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The objective of this study was to determine whether a landmark protocol could reliably gather more anatomically accurate data than the default software setting for an electromagnetic tracking system. Nineteen healthy participants (10 males, 9 females) were measured clinically for pelvic angle (deg), tibiofemoral angle (deg), and navicular drop (mm) and compared to kinematic variables of transverse knee angle, frontal plane knee valgus/varus angle, and sagittal plane pelvic angle obtained from both the default and landmark digitization protocols (counterbalanced). Day-to-day reliability for both digitization protocols ranged from an ICC of –0.44(9.5°) to 0.72(2.3°). Kinematic values obtained from the landmark protocol were generally larger and more variable than those obtained from the default setting, and tended to correlate better with the clinical measures of anatomical alignment. While further study is needed, the landmark protocol shows promise as a method for collecting kinematic data that more closely approximates anatomical alignment of the lower extremity.

DEVELOPMENT OF AN ANATOMICAL LANDMARK PROTOCOL FOR CONSTRUCTING SEGMENT AXES FOR LOWER EXTREMITY KINEMATIC ANALYSIS

by

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Approved by

_____

Committee Chair

To my mother, Patricia, who has supported me in every way in all my endeavors.

It is because of you that I succeed.

APPROVAL PAGE

This thesis has been approved by the following committee of the

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CHAPTER I

INTRODUCTION

Lower extremity malalignments have been proposed as risk factors for a variety of lower extremity injuries, including osteoarthritis (Eckhoff, 1994; Elahi, Cahue, Felson, Engelman, & Sharma, 2000), patellofemoral stress syndrome (Krivickas, 1997; Tiberio, 1987), medial tibial stress syndrome (Krivickas, 1997), iliotibial band friction syndrome (Krivickas, 1997), stress fractures of the tibia (Krivickas, 1997), and ACL injury (Allen & Glasoe, 2000; Beckett, Massie, Bowers, & Stoll, 1992; Bonci, 1999; J.K. Loudon, Goist, & Loudon, 1998; J K Loudon, Jenkins, & Loudon, 1996; Woodford-Rogers, Cyphert, & Denegar, 1994). However, the specific role of anatomical malalignments in injury is still inconclusive (Murphy, Connolly, & Beynnon, 2003). While relationships between anatomical malalignment and injury have been noted, it is yet to be determined how these malalignments specifically affect lower extremity function and may predispose an individual to injury (McClay-Davis & Ireland, 2003). In an attempt to better understand the influence of lower extremity malalignment on injury, studies are beginning to examine the influence of lower extremity malalignment on lower extremity biomechanics using three-dimensional motion analysis (Chaudhari, Hearn, Leveille, Johnson, & Andriacchi, 2003; Ford, Myer, & Hewett, 2003).

Electromagnetic tracking systems are commonly used to study kinematics of the lower extremity during dynamic tasks (Cheng & Pearcy, 2001; Lephart, Ferris, Riemann,

Myers, & Fu, 2002; Schmitz, Riemann, & Thompson, 2002; Schmitz, Shultz, Kulas, Windley, & Perrin, 2004). Major benefits of an electromagnetic tracking system over video analysis are that visibility of the markers by a particular camera are not a concern, and markers need not be placed directly on the landmarks, which is beneficial when the landmark is on an uneven surface, or in an awkward location. The hardware system (Ascension Star Hardware, Ascension Technology Inc., Burlington, VT, USA, http://www.ascension-tech.com) consists of a transmitter containing 3 concentrically arranged antennae that generate DC magnetic fields, and individual sensors that contain 3 orthogonally arranged antennae (X, Y, & Z) to receive the DC signals from the transmitter. Signal processing electronics compute position and orientation data, based on the strength of the received signal from each of the sensor's antennae. From the acquired data, a software program computes motions and forces that are imposed on the human body. However, the settings and parameters that are used to define segment axes and calculate joint motion and forces with these instruments may have a tremendous influence on the examination of these relationships.

For example, the default setting for the software (MotionMonitor™, Innovative Sports Training Inc., Chicago, USA, http://www.innsport.com) used with the electromagnetic tracking system does not take into account the unique anatomical shape and alignment of individual bones when constructing segment axes. Hence, initial joint angles and segment orientations may not be accurately represented, and interpretation of the resulting data may lack important biomechanical information. Specific to lower extremity alignment, malalignments in bony orientation and inter-segment positioning

may not be apparent when dynamic motion is analyzed using the default setting or other less anatomically-defined parameters. Accounting for variations in anatomical alignment is critical if the measures provided by kinematic analyses are to be a valid and accurate representation of the absolute positions and range of joint motions occurring in the lower extremity. In order to accurately assess the effects of lower extremity malalignment on lower extremity biomechanics, there is a need to establish a digitization protocol that accurately references initial joint angles and segment orientations. By utilizing a landmark protocol that can better approximate initial joint angles and bony alignment, data will be more representative of actual joint positions and motions, and future research examining the effects of lower extremity alignment on biomechanics will have improved validity.

Problem Statement

It is important to determine whether or not the use of an anatomical landmark protocol can reliably gather more anatomically accurate data than the default setting of the software. This equipment has the potential to utilize anatomical landmarks to define segment axes, and confirmation of a specific landmark protocol that will yield reliable, and accurate kinematic data would be a helpful development. Several suggestions have been made for the selection of anatomical landmarks for kinematic study in general (Cappozzo, Catani, Croce, & Leardini, 1995; Craik & Oatis, 1995), but this particular equipment represents unique capabilities and challenges for the development of such a protocol.

Purpose Statement

This study compared an anatomical landmark protocol for constructing body segment axes with the default software setting for the electromagnetic tracking system. Specifically, the purpose of this study was to: 1) assess the test-retest reliability of kinematic variables obtained from both the landmark protocol and the default settings, 2) determine whether there is a significant difference in initial joint angles and bony orientations obtained from the two techniques, and 3) assess which method best correlates with clinical measures of anatomical alignment.

Operational Definitions

1) The landmark protocol is defined as the protocol that uses anatomical landmarks on the pelvis, femur, tibia and foot to set up the segment axes for the electromagnetic tracking system.

2) The default setting for the electromagnetic tracking system is defined as the software setting where all segment axes are aligned with the global axes, which positions them parallel to one another in the transverse plane. This setting simply requires joint centers to be located and digitized.

3) Pelvic angle is defined as the amount of anterior or posterior pelvic "tilt" in reference to true horizontal as measured clinically using an inclinometer, and as measured by the electromagnetic tracking system. Positive values denote anterior pelvic tilt [the position of the ASISs (anterior superior iliac spines) as lower than the PSISs (posterior superior iliac spines)]. Negative values denote posterior pelvic tilt (when the PSISs are lower then the ASISs).

4) Knee valgus/varus angle is defined as the knee angle in the frontal plane about the x-axis, as measured by the electromagnetic tracking system. Positive numbers represent knee valgus, while negative numbers indicate knee varus.

5) Knee rotation angle is defined as the knee angle in the transverse plane about the y-axis, as measured by the electromagnetic tracking system. Positive numbers denote internal tibial rotation on the femur at the tibio-femoral articulation, while negative values indicate external rotation.

6) Tibiofemoral angle is defined as the longitudinal alignment of the tibia and femur in the frontal plane as measured clinically using a standard goniometer. Positive numbers represent knee valgus, while negative numbers indicate knee varus.

7) Navicular drop is defined as the difference in the height of the navicular bone from subtalar joint neutral to relaxed standing. It is used to quantify the amount of pronation available, and is measured clinically in millimeters using a standard ruler.

Variables

Independent Variables

1) The anatomical landmark protocol for the software used with an electromagnetic tracking system to measure knee kinematics.

2) The default setting for the software used with an electromagnetic tracking system to measure knee kinematics.

Dependent Variables

1) Pelvic angle in reference to the global horizontal.

2) Knee valgus/varus angle in the frontal plane about the x-axis.

3) Knee rotation angle in the transverse plane about the y-axis.

Criterion Variables

1) Pelvic angle as measured clinically.

2) Tibiofemoral angle as measured clinically.

3) Navicular drop as measured clinically.

Hypotheses

The primary hypothesis of this study was that specific angles and orientations of the lower extremity derived from the landmark protocol would be reliable day to day, and would better correlate with clinical measures of anatomical alignment than angles and orientations derived from the default setting. Specifically, we expected to find:

1) The kinematic values obtained for pelvic angle, varus/valgus angle and tibial rotation from the landmark protocol would be as or more reliable between days than the default setting.

2) The kinematic values for pelvic angle, varus/valgus angle, and tibial rotation obtained from the landmark protocol would be greater than zero, and more variable between subjects compared to the kinematic values obtained from the default setting.

3) The kinematic values obtained from the landmark protocol would better correlate with and predict clinical measures of anatomical alignment. Specifically:

a) Pelvic angle (referenced to horizontal of the global reference system) obtained from the landmark protocol would be a better predictor of pelvic angle (referenced to the horizontal as measured by a pelvic inclinometer) than pelvic angle obtained from the default setting.

b) Knee valgus angle (as measured by the electromagnetic system) obtained from the landmark protocol would be a better predictor of tibiofemoral angle (as measured with a goniometer) than knee valgus angle obtained from the default setting.

c) Internal knee rotation angle (as measured by the electromagnetic tracking system) obtained from the landmark protocol would be a better predictor of navicular drop scores than internal tibial rotation angle obtained from the default setting.

Assumptions/Delimitations

For the purposes of this study, the following assumptions and delimitations were accepted:

1) The specific landmarks selected would adequately represent anatomical orientation of each of the lower extremity bony segments.
2) An individual's anatomical alignment does not change from day to day.
3) The electromagnetic tracking system is an accurate and reliable instrument for measuring joint motion.
4) Kinematic data were limited to that recorded by the MotionMonitor™ software used specifically in conjunction with the electromagnetic tracking system. While the landmarks used for this study may also be used with video analysis, some of the landmarks may be in locations that are difficult to use with video systems depending on the capabilities of the particular system. Therefore the results are limited to electromagnetic tracking systems.

5) Tibiofemoral angle, pelvic tilt and navicular drop are clinically accepted and reliable measures of anatomic alignment, and were used to approximate true lower extremity postural alignment.

Limitations

1) Only healthy, relatively lean (BMI < 30) subjects were used in this study, and the ability to generalize these findings to other populations is unknown.
2) Measuring actual lower extremity alignment is not practical or possible without costly, 3-dimensional radiographs. While the clinical measures used to compare the default method and the landmark protocol have been found to correlate well with radiographic measures, they are not without error, but rather represent acceptable, and widely used clinical estimations of alignment.
3) Only one tester was used in this study. As there may be variation between testers in finding specific landmarks, the ability to generalize these findings to other testers is limited.
4) For the purposes of this study, only 3 clinical measures and 3 kinematic variables were selected. Therefore, the results of this study are limited to these specific measures. No other clinical measures of anatomical alignment can be assumed to have a relationship to either of the digitization procedures.

CHAPTER II

LITERATURE REVIEW

Initial joint positions and static postural alignments often have clinical relevance in biomechanical assessment. Hence, the purpose of this literature review was to examine the need for using a landmark protocol when constructing segment axes with an electromagnetic tracking system in order to gain accurate initial joint position data. First, the various reference systems that are used when collecting kinematic data are described. Then, the criteria for selecting appropriate landmarks are discussed. The clinical importance of considering lower extremity malalignments, and the ways to quantify them during clinical and kinematic assessments is then reviewed. Additionally, the limitations associated with the default setting of the software used with the electromagnetic tracking system when evaluating lower extremity kinematics is also described.

Electromagnetic Tracking Systems

Electromagnetic tracking systems are commonly employed to study kinematics of the lower extremity during dynamic tasks (Cheng & Pearcy, 2001; Lephart et al., 2002; Schmitz et al., 2002; Schmitz et al., 2004). One of the major benefits of an electromagnetic tracking system over video analysis is that visibility of the markers to a particular camera is not a concern. As long as the investigator can accurately and reliably point to the landmark with the stylus, the issue of marker placement is less problematic.

Further, since the landmarks are digitized with a stylus, markers need not be placed directly on the landmarks. This is beneficial when the landmark is on an uneven surface, or in an awkward location.

The electromagnetic tracking system consists of a transmitter containing 3 concentrically arranged antennae that generate DC magnetic fields. Individual sensors that contain 3 orthogonally arranged antennae (X, Y, & Z) receive the DC signals from the transmitter. The earth's magnetic field is also measured by the sensors and subtracted from the signal received from the transmitter ("Flock of Birds six degrees-of-freedom measurement device: technical description of DC magnetic trackers,"). Signal processing electronics compute position and orientation data based on the strength of the received signal from each of the sensor's antennae, and up to 144 position and orientation measurements are made every second. Three-dimensional space is mapped using a Cartesian coordinate system with X, Y, & Z-axes. The sensor obtains X, Y, & Z coordinates for each of the individual measurements. The values are then exported to a computer where data acquisition software allows for the computation of kinematic data, i.e. position, velocity, and acceleration (McQuade, Finely, Harris-Love, & McCombe-Waller, 2002).

Reference Systems

In order to accurately describe human motion, a reference system is required to quantify position in space. Several coordinate systems are currently used to describe the kinematics of the lower extremity. The most common reference systems are the absolute

or global reference system, an anatomical or segmental system (also called a bone embedded system), and the joint coordinate system (Craik & Oatis, 1995).

Global Reference System

The absolute or global system is one that is rigidly fixed in space. Cartesian coordinates can be used to define any position in that space (Craik & Oatis, 1995). A right-handed orthogonal triad is used with the +Y-axis directed upward, the +X-axis directed in the direction of travel, and the Z-axis perpendicular to both the X and Y-axes (Wu & Cavanagh, 1995). This allows for the location of anything in this space to be described. To describe the shape and relative orientation of body segments to one another, a segmental or anatomical reference system is essential (Grood & Suntay, 1983).

Segmental Reference System

The segmental reference system uses Cartesian coordinates that are fixed or embedded in the bones of the segments (Craik & Oatis, 1995). For the segmental reference system the +x-axis is always directed anteriorly, +y-axis is always directed proximally, and the +z-axis is always directed to the right side of the body (Wu & Cavanagh, 1995). From these data, the shape and orientation of body segments in relation to one another is determined. By tracking the position of these segments in reference to the global reference system, translational motion can be measured, and by tracking the position of the segments relative to one another using Euler angles, joint motion can be measured.

In order for anatomically meaningful axes to be created, anatomical landmarks should be utilized (Cappozzo et al., 1995; Craik & Oatis, 1995). The landmarks should be

selected as to create a model that best approximates the bone of the particular segment. This is the main advantage of this system, as the axes have anatomical meaning since they are based on bony alignments (Craik & Oatis, 1995; Grood & Suntay, 1983). In this way the segmental reference system is a rough model of the bone.

