E. & Sigward, 2018; Milandri et al., 2017). These five individuals, again, did not appear to be similar based upon time since surgery. There did not appear to be a trend among individuals for between-limb differences in peak internal knee extension moment. Therefore, this could also suggest the use of a compensation pattern that changes the mechanics at other joints in order to normalize knee kinetics long-term in both limbs, even with a decrease in peak shank angular velocity.

Numerous whole-body kinematic and kinetic differences beyond the aforementioned risk factors were identified between groups. Significantly greater hip flexion, knee flexion, and ankle dorsiflexion at initial contact were identified for the affected limb. This lends credence to the suggestion that these individuals used a whole-body compensation method in an attempt to normalize the knee kinematics and kinetics throughout stance. These findings may also explain the increased hip range of motion, ankle range of motion, peak internal hip extension moment, and peak internal ankle dorsiflexion moment that were observed. It is likely that these individuals displayed decreases in knee flexion soon after surgery (Webster, K. E., Wittwer, O'Brien, & Feller, 2005). By increasing their hip flexion at initial contact, it is possible that, given the pelvis did not anteriorly tilt, knee flexion at initial contact would also increase. Greater hip range of motion during this period, given a larger hip flexion angle at initial contact, may suggest that more excursion and thus a greater peak hip extension moment is necessary to return the hip to a position that is more symmetrical to the unaffected limb, which did not show a significant difference from the healthy limb. This pattern of increased hip flexion at initial contact has been shown in males five years post-reconstruction (Milandri et al., 2017). It is possible the movement pattern observed in the present study is also a means to decrease the vertical ground reaction force, as the body may be less vertical during the early portion of this phase of stance. This would explain the lack of a significant different in vertical ground reaction force between groups and would agree with the findings of Milandri and colleagues, who displayed no significant difference in peak vertical ground reaction force for males with increased hip flexion (Milandri et al., 2017). Finally, the larger dorsiflexion angle at initial contact may be due to a more vertical orientation of the shank at initial contact in order to also increase knee flexion. Abnormalities in heel rocker mechanics, such as this, have been suggested

previously for individuals with a prior ACL reconstruction (Lin, P. E. & Sigward, 2018). A larger dorsiflexion angle would then be necessary to maintain a heel strike pattern. This would also explain the significantly greater peak internal ankle dorsiflexion moment that was observed in the affected limb as compared to the healthy limb, as a greater internal dorsiflexion moment is necessary to control plantarflexion movement from a larger initial dorsiflexion position following initial contact.

Additionally, while no significant differences were found between the healthy and affected limbs for peak ankle plantarflexion, the range of motion from the time of peak ankle plantarflexion to the time of peak knee flexion was significantly less in the affected limb as compared to the healthy limb. This time period for ankle range of motion was chosen in order to assess the time over which the shank is primarily rotating over the ankle following peak plantarflexion, as this is also when the peak shank angular velocity also occurs. Sagittal plane ankle mechanics in this population have not been examined as widely as hip and knee mechanics. However, it is possible that this observed difference may help to explain the decrease in the primary measure of peak shank angular velocity given the lack of difference in knee mechanics. It is possible that, as the ankle goes through less dorsiflexion during this loading phase, the shank also goes through less movement. The shank may particularly move less if it is already oriented more vertically upon initial contact, as has been posited. A decreased range of dorsiflexion for the ankle to move through, and thus a decreased range of motion for the shank, would require less angular velocity. This could then decrease the peak shank angular velocity. While no significant differences were found for ankle kinematics between the affected and unaffected limbs, it does appear that three individuals displayed far more ankle range of motion in the unaffected limb. Interestingly, these three displayed the greatest peak shank angular

velocities, and two of these individuals also displayed the largest between limb differences in peak shank angular velocity. Additionally, three of the individuals with the lowest ankle range of motion were only about two years post-surgery. Further research examining ankle mechanics in relation to both time post-ACL reconstruction and the inherent abnormal mechanics would be beneficial for understanding the effect that ankle mechanics have throughout the recovery process on the risk of this population developing knee osteoarthritis.

This study is significant in that it identifies potential whole-body mechanical changes that may be made long-term post-ACL reconstruction. Specifically, this study shows that the affected limb still displays decreased peak shank angular velocity up to four years post-surgery, suggesting these gait pattern abnormalities can be identified through the use of a small, inexpensive device. This is important in these gait abnormalities may lead to the development of knee osteoarthritis, and the use of a small, inexpensive device to detect these changes long-term would allow clinicians to both detect and potentially target peak shank angular velocity via an IMU in a rehabilitation protocol long after the initial recovery finishes.

A limitation of this study is the small sample size for the ACL-reconstructed group due to the disruption to human subjects research as a result of COVID-19. It is likely that the small sample size of seven for this group does not give the current study enough power to identify some significant between group and within group differences. It is reasonable to examine the results of the current study as pilot data, with additional research that includes more participants necessary to reach stronger conclusions. While there were significant differences observed from the present results, it is possible that some of the comparisons that were trending towards significance may reach significance with a larger sample size. Additionally, the subjects in the ACL-reconstructed group were not matched with controls for age, mass, or height. As such, this

may have affected some of the between subject comparisons, particularly for kinetics. However, kinetic variables were adjusted for body mass and body weight where appropriate, which should remediate some of the potential effects that a lack of matched controls may have on the findings.

Conclusion

The hypothesis for this study was partially supported. Decreases in peak shank angular velocity were present in individuals who were between one to four years post-ACL reconstruction. However, no significant differences were present between limbs. The average gait pattern for this group did display significant changes in hip and ankle kinematics and kinetics, which suggests that individuals may maintain a compensatory gait pattern with whole-body mechanical changes well after surgery. This may occur without abnormalities in known knee kinematic and kinetic risk factors for osteoarthritis. Ultimately, although decreases in peak shank angular velocity may not always occur in combination with decreases in knee flexion range of motion and peak internal knee extension moment, it is possible that decreases in peak shank angular velocity may still occur in combination with other abnormal compensation patterns.

Chapter 3: Use of Inertial Measurement Units to Measure Traditional Gait Parameters Post-Anterior Cruciate Ligament Reconstruction

Introduction

Osteoarthritis is a degenerative joint disease that progresses with age and is a common health problem for older individuals (Buckwalter et al., 2004; Dillon et al., 2006). The knee, specifically, is one of the most common joints at which osteoarthritis can occur (Dillon et al., 2006; Woolf & Pfleger, 2003). While there is a high prevalence of knee OA in elderly individuals (Dillon et al., 2006), early onset knee OA is also becoming more prevalent in younger individuals (Lohmander et al., 2004). Early onset knee osteoarthritis is particularly prevalent among athletes who incur an anterior cruciate ligament (ACL) injury that requires surgery to reconstruct the ligament (Buller et al., 2015). In fact, knee osteoarthritis is between 3 and 4 times more likely to occur in ACL-reconstructed knees as compared to contralateral uninjured knees (Ajuied et al., 2014; Lohmander et al., 2007). Knee osteoarthritis can become a significant burden financially, particularly as total joint replacement surgery becomes more common as a treatment option (Buckwalter et al., 2004; Murphy & Helmick, 2012).

It has been suggested that ACL reconstruction can somewhat decrease the risk for osteoarthritis (Paschos, 2017). However, there still remains an increased risk for osteoarthritis in the ACL-reconstructed population. Meniscal and cartilage damage at the time of injury have been linked to an increased risk for osteoarthritis (Paschos, 2017). While this explains part of the risk for osteoarthritis, it has also been shown that individuals that undergo an ACL reconstruction without having prior meniscal or cartilage damage are also at greater risk for developing osteoarthritis compared to healthy individuals (Paschos, 2017). Another explanation for this increased risk has been a change in gait mechanics following reconstruction (Lin, P., 2018; Lin,

P. E. & Sigward, 2018; Paschos, 2017; Sigward et al., 2016). It has been posited that abnormal gait patterns lead to changes in the location and size of the cartilage contact area in the medial compartment of the ACL-reconstructed knee that have been observed in vivo, which may explain the early softening of the cartilage that has been observed and which may lead to the development of knee osteoarthritis in these individuals (Lin, P., 2018; Tashman et al., 2016).

Typically, the aforementioned gait parameters are assessed in a laboratory setting that requires a costly three-dimensional motion capture system. However, this system is not easily accessible for clinical use. Use of wearable inertial measurement units (IMUs) in research as a substitute for three-dimensional motion capture has increased recently (Crowell et al., 2010; Dowling, Ariel V. et al., 2011; Willy et al., 2016). IMUs are small, relatively inexpensive sensors that contain accelerometers, gyroscopes, and magnetometers to measure orientation and joint kinematics, and may prove much easier for clinicians and the general population to use. IMUs have been used previously to successfully detect three-dimensional kinematics during gait (Zhang et al., 2013). The angles collected from the IMU system displayed a strong association with angles collected from the three-dimensional motion capture system. This suggests that IMUs as wearable sensors are capable of replicating three-dimensional motion capture in terms of tracking movement, which is of great importance in assessing and altering abnormal movement parameters, particularly as it relates to gait for individuals with a prior ACL reconstruction.

Peak shank angular velocity in the sagittal plane, as measured by a single IMU, can be used to measure forward progression of the tibia over the foot, with normal gait displaying angular velocities between 180 to 200 degrees per second (Lin, P. E. & Sigward, 2018; Sigward et al., 2016). Studies have suggested that during gait, individuals who have undergone an ACL

reconstruction will walk with significant reductions in peak shank angular velocity of at least 20 degrees per second have been observed in the affected limb three to four months post-surgery (Lin, P. E. & Sigward, 2018; Patterson et al., 2014; Sigward et al., 2016). Additionally, significant correlations between peak shank angular velocity and peak internal knee extension moment, knee flexion range of motion, and vertical and posterior ground reaction forces in both the affected and unaffected limbs of those with a prior ACL reconstruction three to four months post-surgery (Lin, P. E. & Sigward, 2018; Patterson et al., 2014; Sigward et al., 2016). However, the long-term relationships between peak shank angular velocity and these gait parameters in the affected limb are unknown.

The purpose of this study was to examine the relationship between traditionally measured gait parameters and IMU-based peak shank angular velocity in the sagittal plane in both limbs of those with a single limb ACL reconstruction that occurred one to four years ago. It was expected that the IMU-based measure would significantly correlate with traditionally measured gait parameters that have been linked to an increased risk for knee osteoarthritis. Examining these relationships will provide insight regarding the ability of a single IMU to explain abnormalities in gait parameters known to indicate an increased risk for knee osteoarthritis up to four years post-ACL reconstruction.

Methods

Participants. Please see the Participants subsection under the Methods section in Chapter 2 for all details about participant recruitment, criteria, and general information.

Experimental setup and protocol. Please see the Experimental setup and Experimental protocol subsections under the Methods section in Chapter 2 for all details regarding equipment setup and experimental procedures.

Data reduction. Please see the Data reduction subsection under the Methods section in Chapter2 for all details regarding data analysis. All variables for Chapter 2 remain the same for Chapter3.

Statistical design & analysis. Tests for normality were performed prior to additional statistical tests being performed. Pearson product moment correlations were conducted to assess the relationships between peak shank angular velocity and the following variables across the healthy and ACL-reconstructed groups: sagittal plane hip, knee, and ankle angle at initial contact, peak knee flexion during the loading phase, peak ankle plantarflexion during the loading phase, range of motion for hip and knee from initial contact to the time of peak knee flexion during the loading portion of the stance phase, peak internal knee extensor moment, peak internal hip extension moment, peak internal ankle dorsiflexion moment, peak vertical ground reaction force, and peak posterior ground reaction force following initial contact within the first thirty-percent of the stance phase. Weak and moderate correlations were defined as coefficients between 0 and 0.3, and 0.3 and 0.7, respectively. A significance level of $\alpha = 0.05$ was used for all statistical analyses. All statistical analyses were performed using SPSS (v19.0 SPSS Inc., Chicago, IL).

Results

Examining Pearson product moment correlations for the relationships between peak shank angular velocity and each of the kinematic and kinetic variables across groups displayed several significant correlations. Moderate, positive correlations were identified with knee range

of motion and peak internal knee extension moment. A moderate, negative correlation was found with hip range of motion. Additional weak correlations were found with knee flexion at initial contact, peak knee flexion, ankle angle at initial contact, peak ankle plantarflexion, ankle range of motion, and peak posterior ground reaction force (Table 6). Scatterplots displaying these relationships are presented in Figures 9 and 10.

| | PSAV (°/s) |
|---|------------|
| Knee Flexion at Initial Contact (°) | -0.271* |
| Peak Knee Flexion (°) | 0.179* |
| Knee Range of Motion (°) | 0.489* |
| Hip Angle at Initial Contact (°) | 0.027 |
| Hip Range of Motion (°) | -0.352* |
| Ankle Angle at Initial Contact (°) | -0.220* |
| Peak Ankle Plantarflexion (°) | -0.198* |
| Ankle Range of Motion (°) | 0.267* |
| Peak Internal Knee Extension Moment (Nm/kg) | 0.382* |
| Peak Internal Hip Extension Moment (Nm/kg) | 0.064 |
| Peak Internal Ankle Dorsiflexion Moment (Nm/kg) | -0.007 |
| Peak Vertical Ground Reaction Force (N/BW) | 0.100 |
| Peak Posterior Ground Reaction Force (N/BW) | -0.294* |
| <i>Note</i> . * indicates $p < 0.05$. | |

 Table 6. Correlations Between Peak Shank Angular Velocity and Traditional Kinematic and

 Kinetic Gait Parameters for the Affected Limb



Figure 9. Scatterplots displaying relationships between peak shank angular velocity and kinematic variables. IC indicates initial contact.



Figure 10. Scatterplots displaying relationships between peak shank angular velocity and kinetic variables. DF indicates dorsiflexion. VGRF and PGRF indicate vertical and posterior ground reaction forces, respectively.

Discussion

The primary objective of this study was to examine the relationships between peak shank angular velocity and traditionally measured gait kinematics and kinetics. This was examined across a healthy group and both limbs of an ACL-reconstructed group. The hypothesis that this group would display significant correlations between peak shank angular velocity and both knee range of motion and peak internal knee extension moment during the loading phase of stance was supported by the findings of this study. While the correlations were not strong, the results suggest that peak shank angular velocity may serve as a marker for changes in knee kinematics and kinetics long-term post-ACL reconstruction.

A moderate, positive correlation with peak internal knee extension moment was identified. This correlation suggests that as peak shank angular velocity decreases, so too does peak internal knee extension moment. Lin and colleagues have displayed a similar correlation within the affected and unaffected limbs three to four months post-ACL reconstruction (Lin, P. E. & Sigward, 2018). The ability to detect changes in peak internal knee extension moment within the affected limb with peak shank angular velocity is important, as decreased peak internal knee extension moment during gait has been identified as a risk factor developing knee osteoarthritis post-ACL reconstruction (Kaur et al., 2016; Noehren et al., 2013; Tashman et al., 2016). This is particularly important for rehabilitation protocols, as an IMU could serve as an inexpensive and easier method of both identifying and changing subtle gait abnormalities.

A similar moderate correlation between peak shank angular velocity and knee range of motion during the loading phase of stance was also identified and further supports the hypothesis for this study. These results show that as knee range of motion increases, so too does peak shank angular velocity. Lin and colleagues also previously identified a moderate, positive correlation

between knee range of motion and peak shank angular velocity (Lin, P. E. & Sigward, 2018). As the knee moves through a greater range of motion, the shank then rotates over the ankle at a faster rate. Decreases in knee range of motion during the loading phase of stance have been suggested previously as a risk factor for developing knee osteoarthritis as this represents a more rigid gait pattern that can ultimately lead to decreases in peak internal knee extension moment. (Kaur et al., 2016; Noehren et al., 2013; Tashman et al., 2016). As such, this correlation suggests that an IMU measuring peak shank angular velocity can both potentially detect these changes in knee mechanics across groups and potentially lead to changes towards healthy knee mechanics given simultaneous changes in peak shank angular velocity.

The additional weak positive correlation found with peak knee flexion and the weak negative correlation found with knee flexion at initial contact may be explained given this moderate, positive correlation between peak shank angular velocity and knee range of motion. Given that this study shows that peak shank angular velocity increases with an increase in knee range of motion, decreased knee flexion at initial contact would likely indicate the need for a greater knee range of motion to maintain a healthy gait pattern and thus an increased peak shank angular velocity. Conversely, increased knee flexion at initial contact may indicate an attempt to alter the gait pattern in some capacity beginning at initial contact. This may either decrease knee range of motion or lead to a larger peak knee flexion with a more standard knee range of motion. Peak shank angular velocity would then change accordingly. The relationship between these last two variables and peak shank angular velocity is measured during the course of the knee moving between initial contact and peak, rather than at either of these discrete time points.

In addition to the correlations present between peak shank angular velocity and knee kinematics and kinetics, a moderate correlation was identified with hip range of motion and weak correlations were identified with all ankle kinematic variables. There is a gap in the literature with regards to relationships between peak shank angular velocity and both hip and ankle mechanics. However, this shows that as peak shank angular velocity decreases, hip range of motion increases. This suggests that individuals with decreased peak shank angular velocity, particularly within the ACL-reconstructed group, may rely more on increased hip range of motion through the loading phase, whereas healthy individuals with larger peak shank angular velocities may not need to rely on hip range of motion as much to maintain their gait pattern. Additionally, peak shank angular velocity increases are observed with increases in ankle range of motion and peak ankle plantarflexion magnitude and decreases in ankle dorsiflexion at initial contact. It is likely that as the ankle dorsiflexes over a decreased range during the heel rocker phase of gait, the shank also will rotate slower over the ankle. Additionally, if the ankle begins in less plantarflexion, it is more likely that the ankle will have a decreased range of motion following this time point. This would explain the ability of the IMU to potentially detect each of these changes given decreases in peak shank angular velocity. Finally, the negative correlation with ankle dorsiflexion at initial contact may be due to potential changes in shank orientation at initial contact. If the shank is oriented more vertically at initial contact in the ACL population compared to the healthy population, as has been suggested by Lin and colleagues, a larger ankle dorsiflexion angle would be necessary to maintain a heel strike pattern (Lin, P., 2018; Lin, P. E. & Sigward, 2018). These individuals in turn have displayed decreases in peak shank angular velocity (Lin, P. E. & Sigward, 2018). It is possible that each of these correlations represent the ability of an IMU measuring peak shank angular velocity to detect changes in whole-body

mechanics from values for those mechanics that have been established by a healthy group. This would indicate that using training to alter peak shank angular velocity, particularly in the ACL-reconstructed group, could lead to changes in hip, knee and ankle joint mechanics that may decrease gait abnormalities and thus the risk for knee osteoarthritis.

A significant, weak correlation was also identified with peak posterior ground reaction force. This shows that, as peak shank angular velocity increased, peak posterior ground reaction force increased in magnitude. A significant correlation between these two variables was also expected as previous literature has shown a strong, significant correlation in the same direction between these two variables for the affected limb, and a moderate correlation for the unaffected limb, for individuals three to four months post-ACL reconstruction (Lin, P. E. & Sigward, 2018). Decreased posterior ground reaction force and peak shank angular velocity have also been displayed in the affected limb compared to the unaffected limb three months post-ACL reconstruction (Lin, P. E. & Sigward, 2019). Decreased posterior ground reaction force has been suggested as an indicator of changes in whole body mechanics separate from the knee to reduce knee loading (Lin, P. E. & Sigward, 2019). Taken together with the aforementioned correlations with hip and ankle mechanics, this suggests that an IMU may be able to detect subtle changes in some whole-body mechanics from those of healthy individuals in addition to changes in knee mechanics. The present study does differ from other literature in that there is a weak, positive correlation with peak vertical ground reaction force, as opposed to the strong, positive correlation found by Lin and colleagues within the affected limb (Lin, P. E. & Sigward, 2018). The correlation weakens in the unaffected limb based on prior literature (Lin, P. E. & Sigward, 2018), and as such it is possible that the IMU cannot detect changes in vertical ground reaction force in the unaffected limb and healthy individuals. It is also possible that the relationship

weakens in the affected limb based on typical gait alterations made long-term as opposed to three months post-surgery.

This study is significant in that it identifies moderate relationships for a group consisting of healthy individuals and individuals one to four years post-ACL reconstruction between peak shank angular velocity as measured by an IMU and both knee range of motion and peak internal knee extension moment. Additionally, weak to moderate relationships were also identified between peak shank angular velocity and kinematics at the hip and ankle joints. These findings are novel as these relationships have not been examined in a group containing individuals with longer times since surgery, nor have relationships with hip and ankle mechanics been examined. This is important in that these relationships may indicate that clinicians could use IMUs to detect and change abnormal gait mechanics long-term post-ACL reconstruction via changes in peak shank angular velocity.

