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Reliability and Validity of the Star Excursion Balance Test in Patients with Knee Osteoarthritis

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Graduate Program in Kinesiology
A thesis submitted in partial fulfillment of the requirements for the degree in Master of Science
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Abstract

The purpose of this study was to investigate the measurement properties of the star excursion balance test (SEBT) in patients with knee osteoarthritis (OA). Specific objectives were to estimate: 1) test-retest reliability, 2) concurrent validity of observer measurements compared to a 3D motion capture system, and 3) longitudinal validity in response to 12 weeks of neuromuscular exercises. Thirty-eight patients diagnosed with knee OA participated. They performed the SEBT on three test occasions. The first two test sessions were completed within one week and the third was 12 weeks later. Participants performed exercises at home over the 12-week period. Intraclass correlation coefficients (ICC) ranging from 0.70-to-0.94 suggested good-to-excellent reliability. Pearson $r \geq 0.96$ between observer and motion capture measures suggested excellent concurrent validity. Participants significantly improved ($p \leq 0.05$) on six directions and the composite score of the SEBT, with standardized response means > 0.4 . Improvements in the SEBT were low-to-moderately correlated with improvements in 40m walk times and patient-reported outcomes ($r = 0.24-0.48$) suggesting adequate longitudinal validity. The present results suggest appropriate measurement properties for the SEBT in patients with knee OA and support its use in clinical and research settings.

Keywords

Star excursion, standing balance, knee osteoarthritis, test-retest reliability, concurrent validity, longitudinal validity, neuromuscular control

Co-Authorship Statement

Lauren Kanko was the sole author of all chapters in this thesis. Trevor Birmingham reviewed each chapter, assisted with revisions and approved the submitted thesis.

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List of Abbreviations

ACL	Anterior Cruciate Ligament
ADL	Activities of Daily Living/Function in Daily Living KOOS subscale
AL	Anterolateral Direction of the SEBT relative to stance leg
AN	Anterior Direction of the SEBT relative to stance leg
AM	Anteromedial Direction of the SEBT relative to stance leg
CAI	Chronic Ankle Instability
ICC	Intraclass Correlation Coefficient
KOOS	Knee Injury and Osteoarthritis Outcome Score
LA	Lateral Direction of the SEBT relative to stance leg
LAS	Lateral Ankle Sprain
LOS	Limits of Stability
MDC	Minimum Detectable Change
ME	Medial Direction of the SEBT relative to stance leg
OA	Osteoarthritis
PL	Posterolateral Direction of the SEBT relative to stance leg
PM	Posteromedial Direction of the SEBT relative to stance leg
PO	Posterior Direction of the SEBT relative to stance leg
QOL	Quality of Life
ROM	Range of Motion
SEBT	Star Excursion Balance Test
SEM	Standard Error of Measurement
SRM	Standardized Response Mean
YLD	Years Lived with Disability

Chapter 1

1 Introduction

1.1 Background and Rationale

Knee osteoarthritis (OA) is a musculoskeletal disease that affects over 241 million people worldwide, causing significant pain and disability¹. Osteoarthritis is the most common type of arthritis and results in a significant burden on health care systems²⁻⁴. The knee is one of the most common joints affected by OA². Although once considered a disease primarily of the articular cartilage, knee OA is now considered to affect the whole joint⁴. Knee OA involves the breakdown and abnormalities of cartilage, bone, muscles, and ligaments in the joint. In comparison to healthy individuals, those with OA have decreased quadriceps muscle strength, postural control and joint proprioception⁵. As a result, individuals experience pain, decreased muscle strength and function, disability, and lowered quality of life.

Although there is presently no cure for OA, there are a variety of treatment options. Initial conservative treatment should include exercise and patient education, with pharmacological treatment options explored if no improvements are seen. Surgical treatments for knee OA are considered when improvements are no longer satisfactory with solely non-operative management options. The main goals of non-operative treatments are to educate patients, control pain, improve function and potentially slow the progression of disease^{4,6,7}.

Exercise therapy and weight management are the primary non-operative treatment options for knee OA and include aerobic and resistance exercises with patient education regarding diet and managing symptoms. Through exercise, individuals can increase aerobic fitness, assist weight loss, and increase muscle strength and endurance⁴. Aerobic and resistance exercise can help reduce pain and increase function in individuals with knee OA⁴. Exercise programs that focus on neuromuscular control of the knee are suggested to be particularly helpful for patients with OA^{8,9}. Such neuromuscular exercises typically consist of quadriceps and hamstring strengthening exercises, balance

and postural control exercises, and functional movements such as stepping or lunging with the aim of improving neuromuscular control^{10,11}. Neuromuscular control requires both the coordinated muscle activity to produce the desired movement and functional stability to keep the joint stable during that movement¹⁰.

Although neuromuscular exercise has become a mainstay in the treatment of knee OA, there is no widely accepted clinical tool to monitor patient progress in neuromuscular control of the knee⁸⁻¹⁰. Many tests used in research and clinical settings are appropriate to monitor disability and function in individuals with knee OA. Commonly used walking and sit to stand tests include the 40m fast-paced walking test, 80m fast-paced walking test, six-minute walk test, timed up and go, and 30-s chair-stand test¹². Tests of static balance, the use of force plates to measure postural sway, the Berg Balance Scale, and the Community Balance and Mobility Scale are commonly used to assess standing balance¹³. However, many of these test static balance, physical function or a combination of walking and stairs. The Berg Balance Scale has also demonstrated ceiling effects in ambulatory older adults.¹³ Therefore, there is no widely used clinical test that can be used to assess improvements in neuromuscular control, which requires functional stability and sensorimotor control produced through quality movement⁹.

We propose that the Star Excursion Balance Test (SEBT), a test of dynamic balance and postural control, may fill this need. The SEBT requires participants to maintain a single leg stance and reach with the other leg as far as possible along a line marked on the ground^{14,15}. The participant makes a light touch at maximal reach, returns to the centre, and repeats this for all eight directions of the star. The maximal reach for each direction is normalized to leg length to provide the measure of performance¹⁶. The SEBT is a challenging dynamic task that requires postural control to maintain balance over the base of support and adequate neuromuscular control of the stance leg to maximize reach distance¹⁵.

The SEBT has good test-retest reliability and inter-rater reliability in healthy participants with low standard errors of measurement (SEM) and minimum detectable change (MDC) values^{17,18}. It is sensitive to reach deficits in patients with lateral ankle sprain, chronic

ankle instability (CAI) and after anterior cruciate ligament (ACL) reconstruction compared to healthy individuals¹⁹⁻²². A three-direction version of the test (anteromedial, medial, posteromedial) has been used to reduce the amount of time necessary to perform the test and includes the directions most sensitive to reach deficits in individuals with CAI^{23,24}. In individuals with knee OA, improvements were seen on the anterior and medial directions of the SEBT following a six week lower extremity exercise program²⁵.

The SEBT is commonly used in young healthy populations and in those with acute lower extremity injuries, but the measurement properties have yet to be estimated in patients with knee OA. The aim of this study was to estimate test-retest reliability, concurrent validity of observer measurements compared to a 3D motion capture system, and longitudinal validity in response to 12 weeks of neuromuscular exercises.

1.2 Objectives

The purpose of this study was to estimate the measurement properties of the Star Excursion Balance Test (SEBT) in patients with knee osteoarthritis (OA).

The specific objectives of the study were to:

- 1) Estimate the relative and absolute test-retest reliability; the agreement between SEBT measurements completed on two separate days within one week
- 2) Estimate concurrent validity; the association between the observer and motion capture technology measurements of patient performance during the SEBT
- 3) Estimate longitudinal validity of SEBT measurements in response to 12 weeks of neuromuscular exercises

1.3 Hypotheses

We hypothesized:

- 1) Excellent test-retest reliability, characterized by an intraclass correlation coefficient (ICC) of at least 0.85. We also hypothesize that there will be relatively low standard errors of measurement (SEM) and minimum detectable changes (MDC).
- 2) Observer and camera measures of performance (distance reached) will be highly correlated (Pearson $r > 0.75$)
- 3) Performance of the SEBT will improve significantly ($p < 0.05$) following 12 weeks of neuromuscular exercise, with a standardized response mean (SRM) of greater than 0.4 (i.e. a small-to-moderate effect). There will be low-to-moderate correlations ($r = 0.2$ to 0.5) between improvements in SEBT scores and improvements in 40-metre shuttle walk times and Knee Injury and Osteoarthritis Outcome scores (KOOS).

Chapter 2

2 Literature Review

2.1 Anatomy of the Knee Joint

The knee joint is the articulation between the tibia, femur, and patella including the menisci and ligaments²⁶. As a modified hinge joint, the tibiofemoral joint and the patellofemoral joint allow flexion and rotation of the lower limb and are supported by ligaments, muscles, and the joint capsule²⁷. The concave medial tibial plateau articulates with the medial femoral condyle and is supported by the medial meniscus, while the lateral tibial plateau articulates with the femoral condyle and has a more convex surface which allows for internal rotation²⁶. The quadriceps muscles, composed of the rectus femoris, the vastus lateralis, the vastus medialis, and the vastus intermedius, act to extend the knee, while the hamstrings, composed of the semitendinosus, semimembranosus, and biceps femoris, act to flex the knee²⁶. The patellofemoral joint articulates with the trochlea of the anterior femur and acts to increase the lever arm of the quadriceps extensors²⁶.

2.2 Knee Osteoarthritis

Knee osteoarthritis (OA) is a progressive disease of abnormalities and breakdown of the tissues, cartilage, muscles, and ligaments in the knee joint, often leading to pain and disability²⁸. It is the most prevalent kind of arthritis and usually presents as joint pain, causing decreased function or disability for older adults⁴. There is currently no cure, but total knee replacement is the usual treatment for end-stage knee OA. However, knee OA causes pain, loss of function and disability well before joint replacements are considered. Knee OA is now known to be a whole joint disease, with changes seen in breakdown of the articular cartilage, subchondral sclerosis, osteophyte formation, and changes in the synovium²⁹. Malalignment, muscle weakness, and structural damage can cause further progression of disease in individuals already at risk⁴.