Joint Reference System

Another reference system that may be used is the joint coordinate system. This system is fixed to a joint, and each joint in the extremity has its own individual reference system (Grood & Suntay, 1983). Two of the axes are based on anatomical landmarks and the other is a floating axis that is perpendicular to the other segmental axes (Craik & Oatis, 1995). The first axis is based on landmarks of the proximal bone, while the second is formulated from the distal bone (Grood & Suntay, 1983). The joint coordinate system described by Grood and Suntay (Grood & Suntay, 1983) has the benefit of describing joint rotations and translations in clinical terms without the need to specify the order of rotations, as is necessary when using Euler angles that define segment coordinate systems. This system is another way to track joint motion by combining axes from each segment to form one reference system centering about the joint, unlike the segment system that tracks each segment axes in relation to one another.

If using a joint coordinate system, it is necessary to include a segment coordinate system to describe the shape and orientation of the individual bones (Grood & Suntay, 1983). It is also necessary to describe a translational reference point, so that translation between bones can be accurately measured (Grood & Suntay, 1983). This may be

accomplished by locating the origins of the segment coordinate system as close to the joint of interest as possible, so that they coincide with translational reference points.

The problem with using the joint coordinate system without an anatomically defined segment reference system is that both segments are used to create one axis (Grood & Suntay, 1983), so differences in alignment of the two bones are not evident. The addition of an anatomically based segment reference system allows for alignment of the x-axis of each segment to be more representative of the actual bony alignment (Cappozzo et al., 1995; Craik & Oatis, 1995). The frontal planes of each segment are oriented according to bony landmarks, instead of creating only one x-axis for both bones.

Influence of Digitization Protocols in Determining Initial Joint Positions

The data obtained from an electromagnetic tracking system is dependent on the type of digitization protocol used by the integrated software. The default software setting does not allow for the segment reference system to be established using anatomical landmarks, so this setting is unable to accurately represent initial joint positions (orientation of the two segments to one another). It is logical to conclude that using landmarks to establish the segment reference system should provide a more accurate representation of actual bony alignment, and thus better initial joint position data can be acquired. The following sections describe the 2 digitization protocols in more detail.

Default Setting

The default software setting may be used with segmental and/or joint reference systems. When using the default setting for digitization, only the joint centers are digitized. No other information is used to define the segment axes. This means that the

x, y, and z-axis for each of the segmental axes are aligned exactly parallel with one another in the transverse plane, regardless of anatomical alignment. For example, the x-axes of the femur and the tibia are parallel with one another facing directly anteriorly, regardless of the degree of pronation and subsequent internal tibial rotation. Subjects with different anatomical alignments are treated as all being in the same neutral stance, and having the same bony orientations. In this way, individual anatomical alignment is not accounted for, and the initial or starting angle for the joints may not be accurate. This may hinder accurate interpretation of data relative to the actual joint angles. While the amount of total joint excursion during a movement may be accurately expressed, the absolute initial and end position of the joint cannot be accurately determined.

Landmark Protocol

In order to accurately model the shape and orientation of the limbs of the lower extremity, an anatomical reference system should be used (Cappozzo et al., 1995; Grood & Suntay, 1983). This system is frequently termed a bone-embedded frame, and consists of segment axes in each of the major body segments of the lower extremity (i.e. the pelvis, thigh, leg, and foot) (Cappozzo et al., 1995; Craik & Oatis, 1995). In order to construct segment axes that depict an accurate estimate of bony shape and orientation, anatomical landmarks are identified and digitized on each body segment (i.e. pelvis, femur, tibia and foot) (Cappozzo et al., 1995; Craik & Oatis, 1995). Previous literature has described and suggested several possible landmarks for each of the body segments (Cappozzo et al., 1995; Craik & Oatis, 1995), with the stipulation that at least 3 landmarks must be used for each segment (Craik & Oatis, 1995). All of the suggested

landmarks for each segment cannot be used with the electromagnetic tracking system due to software limitations; therefore, 3 landmarks for each segment must be selected for the landmark protocol that best estimate the anatomical shape and alignment of each segment for the analysis in question.

The landmarks selected for the protocol should be chosen in accord with the following criterion for selecting appropriate landmarks as described by Cappozzo: 1) they should be identified reliably both within and between investigators, 2) they should be compatible with joint reference systems, 3) they should permit easy estimation of the body's center of mass and intersegmental loads, and 4) they should allow for descriptions of muscular and ligamentous lines of action as well as locations and orientations of joint articulations (Cappozzo et al., 1995).

Clinical Implications of Alignment

Lower extremity malalignments at the hip, knee and ankle have been proposed as potential risk factors for a variety of lower extremity injuries, including osteoarthritis (Eckhoff, 1994; Elahi et al., 2000), patellofemoral stress syndrome (Krivickas, 1997; Tiberio, 1987), medial tibial stress syndrome (Krivickas, 1997), iliotibial band friction syndrome (Krivickas, 1997), stress fractures of the tibia (Krivickas, 1997), and ACL injury (Allen & Glasoe, 2000; Beckett et al., 1992; Bonci, 1999; J.K. Loudon et al., 1998; J K Loudon et al., 1996; Woodford-Rogers et al., 1994). However, the specific role of anatomical malalignments on injury is still inconclusive (Murphy et al., 2003). While relationships between anatomical malalignment and injury have been noted, it is yet to be determined how these malalignments specifically affect dynamic lower extremity

function and predispose an individual to injury (McClay-Davis & Ireland, 2003). In an attempt to better understand the influence of lower extremity malalignment on injury, studies are beginning to examine the influence of static lower extremity malalignments on functional lower extremity biomechanics using 3-dimensional motion analysis (Chaudhari et al., 2003; Ford et al., 2003).

Based on the previous discussion, including anatomical alignment and bony orientations in the construction of segment axes when using an electromagnetic tracking system is important, as this allows for more accurate clinical interpretation of kinematic data relative to initial joint angles, thus actual joint angles throughout the movement. Anatomical alignment is especially influential in weightbearing due to kinetic chain influences of the lower extremity on the pelvis and trunk, as well as the reverse effects of the pelvis and trunk on the lower extremity (Hruska, 1998; Riegger-Krugh & Keysor, 1996). This section provides a few examples of how anatomical alignment has been identified as an important factor in injuries and clinical conditions, and how several clinical measures are used to describe these alignments.

Foot Pronation

Pronation is described as talar plantarflexion and adduction, calcaneal (subtalar) eversion, and foot abduction (Perry, 1992). As the subtalar joint moves into eversion, the tibia internally rotates (Hintermann & Nigg, 1998). Pronation is essential for shock absorption during the loading phase of gait (Perry, 1992). However, pronation becomes problematic when it occurs to an excessive degree or continues into the stance and push off phases (Vogelbach & Combs, 1987).

Measures of Foot Pronation. Pronation has been quantified a number of ways, however one of the most frequently used methods is to measure navicular drop. This entails measuring the height of the navicular tubercle from the floor with the subject's subtalar joint in a neutral position (talar dome is equally palpable on both sides), and then subtracting the height of the navicular tubercle while the subject is standing normally (Menz, 1998). This clinical measure is considered to be a good indicator of subtalar joint pronation (Mueller, Host, & Norton, 1993), and is frequently used to quantify pronation both in research and clinical practice (Allen & Glasoe, 2000; Beckett et al., 1992; Brody, 1982; Hargrave, Carcia, Gansneder, & Shultz, 2003; Hertel, Dorfman, & Braham, 2004; J K Loudon et al., 1996; Menz, 1998; Mueller et al., 1993; Smith, Szczerba, Arnold, Martin, & Perrin, 1997; Woodford-Rogers et al., 1994). Numerous studies have confirmed the ability of clinicians and investigators to reliability measure navicular drop (Allen & Glasoe, 2000; Hargrave et al., 2003; J K Loudon et al., 1996; Mueller et al., 1993; Picciano, Rowlands, & Worrell, 1993; Smith et al., 1997; Trimble, Bishop, Buckley, Fields, & Rozea, 2002).

Pronation and Injury. Various injuries and conditions have been associated with excessive pronation. In an extensive review, Krivickas (Krivickas, 1997) found excessive pronation to be associated with patellofemoral stress syndrome, medial tibial stress syndrome, iliotibial band friction syndrome, plantar fasciitis, and stress fractures. Coplan (Coplan, 1989) theorized that opposing rotary torques between the tibia and thigh occur during the midstance of gait with excessive pronation, and may be responsible for knee pain. Tiberio (Tiberio, 1987) theorized that the thigh must internally rotate on the

tibia when excessive and prolonged pronation occurs during the stance phase, in order to provide normal knee extension. It is this "compensatory internal rotation of the femur" that is thought to cause patellofemoral knee pain (Tiberio, 1987).

Retrospective studies have identified an association between ACL injury and excessive pronation, finding that those who had sustained an ACL injury had significantly greater foot pronation as measured by navicular drop (Allen & Glasoe, 2000; Beckett et al., 1992; Hertel et al., 2004; J K Loudon et al., 1996; Woodford-Rogers et al., 1994). This appears to be true for both the injured and uninjured limbs (Allen & Glasoe, 2000), suggesting that the excessive pronation was inherent to the individual, and not a result of the injury. Greater pronation as measured by navicular drop, has also been positively correlated with increased anterior tibial translation as measured by a KT-1000 (Trimble et al., 2002). It is thought that these concomitant increases in knee laxity and tibial rotation with excessive pronation may potentially alter lower extremity biomechanics, and lead to injury (Chomiak, Junge, & Peterson, 2000; Ekstrand & Gillquist, 1983; Orchard, Seward, McGivern, & Hood, 2001).

Due to the congruency of the talus in the ankle mortise, internal tibial rotation occurs when the subtalar joint pronates (Hintermann & Nigg, 1998). Studies have shown that subjects with greater pronation have significantly greater tibial internal rotation during running (McClay & Manal, 1997), as well as greater passive range of knee rotation in non-weight bearing (Coplan, 1989). The subsequent tibial internal rotation brought about by excessive pronation is thought to create a pre-loading stress on the ACL (Beckett et al., 1992), which may predispose those individuals to ACL injury. The

simple act of weightbearing also increases strain in the ACL (B. C. Fleming, Renstrom, Beynnon, Engstrom, Peura, Badger, & Johnson, 2001), and strain is increased further when mild to moderate internal rotation torques and anterior shear forces are applied (Arms, Pope, Johnson, Fischer, Arvidsson, & Eriksson, 1984; R. E. Fleming, Blatz, & McCarroll, 1983). Because the ACL tightens with both anterior translation and internal rotation of the tibia, it would be beneficial to know the initial relationship of the foot, proximal tibia, and distal femur to one another when studying dynamic tasks.

Implications of Pronation on Kinematic Analysis. Kinematic and kinetic data are often used to make inferences about ACL strain, and if initial angles are inaccurate due to non-anatomically based segment axes, then these inferences may also be inaccurate. Because the default software setting for the electromagnetic tracking system aligns all of the x-axes for each segment parallel to one another in the transverse plane (straight anterior) regardless of the amount of initial internal knee rotation due to weightbearing, the true range of knee rotation that occurs during dynamic motion analysis cannot be determined. If an individual with excessive pronation is fully pronated when the axes are established in quiet standing, then the tibia is already internally rotated, and the knee has torsional stress on it. This situation, however, will not be observable since the x-axes of the femur and tibia are arranged parallel to one another in the transverse plane.

Given the relationship between pronation and internal tibial rotation previously described, kinematic measures of transverse knee angle may be related to clinical measures of navicular drop. Although radiographs are the preferred method to determine true initial knee rotation angle, many laboratories do not have these capabilities, and an

alternative criterion method is needed to determine if the landmark protocol is a better estimate of initial knee rotation angle. Since pronation causes obligatory internal tibial rotation (Hintermann & Nigg, 1998), those with greater pronation should display greater internal tibial rotation. Comparing navicular drop with initial knee rotation angles acquired in quiet standing from the default setting and the landmark protocol should allow determination of which method best captures this initial knee rotation angle.

Valgus/Varus Knee Angle

Valgus/varus knee angle is the angle of the knee in the frontal plane. This angle is formed by the relationship between the long axes of the femur and tibia. Genu valgum occurs when the knees touch but the ankles are greater than 8cm apart, presenting a knocked-kneed appearance (Magee, 1997). Genu varum is present when the ankles touch, but space remains between the knees, presenting a bow-legged appearance (Magee, 1997).

Measures of Valgus/Varus Angle. Eckhoff et al. (Eckhoff, 1994) explained that several different axes are used to describe the axial alignment of the lower extremity in the frontal plane. One axis is the anatomic axis, which follows the long axis of the shaft of the tibia and femur (Eckhoff, 1994). Another axis is the reference axis, which is composed of two arbitrary bony points at the distal and proximal ends of the tibia and femur (Eckhoff, 1994). Finally, the mechanical axis is defined by the center of the femoral head, the center of the knee, and the center of the ankle (Eckhoff, 1994).

Clinicians often utilize a goniometer to measure tibiofemoral angle as an estimate of knee valgus/varus. Clinical measures of tibiofemoral angle vary in their use of

landmarks, while some use the ASIS, center of the patella, and midpoint of the ankle (Arazi, Ogun, & Memik, 2001; Cahuzac, Vardon, & Gauzy, 1995), others use the palpable shafts of the femur and tibia (Ilahi, Kadakia, & Huo, 2001), and still others use the point midway between the anterior superior iliac spine (ASIS) and the most prominent part of the greater trochanter, the center of the anterior knee joint line, and midway between the malleoli on the anterior ankle (Shultz, Nguyen, Windley, Kulas, Botic, & Beynnon, In Review; Windley, Kulas, Schmitz, Perrin, & Shultz, 2004). All of these methods attempt to replicate the anatomical axis of the lower extremity. While several authors recommend that the mechanical axis of the lower extremity be used to characterize valgus/varus alignment (Chao, Neluheni, Hsu, & Paley, 1994; Eckhoff, 1994; Elahi et al., 2000), this is not easily done in the clinical setting due to the difficulty of locating the center of the hip joint without the use of radiographs. Further, validation of tibiofemoral angle using radiographic measures of the anatomical axis of the lower extremity confirms close agreement. Ilahi et al. (2001) found that the mean tibiofemoral angle was 5.6^{o} of valgus for clinical measures, and the mean for radiographic measures was 4^{o} of valgus, a difference of 1.6^{o}. 95% of the measured differences were within 5^{o} of each other.

Valgus/Varus Angle and Injury. The valgus/varus angle of the knee has clinical implications on lower extremity joint biomechanics and injury. Varus/valgus alignment of the knee can influence contact pressures at the lower extremity joints (McKellop, Llinas, & Sarmiento, 1994) and the moments imposed on the knee when the foot contacts the ground (Chaudhari et al., 2003). Further, valgus knee malalignments have been

associated with tibiofemoral and patellafemoral osteoarthritis (Elahi et al., 2000), as well as ACL injury in connection with landing, planting and cutting (Olsen, Myklebust, Engebretsen, & Behr, 2004). The later is likely due to the important role of the ACL in resisting valgus forces in the unconstrained knee (Inoue, McGurk-Burleson, Hollis, & Woo, 1987). Given the clinical implications of excessive valgus/varus malalignment, it becomes important to accurately identify accurate absolute joint angles when conducting kinematic studies.