Since gait speed was controlled in the present study, it cannot be determined whether these relationships are maintained for different walking speeds. A set gait speed was necessary, as research has shown that changes in gait speed causes changes in peak shank angular velocity (Alshehri et al., 2020). However, it would be useful for future research to examine the relationships between peak shank angular velocity and these traditionally measured gait kinematics and kinetics, as any potential rehabilitation would occur at a patient's self-selected speed. It is also possible that, as subtle changes in whole-body mechanics may change over time post-ACL reconstruction, these relationships may change over time as well. It would thus be beneficial to identify these correlations with hip and ankle joint mechanics for individuals soon after ACL reconstruction as well.

Conclusion

The hypothesis for this study was supported. An IMU measuring peak shank angular velocity displayed significant, moderate correlations with knee kinematic and kinetic variables that have been previously identified as risk factors for developing knee osteoarthritis following ACL reconstruction. Additional moderate to weak correlations were identified for hip and ankle kinematics and peak posterior ground reaction force, all during the loading phase of stance. This suggests that peak shank angular velocity as measured via an IMU may be able to detect changes in both knee-specific risk factors and whole-body mechanical changes in healthy individuals and in individuals up to four years post-ACL reconstruction.

Chapter 4: Use of Inertial Measurement Unit-Based Auditory Biofeedback in Real-Time to Alter Gait Post-ACL Reconstruction

Introduction

Early onset knee osteoarthritis, a degenerative disease that affects the cartilage at the tibiofemoral joint and causes both limited mobility and significant pain, is prevalent among athletes who incur an anterior cruciate ligament (ACL) injury that requires surgery to reconstruct the ligament (Buller et al., 2015). Knee osteoarthritis is between 3 and 4 times more likely to occur in ACL-reconstructed knees as compared to contralateral uninjured knees (Ajuied et al., 2014; Lohmander et al., 2007). Individuals have been shown to develop early onset knee osteoarthritis as early as ten years following ACL injury (Lohmander et al., 2004; Roos et al., 1995).

Studies suggest that there are discrete differences in kinematics and kinetics during gait between healthy individuals and individuals with ACL reconstructions. Decreased knee flexion angle and decreased internal knee extension moment were observed in the affected knee during gait (Herrington et al., 2017; Milandri et al., 2017; Roewer et al., 2011). Additionally, increased vertical impact force and loading rate have been shown in the affected limb of individuals with ACL reconstructions as compared to healthy controls (Noehren et al., 2013), while decreased posterior ground reaction force have also been observed (Lin, P. E. & Sigward, 2018). While gait mechanics are expected to normalize two to three months post-surgery, reductions in sagittal plane knee ROM have been shown to persist at least three years post-surgery (Hart et al., 2016; Roewer et al., 2011).

These aforementioned gait changes can be subtle and may not be observable without the use of technology, which can lead to individuals being cleared for activity while retaining these gait asymmetries over time (Sigward et al., 2016). Typically, gait mechanics are assessed in a laboratory setting that requires a costly three-dimensional motion capture system. However, this system is not easily accessible for clinical use. Use of wearable inertial measurement units (IMUs) in research as a substitute for three-dimensional motion capture has increased recently (Crowell et al., 2010; Dowling, Ariel V. et al., 2011; Willy et al., 2016). Regarding measuring gait post-ACL reconstruction, a single IMU has been used to measure the angular velocity of the shank in the sagittal plane through the first thirty percent of the gait cycle. Significant reductions in peak shank angular velocity of at least 20 degrees per second have been observed in the affected limb for these individuals at four months post-surgery (Lin, P. E. & Sigward, 2018; Patterson et al., 2014; Sigward et al., 2016). Additionally, this measure has been significantly correlated with sagittal plane knee range of motion, peak internal knee extension moment, and both peak vertical and posterior ground reaction forces (Lin, P. E. & Sigward, 2018; Patterson et al., 2014; Sigward et al., 2016). This suggests that a real-time biofeedback program targeting peak shank angular velocity may have the potential to guide traditionally measured kinematics and kinetics of the affected limb towards that of healthy individuals, thereby potentially decreasing the risk for developing knee osteoarthritis.

Real-time biofeedback protocols using IMUs have been previously researched as methods of changing movement behavior. One method, auditory biofeedback, provides real-time feedback based on IMU data by means of a sound to significantly reduce landing accelerations (Wood & Kipp, 2014). This is useful, particularly for individuals that use mobile devices, as an individual can wear headphones while performing a task that requires their visual attention, such

as with playing sports. A sound can be provided if the data is too far away from a goal, or can change pitch, volume, or frequency, depending on where the data is in relation to the goal (Wood & Kipp, 2014).

Thresholds used for providing biofeedback have varied in IMU-based biofeedback studies, from using ten (Wood & Kipp, 2014) to fifty percent (Crowell & Davis, 2011) alterations from baseline, to using a healthy standard as a goal (Dowling, A. V., Favre, & Andriacchi, 2012a). While these studies have shown promising results, there are not as many studies examining the use of IMUs to provide real-time biofeedback as compared to studies that have used other forms of technology, such as three-dimensional motion capture, to provide realtime biofeedback (Ericksen et al., 2016; Ford, K. R. et al., 2015). This is particularly true for gait retraining studies. As such, there is a distinct need for further research on gait retraining in realtime using IMU data.

The purpose of this study was to examine the effect of a real-time IMU-based biofeedback protocol using an auditory stimulus to increase peak shank angular velocity in the sagittal plane during gait for individuals with a prior ACL reconstruction. This ACL reconstruction was to have occurred one to four years prior to study, to assess the effect of the biofeedback protocol on those individuals who have retained gait abnormalities post-ACL surgery. Peak shank angular velocity as measured by a single IMU, along with traditional kinematic and kinetic gait measures, were compared before and after a biofeedback protocol. These comparisons were made both for treadmill and over-ground walking. Peak shank angular velocity was also examined during the biofeedback protocol. It was expected that values for these variables would change towards that established by healthy individuals. In particular, it was anticipated that peak shank angular velocity would increase both during and after the
biofeedback protocol, and that an associated increase in knee flexion range of motion and peak internal knee extension moment would be observed post-biofeedback. Examining the effect of this biofeedback protocol will provide an understanding of how to target and change previously observed gait abnormalities in this population, particularly to decrease the risk for developing knee osteoarthritis following an ACL reconstruction.

Methods

Participants. Recreationally active individuals with an ACL reconstruction that occurred one to four years prior to the study were recruited to participate in this study. These participants were recruited from the ACL-reconstructed group that participated in a previous study (Chapter 2), as well as the University of Wisconsin-Milwaukee. The average peak shank angular velocity for healthy participants collected from a prior study (Chapter 2) was used as a threshold for the current study. ACL-reconstructed participants were asked to walk over-ground at 1.4 m/s, with an IMU attached to the anteromedial portion of the affected limb's tibia. If the average peak shank angular velocity over five trials was at least one standard deviation below that of the healthy participants, the individual qualified for the current study.

A power analysis indicated that a minimum of 14 participants would be necessary to detect a significant difference in peak shank angular velocity across time using a repeated measures ANOVA with eighty percent power (G*Power 3.1.9.2). However, due to a disruption to human subjects research resulting from COVID-19, the study was limited to seven total participants. One participant was screened and did not meet the peak shank angular velocity

qualification, and thus six participants were included for analysis in the current study. Exclusion criteria remained the same as for the ACL-reconstructed participants in Chapter 2.

Experimental setup. A single session was used to collect data on these ACL-reconstructed participants. Testing occurred in the Neuromechanics Laboratory at the University of Wisconsin-Milwaukee. Three-dimensional motion capture, IMU, and accelerometer setup were presented in Chapter 2. Angular velocity data was streamed via a custom MATLAB program (The MathWorks, Inc., Natick, MA) and audio biofeedback based upon the angular velocity data was provided through a single speaker facing the participant (Figure 11) (Cyber Acoustics, Vancouver, WA). A treadmill was used for walking when biofeedback was provided (Precor USA C964i, Precor Inc., Bothell, WA).



Figure 11. Participants walked on a treadmill while receiving biofeedback. Audio biofeedback was provided through a computer and speaker placed in front of the treadmill.

Experimental protocol. Informed consent protocol followed the outline presented in Chapter 2. The Visual Analog Scale was be used to assess pain prior to and following the biofeedback session (AHCPR, 1994). Participants changed into the Saucony Jazz shoes prior to application of reflective markers and sensors. Application of the reflective markers, IMU, and accelerometer, along with the collection of standing calibration trials, followed the protocol presented in Chapter 2 for ACL-reconstructed participants.

Participants were then instructed to walk across a force plate embedded in a raised platform in the laboratory at 1.4 m/s, based on previous literature (Lin 2018). This protocol was outlined in Chapter 2. Next, participants were instructed to walk at 1.4 m/s on a treadmill. A custom MATLAB program was used to stream angular velocity data of the shank of the affected limb from the Shimmer IMU in real-time. Participants first walked for two minutes to become accustomed to the walking speed. The average peak shank angular velocity during the initial loading phase of the gait cycle across the five trials collected during over-ground walking for the intact limb was used as a goal for biofeedback. Biofeedback was provided in an audio format through a speaker facing the participant. Participants were instructed to walk for ten minutes on the treadmill while receiving audio biofeedback. Biofeedback consisted of a low-pitched chime that sounded if the peak shank angular velocity during the first thirty percent of the initial loading phase of the gait cycle was within a range that was ten percent more or less than the goal shank angular velocity. Additionally, a different aspect of the biofeedback consisted of a highpitched chime that sounded if the peak shank angular velocity was above this range. Participants were instructed to walk such that they maintained the low-pitched chime with each stride. Participants were also given instructions to change their walking pattern if the chime was high-

pitched or if no chime was present, and that a method to do this could be to flex the knee more after the foot contacts the ground. No other verbal feedback was provided prior to or during testing. Next, participants were asked to continue walking for five minutes on the treadmill without audio biofeedback. Finally, participants were instructed to walk an additional five minutes with biofeedback and five minutes without biofeedback, for a total of twenty-seven minutes of treadmill walking. IMU data was collected for ten strides every 2.5 minutes. Motion capture data was collected for ten strides immediately prior to biofeedback and immediately following the twenty-seven minute session.

Finally, participants were instructed to walk at 1.4 m/s over a force plate embedded in a raised platform. This protocol followed the protocol used for over-ground walking prior to walking with biofeedback.

Data reduction. Three-dimensional kinematic and kinetic data from the motion capture system and sagittal plane peak shank angular velocity was measured during both over-ground and treadmill walking. Stance time was measured for over-ground walking. Initial contact during over-ground walking was defined as the time at which the vertical ground reaction force was greater than 30 N. Initial contact during treadmill walking was determined as the first positive peak shank angular velocity in the sagittal plane just after a peak negative shank angular velocity that represented the swing phase (Patterson et al., 2014).

Kinematic and kinetic data were processed using Visual3D as was discussed in Chapter 2 (v6.00.15, C-Motion, Inc., Rockville, MD). IMU and accelerometer data were not be filtered. During over-ground walking, all variables assessed in Chapter 2 were collected. Peak positive

shank angular velocity following initial contact within the first thirty-percent of the stance phase was measured for both over-ground and treadmill walking. Hip, knee, and ankle kinematics were also assessed for ten strides on the treadmill pre- and post-biofeedback.

Statistical design & analysis. The primary dependent variable for this study was peak positive shank angular velocity following initial contact while walking over-ground and on the treadmill. Dependent t-tests were used to compare all over-ground and treadmill-based kinematic and kinetic variables pre- to post-biofeedback within each limb and between limbs post-biofeedback. A repeated measures ANOVA was conducted to analyze the effect of biofeedback on peak shank angular velocity of the affected limb. Effect sizes were calculated for all comparisons using Cohen's d. A significance level of $\alpha = 0.05$ was used for all statistical analyses. All statistical analyses were performed using SPSS (v19.0 SPSS Inc., Chicago, IL).

Results

All participants in the ACL-reconstructed group indicated no pain on the Visual Analog Scale, both before and after the biofeedback session. In comparing kinematics for over-ground walking pre- to post-biofeedback, significant increases in peak shank angular velocity for both the affected limb (p < 0.001, ES: 1.91) and the unaffected limb (p < 0.001, ES: 1.62) were found. Additionally, significant increases in the hip range of motion (p = 0.032, ES: 0.55) and ankle dorsiflexion at initial contact (p = 0.045, ES: 0.52) for the unaffected limb and a significant decrease in stance time for the affected limb (p = 0.021, ES: 0.29) were indicated. Finally, in comparing the affected and unaffected limbs post-biofeedback, the unaffected limb displayed

significantly greater peak shank angular velocity (p = 0.020, ES: 0.62), and the affected limb exhibited significantly greater knee flexion at initial contact (p = 0.006, ES: 0.74) and peak knee flexion (p = 0.028, ES: 0.57) (Table 7). Different individual kinematic responses for the affected limb are presented in Figures 12 and 13.

Table 7

| | Affected | | Unaffected | |
|-------------------------------------|--------------|--------------|---------------|---------------------------|
| | PRE | POST | PRE | POST |
| Peak Shank Angular Velocity (°/s) | 141.1 (9.3)* | 176.3 (24.4) | 149.6 (17.0)* | 195.2 (35.9 ^{)†} |
| Knee Flexion at Initial Contact (°) | 5.9 (3.5) | 6.4 (4.5) | 3.7 (2.7) | 3.6 (2.9 ^{)†} |
| Peak Knee Flexion (°) | 21.5 (2.1) | 21.6 (4.4) | 20.2 (3.5) | 19.1 (4.4 ^{)†} |
| Knee Range of Motion (°) | 15.6 (3.3) | 15.2 (2.2) | 16.5 (3.6) | 15.4 (3.9) |
| Hip Angle at Initial Contact (°) | 30.0 (6.8) | 31.3 (7.5) | 29.4 (6.6) | 28.3 (4.6) |
| Hip Range of Motion (°) | 6.6 (2.7) | 7.3 (2.3) | 5.8 (2.2)* | 6.9 (1.8) |
| Ankle Angle at Initial Contact (°) | 13.3 (2.8) | 14.5 (4.8) | 13.2 (3.3)* | 15.4 (5.0) |
| Peak Ankle Plantarflexion (°) | -6.2 (1.9) | -6.1 (5.4) | -6.2 (3.4) | -4.8 (5.5) |
| Ankle Range of Motion (°) | 5.4 (1.8) | 5.4 (2.9) | 6.2 (3.6) | 5.7 (3.3) |
| Stance Time (s) | 0.62 (0.03)* | 0.60 (0.04) | 0.62 (0.03) | 0.60 (0.04) |

Kinematic Comparisons Pre- to Post-Biofeedback for Over-ground Walking

Note * indicates a significant difference pre- to post-biofeedback (p < 0.05). [†] indicates significant a difference between affected and unaffected limbs post-biofeedback (p < 0.05).



Figure 12. Average values for peak shank angular velocity, knee kinematics and hip kinematics for each subject's affected limb. White bars represent pre-biofeedback. Black bars represent post-biofeedback. Error bars represent standard deviations.



Figure 13. Average values for ankle kinematics for each subject's affected limb. White bars represent pre-biofeedback. Black bars represent post-biofeedback. Error bars represent standard deviations.

Regarding kinetic variables for over-ground walking pre- to post-biofeedback, dependent t-tests indicated a significantly greater peak internal hip extension moment post-biofeedback for both the affected (p = 0.010, ES: 0.68) and unaffected (p = 0.003, ES: 0.82) limbs (Table 8). Different individual kinetic responses for the affected limb are presented in Figure 14.

Table 8.

| | Affected | | Unaffected | |
|---|---------------|--------------|---------------|--------------|
| | PRE | POST | PRE | POST |
| Peak Internal Knee Extension Moment (Nm/kg) | 0.80 (0.27) | 0.72 (0.31) | 0.75 (0.20) | 0.79 (0.42) |
| Peak Internal Hip Extension Moment (Nm/kg) | -1.24 (0.31)* | -1.47 (0.36) | -1.16 (0.26)* | -1.48 (0.49) |
| Peak Internal Ankle Dorsiflexion Moment (Nm/kg) | 0.45 (0.09) | 0.41 (0.09) | 0.47 (0.12) | 0.44 (0.13) |
| Peak Vertical Ground Reaction Force (N/BW) | 1.18 (0.10) | 1.19 (0.09) | 1.20 (0.12) | 1.22 (0.11) |
| Peak Posterior Ground Reaction Force (N/BW) | -0.24 (0.06) | -0.22 (0.05) | -0.23 (0.07) | -0.22 (0.06) |

Kinetic Comparisons Pre- to Post-Biofeedback for Over-ground Walking

Note * indicates p < 0.05.



Figure 14. Average values for hip, knee and ankle kinetics, and peak vertical and posterior ground reaction forces for each subject's affected limb. White bars represent pre-biofeedback. Black bars represent post-biofeedback. Error bars represent standard deviations.

Dependent t-tests analyzing the effect of biofeedback on sagittal plane kinematics during treadmill walking indicated a significant increase in knee range of motion for the affected limb (p = 0.029, ES: 2.28) and the unaffected limb (p = 0.046, ES: 1.04) (Table 9). A repeated measures ANOVA examining the change in peak shank angular velocity over the different phases of treadmill biofeedback indicated significantly greater peak shank angular velocity values for all phases from the second biofeedback phase to the last phase without biofeedback as compared to the baseline peak shank angular velocity. No significant difference was found between peak shank angular velocity at baseline and the first biofeedback phase (Table 10, Figure 15).

Table 9

Kinematic Comparisons Pre- to Post-Biofeedback for Treadmill Walking

| | Affected | | Unaffected | |
|-------------------------------|------------|-------------|------------|-------------|
| | PRE | POST | PRE | POST |
| Knee ROM* | 12.6 (0.5) | 14.7 (1.2)* | 13.1 (2.4) | 15.5 (2.2)* |
| Hip ROM | 6.4 (2.1) | 7.2 (1.9) | 5.0 (1.8) | 4.8 (1.6) |
| Ankle ROM | 6.1 (1.7) | 6.6 (4.2) | 5.3 (2.4) | 6.8 (3.8) |
| Note $*$ indicates $n < 0.05$ | | | | |

Note * indicates p < 0.05.

Table 10

| | Peak Shank Angular Velocity (%) | | Baseline | | |
|----------|---------------------------------|---------|-------------|--|--|
| | | p-value | Effect Size | | |
| Baseline | 131.7 (7.2) | | | | |
| FB1 | 145.0 (14.7) | | | | |
| FB2 | 152.4 (5.3) | 0.005 | 3.3 | | |
| FB3 | 152.9 (9.5) | 0.045 | 2.5 | | |
| FB4 | 155.0 (9.9) | 0.024 | 2.7 | | |
| NFB1 | 159.8 (11.4) | 0.038 | 2.9 | | |
| NFB2 | 162.7 (9.2) | 0.012 | 3.8 | | |
| FB5 | 153.6 (7.2) | 0.005 | 3.0 | | |
| FB6 | 160.2 (8.8) | 0.004 | 3.5 | | |
| NFB3 | 159.9 (7.8) | 0.013 | 3.8 | | |
| NFB4 | 162.3 (8.0) | 0.013 | 4.0 | | |

Peak Shank Angular Velocity Comparisons Across Biofeedback Phases

Note. FB indicates a session with biofeedback. NFB indicates a session without biofeedback.



Figure 15. Peak shank angular velocity across each biofeedback phase for treadmill walking. *indicates p < 0.05 as compared to baseline. FB indicates a session with biofeedback. NFB indicates a session without biofeedback.

Discussion

The main objective of this study was to examine the effect of an audio-based biofeedback protocol targeting peak shank angular velocity of the affected limb on the gait mechanics of individuals one to four years post-ACL reconstruction. It was hypothesized that a biofeedback protocol aimed at increasing peak shank angular velocity in the affected limb to the level of a healthy control group would lead to increases in peak shank angular velocity, knee range of motion, and peak internal knee extension moment during the loading phase of stance. The hypothesis was partially supported in that peak shank angular velocity did significantly increase in the affected limb following biofeedback for over-ground walking. This shows that peak shank angular velocity is a gait variable that can be targeted and altered via one session of biofeedback on a treadmill. Furthermore, this shows that changes in peak shank angular velocity as a result of a biofeedback session on a treadmill do transfer to over-ground walking at the same gait speed. Finally, these findings show that individuals were able to increase the peak shank angular velocity of the affected limb to within ten percent of the threshold established by the healthy controls. Similar results have been shown previously in studies examining the ability to alter gait through changing IMU-based gait parameters such as vertical acceleration via different forms of biofeedback (Crowell & Davis, 2011; Wood & Kipp, 2014).