2.2.1 Diagnosis

Knee OA can be discussed in terms of imaging (x-rays, MRI) and patient-reported outcomes. The Kellgren-Lawrence (KL) scale used to classify radiographic OA is divided into five categories: no changes, possible osteophytes, definite osteophytes and possible joint space narrowing, moderate osteophytes and definite joint space narrowing, and severe osteophytes with joint space narrowing³⁰. Joint-space narrowing of the tibiofemoral joint and osteophytes as seen on X-ray evaluation can reflect advanced OA, but this does not represent the full extent of the disease as soft tissues cannot be seen on X-rays^{4,28}. Patient-reported pain and limitations are important; a clinical diagnosis would be made according to a patient's pain, stiffness, disability, crepitus, reduced movement, and increased age^{4,31}. Although radiographs are the preferred method for diagnosis, many patients can be asymptomatic and therefore clinical criteria to classify patients are also important³². According to the Altman criteria, OA classification by clinical exam requires the patient to have knee pain as well as at least three of six clinical findings; age greater than 50 years, morning stiffness less than 30 minutes, crepitus, bony tenderness on the joint, bony enlargement, and a lack of palpable warmth³². These criteria are 95% sensitive and 69% specific³². MRI may be used to identify other causes of knee pain, but many patients may have meniscal damage that does not aggravate symptoms⁴. MRI can be used to quantitatively measure articular cartilage and relaxation time measures may provide further insight into the joint, however these are costly and are not necessary for general diagnosis³³.

2.2.2 Epidemiology

Osteoarthritis is most common in the hand, hip, and knee joints, and incidence usually increases with age and in females^{2,33}. It is the most common form of arthritis and the societal burden of the disease is expected to increase with the aging population⁴. Estimating the prevalence of OA is difficult because diagnosis includes reading radiographs, and many patients with radiographic OA may be asymptomatic³⁴.

A review in 2011 conducted by Pereira et al.³¹ analyzed 72 articles to examine the differences in prevalence and incidence estimates of knee, hip, and hand OA depending on case definitions. When radiographic definitions were used, prevalence ranged from 7.1% in Croatia to 70.8% in Japan³¹. Using a symptomatic definition, prevalence ranged from 5.4% in Italy to 24.2% in Korea. The authors suggest that radiographic definitions tend to result in over-estimates of prevalence. Knee OA prevalence was higher in women than in men regardless of the case definition³¹.

In 2014, Cross et al.³ conducted a systematic review as part of the Global Burden of Disease study to identify the global disease burden of hip and knee OA. Seventy-two studies were included for knee OA and 45 studies for hip OA. Of the 291 conditions investigated in the overall study, hip and knee OA were identified as 11th for diseases contributing to disability, as measured through years lived with disability (YLD). The global prevalence of radiographically confirmed symptomatic knee OA was 3.8% with a peak at age 50³.

2.2.3 Risk Factors for Knee OA

There is a genetic component to OA, but the specific genes involved have not yet been identified⁴. Other risk factors that are associated with knee OA include increased BMI, age, lower limb malalignment, being female, previous knee injury, overuse, and high bone mineral density^{29,35-37}. Overuse from sports participation is a risk factor for knee osteoarthritis as repetitive joint loading and torque causing knee injuries are associated with joint degeneration³⁵. Smoking does not have a significant association with knee OA onset³⁶. In addition to being a risk factor for OA, lower limb malalignment and muscle weakness is related to disease progression in those already at risk^{4,37}. Alignment is measured as the angle at the intersection of the axes of the femur and the tibia, with the load-bearing line drawn through the mid femoral head to mid ankle³⁸. Varus alignment occurs when the line passes on the medial side of the knee and valgus on the lateral side of the knee^{37,38}. Varus and valgus alignment may be due to genetic factors but alignment can also change as a result of cartilage loss, furthering the progression of knee OA and

increasing malalignment³⁸. Varus alignment increases risk of medial knee OA progression in people with knee OA and valgus alignment increases risk of lateral knee OA progression³⁸. BMI is one of the few risk factors for OA that can be modified through interventions. Targeting diet, exercise and patient education in the management of knee OA can have a positive impact on BMI and reduce pain and disability³⁹.

2.3 Management of Knee OA

The overall goal for management of knee OA is to educate patients, manage pain, and improve function⁴. With the rising incidence of OA, mainly as a result of an aging and overweight population, it is becoming increasingly important to diagnose and treat OA early. Although it is difficult to diagnose early in the disease stage, treatment such as exercise and weight management should be considered well before the end-stage of the disease is reached and joint replacement is the primary treatment. Treatment should emphasize patient education and should be individualized according to risk factors, pain, and level of structural damage^{6,40}. Treatment is usually classified as non-pharmacological, pharmacological, and surgical, and often patients will benefit most from combined treatment^{6,7,33}.

2.3.1 Pharmacological Management

Pharmacological treatment usually includes acetaminophen for management of pain in mild to moderate knee OA because it is safe, effective, and can be taken as a first line of treatment^{4,7,33,39}. For individuals who don't respond to acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) may be used with caution but are not indicated for long term use because of their possible negative effects on individuals with cardiorespiratory and gastrointestinal risk factors and their potential toxicity^{4,7,33,39}. Intra-articular (IA) injection of glucocorticoids or hyaluronic acid (HA) can be used to provide longer lasting (one week) pain relief for individuals who don't respond to analgesics^{4,7,33}. IA corticosteroids are suggested to provide more short term benefit than IA hyaluronic acid,

however HA may provide better long lasting relief³⁹. Therefore, with pharmacological treatment options used mainly for pain relief, conservative treatment usually begins with non-pharmacological management including exercise and weight loss.

2.3.2 Non-pharmacological Management

Non-pharmacological treatment includes education, exercise, strength training, and weight management through exercise and diet^{33,39}. Walking aids, braces, and footwear may also be used as part of conservative treatment. Quadriceps muscle weakness is thought to occur in individuals with painful knee OA because of atrophy from disuse, but it has also been seen in individuals without painful OA³⁵. Therefore, as a common symptom of OA, it is important to target quadriceps strength through exercise programs. Exercise programs, which are often a combination of aerobic activity and muscle strengthening, provide a small to moderate treatment benefit for patients with knee OA in terms of pain, physical function and quality of life⁴¹. Mixed programs are recommended as both aerobic exercise and quadriceps strengthening provide patient improvements on pain and function^{40,42,43}. Neuromuscular programs are recommended to target not only muscle strengthening but also muscle activation and proprioception associated with postural control and functional stability^{8,10}. Biomechanical interventions such as knee braces and orthoses are also included in the guidelines for non-pharmacological management^{4,7,39}.

2.3.3 Surgical Management

Surgical interventions are often considered after non-operative management options fail to provide satisfactory improvements in pain and function. Surgeries include arthroscopy, osteotomy and joint replacement⁴. Arthroscopic debridement was thought to help with pain and function by removing cartilage and debris in the joint^{44,45}. However, arthroscopic debridement does not provide significant patient improvements for knee OA^{45,46}. Medial opening wedge high tibial osteotomy provides improvements in dynamic

knee joint loading and patient-reported outcomes for patients with medial knee OA⁴⁷. It is suggested for younger patients with symptomatic knee OA to delay knee replacement surgery^{7,47}. Knee replacement surgery is now increasingly common, and is cost-effective for treatment of end-stage arthritis when other treatments have failed^{4,48}. Preoperative function is an important indication of function postoperatively, therefore non-surgical management such as exercise should continue even if total joint replacement may eventually be necessary⁴.

2.4 Research Outcomes in Knee OA

In clinical research of knee OA, both performance-based tests of physical function and self-reported measures are commonly used. The Osteoarthritis Research Society International has recommended the use of the 30-s chair-stand test, 40m fast-paced walk test, a stair-climb test, timed up-and-go test, and 6-minute walk test for patients with hip and knee osteoarthritis¹². The Knee Injury and Osteoarthritis Outcome Score (KOOS) and WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) are commonly used self-reported measures for knee OA^{49,50}. It is recommended that both performance-based tests of physical function and self-reported measures be used in research, as they measure somewhat different parameters. These types of outcome measures often show only moderate correlations with one another. For example, many performance-based tests do not capture the breadth of information covered in a self-reported measure and vice-versa⁵¹⁻⁵³.

2.4.1 Reliability and Validity

Good measurement properties of rehabilitation outcomes are necessary to ensure that measurements are free from error and give accurate information about the construct that the outcome is supposed to measure. Reliability is arguably one of the most important, fundamental measurement properties suggesting a tool's usefulness because it represents the extent to which a measure is free from error⁵⁴. Test-retest reliability is essential to

determine that measures do not change within a specified amount of time when no change has occurred. Relative reliability gives an estimate of the ratio of subject variability compared to the total variability, which includes subject variability and measurement error⁵⁵. This enables researchers and clinicians to determine the variability due to error expected beyond the subject variability. Absolute reliability, calculated as the standard error of measurement (SEM), gives an indication of the error of a measurement and is expressed in the same units as the original test^{54,56}. The SEM can be used to indicate the expected range of scores due to error in retesting and is used to calculate the minimum detectable change (MDC) that would be needed for a true change to occur⁵⁴. Validity is also important because it provides an indication of the accuracy of an instrument and whether the tool measures what it intends to measure⁵⁴. Longitudinal validity evaluates the validity of a test over time, which can be related to responsiveness. However responsiveness includes the ability of the tool to detect a meaningful change over time, which involves a minimal clinically important difference^{54,55}. This value is usually determined through clinician expertise, determining whether the change is significant to the patient, or with the use of an additional health status measure⁵⁴. Another facet of validity is concurrent validity, which compares the tool against another tool measuring the same construct at the same time^{54,55}. Adequate measurement properties are important to ensure tools being used in rehabilitation and research measure what they intend to measure with low error.