Implications of Valgus/Varus Knee Angle on Kinematic Analysis. The default software setting for the electromagnetic tracking system uses the hip, knee, and ankle joint centers to determine the valgus/varus alignment of the lower extremity. While this approximates the mechanical axis, the clinically measured anatomical axis is not accounted for. Using a reference axis that approximates the anatomical axis of the lower extremity when selecting landmarks to digitize a subject into the electromagnetic tracking system may be more appropriate, since it provides information on tibiofemoral alignment that is more easily interpreted and measured by clinicians.

Pelvic Angle

Pelvic angle is the amount of anterior-posterior "tilt" of the pelvis in the sagittal plane, as referenced to the horizontal. Anterior pelvic tilt describes the position of the ASIS as lower than the PSIS, while posterior pelvic tilt is present when the PSIS is lower then the ASIS.

Measures of Pelvic Angle. Pelvic angle is often measured clinically using a caliper inclinometer, and the level of the ASIS and PSIS are compared in the horizontal

plane. Previous research had demonstrated clinical measurements of pelvic angle to have excellent intratester (.93-.96) and intertester reliability (.95) (Gilliam, Brunt, MacMillan, Kinard, & Montgomery, 1994). Prior research has also attempted to validate the clinical measure to radiographs (Gilliam et al., 1994). Gilliam et al. (1994) noted that while correlations between pelvic angle as measured clinically with 2 measurements using radiographs were not high (.85 & .68), the clinical measures had greater intertester reliability (.95) than the radiographic measures (.88), and concluded that perhaps radiographic measurements are not the ideal standard to judge the accuracy of pelvic angle measurement techniques.

Clinicians often consider the amount of pelvic tilt when performing evaluations, and intervene with stretching and strengthening programs designed to correct excessive tilt. Anterior pelvic tilt is the more common malalignment, and is often a result of tight hip flexors (mainly the iliopsoas), tight lower back muscles, weak hamstrings, and weak abdominals (Kendall, McCreary, & Provance, 1993).

Pelvic Alignment and Injury. The pelvis plays an important role in lower extremity kinematics. In an extensive review, Schache (Schache, Bennell, Blanch, & Wrigley, 1999) cited that pelvic tilt during running is correlated to both trunk and hip rotation about medial-lateral axes. Hruska (1998) explained that the pelvic angle influences femoral rotation by altering the placement of the acetabulum, resulting in femoral internal rotation, genu valgus, genu recurvatum, and pronation. These postures and alignments may have clinical implications to injury. J K Loudon et al. (1996) found a significant relationship between an anterior pelvic tilt and ACL injury when pelvic tilt

was analyzed as a univariate measure. The fact that no significant relationship was demonstrated with a multivariate test suggests that pelvic tilt may be significantly correlated with other lower extremity alignment variables. Another study noted that individuals with a larger degree of anterior pelvic tilt (>3.89º) were 5.2 times more likely to have sustained an ACL injury than those with lower amounts of anterior pelvic tilt (<1º) (Hertel et al., 2004). While there is relatively limited research in the area of pelvic malalignment and lower extremity injury, it remains a plausible risk factor worthy of further study.

Implications of Pelvic Angle on Kinematic Analysis. The default software setting for the electromagnetic tracking device fails to account for the shape of the pelvis when calculating the initial pelvic angle in relation to the global reference system. Therefore the amount of pelvic tilt cannot be determined with this method. The landmark protocol ameliorates this issue, by setting up segment axes for the pelvis using the same anatomical landmarks that clinicians use when measuring pelvic angle. Since the pelvis is an important link in the kinetic chain, knowing the initial orientation of the pelvis at the beginning of a dynamic task is important information that can be gained with the use of a landmark protocol.

Summary

In summary, anatomical malalignment has been proposed as a risk factor in various lower extremity injuries and conditions. Excessive pronation has been associated with patellofemoral stress syndrome, medial tibial stress syndrome, iliotibial band friction syndrome, plantar fasciitis, stress fractures, and ACL injury (Allen & Glasoe, 2000;

Beckett et al., 1992; Krivickas, 1997; J K Loudon et al., 1996; Woodford-Rogers et al., 1994). Valgus/varus malalignment has been associated with tibio-femoral and patellofemoral osteoarthritis (Elahi et al., 2000), and ACL injury has been associated with landing as well as planting and cutting with the knee in valgus alignment (Olsen et al., 2004). Pelvic angle has been implicated as perpetuating malalignments that lead to lower extremity injury (Hruska, 1998; J K Loudon et al., 1996). Given the association between malalignments and acute and chronic injury of the knee, clinicians often use clinically accepted measures to determine the degree of malalignment, and devise possible interventions accordingly.

Electromagnetic tracking systems are often used to study kinematics of the lower extremity during dynamic tasks (Cheng & Pearcy, 2001; Lephart et al., 2002; Schmitz et al., 2002; Schmitz et al., 2004), and recent research has used 3-dimensional motion analysis to study anatomical malalignments as they relate to the biomechanics of injury (Chaudhari et al., 2003; Ford et al., 2003). In order for researchers to be able to adequately interpret the effects of these malalignments on biomechanics and injury using these systems, bony anatomical alignments should be considered and accurately identified when setting up segment axes.

The default software setting for the electromagnetic tracking system does not account for the unique bony alignments of the individual segments when constructing segment axes, which may lead to inaccurate initial joint angle data. Hence, the development of a specific protocol utilizing anatomical landmarks to define segment axes may ameliorate this problem. By using a landmark protocol to define segment axes,

inferences about the effects of anatomical alignment during dynamic motion should be facilitated, and data for initial knee and pelvic angles at the start of a dynamic activity should be improved. This would likely enhance the ability of researchers to provide clinicians with data that are more easily interpreted, and better applied to clinical practice.

CHAPTER III

METHODS

Research Design

A within-subjects repeated measures design was used to compare default and landmark digitization methods on kinematic joint positions. Data were collected on 2 days for each subject to assess the reliability of the clinical measures, and the joint positions derived from the landmark protocol and default setting. The landmark protocol and the default setting were then tested for significant differences in initial angles and bony orientations. If significant differences existed, each method was then compared with clinical measures of anatomical alignment via correlation and regression analyses. All data were collected in the Applied Neuromechanics Research Laboratory located on the University of North Carolina at Greensboro campus.

Participants

A total of 19 subjects (10 male, 9 female) [mean (SD): 25.4 (4.7) years, 170.7 (7.9) cm, 71.9 (12.8) kg, and 24.5 (3.0) BMI], were recruited from the University and surrounding communities. In order to participate in the study, subjects had to have a body mass index (BMI) of less than 30.0, and had to be free from current musculoskeletal injury (e.g., fractures, ligament sprains, or other injuries) that would have affected their ability to complete the study. All subjects read and signed a human subject consent form,

approved by the University's Institutional Review Board, before participation in the study.

Measures/Instruments

For this study an electromagnetic tracking system (Ascension Star Hardware, Ascension Technology Inc., Burlington, VT, USA, http://www.ascension-tech.com) was used in conjunction with motion analysis software (MotionMonitor™, Innovative Sports Training Inc., Chicago, USA, http://www.innsport.com) to gather kinematic data. A caliper inclinometer (PALpation Meter, Performance Attainment Associates, St. Paul, MN) was used to measure pelvic inclination, and a standard plastic goniometer (modified with an adjustable extension bar on the stationary arm) was used to measure tibiofemoral angle. Navicular drop was measured with a small plastic ruler.

Procedures

On day 1, demographics of age, height, weight, and sex were recorded once subjects gave their consent to participate in the study. Then, clinical measurements of anatomical alignment (pelvic angle, tibiofemoral angle, and navicular drop) were collected on each subject. Subjects were then fitted with sensors from the electromagnetic tracking system, then digitized into the system using either than landmark protocol or default setting in a counterbalanced order. Three trials of 2 seconds of data were collected in quiet standing for each digitization protocol. Identical procedures were performed on day 2 to assess measurement reliability. The following sections describe the specific procedures used for each aspect of the study.

Clinical Measures of Anatomic Alignment

The following procedures were used to measure anatomical alignment on the right lower extremity of each subject.

Pelvic Angle. Pelvic angle was measured using a modification of the technique described by Gilliam et al. (1994). The subject stood erect with the feet biacromial width apart and facing forward. The ASIS and PSIS were palpated on the subject's right side and the caliper inclinometer was positioned directly over them. The angle from the horizontal was measured in degrees. Anterior pelvic tilt (positive value) describes the position of the ASISs as lower than the PSISs. Posterior pelvic tilt (negative value) is present when the PSISs are lower then the ASISs. The examiner has previously established intratester reliability with this measure (ICC = .78, SEM = 2.2 ^{o}) (Shultz et al., In Review).

Tibiofemoral Angle. Since there is variation in the methods that have been used to determine the anatomical axis of the lower extremity for the purposes of measuring tibiofemoral angle, landmarks for this study were selected based on previous literature (Shultz et al., In Review; Windley et al., 2004) that was consistent with the anatomical axis of the lower extremity as described by Chao (1994). Tibiofemoral angle was measured to the nearest degree with a standard plastic goniometer, modified with an adjustable extension bar on the stationary arm. This allowed for improved accuracy along the length of the thigh. The subject stood erect with the feet biacromial width apart and facing forward. Marks were placed at the center of the knee at the anterior joint line, and midway between the malleoli on the anterior ankle. The stationary arm of the

goniometer was positioned at the point midway between the ASIS and the most prominent part of the greater trochanter. The axis of the goniometer was centered over the mark at the anterior knee, while the movable arm was aligned with the mark on the ankle. The measurement was taken to the nearest degree. These methods have been used in previous literature (Shultz et al., In Review; Windley et al., 2004), and the examiner has established intratester reliability with this measure (ICC = .85, SEM = 1.1^{o}) (Shultz et al., In Review).

Navicular Drop. Navicular drop (ND) was measured using a modification of the technique described by Brody (1982). With the subject standing, the most prominent aspect of the navicular was marked. The thumb and forefinger was used to palpate the anterior medial and anterior lateral head of the talus. Then, by instructing the subject to roll his or her ankle in and out while palpating the dome of the talus, subtalar joint neutral (STJN) was determined. STJN is defined as the position where the medial and lateral aspects of the talar dome are equally palpable. With the subject standing in STJN, a straight ruler was used to measure the distance from the floor to the mark on the navicular to the nearest millimeter. Once the height of the navicular was measured in STJN, the subject was asked to relax their foot and ankle, and stand normally. Again, the distance from the floor and the mark on the navicular was measured. The ruler was maintained perpendicular to the transverse plane during all measurements. ND was calculated by subtracting the height of the navicular with the foot and ankle relaxed from the height of the navicular while standing in STJN. The examiner has previously established intratester reliability with this measure (ICC = .95, SEM = .59mm) (Shultz et al., In Review).

Kinematic Assessment

After the clinical measurements of anatomical alignment were completed, subjects were fitted with sensors from the electromagnetic tracking system. For both the default and landmark methods, the electromagnetic sensors were positioned at the same locations. Four sensors were used, and were secured with 2-sided tape. One sensor each was placed directly over: 1) the sacrum, 2) the middle of the lateral thigh, over the iliotibial band, 3) the middle of the medial aspect of the tibial shaft, and 4) the lateral tarsal bones of the foot. These locations have been used in previous studies (Schmitz et al., 2002; Schmitz et al., 2004). Data were sampled at 140 Hz for both digitization methods.

Default Setting Digitization. With the sensors secured, the participants were digitized using the default software setting. Joint centers were defined by the joint centroid method used with the MotionMonitor™ software interfaced with the electromagnetic tracking system. The knee was digitized by pointing a stylus at the medial and lateral aspect of the knee, just above the joint line, and at the midpoints of the femur in the sagittal plane. The ankle was digitized using the medial and lateral malleolus along with the distal end of the second phalanx. The hip center was digitized using a functional method described by Leardini (Leardini, Cappozzo, Catani, Toksvig-Larsen, Petitto, Sforza, Cassanelli, & Giannini, 1999). Once digitized, 3 trials of 2 seconds of data were collected in quiet standing.

Landmark Protocol Digitization. With the sensors secured in place, subjects were digitized into the system using the landmark protocol to construct the individual segment

axes. Joint centers were defined in the same manner as described with the default setting. Bony landmarks were selected from previous literature (Cappozzo et al., 1995; Craik & Oatis, 1995) in an attempt to best represent each body segment when collecting data on the right lower extremity (simple modifications may be used to collect the left or both lower extremities). The pelvis was represented by both ASISs and the right PSIS (Cappozzo et al., 1995; Craik & Oatis, 1995). The +z-axis of the pelvis was oriented from the left ASIS to the right ASIS. The +x-axis was orientated from the right PSIS toward the ASISs. The +y-axis was orthogonal to the x and z-axes and directed proximal. The origin for the pelvic axis was the right ASIS.

The femur was represented by the greater trochanter, and the medial and lateral femoral epicondyles (Cappozzo et al., 1995; Craik & Oatis, 1995). The +z-axis was from the medial epicondyle to the lateral epicondyle. The +y-axis was oriented from the lateral epicondyle to the most prominent part of the greater trochanter. The +x-axis was orthogonal to the z and y-axes and directed anteriorly. The femoral origin was the midpoint of the epicondyles. This origin was selected to provide the greatest sensitivity to knee kinematics.

The tibia was described using the most medial and lateral points on the ridges of the tibial plateaus (Cappozzo et al., 1995), and the midpoint of the malleoli. The +z-axis was orientated from the most medial ridge of the tibial plateau to the most lateral ridge of the tibial plateau. The +y-axis was directed from the midpoint of the malleoli anteriorly toward the ridges of the tibial plateaus. The +x-axis was orthogonal to the z and y-axes and directed anteriorly. The midpoint of the malleoli was selected so as to provide an

alignment more representative of tibiofemoral angle. The tibial origin was located at the prominence of the tibial tuberosity (Cappozzo et al., 1995; Craik & Oatis, 1995). Again, the origin of the shank was located close to the knee in an effort to best approximate knee joint motion.

The foot was represented by the lateral aspect of the 5th metatarsal head, the most distal aspect of the fibula (lateral malleolus), and the most inferior, lateral, and posterior portion of the calcaneus (Vaughan, Davis, & O'Conner, 1992). The +x-axis was oriented from the most inferior, lateral, and posterior aspect of the calcaneus toward the lateral aspect of the 5th metatarsal head. The +y-axis was directed from the lateral aspect of the 5th metatarsal head to the most distal aspect of the fibula. The +z-axis was orthogonal to the x and y-axes and directed to the right. The origin of the foot was the most distal aspect of the fibula.

Once the subject was digitized using the landmark protocol, 3 trials of 2 seconds of data were collected under quiet standing conditions.