It was also expected that, during the biofeedback protocol, peak shank angular velocity would increase towards the threshold when the feedback was present and gradually decrease away from the threshold during the phases without feedback present. Previous single session biofeedback protocols implementing phases without biofeedback have displayed changes away from a goal value during these phases (Wood & Kipp, 2014). Although no significant differences were found in peak shank angular velocity for any of the phases of the biofeedback protocol

beyond baseline, the average peak shank angular velocities measured every two and a half minutes appeared to show an increase during the non-feedback retention phases beyond the increases observed during the feedback phases. This was unexpected but could be explained in that the present study implemented bandwidth feedback (Lai & Shea, 1999). While some individuals may have decreased during this time, it is possible that any individuals near the top end of the range during feedback may have further increased their peak shank angular velocity above the range without feedback. This would increase the average peak shank angular velocities during the first two phases without biofeedback. In addition, upon receiving the next phase of biofeedback, these individuals at the top end of the range would likely end up decreasing their peak shank angular velocity due to the feedback provided, which would explain the trend towards a decrease in the fifth feedback phase.

Although changes in peak shank angular velocity were observed in the affected limb, the hypothesis for this study was partially unsupported in that no significant over-ground changes in knee range of motion were shown post-biofeedback. However, a significant increase in knee range of motion was observed in the affected limb when comparing pre-to post-biofeedback gait patterns for treadmill walking. This may show that, while individuals may have been able to alter knee range of motion as a result of increasing peak shank angular velocity on the treadmill, this learned gait pattern may not have transferred to over-ground walking. Interestingly, four individuals subjects did display an increase in peak knee flexion, while three of these same individuals displayed an increase in knee flexion at initial contact. It is possible that, while knee range of motion did not significantly change, some subjects were able to successfully increase knee flexion at the beginning and end points of this range. The magnitude of knee range of motion on the treadmill pre-biofeedback did appear to be less than the magnitude while walking

over-ground, while the magnitude following biofeedback was similar to over-ground knee range of motion. It is possible that changing knee range of motion was less important for maintaining an increased peak shank angular velocity over-ground than changing other gait mechanics. It is also possible that one biofeedback session is not enough to see transfer effects in knee mechanics from treadmill to over-ground walking. A clinician would likely use a treadmill rather than overground walking to provide this form of biofeedback. As such, further research examining transfer from treadmill to over-ground walking following prolonged exposure to this form of biofeedback would be beneficial in establishing potential rehabilitation protocols. Similarly, no changes in peak internal knee extension moment for the affected limb were observed for overground walking post-biofeedback. It was not possible to measure kinetics during treadmill walking and as such it is unknown whether peak internal knee extension moment would have changed along with knee range of motion during the treadmill-based biofeedback. However, it is possible that peak internal knee extension moment did not change post-biofeedback because knee range of motion did not appear to change while other gait changes may have been prioritized to increase peak shank angular velocity.

In examining the post-biofeedback over-ground gait pattern of the affected limb, the only significant changes that were shown in combination with an increase in peak shank angular velocity were a decrease in stance time and an increase in peak hip extension moment. Intuitively, the change in stance time makes sense as a decrease in stance time likely indicates a decrease in step time, and thus a decrease in step length with an increase in cadence. This may decrease the amount of time available for the shank to rotate over the ankle, which may have led to the increase in peak shank angular velocity. The increase in peak internal hip extension moment may indicate more of a reliance on the hip extensors following initial contact to stabilize

the knee given the decrease in stance time could lead to greater instability. This could also indicate a greater reliance on the hip extensors to move the center of mass forward more quickly. It also has previously been suggested that observed increases in internal hip extensor moment post-ACL reconstruction in combination with decreased internal knee extension moment may be part of a compensatory gait pattern to avoid strain on the ACL (Hall, Stevermer, & Gillette, 2012). As such, the priority in the present study may have been to avoid increasing peak internal knee extension moment, instead possibly increasing peak internal hip extension moment to maintain stability and progress the center of mass forward more quickly with a simultaneous decrease in stance time to increase peak shank angular velocity in the affected limb. However, as individuals post-ACL injury and reconstruction display an increased risk for developing knee osteoarthritis while still displaying increased internal hip extension moment, it is possible that this alteration does not help to decrease the risk for osteoarthritis. It could be that this gait pattern may in fact play a role in the changes that have been observed in cartilage contact area that may lead to knee osteoarthritis (Hall et al., 2012; Tashman et al., 2016). As such, although peak shank angular velocity was increased in the affected limb post-biofeedback, it is possible that the method to achieve this does not address the overall issue.

Interestingly, the unaffected limb displayed a significant increase in peak shank angular velocity that was also significantly greater post-biofeedback as compared to the affected limb. It was not expected that biofeedback would have a bilateral effect on peak shank angular velocity. However, stance time was significantly decreased and trending towards a significant decrease in the affected and unaffected limbs, respectively. As such, it is possible that, as stance time decreased for the affected limb, individuals may have attempted to maintain symmetry by decreasing stance time in the unaffected limb as well, thereby increasing peak shank angular

velocity in the unaffected limb. The alterations in gait pattern for the unaffected limb to achieve this increase in peak shank angular velocity were very similar to the affected limb, as peak internal hip extension moment significantly increased. However, the unaffected limb also displayed increased hip range of motion and ankle angle at initial contact post-biofeedback. Given that hip flexion at initial contact did not change post-biofeedback, this may indicate that this group moved through a greater hip range of motion in a decreased amount of time in order to move the center of mass forward faster as these individuals also attempted to rotate the shank forward at a faster rate. Greater ankle dorsiflexion at initial contact may also be necessary to ensure clearance and a heel strike pattern given a decreased stance time and thus shorter steps. Additionally, it was not expected that peak shank angular velocity post-biofeedback would be significantly greater in the unaffected limb compared to the affect limb. The significantly lower knee flexion at initial contact and peak knee flexion in the unaffected limb post-biofeedback compared to the affected limb may provide further evidence for the idea that, given the same gait speed, a decrease in stance time may lead to more of a reliance on movement and torque at the hip joint to increase peak shank angular velocity. As such, a decreased overall magnitude of knee flexion at these two time points compared to the affected limb may simply indicate that there are multiple methods to achieve an increase in peak shank angular velocity. If the stance time were to remain the same, it could be that changes in knee mechanics might be prioritized.

This study is scientifically significant in that it shows that peak shank angular velocity can be altered through the use of an audio-based biofeedback protocol. However, the pattern implemented by subjects to increase peak shank angular velocity appears to have put more emphasis on mechanical changes at the hip and ankle and temporal changes to stance time that may also need to be avoided to decrease the risk for knee osteoarthritis. This is important in that

a self-selected speed for this form of biofeedback may be more effective in changing the appropriate mechanics to decrease the risk for knee osteoarthritis. Although a standardized gait speed was implemented to standardize measurements of peak shank angular velocity as this variable has been shown to change with changes in gait speed (Alshehri et al., 2020), it is likely that a biofeedback protocol using self-selected speed may be more applicable to a clinical situation. As such, future research should examine a biofeedback protocol based upon peak shank angular velocity using a self-selected gait speed. An additional limitation for the present study was that changes in kinetics during the biofeedback session on the treadmill could not be measured. It is possible that, given knee range of motion did significantly increase on the treadmill, increases in peak internal knee extension moment may have been observed as well. Future research examining this would be beneficial in understanding the kinetic changes resulting from this form of biofeedback during treadmill walking.

Conclusion

The hypothesis for this study was partially supported. An audio-based biofeedback protocol was successful in increasing peak shank angular velocity during over-ground walking in the affected limb one to four years post-ACL reconstruction. However, no significant changes were observed in knee mechanics. It may be that these individuals relied primarily on changes in hip mechanics and a decrease in stance time to achieve this increase in peak shank angular velocity. Additionally, a bilateral effect of the biofeedback was observed in the unaffected limb, potentially due to these individuals maintaining temporal symmetry during gait. Finally, the unaffected limb displayed greater peak shank angular velocity and decreases in both knee flexion at initial contact and peak flexion post-biofeedback compared to the affected limb. This suggests

that these differences may have been maintained as changes at the hip were prioritized. As such, although peak shank angular velocity can be altered through a biofeedback protocol, further research examining changes to the biofeedback protocol are necessary to determine if knee mechanics can also be altered in individuals post-ACL reconstruction.

Chapter 5: Summary and Conclusions

The objectives of this study were to (a) determine if abnormal gait patterns during the loading phase of gait exist in individuals one to four years post-ACL reconstruction; (b) examine the relationship between peak shank angular velocity as measured by an IMU and traditional gait parameters as measured by a three-dimensional motion capture system for healthy individuals and individuals one to four years post-ACL reconstruction; (c) assess the feasibility of using an IMU to provide real-time biofeedback to increase peak shank angular velocity, sagittal plane knee range of motion, and peak internal knee extension moment in individuals with abnormal gait mechanics.

Twenty healthy, recreationally active females and seven recreationally active females one to four years post-ACL reconstruction were included in this study. Participants walked at 1.4 m/s over-ground while kinematics and kinetics at the hip, knee and ankle joints and ground reaction forces were measured by a three-dimensional motion capture system, and peak shank angular velocity in the sagittal plane was measured by an IMU. The IMU was placed on the anteromedial aspect of the right tibia for the healthy group and on both limbs for the ACL-reconstructed group. Kinematic and kinetic comparisons were made between groups and across limbs within the ACL-reconstructed group. Additionally, correlations between peak shank angular velocity as measured by an IMU and traditionally measured gait mechanics were assessed for all twenty-seven participants. Finally, six of the seven individuals in the ACL-reconstructed group were included based upon average peak shank angular velocity to examine the effect of an audio-based biofeedback protocol on a treadmill that was intended to increase peak shank angular velocity. Gait mechanics for these individuals were measured pre- and post-biofeedback for over-ground walking.

Decreases in peak shank angular velocity were detected by a single IMU in both the affected and unaffected limbs of the individuals in the ACL-reconstructed group as compared to the healthy group. No significant differences were present between limbs in peak shank angular velocity, and the only asymmetry identified was a decreased knee flexion angle at initial contact in the unaffected limb. The gait pattern post-ACL reconstruction did show significant changes in hip and ankle mechanics as compared to healthy individuals, which suggests that a compensatory gait pattern may be implemented that incorporates use of these joints well after surgery. This may occur without differences in knee mechanics as compared to healthy individuals, which suggests that this compensatory gait pattern may be implemented to normalize knee mechanics.

Several significant correlations were displayed between peak shank angular velocity and traditionally measured gait kinematics and kinetics. Knee range of motion and peak internal knee extension moment were moderately and positively correlated with peak shank angular velocity. This suggests that, for individuals that are long-term post-ACL reconstruction, an IMU measuring peak shank angular velocity may be able to detect changes in knee mechanical variables that have been previously identified as risk factors for developing knee osteoarthritis following surgery. Additional moderate and weak correlations were identified with hip and ankle kinematics, and posterior ground reaction force, suggesting that an IMU may also be able to detect compensatory gait pattern changes that may still lead to the increased risk in developing knee osteoarthritis for this population.

Finally, a biofeedback protocol on the treadmill targeting peak shank angular velocity in the affected limb led to a significant increase in peak shank angular velocity for both treadmill and over-ground walking. It was expected that knee range of motion and peak internal knee extension moment would increase with an associated increase in peak shank angular velocity,

however, this was not observed for over-ground walking. Instead, participants appeared to adopt a gait pattern that involved a decreased stance time, and potentially a decreased step length and increased step rate, in addition to an increased peak internal hip extension moment. It appeared that the participants may have applied more torque at the hip to better move their center of mass forward, and the decreased stance time suggests that they may have done this at a faster rate. This ultimately appeared to increase the rate at which the shank began to rotate over the ankle during the loading phase of the stance phase. As such, this study suggests that when gait speed is standardized, individuals one to four years post-ACL reconstruction may prioritize changes in hip mechanics and temporal gait parameters over changes in knee mechanics as a result of this biofeedback protocol. Additionally, although the biofeedback only targeted the affected limb, bilateral effects were observed that led to significant differences between limbs in peak shank angular velocity and knee flexion at initial contact and peak knee flexion. These bilateral effects may have been a result of temporal changes that were made to the gait pattern.

This study demonstrates that a single IMU measuring angular velocity of the shank may be able to detect gait abnormalities as measured by a three-dimensional motion capture system that last up to four years post-ACL reconstruction. While the gait abnormalities shown were not expected, these findings demonstrate that an IMU can potentially detect changes in mechanics at the hip and ankle. As such, although peak shank angular velocity may not always act as a proxy for measuring specific knee kinematics and kinetics as was originally hypothesized, the findings of this study do suggest that clinicians could use an IMU to identify subtle whole-body changes in gait pattern that may still increase the risk for knee osteoarthritis. Further research is necessary to fully understand the effects of these whole-body changes on the development of knee osteoarthritis for individuals who are long-term post-ACL reconstruction. Additionally, as

significant relationships were established for individuals up to four years post-ACL reconstruction between peak shank angular velocity and both knee range of motion and peak internal knee extension moment, this study could provide the framework for a biofeedback protocol that may lead to changes in knee mechanics. Incorporating self-selected speed may also reduce the bilateral effect of this biofeedback protocol. Further research examining a biofeedback protocol that targets peak shank angular velocity, particularly in individuals already exhibiting asymmetries and abnormalities in knee mechanics, is necessary to better understand the ability to change knee mechanics in the affected limb with a change in peak shank angular velocity. This may be more applicable in individuals under six months post-surgery, and as such, future research should also examine the effect of a similar biofeedback protocol on individuals who are shorter-term post-ACL reconstruction.

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Appendix A: Literature Review

Anterior Cruciate Ligament

The Anterior Cruciate Ligament (ACL) is a structure within the knee joint composed of collagen fibers running obliquely from the femur to the tibia (Duthon et al., 2006). It is connected on both the posterior aspect of the lateral femoral condyle and the anterior aspect of the proximal tibia (Duthon et al., 2006). The ACL traverses through the intercondylar notch, which is located on the distal end of the femur and is defined as the space between the medial aspect of the lateral femoral condyle and the lateral aspect of the medial femoral condyle (Shelbourne, Davis, & Klootwyk, 1998). There are two functional bundles of the ACL – the anteromedial and posterolateral bundles – that are named based on where they attach to the proximal tibia (Takahashi, Doi, Abe, Suzuki, & Nagano, 2006). Though these two bundles are not as clearly defined in terms of their anatomy, functionally it has been suggested that they undergo tension at different degrees of movement, particularly in the sagittal plane (Amis & Dawkins, 1991; Gabriel, Wong, Woo, Yagi, & Debski, 2004; Yasuda et al., 2008; Yoo et al., 2010).

The primary role of the ACL is to stabilize the knee joint by resisting anterior translation of the tibia relative to the femur (Butler et al., 1980). Secondary roles of the ACL include resisting internal and external rotation of the tibia relative to the femur, as well as varus and valgus angles at the knee joint (Beynnon et al., 2003). The ACL stabilizes the knee and resists movement in the frontal and transverse planes by elongating and becoming taut upon reaching certain degrees of movement (Butler et al., 1980; Zantop, Herbort, Raschke, Fu, & Petersen, 2007). For example, the tension in the ACL, and as a result the amount that it is taut, changes depending on the degree of knee flexion or extension (Amis & Dawkins, 1991; Butler et al.,

1980; Zantop et al., 2007). As the knee moves into more extension, particularly with contraction of the quadriceps, the collagen fibers of the ACL become more taut to stabilize the knee, thereby limiting the amount of anterior translation that the knee can experience (Amis & Dawkins, 1991). Furthermore, mechanoreceptors located in the ACL provide some amount of proprioception, which can then be used to coordinate muscle strategies to further stabilize the knee. The ACL itself provides about 85% of the resistance to anterior translation in the knee (Butler et al., 1980).

ACL Injury Mechanisms

The annual incidence of ACL injuries from 2010, when adjusted for both age and sex, was approximately 68 per 100,000 person-years (Sanders et al., 2016). As such, tears to the ACL are still a common injury, particularly as a result of participating in sports. Basketball and soccer remain the sports with the highest incidence of ACL injury (Prodromos et al., 2007). ACL injuries can occur with or without contact to either the tibia or the femur. In the case of both contact and non-contact injuries, the ACL is loaded via anterior translation or rotation of the tibia relative to the femur, or via frontal plane angulation of the knee joint (Duthon et al., 2006). Failure of the ACL commonly occurs in both of these scenarios as a result of a rapid strain of the already taut ligament, leading to stress levels beyond what the ACL is capable of withstanding. Contact ACL injuries are typically the result of a large force applied to the lower extremity. Noncontact ACL injuries make up about 70% of all annual ACL injuries (Agel, Arendt, & Bershadsky, 2005; Griffin et al., 2000). Non-contact ACL injuries are a result of a variety of factors, two of which include neuromechanical and anatomical risk factors (Shultz et al., 2015).

Neuromechanical risk factors involve the positioning of the knee, particularly upon landing. ACL injuries often occur when an individual lands with decreased knee flexion, increased knee abduction, and increased knee internal rotation (Hewett et al., 2005; Laughlin et al., 2011; Norcross et al., 2013; Oh, Lipps, Ashton-Miller, & Wojtys, 2012). These positions put an increased stress on the ACL. Furthermore, gender differences in the number of ACL injuries have been documented, as females are two to eight times more likely than males to experience an ACL injury (Harmon & Ireland, 2000). Women have been shown to land or perform lateral movements with greater knee extension and greater knee abduction than males, which can partially explain the gender differences that have been observed in the ACL injury literature (Ford, Kevin R., Myer, Toms, & Hewett, 2005; Kernozek, Torry, Van Hoof, Cowley, & Tanner, 2005). Anatomical risk factors can range from the angle at which the quadriceps force is distributed across the ACL (Shambaugh, Klein, & Herbert, 1991), to a smaller intercondylar notch width (Chen et al., 2016; Shelbourne et al., 1998; Souryal & Freeman, 1993), to increased joint laxity (Ramesh, Von Arx, Azzopardi, & Schranz, 2005). Each of these factors can affect both the mechanics of the knee and the stress on the ACL.

ACL Reconstruction

There are two types of treatment options for an ACL injury: conservative and surgical. Conservative treatment involves changing an individual's participation in sports or activities to those that do not involve movements that can put the knee at further risk for injury, such as cutting or rapidly decelerating, or introducing a rehabilitation protocol to improve muscular strength and coordination to reduce instability at the knee (Casteleyn & Handelberg, 1996; Kessler et al., 2008; Kostogiannis et al., 2007). However, this does not always ensure that an individual will be able to return to their previous level of activity and patients may experience greater instability at the knee joint (Kessler et al., 2008; Strehl & Eggli, 2007). As a result, surgical treatment is often chosen as a means to prevent instability at the knee and return to sport or activity (Lynch et al., 2015). Surgical treatment involves a reconstruction of the ACL within the knee joint, which is done by connecting a graft between the proximal tibia and the distal femur (Markatos et al., 2013). One primary goal of the graft is to mimic the anatomy and kinematics of the original ACL (Markatos et al., 2013). The graft chosen can either be an autograft, involving tissue taken from the patient, an allograft, involving tissue taken from a donor, or a synthetic graft (Bottoni et al., 2015; Engelman, Carry, Hitt, Polousky, & Vidal, 2014; Kraeutler et al., 2013; Mariscalco et al., 2014). The average age of those undergoing ACL reconstructions has been shown to be around 30 years old (Seon, Song, & Park, 2006). ACL reconstructions have significantly increased from 1994 to 2006 in the United States (Mall et al., 2014). In addition, the number of ACL reconstructions in the United States in both individuals under 20 years old and individuals over 40 years old has significantly increased (Mall et al., 2014). Furthermore, the number of ACL reconstruction procedures has significantly increased in females as of 2006 (Mall et al., 2014). Ninety-five percent of these reconstructions, as of 2006, were being performed as outpatient surgeries, a significant increase from forty-three percent in 1994 (Mall et al., 2014).

The gold standard for grafts when performing an ACL reconstruction is the use of a patellar tendon autograft (Carmichael & Cross, 2009). The patellar tendon is often chosen due to the decreased level of joint laxity following reconstruction, thereby maintaining knee stability (Carmichael & Cross, 2009). The patellar tendon autograft has also been shown to be quite durable, and it is easier to replicate the size of the ACL by using a patellar tendon autograft as

compared to other options (Carmichael & Cross, 2009; Hospodar & Miller, 2009; Kraeutler et al., 2013). Another option involves the use of the hamstring tendon autograft. The hamstring tendon autograft option may be chosen to avoid anterior knee pain that could occur with the use of a patellar tendon autograft (Pinczewski et al., 2007). The use of a hamstring tendon autograft can also keep knee extensor strength closer to ideal as the knee extensors are affected when the autograft is taken from the patellar tendon, however, this can lead to knee flexion weakness instead (Makihara, Nishino, Fukubayashi, & Kanamori, 2006).