2.5 Postural Control

Postural control is a complex motor skill that allows us to identify a threat of our line of gravity falling outside our base of support, and respond with muscle and central nervous system changes to maintain balance⁵⁷. Joint proprioception combines the sense of motion of a joint and the sense of joint position and uses feedback from mechanoreceptors to activate muscles and modify position⁵⁸. Sensorimotor or neuromuscular control requires coordinated muscle activity to make controlled movements⁸. As sensory deficits and poor muscle strength or activation may impede neuromuscular control, it is an important measure to monitor during knee OA management.

2.6 Postural Control in Patients with Knee OA

2.6.1 Static Balance

Patients with knee OA performed significantly worse than healthy controls on static (standing) balance tests¹³. Patients with knee OA demonstrated impaired balance compared to healthy controls when tested on dynamic and static balance conditions on a Biodex Stability System⁵⁹. Balance tests that have been used to study patients with knee OA include the Step Test, the Berg Balance Scale, Single Leg Stance Test, and Functional Reach Test¹³. However, the Step Test, Single Leg Stance Test, and Functional Reach Test are all primarily measures of static or standing balance¹³ and their functional relevance is questionable. The Berg Balance Scale measures static and dynamic balance through 14 different tasks, but it has demonstrated ceiling effects in an OA population^{13,60}.

2.6.2 Dynamic Balance

Individuals with knee OA demonstrate postural control impairments on dynamic balance tasks compared to healthy controls^{5,61,62}. Dynamic postural control can be negatively affected in individuals with knee OA through reduced proprioception, muscle weakness, and joint pain^{63,64}. Individuals with knee OA show greater postural sway compared to healthy controls in both eyes open and eyes closed static and dynamic sway testing⁶⁵. In addition to greater postural sway, individuals with knee OA also demonstrate frontal and sagittal plane knee instability compared to healthy controls⁶⁶. Voluntary quadriceps force production is lower in individuals with knee OA compared to healthy controls and individuals have decreased joint proprioception^{5,62}. Better single leg balance performance in individuals with knee OA is associated with less pain and varus alignment, and better quadriceps torque⁶⁷. Standing balance and varus alignment are related to degenerative changes in individuals with knee OA, indicating that standing balance tests are useful in evaluating neuromuscular performance⁶⁸. Balance and postural control impairments may

decrease functional abilities and increase fall risk in patients with knee OA. Individuals with knee OA demonstrate static and dynamic balance deficits compared to healthy individuals as a result of many factors including muscle and proprioception deficits. However, there are not many challenging dynamic balance tests that require neuromuscular control for a population with knee OA. Therefore, it is difficult to evaluate improvements following exercise programs that target lower limb strength and neuromuscular control.

2.6.3 Balance and Neuromuscular Training in Patients with Knee OA

Exercise is one of the most important non-surgical treatment modalities for knee OA, and this includes land exercise, water exercise, and strength training³⁹. Low impact exercise can increase muscle strength, aerobic capacity, and is also important for weight loss and management⁶⁹. Patients with knee OA have muscle weakness, particularly in the quadriceps, and functional deficits in postural control¹⁰. Neuromuscular training programs incorporate weight-bearing exercises that often resemble functional activities to build strength and emphasize movement control and quality^{8,10}. Training programs are individualized, with a focus on strength, balance, coordination, and proprioception, while challenging individuals to maintain movement quality during functional tasks⁸.

Neuromuscular training can be applied to a spectrum of degenerative knee disease, from younger individuals after a major injury to older adults with knee OA⁸. Neuromuscular training is feasible for patients with knee OA in terms of self-reported pain and shows promise for improvements in self-reported pain and physical function^{9,10}. Individuals with knee OA have demonstrated improvements in dynamic balance and strength on the affected limb following a six-week exercise program focused on lower extremity muscles²⁵.

2.7 The Star Excursion Balance Test

The star excursion balance test is a test of dynamic balance that requires participants to maintain a single leg stance and reach with the other leg as far as possible along a line marked on the ground¹⁴. The maximum reach is measured for each direction and the scores are interpreted as a measure of dynamic balance¹⁴. Eight lines are taped on the floor at 45° to each other, and the participant stands at the centre of the eight lines¹⁵. The participant is instructed to reach as far as possible with the non-weightbearing leg in each direction, tap lightly on the tape, and return to the centre. This is performed for all eight directions of the star, which are termed anterior (AN), anteromedial (AM), medial (ME), posteromedial (PM), posterior (PO), posterolateral (PL), lateral (LA), and anterolateral (AL), all relative to the stance leg¹⁵. The test challenges the postural control system as the leg reaches outside of the centre of mass, and adequate neuromuscular control is required to increase the excursion distance of the reaching leg¹⁵.

Trials are discarded and repeated if the participant lifts or moves the stance foot, loses equilibrium at any point, places considerable support on the reaching foot, does not tap lightly on the line, or fails to return to the starting position^{15,19}. The SEBT is performed in all eight directions for each stance leg. Reach distances are normalized to leg length, defined as the anterior superior iliac spine to the centre of the ipsilateral medial malleolus, to control for variation among individuals¹⁶. Four practice trials and three test trials are usually conducted^{17,24}.

2.8 Reliability and Validity of the SEBT

Reliability of rehabilitation tests is essential to determine that the measurement error of a test is small enough such that the tool can detect actual changes in the value being measured^{70,71}. Measurement of health status and function over time is an important aspect of monitoring OA progression, but there is no gold standard test of function⁷². Well-conducted studies that investigate measurement properties of physical function tests are

important to provide clinicians and researchers with the information to choose appropriate tests and to interpret when meaningful change has occurred.

2.8.1 Reliability

The first study of the reliability of the SEBT was conducted with 20 healthy young participants who performed the SEBT on two separate occasions, seven days apart¹⁴. Five trials were performed in each of the four directions; right-anterior, left-anterior, right-posterior, and left-posterior. An average of the three best trials for each direction was used in the analyses. The results demonstrated moderate reliability for the four directions, with estimates of 0.67-0.87. The results from the Spearman Brown prophecy indicated that in order to achieve a reliability estimate of 0.86-0.95, a minimum of six practice sessions would be needed, with the best three of five trials used per direction per session.

A later study was conducted to evaluate the intratester and intertester reliability of the SEBT for two testers, repeated on two days¹⁵. Sixteen healthy young participants performed one practice trial in each direction on each leg and three test trials consecutively in each direction. They performed the full test for the first examiner, and repeated the test on both legs for the second examiner. This was repeated for both examiners one week later. Intratester reliability was estimated from the three trials in each bout on each day using ICCs and standard errors of measurement and intertester reliability was estimated using ICCs and SEMs from the six trials on each day. Estimates of intratester reliability ranged from 0.78 to 0.96 for one tester and 0.82 to 0.96 for the other tester. Estimates of intertester reliability on day one ranged from 0.35 to 0.84, and on day two from 0.81 to 0.93. The results from this study illustrate relatively high intratester and intertester reliability. However, the longest reaches were recorded for trials seven to nine, leading the authors to suggest six practice trials in each direction should be used. Subjects were allowed to use any movement strategy they wanted, which may have led to learning effects and variability in performance.

In an effort to simplify the SEBT, Robinson and Gribble conducted a study to determine how many trials were necessary for the SEBT scores to stabilize²⁴. Twenty healthy young adults performed six practice trials and three test trials for each direction of the SEBT on each leg, and the direction of reach was randomized. Reach distances normalized to leg length were used for analysis. All reach directions except AM demonstrated an increase in normalized reach scores across trials. However, the authors concluded that most directions stabilized within the first four practice trials, leading them to conclude that four practice trials and three test trials may be used.

Further research was done with healthy young adults to examine the intertester and intratester reliability of the SEBT and the relationship between leg dominance and test performance⁷³. Participants performed ten trials of all eight directions of the SEBT on both legs⁷³. No significant differences were found in reach score between the dominant and non-dominant legs, and interrater reliability (ICC>0.99) and intrarater reliability (ICC 0.92-0.99) were high. The reliability values were higher than previous studies, but this was attributed to the placement of the measurement scale on the line rather than being held by the tester, which may have led to more accurate readings. The authors suggest that using the AN, ME, PO, and LA directions may shorten the test and have the same validity as the eight direction test, however it is also suggested that future research is needed to examine different muscle activation for the various directions.

The early reliability studies for the SEBT varied in number of trials and directions used, therefore another study was done to investigate between session reliability and the number of trials needed for measures to stabilize¹⁷. The secondary objective was to determine error scores for the SEBT to be able to indicate when true change occurs. Twenty-two healthy participants attended three testing sessions, each separated by a week. Participants performed seven trials in each direction on each leg, with reach direction order and stance leg order randomized, and results were reported normalized to leg length. The results showed no significant differences between males and females or between limbs. Results demonstrated that scores stabilised after 4 trials and ICC values ranged from 0.84 to 0.92, which the authors interpreted as good reliability. The normalized SEM values were 2.2 to 2.9%, suggesting that an individual's true score

would fall in this range, and a minimal detectable change would occur if a change of 6.8% or more was demonstrated between tests. However, these results are limited to a healthy university student population.

To further assess reliability, a study was done at two sites with a group of investigators to assess interrater reliability¹⁸. Participants performed three test trials in each of the AN, PM, and PL directions for each of the three raters, with a five-minute rest in between. The average of the three test trials for each direction and a composite score were used as raw data, and scores normalized to leg length were also reported. ICCs ranged from 0.86 to 0.92 for normalized scores, demonstrating excellent reliability, while ICCs for non-normalized scores ranged from 0.89 to 0.94. This study demonstrates that the SEBT can be reliable in the hands of raters of different levels of experience as long as they are trained by an experienced rater.