Data Reduction and Analyses

Kinematic data were low passed filtered at 12 Hz using a 4th order, zero lag digital Butterworth filter, and exported to excel for reduction. The average of all data points acquired in each 2-second data collection was averaged for the 3 trials and used for kinematic assessment of transverse knee angle, frontal plane knee valgus/varus angle, and sagittal plane pelvic angle for each digitization protocol. Conventions were assigned so that positive numbers indicate anterior pelvic tilt, knee valgus, and internal tibial rotation, while negative numbers denote posterior pelvic tilt, knee varus, and external tibial

rotation. The mean of 3 measurements taken for each clinical measure of pelvic tilt, tibiofemoral angle, and navicular drop was used for analysis. All analyses were conducted using SPSS 11.5.

To test hypothesis 1, a repeated measures ANOVA for each measure was used to compare values across repeated tests (day), and to compute measurement reliability and precision using the interclass correlation (ICC) formula 2,k and standard error of the measurement (SEM). Separate repeated measures ANOVA were used to determine if kinematic values obtained from the default setting and the landmark protocol were significantly different for measures of pelvic angle, tibial rotation, and varus/valgus knee position. Linear regression analyses were used to determine whether the default or landmark protocol digitization procedures (predictor variables) best predicted each clinical measure (dependent variable).

CHAPTER IV

RESULTS

To follow are the results, presented according to each hypothesis tested.

Measurement Reliability (Hypothesis 1)

Tables 1 and 2 list the means ± sd for the clinical and kinematic lower extremity alignment measures, respectively, for day 1 and 2. Table 3 presents the reliability coefficients and SEMs for the clinical measures of anatomical alignment, as well as the kinematic measures for each digitization method. Assessment of day-to-day measurement consistency revealed that intratester ICC's for each clinical measurement were good to excellent, PA = .79(1.6^{o}), TFA = .93(.79^{o}), and ND = .93(.83 ^{o}). Intratester ICC's comparing day 1 and day 2 measures using the default [DPA = .24(6.0 ^{o}), DKR = .20(2.5 ^{o}), and DVV = .72(2.3 ^{o})] and landmark protocol [LPA = .50(8.1 ^{o}), LKR = .00(9.5^{o}), LVV = .63(3.2 ^{o})] settings were rather inconsistent and often poor.

Table 1. Means + SD for Clinical Measures on Day 1 and Day 2

Variable	**Mean ± SD**	**Mean ± SD**
	Day 1	Day 2
Pelvic Angle (deg)	13.46 ± 3.15	13.35 ± 3.48
Tibiofemoral Angle (deg)	10.77 ± 2.87	10.88 ± 2.78
Navicular Drop (mm)	7.42 ± 2.87	7.54 ± 3.26

Table 2. Means + SD for all Kinematic Measures on Day 1 and Day 2

Day 1	Default Mean ± SD	Landmark Mean ± SD	*t* Value	*P* Value (2-tailed)
Pelvic Angle (deg)	-3.30 ± 6.85	9.43 ± 11.45	4.3	<0.001*
Knee Rotation Angle (deg)	0.75 ± 2.79	-1.56 ± 6.93	1.35	0.190
Valgus/varus Angle (deg)	-4.74 ± 4.33	-1.85 ± 5.22	2.72	0.010*
Day 2				
Pelvic Angle (deg)	-0.95 ± 3.83	8.05 ± 7.50	4.1	<0.001*
Knee Rotation Angle (deg)	-0.43 ± 2.50	3.64 ± 7.88	-1.91	0.070
Valgus/varus Angle (deg)	-5.11 ± 3.23	-0.13 ± 4.18	5.65	<0.001*

*Significant difference from default setting ($P < .05$)

Table 3. Intraclass Correlation Coefficients ($ICC_{2,k}$) and Standard Error of Measurements (SEM) Assessing Day to Day Reliability of Clinical and Kinematic Alignment Measures

Variable (deg except where indicated)	$ICC_{2,k}$	SEM	TMS	EMS	BMS
Clinical Measures					
Pelvic Angle	0.79	1.58	0.00	0.18	0.82
Tibiofemoral Angle	0.93	0.79	0.01	0.07	0.92
Navicular Drop (mm)	0.93	0.83	0.01	0.06	0.93
Default Protocol					
Pelvic Angle	0.24	5.97	0.46	0.23	0.31
Knee Rotation	0.20	2.49	0.49	0.23	0.29
Valgus/Varus	0.72	2.30	0.04	0.22	0.74
Landmark Protocol					
Pelvic Angle	0.50	8.06	0.09	0.31	0.61
Knee Rotation	-0.44	9.47	0.70	0.18	0.12
Valgus/Varus	0.63	3.18	0.38	0.16	0.45

TMS = Trial mean square, EMS = Error mean square, BMS = Between subjects mean square

Comparison of Default and Landmark Digitization Protocols (Hypothesis 2)

Table 2 also lists the results from the paired-samples t-tests comparing the kinematic values obtained for the default and landmark digitization protocols for pelvic angle, tibial rotation and varus/valgus. On both days, the landmark protocol yielded significantly greater anterior pelvic angles (9.43 ± 11.45 vs. -3.30 ± 6.85 on day 1 and 8.05 ± 7.50 vs. -0.95 ± 3.83 on day 2), and less varus knee angulation (-1.85 ± 5.22 vs. -4.74 ± 4.33 on day 1 and -0.13 ± 4.18 vs. -5.11 ± 3.23 on day 2) than the default protocol. Knee rotation values were not significantly different between digitization methods. For all variables, standard deviations for the landmark protocol were generally higher than the default setting, indicating greater variability between subjects when using the landmark protocol.

Prediction of Clinical Alignment Measures (Hypothesis 3)

Table 4 presents the Pearson R correlations for the relationships between clinical measurements and kinematic values for each digitization method. Tables 5 through 10 list the model summaries for the regression analysis used to determine whether the default or landmark digitization protocols best predicted clinical alignment measures on day 1 and day 2. Generally, relationships were stronger on day 2 as compared to day 1.

Table 4. Person R Correlations for Relationships Between Clinical and Kinematic Alignment Measurements

Clinical / Kinematic Measures	Day	Default	Landmark
Pelvic Angle / Pelvic Angle	1	r = -.001	r = .275
	2	r = -.105	r = .550*
Tibiofemoral Angle / Valgus/Varus Angle	1	r = .575*	r = .208
	2	r = .450*	r = .455*
Navicular Drop / Knee Rotation Angle	1	r = -.059	r = -.001
	2	r = -.351	r = .510*

*Significant Correlation ($P < .05$)

Table 5. Regression Model Summary for Predicting Pelvic Angle on Day 1

					Change Statistics				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	.275(a)	.076	.021	3.11727	.076	1.391	1	17	.254

a Predictors: (Constant), Landmark Pelvic Angle

b Dependent Variable: Pelvic Angle

Table 6. Regression Model Summary for Predicting Pelvic Angle on Day 2

					Change Statistics				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	.550(a)	.302	.261	2.99407	.302	7.355	1	17	.015

a Predictors: (Constant), Landmark Pelvic Angle

b Dependent Variable: Pelvic Angle

Table 7. Regression Model Summary for Predicting Tibiofemoral Angle on Day 1

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.575(a)	.331	.292	2.41852	.331	8.418	1	17	.010

a Predictors: (Constant), Default Varus/Valgus Angle

b Dependent Variable: Tibiofemoral Angle

Table 8. Regression Model Summary for Predicting Tibiofemoral Angle on Day 2

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.455(a)	.207	.160	2.55225	.207	4.431	1	17	.050
2	.524(b)	.275	.184	2.51505	.068	1.507	1	16	.237

a Predictors: (Constant), Landmark Varus/Valgus Angle

b Predictors: (Constant), Landmark Varus/Valgus Angle; Default Varus/Valgus Angle

c Dependent Variable: Tibiofemoral Angle

Table 9. Regression Model Summary for Predicting Navicular Drop on Day 1

Variables Entered/Removed: None

Dependent Variable: Navicular Drop

Table 10. Regression Model Summary for Predicting Navicular Drop on Day 2

						Change Statistics			
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	.510(a)	.260	.216	2.88500	.260	5.967	1	17	.026

a Predictors: (Constant), Landmark Knee Rotation Angle

b Dependent Variable: Navicular Drop

Pelvic Angle

Neither the landmark or default protocol values obtained for pelvic angle were significantly correlated, or found to be significant predictors of clinical measures of pelvic angle on day 1. However, on day 2, moderate positive correlations were noted between the landmark protocol and clinical measures of pelvic tilt (r = .550; P = .007), with the landmark protocol explaining 30.0% of the variance in the clinical pelvic angle measure (AdjR^2= 26.1; F Change $_{(1,17)}$ = 7.355; P = .015). (See tables 4 - 6)

Knee Valgus/Varus Angle and Tibiofemoral Angle

Knee varus/valgus angles obtained from the default setting on day 1 (r = .575; P = .005), and the default (r = .450; P = .027) and landmark (r = .455; P = .025) protocols on day 2 were positively correlated to clinical measures of tibiofemoral angle. While values obtained from the default setting entered the regression model first on day 1, explaining 33.1% of the variance in tibiofemoral angle (AdjR^2 = 29.2%; F Change $_{(1,17)}$ = 8.418, P = .010), values obtained from the landmark protocol entered the regression model first on day 2, explaining 20.7% of the variance in tibiofemoral angle (AdjR^2 = 16.0%; F Change $_{(1,17)}$ = 4.431, P = .050). Varus/valgus angle from the default setting also entered the model on day 2, explaining an additional 6.8% of the variance, but this was not found to be a significant contributor to the model (AdjR^2 = 18.4%; F Change $_{(1,17)}$ = 1.507, P = .237). (See tables 4, 7 and 8)

Tibial Rotation and Navicular Drop

When examining the relationship between kinematic measures of tibial rotation and clinical measures of navicular drop, no relationships were noted on day 1 for either

the landmark protocol or default setting, and neither value was able to predict any portion of the variance in navicular drop. However, on day 2, significant correlations were noted between the tibial rotation values from the landmark protocol and navicular drop measures (r = .510; P = .013), but not between the tibial rotation values from the default setting and navicular drop measures (r = -.351; P = .070). As such, tibial rotation values obtained from the landmark protocol entered the regression model first with the highest zero-order correlation with navicular drop, explaining 26% of the variance ($AdjR^2$ = 21.6%; F Change $_{(1,17)}$ = 5.967, P = .026). (See tables 4, 9 and 10)

CHAPTER V

DISCUSSION

The primary findings of this study indicate that day-to-day measurement consistency was difficult to obtain for both the landmark and default setting protocols. Although results do not support the first hypothesis that the landmark protocol would yield more consistent values day to day than the default setting, the landmark protocol did appear to yield values that were significantly different from and more variable than the default setting for pelvic angle and varus/valgus, supporting the second hypothesis. Of interest, day 2 values appeared to be more stable than day 1, generally yielding stronger correlations between kinematic and clinical alignment measures on day 2. Regression analyses from day 2 indicate that values obtained from the landmark protocol were stronger predictors of clinical alignment measures than measures obtained from the default setting, supporting the third hypothesis.

Measurement Reliability

When interpreting these results, it is first important to insure that the clinical anatomical alignment measures that were used as the criterion variables for assessing the kinematic measures be reliably obtained. Results indicate that the tester could consistently locate the anatomical landmarks involved in each measure, and measure them in the same manner from day to day. These reliability estimates for this examiner

have generally improved when compared with a previous study that utilized the same measurements (Shultz et al., In Review).

It is equally important that methods used for kinematic analysis also be reliably obtained in order to accurately interpret meaningful relationships. Day-to-day reliability of both the landmark and default digitization methods was rather inconsistent and unreliable. The default setting had poor reliability for pelvic angle and knee rotation measures as evidenced by the low ICC's. SEMs for these measures were also large when compared to the standard deviations for those measures, suggesting poor measurement precision that would make it difficult to detect meaningful differences in the sample population. Much of the variance for these measures was accounted for by systematic error, as indicated by the high proportion of variance attributed to the trial mean square (TMS) for pelvic angle (default) and knee rotation (default and landmark settings) (see Table 3). The ICC and SEM for the valgus/varus measure showed moderate to good consistency, with a much lower proportion of systematic error for the default setting.

While both methods yielded moderate to low ICC's, the default setting appeared to be somewhat more reliable that the landmark method for knee rotation and varus/valgus, but not pelvic angle. The low reliability found for the default setting in this study is troubling because good to excellent reliability for initial knee rotation and varus/valgus joint angles has been demonstrated in previous research using this digitization method (Schmitz et al., 2004). This suggests methodological problems, rather than instrumentation limitations may be the cause for the poor reliability.

Sources of error that may contribute to the poor reliability estimates may include digitization errors, improper and inconsistent location of anatomical landmarks by the tester, and inconsistencies in the stance of the subjects.

Digitization Errors

In order to digitize the subjects, both methods require the location of joint centers by the joint centroid method. This method requires the tester to correctly locate several landmarks. The knee is digitized by pointing a stylus at the medial and lateral aspects of the knee just above the joint line, and at the midpoints of the femur in the sagittal plane. The ankle is digitized using the medial and lateral malleolus along with the distal end of the second phalanx, and the hip center is digitized using a functional method described by Leardini (1999). If these landmarks were not identified with sufficient precision and consistency day to day, inconsistencies in initial joint angles from one digitization session to the next may occur. The fact that large systematic differences were noted from day to day, and that relationships between clinical and kinematic measures were stronger on day 2, suggest the tester may have improved in his digitization of individual subjects on day 2. Further, there were no established criteria for determining when a digitization was unacceptable, and redigitization required before proceeding with data collection. However, it is acknowledged that the nature of this particular equipment is such that there are often sensor or digitization errors that require redigitization.

A clear criterion for what should be considered a successful digitization may be necessary to identify substantial digitization errors, and improve measurement reliability. Having a criterion to identify a poor or unsuccessful digitization may be necessary to

allow for the correction of any equipment related errors, as well as any major errors in the location of anatomical landmarks by the investigator. If clinical measures were taken first, and then used to judge whether or not a digitization was successful, severe digitization errors may be avoided, thus improving accuracy and reliability of the measure.

Inconsistencies in Location of Anatomical Landmarks

While both methods require the location and digitization of joint centers, the digitization process for the landmark protocol requires approximately 20 additional steps. Three anatomical landmarks are use to define the axis of each body segment (pelvis, thigh, shank, and foot), and a 4^{th} point is used to define the orientation of the plane for each segment. In addition, the origin for each segment axis (where the axis is physically located on the segment) is also input. Therefore, given the number of landmarks that must be identified, there are clearly more chances for error to occur in the location and digitization of each segment. This may explain why the default method had slightly better ICC's and SEMs than the landmark protocol for most measures.

Eckhoff (1994) has explained that while the use of surface landmarks has several advantages, the disadvantage to their use for determining lower extremity rotation is that they are often variable and inaccurate. Given the many opportunities for digitization errors using the landmark protocol, it becomes imperative that the investigator receive sufficient practice to improve his or her ability to consistently and accurately locate the anatomical landmarks used in the landmark protocol. This must be established first prior to using this digitization protocol in future research protocols.