With regards to choosing an autograft versus an allograft, the autograft can be a beneficial choice in that the body is more likely to accept the autograft as it comes from the patient's own tissue and thus decrease the risk of disease transmission (Arnoczky, 2006; Eagan & McAllister, 2009). Additionally, failure rate for the autograft has tended to be less as compared to allografts (Bottoni et al., 2015; Engelman et al., 2014; Kraeutler et al., 2013). While there are conflicting results in terms of patients' return to their previous activity levels between autografts and allografts, patellar tendon autografts have shown improved results compared to allografts on the single-leg hop test, which reflects an individual's ability to return to physical activity or sport (Engelman et al., 2014; Kraeutler et al., 2013). However, one of the primary advantages of choosing an allograft as opposed to an autograft is that an allograft avoids pain at the site from which an autograft might be taken (Bushnell, Sakryd, & Noonan, 2010; Kartus, Movin, & Karlsson, 2001). Additionally, by avoiding harvesting tissue from a donor site, the allograft does not run the risk of donor site morbidity leading to weakness (Kartus et al., 2001). Allografts are also useful in that there are multiple options for tissue type and size to improve joint stability and there is a shorter time for operation (Chechik et al., 2013). There are some differences in findings with regards to the cost of autografts as compared to allografts for ACL

reconstructions, and as such one does not clearly cost more than the other (Cole et al., 2005; Nagda, Altobelli, Bowdry, Brewster, & Lombardo, 2010). Finally, studies have displayed no significant differences between the two graft types in terms of joint laxity or activity level following the procedure (Edgar, Zimmer, Kakar, Jones, & Schepsis, 2008; Sun et al., 2011).

Knee Osteoarthritis

Osteoarthritis is a degenerative joint disease that progresses with age and is a common health problem for older individuals (Buckwalter et al., 2004; Dillon et al., 2006). The knee, specifically, is one of the most common joints at which osteoarthritis can occur (Dillon et al., 2006; Woolf & Pfleger, 2003). Knee osteoarthritis negatively affects the cartilage at the medial aspect of the tibiofemoral joint (Cicuttini et al., 2001). This can result from a cyclical loading of the medial compartment of the knee that is significantly greater than in the lateral compartment (Andriacchi & Mündermann, 2006; Mündermann et al., 2005). While there is a high prevalence of knee OA in elderly individuals (Dillon et al., 2006), early onset knee OA is also becoming more prevalent in younger individuals (Lohmander et al., 2004). Knee osteoarthritis can occur at either the tibiofemoral joint or the patellofemoral joint. In either of these cases, the osteoarthritis causes limited mobility and significant pain, leading to a decrease in ability or an inability to perform activities of daily living (Fautrel et al., 2005; Hurwitz et al., 2000; Lohmander et al., 2004). Knee osteoarthritis is more common in women (22%) than in men (14%), which may be due to a multitude of factors including anatomy and mechanics (Woolf & Pfleger, 2003). Additionally, knee osteoarthritis can become a significant burden financially, particularly as total joint replacement surgery becomes more common as a treatment option (Buckwalter et al., 2004; Murphy & Helmick, 2012).

Osteoarthritis is often identified via radiograph or magnetic resonance imaging, in combination with external symptoms such as pain and loss of joint function (Schiphof, Boers, & Bierma-Zeinstra, 2008). Common internal changes that occur with osteoarthritis include a loss of cartilage at the joint, the presence of osteophytes, or bony growths, cysts, and further bone deformation (Schiphof et al., 2008). While there is no gold standard means of classifying osteoarthritis, the most common means of classification is via the Kellgren and Lawrence system (Kellgren & Lawrence, 1957; Schiphof et al., 2008). There are five grades included in this system, with the most severe being level four and a normal joint represented by zero. This system examines changes in osteocyte formation, the size of the joint space, cysts in the bone, and deformation of the bone to grade the level of the osteoarthritis, specifically in the knee. A grade of one is given if there is possible narrowing of the joint space and possible presence of osteophytes. A grade of two is given if there is possible narrowing of the joint space with the definite presence of osteophytes. A grade of three is given if the joint space narrowing is definitive, if there are multiple osteophytes, and if some bone deformity is possibly present. Finally, a grade of four represents the most severe signs, with large osteophytes, severe narrowing of the joint space, and definite deformities of the bone (Kellgren & Lawrence, 1957; Schiphof et al., 2008).

Knee osteoarthritis in individuals with ACL reconstruction. Early onset knee osteoarthritis is particularly prevalent among athletes who incur an anterior cruciate ligament (ACL) injury that requires surgery to reconstruct the ligament (Buller et al., 2015). In fact, knee osteoarthritis is between 3 and 4 times more likely to occur in ACL-reconstructed knees as compared to contralateral uninjured knees (Ajuied et al., 2014; Lohmander et al., 2007). Knee osteoarthritis in

individuals with a previous ACL reconstruction often falls between mild and moderate osteoarthritis (Keays et al., 2010). This corresponds to a grade of two on the Kellgren & Lawrence scale. Individuals have been shown to reach this grade for early onset knee osteoarthritis as early as ten years following ACL injury (Lohmander et al., 2004; Roos et al., 1995). Additionally, the average age of ACL injury in female soccer players has been found to be around 19 years old (Lohmander et al., 2004; Roos et al., 1995) This suggests that early onset knee osteoarthritis could be observed as early as age 29 (Lohmander et al., 2004; Roos et al., 1995; Roos et al., 1995).

Knees receiving conservative treatment have shown a greater risk for knee osteoarthritis as compared to ACL-reconstructed knees, suggesting that ACL reconstruction can somewhat decrease the risk for osteoarthritis (Paschos, 2017). However, there still remains an increased risk for osteoarthritis in the ACL-reconstructed population. It has been shown that meniscal and cartilage damage at the time of injury can be linked to an increased risk for osteoarthritis (Paschos, 2017). While this explains part of the risk for osteoarthritis, it has also been shown that individuals that undergo an ACL reconstruction without having prior meniscal or cartilage damage are also at greater risk for developing osteoarthritis compared to healthy individuals (Paschos, 2017). Another explanation for this increased risk has been a change in gait mechanics following reconstruction (Lin, P., 2018; Lin, P. E. & Sigward, 2018; Paschos, 2017; Sigward et al., 2016). It has been posited that abnormal gait patterns lead to changes in the location and size of the cartilage contact area in the medial compartment of the ACL-reconstructed knee that have been observed in vivo, which may explain the early softening of the cartilage that has been observed and which may lead to the development of knee osteoarthritis in these individuals (Lin, P., 2018; Tashman et al., 2016).

Gait Mechanics

Normal gait mechanics. The initial weight acceptance phase of the gait cycle is of primary importance when examining individuals with both ACL reconstructions and knee osteoarthritis. During normal gait, the knee will begin with about 5 degrees of flexion upon initial contact (Neumann, 2009). The knee will then flex to about 15 to 20 degrees of flexion directly following heel strike, during the first 15% of the gait cycle (Neumann, 2009). This flexion occurs around the same time as a large internal knee extension moment that acts to control the knee flexion and allow the lower extremity to accept the body's weight (Neumann, 2009). It is during this time that peak vertical and posterior ground reaction forces are also observed, as the lower extremity is accepting the body's weight and applying a breaking force to the ground (Lin, P. E. & Sigward, 2018; Neumann, 2009). Finally, a positive peak sagittal plane angular velocity of the lower leg is observed at around 10% of the gait cycle (Lin, P. E. & Sigward, 2018). This peak sagittal plane angular velocity can be used to measure the maximum forward angular progression of the tibia over the foot. Normal gait typically displays peak angular velocities between 180 to 200 degrees per second (Lin, P. E. & Sigward, 2018; Sigward et al., 2016).

Gait mechanics for individuals with ACL reconstruction. Studies suggest that there are discrete differences in kinematics and kinetics during gait between healthy individuals and individuals with ACL reconstructions. In the frontal plane, decreased knee adduction moment and decreased knee adduction angle during walking have both been identified in those with ACL-reconstructed knees (Milandri et al., 2017; Webster, Kate E. et al., 2012). Furthermore, in the sagittal plane, decreased knee flexion angle and decreased internal knee extension moment were observed in the ACL-reconstructed knee during running (Herrington et al., 2017; Milandri

et al., 2017; Roewer et al., 2011). In the transverse plane, decreased rotation in the affected limb has been shown throughout the walking gait pattern as compared to an increased internal rotation of the knee in the contralateral limb during mid-stance and toe-off (Webster, Kate E. et al., 2012) and an increased maximum external rotation of the tibia (Georgoulis, Papadonikolakis, Papageorgiou, Mitsou, & Stergiou, 2003) to coincide with the knee mechanics. Finally, significant reductions in peak shank angular velocity of at least 20 degrees per second have been observed in the affected limb (Lin, P. E. & Sigward, 2018; Patterson et al., 2014; Sigward et al., 2016). While gait mechanics are expected to normalize two to three months post-surgery, reductions in sagittal plane knee ROM have been shown to persist at least three years postsurgery, and reductions in peak shank angular velocity have been displayed at four months postsurgery (Hart et al., 2016; Lin, P. E. & Sigward, 2018; Roewer et al., 2011).

With regards to kinetics, increased vertical impact force and loading rate have been shown in individuals with ACL reconstructions as compared to healthy controls (Noehren et al., 2013), while decreased posterior ground reaction forces have also been observed (Lin, P. E. & Sigward, 2018). Additionally, decreased internal knee extension moment has been shown post-ACL reconstruction, which may be related to early decreases in quadriceps strength (Herrington et al., 2017; Keays et al., 2010; Milandri et al., 2017). However, quadriceps strength has been shown to return to normal levels six months post-surgery while gait deviations remain at least two years post-surgery (Roewer et al., 2011; White et al., 2013). The return of quadriceps strength to normal levels is also a marker for an athlete to return to play. However, these athletes that regain strength and return to play still retain these abnormal gait patterns that can lead to decreased internal knee extension moments (Roewer et al., 2011; White et al., 2013). This suggests that quadriceps strength alone may not fully explain these gait deviations, and that it is likely due to differences in kinematics and ground reaction forces.

These changes in kinematics and kinetics are observed without significant temporal differences in the gait patterns between limbs or between groups, suggesting that individuals with ACL reconstructions may be attempting to make up for the aforementioned changes in other aspects of their gait pattern, in order to keep the appearance of their gait as normal as possible while minimizing strain on the ACL (Lin, P. E. & Sigward, 2019; Patterson et al., 2014). As these changes can be subtle and may not be observable without the use of technology, this can lead to individuals being cleared for activity while retaining these gait asymmetries (Sigward et al., 2016). These gait asymmetries may ultimately help to explain the increased risk for knee osteoarthritis beyond the initial trauma and strength decreases that have been observed and are important to target when implementing early rehabilitation strategies to reduce the risk for knee osteoarthritis.

Biofeedback

Biofeedback is a means by which information regarding body functions can be provided to an individual (Giggins et al., 2013). The primary goal in using biofeedback is to make some sort of change to how the body is functioning. The information provided via biofeedback can guide the user towards a target goal or inform the user of errors (Giggins et al., 2013). Feedback, in general, can be considered intrinsic or extrinsic. Intrinsic, or internal, feedback primarily involves an individual's own senses or information that they perceive (van Vliet & Wulf, 2006). This can include information from touch, hearing, or proprioception (van Vliet & Wulf, 2006).

Often, this involves an individual focusing on their own body performance during a task (Torp, Thomas, & Donovan, 2019). Alternatively, extrinsic or external feedback comes from an external source and is used to provide information about the outcome of a task (van Vliet & Wulf, 2006). Information from biofeedback is typically considered external feedback, as the information comes from an outside source, provides the user with either a knowledge of their results or a knowledge of their performance, and can augment any intrinsic feedback (Giggins et al., 2013; Torp et al., 2019; van Vliet & Wulf, 2006). Additionally, feedback, particularly involving knowledge of results, can be provided in a positive or negative manner. Positive feedback involves providing information to the user during good, or correct, trials, while negative feedback involves providing information during poor, or incorrect, trials (Saemi, Porter, Ghotbi-Varzaneh, Zarghami, & Maleki, 2012). Individuals have displayed improved learning and motor performance following positive feedback as opposed to negative feedback in a variety of tasks (Badami, VaezMousavi, Wulf, & Namazizadeh, 2011; Chiviacowsky & Wulf, 2007). Positive feedback can be based either on a discrete value or within a range of values. Feedback involving a range is termed bandwidth feedback and has been shown to promote retention of a learned performance as compared to positive feedback based on a discrete value (Lai & Shea, 1999).

Information from biofeedback can be provided in a variety of manners. One common means of providing biofeedback is through the use of a computer program, which is often times coupled with something that a user may see on a computer screen (Crowell & Davis, 2011). As technology has advanced, it is becoming more common to see biofeedback provided via mobile devices or other instruments in a similar manner to the computer (Willy et al., 2016). The amount of information provided, and the manner in which the information is disseminated, varies

greatly depending on the type of biofeedback being provided and the type of data being collected. One manner in which the feedback can be received by the user, as was stated previously, is visually through the use of a screen. This data can be provided as a graph with a target line for individuals to attempt to attain (Crowell & Davis, 2011). The data can also be simplified, for example, by simply providing discrete variables as opposed to continuous data (Dowling, A. V. et al., 2012a). This data can be provided at the conclusion of a task or in real time with the task. Graphs or indicators providing data in real time will change as the individual moves closer to or farther away from a goal, allowing individuals to change behavior while performing an activity, while data provided at the conclusion of a task allows individuals to assess potential changes prior to completing a task again. Further examples of real-time biofeedback, and the benefits of using this type of biofeedback, will be discussed in a later section.

While visual biofeedback has been shown to be effective, not all tasks are easily, or realistically, accomplished with the individual focused on a screen. As such, research has also been performed to examine auditory and haptic biofeedback. Auditory biofeedback can be provided by means of a sound (Wood & Kipp, 2014). This is useful, particularly for individuals that use mobile devices, as an individual can wear headphones while performing a task that requires their visual attention, such as with playing sports. A sound can be provided if the data is too far away from a goal, or can change pitch, volume, or frequency, depending on where the data is in relation to the goal (Wood & Kipp, 2014).

Haptic biofeedback, like auditory biofeedback, can be used when an individual needs to attend to visual stimuli. Instead of providing a sound, however, haptic biofeedback involves an instrument providing tactile sensations. This can be seen in studies that have used wristbands or

watches to provide this haptic biofeedback (Dowling, A. V. et al., 2010). This form of biofeedback can be incorporated if an individual has to attend to auditory stimuli in addition to visual stimuli. Part of the decision-making regarding the type of biofeedback to use revolves around personal preference (Brongers, 2017). Additionally, setting and cost also play a role in choosing a form of biofeedback (Brongers, 2017). Finally, the type of data being collected and the task being performed may determine the type of biofeedback that is used, and how it is provided to the user to direct them to a given goal (Giggins et al., 2013).

Biofeedback for gait retraining. Due to the novelty of biofeedback technology, the majority of gait retraining studies have focused on a single set of short-term sessions within a laboratory setting, primarily extending to one-month following the initial session (Van Gelder et al., 2018). About 70% of studies have shown beneficial short-term changes to gait patterns (Van Gelder et al., 2018). One current review found that only eight percent of gait retraining studies incorporating biofeedback established the long-term retention rate of the learned gait parameter, suggesting that the inclusion of long-term retention in future studies is crucial to establishing efficacy of the biofeedback (Agresta & Brown, 2015; Tate & Milner, 2010; Van Gelder et al., 2018). However, eighty-four percent of those studies did show beneficial effects long-term, suggesting that gait retraining using biofeedback is a viable option for positively altering gait mechanics (Van Gelder et al., 2018).

Although not as generalizable as testing biofeedback in the field, it is important to test the validity of using biofeedback in the laboratory to promote short-term changes first. While visual biofeedback has been provided more frequently among gait biofeedback studies, no biofeedback type has been shown to be better than the other (Agresta & Brown, 2015). Laboratory gait

retraining studies have incorporated biofeedback during either over-ground walking or treadmill walking (Van Gelder et al., 2018). As it may be more likely that a treadmill will be used in a clinical setting to assess and retrain gait parameters due to space constraints, it is important that learned treadmill gait be similar to and carry over to over-ground gait. Despite detectable differences in treadmill versus over-ground gait kinematics and kinetics, gait patterns, particularly in the knee, have been shown to be similar and within the range of variability of over-ground gait when compared to treadmill walking (Matsas, Taylor, & McBurney, 2000; Riley, Paolini, Della Croce, Paylo, & Kerrigan, 2006). Knee kinematics in particular have been highly correlated between treadmill and over-ground walking (Matsas et al., 2000).

Wearable Sensors

Wearable technology involves the incorporation of smart technology that can be applied to the body to track body functions, activity, or movement (Cardinale & Varley, 2016). These can be worn in one's clothing, worn as a part of an accessory or incorporated as an implant. Examples of smart technology that can be worn on the body to collect data includes electromyography sensors, accelerometers, and force sensors (Cardinale & Varley, 2016). The use of wearable technology within the realm of exercise and sport science has been growing exponentially in recent years. The ability to easily track and quantify body functions, activity, or movements has played a large role in this growth. Current smart technology gives consumers access to this data in easy to use, cost effective devices. Often, these devices can be paired with other wearable devices to provide a holistic view of the body's functions. This allows consumers to track, target, and change desired parameters in real-time. One example of this technology is the use of the heart rate monitor (Laukkanen & Virtanen, 1998). While this has been available since the 1980's via the use of a wrist-worn device paired with electrodes placed on the chest, the recent development of wrist-worn devices using photoplethysmography to measure heart rate has become more prevalent as chest electrodes are not required and the device is easy to use (Parak & Korhonen, August 2014). Research has displayed contradicting findings regarding the accuracy and validity of this new technology, however, the technology is still being refined to reduce errors (Parak & Korhonen, August 2014; Wallen, Gomersall, Keating, Wisløff, & Coombes, 2016).

Another example of wearable technology used in exercise and sport science is the incorporation of electromyographic and mechanomyographic sensors into smart textiles (Belbasis & Fuss, 2018; Finni, Hu, Kettunen, Vilavuo, & Cheng, 2007). Surface electromyography is used as a means of assessing muscle activity (De Luca, 1997). However, electromyography technology often used in research is not portable, and thus not conducive to consumer use. Smart textiles have been developed that incorporate both electromyographic and mechanomyographic sensors to quantify the activity of commonly used muscles in the field (Belbasis & Fuss, 2018; Finni et al., 2007). These types of clothing can be worn during training to assess changes in the activity of muscles during specific activities. However, the current validity of this data is somewhat suspect due to the inherent potential for errors when using electromyographic sensors, particularly during dynamic movement in the field, as well as the manner in which data from the sensors in the clothing is collected (Finni et al., 2007). Additionally, further research is necessary to assess the viability of using mechanomyography technology in the field due to a lack of a gold standard to compare findings with and assess validity (Belbasis & Fuss, 2018).

Inertial measurement units. While this newer technology measuring heart rate and muscle activity can measure internal variables during sport and exercise, inertial measurement units (IMUs) as wearable devices are more commonly used to assess external variables in the field (Cardinale & Varley, 2016). Typically, gait mechanics are assessed in a laboratory setting that requires a costly three-dimensional motion capture system. However, this system is not easily accessible for clinical use. Use of wearable IMUs in research as a substitute for threedimensional motion capture has increased recently (Crowell et al., 2010; Dowling, Ariel V. et al., 2011; Willy et al., 2016). IMUs are small, relatively inexpensive sensors that contain accelerometers, gyroscopes, and magnetometers to measure orientation and joint kinematics, and may prove much easier for clinicians and the general population to use. IMUs have been used previously to successfully detect three-dimensional kinematics during gait (Zhang et al., 2013). This study utilized an IMU system to measure lower limb kinematics for different walking conditions. The angles collected from the IMU system displayed a strong association with angles collected from the three-dimensional motion capture system. In addition, IMUs have been used during walking to successfully detect gait events based upon joint movements and limb accelerations (Mariani, Rouhani, Crevoisier, & Aminian, 2012).