2.8.2 Construct Validity

Glave and colleagues⁷⁴ conducted a study to determine if the SEBT and the limits of stability test (LOS) both measure similar constructs of dynamic postural stability. Thirty-one healthy participants performed three trials of the SEBT in all eight directions, as well as three trials at each level 12 (stable) and level 6 (moderately unstable) of the LOS test on the Biodex Balance System. Normalized scores for each direction of the SEBT were reported and non-normalized scores for the LOS were reported because the system adjusts for height. Results showed that scores on the two tests were not positively correlated indicating that the tests may measure different aspects of postural stability or that postural stability may include several sub-types. The LOS is a double-leg stance test while the SEBT is a single-leg stance test, which may influence the type of postural stability being measured. Further research is necessary to determine what aspects of balance each test measures and the situations in which each test might be most useful.

2.8.3 Concurrent and Discriminant Validity

Bastien and colleagues⁷⁵ conducted a study to evaluate the concurrent validity between the observer's measurement and the motion capture system measurement of maximal reach distance of the SEBT in military personnel with and without lateral ankle sprain (LAS). Secondary objectives were to evaluate discriminant validity of the SEBT maximal reach measurements for the two groups and to determine whether height or leg length was more appropriate for normalization. Ten participants with LAS and ten healthy participants performed a single testing session of three trials in each of the AM, M, and PM directions. The observer maximal reach distance for all three directions was compared to the motion capture maximal reach distance to assess concurrent validity. Significant correlations were found for the motion capture measurements and the observer measurements ($R^2=0.98$) and there was excellent agreement for both groups and all three reach directions (ICC=0.99). The SEBT measurements were significantly different between the healthy and LAS groups for the composite score (6.06%) and for each direction individually, with the A direction showing the largest differences (7.84%). The maximal reach distance for limbs within subjects did not differ significantly. As well, the correlation for height and maximal reach distance was slightly higher than the correlation with leg length. The authors conclude that the observer estimation of maximal reach distance is highly valid and accurate, and that the normalization of reach by height can help increase discriminate validity for LAS participants from healthy participants.

2.9 Kinematics and Muscle Activation of the SEBT

Different movement patterns are seen for each direction of the SEBT and it is suggested that increasing the reach distance in various directions would require an increase in range of motion (ROM) and neuromuscular control at the hip, knee, and ankle⁷⁶.

A number of studies have investigated muscle activity, ROM, and kinematics of the stance leg during SEBT performance. From a study examining surface EMG on the vastus medialis obliquus, vastus lateralis, medial hamstrings, biceps femoris, tibialis anterior, and gastrocnemius, significant differences were reported for all muscles except

the gastrocnemius for the different reach directions ($p < 0.05$)⁷⁶. The AN direction demonstrates vastus medialis and vastus lateralis activity, the AL direction demonstrates medial hamstrings, the LA, PL, and PO directions demonstrate biceps femoris and anterior tibialis, and the PM and ME demonstrate tibialis anterior activation⁷⁶. The authors suggest that these reach differences may be important for clinicians choosing exercises for rehabilitation of specific injuries.

From examining kinematics of the stance leg, results suggest that further reaches are accomplished through greater stance leg hip or knee flexion, or both⁷⁷. Hip and knee flexion in combination accounted for 78% and 88% of the variance in the AN and LA reach directions⁷⁷. In patients with CAI, results demonstrated that frontal plane displacement of the trunk, hip, and ankle explained 81% of the variance in the maximal AN reach and weightbearing dorsiflexion ROM was significantly correlated with maximal AN reach⁷⁸. Investigating kinematic data for different reach directions has led authors to conclude that future research is needed to determine which directions are most useful for specific lower extremity injuries. Individuals with lower extremity injuries may use different movement patterns on specific SEBT directions compared to healthy individuals^{76,78}.

2.10 Simplifying the SEBT to 3 Directions

Hertel and colleagues²³ conducted an exploratory study to perform factor analyses on the SEBT to attempt to reduce the number of reach directions and to determine which directions are most affected by CAI. Their results indicated that the PM direction was most representative of the overall performance in both healthy and CAI participants and that the AM, ME, and PM directions demonstrated significant reach deficits for those with CAI compared to the control group. Further research with healthy participants was conducted to investigate how many trials were necessary for the SEBT to stabilize with a secondary purpose of examining sagittal plane movement at the knee and frontal, sagittal, and transverse movement at the hip of the stance leg to determine when movement stabilizes across trials²⁴. The authors agree with previous research by Hertel et al.²³ which

suggested that AM, ME, and PM directions could be used to streamline the testing procedure. A commercially available Y Balance Test (YBT) has been compared to the SEBT to determine if differences in reach distance exist between the AN, PM, and PL directions of SEBT⁷⁹. Participants reached further in the A direction on both legs on the SEBT than the YBT ($p < 0.005$), while no differences were observed in the PM and PL directions⁷⁹. This may be a result of different visual feedback available, but indicates that reach distance values may not be transferrable from the SEBT to the YBT. The reach distances and associated kinematic patterns of the SEBT and YBT were also explored, with participants reaching further on the AN direction of the SEBT (67.05 ± 4.97) than the YBT (59.74 ± 4.85) but no significant differences seen in the PM and PL directions⁸⁰. In the anterior direction, hip joint angular displacement was significantly higher on the YBT than the SEBT, while no significant differences in knee and ankle sagittal plane displacements were observed between the YBT and SEBT⁸⁰. The differences in reach and hip kinematics on the AN direction of the YBT and SEBT indicate that these tests should not be used interchangeably.

2.11 Ability to Detect Deficits and Improvements

The SEBT requires ankle, knee and hip mobility and adequate strength to perform maximal reaches in eight directions. As a dynamic balance task, it has been used to demonstrate deficits in injured populations compared to healthy controls. It has also been used to assess function before and after rehabilitation and neuromuscular training programs.

2.11.1 Ankle Injuries

Several studies have examined the performance of the SEBT with individuals with chronic ankle instability (CAI)^{19,20,81,82}. Olmsted et al. reported a decreased reach for the injured side of the CAI group compared to their non-injured side (78.6cm vs. 81.2cm) and compared to the matched side of the control group (78.6cm vs. 82.8cm)¹⁹. De la

Motte et al. found no significant differences between groups for any of the reach directions (AM, ME, PM), and no significant kinematic differences were seen between groups for the PM direction⁸¹. In the AM direction, CAI participants exhibited greater hip flexion (mean difference=-12.95) and trunk rotation (mean difference=26.59) away from the reaching leg than the healthy participants. Pionnier et al. examined the normalized reach as well as the COP, ground reaction forces, and the error of toe touchdown²⁰. They found that participants with CAI had a shorter normalized reach ($79.9 \pm 9.9\%$ of leg length) than control participants ($84.7 \pm 7.6\%$ of leg length), as well as an increased error in toe touchdown location compared to control participants. Movement differences observed in those with CAI compared to healthy participants suggests that the SEBT is sensitive to CAI reach deficits and may be useful in rehabilitation programs to assess CAI function and deficits.

Hale et al. examined the effects of a four-week comprehensive rehabilitation program on functional limitations and postural control for those with CAI⁸². At baseline there were no significant differences in SEBT reach scores between participants with and without CAI, and there were no significant differences between CAI control and intervention groups. The authors reported that the CAI intervention group had greater improvements than the CAI control group and the healthy group on the PM, PL, and LA directions of the SEBT. Doherty et al. conducted a case-control study examining kinematics of the lower extremity and centre of pressure (COP) during the AN, PM, and PL directions of the SEBT in 81 participants with LAS compared to 19 healthy controls²¹. The LAS group had lower normalized reach distances for both legs compared to the healthy group. The LAS group also had a lower measure of COP shape than the healthy group for all reach directions, which may suggest that the LAS group has an impaired ability to use the base of support. Reduced flexion at the hip, knee, and ankle was also seen for the LAS group. The authors conclude that the SEBT may be a useful clinical tool for patients with CAI and LAS as it can detect improvements following rehabilitation and deficits in injured compared to healthy populations. However, further research is necessary to investigate sensitivity to change of specific directions and replicate studies with larger sample sizes.

2.11.2 Knee Injuries

Knee injuries, in particular anterior cruciate ligament (ACL) injuries are common in sports. ACL injuries are associated with decreased proprioceptive performance, and therefore postural stability and neuromuscular control is an important focus for injury rehabilitation⁸³. The SEBT is a sufficient challenging functional test to assess dynamic balance in ACL deficient patients (ACLD)⁸³.

Previous research has been done to investigate if SEBT performance deficits can be detected in ACLD patients and patients who had undergone ACL reconstruction. Significant differences were seen in movement between the ACLD limb and the control group for the AN, PM, and M directions ($p \leq 0.005$) with no significant differences between the ACL deficient limb and the uninjured limb of the ACL group for all directions⁸³. In individuals who have had ACL reconstruction, the reach scores for the PM and PL directions were lower for the ACLR group than healthy controls and the ACLR group demonstrated decreased knee flexion on all three directions²². ACLD affects dynamic postural control but more research is needed in this area to investigate the relationship between postural control and predisposition to ACL injury.

2.11.3 Limb Asymmetry

Overmoyer and Reiser conducted a study to examine the relationship between lower-extremity functional asymmetries on various lower-extremity function tasks including the SEBT⁸⁴. Twenty healthy, recreationally active participants performed three trials of the SEBT in the AN, PM and PL directions, and the normalized mean and composite score were used. Participants also performed bodyweight squats, quiet standing, countermovement jumps, and single-leg drop landings and the primary outcome was correlation of asymmetries between tasks. The SEBT limb asymmetry was calculated by subtracting the dominant leg normalized score from the non-dominant leg normalized score. No significant differences were observed between non-dominant and dominant leg in the SEBT mean performance. Mild to moderate correlations were seen between SEBT

asymmetry and the lower-extremity functional asymmetries of the other tasks as well as between reach distances among bilateral differences.