Inconsistencies in Subject Stance

Another possible reason for the low reliability could be due to inconsistencies in the stance of the subjects between days. While the stance of the subject was standardized, perhaps this was not accomplished to the extent necessary. The instructions given to the subjects were to stand upright, with the feet shoulder width apart and facing forward. No other instruction was provided. These instructions may not entirely restrict variations in pelvic inclination, knee flexion, and hip rotation angles which may, through kinetic chain influences, affect the outcome measures for this study. For example, variations in the position of the pelvis would directly impact the pelvic angle measure. Furthermore, since pelvic positioning affects the position of the acetabulum, which affects hip rotation and positioning of the femur (Hruska, 1998), knee outcome measures may be altered. Kendall (1993) has also stressed the importance of pelvic positioning in the alignment of the lower extremity. Therefore, it is important to standardize the stance in regard to pelvic positioning, and while this was attempted in the current study, more rigorous standardization methods for positioning the trunk and pelvis may be required.

Slight alterations in knee flexion could have also affected the amount of knee rotation measured. In a review of literature involving the screw home mechanism, Piazza (Piazza & Cavanagh, 2000) noted that the external rotation of the tibia that accompanies knee extension has ranged from 0 degrees to 37 degrees, and that subjects could voluntarily produce tibial rotation in either direction. Therefore, slight variations in the amount of knee flexion of the subjects could have altered the amount of knee rotation

observed in this study. This highlights the need to standardize knee flexion to a greater extent than simply instructing the subjects to stand upright.

Previous literature that reported good to excellent ICC's for initial knee rotation and adduction angles [from 0.87(2.1 ^{o}) to 0.88(2.0°) and 0.90(1.5°) to 0.91(1.5 ^{o}) respectively], utilized a very specific protocol to achieve a single leg stance (Schmitz et al., 2004). For that study, an electrogoniometer was used to standardize the knee flexion angle at 30 degrees, a plum bob was used to ensure that the greater trochanter was directly over the area between the 1st metatarsophalangeal joint and the navicular bone, and the center of pressure was maintained between the 1st metatarsophalangeal joint and the navicular bone with the assistance of a feedback monitor. For the current study, simple verbal instructions were provided to the subjects, and there was no means for quantitatively assessing their position.

To insure a more standard and consistent stance in future studies; perhaps the subject should complete a "setting" motion, such as a glute contraction and relaxation, just prior to data collection. Another option could be to have the subject perform a mini squat, or full knee extension and relaxation just prior to data collection. These motions may serve to position subjects in a uniform stance. Also, including a target angle for knee flexion, perhaps 0 ± 2 degrees of knee flexion, may better ensure a standardized stance. Future research is needed to determine what procedure would best standardize the subject's stance.

Comparison of Kinematic Values Obtained from Default and Landmark Protocols

The second research hypothesis was that the landmark protocol would return results that were significantly greater and more variable than the default setting. Because the default setting does not relate the initial pelvic angle to the global horizontal, and whatever initial position the pelvis is in during digitization is considered zero, pelvic angles obtained from the default setting should be close to zero. Alternatively, the landmark protocol relates bony landmarks on the pelvis to the global horizontal to determine the amount of initial pelvic angle, thus the values obtained should be more consistent with the actual amount of pelvic tilt. The results revealed that the landmark protocol yielded values that characterized the subjects' postural position in more anterior pelvic tilt ($P < 0.001$) and relative knee valgus ($P = 0.01$), compared to the default digitization protocol. Thus, the landmark protocol was more consistent with clinical measures of anatomical alignment, where all subjects were found to have an anterior pelvic tilt and valgus angulation at the knee.

Pelvic Angle

Previous literature using multiple radiologists taking multiple measures of pelvic angle on x-ray film yielded means ranging from 11.6° to 15.4° (Gilliam et al., 1994), which were consistent with the clinical measures of pelvic angle obtained in this study. Interestingly, the landmark protocol measures were similar, but slightly lower than both the clinical measures from the current study, and the radiologic measures from previous literature (Gilliam et al., 1994). Further, the landmark protocol pelvic angle values were consistent with clinical measures from previous literature, with means ranging from 5.5°

to 9.1° (Gilliam et al., 1994). Overall, when compared to the default setting the landmark protocol appears to yield pelvic angle values that are more consistent with clinical measures obtained in the current study, as well as clinical and radiological measures reported in previous literature.

Varus/Valgus

To determine knee varus/valgus, the default setting uses the joint centers of the ankle, knee, and hip, which is consistent with the mechanical axis of the lower extremity. The mechanical axis follows the line of the ground reaction forces applied during normal stance, and is defined by the center of the femoral head, the center of the knee, and the center of the ankle (Eckhoff, 1994). The values obtained for valgus/varus angles using the default method were consistent with previous literature using the mechanical axis, which found a varus angle of $3.9^{o} \pm 2.7^{o}$ using MRI imaging, and $3.0^{o} \pm 3.0^{o}$ with radiographs (Matsuda, Miura, Nagamine, Urabe, Mawatari, & Iwamoto, 2003).

Conversely, the landmark protocol uses bony landmarks on the segments to approximate the anatomical axis of the lower extremity to measure varus/valgus angle. Therefore, the landmark protocol should be more consistent with the clinical measure of tibiofemoral angle, which uses a point midway between the greater trochanter and the ASIS, the center of the anterior knee joint line, and a point midway between the malleoli on the anterior ankle to approximate the anatomical axis. It should be noted that for this study, means for the valgus/varus measure for the landmark protocol are less negative than those for the default setting. Therefore, use of the landmark protocol results in segment orientations that are in less varus (i.e. more relative valgus) than the default

setting, which is more consistent with the clinical measures where all subjects had a valgus angulation.

Previous literature using radiographs to measure the amount of tibiofemoral angle based on the anatomical axis of the lower extremity resulted in means that ranged from 3.2° ± 2.6° of valgus (Ilahi et al., 2001) to as much as 6.0° ± 1.0° of valgus (Moreland, Bassett, & Hanker, 1987), depending on what specific landmarks were used to define the anatomical axis. It is uncertain why the kinematic values obtained from the landmark protocol indicated less valgus than radiographic measurements from previous studies. There was less varus than the default setting which uses the joint centers of the lower extremity, and less valgus than the clinical and radiologic measures that approximate the anatomical axis. Information on exactly how the axis is aligned using the landmark protocol software setting is not readily available. However, since both the joint centers and landmarks, such as the greater trochanter, are input into the software when using the landmark protocol, and the values obtained from the landmark protocol lie in between those of prior research using the mechanical and anatomical axes; perhaps the software integrates both the hip joint center and greater trochanter to calculate the axis for the landmark protocol, which may have reduced the amount of valgus observed.

Tibial Rotation

Since the default setting aligns both the femoral and tibial x-axes in the transverse plane during digitization, knee rotation angle during quiet standing should be near zero. The landmark protocol uses bony landmarks on the femur and tibia to create the segment axes for those respective bones, so that any initial knee rotation between these bones

should be detected. While differences of 2-4 degrees were noted in tibial rotation values between the two protocols, these differences were not significant, and the direction of difference (i.e. greater internal vs. external rotation) were not consistent between day 1 and day 2. When using the landmark protocol, the amount of transverse knee rotation depends mostly on the location of 2 specific landmarks, the most medial and lateral points on the ridges of the tibial plateaus. The tester subjectively noted that these landmarks were among the most difficult to locate, which may account for the inconsistency in knee rotation between days. Additionally, variations in the stance of the subjects, as described earlier, may have contributed to the day-to-day inconsistencies.

It is also evident from the descriptive data presented in Table 2 that the standard deviations of the measures within the sample were substantially greater with the landmark protocol compared to the default setting. Hence, with the exception of mean differences for tibial rotation, hypothesis 2 was in large part supported, with the landmark protocol producing joint angles more consistent with clinical posture, and better representing the variations between subjects in the sample population. It should be noted however that the standard deviations for the kinematic measures were substantially larger than those obtained from the clinical measures (see Table 1), which may be indicative of more measurement error in the kinematic data, rather than simply being a function of better describing the inter-subject variability in the population.

With clear differences in values obtained from the two digitization protocols realized, which kinematic digitization protocol yielded measures that were most consistent with the subject's clinical alignment measures was then explored.

Relationship Between Kinematic and Clinical Alignment Measures

Regression analysis revealed that, in general, the landmark protocol was a better predictor of the clinical measurements than was the default protocol. This was particularly apparent on day 2. Aside from valgus/varus angle on day 1, the landmark protocol out performed the default setting for each clinical measure in predicting the clinical measurement. Assuming that the clinical measurements are fairly accurate representations of anatomical alignment, these data suggest that the landmark protocol more accurately represents actual postural alignments compared to the default setting. This is important if researchers wish to take anatomical alignment into consideration when collecting kinematic data using an electromagnetic tracking system. However, the issue of poor reliability will have to be resolved before any definite conclusions can be drawn.

While the regression results show promise for the landmark method to more accurately predict postural alignment, the percent of variance explained ranged from 8-30% or less, leaving a substantial amount of the variance in the measure unaccounted for. Improving measurement reliability would serve to decrease the measurement error, which may yield even stronger relationships. This is somewhat supported by stronger relationships on day 2 versus day 1, suggesting more stable measures may have been obtained on day 2 as the examiner became more familiar with digitizing each subject's anatomical landmarks. Further, there may be a degree of a trade off between measurement accuracy and reliability, given the default setting was slightly more reliable,

and the landmark protocol more accurate. Further research is needed to explore these relationships once satisfactory measurement reliability is achieved.

Limitations and Future Directions

This study has several limitations. First, findings are limited to a single tester, and it is unknown if similar findings would be obtained from other testers. This is particularly important if more than 1 tester is used in a particular study. Future research should include more testers to determine their ability to digitize subjects in a consistent manner. Second, the results of this study are limited to a static stance to obtain initial joint angles. It is recognized that greater variability and measurement error may be associated with dynamic motion, and further research is needed to generalize our findings to dynamic motion. Third, these results are limited to a young, healthy population with a BMI of less than 30.0. Finally, the major limitation of the study is that the poor reliability hinders interpretation of the data, and limits the ability to draw definitive conclusions relative to the 2nd and 3rd hypothesis. Because the default setting has been demonstrated to be reliable in previous studies (Schmitz et al., 2004), sources of error are apparent in this particular study and need to be addressed in future studies.

Conclusions

Both the landmark and default digitization protocols present challenges for obtaining consistent measures from day to day. Even with this poor reliability, significant differences were clearly apparent between the two digitization methods, with the landmark method appearing to be better correlated with clinical measures of anatomical alignment. However, while the landmark protocol shows promise, the

amount of variance in clinical alignment measures explained by the landmark protocol was limited to 30%. Until the issue of measurement reliability is addressed, it is difficult to be certain which digitization method is truly superior, and to what extent each measurement method approximates clinical posture. Future research is recommended to first determine measurement procedures that will yield acceptable measurement consistency across days, then re-examine the relationship between the landmark and digitization protocols with clinical postural alignment measures.

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APPENDIX A. IRB APPLICATION & CONSENT FORM

Review Process Log
Applications for the Use of Human Participants in Research

Principal Investigator: Complete the top section of this form only and submit it with the IRB checklist.

Researcher:	Timothy Botic ATC-L,CSCS	Faculty Sponsor:	Sandy Shultz PhD, ATC
Original Date of Submission to Departmental Reviewer:	02/02/2005	Projected Date of First Data Collection:	02/21/2005

Departmental Reviewer:

IRB USE ONLY

Date of First Receipt by Departmental Reviewer:

First Review by Departmental Reviewer:

Disposition by Departmental Reviewer	**Date**	**Notes**
Returned complete application to PI		
Requested Major Revisions		
Requested Minor Revisions		
Forwarded to ORC		

Second Review by Departmental Reviewer:

Disposition by Departmental Reviewer	**Date**	**Notes**
Returned complete application to PI		
Requested Major Revisions		
Requested Minor Revisions		
Forwarded to ORC		

Third Review by Departmental Reviewer:

Disposition by Departmental Reviewer	**Date**	**Notes**
Returned complete application to PI		
Requested Major Revisions		
Requested Minor Revisions		
Forwarded to ORC		

Review by IRB Chair:

Disposition by IRB Chair	**Date**	**Notes**
Requested Major Revisions		
Requested Minor Revisions		
Forwarded to ORC		

Review Checklist

Applications for the Use of Human Participants in Research

Researcher:	Timothy Botic ATC-L,CSCS	Faculty Sponsor	Sandy Shultz PhD, ATC
Submission Date:	02/02/2005	Projected Date of First Data Collection	02/21/2005

Faculty and staff members should complete this checklist before they submit an application for their own research or when they serve as the faculty sponsor for a student's research. Please submit two complete copies of the application.

Review Criteria	Check by Researcher or Faculty Sponsor	Check by IRB Reviewer
Part A is complete.	☐	
Evidence of training in the protection of human participants in research is attached for all principal investigators.	☐	
If the principal investigator is a student, evidence of training in the protection of human participants in research is attached for the faculty sponsor.	☐	
Part B: The researcher has answered questions 1-8 on separate paper. **(DO NOT EXCEED THREE PAGES.)**	☐	
1. Goals for the project are clearly stated and suggest the need for human participants' consent.	☐	
2. The protocol discusses:	☐	
a. data gathering procedures and tools (copies of tools must be attached to the application, unless the tool is well known).	☐	
b. data recording procedures.	☐	
c. the number of participants, justification for this number, and procedures for selecting participants.	☐	
d. the length of time for procedures.	☐	
e. relationship between the researcher, participants, and participating institutions/agencies.	☐	
f. any need for deception or less than full disclosure.	☐	
g. if the research is conducted in class, what students who are not participating will do.	☐	
h. copies of letters from any agencies involved with recruitment of participants or data collection.	☐	
i. how consent will be obtained.	☐	
j. provisions for providing copies of consent documents to participants.	☐	
3. The protocol describes the benefits to individual participants AND society.	☐	
4. The protocol addresses the risks to participants, including:		
a. the level of risk for participants (none, minimal, more than minimal).	☐	
b. description of the risks to participants.	☐	

Review Criteria	Check by Researcher or Faculty Sponsor	Check by IRB Reviewer
c. precautions taken to minimize risks to participants		
d. how confidentiality will be maintained.	☐	
e. how long data will be kept	☐	
f. how data will eventually be destroyed.	☐	
5. The protocol describes the participant population and justifies any decision to exclude persons on the basis of gender, race, or ethnicity.	☐	
6. Materials to be used in recruiting participants are attached to the protocol.	☐	
7. The CONFLICT OF INTEREST question is answered N/A, NO, or YES. (If the answer is YES, a completed *Potential Conflict of Interest in Research* form is attached.)	☐	
8. The USE of PHI is answered NO or YES. (If the answer is YES, a completed *Application to USE PHI in Research* form is attached. If a waiver from the UNCG IRB is requested, a completed *UNCG Request for Waiver of Authorization* form is attached.)	☐	
9. The researcher has indicated that s/he will keep Confidentiality Certificates on file for all persons who assist with data collection or analysis during the research.	☐	
Part C: The Consent Form includes:	☐	
1. a clear explanation of the purpose of the research.	☐	
2. a clear explanation of the procedures to be used.		
3. a description of the benefits to participants and/or society.	☐	

Review Criteria	Check by Researcher or Faculty Sponsor	Check by IRB Reviewer
4. the risks of participation. (If more than minimum risk is indicated, the Consent Form includes a statement regarding compensation, availability of treatment, and directions to contact Eric Allen.)	☐	
5. the opportunity to ask questions.	☐	
6. the opportunity to withdraw from the research without penalty.		
7. the amount of time required for participation.	☐	
8. how confidentiality will be maintained.	☐	
9. how long data will be kept.		
10. how data will eventually be destroyed.		
11. the researchers name and phone number for questions about the research.	☐	
12. Eric Allen's name and phone number for questions about the rights of human participants in research.	☐	
13. a place for the signature of a witness to the oral presentation, when the short form is used).	☐	
14. a separate form for the assent of minors, if applicable.	☐	

Your signature indicates that you have reviewed the IRB application and believe it to be in approvable form.