Additionally, IMUs have been used previously to successfully detect differences in landing mechanics in order to identify individuals who may be at risk for developing an ACL injury (Dowling, Ariel V. et al., 2011). This study utilized an IMU system to measure knee flexion angle during a landing task and compared these findings to a reference, threedimensional motion capture system. The angles collected from the IMU system displayed a strong association with angles collected from the three-dimensional motion capture system, and as such the IMU system was able to detect individuals with knee angles that may have placed

them at risk for developing an ACL injury. Similar findings have been shown for segmental angular velocities as obtained via an IMU system (Dowling, A. V., Favre, & Andriacchi, 2012b). In addition, IMUs have been used during running to successfully detect larger landing accelerations indicative of stiffer landing mechanics and both higher impact forces and larger loading rates (Crowell & Davis, 2011; Crowell et al., 2010). Taken together, these findings suggest that IMUs as wearable sensors are capable of replicating three-dimensional motion capture in terms of tracking movement, which is of great importance in assessing and altering abnormal movement parameters.

Real-time biofeedback interventions using inertial measurement units. Real-time biofeedback protocols using IMUs have been previously researched as methods of changing movement behavior. Some protocols examining tibial stress fracture have focused on altering the loading of the lower extremity during stance in real-time to reduce stress fracture risk (Crowell & Davis, 2011; Wood & Kipp, 2014). Additionally, IMUs have been used to alter running in real-time such that peak knee adduction moment is reduced, thereby reducing the risk for knee osteoarthritis in some runners (Dowling, A. V. et al., 2010). With regards to walking, IMUs have been used to provide real-time biofeedback to successfully reduce trunk sway during gait in both young and elderly individuals (Verhoeff, Horlings, Janssen, Bridenbaugh, & Allum, 2009). Trunk sway has also been targeted during gait in knee osteoarthritis patients to decrease knee adduction moment using IMUs and multiple forms of real-time biofeedback (Brongers, 2017). Thresholds used for providing biofeedback have varied in each of these studies, from using ten (Wood & Kipp, 2014) to fifty percent (Clansey, Hanlon, Wallace, Nevill, & Lake, 2014; Crowell & Davis, 2011) alterations from baseline, to using a healthy standard as a goal (Dowling, A. V.

et al., 2012a). While these studies have shown promising results, there are not as many studies examining the use of IMUs to provide real-time biofeedback as compared to studies that have used other forms of technology, such as three-dimensional motion capture, to provide real-time biofeedback (Ericksen et al., 2016; Ford, K. R. et al., 2015). This is particularly true for gait retraining studies. As such, there is a distinct need for further research on gait retraining in realtime using IMU data.

Appendix B: Protocol Summaries

Instructions: Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the **colored boxes** or place an "X" in front of the appropriate response(s). If the question does not apply, write "N/A."

| SECTION A: Ti | le |
|----------------|----|
| | |
| A1. Full Study | |

Title:

Use of wearable technology to detect subtle gait asymmetries following anterior cruciate ligament reconstruction

SECTION B: Study Duration

B1. What is the expected start date? *Data collection, screening, recruitment, enrollment, or consenting activities may not begin until IRB approval has been granted. Format:* 07/31/2011

01/07/2020

B2. What is the expected end date? *Expected end date should take into account data analysis, queries, and paper write-up. Format: 07/05/2014*

07/01/2021

SECTION C: Summary

C1. Write a brief descriptive summary of this study in Layman Terms (non-technical language):

A group of 25 recreational female athletes that have had their anterior cruciate ligament in their knee surgically repaired between one and four years previously and a group of 25 that is uninjured will be recruited. All participants will walk across a force plate to measure movement of their legs. Movement will be recorded via traditional motion capture cameras that detect reflective markers placed on the body at specific bony landmarks and via inertial

measurement sensors placed on the lower legs. Walking mechanics between groups and the measurements between measurement methods will be compared.

C2. Describe the purpose/objective and the significance of the research:

The ability to both detect subtle gait deviations in a clinical setting and to provide patients with immediate feedback on those deviations has the potential to dramatically improve rehabilitation and reduce the risk of developing knee osteoarthritis following anterior cruciate ligament reconstruction. Additionally, an inertial measurement unit has potential as a relatively inexpensive and easily usable device to achieve these goals. Therefore, the purpose of this research is to assess the use of an inertial measurement unit as a proxy for measuring knee joint mechanics in healthy individuals and individuals that are one to four years post-anterior cruciate ligament reconstruction.

C3. Cite the most relevant literature pertaining to the proposed research:

Knee osteoarthritis is a common degenerative joint disease that can result from cyclical loading of the knee with abnormal gait mechanics and can lead to significant pain and limitations (Andriacchi & Mundermann, 2006; Cicuttini et al., 2001; Lohmander et al., 2004). While there is a high prevalence of knee osteoarthritis in elderly individuals, early onset knee osteoarthritis is becoming more prevalent in younger individuals (Lohmander et al., 2004). In fact, individuals who incur an anterior cruciate ligament injury that requires surgery to reconstruct the ligament are three to four times more likely to develop knee osteoarthritis (Lohmander et al., 2007).

Although the reconstruction is meant to improve stability of the knee and mimic the mechanics of the original ligament, it has been suggested that, following reconstruction, individuals make subtle but clinically significant changes to their gait pattern to avoid putting stress on the reconstructed ligament (Herrington et al., 2017; Lin & Sigward, 2018). Critical changes occur during the initial contact and loading phases of the gait cycle, where decreased knee flexion, decreased internal knee extension moment, and decreased peak angular velocity of the shank moving over the ankle have been observed in the affected limb (Lin & Sigward, 2018; Sigward et al., 2016; Roewer et al., 2011). These changes have been observed during walking following surgery and extending out to four years post-surgery (Roewer et al., 2011). This indicates that these individuals are landing more stiffly and in doing so are changing the

contact area of the cartilage within the knee joint, which may explain the early development of knee osteoarthritis in these individuals (Tashman et al., 2016).

While these changes are subtle enough that they are difficult to detect clinically, it is important to target these changes to restore the gait pattern to normal (Lin, 2018). However, a single inertial measurement unit only measures angular velocity as compared to traditionally assessed kinematics and kinetics. As such, it is important to assess the ability of inertial measurement units to act as a proxy for detecting differences in traditionally measured knee mechanics between healthy individuals and individuals one to four years post-anterior cruciate ligament reconstruction.

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SECTION D: Subject Population

Section Notes...

• D1. If this study involves analysis of de-identified data only (i.e., no human subject interaction), IRB submission/review may not be necessary. Please review the <u>UWM</u> IRB Determination Form for more details.

| D1 all | D1. Identify any population(s) that you will be <u>specifically targeting</u> for the study. Check all that apply: (Place an "X" in the column next to the name of the special population.) | | | | |
|-----------|--|---|--|--|--|
| | Existing Dataset(s) | Institutionalized/ Nursing home residents recruited in the nursing home | | | |
| X | UWM Students of PI or study staff | Diagnosable Psychological Disorder/Psychiatrically impaired | | | |
| X | UWM Students (but not of PI or study staff) | Decisionally/Cognitively Impaired | | | |
| | Non-UWM students to be recruited in their educational setting, i.e. in class or at school | Economically/Educationally Disadvantaged | | | |
| X | UWM Staff or Faculty | Prisoners | | | |
| | Pregnant Women/Neonates | International Subjects (residing outside of the US) | | | |
| | Minors under 18 and ARE NOT wards of the State | Non-English Speaking | | | |

| | Minors under 18 and ARE wards of the State | | Terminally ill |
|---|--|------|----------------|
| Χ | Other (Please identify): Community memb | bers | 5 |

D2. Describe the subject group and enter the total number to be enrolled for each group.

For example: teachers-50, students-200, parents-25, student control-30, student experimental-30, medical charts-500, dataset of 1500, etc. Then enter the total number of subjects below. Be sure to account for expected drop outs. For example, if you need 100 subjects to complete the entire study, but you expect 5 people will enroll but "drop out" of the study, please enter 105 (not 100).

| Describe subject group: | Number: |
|--|---------|
| Healthy, recreationally active females | 25 |
| Recreationally active females with prior Anterior | |
| Cruciate Ligament Reconstruction (1 to 4 years post- | 25 |
| surgery) | |
| | |
| | |
| | |
| | |
| TOTAL # OF SUBJECTS: | 50 |
| TOTAL # OF SUBJECTS | |
| (If UWM is a collaborating site for a multi | |
| institutional project): | |

D3. For each subject group, list any major inclusion and exclusion criteria (e.g., age, gender, health status/condition, ethnicity, location, English speaking, etc.) and state the justification for the inclusion and exclusion criteria:

Healthy Group

Inclusion criteria:

- Females, ages 18 to 29
 - Want age range to include able-bodied population and match anterior cruciate ligament reconstruction group.
 - Females have been shown to have significantly different gait mechanics compared to males. Limiting enrollment to females will help to control for gait differences between sexes.
- Must be recreationally active
 - Physically active at least three times per week for at least 30 minutes per activity

Exclusion criteria:

- Must not have any current injuries to lower extremities
 - Pain and injury may alter gait mechanics
- Must not have had an injury to lower extremities in last 6 months
 - Prior injuries may affect joint mechanics of the lower extremity
- Must not have had a knee injury requiring surgical repair
 - Prior surgery may affect normal joint mechanics
- Must not be pregnant
 - Pregnancy may influence normal gait mechanics
- Must not have a medical condition that may impair walking ability (i.e. concussion, neurological impairments, etc)
 - Normal walking ability will be evaluated
- Must not be taking medications/drugs that may cause dizziness or tiredness (i.e. cold medications, sleeping medications, muscle relaxants)
 - Normal walking ability will be evaluated

Anterior Cruciate Ligament Reconstructed Group

Inclusion criteria:

- Females, ages 18 to 29
 - Females are more likely to have reconstruction surgery than males. Ages 18 to 29 represent time where injuries often occur prior to earliest possible change of early development of knee osteoarthritis
 - Females have been shown to have significantly different gait mechanics compared to males. Limiting enrollment to females will help to control for gait differences between sexes.
- Must be recreationally active
 - Physically active at least three times per week for at least 30 minutes per activity
- Must have a bone-patellar tendon-bone graft used during reconstruction
 - This is the most common graft choice and will control for the effect of graft type on gait mechanics

Exclusion criteria:

- Must not have had reconstruction surgery within past year or more than four years prior to inclusion in study
 - Long term effect of reconstruction on gait mechanics will be evaluated and targeted
- Must not have any current injuries to lower extremities
 - Pain and injury may alter gait mechanics
- Must not have had an injury to lower extremities in last 6 months
 - Prior injuries may affect joint mechanics of the lower extremity
- Must not have had an injury requiring anterior cruciate ligament surgery on the limb opposite the reconstructed limb of interest
 - Intact and affected limbs will be compared
- Must not be pregnant
 - Pregnancy may influence normal gait mechanics
- Must not have a medical condition that may impair walking ability (i.e. concussion, neurological impairments, etc)
 - Normal walking ability will be evaluated
- Must not be taking medications/drugs that may cause dizziness or tiredness (i.e. cold medications, sleeping medications, muscle relaxants)
 - Normal walking ability will be evaluated

SECTION E: Study Activities: Recruitment, Informed Consent, and Data Collection

Section Notes...

- Reminder, all recruitment materials, consent forms, data collection instruments, etc. should be attached for IRB review.
- The IRB welcomes the use of flowcharts and tables in the consent form for complex/ multiple study activities.

In the table below, chronologically describe all study activities where human subjects are involved.

- In <u>column A</u>, give the activity a short name. Please note that Recruitment, Screening, and consenting will be activities for almost all studies. Other activities may include: Obtaining Dataset, Records Review, Interview, Online Survey, Lab Visit 1, 4 Week Follow-Up, Debriefing, etc.
- In <u>column B</u>, describe who will be conducting the study activity and his/her training and/or qualifications to complete the activity. You may use a title (i.e. Research Assistant) rather than a specific name, but training/qualifications must still be described.

• In <u>column C</u>, describe in greater detail the activities (recruitment, screening, consent, surveys, audiotaped interviews, tasks, etc.) research participants will be engaged in. Address where, how long, and when each activity takes place.

| • | | | |
|--|--|--|--|
| A. Activity Name: | B. Person(s) Conducting Activity | C. Activity Description (Please describe any forms used): | D. Activity Risks and Safeguards: |
| Recruitment | Alexander Morgan – Completed IRB training, Constructed study design, PhD Student in Neuromechanics Lab | A Recruitment Flyer will be posted around the UWM campus to encourage potential participants to contact the investigator about participation. | |
| Obtaining Consent | Alexander Morgan – Completed IRB training, Constructed study design, PhD Student in Neuromechanics Lab | Participants will be informed about the study and asked for consent to participate via the Consent Form. | |
| Screening | Alexander Morgan – Completed IRB training, Constructed study design, PhD Student in Neuromechanics Lab | Participants will be given the Screening Questionnaire after they provide informed consent to determine if they are eligible for the study. | |
| List all other study activities in | Alexander Morgan – Completed IRB training, | Demographic information (height, weight, age, sex, | Participants may experience minor muscle soreness as a result of the biomechanics testing. Participants may |

| the | Constructed | time since surgery) will be | suffer musculoskeletal injury |
|-----------|----------------|--------------------------------|---------------------------------|
| following | study design, | recorded. | such as muscle strain or |
| Tomowing | PhD Student in | | ankle sprain as a result of the |
| rows | Neuromechanics | | biomechanics testing. |
| | Lab | Participants will fill out the | Participants may also |
| | | Tampa Scale to assess | experience minor skin |
| | | kinesiophobia and the Visual | irritation due to the adhesive |
| | | Analog Scale to assess pain | (very unlikely). There are no |
| | | prior to and following gait | anticipated psychosocial or |
| | | analysis. | privacy risks due to |
| | | | participation in the study. |
| | | | Because participants are |
| | | Special retro-reflective | required to be physically |
| | | markers will be applied to | active they will be |
| | | the participant's pelvis, | accustomed to the type of |
| | | thigh, shank and foot using | activity performed during the |
| | | straps and adhesive tapes. | testing sessions. First-aid |
| | | Inertial sensors will be | medical treatment will be |
| | | attached to the participant's | event of physical injury |
| | | shanks using straps and | resulting from participation |
| | | adhesive tapes. | in this project. In case of |
| | | | hasic first-aid all research |
| | | Douticing at a in the Healther | personnel involved are |
| | | and Anterior Cruciete | trained in basic first-aid and |
| | | Ligament Reconstruction | CPR and will provide |
| | | Groups will be asked to | appropriate care. In the event |
| | | perform three five-second | that some emergency |
| | | maximal voluntary | treatment may be necessary, |
| | | contractions of the | 911 will be called as a |
| | | quadriceps and hamstrings of | standard operation procedure |
| | | both limbs while seated on a | and the subject will be |
| | | training table to assess | individually responsible for |
| | | strength. Thirty-seconds rest | the cost(s) associated with |
| | | will be provided after each | that treatment. If this event |
| | | contraction. | is unexpected, a full report |
| | | | will be submitted to the IRB. |
| | | | |
| | | Participants in the Healthy | |
| | | and Anterior Cruciate | |
| | | Ligament Reconstruction | |
| | | groups will be asked to walk | |
| | | over a force plate at 1.4 m/s. | |

| Five trials in which the right foot completely strikes the force plate for the Healthy group will be collected. Ten trials in which one foot completely strikes the force plate (5 for the left and 5 for the right foot) will be collected for the Reconstruction group. The force plate will record force data, a motion-capture camera system will track three-dimensional position data of retro-reflective markers on the body, and inertial measurement units will track angular velocity of the shank in the sagittal plane. | |
|--|--|
| Measurement Equipment Force plate: • Name: FP4060-NC • Manufacturer: Bertec Corporation • Safety: The force plate is embedded into to a platform. The platform is the ground level. | |
| Multi-Camera-System: Name: Cortex Motion Capture Manufacturer: Motion Analysis, Inc. Safety: The camera is not in physical contact with the participant | |

| Inertial Measurement Unit Name: Shimmer3 IMU Manufacturer: Shimmer Safety: The inertial measurement unit will not affect participant movement | |
|---|--|
| Timing Gates: Name: Timer model 54035A Manufacturer: Lafayette Instrument Company Safety: The timing gates are not in physical contact with the participant | |
| Handheld Dynamometer: Name: Manual muscle tester model 01165 Manufacturer: Lafayette Instrument Company Safety: The handheld dynamometer will not affect participant | |
| Other: • 10-mm diameter retro reflective markers • Safety: The retro reflective markers will | |

| | not affect participant | |
|--|---------------------------|--|
| | | |
| | | |
| | | |
| | | |
| | | |

E2. Explain how the data will be analyzed or studied (i.e. quantitatively or qualitatively) and how the data will be reported (i.e. aggregated, anonymously, pseudonyms for participants, etc.):

Three-dimensional kinematic and kinetic data, along with inertial measurement unit data, will be collected during each walking trial. Maximal strength data will be measured as the largest force value for each limb, for both the quadriceps and hamstrings. The quantitative data will be processed to represent joint angles and moments, segment angular velocities, and handheld dynamometer forces. The mean, maximum, minimum and standard deviation of the joint angles and moments, and segment angular velocities, will be determined for each trial. Relationships will be quantitatively assessed with Pearson product moment correlations. Comparisons will be made using one-way MANOVAs. All data will be presented in aggregate form.

SECTION F: Data Security and Confidentiality

Section Notes...

• Please read the <u>IRB Guidance Document on Data Confidentiality</u> for more details and recommendations about data security and confidentiality.

F1. Explain how study data/responses will be stored in relation to any identifying information (name, birthdate, address, IP address, etc.)? Check all that apply.

[__] Identifiable - Identifiers are collected and stored with study data.

[__] Coded - Identifiers are collected and stored separately from study data, but a key exists to link data to identifiable information.

[X] De-identified - Identifiers are collected and stored separately from study data without the possibility of linking to data.

[__] Anonymous - No identifying information is collected.

If more than one method is used, explain which method is used for which data.

F2. Will any recordings (audio/video/photos) be done as part of the study?

[__] Yes

[X] No [SKIP THIS SECTION]

If yes, explain what activities will be recorded and what recording method(s) will be used. Will the recordings be used in publications or presentations?

F3. In the table below, describe the data storage and security measures in place to prevent a breach of confidentiality.

| A. Type of Data | B. Storage Location | C. Security Measures | D. Who will have access | E. Estimated date of disposal |
|-----------------------------------|-------------------------|--------------------------------|-------------------------|-------------------------------------|
| Demographic Information, Tampa | File cabinet in END 132 | File cabinet will be locked | Alexander Morgan | 7/1/2021 |

| Scale, and Visual Analog Scale | | | | |
|---|-----------------------------------|------------------------------------|---------------------|----------|
| Kinematic, Kinetic and Inertial Measurement Unit Data | Desktop computer in END 132 | Folder is password protected | Alexander Morgan | 7/1/2021 |
| | | | | |

F4. Will data be retained for uses beyond this study? If so, please explain and notify participants in the consent form.



SECTION G: Benefits and Risk/Benefit Analysis

Section Notes...

• Do not include Incentives/ Compensations in this section.

G1. Describe any benefits to the individual participants. If there are no anticipated benefits to the subject directly, state so. Describe potential benefits to society (i.e., further knowledge to the area of study) or a specific group of individuals (i.e., teachers, foster children).

There are no direct anticipated benefits to the subjects participating in this study. However, clinicians will benefit from the findings in that a simple and cost-effective means of assessing subtle but clinically significant changes in gait mechanics postanterior cruciate ligament reconstruction could be established. As a result, a great number of individuals who may require anterior cruciate ligament reconstruction will benefit from the use of such a system in rehabilitation protocols. The risks associated with participation in this study are minimal compared to the potential benefits.

G2. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of how the anticipated risks to participants and steps taken to minimize these risks (as described in Section E), balance against anticipated benefits to the individual or to society.
The risks to participants are minimal. Patients will be informed that they may discontinue their participation within this study at any time. Participants may experience minor muscle soreness as a result of the biomechanics testing. Participants may suffer musculoskeletal injury such as muscle strain or ankle sprain as a result of the biomechanics testing. Participants may also experience minor skin irritation due to the adhesive (very unlikely). There are no anticipated psychosocial or privacy risks due to participation in the study. Because participants will be accustomed to walking regularly they will not have difficulty with participating in this study. First-aid medical treatment will be provided in the unlikely event of physical injury resulting from participation in this project. In case of basic first-aid, all research personnel involved are trained in basic first-aid and CPR and will provide appropriate care. In the event that some emergency treatment may be necessary, 911 will be called as a standard operation procedure and the subject will be individually responsible for the cost(s) associated with that treatment. If this event is unexpected, a full report will be submitted to the IRB.

SECTION H: Subject Incentives/ Compensations

Section Notes...

- H2 & H3. The IRB recognizes the potential for undue influence and coercion when extra credit is offered. The UWM IRB, as also recommended by OHRP and APA Code of Ethics, agrees when extra credit is offered or required, prospective subjects must be given the choice of an equitable, non-research alternative. The extra credit value and the non-research alternative must be described in the recruitment material and the consent form.
- H4. If you intend to submit to Accounts Payable for reimbursement purposes make sure you understand the UWM "Payments to Research Subjects" Procedure 2.4.6 and what each level of payment confidentiality means (click here for additional information).