2.12 Neuromuscular Training Programs

Neuromuscular training programs have been used in rehabilitation and injury prevention contexts to target muscular strength, instability, sensorimotor deficiencies and postural and neuromuscular control^{8,85}. Although many demonstrate patient improvements, very few use the SEBT as a measure of dynamic balance.

Ageberg, Nilsson, Kosek and Roos conducted a study to examine baseline measures of a severe knee and hip OA population compared to a reference group and to examine the effects of a neuromuscular training program on patient-reported and functional outcomes⁹. The 38 patients with hip OA, 49 patients with knee OA, and 43 reference participants completed the KOOS, chair stands, knee bends per 30 seconds, knee extensor strength, and a 20m walk test at baseline. The OA patients underwent the neuromuscular training program (mean=12 weeks) and repeated the tests prior to total joint arthroplasty. Patients were worse on all measures at baseline compared to the reference group. Improvements were seen on all outcomes except number of knee bends in 30 seconds. Therefore, neuromuscular training has positive potential for patient important improvements in function in patients with severe hip and knee OA. However, this before-and-after study did not randomly allocate exercise and control groups and did not directly assess neuromuscular control or dynamic balance. Future research should be done with a larger group of patients with knee OA using measures of dynamic balance.

Filipa, Byrnes, Paterno, Myer, and Hewett conducted a repeated measures study to investigate SEBT performance changes in young female athletes following an eight-week neuromuscular training program⁸⁵. Nine participants in the intervention group and seven in the control group participated in pre-testing, eight weeks of either bi-weekly neuromuscular training program or regular activity, and a final post-test session. Six practice trials and one test trial were performed in the AN, PM, and PL directions on each

leg using a normalized score for each direction and a composite score as outcomes. Pre-test SEBT scores were not significantly different between groups. There was no significant change in SEBT scores in the control group after eight weeks, while the training group showed significantly improved composite scores on both limbs ($p \leq 0.04$). The mean composite score of the right limb improved from $96.4 \pm 11.7\%$ to $104.6 \pm 6.1\%$ of leg length and the left limb improved from $96.9 \pm 10.1\%$ to $103.4 \pm 8.0\%$. However, no differences were observed in the anterior reach directions for the training group, indicating that different directions may be influenced by different factors. This study demonstrates the longitudinal validity of the SEBT in detecting performance improvements, but cannot be generalized beyond young healthy athletes.

Al-Khlaifat et al. conducted a pilot study to determine the effect of a six-week lower extremity exercise program and patient education on dynamic balance in patients with knee OA²⁵. Prior to this study, the investigators examined the test-retest reliability of the SEBT in 10 healthy volunteers (mean age 46 ± 5.23 years). They reported high reliability ($ICC > 0.75$) and SEM values ranging from $2.34 \pm 4.60\%$ LL to $3.49 \pm 6.85\%$ LL²⁵. The normalized MDC values ranged from 6.5 to 9.69 %LL for the anterior and medial directions. Nineteen participants were enrolled in the study and fourteen completed the study (12 women, 2 men). The main outcomes were balance, pain, and muscle strength, with balance reported from the normalized mean for each of the A and M directions of the SEBT. Pain was measured using the KOOS pain and function in daily living activities subscales, and muscle strength was determined through the average peak torque of the hip abductors, knee flexors and knee extensors. The results showed good adherence to the exercise program (mean attendance was 5.36 ± 0.84 out of 6 sessions). Participants improved significantly in both the AN (mean difference, $-5.06 \pm 7.27\%$ of leg length) and ME (mean difference, $-6.59 \pm 7.77\%$ of leg length) directions on the affected leg, but only in the AN direction (mean difference $-5.58 \pm 5.35\%$ of leg length) on the unaffected leg. Concentric strength at the knee and isometric strength of the hip also improved significantly ($p \leq 0.001$). Pain and function in daily living significantly improved ($p < 0.001$) at six weeks compared to baseline. Exercise programs that focus on lower extremity strength and balance may help improve dynamic balance, and the star excursion balance test may be a useful measure of dynamic balance in this population.

2.13 Summary

The SEBT is a performance-based outcome measure that may be particularly useful for the assessment of patients with knee OA undergoing neuromuscular exercise therapy. The SEBT has demonstrated good-to-excellent reliability in healthy participants (for four practice trials and three test trials). It has been shown to detect reach deficits in patients with lateral ankle sprain, chronic ankle instability, and ACL deficiency. Substantial evidence suggests the SEBT improves after neuromuscular exercise programs in young athletes. There is very limited research, however, investigating the SEBT in people with knee OA.

Chapter 3

3 Methods

3.1 Study Design

This study was conducted in the Wolf Orthopaedic Biomechanics Laboratory and the Fowler Kennedy Sport Medicine Clinic at the University of Western Ontario. The study design is illustrated in Figure 1. Two test sessions were completed within one week to assess test-retest reliability. A motion capture system was also used during the initial test session to assess concurrent validity. A third test session was completed after 12 weeks of neuromuscular exercise to assess longitudinal validity. Participants provided written informed consent. The Letter of Information and Ethics Approval Notice are provided in Appendices A and B respectively.

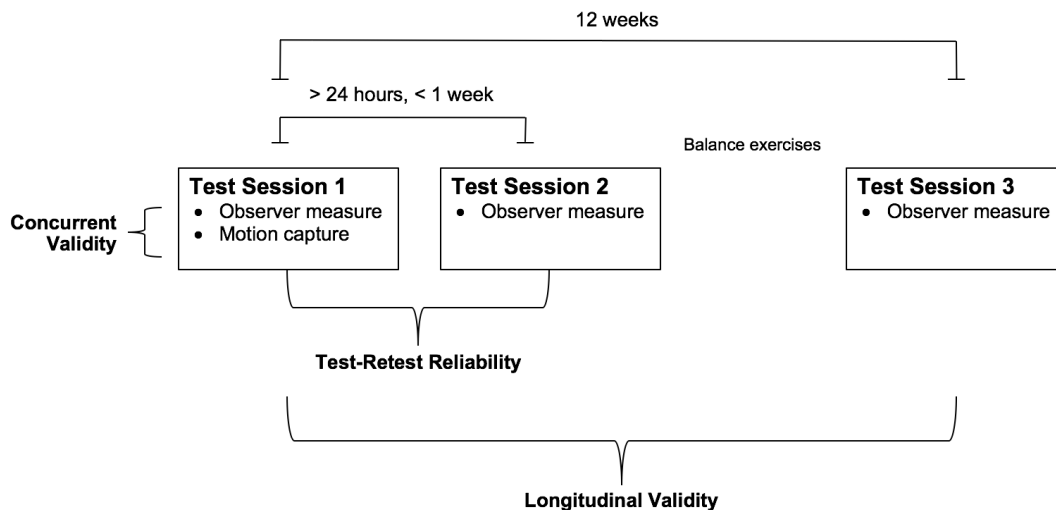


Figure 1. Study design: testing procedures for assessing reliability and validity of the star excursion balance test in patients with knee osteoarthritis.

3.2 Participants

3.2.1 Eligibility Criteria

We recruited patients with knee OA from the Fowler Kennedy Sport Medicine Clinic and through poster advertisements. Males and females with clinical knee OA according to the Altman classification were eligible for the study. The Altman classification requires knee pain with at least three of six clinical findings including age greater than 50 years, morning stiffness less than 30 minutes, crepitus, bony tenderness on the joint, bony enlargement, and lack of palpable warmth³². Participants were recruited after physician diagnosis of knee OA. Exclusion criteria included previous joint replacement, inflammatory or infectious arthritis of the knee, major neurological disorder, major medical illness, inability to read English, psychiatric illness that limits informed consent, and inability to stand on one limb for five seconds.

3.3 Outcome Measures

The star excursion balance test (SEBT) was performed at all testing sessions using all eight directions of the star¹⁵. Pain was assessed immediately before and after each SEBT. The Knee Injury and Osteoarthritis Outcome Score (KOOS) and the 40m fast paced walk test were assessed at the first and last testing sessions. The participant's age, height, weight and leg length (anterior superior iliac spine to the ipsilateral medial malleolus) were measured at the first test session.

3.3.1 SEBT Test Protocol

The SEBT was performed on eight lines taped to the floor, each at 45° to each other with centimeters marked to determine reach distance. All participants performed the test barefoot. The participant was positioned with their stance leg at the centre of the star, with the first medial cuneiform and arch of the foot over the centre mark. The participant reached with the opposite leg as far as possible in the specified direction while

maintaining balance on the stance leg. They made a light touch with their toe at the maximal reach, and returned to the original double leg stance position. The participant was required to have their hands on their hips for the entire trial, and the stance foot could not move. A tester monitored the participant's position and observed and recorded the maximal reach distance for each trial. Trials were discarded and repeated if the observer determined that 1) an appropriate position of the stance limb was not maintained with the knee moving out of line with the toe, 2) the stance foot was lifted or moved from the centre of the grid, 3) the participant did not touch down, or touched down more than once, during the trial, 4) considerable support was put in the reaching leg when touching the ground, or 5) the participant lost balance at any point or failed to return to the starting position.

All participants received verbal and visual instructions before completing the SEBT. One practice trial was performed standing on the unaffected leg in each of the eight directions, and one practice trial was repeated in each direction standing on the affected leg. The order of test direction was performed as follows, relative to stance leg: anterior, anteromedial, medial, posteromedial, posterior, posterolateral, lateral, and anterolateral (Figure 2). Two trials were recorded consecutively for each test direction and the average was calculated and used in subsequent analyses. All participants performed the SEBT on their unaffected (less symptomatic) leg first and then on their affected leg. Knee pain scores ranging from zero (no pain) to ten (maximal pain) were recorded before and after the SEBT.