Researcher's Signature	Date
Faculty Sponsor's Signature	Date
IRB Initial Reviewer's Signature	Date

THE UNIVERSITY OF NORTH CAROLINA

GREENSBORO

Instructions for Completing the Application for the Use of Human Participants in Research

All research with human participants conducted by students, faculty, or staff at UNCG must be reviewed initially by a member of the University's Institutional Review Board, whether or not requests for outside funding are involved. To initiate this review, the investigator/project director must complete this application and submit it to the IRB member in his/her college/school/department. The IRB member determines the category of review appropriate for the study and forwards it to the Office of Research Compliance. The University IRB meets if full committee review is necessary. Criteria for exempt, expedited, and full committee review are available at: <http://www.ohrp.osophs.dhhs.gov/polasur.htm>.

Please submit **the original and one copy** of this human participants application at least one month prior to the date you wish to initiate data collection. (You are advised to keep a copy for your records also.) **YOU MAY NOT COLLECT DATA PRIOR TO RECEIVING AN APPROVAL FORM FROM THE IRB.**

Faculty members will be informed by the IRB regarding the disposition of their applications and those of students they are sponsoring. Students do not receive direct notification of IRB disposition of proposals. Any changes in research protocol that affect human participants must be approved by the IRB prior to implementation unless the changes are necessary to eliminate apparent immediate hazards to the participant. Any unanticipated problems involving risks to participants or others must be promptly reported to the IRB.

COMPLETE PART A (ON THIS PAGE) AND NUMBERS 1-8 ON PAGE 3. ATTACH THE APPROPRIATE CONSENT FORM INFORMATION. BE SURE TO SIGN THIS APPLICATION ON PAGE 3.

Part A

Date: 01/20/2005

Project Title: DEVELOPMENT OF A LANDMARK METHOD FOR CONSTRUCTING SEGMENT AXES FOR LOWER EXTREMITY KINEMATIC ANALYSIS

Principal Investigator(s): Tim Botic

Email Address of Principal Investigator: tlbotic@uncg.edu

Phone Number of Principal Investigator: (336) 334-3039

Address of Principal Investigator: 237 HHP Bldg

Relationship to the University (specify): Faculty ☐ Student ☒ Other ☐

If student, name of faculty sponsor: Sandra J Shultz PhD, ATC

Faculty sponsor's email address: sjshultz@uncg.edu

School/College: HHP Department: Exercise and Sport Science

Funding Agency/Sponsor (if applicable): N/A

Projected data collection dates*: From 02/21/2005 To 02/20/2006

Have the investigators attached certificates of completion of training in the use of humans in research? YES

* Beginning date should be at least 1 month after submission of IRB application. Data collection cannot begin before IRB approval is received.

THIS PAGE IS FOR IRB USE ONLY

(IRB Representative: Indicate appropriate category of review: exempt, expedited, or full review. Note: the standard requirements for informed consent apply regardless of the type of review utilized by the IRB.)

Part B - Exempt

This proposed research is judged to be exempt from full committee review because it falls in one or more of the following categories (see 45 CFR 46, June 18, 1991, p. 5). Check all that apply:

_1. 46.101 (b)(1)	_ 4. 46.101 (b)(4)
_ 2. 46.101 (b)(2)	_ 5. 46.101 (b)(5)
_ 3. 46.101 (b)(3)	_ 6. 46.101 (b)(6)

Part C - Expedited or Full Review

This proposed project has been reviewed and was found to require:

____ Expedited Review (63 FR 60364-60367, November 9, 1998)

Expedited category. Check all that apply:

___1. (a)	___6.
___1. (b)	___7.
___2. (a)	___8. (a)
___2. (b)	___8. (b)
___3.	___8. (c)
___4.	___9.
___5.	

____ Full IRB Review. Please explain: _____

I certify that this project has been reviewed by me as an IRB member and that the research was not proposed by me or by a student working under my supervision.

_____ ____
IRB Signature Date

_____ _____
Print Name Dept. /School

Send this application package to: IRB, Office of Research Compliance, 203 Foust Building.

Part D - IRB Action

__ Exempt Review (Date: / /)

__ Expedited Review (Date: / /)

__ Full Review (Date: / /)

Comments:

IRB Chairperson ORC Representative

RESPOND TO NUMBERS 1 THROUGH 8 ON SEPARATE PAPER. SUBMIT NO MORE THAN 3 PAGES FOR YOUR ANSWERS. Supporting materials (e.g. letters and consent forms) should be attached.

1. BRIEF STATEMENT OF PROJECT GOALS

2. PROTOCOL: Procedures: what will be done? How long will subjects require to complete procedures?

- Name and description of data gathering tool (if not well known, attach a copy)
- How will data be recorded? (audiotapes, videotapes, written records)
- Number of participants, respondents, or participants. From where will participants be obtained?
- What, if any, relationship exists between the researcher and the participants, and between the researcher and agencies (e.g., schools, hospitals) participating in data collection? (Example: Is researcher employed at the agency?)
- Any special situations (Example: Deception used because full disclosure prior to procedure would bias data.)
- If data collection is done in class, explain what students who do not participate will be doing.
- Attach statement of approval from any agencies (e.g., schools, hospitals) that will be involved with recruitment of participants or data collection.

3. BENEFITS: Describe the benefits to individual participants and to society.

4. RISKS: Describe the risks to the participants and precautions that will be taken to minimize them. This includes physical, psychological, and sociological risks.

- How will confidentiality of data be maintained? Attach signed confidentiality agreements (form attached) for members of research team who will have access to personal data on human research participants.
- Final disposition of data (What will be done with questionnaires, inventories, videotapes, and/or audiotapes? How long will they be stored, and how will they be destroyed?)
- How would you describe the level of risk for participants taking part in this project?

☒ No risks ☐ Minimal risks ☐ More than minimal risks

5. POPULATION: Briefly describe your participant population. Will you exclude persons on the basis of gender, race, color, or any other demographic characteristic? If so, justify.

6. PARTICIPANT CONSENT: Describe how and where participants will be informed of their rights and how informed consent will be obtained and documented. Attach a copy of consent form, oral presentation (if used), and any materials to be used in recruitment (e.g. fliers, advertisements). *See next page for details on content of Consent Forms.*

Note: Signed consent forms must be retained in a secure location, for a minimum of three (3) years, after completion and available for IRB review.

7. CONFLICT OF INTEREST: At any time will any members of the research team or their immediate family members have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study, or otherwise have potential conflict of interest regarding conduct of this study?

☒ N/A no industry sponsors ☐ NO ☐ YES If yes, attach Potential Conflict of Interest in Research form.

8. PHI: Personally identifiable health information (PHI) is defined by HIPAA to include data on a person's physical or mental heath, health care, or payment for health care. As part of this study, will you obtain PHI from a hospital, health care provider, or other HIPAA-defined Covered Entity? (If unsure, read the Application to Use PHI in Research.)
☒ NO ☐ YES If yes, attach the Application to Use PHI in Research (available from ORC website.)

I certify that the statements made herein are accurate and complete. I agree to inform the Board in writing of any emergent problems or proposed procedural changes. Should changes be made, I further agree not to proceed with the research until the Board has reviewed and approved the changes that I propose to make in the protocol.

_____ _____
Principal Investigator Date

_____ _____
Faculty Sponsor (for student investigators) Date

1. BRIEF STATEMENT OF PROJECT GOALS:

   The purpose of the study is to determine if identifying bony landmarks as part of the digitization of subjects into the MotionStar electromagnetic tracking system (that measures joint motion and forces) will yield more accurate kinematic (movement) data then using the system's default protocol for data collection.

2. PROTOCOL:

Procedures and Instrumentation: On day 1, once subjects give their consent to participate in the study, demographics of age, height, weight, and sex will be recorded. Then, clinical measurements of anatomical alignment (pelvic tilt (pelvic angle), tibio-femoral angle (knee angle), and navicular drop (foot angle)) will be collected on each subject's right side with an inclinometer, protractor and ruler, respectively.

After the clinical measurements of anatomical alignment are completed, subjects will be fitted with sensors from the electromagnetic tracking system. For both the default and landmark settings, the electromagnetic sensors will be positioned at the same locations. Four sensors will be used, and will be secured with 2-sided tape. One sensor each will be placed directly over: 1) the sacrum, 2) the middle of the lateral thigh, over the iliotibial band, 3) the middle of the medial aspect of the tibial shaft, and 4) the lateral tarsal bones of the foot.

Once electrodes are secured, the participant will be digitized using the default setting. The center of the hip, knee and ankle will be identified and digitized by pointing a stylus at specific joint locations per manufacturer guidelines. Once digitized, 3 trials of 2 seconds of quiet data will be collected in quiet standing.

Landmark Protocol Digitization: With the sensors still in place, subjects will be digitized into the system using the landmark protocol to construct the orientation of individual segment axes. Joint centers will be defined in the same manner as with the default setting. Specific bony landmarks on the pelvis, thigh and leg will be digitized by pointing at them with a stylus. Landmarks were selected from those used in previous literature.

Data Reduction: The average of all data points acquired in each 2-second data collection will be averaged for the 3 trials and used to determine knee rotation angle, tibiofemoral (knee) angle, and pelvic angle as measured by the MotionStar for each digitization protocol. The mean of 3 measurements taken for each clinical measure of pelvic tilt, tibio-femoral angle, and navicular drop will be used to compare against the angles measured by the MotionStar. All analyses will be conducted using SPSS 11.5. Day-to-day consistency among the clinical measures as well as initial knee angles for both the default setting and landmark protocol will be examined with Intratester ICC's. A repeated measures ANOVA will be used to determine if there are significant differences between the default and the landmark protocol for the measures of pelvic angle, tibio-femoral (knee) angle, and knee rotation angle. Using results from the ANOVA, interclass correlation coefficients (ICC) will be calculated to determine the consistency of both protocols across days. Multiple linear regressions will determine which digitization procedure method best predicts the clinical measures.

Name and description of data gathering tool (if not well known, attach a copy)

For this study a MotionStar electromagnetic tracking system will be used (Ascension Technology Inc. P.O. Box 527, Burlington, Vermont 05402, http://www.ascension-tech.com). The system consists of a transmitter that generate DC magnetic fields. Individual sensors placed on the body receive the DC signals from the transmitter. Signal processing electronics compute position and orientation data based on the strength of the received signal from each of the sensors. The values are then exported to a computer where data acquisition software (MotionMoniter, Innovative Sports Training Inc., Chicago) allows for the computation of kinematic data i.e. position, velocity, and acceleration.

A caliper inclinometer (PALpation Meter, PALM, Performance Attainment Associates, St. Paul, MN) will be used to measure pelvic inclination. A standard plastic goniometer (modified with an adjustable extension bar on the stationary arm) will be used to measure tibio-femoral angle. Navicular drop will be measured with a small plastic ruler. All of these devices are routinely used for these measures, and have been utilized in previously approved protocols.

How will data be recorded? (Audiotapes, videotapes, written records)

Data will be obtained and maintained in electronic and written format. Demographic and non-invasive lower extremity alignment measures will be recorded manually, and entered into a computer database for storage and later analysis. All data will then be transferred to computer storage disks for later offline analyses. Data will be stored in a locked room, identified by subject code number, accessible only to the investigators. Electronic data will be maintained indefinitely until all manuscripts have been published then data will be permanently erased.

Number of subjects, respondents, or participants.

For this study 15 recreationally active and apparently healthy subjects between the ages of 18 and 40 will be recruited.

From where will subjects be obtained?

Subjects will be recruited from the general student body and surrounding community.

How long will procedures take?

Each testing session (2) will last approximately 1 hour.

What, if any, relationship exists between the researcher and the subjects?

Subjects may be fellow students in the ESS department.

What, if any, relationship exists between the researcher and agencies (e.g., schools, hospitals) participating in data collection? (Example: Is researcher employed at the agency? In what capacity?) –

N/A

Any special situations (Example: Deception - Full disclosure prior to procedure is not feasible because biased data will result.) None

If data collection is done in class, explain what students who do not participate will be doing. –

N/A

-

Attach statement of approval from any agencies (e.g., schools, hospitals) that will be involved with recruitment of subjects/participants or data collection. –

N/A

3. BENEFITS: Describe the benefits to individual participants and to society

The individual will receive no direct benefit for participating in this study. This study will demonstrate whether or not a landmark protocol will yield more accurate data than the default setting of the MotionStar electromagnetic tracking system. This may benefit future clinical research that utilizes this device.

4. RISKS: Describe the risks to the subjects/participants and precautions that will be taken to minimize them. This includes physical, psychological, and sociological risks.

There are no anticipated risks in this study.

How will confidentiality of data be maintained?

Code numbers will be assigned to the data. The list linking the names to the code numbers will be kept in a locked file, accessible only to the investigators.

Final disposition of data (What will be done with questionnaires, inventories, videotapes, and/or audiotapes? How long will they be stored, and how will they be destroyed?)

Data will be stored on a PC hard drive in the ANRL in a locked office. Data will be retained for two years following publication of manuscripts.

How would you describe the level of risk for subjects participating in this project?

_X_ No risks __ Minimal risks ___ More than minimal risks

5. Briefly describe your subject population. Will you exclude persons on the basis of gender, race, color, or any
other demographic characteristic? If so, justify.

Healthy, active, college-aged students will participate in the experiment. Healthy is operationally defined as having no current history of injuries to the lower extremity, or any past injury history that would alter lower extremity posture. Subjects will not be excluded on basis of gender, race, color, or any other demographic characteristic.

6. Subject Consent: Describe how subjects will be informed of their rights and how informed consent will be obtained and documented. Attach a copy of consent form, oral presentation (if used), and any materials to be used in recruitment (e.g. fliers, advertisements).

- See next pages for details on content of Consent Forms

  Subjects will be informed verbally and in writing of their rights, and written consent will be documented.