H1. Does this study involve incentives or compensation to the subjects? For example cash, class extra credit, gift cards, or items.

X Yes

[__] No [SKIP THIS SECTION]

H2. Explain what (a) the item is, (b) the amount or approximate value of the item, and (c) when it will be given. For extra credit, state the number of credit hours and/or points. (e.g., \$5 after completing each survey, subject will receive [item] even if they do not complete the procedure, extra credit will be award at the end of the semester):

The incentive will be a \$20 gift card for each participant in each group listed above. This will be provided upon completion of the experimental protocol.

H3. If extra credit is offered as compensation/incentive, please describe the specific alternative activity which will be offered. The alternative activity should be similar in the amount of time involved to complete and worth the same number of extra credit points/hours. Other research studies can be offered as additional alternatives, but a non-research alternative is required.



H4. If cash or gift cards, select the appropriate confidentiality level for payments (see section notes):

[X] Level 1 indicates that confidentiality of the subjects is not a serious issue, e.g., providing a social security number or other identifying information for payment would not pose a serious risk to subjects.

- For payments over \$50, choosing Level 1 requires the researcher to collect and maintain a record of the following: The payee's name, address, and social security number, the amount paid, and signature indicating receipt of payment (for cash or gift cards).
- When Level 1 is selected, a formal notice is not issued by the IRB and the Account Payable assumes Level 1.
- Level 1 payment information will be retained in the extramural account folder at UWM/Research Services and attached to the voucher in Accounts Payable. These are public documents, potentially open to public review.

[__] Level 2 indicates that confidentiality is an issue, but is not paramount to the study, e.g., the participant will be involved in a study researching sensitive, yet not illegal issues.

- Choosing a Level 2 requires the researcher to maintain a record of the following: The payee's name, address, and social security number, the amount paid, and signature indicating receipt of payment (for cash or gift cards).
- When Level 2 is selected, a formal notice will be issued by the IRB.
- Level 2 payment information, including the names, are attached to the PIR and become part of the voucher in Accounts Payable. The records retained by Accounts Payable are not considered public record.

[__] Level 3 indicates that confidentiality of the subjects must be guaranteed. In this category, identifying information such as a social security number would put a subject at increased risk.

- Choosing a Level 3 requires the researcher to maintain a record of the following: research subject's name and corresponding coded identification. This will be the only record of payee names, and it will stay in the control of the PI.
- Payments are made to the research subjects by either personal check or cash. Gift cards are considered cash.
- If a cash payment is made, the PI must obtain signed receipts.
- If the total payment to an individual subject is over \$600 per calendar year, Level 3 cannot be selected.

If Confidentiality Level 2 or 3 is selected, please provide justification.

SECTION I: Deception/ Incomplete Disclosure (INSERT "NA" IF NOT APPLICABLE)

Section Notes...

• If you cannot adequately state the true purpose of the study to the subject in the informed consent, deception/ incomplete disclosure is involved.

I1. Describe (a) what information will be withheld from the subject (b) why such deception/ incomplete disclosure is necessary, and (c) when the subjects will be debriefed about the deception/ incomplete disclosure.

N/A

Instructions: Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the colored boxes or place an "X" in front of the appropriate response(s). If the question does not apply, write "N/A."

SECTION A: Title

A1. Full Study Title:

Use of real-time biofeedback to alter gait mechanics following anterior cruciate ligament reconstruction

SECTION B: Study Duration

B1. What is the expected start date? *Data collection, screening, recruitment, enrollment, or consenting activities may not begin until IRB approval has been granted. Format: 07/31/2011*

01/07/2020

B2. What is the expected end date? *Expected end date should take into account data analysis, queries, and paper write-up. Format: 07/05/2014*

07/31/2021

SECTION C: Summary

C1. Write a brief descriptive summary of this study in Layman Terms (non-technical language):

Female recreational athletes that have had an injury to their anterior cruciate ligament in their knee that required reconstruction one to four years prior to the time of the study will be recruited. All participants will walk across a force plate ten times to measure movement of the legs. Movement will be recorded via traditional motion capture cameras that detect reflective markers placed on the body at specific bony landmarks and via inertial measurement units (IMUs) placed on the lower legs. Additionally, participants will walk on a treadmill for 28 minutes while receiving biofeedback in realtime based on information from the IMUs to modify knee flexion of their injured side to match their healthy side. The result will be the comparison of gait mechanics pre- to post-biofeedback.

C2. Describe the purpose/objective and the significance of the research:

The ability to both detect subtle gait deviations in a clinical setting and to provide patients with immediate feedback on those deviations has the potential to dramatically improve rehabilitation and reduce the risk of developing knee osteoarthritis following anterior cruciate ligament reconstruction. Additionally, an inertial measurement unit has potential as a relatively inexpensive and easily usable device to achieve these goals. Therefore, the purpose of this research is to assess the use of an inertial measurement unit as a proxy for measuring knee joint mechanics and as a means of providing realtime biofeedback to increase knee flexion and internal knee extension moment in individuals that are one to four years post-anterior cruciate ligament reconstruction.

C3. Cite the most relevant literature pertaining to the proposed research:

Knee osteoarthritis is a common degenerative joint disease that can result from cyclical loading of the knee with abnormal gait mechanics and can lead to significant pain and limitations (Andriacchi & Mundermann, 2006; Cicuttini et al., 2001; Lohmander et al., 2004). While there is a high prevalence of knee osteoarthritis in elderly individuals, early onset knee osteoarthritis is becoming more prevalent in younger individuals (Lohmander et al., 2004). In fact, individuals who incur an anterior cruciate ligament injury that requires surgery to reconstruct the ligament are three to four times more likely to develop knee osteoarthritis (Lohmander et al., 2007).

Although the reconstruction is meant to improve stability of the knee and mimic the mechanics of the original ligament, it has been suggested that, following reconstruction, individuals make subtle but clinically significant changes to their gait pattern to avoid

putting stress on the reconstructed ligament (Herrington et al., 2017; Lin & Sigward, 2018). Critical changes occur during the initial contact and loading phases of the gait cycle, where decreased knee flexion, decreased internal knee extension moment, and decreased peak angular velocity of the shank moving over the ankle have been observed in the affected limb (Lin & Sigward, 2018; Sigward et al., 2016; Roewer et al., 2011). These changes have been observed during walking following surgery and extending out to four years post-surgery (Roewer et al., 2011). This indicates that these individuals are landing more stiffly and in doing so are changing the contact area of the cartilage within the knee joint, which may explain the early development of knee osteoarthritis in these individuals (Tashman et al., 2016).

While these changes are subtle enough that they are difficult to detect clinically, it is important to target these changes to restore the gait pattern to normal (Lin, 2018). Realtime biofeedback has been used to alter gait mechanics previously (Tate & Milner, 2010; Van Gelder et al., 2018). Additionally, inertial measurement units, which are small, easy to use, and relatively inexpensive, have been incorporated in biofeedback paradigms recently (Crowell et al., 2010; Wood & Kipp, 2014). As such, it is important to assess the ability to change gait mechanics via a real-time biofeedback protocol that incorporates an inertial measurement unit.

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Van Gelder, L., Barnes, A., Wheat, J. S., & Heller, B. W. (2018, /11/01). The use of biofeedback for gait retraining: A mapping review. *Clinical Biomechanics*, *59*, 159-166. doi:10.1016/j.clinbiomech.2018.09.020 Retrieved from <u>https://www-sciencedirect-com.ezproxy.lib.uwm.edu/science/article/pii/S0268003318302377</u>

Wood, C., & Kipp, K. (2014). Use of audio biofeedback to reduce tibial impact accelerations during running. *Journal of Biomechanics*, 47, 1739-1741.

SECTION D: Subject Population

Section Notes...

• D1. If this study involves analysis of de-identified data only (i.e., no human subject interaction), IRB submission/review may not be necessary. Please review the <u>UWM IRB Determination Form</u> for more details.

| D1 all | D1. Identify any population(s) that you will be <u>specifically targeting</u> for the study. Check all that apply: (Place an "X" in the column next to the name of the special population.) | | | | |
|-----------|--|--|--|--|--|
| | Existing Dataset(s)Institutionalized/ Nursing home residen recruited in the nursing home | | | | |
| X | UWM Students of PI or study staff | Diagnosable Psychological Disorder/Psychiatrically impaired | | | |
| X | UWM Students (but not of PI or study staff) | Decisionally/Cognitively Impaired | | | |
| | Non-UWM students to be recruited in their educational setting, i.e. in class or at school | Economically/Educationally Disadvantaged | | | |
| X | UWM Staff or Faculty | Prisoners | | | |
| | Pregnant Women/Neonates | International Subjects (residing outside of the US) | | | |
| | Minors under 18 and ARE NOT wards of the State | Non-English Speaking | | | |
| | Minors under 18 and ARE wards of the State | Terminally ill | | | |
| X | Community members | | | | |

D2. Describe the subject group and enter the total number to be enrolled for each group. For example: teachers-50, students-200, parents-25, student control-30, student experimental-30, medical charts-500, dataset of 1500, etc. Then enter the total number of subjects below. Be sure to account for expected drop outs. For example, if you need 100 subjects to complete the entire study, but you expect 5 people will enroll but "drop out" of the study, please enter 105 (not 100).

| Describe subject group: | Number: |
|--|---------|
| Recreationally active females with prior Anterior Cruciate Ligament Reconstruction (1 to 4 years post-surgery) | 20 |

| TOTAL # OF SUBJECTS: | 20 |
|---|----|
| TOTAL # OF SUBJECTS (If UWM is a collaborating site for a multi institutional project): | |

D3. For each subject group, list any major inclusion and exclusion criteria (e.g., age, gender, health status/condition, ethnicity, location, English speaking, etc.) and state the justification for the inclusion and exclusion criteria:

Anterior Cruciate Ligament Reconstructed Group – Biofeedback

Inclusion criteria:

- Females, ages 18 to 29
 - Females are more likely to have reconstruction surgery than males. Ages 18 to 29 represent time where injuries often occur prior to earliest possible change of early development of knee osteoarthritis
 - Females have been shown to have significantly different gait mechanics compared to males. Limiting enrollment to females will help to control for gait differences between sexes.
- Must be recreationally active
 - Physically active at least three times per week for at least 30 minutes per activity
- Must have a bone-patellar tendon-bone graft used during reconstruction
 - This is the most common graft choice and will control for the effect of graft type on gait mechanics
- Must have peak shank angular velocity during gait at least one standard deviation below that of healthy participants

• Increases in knee flexion, internal knee extension moment, and peak shank angular velocity will be evaluated and biofeedback may not alter gait for individuals within one standard deviation.

Exclusion criteria:

- Must not have had reconstruction surgery within past year or more than four years prior to inclusion in study
 - Long term effect of reconstruction on gait mechanics will be evaluated and targeted
- Must not have any current injuries to lower extremities
 - Pain and injury may alter gait mechanics
- Must not have had an injury to lower extremities in last 6 months
 - Prior injuries may affect joint mechanics of the lower extremity
- Must not have had an injury requiring anterior cruciate ligament surgery on the limb opposite the reconstructed limb of interest
 - Intact and affected limbs will be compared
- Must not be pregnant
 - Pregnancy may influence normal gait mechanics
- Must not have a medical condition that may impair walking ability (i.e. concussion, neurological impairments, etc)
 - Normal walking ability will be evaluated
- Must not be taking medications/drugs that may cause dizziness or tiredness (i.e. cold medications, sleeping medications, muscle relaxants)
 - Normal walking ability will be evaluated

SECTION E: Study Activities: Recruitment, Informed Consent, and Data Collection

Section Notes...

- Reminder, all recruitment materials, consent forms, data collection instruments, etc. should be attached for IRB review.
- The IRB welcomes the use of flowcharts and tables in the consent form for complex/ multiple study activities.

In the table below, chronologically describe all study activities where human subjects are involved.

- In <u>column A</u>, give the activity a short name. Please note that Recruitment, Screening, and consenting will be activities for almost all studies. Other activities may include: Obtaining Dataset, Records Review, Interview, Online Survey, Lab Visit 1, 4 Week Follow-Up, Debriefing, etc.
- In <u>column B</u>, describe who will be conducting the study activity and his/her training and/or qualifications to complete the activity. You may use a title (i.e. Research Assistant) rather than a specific name, but training/qualifications must still be described.
- In <u>column C</u>, describe in greater detail the activities (recruitment, screening, consent, surveys, audiotaped interviews, tasks, etc.) research participants will be engaged in. Address where, how long, and when each activity takes place.
- In <u>column D</u>, describe any possible risks (e.g., physical, psychological, social, economic, legal, etc.) the subject may *reasonably* encounter. Describe the safeguards that will be put into place to minimize possible risks (e.g., interviews are in a private location, data is anonymous, assigning pseudonyms, where data is stored, coded data, etc.) and what happens if the participant gets hurt or upset (e.g., referred to Norris Health Center, PI will stop the interview and assess, given referral, etc.).

| A. Activity Name: | B. Person(s) Conducting Activity | C. Activity Description (Please describe any forms used): | D. Activity Risks and Safeguards: |
|----------------------|--|---|--------------------------------------|
| Recruitment | Alexander Morgan – Completed IRB training, Constructed study design, PhD Student in Neuromechanics Lab | A Recruitment Flyer will be posted around the UWM campus to encourage potential participants to contact the investigator about participation. | |
| Obtaining Consent | Alexander Morgan – Completed IRB training, Constructed | Participants will be informed about the study and asked for consent to participate via the Consent Form. | |

| | study design, PhD Student in Neuromechanics Lab | | |
|-------------------------|--|--|---|
| Screening | Alexander Morgan – Completed IRB training, Constructed study design, PhD Student in Neuromechanics Lab | Participants will be given the Screening Questionnaire after they provide informed consent to determine if they are eligible for the study. Additionally, following the participant providing informed consent, the participant will have an inertial sensor attached over the shank of the affected limb using straps and adhesive tapes. They will then be asked to walk over-ground at 1.4 m/s. Five steps will be collected, and average peak shank angular velocity for all steps will be assessed. Participants will be excluded and withdrawn at this point if the average peak shank angular velocity is less than one standard deviation below that of healthy participants. The average peak shank angular velocity of healthy participants will be determined in a separate study prior to this data collection. | |
| List all other study | Alexander Morgan – | Demographic information (height, weight, age, sex, | Participants may experience minor muscle |

| activities in | Completed IRB | time since surgery) will be | soreness as a result of the |
|---------------|----------------------|------------------------------|--|
| the | training, | recorded. | biomechanics testing. |
| following | Constructed | | Participants may suffer |
| rows | study design, | | musculoskeletal injury |
| | PhD Student in | Participants will fill out | such as muscle strain or |
| | Neuromechanics | the Tampa Scale to assess | ankle sprain as a result of |
| | Lab | kinesiophobia and the | the biomechanics testing. |
| | | Visual Analog Scale to | Participants may also |
| | | assess pain prior to and | experience minor skin |
| | | following gait analysis. | irritation due to the |
| | | | adhesive (very unlikely). |
| | | | There are no anticipated |
| | | Special retro-reflective | psychosocial or privacy |
| | | markers will be applied to | risks due to participation |
| | | the participant's pelvis, | in the study. Because |
| | | thigh, shank and foot | participants are required |
| | | using straps and adhesive | to be physically active |
| | | tapes. Inertial sensors will | they will be accustomed to |
| | | be attached to the | the type of activity |
| | | participant's shanks using | performed during the |
| | | straps and adhesive tapes. | testing sessions. First-ald |
| | | | medical treatment will be |
| | | | provided in the unlikely |
| | | Participants will be asked | event of physical injury |
| | | to perform three, five | norticipation in this |
| | | second maximal voluntary | participation in this project. In case of basic |
| | | contractions of the | first-aid all research |
| | | quadriceps and | nersonnel involved are |
| | | namstrings of both limbs | trained in basic first-aid |
| | | table to access strength | and CPR and will provide |
| | | table to assess strength. | appropriate care. In the |
| | | nrovided after each | event that some |
| | | contraction | emergency treatment may |
| | | contraction. | be necessary, 911 will be |
| | | | called as a standard |
| | | Particinants will be asked | operation procedure and |
| | | to walk over a force nlate | the subject will be |
| | | at 1.4 m/s. Ten trials in | individually responsible |
| | | which one foot completely | for the cost(s) associated |
| | | strikes the force plate (5 | with that treatment. If |
| | | for the left and 5 for the | this event is unexpected, a |
| | | right foot) will be | |
| | | 0 | |

| | collected. The force plate | full report will be |
|--|-----------------------------|-----------------------|
| | will record force data, a | submitted to the IRB. |
| | motion-capture camera | |
| | system will track three- | |
| | dimensional position data | |
| | of retro-reflective markers | |
| | on the body, and inertial | |
| | measurement units will | |
| | track angular velocity of | |
| | the shank in the societal | |
| | nlene | |
| | plane. | |
| | | |
| | Danticin and a will than he | |
| | Participants will then be | |
| | asked to walk on a | |
| | treadmill for 28 minutes | |
| | at 1.4 m/s. Participants | |
| | will first walk for three | |
| | minutes to become | |
| | accustomed to the walking | |
| | speed. Participants will | |
| | then walk for ten minutes | |
| | while receiving audio | |
| | biofeedback from a | |
| | speaker placed in front of | |
| | them. The audio | |
| | biofeedback will consist of | |
| | the low-pitched chime that | |
| | will sound if the peak | |
| | shank angular velocity | |
| | from the inertial | |
| | measurement unit on the | |
| | affected limb is within a | |
| | +/- 10% range of the | |
| | angular velocity of the | |
| | intact limb. A high- | |
| | pitched chime will sound | |
| | if the peak angular | |
| | velocity is above the +/- | |
| | 10% range, and no sound | |
| | will be heard if this | |
| | variable is below the +/- | |
| | 10% range. Participants | |

| will be instructed to maintain the low-pitched chime by flexing the knee more during walking. Participants will then walk on the treadmill for five minutes with no biofeedback, five minutes with the same biofeedback, and five minutes with no biofeedback. | |
|---|--|
| Measurement Equipment Force plate: Name: FP4060-NC Manufacturer: Bertec Corporation Safety: The force plate is embedded into to a platform. The platform is the ground level. | |
| Multi-Camera-System: Name: Cortex Motion Capture Manufacturer: Motion Analysis, Inc. Safety: The camera is not in physical contact with the participant | |

| Inertial Measurement Unit Name: Shimmer3 IMU Manufacturer: Shimmer Safety: The inertial measurement unit will not affect participant movement | |
|--|--|
| Timing Gates: Name: Timer model 54035A Manufacturer: Lafayette Instrument Company Safety: The timing gates are not in physical contact with the participant | |
| Handheld Dynamometer: • Name: Manual muscle tester model 01165 • Manufacturer: Lafayette Instrument Company • Safety: The handheld | |

| dynamometer will not affect participant | |
|---|--|
| Treadmill: | |
| Name: Precor USA C964i Treadmill Manufacturer: Precor Inc. Safety: Participants will be provided time to become accustomed to walking on the treadmill. A safety switch will be attached to the participant to ensure the treadmill stops in case of fall | |
| (unlikely). Other: • 10-mm diameter retro reflective markers • Safety: The retro | |
| reflective markers will not affect participant | |

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E2. Explain how the data will be analyzed or studied (i.e. quantitatively or qualitatively) and how the data will be reported (i.e. aggregated, anonymously, pseudonyms for participants, etc.):

Three-dimensional kinematic and kinetic data, along with inertial measurement unit data, will be collected during each walking trial and at the beginning and end of each biofeedback segment during treadmill walking. Maximal strength data will be measured as the largest force value for each limb, for both the quadriceps and hamstrings. The quantitative data will be processed to represent joint angles and moments, segment angular velocities, and handheld dynamometer forces. The mean, maximum, minimum and standard deviation of the joint angles and moments, and segment angular velocities, will be determined for each measurement. Comparisons will be made pre- to postbiofeedback using dependent t-tests. All data will be presented in aggregate form.

SECTION F: Data Security and Confidentiality

Section Notes...

• Please read the <u>IRB Guidance Document on Data Confidentiality</u> for more details and recommendations about data security and confidentiality.

F1. Explain how study data/responses will be stored in relation to any identifying information (name, birthdate, address, IP address, etc.)? Check all that apply.

[__] Identifiable - Identifiers are collected and stored with study data.

[__] Coded - Identifiers are collected and stored separately from study data, but a key exists to link data to identifiable information.

[X] De-identified - Identifiers are collected and stored separately from study data without the possibility of linking to data.

[__] Anonymous - No identifying information is collected.