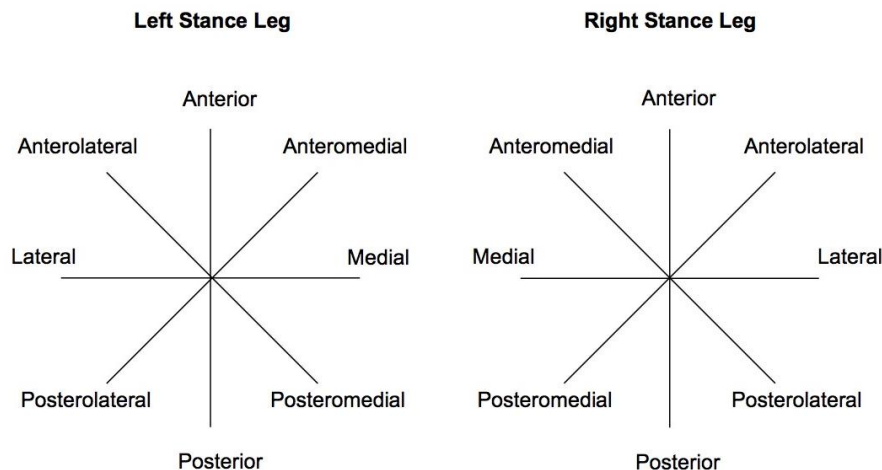


Figure 2. The star excursion balance test set-up for the left and right stance legs.

3.3.2 Motion Capture System

A 12-camera motion capture system and motion capture software (Cortex, Motion Analysis Corporation, Santa Rosa, CA) were used to provide a gold standard assessment of the participants' maximal reach distances during the SEBT. The system was calibrated each morning with a seed and wand calibration. The seed calibration was done with a calibration L-frame set on the force plate to indicate the exact positions of the L frame and the origin of the marker system. The wand calibration was done by waving a wand with three markers at known lengths in the data collection area. This ensures that the measurements made by the cameras match the direct measurement of the wand of known length in the capture area⁸⁶.

3.3.3 Subject Preparation

Twenty-six markers were placed on anatomical landmarks using adhesive stickers according to a modified Helen Hayes marker set⁸⁷. Participants performed two standing

“static trials” standing still on a force plate to collect the participant’s mass and assist with building the individualized marker set. Four markers from the medial knee joint line and medial malleolus were removed following the static trial. These markers are used to help define the joint centres of the knee and ankle. The SEBT was then performed, with the first of the two trials in each direction being recorded by the motion capture system. Marker data were captured at a rate of 60 frames per second.

3.3.4 Knee Injury and Osteoarthritis Outcome Score (KOOS)

The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a patient-reported questionnaire comprised of five subscales: pain, symptoms, function in daily living (ADL), function in sport and recreation (Sport/Rec), and knee related quality of life (QOL). Each subscale has a number of questions that are rated with a 5-option Likert scale from zero to four, which is then transformed to a score from 0 to 100. A score of zero indicates extreme knee problems while a score of 100 indicates no knee problems⁴⁹. The KOOS has been used in male and female populations to assess various knee injuries and degrees of OA and a change of 10 points or more has been suggested to represent a clinical difference⁸⁸. Participants filled out the KOOS at their first and last test sessions.

3.3.5 40m Fast Paced Walk Test

The 40m Fast Paced Walk Test requires patients to walk four sets of 10m distances. It is the recommended short distance walking test by Osteoarthritis Research Society International (OARSI) because it is feasible, demonstrates appropriate measurement properties and a range of abilities across degrees of OA¹². Participants began at one cone with the other cone placed 10m away. They were instructed to walk quickly without running to the far cone and back twice, ending at the cone at which they began for a total of 40m.

3.4 Exercise Program

Following testing on the first session, all participants were instructed on balance and strengthening exercises similar to those included in neuromuscular exercise programs for individuals with knee OA¹⁰. Patients were instructed to complete the exercises at home three times a week for twelve weeks. Good alignment of the stance knee over the stance foot was emphasized. The exercise program began with range of motion and stretching exercises for the knee. Knee and hip strengthening exercises such as step ups, forward lunges, chair stands, and clam shells were included followed by single and two-leg stance balance exercises. If participants experienced unusual pain or discomfort, we suggested that they stop the exercises and try again the following day.

3.5 Data Reduction

Test-retest reliability and longitudinal validity were estimated using the mean SEBT reach distance, normalized to leg length, for each direction and for a composite score for all eight directions. Concurrent validity was estimated using the raw data (distances) from the first trial of each direction compared to the motion capture measurement.

Motion capture data were processed (Cortex, Motion Analysis Corporation, Santa Rosa, CA) to determine maximal reach distance. Marker data were filtered using a Butterworth filter with a cut-off frequency of 6Hz. Custom post-processing methods used Skeleton Builder models (Cortex, Motion Analysis Corporation, Santa Rosa, CA) to determine joint centres and anatomical segments. One fixed virtual marker was created on the centre of the force plate and both toe virtual markers were created using the participant's foot length, the original marker set and the known anatomical offsets. Analysis graphs were used to calculate the distance between the centre of the force plate and the virtual toe marker at touchdown to determine the overall distance reached.

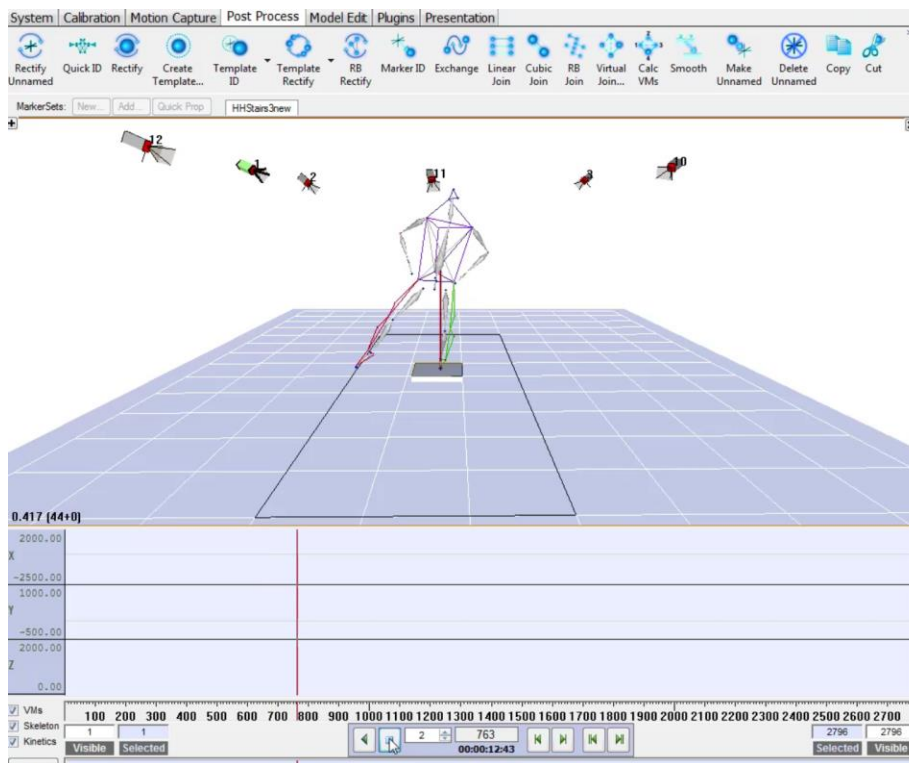


Figure 3. The motion capture computer software used to calculate the maximum reach for concurrent validity of each reach measurement.

3.6 Statistical Analysis

The mean of the two maximum reach trials for each direction was calculated for each test session. A normalized value was then calculated by dividing the mean score by lower limb length and multiplying by 100%. A composite reach score was calculated by adding the normalized mean reach for each direction and dividing by 8. The 12-week change scores for SEBT scores, the five domains of the KOOS and the 40m fast paced walk test were calculated from test sessions 1 to 3. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 24 (IBM Corp, Armonk, NY).

3.6.1 Test-retest Reliability

We calculated intraclass correlation coefficients (ICC) using a two-way random model for absolute agreement (ICC 2,1)⁷⁰. We calculated the standard errors of measurement (SEMs) to find the error associated with an individual's score. This was estimated by using the mean square error term from an ANOVA such that $SEM = \sqrt{MSE}$ ⁵⁶. We then used the z value for 95% confidence (1.96) to calculate the error associated with an individual's SEBT change score (i.e. the minimal detectable change (MDC) at 95% confidence, where $MDC = SEM \times 1.96 \times \sqrt{2}$)⁸⁹. We also plotted the difference between the first and second SEBT measurements against the mean of the first and second measurements to provide Bland and Altman plots as a visual representation of reliability.

3.6.2 Concurrent Validity

To investigate concurrent validity, we estimated the association between the observer's measurement of maximum reach and the motion capture maximum reach measurement using Pearson r correlations. This was calculated for each of the eight directions of the star using the raw data for one reach trial and the corresponding measured distance from the motion capture software.

3.6.3 Longitudinal Validity

To estimate longitudinal validity, we calculated paired t-tests and standardized response means (SRMs). Paired t-tests were calculated using the normalized mean reach for each direction at the first and last visits, and the normalized composite score at the first visit and last visits (significance level set at $p < 0.05$). We calculated SRMs as the mean change divided by the standard deviation of change. This was calculated from the normalized mean reach for each direction and the normalized composite score at the first and last visits. We calculated Pearson Correlation Coefficients (r) to determine the correlation between the change in composite normalized SEBT and the change in the 40m fast paced walk test, as well as the change in the five KOOS domains. Correlation coefficients of

>0.5 were classified as good, 0.36-0.5 as moderate, 0.2-0.35 as low and $r < 0.2$ as no evidence⁹⁰.