I certify that the statements made herein are accurate and complete. I agree to inform the Board in writing of any emergent problems or proposed procedural changes. Should changes be made, I further agree not to proceed with the research until the Board has reviewed and approved the changes that I propose to make in the protocol.

_____	_____
Principal Investigator	Date
_____	_____
Faculty Sponsor (for student investigators)	Date

CONSENT FORMS

Read very carefully.

1. Consent forms must be written in simple language that is understandable to the participants. A reading level of 4-7th grade is recommended for most populations.

2. Consent forms should NOT be written in the first person (e.g. they should NOT say "I understand the procedures and risks and agree to participate in this study...."). Sections of the consent form may be in the third person (e.g, "Subjects in this study will be interviewed.....") and the actual agreements to participate should be in the second person (e.g., "By signing this consent form, you are agreeing that you understand the procedures and risks..."). (See attached sample consent forms.)

3. When research involves minors or those who are not legally competent, informed consent must be obtained from the parent or guardian and, in some cases, assent obtained from the participant.

4. A copy of the consent form must be provided to each participant and a signed copy retained by the principal investigator. EXCEPTION: A letter containing all aspects of informed consent may be used for data collected by mailed survey. Participants need not sign a consent form since returning the questionnaire is implied consent.

5. Consent may be obtained through either the Long Form or the Short Form with Oral Presentation. Research design dictates which form is appropriate for a given study. Either format must ensure that participants are apprised of all aspects of informed consent (see list below).

ASPECTS OF INFORMED CONSENT (required in all studies)

1. Explanation of research purpose and procedures (including participant selection)
2. Benefits
3. Risks (if study poses more than minimal risk, must include statement regarding compensation/treatment for injury, and directions to contact Mr. Eric Allen at (336) 256-1482 about any research-related injuries)
4. The opportunity to withdraw without penalty
5. The opportunity to ask questions
6. The amount of time required of the participants
7. Confidentiality of data and final disposition of data
8. Phone number and name for questions on research
9. Phone number and name to ask about the rights of research participants (Mr. Eric Allen at 336-256-1482)

A. Long Form: The long form must be used when research procedures are complicated or when the researcher will have no direct contact with the participants. Information should be included in the spaces provided on the form. N/A should be inserted for sections not applicable to a specific

study. **THE FORM MAY BE REVISED BUT MUST INCLUDE ALL ASPECTS OF INFORMED CONSENT** (see list above). Some research requires that other information be included in the consent document. Your IRB representative will inform you if additional information is needed for your study.

B. Short Form with Oral Presentation: A short form with an oral presentation may be used when procedures are rather simple and when the researcher will have direct contact with the participants. The oral presentation must include the aspects of informed consent. A witness unaffiliated with the study must sign the oral presentation. The witness can be a subject or a family member, but NOT a member of the research team.

Oral Presentation must include:

1. Explanation of research purpose and procedures (including participant selection)
2. Benefits
3. Risks (if study poses more than minimal risk, must include statement regarding compensation/treatment for injury, and directions to contact Mr. Eric Allen at (336) 256-1482 about any research-related injuries)
4. The opportunity to withdraw without penalty
5. The opportunity to ask questions
6. The amount of time required of the participants
7. Confidentiality of data and final disposition of data

The oral presentation does not require the participants' signatures but must include the date on which it was read to participants.

IF AN ORAL PRESENTATION IS PLANNED, INCLUDE THE CONTENT OF THE PRESENTATION ON THE FORM.

Sample consent forms appear on the following pages. **Attach only the forms that you plan to use.** For special situations in obtaining consent, please see your IRB representative or call the Office of Research Compliance.

THE UNIVERSITY OF NORTH CAROLINA

GREENSBORO

CONSENT TO ACT AS A HUMAN PARTICIPANT: LONG FORM

Project Title: Development Of A Landmark Method For Constructing Segment Axes In Lower Extremity Kinematic Analysis

Project Director: Timothy Botic ATC-L,CSCS

Participant's Name: _____

DESCRIPTION AND EXPLANATION OF PROCEDURES:

The purpose of the study is to compare the accuracy of two different procedures to set up subjects in an electromagnetic tracking system that measures joint motions during activity. In order to qualify for this investigation, you must have no current history of injury to the lower extremity, or any previous history that would affect the alignment or motion of your lower extremity joints (i.e. hip, knee or ankle). If you meet these criteria, you will be asked to attend two, 1-hour testing sessions scheduled at least 24 hours apart. During the first testing the investigator will record your height, weight, and age. During each testing session, we will measure the angle of your pelvis, knee and ankle using a caliper, a goniometer, and a ruler, respectively. Next, sensors will be placed on your lower back, thigh, leg and foot. You will be "digitized" into the system using the instrument's default setting, and 3 trials of 2 seconds of data will be collected while you stand upright. Then, a second protocol using the identification of specific bony landmarks on your pelvis, thigh, leg, and foot will be used to "digitize" you into the system, and another 3 trials of 2 seconds of data will be collected while you stand upright. The total time required over the two days is about 2 hours.

RISKS AND DISCOMFORTS:

There are no anticipated risks. If at anytime the measurements cause you any discomfort or concern, please notify the examiner immediately.

POTENTIAL BENEFITS:

There are no direct benefits to you from participating in this study.

CONSENT:

By signing this consent form, you agree that you are 18 years of age or older and understand the procedures and any risks and benefits involved in this research. You are

free to refuse to participate or to withdraw your consent to participate in this research at any time without penalty or prejudice; your participation is entirely voluntary. Your privacy will be protected because you will not be identified by name as a participant in this project.

The research and this consent form have been approved by the University of North Carolina at Greensboro Institutional Review Board, which insures that research involving people follows federal regulations. Questions regarding your rights as a participant in this project can be answered by calling Mr. Eric Allen at (336) 256-1482. Questions regarding the research itself will be answered by Timothy Botic ATC-L,CSCS by calling (336) 334-3039 or by Sandy Shultz PhD, ATC by calling (336) 334-3027. Any new information that develops during the project will be provided to you if the information might affect your willingness to continue participation in the project.

By signing this form, you are agreeing to participate in the project described to you by

Timothy Botic ATC-L,CSCS.

_____ _____

Participant's Signature Date

You will receive a copy of this consent form.

THE UNIVERSITY OF NORTH CAROLINA

GREENSBORO

Instructions for Completing the Application for Modification to an Approved IRB Protocol

Any changes in research protocols that affect human participants must be approved by the IRB prior to implementation unless the changes are necessary to eliminate apparent immediate hazards to participants. Any unanticipated problems involving risks to participants or others must be promptly reported to the IRB.

To initiate a request for modification to a research protocol, the investigator/project director must complete this application and submit it to the IRB member in his/her college/school/department. The IRB member determines the category of review appropriate for the modification and forwards it to the Office of Research Compliance. The University IRB meets if full committee review is necessary. Criteria for exempt, expedited, and full committee review are available at: <http://www.ohrp.osophs.dhhs.gov/polasur.htm>.

NOTE: MODIFICATIONS CAN ONLY BE MADE TO STUDIES WITH CURRENT IRB APPROVAL. IF APPROVAL FOR A STUDY HAS EXPIRED, A NEW IRB APPLICATION (RATHER THAN AN APPLICATION FOR MODIFICATION) MUST BE SUBMITTED.

Please submit **the original and one copy** of this Application for Modification at least one month prior to the date you wish to initiate the change. (You are advised to keep a copy for your records also.) **YOU MAY NOT IMPLEMENT THE MODIFICATION PRIOR TO RECEIVING AN APPROVAL FORM FROM THE IRB.**

Faculty members will be informed by the IRB regarding the disposition of their applications and those of students they are sponsoring. Students do not receive direct notification of IRB disposition of applications.

COMPLETE THIS PAGE AND NUMBERS 1-8 ON PAGE 3. BE SURE TO SIGN THIS APPLICATION ON PAGE 3.

Today's Date: 02/21/2005 IRB Number of Original Application: 045183

Title (as on original IRB Application): DEVELOPMENT OF A LANDMARK METHOD FOR CONSTRUCTING SEGMENT AXES FOR LOWER EXTREMITY KINEMATIC ANALYSIS

Date of Approval of Orignial IRB Application: 2/15/2005 Expiration Date of Current IRB Approval: 2/15/2006

Principal Investigator(s): Tim Botic

Email Address of Principal Investigator: tlbotic@uncg.edu

Phone Number of Principal Investigator: (336) 334-3039

Address of Principal Investigator: 237 HHP Bldg

Relationship to the University (specify): Faculty ☐ Student ☒ Other ☐

If student, name of faculty sponsor: Sandra J Shultz PhD, ATC

Faculty sponsor's email address: sjshultz@uncg.edu

School/College: HHP Department: ESS

THIS PAGE IS FOR IRB USE ONLY

(IRB Representative: Indicate appropriate category of review: exempt, expedited, or full review. Note: the standard requirements for informed consent apply regardless of the type of review utilized by the IRB.)

Part B - Exempt

This proposed modification to previously approved project is judged to be exempt from full committee review because it falls in one or more of the following categories (see 45 CFR 46, June 18, 1991, p. 5). Check all that apply:

__1. 46.101 (b)(1)	__ 4. 46.101 (b)(4)
__ 2. 46.101 (b)(2)	__ 5. 46.101 (b)(5)
__ 3. 46.101 (b)(3)	__ 6. 46.101 (b)(6)

Part C - Expedited or Full Review

This proposed modification to a previously approved project has been reviewed and was found to require:

____ Expedited Review (63 FR 60364-60367, November 9, 1998)

Expedited category. Check all that apply:

___1. (a)	___6.
___1. (b)	___7.
___2. (a)	___8. (a)
___2. (b)	___8. (b)
___3.	___8. (c)
___4.	___9.
___5.	

____ Full IRB Review. Please explain: _____

I certify that this application for modification to a previously approved project has been reviewed by me as an IRB member and that the research was not proposed by me or by a student working under my supervision.

_____

IRB Signature Date

_____

Print Name Dept. /School

Send this application package to: IRB, Office of Research Compliance, 204 Foust Building, The Campus.

Part D - IRB Action on Application for Modification

__ Exempt Review (Date: / /)

__ Expedited Review (Date: / /)

__ Full Review (Date: / /)

Comments:

IRB Chairperson

ORC Representative

RESPOND TO NUMBERS 1 THROUGH 8 ON SEPARATE PAPER. Attach supporting materials.

1. MODIFICATION: Describe how the study will be modified, with a brief rationale for the proposed modifications. Include a description of any changes that will be made to:

- Procedures
- Data gathering tools (attach copies if not well known.) and methods of recording data
- Number, types, or sources of participants, respondents, or participants
- How confidentiality of data be maintained and final disposition of data
- Procedures for obtaining and documenting informed consent.

NOTE: Describe only aspects of the study that will be modified. Do NOT detail study procedures that will be unaffected by the proposed modifications.

2. SPECIAL SITUATIONS: Do the proposed modifications change any of the following?

- The relationship, if any, between the researcher and the participants, or between the researcher and agencies (e.g., schools, hospitals) participating in data collection?
- Any special situations? (Example: Use of deception because full disclosure prior to procedure would bias data.)
- Collection of data in class? (If data collection in class is to be added, explain what nonparticipants will be doing.)

3. BENEFITS: Do the proposed modifications change the benefits to individual participants or to society? If yes, describe.

4. RISKS: Do the proposed modifications change the risks to participants? If yes, describe:

- How risks will be changed by the modification. This includes physical, psychological, and sociological risks.
- Any changed precautions that will be taken to minimize risks.
- How would you describe the level of risk for participants taking part in the modified project?

☒ No risks ☐ Minimal risks ☐ More than minimal risks

5. NEW OR REVISED MATERIALS: Attach a copy of any new or revised materials, including new or revised consent forms, oral presentations, or recruitment materials. Indicate "N/A" if no new or revised materials will be used.

6. AGENCY APPROVAL: Attach statement of approval from any new agencies (e.g., schools, hospitals) that will be involved with recruitment of participants or data collection. If procedures will be revised substantially, attach statements from previously-approved agencies indicating their agreement to the proposed changes. Indicate "N/A" if not applicable.

HEALTH INFORMATION: Personally identifiable health information (PHI) is broadly defined by HIPAA to include data on a person's physical or mental heath, health care, or payment for health care. Will the proposed modification involve additional use of PHI obtained from a hospital, health care provider, insurance agency or other HIPAA-defined Covered Entity (beyond any use already approved for the study)?

☒ NO ☐ YES If yes, attach the Application to Use PHI in Research (available from ORC website.)

If unsure, read the Application to Use PHI in Research.

8. CURRENT APPROVAL: For studies that have been approved less than a year, attach a copy of the original IRB approval form. For studies that have been approved more than a year, attach a copy of the most recent IRB renewal approval. MODIFICATIONS CAN ONLY BE MADE TO STUDIES WITH CURRENT IRB APPROVAL. IF APPROVAL HAS EXPIRED, A NEW IRB APPLICATION (RATHER THAN AN APPLICATION FOR MODIFICATION) MUST BE SUBMITTED.

I certify that the statements made herein are accurate and complete. I agree to inform the Board in writing of any emergent problems or proposed procedural changes. Should changes be made, I further agree not to proceed with the research until the Board has reviewed and approved the changes that I propose to make in the protocol.

_____ _____

Principal Investigator Date

_____ _____

Faculty Sponsor (for student investigators) Date

1. MODIFICATION: Exclusion criteria will be modified to exclude anyone who has a body mass index (BMI) of greater than 25. BMI is calculated by the following: weight [kg] / height $[(m)^2]$. This will be done because the study requires palpation of bony anatomical landmarks. These landmarks are much more difficult to locate reliably in subjects with large body fat deposits, and thus the inclusion of subjects with a BMI greater than 25 may decrease the reliability of the study.