If more than one method is used, explain which method is used for which data.

F2. Will any recordings (audio/video/photos) be done as part of the study?

[__] Yes

[X] No [SKIP THIS SECTION]

If yes, explain what activities will be recorded and what recording method(s) will be used. Will the recordings be used in publications or presentations?

F3. In the table below, describe the data storage and security measures in place to prevent a breach of confidentiality.

| A. Type of Data | B. Storage Location | C. Security Measures | D. Who will have access | E. Estimated date of disposal |
|---|----------------------------|-----------------------------|----------------------------|--|
| Demographic Information, Tampa Scale, and Visual Analog Scale | File cabinet in END 132 | File cabinet will be locked | Alexander Morgan | 7/1/2021 |

| Kinematic, Kinetic and Inertial Measurement Unit Data | Desktop computer in END 132 | Folder is password protected | Alexander Morgan | 7/1/2021 |
|---|-----------------------------------|---------------------------------|---------------------|----------|
| | | | | |

F4. Will data be retained for uses beyond this study? If so, please explain and notify participants in the consent form.

No

SECTION G: Benefits and Risk/Benefit Analysis

Section Notes...

• Do not include Incentives/ Compensations in this section.

G1. Describe any benefits to the individual participants. If there are no anticipated benefits to the subject directly, state so. Describe potential benefits to society (i.e., further knowledge to the area of study) or a specific group of individuals (i.e., teachers, foster children).

There are no direct anticipated benefits to the subjects participating in this study. However, clinicians will benefit from the findings in that a simple and cost-effective means of altering subtle but clinically significant changes in gait mechanics post-anterior cruciate ligament reconstruction could be established. As a result, a great number of individuals who may require anterior cruciate ligament reconstruction will benefit from the use of such a system in rehabilitation protocols. The risks associated with participation in this study are minimal compared to the potential benefits.

G2. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of how the anticipated risks to participants and steps taken to minimize these risks (as described in Section E), balance against anticipated benefits to the individual or to society.

The risks to participants are minimal. Patients will be informed that they may discontinue their participation within this study at any time. Participants may experience minor muscle soreness as a result of the biomechanics testing. Participants may suffer musculoskeletal injury such as muscle strain or ankle sprain as a result of the biomechanics testing. Participants may also experience minor skin irritation due to the adhesive (very unlikely). There are no anticipated psychosocial or privacy risks due to participation in the study. Because participants will be accustomed to walking regularly they will not have difficulty with participating in this study. First-aid medical treatment will be provided in the unlikely event of physical injury resulting from participation in this project. In case of basic first-aid, all research personnel involved are trained in basic first-aid and CPR and will provide appropriate care. In the event that some emergency treatment may be necessary, 911 will be called as a standard operation procedure and the subject will be individually responsible for the cost(s) associated with that treatment. If this event is unexpected, a full report will be submitted to the IRB.

SECTION H: Subject Incentives/ Compensations

Section Notes...

- H2 & H3. The IRB recognizes the potential for undue influence and coercion when extra credit is offered. The UWM IRB, as also recommended by OHRP and APA Code of Ethics, agrees when extra credit is offered or required, prospective subjects must be given the choice of an equitable, non-research alternative. The extra credit value and the non-research alternative must be described in the recruitment material and the consent form.
- H4. If you intend to submit to Accounts Payable for reimbursement purposes make sure you understand the UWM "Payments to Research Subjects" Procedure 2.4.6 and what each level of payment confidentiality means <u>(click here for additional information)</u>.

H1. Does this study involve incentives or compensation to the subjects? For example cash, class extra credit, gift cards, or items.

[X] Yes [__] No [SKIP THIS SECTION]

H2. Explain what (a) the item is, (b) the amount or approximate value of the item, and (c) when it will be given. For extra credit, state the number of credit hours and/or points. (e.g.,

\$5 after completing each survey, subject will receive [item] even if they do not complete the procedure, extra credit will be award at the end of the semester):

The incentive will be a \$20 gift card for each participant. This will be provided only upon completion of the experimental protocol and will not be provided if the participant is withdrawn during the screening phase.

H3. If extra credit is offered as compensation/incentive, please describe the specific alternative activity which will be offered. The alternative activity should be similar in the amount of time involved to complete and worth the same number of extra credit points/hours. Other research studies can be offered as additional alternatives, but a non-research alternative is required.

| N/A | |
|-----|--|
| | |
| | |
| | |

H4. If cash or gift cards, select the appropriate confidentiality level for payments (see section notes):

[X] Level 1 indicates that confidentiality of the subjects is not a serious issue, e.g., providing a social security number or other identifying information for payment would not pose a serious risk to subjects.

- For payments over \$50, choosing Level 1 requires the researcher to collect and maintain a record of the following: The payee's name, address, and social security number, the amount paid, and signature indicating receipt of payment (for cash or gift cards).
- When Level 1 is selected, a formal notice is not issued by the IRB and the Account Payable assumes Level 1.
- Level 1 payment information will be retained in the extramural account folder at UWM/Research Services and attached to the voucher in Accounts Payable. These are public documents, potentially open to public review.

[__] Level 2 indicates that confidentiality is an issue, but is not paramount to the study, e.g., the participant will be involved in a study researching sensitive, yet not illegal issues.

 Choosing a Level 2 requires the researcher to maintain a record of the following: The payee's name, address, and social security number, the amount paid, and signature indicating receipt of payment (for cash or gift cards).

- When Level 2 is selected, a formal notice will be issued by the IRB.
- Level 2 payment information, including the names, are attached to the PIR and become part of the voucher in Accounts Payable. The records retained by Accounts Payable are not considered public record.

[__] Level 3 indicates that confidentiality of the subjects must be guaranteed. In this category, identifying information such as a social security number would put a subject at increased risk.

- Choosing a Level 3 requires the researcher to maintain a record of the following: research subject's name and corresponding coded identification. This will be the only record of payee names, and it will stay in the control of the PI.
- Payments are made to the research subjects by either personal check or cash. Gift cards are considered cash.
- If a cash payment is made, the PI must obtain signed receipts.
- If the total payment to an individual subject is over \$600 per calendar year, Level 3 cannot be selected.

If Confidentiality Level 2 or 3 is selected, please provide justification.

SECTION I: Deception/ Incomplete Disclosure (INSERT "NA" IF NOT APPLICABLE)

Section Notes...

• If you cannot adequately state the true purpose of the study to the subject in the informed consent, deception/ incomplete disclosure is involved.

I1. Describe (a) what information will be withheld from the subject (b) why such deception/ incomplete disclosure is necessary, and (c) when the subjects will be debriefed about the deception/ incomplete disclosure.

| N/A | | | |
|-----|------|------|--|
| | | | |

Appendix C: Recruitment Flyers

PARTICIPANTS NEEDED FOR RESEARCH STUDY

Title: Use of wearable technology to detect subtle gait asymmetries following anterior cruciate ligament reconstruction

Purpose: We want to study the ways in which healthy individuals walk compared to individuals who have had surgery to the anterior cruciate ligament in their knee.

Where Will This Take Place?

Enderis Hall – Room 132

Who Can Participate?

- Women, ages 18 to 29
- Must be recreationally active (at least three times a week)
- Must not have any current knee injuries
- Must not have had any knee injuries in the last 6 months
- Must not have had a knee injury requiring surgical repair
- Must not be pregnant
- Must not be taking medications/drugs that will impact ability to walk

What Does This Study Involve?

- One testing session (1 hour long)
 - o Filling out a questionnaire and surveys
 - o Testing leg muscle strength
 - o Walk across the lab multiple times while wearing special sensors to track movement

Compensation

\$20 Gift Card

To volunteer or in case of questions, please contact:

Alex Morgan University of Wisconsin-Milwaukee morgan28@uwm.edu (414) 491-1740

This research project has been approved by the University of Wisconsin-Milwaukee Institutional Review Board

| Alex Morgan |
|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| morgan28@uwm.edu |

PARTICIPANTS NEEDED FOR RESEARCH STUDY

Title: Use of wearable technology to detect subtle gait asymmetries following anterior cruciate ligament reconstruction

Purpose: We want to study the ways in which individuals with an anterior cruciate ligament reconstruction walk compared to healthy individuals.

Where Will This Take Place?

Enderis Hall – Room 132

Who Can Participate?

- Women, ages 18 to 29
- <u>Must have had an anterior cruciate ligament reconstruction between 1 to 4 years prior to</u> participation in the study

Must have had a bone-patellar tendon-bone graft

- Must be recreationally active (at least three times per week)
- Must not have any current knee injuries
- Must not have had any knee injuries in the last 6 months
- Must not have had a knee injury requiring surgical repair to the opposite knee
- Must not be pregnant
- · Must not be taking medications/drugs that will impact ability to jump and land

What Does This Study Involve?

- One testing session (1 hour long)
 - o Filling out a questionnaire and surveys
 - o Testing leg muscle strength
 - o Walk across the lab multiple times while wearing special sensors to track movement

Compensation

\$20 Gift Card

To volunteer or in case of questions, please contact:

Alex Morgan

University of Wisconsin-Milwaukee morgan28@uwm.edu (414) 491-1740



College of Health Sciences Department of Kinesiology

This research project has been approved by the University of Wisconsin-Milwaukee Institutional Review Board

PARTICIPANTS NEEDED FOR RESEARCH STUDY

Title: Use of real-time biofeedback to alter gait mechanics following anterior cruciate ligament reconstruction

Purpose: We want to study the ways in which wearable technology in combination with gait biofeedback can change the way individuals with an anterior cruciate ligament reconstruction walk.

Where Will This Take Place?

Enderis Hall – Room 132

Who Can Participate?

- Women, ages 18 to 29
- <u>Must have had an anterior cruciate ligament reconstruction between 1 to 4 years prior to</u> participation in the study
 - <u>Must have had a bone-patellar tendon-bone graft</u>
- Must be recreationally active (at least three times per week)
- Must not have any current knee injuries
- Must not have had any knee injuries in the last 6 months
- Must not have had a knee injury requiring surgical repair to the opposite knee
- Must not be pregnant
- Must not be taking medications/drugs that will impact ability to jump and land

What Does This Study Involve?

- One testing session (1 hour and 40 minutes long)
 - o Filling out a questionnaire and surveys
 - Testing leg muscle strength
 - o Walk across the lab multiple times while wearing special sensors to track movement
 - Walk on a treadmill while listening to beeping sounds from a speaker that will help direct you to change your walking style

Compensation

\$20 Gift Card

To volunteer or in case of questions, please contact:

Alex Morgan University of Wisconsin-Milwaukee morgan28@uwm.edu (414) 491-1740

This research project has been approved by the University of Wisconsin-Milwaukee Institutional Review Board

| Alex Morgan |
|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| morgan28@uwm.edu |

Appendix D: Consent Forms



Informed Consent for Research Participation IRB #: 20.117 IRB Approval Date: March 3, 2020

| Study title | Use of wearable technology to detect subtle gait asymmetries following anterior |
|-------------|---|
| - | cruciate ligament reconstruction |
| Researcher | Alexander Morgan, PhD student in the Department of Kinesiology |

We're inviting you to participate in a research study. Participation is completely voluntary. If you agree to participate now, you can always change your mind later. There are no negative consequences, whatever you decide.

What is the purpose of this study?

We want to study the ways in which healthy individuals walk compared to individuals who have had surgery to the anterior cruciate ligament in their knee. What will I do? In our lab:

- You'll complete a screening questionnaire to determine your eligibility for this study. (5 minutes)
- You'll complete a questionnaire about your demographics and your health history. (5 minutes)
- · We'll measure your height and weight. (5 minutes)
- · You'll be asked to put on tight-fitting shorts, which will be provided (5 minutes)
- You'll complete two surveys about any pain or discomfort with movement that you may be experiencing (5 minutes)
- We'll measure the strength of your leg muscles (10 minutes)
- We'll place special sensors on top of your skin and clothes and will measure how you walk using these sensors (25 minutes)

Risks

| Possible risks | How we're minimizing these risks |
|---|---|
| Breach of confidentiality (your data being seen by someone who shouldn't have access to it) | All identifying information is removed and replaced with a study ID. We'll store all electronic data on a password-protected, encrypted computer. We'll store all paper data in a locked filing cabinet in a locked office. |
| Minor muscle soreness, muscle strain, or ligament strain (Unlikely) | We will not be asking you perform activities beyond your normal day-to-day walking Practice trials will be performed to allow you to become familiar with the protocol We'll provide first-aid medical treatment in the unlikely event of physical injury Students will be referred to the Norris Health Center for follow-up care. Non-students will be referred to their primary care physician and will be responsible for all expenses incurred. |
| Minor skin irritation (Unlikely) | If you feel any irritation while participating, please tell the investigators as soon as possible Students will be referred to the Norris Health Center for follow-up care. Non-students will be referred to their primary care physician and will be responsible for all expenses incurred. |



There may be risks we don't know about yet. Throughout the study, we'll tell you if we learn anything that might affect your decision to participate.

Other Study Information

| Possible benefits | Clinicians may benefit from a simple and cost-effective way to assess differences in how people walk after anterior cruciate ligament reconstruction Patients may benefit from rehabilitation systems based on this information as well. |
|----------------------------------|---|
| Estimated number of participants | 25 healthy, recreationally active females (18-29 years old) |
| | 25 recreationally active females with anterior cruciate ligament reconstruction 1 to 4 years prior to the study (18-29 years old) |
| How long will it take? | One hour |
| Costs | On campus parking |
| Compensation | \$20 gift card upon completion of the study |
| | Due to UWM policy and IRS regulations, we may have to collect |
| | your name, address, social security / tax ID number, and |
| | signature to give you this compensation. |
| Future research | Your data won't be used or shared for any future research studies. |
| Funding source | Department of Kinesiology |

What if I am harmed because I was in this study?

If you're harmed from being in this study, let us know. If it's an emergency, get help from 911 or your doctor right away and tell us afterward. We can help you find resources if you need psychological help. You or your insurance will have to pay for all costs of any treatment you need.

Confidentiality and Data Security

We'll collect the following identifying information for the research: your name and address. This information is necessary so that you can receive compensation for completing the study.

| Where will data be stored? | ? Electronic data will be stored on a desktop computer in END 132, | | |
|----------------------------|--|--|--|
| | which will be password protected. Data collected on paper will be | | |
| | stored in a file cabinet in END 132, which will be locked. | | |
| How long will it be kept? | Until July 1st, 2021 | | |

| Who can see my data? | Why? | Type of data |
|----------------------|----------------------------------|----------------------------------|
| The researchers | To conduct the study and analyze | Coded data including height, |
| | the data | weight, muscle strength, and |
| | | walking data (names will be |
| | | removed and labeled with a study |
| | | ID) |



Informed Consent for Research Participation IRB #: 20.117 IRB Approval Date: March 3, 2020

| The IRB (Institutional Review Board) at UWM | To ensure we're following laws and ethical guidelines | Coded data including height, weight, muscle strength, and |
|--|--|--|
| The Office for Human Research Protections (OHRP) or other federal agencies | | walking data (names will be removed and labeled with a study ID) |
| Anyone (public) | If we share our findings in publications or presentations | Aggregate (grouped) data |

Contact information:

| For questions about the research | PI: Dr. Kristian O'Connor | 414-229-6080 / krisocon@uwm.edu |
|----------------------------------|--------------------------------------|---------------------------------|
| | SPI: Alexander Morgan | 414-491-1740 / morgan28@uwm.edu |
| For questions about your rights | IRB (Institutional Review | 414-229-3173 / irbinfo@uwm.edu |
| as a research participant | Board; provides ethics oversight) | |
| For complaints or problems | PI: Dr. Kristian O'Connor | 414-229-6080 / krisocon@uwm.edu |
| | SPI: Alexander Morgan | 414-491-1740 / morgan28@uwm.edu |
| | IRB | 414-229-3173 / irbinfo@uwm.edu |

Signatures

If you have had all your questions answered and would like to participate in this study, sign on the lines below. Remember, your participation is completely voluntary, and you're free to withdraw from the study at any time.

Name of Participant (print)

Signature of Participant

Date

Name of Researcher obtaining consent (print)

Signature of Researcher obtaining consent

Date



Informed Consent for Research Participation IRB #: 20.116 IRB Approval Date: January 7, 2020

| Study title | Use of real-time biofeedback to alter gait mechanics following anterior cruciate |
|-------------|--|
| Researcher | Alexander Morgan, PhD student in the Department of Kinesiology |

We're inviting you to participate in a research study. Participation is completely voluntary. If you agree to participate now, you can always change your mind later. There are no negative consequences, whatever you decide.

What is the purpose of this study?

We want to study the ways in which wearable technology in combination with gait biofeedback can change the way individuals with an anterior cruciate ligament reconstruction walk.

What will I do?

In our lab:

- You'll complete a screening questionnaire to determine your eligibility for this study. (5 minutes)
- · You'll be asked to put on tight-fitting shorts, which will be provided (5 minutes)
- You'll be asked to walk briefly across the laboratory with a special sensor placed on top of the leg that
 was surgically repaired to further determine your eligibility for this study. (5 minutes).
- · You'll complete a questionnaire about your demographics and your health history. (5 minutes)
- We'll measure your height and weight. (5 minutes)
- You'll complete two surveys about any pain or discomfort with movement that you may be experiencing (5 minutes)
- We'll measure the strength of your leg muscles (10 minutes)
- We'll place special sensors on top of your skin and clothes and will measure how you walk using these sensors (35 minutes)
- You'll be asked to walk on a treadmill. You will be listening to beeping sounds from a speaker that will help direct you to change your walking style (30 minutes)

Risks

| Possible risks | How we're minimizing these risks |
|---------------------------------------|--|
| Breach of confidentiality (your data | All identifying information is removed and replaced with a study ID. |
| being seen by someone who | We'll store all electronic data on a password-protected, encrypted |
| shouldn't have access to it) | computer. |
| | We'll store all paper data in a locked filing cabinet in a locked |
| | office. |
| Minor muscle soreness, muscle | We will not be asking you perform activities beyond your normal |
| strain, or ligament strain (Unlikely) | day-to-day walking |
| | Practice trials will be performed to allow you to become familiar |
| | with the protocol |
| | We'll provide first-aid medical treatment in the unlikely event of |
| | physical injury |
| | Students will be referred to the Norris Health Center for follow-up |
| | care. Non-students will be referred to their primary care physician |
| | and will be responsible for all expenses incurred. |



| Minor skin irritation (Unlikely) | If you feel any irritation while participating, please tell the investigators as soon as possible Students will be referred to the Norris Health Center for follow-up care. Non-students will be referred to their primary care physician |
|----------------------------------|--|
| | and will be responsible for all expenses incurred. |

There may be risks we don't know about yet. Throughout the study, we'll tell you if we learn anything that might affect your decision to participate.

Other Study Information

| Possible benefits | Clinicians may benefit from a simple and cost-effective way to change how people walk after anterior cruciate ligament reconstruction Patients may benefit from rehabilitation systems based on this information as well. |
|----------------------------------|--|
| Estimated number of participants | 25 recreationally active females with anterior cruciate ligament |
| | reconstruction 1 to 4 years prior to the study (18-29 years old) |
| How long will it take? | One hour and 40 minutes |
| Costs | On campus parking |
| Compensation | \$20 gift card upon completion of the study |
| | Due to UWM policy and IRS regulations, we may have to collect |
| | your name, address, social security / tax ID number, and |
| | signature to give you this compensation. |
| Future research | Your data won't be used or shared for any future research studies. |
| Funding source | Department of Kinesiology |

What if I am harmed because I was in this study?

If you're harmed from being in this study, let us know. If it's an emergency, get help from 911 or your doctor right away and tell us afterward. We can help you find resources if you need psychological help. You or your insurance will have to pay for all costs of any treatment you need.

Confidentiality and Data Security

We'll collect the following identifying information for the research: your name and address. This information is necessary so that you can receive compensation for completing the study.

| Where will data be stored? | Electronic data will be stored on a desktop computer in END 132, | |
|----------------------------|---|--|
| | which will be password protected. Data collected on paper will be | |
| | stored in a file cabinet in END 132, which will be locked. | |
| How long will it be kept? | Until July 1st, 2021 | |

| Who can see my data? | Why? | Type of data |
|----------------------|----------------------------------|------------------------------|
| The researchers | To conduct the study and analyze | Coded data including height, |
| | the data | weight, muscle strength, and |



Informed Consent for Research Participation IRB #: 20.116 IRB Approval Date: January 7, 2020

| | | walking data (names will be removed and labeled with a study ID) |
|--|--|--|
| The IRB (Institutional Review Board) at UWM The Office for Human Research Protections (OHRP) or other federal agencies | To ensure we're following laws and ethical guidelines | Coded data including height, weight, muscle strength, and walking data (names will be removed and labeled with a study ID) |
| Anyone (public) | If we share our findings in publications or presentations | Aggregate (grouped) data |

Contact information:

| For questions about the research | PI: Dr. Kristian O'Connor | 414-229-6080 / krisocon@uwm.edu |
|----------------------------------|--------------------------------------|---------------------------------|
| | SPI: Alexander Morgan | 414-491-1740 / morgan28@uwm.edu |
| For questions about your rights | IRB (Institutional Review | 414-229-3173 / irbinfo@uwm.edu |
| as a research participant | Board; provides ethics oversight) | |
| For complaints or problems | PI: Dr. Kristian O'Connor | 414-229-6080 / krisocon@uwm.edu |
| | SPI: Alexander Morgan | 414-491-1740 / morgan28@uwm.edu |
| | IRB | 414-229-3173 / irbinfo@uwm.edu |

Signatures

If you have had all your questions answered and would like to participate in this study, sign on the lines below. Remember, your participation is completely voluntary, and you're free to withdraw from the study at any time.