3.6.4 Sample Size Justification

The sample size was calculated for test-retest reliability based on an ICC of at least 0.85, an alpha of 0.05, beta of 0.2, and a confidence interval width of +/- 0.1. It was determined that 35 participants were necessary⁹¹. Our aim was to recruit 38 participants to account for approximately 10% dropout. Thirty-five participants would also provide 80% power (two-sided alpha=0.05) to detect an effect size of approximately 0.5 following 12 weeks of exercise⁹². With only 21 participants included in the longitudinal analyses thus far, we can detect an effect size as low as 0.66⁹².

Chapter 4

4 Results

Participant demographic variables are displayed in Table 1. At this time, 38 participants have completed the first two visits for test-retest reliability and 21 of those participants have completed the third test session for the longitudinal validity outcomes.

Table 1. Participant demographics for the two objectives of test-retest reliability and longitudinal validity

Objective	Test-Retest Reliability	Longitudinal Validity (subset of patients)
Number of participants	n = 38	n = 21
Sex, male / female	30 / 8	19 / 2
Age, years	58.1 ± 8.3	56.6 ± 1.7
Height, m	1.77 ± 0.08	1.78 ± 0.05
Weight, kg	91.0 ± 17.4	91.0 ± 12.0
BMI, kg/m²	29.0 ± 4.8	28.9 ± 3.5
Leg length, cm	90.3 ± 4.3	90.3 ± 4.1
Days Between Test 1 and 2	6.2 ± 2.5	5.8 ± 6.0
Days Between Test 1 and 3	-	83.7 ± 6.2

Values are mean ± SD

4.1 Test-Retest Reliability

The ICC, SEM, and minimal detectable change values for each direction on both stance legs are reported in Table 2. The test-retest reliability for the normalized reach measurements for all eight directions on the affected leg was good (ICC 0.70-0.89). On the unaffected leg, the test-retest reliability for the normalized reach measurements of all eight directions was good-to-excellent (ICC 0.82-0.94). Figure 4 shows the Bland and Altman plot for the composite normalized SEBT.

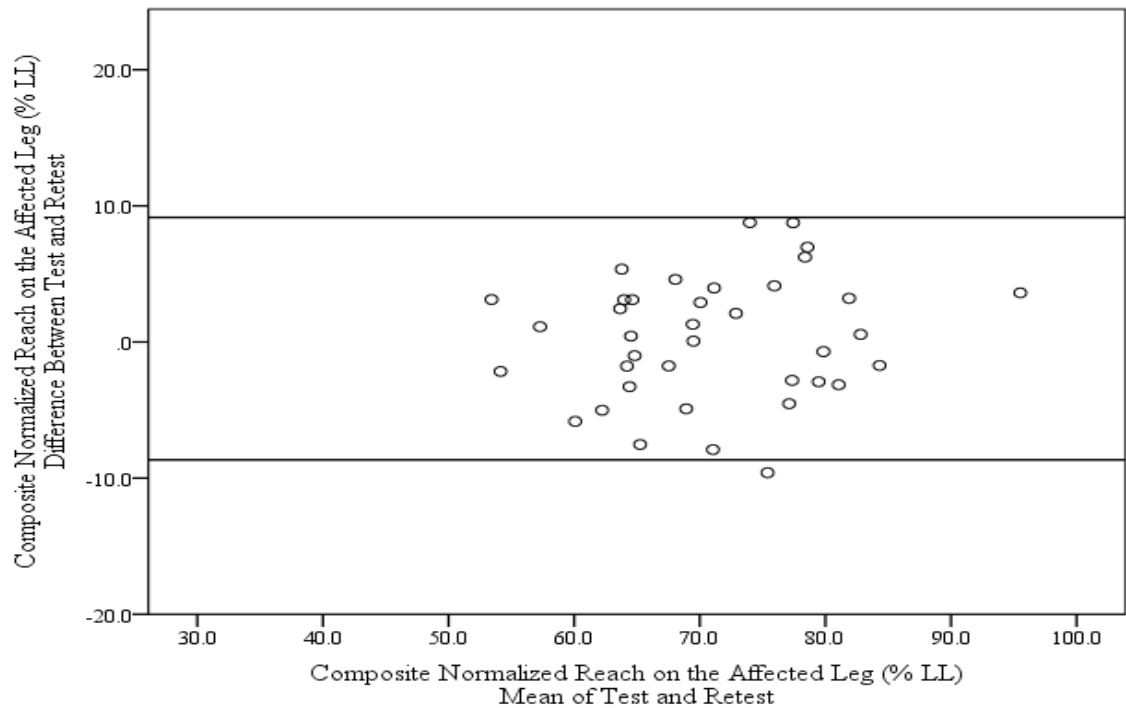


Figure 4. Bland and Altman plot showing the difference between test and retest compared to the mean of test and retest for the composite normalized reach on the affected leg. Horizontal lines indicate the mean $\pm 1.96SD$.

Table 2. ICC point estimates and 95% confidence intervals with the corresponding standard error of measurement and minimum detectable change (95% level of confidence) for all reach directions and legs. $SEM = \sqrt{MSE}$, $MDC = SEM \times 1.96 \times \sqrt{2}$

Affected Leg	ICC (95% CI)	± SEM	MDC 95%
AN	0.89 (0.79, 0.94)	3.15	8.72
AM	0.85 (0.73, 0.92)	3.46	9.60
ME	0.77 (0.60, 0.87)	4.48	12.42
PM	0.70 (0.49, 0.83)	6.30	17.47
PO	0.82 (0.68, 0.90)	5.63	15.61
PL	0.79 (0.63, 0.88)	5.99	16.59
LA	0.87 (0.77, 0.93)	4.61	12.77
AL	0.82 (0.68, 0.90)	3.38	9.37
COMPOSITE	0.88 (0.79, 0.94)	3.21	8.90
Unaffected Leg			
AN	0.86 (0.73, 0.92)	3.71	10.29
AM	0.90 (0.82, 0.95)	3.07	8.51
ME	0.86 (0.75, 0.93)	4.01	11.11
PM	0.82 (0.68, 0.90)	5.28	14.62
PO	0.88 (0.77, 0.93)	5.11	14.18
PL	0.84 (0.71, 0.91)	5.23	14.49
LA	0.94 (0.89, 0.97)	3.37	9.35
AL	0.89 (0.80, 0.94)	2.90	8.03
COMPOSITE	0.92 (0.86, 0.96)	2.82	7.82

SEM and MDC values are % of leg length

4.2 Concurrent Validity

The correlation coefficients between the motion capture measurements and the observer measurements of the reach for both stance legs are shown in Table 3. The motion capture and observer measurements had excellent correlations on both stance legs ($r \geq 0.96$).

Table 3. Pearson correlation coefficients between the raw observed and the motion capture measures of reach for each leg and direction of the SEBT.

Reach Direction	Affected Leg	Unaffected Leg
	Pearson Correlation Coefficient	Pearson Correlation Coefficient
AN	0.99	0.99
AM	0.99	0.99
ME	0.98	0.98
PM	0.96	0.97
PO	0.99	0.99
PL	0.97	0.98
LA	0.96	0.97
AL	0.96	0.99

4.3 Longitudinal Validity

A composite normalized reach value and the mean normalized reach values for each direction on the affected leg are displayed in Table 4 and on the unaffected leg in Table 5. At test session 3, the composite normalized reach on the affected leg (77.42 ± 8.62 %LL) had significantly improved ($p=0.002$) with a mean change of 5.34% of LL (95% CI 2.20, 8.47) and a standardized response mean of 0.78. The composite normalized reach on the unaffected leg (79.27 ± 9.65 %LL) had also significantly improved ($p<0.001$) with a mean change of 5.15% of LL (95% CI 2.81, 7.50) and a standardized response mean of 1.00. Significant improvements ($p\leq 0.03$) were seen for the anterior, anteromedial, medial, posteromedial, posterior, posterolateral, and lateral directions on the affected leg (Figure 5). On the unaffected leg, significant improvements ($p\leq 0.05$) were seen for the anterior, medial, posteromedial, posterior, posterolateral, and lateral directions (Figure 6).

The correlations between the composite normalized change score for each leg and the change in KOOS subscales and 40m walk times are displayed in Table 6 and the correlations for the affected leg by direction are displayed in Table 7. Low-to-moderate correlations ($r=0.24-0.48$) were seen for the change in the composite normalized score on the affected leg and the change in all KOOS subscales and 40m walk time. Low-to-moderate correlations were seen for the change in each direction on the affected leg and the change in 40m walk time.

Table 4. Normalized (% of leg length) reach distances, mean change, and standardized response means for the affected stance leg at test 1 and test 3.