APPENDIX B. SPSS OUTPUT

Descriptives

	N	Range	Minimum	Maximum	Mean	Std.	Variance
PAD	19	12.33	8.33	20.67	13.456	3.1509	9.929
PAD	19	11.67	7.33	19.00	13.350	3.4827	12.12
TFAD	19	11.33	6.67	18.00	10.771	2.8740	8.260
TFAD	19	10.67	7.00	17.67	10.877	2.7849	7.756
NDD	19	9.67	3.00	12.67	7.421	2.8692	8.233
NDD	19	10.00	2.00	12.00	7.543	3.2588	10.62
DPAD	19	24.24	-8.59	15.65	3.297	6.8457	46.86
DPAD	19	16.92	-6.50	10.43	.9519	3.8349	14.70
DKRD	19	12.91	-3.17	9.75	.7543	2.7947	7.811
DKRD	19	9.88	-4.98	4.90	-.4294	2.4980	6.240
DVVD	19	18.43	-3.56	14.87	4.740	4.3297	18.74
DVVD	19	12.11	-.74	11.37	5.106	3.2343	10.46
LPAD	19	47.86	-28.88	18.98	-	11.4485	131.07
LPAD	19	25.31	-19.21	6.10	-	7.4979	56.21
LKRD	19	29.94	-17.82	12.12	-	6.9337	48.07
LKRD	19	24.92	-6.43	18.49	3.641	7.8803	62.10
LVVD	19	20.14	-5.64	14.51	1.845	5.2185	27.23
LVVD	19	16.39	-6.90	9.49	.1293	4.1767	17.44
Valid N	19						

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	DPAD1	3.2972	19	6.84577	1.57053
	LPAD1	-9.4348	19	11.44857	2.62648
Pair 2	DPAD2	.9519	19	3.83496	.87980
	LPAD2	-8.0543	19	7.49794	1.72015
Pair 3	DKRD1	.7543	19	2.79479	.64117
	LKRD1	-1.5624	19	6.93379	1.59072
Pair 4	DKRD2	-.4294	19	2.49807	.57310
	LKRD2	3.6417	19	7.88037	1.80788
Pair 5	DVVD1	4.7407	19	4.32979	.99332
	LVVD1	1.8450	19	5.21852	1.19721
Pair 6	DVVD2	5.1066	19	3.23431	.74200
	LVVD2	.1293	19	4.17674	.95821

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	DPAD1 & LPAD1	19	.072	.770
Pair 2	DPAD2 & LPAD2	19	-.361	.129
Pair 3	DKRD1 & LKRD1	19	.004	.988
Pair 4	DKRD2 & LKRD2	19	-.464	.045
Pair 5	DVVD1 & LVVD1	19	.539	.017
Pair 6	DVVD2 & LVVD2	19	.488	.034

Paired Samples Test

		Paired					t	df	Sig. (2-tailed)
		Mean	Std.	Std. Mean	95% Confidence Interval of Difference Lower	Upper			
Pair	DPAD1 -	12.732	12.9097	2.9617	6.509	18.954	4.299	18	.000
Pair	DPAD2 -	9.006	9.5746	2.1965	4.391	13.621	4.100	18	.001
Pair	DKRD1 -	2.316	7.4661	1.7128	-	5.915	1.353	18	.193
Pair	DKRD2 -	-	9.3064	2.1350	-	.4145	-1.907	18	.073
Pair	DVVD1 -	2.895	4.6486	1.0664	.6551	5.136	2.715	18	.014
Pair	DVVD2 -	4.977	3.8378	.8804	3.127	6.827	5.653	18	.000

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
PAD1	13.4561	3.15096	19
DPAD1	3.2972	6.84577	19
LPAD1	-9.4348	11.44857	19

Correlations

		PAD1	DPAD1	LPAD1
Pearson Correlation	PAD1	1.000	.001	-.275
	DPAD1	.001	1.000	.072
	LPAD1	-.275	.072	1.000
Sig. (1-tailed)	PAD1	.	.498	.127
	DPAD1	.498	.	.385
	LPAD1	.127	.385	.
N	PAD1	19	19	19
	DPAD1	19	19	19
	LPAD1	19	19	19

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	LPAD1	.	Stepwise (Criteria: Probability-of-F-to-enter <= .490, Probability-of-F-to-remove >= .510).

a. Dependent Variable: PAD1

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.275[a]	.076	.021	3.11727	.076	1.391	1	17	.254

a. Predictors: (Constant), LPAD1

b. Dependent Variable: PAD1

ANOVA[b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	13.518	1	13.518	1.391	.254[a]
	Residual	165.195	17	9.717		
	Total	178.713	18			

a. Predictors: (Constant), LPAD1

b. Dependent Variable: PAD1

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	12.742	.937		13.598	.000	10.765	14.719			
	LPAD1	-.076	.064	-.275	-1.179	.254	-.211	.060	-.275	-.275	-.275

a. Dependent Variable: PAD1

Excluded Variables[b]

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	DPAD1	.021[a]	.088	.931	.022	.995

a. Predictors in the Model: (Constant), LPAD1

b. Dependent Variable: PAD1

Coefficient Correlations[a]

Model			LPAD1
1	Correlations	LPAD1	1.000
	Covariances	LPAD1	.004

a. Dependent Variable: PAD1

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	11.3052	14.9280	13.4561	.86660	19
Residual	-5.1224	6.6193	.0000	3.02944	19
Std. Predicted Value	-2.482	1.698	.000	1.000	19
Std. Residual	-1.643	2.123	.000	.972	19

a. Dependent Variable: PAD1

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
PAD2	13.3509	3.48272	19
DPAD2	.9519	3.83496	19
LPAD2	-8.0543	7.49794	19

Correlations

		PAD2	DPAD2	LPAD2
Pearson Correlation	PAD2	1.000	.105	-.550
	DPAD2	.105	1.000	-.361
	LPAD2	-.550	-.361	1.000
Sig. (1-tailed)	PAD2	.	.335	.007
	DPAD2	.335	.	.065
	LPAD2	.007	.065	.
N	PAD2	19	19	19
	DPAD2	19	19	19
	LPAD2	19	19	19

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	LPAD2	.	Stepwise (Criteria: Probability-of-F-to-enter <= .490, Probability-of-F-to-remove >= .510).

a. Dependent Variable: PAD2

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.550[a]	.302	.261	2.99407	.302	7.355	1	17	.015

a. Predictors: (Constant), LPAD2

b. Dependent Variable: PAD2

ANOVA[b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	65.932	1	65.932	7.355	.015[a]
	Residual	152.396	17	8.964		
	Total	218.327	18			

a. Predictors: (Constant), LPAD2

b. Dependent Variable: PAD2

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	11.295	1.023		11.041	.000	9.137	13.453			
	LPAD2	-.255	.094	-.550	-2.712	.015	-.454	-.057	-.550	-.550	-.550

a. Dependent Variable: PAD2

Excluded Variables[b]

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	DPAD2	-.108[a]	-.484	.635	-.120	.870

a. Predictors in the Model: (Constant), LPAD2

b. Dependent Variable: PAD2

Coefficient Correlations[a]

Model			LPAD2
1	Correlations	LPAD2	1.000
	Covariances	LPAD2	.009

a. Dependent Variable: PAD2

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	9.7390	16.1989	13.3509	1.91386	19
Residual	-4.8428	5.3876	.0000	2.90971	19
Std. Predicted Value	-1.887	1.488	.000	1.000	19
Std. Residual	-1.617	1.799	.000	.972	19

a. Dependent Variable: PAD2

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
TFAD1	10.7719	2.87401	19
DVVD1	4.7407	4.32979	19
LVVD1	1.8450	5.21852	19

Correlations

		TFAD1	DVVD1	LVVD1
Pearson Correlation	TFAD1	1.000	-.575	-.208
	DVVD1	-.575	1.000	.539
	LVVD1	-.208	.539	1.000
Sig. (1-tailed)	TFAD1	.	.005	.196
	DVVD1	.005	.	.009
	LVVD1	.196	.009	.
N	TFAD1	19	19	19
	DVVD1	19	19	19
	LVVD1	19	19	19

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	DVVD1	.	Stepwise (Criteria: Probability-of-F-to-enter <= .490, Probability-of-F-to-remove >= .510).

a. Dependent Variable: TFAD1

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.575[a]	.331	.292	2.41852	.331	8.418	1	17	.010

a. Predictors: (Constant), DVVD1

b. Dependent Variable: TFAD1

ANOVA[b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	49.241	1	49.241	8.418	.010[a]
	Residual	99.437	17	5.849		
	Total	148.678	18			

a. Predictors: (Constant), DVVD1

b. Dependent Variable: TFAD1

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	12.583	.835		15.067	.000	10.821	14.345			
	DVVD1	-.382	.132	-.575	-2.901	.010	-.660	-.104	-.575	-.575	-.575

a. Dependent Variable: TFAD1

Excluded Variables[b]

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	LVVD1	.144[a]	.600	.557	.148	.709

a. Predictors in the Model: (Constant), DVVD1

b. Dependent Variable: TFAD1

Coefficient Correlations[a]

Model			DVVD1
1	Correlations	DVVD1	1.000
	Covariances	DVVD1	.017

a. Dependent Variable: TFAD1

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	6.9043	13.9447	10.7719	1.65398	19
Residual	-3.1462	6.9594	.0000	2.35038	19
Std. Predicted Value	-2.338	1.918	.000	1.000	19
Std. Residual	-1.301	2.878	.000	.972	19

a. Dependent Variable: TFAD1

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
TFAD2	10.8772	2.78490	19
DVVD2	5.1066	3.23431	19
LVVD2	.1293	4.17674	19

Correlations

		TFAD2	DVVD2	LVVD2
Pearson Correlation	TFAD2	1.000	-.450	-.455
	DVVD2	-.450	1.000	.488
	LVVD2	-.455	.488	1.000
Sig. (1-tailed)	TFAD2	.	.027	.025
	DVVD2	.027	.	.017
	LVVD2	.025	.017	.
N	TFAD2	19	19	19
	DVVD2	19	19	19
	LVVD2	19	19	19

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	LVVD2	.	Stepwise (Criteria: Probability-of-F-to-enter <= .490, Probability-of-F-to-remove >= .510).
2	DVVD2	.	Stepwise (Criteria: Probability-of-F-to-enter <= .490, Probability-of-F-to-remove >= .510).

a. Dependent Variable: TFAD2

Model Summary[c]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.455[a]	.207	.160	2.55225	.207	4.431	1	17	.050
2	.524[b]	.275	.184	2.51505	.068	1.507	1	16	.237

a. Predictors: (Constant), LVVD2

b. Predictors: (Constant), LVVD2, DVVD2

c. Dependent Variable: TFAD2

ANOVA[c]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	28.864	1	28.864	4.431	.050[a]
	Residual	110.738	17	6.514		
	Total	139.602	18			
2	Regression	38.395	2	19.197	3.035	.076[b]
	Residual	101.208	16	6.325		
	Total	139.602	18			

a. Predictors: (Constant), LVVD2

b. Predictors: (Constant), LVVD2, DVVD2

c. Dependent Variable: TFAD2

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	10.916	.586		18.634	.000	9.680	12.152			
	LVVD2	-.303	.144	-.455	-2.105	.050	-.607	.001	-.455	-.455	-.455
2	(Constant)	12.220	1.209		10.110	.000	9.658	14.782			
	LVVD2	-.206	.163	-.309	-1.266	.224	-.551	.139	-.455	-.302	-.270
	DVVD2	-.258	.210	-.299	-1.227	.237	-.703	.187	-.450	-.293	-.261

a. Dependent Variable: TFAD2

Excluded Variables[b]

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	DVVD2	-.299[a]	-1.227	.237	-.293	.762

a. Predictors in the Model: (Constant), LVVD2

b. Dependent Variable: TFAD2

Coefficient Correlations[a]

Model			LVVD2	DVVD2
1	Correlations	LVVD2	1.000	
	Covariances	LVVD2	.021	
2	Correlations	LVVD2	1.000	-.488
		DVVD2	-.488	1.000
	Covariances	LVVD2	.026	-.017
		DVVD2	-.017	.044

a. Dependent Variable: TFAD2

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	7.3373	13.1548	10.8772	1.46049	19
Residual	-3.7666	5.8221	.0000	2.37121	19
Std. Predicted Value	-2.424	1.559	.000	1.000	19
Std. Residual	-1.498	2.315	.000	.943	19

a. Dependent Variable: TFAD2

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
NDD1	7.4211	2.86925	19
DKRD1	.7543	2.79479	19
LKRD1	-1.5624	6.93379	19

Correlations

		NDD1	DKRD1	LKRD1
Pearson Correlation	NDD1	1.000	-.059	-.001
	DKRD1	-.059	1.000	.004
	LKRD1	-.001	.004	1.000
Sig. (1-tailed)	NDD1	.	.405	.499
	DKRD1	.405	.	.494
	LKRD1	.499	.494	.
N	NDD1	19	19	19
	DKRD1	19	19	19
	LKRD1	19	19	19

Variables Entered/Removed[a]

a. Dependent Variable: NDD1

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
NDD2	7.5439	3.25882	19
DKRD2	-.4294	2.49807	19
LKRD2	3.6417	7.88037	19

Correlations

		NDD2	DKRD2	LKRD2
Pearson Correlation	NDD2	1.000	-.351	.510
	DKRD2	-.351	1.000	-.464
	LKRD2	.510	-.464	1.000
Sig. (1-tailed)	NDD2	.	.070	.013
	DKRD2	.070	.	.023
	LKRD2	.013	.023	.
N	NDD2	19	19	19
	DKRD2	19	19	19
	LKRD2	19	19	19

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	LKRD2	.	Stepwise (Criteria: Probability-of-F-to-enter <= .490, Probability-of-F-to-remove >= .510).

a. Dependent Variable: NDD2

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.510[a]	.260	.216	2.88500	.260	5.967	1	17	.026

a. Predictors: (Constant), LKRD2

b. Dependent Variable: NDD2

ANOVA[b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	49.663	1	49.663	5.967	.026[a]
	Residual	141.495	17	8.323		
	Total	191.158	18			

a. Predictors: (Constant), LKRD2

b. Dependent Variable: NDD2

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B		Correlations		
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part
1	(Constant)	6.776	.733		9.249	.000	5.230	8.322			
	LKRD2	.211	.086	.510	2.443	.026	.029	.393	.510	.510	.510

a. Dependent Variable: NDD2

Excluded Variables[b]

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	DKRD2	-.146[a]	-.610	.550	-.151	.785

a. Predictors in the Model: (Constant), LKRD2

b. Dependent Variable: NDD2

Coefficient Correlations[a]

Model			LKRD2
1	Correlations	LKRD2	1.000
	Covariances	LKRD2	.007

a. Dependent Variable: NDD2

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	5.4203	10.6733	7.5439	1.66104	19
Residual	-5.3691	5.2313	.0000	2.80372	19
Std. Predicted Value	-1.278	1.884	.000	1.000	19
Std. Residual	-1.861	1.813	.000	.972	19

a. Dependent Variable: NDD2

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
TFAD2	10.8772	2.78490	19
DVVD2	5.1066	3.23431	19

Correlations

		TFAD2	DVVD2
Pearson Correlation	TFAD2	1.000	-.450
	DVVD2	-.450	1.000
Sig. (1-tailed)	TFAD2	.	.027
	DVVD2	.027	.
N	TFAD2	19	19
	DVVD2	19	19

Variables Entered/Removed[b]

Model	Variables Entered	Variables Removed	Method
1	DVVD2[a]	.	Enter

a. All requested variables entered.

b. Dependent Variable: TFAD2

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.450[a]	.202	.155	2.55929	.202	4.313	1	17	.053

a. Predictors: (Constant), DVVD2

ANOVA[b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	28.253	1	28.253	4.313	.053[a]
	Residual	111.349	17	6.550		
	Total	139.602	18			

a. Predictors: (Constant), DVVD2

b. Dependent Variable: TFAD2

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	12.855	1.119		11.490	.000	10.495	15.216
	DVVD2	-.387	.187	-.450	-2.077	.053	-.781	.006

a. Dependent Variable: TFAD2