Name of Participant (print)

Signature of Participant

Name of Researcher obtaining consent (print)

Signature of Researcher obtaining consent

Date

Date

Appendix E: Questionnaires and Forms

Approval Date: March 3, 2020

| Participant | Code: | |
|-------------|-------|--|
| Date: | | |

Screening Questionnaire (Healthy Group)

<u>Screening Criteria</u> Please answer the following questions to the best of your ability. Eligible participants will answer "yes" to these questions.

| 🔲 Yes 🔲 No | Are you between the ages of 18 and 29 years old? |
|------------|---|
| 🔲 Yes 🔲 No | Do you engage in physical activity at least three times per week, for at least 30 minutes each? |

For your safety, a list of conditions that would make you unable to participate in this study has been prepared. Please read this list carefully and consider whether any of the conditions apply to you. If any of these conditions are true for you, you will not be able to participate in this study. For each condition, please indicate "yes" or "no" if this is true or not for you.

| 🔲 Yes 🔲 No | Do you have a medical condition that may impair your walking ability (i.e. concussion, neurological impairments, orthopedic problems_etc)? |
|------------|---|
| 🔲 Yes 🔲 No | Are you taking medications/drugs that may make you dizzy or make you tired (i.e. cold medications, sleeping medications, muscle relaxants)? |
| 🔲 Yes 🔲 No | Do you <u>currently</u> have any lower extremity pain or injury(ies)? |
| 🔲 Yes 🔲 No | Have you had any lower extremity injuries in the <u>last 6 months</u> ? |
| 🔲 Yes 🔲 No | Have you <u>previously</u> had any lower extremity injury(jes) that required surgery? |
| 🔲 Yes 🔲 No | Are you pregnant or do you have reason to believe that you may be pregnant? |

Comments/Notes:

Screening Questionnaire (Anterior Cruciate Ligament Reconstruction Group)

Screening Criteria

Please answer the following questions to the best of your ability. Eligible participants will answer "yes" to these questions.

| 🔲 Yes 🔲 No | Are you between the ages of 18 and 29 years old? |
|------------|---|
| 🔲 Yes 🔲 No | Do you engage in physical activity at least three times per week, for at least 30 minutes each? |
| 🔲 Yes 🔲 No | Was a bone-patellar tendon-bone graft used during your anterior cruciate ligament reconstruction? |
| 🔲 Yes 🔲 No | Did your reconstruction surgery occur between one to four years prior to today's date? |
| 🔲 Yes 🔲 No | Is the knee opposite your reconstructed knee "healthy" (no previous surgery on this opposite knee)? |

For your safety, a list of conditions that would make you unable to participate in this study has been prepared. Please read this list carefully and consider whether any of the conditions apply to you. If any of these conditions are true for you, you will not be able to participate in this study. For each condition, please indicate "yes" or "no" if this is true or not for you.

| 🔲 Yes 🔲 No | Do you have a medical condition that may impair your walking ability (i.e. concussion, neurological impairments, orthopedic <u>problems_etc</u>)? |
|------------|--|
| 🔲 Yes 🔲 No | Are you taking medications/drugs that may make you dizzy or make you tired (i.e. cold medications, sleeping medications, muscle relaxants)? |
| 🔲 Yes 🔲 No | Do you <u>currently</u> have any lower extremity pain or injury(ies)? |
| 🔲 Yes 🔲 No | Have you had any lower extremity injuries in the <u>last 6 months</u> ? |
| 🔲 Yes 🔲 No | Are you pregnant or do you have reason to believe that you may be pregnant? |

Comments/Notes:

IRB#: 20.117 Approval Date: March 3. 2020 Participant Code: _____ Date: _____

Demographic and Physical Activity Questionnaire (Healthy Group)

<u>Demographic Questionnaire</u> Please answer the following questions to the best of your ability.

Age: Gender: ______ Height: _____ Weight: _____ If you were to kick a soccer ball, which leg would you kick with? (Determines dominant leg):

What activities do you perform for physical activity, and how often per week (ex: days per week, hours per day)?

Comments/Notes:
IRB#: 20.117 Approval Date: January 7, 2020 Participant Code: _____ Date:

Demographic, Injury/Surgery History & Physical Activity Questionnaire (Anterior Cruciate Ligament Reconstruction Group)

<u>Demographic & Physical Activity Questionnaire</u> Please answer the following questions to the best of your ability.

Age: Gender: ______ Height: ______ Weight: ______ If you were to kick a soccer ball, which leg would you kick with? (Determines dominant leg): Which knee was reconstruction surgery performed on? ______ What was the date of your reconstruction surgery? How was your knee injured? (Sport, contact vs. non-contact, etc.)

Did you play any sports prior to your reconstruction? If so, which?

Do you currently play any sports? If so, which?

What activities do you perform for physical activity, and how often per week (ex: days per week, hours per day)?

Comments/Notes:

Screening Questionnaire (Anterior Cruciate Ligament Reconstruction Group)

Screening Criteria

Please answer the following questions to the best of your ability. Eligible participants will answer "yes" to these questions.

| 🔲 Yes 🔲 No | Are you between the ages of 18 and 29 years old? |
|------------|---|
| 🔲 Yes 🔲 No | Do you engage in physical activity at least three times per week, for at least 30 minutes each? |
| 🔲 Yes 🔲 No | Was a bone-patellar tendon-bone graft used during your anterior cruciate ligament reconstruction? |
| 🔲 Yes 🔲 No | Did your reconstruction surgery occur between one to three years prior to today's date? |
| 🔲 Yes 🔲 No | Is the knee opposite your reconstructed knee "healthy" (no previous surgery on this opposite knee)? |

For your safety, a list of conditions that would make you unable to participate in this study has been prepared. Please read this list carefully and consider whether any of the conditions apply to you. If any of these conditions are true for you, you will not be able to participate in this study. For each condition, please indicate "yes" or "no" if this is true or not for you.

| 🔲 Yes 🔲 No | Do you have a medical condition that may impair your walking ability (i.e. concussion, neurological impairments, orthopedic problems_etc)? |
|------------|---|
| 🔲 Yes 🔲 No | Are you taking medications/drugs that may make you dizzy or make you tired (i.e. cold medications, sleeping medications, muscle relaxants)? |
| 🔲 Yes 🔲 No | Do you <u>currently</u> have any lower extremity pain or injury(ies)? |
| 🔲 Yes 🔲 No | Have you had any lower extremity injuries in the <u>last 6 months</u> ? |
| 🔲 Yes 🔲 No | Are you pregnant or do you have reason to believe that you may be pregnant? |

Comments/Notes:

IRB#: 20.116 Approval Date: January 7, 2020

Demographic, Injury/Surgery History & Physical Activity Questionnaire (Anterior Cruciate Ligament Reconstruction Group)

Demographic & Physical Activity Questionnaire Please answer the following questions to the best of your ability.

Age: Gender: ______ Height: ______ Weight: ______ If you were to kick a soccer ball, which leg would you kick with? (Determines dominant leg): Which knee was reconstruction surgery performed on? ______ What was the date of your reconstruction surgery? How was your knee injured? (Sport, contact vs. non-contact, etc.)

Did you play any sports prior to your reconstruction? If so, which?

Do you currently play any sports? If so, which?

What activities do you perform for physical activity, and how often per week (ex: days per week, hours per day)?

Comments/Notes:

Tampa Scale for Kinesiophobia (Miller, Kori and Todd 1991)

1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

| 1. I'm afraid that I might injury myself if I exercise | 1 | 2 | 3 | 4 |
|--|---|---|---|---|
| If I were to try to overcome it, my pain would increase | 1 | 2 | 3 | 4 |
| My body is telling me I have something dangerously wrong | 1 | 2 | 3 | 4 |
| My pain would probably be relieved if I were to exercise | 1 | 2 | 3 | 4 |
| People aren't taking my medical condition seriously enough | 1 | 2 | 3 | 4 |
| My accident has put my body at risk for the rest of my life | 1 | 2 | 3 | 4 |
| 7. Pain always means I have injured my body | 1 | 2 | 3 | 4 |
| Just because something aggravates my pain does not mean it is dangerous | 1 | 2 | 3 | 4 |
| I am afraid that I might injure myself accidentally | 1 | 2 | 3 | 4 |
| Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening | 1 | 2 | 3 | 4 |
| I wouldn't have this much pain if there weren't something potentially dangerous going on in my body | 1 | 2 | 3 | 4 |
| Although my condition is painful, I would be better off if I were physically active | 1 | 2 | 3 | 4 |
| Pain lets me know when to stop exercising so that I don't injure myself | 1 | 2 | 3 | 4 |
| 14. It's really not safe for a person with a condition like mine to be physically active | 1 | 2 | 3 | 4 |
| 15. I can't do all the things normal people do because it's too easy for me to get injured | 1 | 2 | 3 | 4 |
| Even though something is causing me a lot of pain, I don't think it's actually dangerous | 1 | 2 | 3 | 4 |
| No one should have to exercise when he/she is in pain | 1 | 2 | 3 | 4 |

Visual Analog Scale

Pre-Walking

No Pain

Pain As Bad As It Could Possibly Be

Post-Walking

No Pain As F

Pain As Bad As It Could Possibly Be Pre-Biofeedback

No Pain

Pain As Bad As It Could Possibly Be

Post-Biofeedback

No Pain

Pain As Bad As It Could Possibly Be

Curriculum Vitae

Education

| (Expected August 2020) | Ph.D. University of | Wisconsin-Milwaukee, Milwaukee, WI |
|----------------------------|------------------------|---------------------------------------|
| Kinesiology (Biomecl | hanics Emphasis) | |
| Advisor: Dr. Kristian | O'Connor, PhD | |
| August 2015 | M.S. | Marquette University, Milwaukee, WI |
| Clinical and Translati | onal Rehabilitation He | alth Sciences (Biomechanics Emphasis) |
| Advisor: Dr. Kristof H | Kipp, PhD, CSCS | |
| May 2014 | B.S. | Marquette University, Milwaukee, WI |
| Biomedical Sciences | | |

Teaching Experience

University of Wisconsin-Milwaukee

| Primary Course Instructor (Summe | r 2017) |
|----------------------------------|--|
| Kinesiology 320 | Biomechanics |
| Teaching Assistant | |
| Kinesiology 200 | Introduction to Kinesiology |
| Spring 2019, | Fall 2016, Spring 2017, Fall 2017, Fall 2018, Fall 2019 |
| Kinesiology 230 | Health Aspects of Exercise and Nutrition |
| | Spring 2018 |
| Kinesiology 320 | Biomechanics |
| | Fall 2016, Spring 2017, Spring 2018, Summer 2018, Fall 2018, Spring 2019, Summer 2019, Spring 2020 |
| Kinesiology 360 (460) | Motor Development Across the Lifespan |
| | Fall 2019 |
| Kinesiology 400 | Ethics and Values in the Health and Fitness Professions |
| | Fall 2017 |
| Occupational Therapy 703 | Applied Neuroscience |
| | Spring 2016 |

| Occupational Therapy 704 | Musculoskeletal Analysis and Occupational Function |
|--------------------------|--|
| | Spring 2016 |

Guest Lecturer

| Occupational Therapy 704 | Musculoskeletal Analysis and Occupational Function |
|--------------------------|--|
| | May 9 th , 2016 |
| Kinesiology 200 | Introduction to Kinesiology |
| | March 28 th , 2019 |

Research Experience

University of Wisconsin-Milwaukee (2015 - present)

- Wrote MATLAB program to study effect of biofeedback on gait mechanics for individuals with prior ACL reconstruction
- Compared kinematics and kinetics at the knee with accelerometry data during a drop landing task
- Examined lower extremity loading asymmetries in subjects following ACL surgery
- Wrote LabVIEW program to study unanticipated landing mechanics in subjects following ACL surgery
- Assisted with study using Metria motion capture system to assess effects of inter-tester variability on biomechanical data
- Developed proficiency with the Cortex Motion Analysis system, Shimmer accelerometers, MATLAB and Visual 3D

Medical College of Wisconsin Center for Motion Analysis (2015)

• Assisted in accelerometry and motion capture data collection and analysis to determine effect of music cadence on running biomechanics

Marquette University (2013-2015)

- Performed kinematic testing on student athletes to determine risk of lower extremity injury
- Wrote LabVIEW programs 1) to collect data from accelerometers and a force plate to study prevention of Anterior Cruciate Ligament (ACL) injury and 2) to collect data from accelerometers to study prevention of Tibial Stress Fracture in runners
- Assisted in kinematic data collection and analysis for Milwaukee Brewers Spring Training 2014
- Developed proficiency with Vicon Nexus, LabVIEW, Microstrain accelerometers and Biopac

Publications

• Malloy P, **Morgan A**, Meinerz C, Geiser C, Kipp K. (2015). The association of dorsiflexion flexibility on knee kinematics and kinetics during a drop vertical jump in healthy female athletes. *Knee Surgery Sports Traumatology, Arthroscopy, 23*(12), 3550-3555.

- Malloy P, **Morgan A**, Meinerz C, Geiser C, Kipp K. (2016). Hip external rotator strength is associated with better dynamic control of the lower extremity during landing tasks. *The Journal of Strength and Conditioning Research*, *30*(1), 282-291.
- Lucas LA, England BS, Mason TW, Lanning CR, Miller TM, **Morgan AM**, Almonroeder TG. (2018). Decision-Making Influences Tibial Impact Accelerations During Lateral Cutting. *Journal of Applied Biomechanics*, 1-16.
- Morgan, A. M., & O'Connor, K. M. (2019). Evaluation of an accelerometer to assess knee mechanics during a drop landing. *Journal of biomechanics*, *86*, 125-131.
- Bao, S., **Morgan, A. M.**, Lei, Y., & Wang, J. (2020). Lack of interlimb transfer following visuomotor adaptation in a person with congenital mirror movements. *Neuropsychologia*, *136*, 107265.

Manuscripts in Preparation

- Morgan AM, Cobb S, Gerstle E, Heiderscheit B, Stiffler-Joachim M, O'Connor KM. A New Kinematic-Based Gait Event Detection Algorithm During Treadmill Locomotion.
- Keenan K, Heintz B, Peterson J, **Morgan A**, Fueger C, Rodrigues K, Cobb S. EMG activity and function of abductor hallucis during fatigue and postural sway.

Professional & Academic Presentations

- Morgan AM, Cobb S, Gerstle E, Heiderscheit B, Stiffler-Joachim M, O'Connor KM. A New Kinematic-Based Gait Event Detection Algorithm During Treadmill Locomotion. 42nd Annual Meeting of the American Society of Biomechanics Rapid Podium Presentation. Rochester, MN. 2018.
- Lucas L, England B, Mason T, Lanning C, Miller T, Morgan A, Almonroeder TG. Decision-Making Influences Tibial Impact Accelerations During Lateral Cutting. 42nd Annual Meeting of the American Society of Biomechanics General Poster Session. Rochester, MN. 2018.
- Morgan AM, O'Connor KM. Evaluation of an Accelerometer to Assess Sagittal Plane Knee Mechanics During a Drop Landing. 41st Annual Meeting of the American Society of Biomechanics General Poster Session. Boulder, CO. 2017.
- Morgan AM, O'Connor KM. Evaluation of an Accelerometer to Assess Sagittal Plane Knee Mechanics During a Drop Landing. *University of Wisconsin-Milwaukee College of Health Sciences 2017 Research Symposium*. Milwaukee, WI. 2017.
- Morgan AM, O'Connor KM. Evaluation of Using an Accelerometer to Assess Frontal Plane Knee Mechanics During a Drop Landing. *Midwest American Society of Biomechanics Meeting*. Allendale, MI. 2017.
- Nelson A, Koslakiewicz N, Griebel C, Hartman M, **Morgan A**, Almonroeder T, O'Connor K. Assessment of Knee Kinetic Symmetry Using Force Plate Technology. *American Physical Therapy Association Combined Sections Meeting*. San Antonio, TX. 2017.
- Morgan AM, Safarovic B, Weissenboeck K, Almonroeder T, Tesch B, O'Connor K. Comparison of Gait Parameters Using Anatomical- and Functional-Based Methods of Hip Joint Axis Definitions. 40th Annual Meeting of the American Society of Biomechanics Thematic Poster Session. Raleigh, NC. 2016.

- O'Connor K, Safarovic B, Weissenboeck K, Morgan AM, Almonroeder T, Tesch B. Comparison of Gait Parameters Using Anatomical- and Function-Based Methods of Thigh and Shank Segment Definitions. 40th Annual Meeting of the American Society of Biomechanics General Poster Session. Raleigh, NC. 2016.
- Malloy PJ, **Morgan AM**, Giordanelli M, Geiser CF, Starsky A, Heinrich JT, Neumann D, Kipp, K. Persons with symptomatic femoroacetabular impingement do not demonstrate differences in sagittal plane hip biomechanics during gait despite significantly less hip flexion range of motion and maximal hip flexor torque. *American Physical Therapy Association Combined Sections Meeting 2016 Orthopaedic Section Poster Presentation*. Anaheim, CA. 2016.
- Morgan AM, Geiser CF, Malloy PJ, Kipp K. Audio and Visual Biofeedback as Methods of Gait Retraining to Reduce Tibial Acceleration upon Foot Strike. *39th Annual Meeting of the American Society of Biomechanics General Poster Session*. Columbus, OH. 2015.
- Malloy PJ, **Morgan AM**, Kiely M, Geiser CF, Heinrich J, Kipp K. Patients with Symptomatic Femoroacetabular Impingement (FAI) Demonstrate Different Lower Extremity Joint Coordination Compared to Healthy Controls during a Double Leg Squat Task. 39th Annual Meeting of the American Society of Biomechanics General Poster Session. Columbus, OH. 2015.
- Garbarz JM, Geiser CF, Meinerz CM, Malloy PJ, **Morgan AM**, Kipp K. Analysis of a weight-bearing method to assess bilateral hip muscle strength. *American Physical Therapy Association Combined Sections Meeting 2015 Orthopaedic Section Poster Presentation*. Indianapolis, IN. 2015.
- **Morgan AM**, Meinerz CM, Malloy PJ, Geiser CF, Kipp K. Audio and Visual Biofeedback as Methods of Gait Retraining to Reduce Tibial Acceleration upon Foot Strike. 7th World Congress of Biomechanics MS Poster Competition. Boston, MA. 2014.
- Malloy P, Meinerz CM, **Morgan AM**, Geiser CF, Kipp K. Female athletes with ACL reconstruction demonstrate similar muscle synergy patterns to healthy athletes during a drop vertical jump task. 7th World Congress of Biomechanics General Poster Session. Boston, MA. 2014.
- Kipp K, Wenson S, Meinerz CM, Malloy P, Geiser CF, **Morgan A**. Functional Cluster Analysis of Frontal-Plane Knee Joint Torques. 7th World Congress of Biomechanics General Poster Session. Boston, MA. 2014
- Morgan A, Geiser C, Meinerz C, Malloy P, Malowanski C, Kipp K. Use of Wireless Accelerometry to Examine and Reduce Risk of Anterior Cruciate Ligament (ACL) Injury. *Marquette University Biomedical Sciences Summer Research Program Poster Presentation.* Milwaukee, WI. 2013.

Service

Guest Reviewer: Gait & Posture (December 2019)

Professional Memberships

American Society of Biomechanics (ASB)

Scholarships, Grants & Honors

- Chancellor's Graduate Student Award. University of Wisconsin-Milwaukee. Awarded: \$12.959. (2015-2016).
- University of Wisconsin-Milwaukee Travel Grant (2016, 2017, 2018)
- 7th World Congress of Biomechanics M.S. Student Poster Competition Finalist
- Marquette University Biomedical Sciences Undergraduate Summer Research Program Participant (2013)
- Marquette University Undergraduate College of Health Sciences Dean's List (Spring 2011, Spring 2013)