Affected Leg	Test 1 Reach	Test 3 Reach	Mean Change (95% CI)	p-value	SRM
AN	70.22 ± 9.47	74.49 ± 9.17	4.26 (0.43, 8.10)	0.03	0.51
AM	74.03 ± 9.39	77.77 ± 10.32	3.75 (0.00, 7.50)	0.05	0.46
ME	74.33 ± 9.23	81.13 ± 10.53	6.80 (3.29, 10.31)	0.001	0.88
PM	79.73 ± 10.46	88.01 ± 10.51	8.27 (4.83, 11.71)	<0.001	1.10
PO	82.49 ± 10.23	88.88 ± 10.83	6.38 (2.57, 10.20)	<0.005	0.76
PL	73.72 ± 10.15	80.46 ± 12.03	6.75 (2.25, 11.25)	0.005	0.68
LA	55.69 ± 12.15	61.01 ± 11.69	5.32 (1.24, 9.39)	0.01	0.59
AL	66.47 ± 6.88	67.60 ± 9.18	1.13 (-2.18, 4.45)	0.48	0.16
COMP	72.08 ± 8.25	77.42 ± 8.62	5.34 (2.20, 8.47)	<0.005	0.78

Reach values are expressed as mean ± SD, % of leg length

Table 5. Normalized reach distances, mean change, and standardized response means for the unaffected stance leg at test 1 and test 3

Unaffected Leg	Test 1 Reach	Test 3 Reach	Mean Change (95% CI)	p-value	SRM
AN	72.54 ± 11.09	76.11 ± 9.36	3.58 (1.30, 5.85)	0.004	0.72
AM	77.06 ± 10.79	79.57 ± 9.61	2.51 (-0.25, 5.26)	0.07	0.41
ME	78.42 ± 12.96	82.90 ± 11.04	4.48 (1.74, 7.22)	0.003	0.74
PM	82.84 ± 13.48	89.65 ± 12.64	6.81 (3.14, 10.47)	0.001	0.85
PO	82.30 ± 14.37	91.36 ± 12.66	9.06 (4.94, 13.18)	<0.001	1.00
PL	74.56 ± 12.44	82.63 ± 14.51	8.06 (3.25, 12.88)	0.002	0.76
LA	57.50 ± 13.55	63.25 ± 12.41	5.75 (2.07, 9.44)	0.004	0.71
AL	67.72 ± 8.86	68.66 ± 8.41	0.95 (-1.48, 3.38)	0.43	0.18
COMP	74.12 ± 10.45	79.27 ± 9.65	5.15 (2.81, 7.50)	<0.001	1.00

Reach values are expressed as mean ± SD, % of leg length

Table 6. Correlation coefficients between mean change SEBT scores and change in functional and questionnaire outcomes to examine longitudinal validity.

	40m Walk	KOOS Pain	KOOS Symptoms	KOOS ADL	KOOS Sport Rec	KOOS QOL
Mean Change Affected Leg	0.48	0.24	0.30	0.26	0.24	0.26
Mean Change Unaffected Leg	0.41	0.09	0.04	-0.06	-0.03	-0.01

Table 7. Correlation coefficients for the change from test 1 to test 3 in reach on the affected leg and change in the KOOS subscales and 40m walk test.

Reach Direction	40m Walk	KOOS Pain	KOOS Symptoms	KOOS ADL	KOOS Sport Rec	KOOS QOL
AN	0.56	0.33	0.34	0.31	0.42	0.19
AM	0.66	0.34	0.29	0.25	0.34	0.19
ME	0.58	0.29	0.32	0.29	0.24	0.27
PM	0.39	0.12	0.11	0.11	0.04	0.07
PO	0.24	0.25	0.30	0.22	0.08	0.19
PL	0.21	0.03	0.10	0.09	0.07	0.19
LA	0.33	0.19	0.22	0.20	0.17	0.26
AL	0.29	0.09	0.36	0.31	0.23	0.36

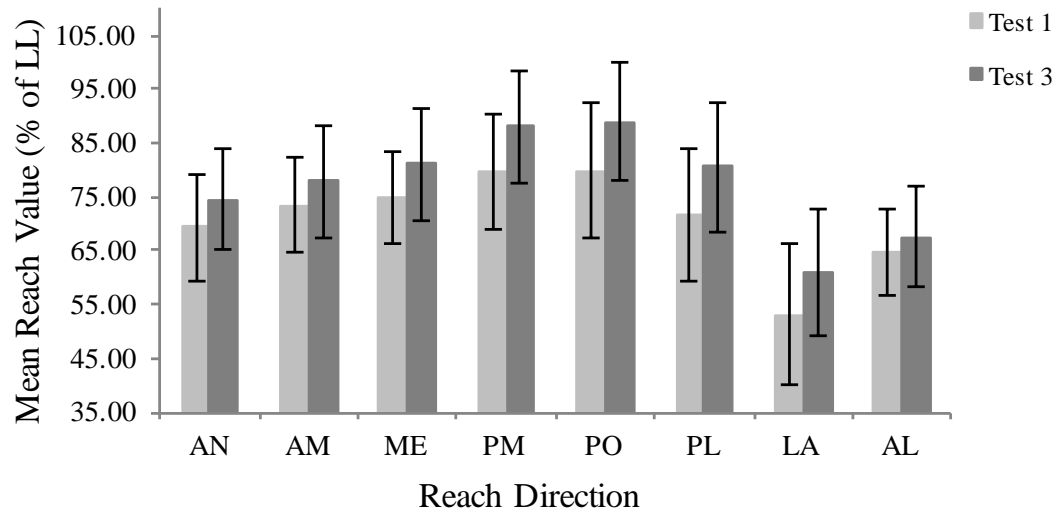


Figure 5. Mean normalized (% of leg length) reach values with standard deviations on the affected leg for all eight reach directions at the first and last test sessions.

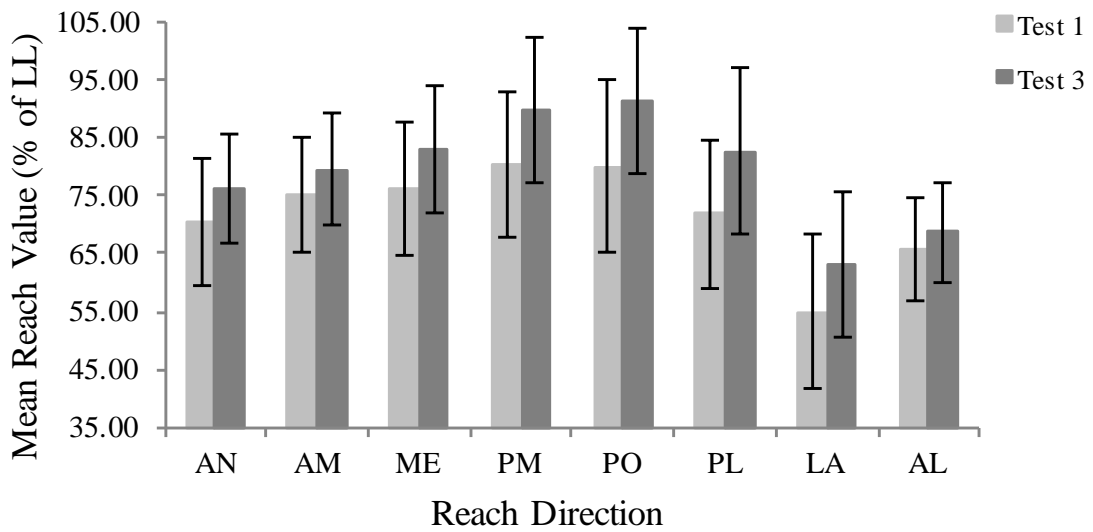


Figure 6. Mean normalized (% of leg length) reach values with standard deviations on the unaffected leg for all eight reach directions at the first and last test sessions.

Chapter 5

5 Discussion

5.1 Test-Retest Reliability

The current results indicate that the SEBT has moderate-to-excellent test-retest reliability in patients with knee OA. The ICCs for all eight directions on both legs range from 0.70 to 0.94. The composite score ICCs were 0.88 (95% CI 0.79, 0.94) and 0.92 (95% CI 0.86, 0.96) for the affected and unaffected legs, respectively. Our results are generally consistent with our hypothesis. The ICC is an indication of relative reliability, calculated as a ratio of the variability between patients to the total variability^{55,56}. This represents the ability of a test to distinguish between patients, with a value closer to one suggesting that the between patient variability is high while the within patient variability (or measurement error) is low.

Our results are similar to previous studies investigating the reliability of the SEBT in different populations. The ICCs of all eight directions in healthy recreational athletes were reported as ranging from 0.84 to 0.92¹⁷. In healthy older adults (mean age 46 ± 5.23 years), ICCs were 0.78 and 0.81 for the anterior direction and 0.86 and 0.88 for the medial direction, for the right and left side respectively²⁵. A previous study recommended using only three directions of the SEBT (AM, ME, PM) to streamline the test because all directions were reliable and those three were most sensitive to chronic ankle instability deficits²³. We have demonstrated adequate reliability for all directions but the posteromedial, posterior, and posterolateral directions show the lowest reliability of the eight directions. However, these directions show the highest mean change following exercise. Therefore at this time, we do not suggest that any directions be removed on the basis of poor reliability because they may show important changes in patients with OA. The composite measures were highly reliable and showed significant change following exercise. This supports the inclusion of all eight directions so that a composite measure may be used as it may be most relevant in knee OA focused clinical practice and research.

The SEM, a measure of absolute reliability, is expressed in the same units as the original measurement and can be used to provide an estimate of reliability for individual scores^{55,56,89}. Values closer to zero indicate better reliability. Our results demonstrate that the SEM values range from 2.82 to 6.30 % of leg length. These are slightly higher than the SEM values ranging from 2.21 to 2.94 %LL reported for healthy recreational athletes¹⁷. However, these athletes were tested on three separate occasions with three trials from each used for analyses, while we selected to mimic clinical practice as much as possible and only used two trials from two test sessions for reliability analyses. Additionally, the present SEM values are similar to those found in previous research with healthy older adults, which reported SEMs ranging from 2.34 to 3.49 %LL for the anterior and medial directions of the SEBT. The higher SEM values reported presently may be a result of the inclusion of all eight directions of the SEBT. Higher SEM values were seen for the posteromedial, posterior, and posterolateral directions, which were not investigated in the previously mentioned study.

From the SEM, we first considered the error associated with an individual's score at one point in time. For example, from the anterior reach direction of the affected stance leg, the SEM is 3.15%LL. This indicates that an individual's score on one test session of 70.2 %LL can vary from 64.0 to 76.4 %LL simply due to measurement error (i.e. $SEM * 1.96 = \pm 6.2$). From the SEM, we also calculated the MDC, which is the amount of change needed to be considered real change, above the variability seen between test sessions⁸⁹. From the calculated MDC of 8.72% (i.e. $SEM * 1.96 * \sqrt{2} = 8.72\%LL$), an individual's score would have to change by at least 8.7 %LL between test sessions to be confident a true change had occurred. In other words, for the individual who scored 70.2 %LL on the first test, we can be very confident that a true improvement has occurred if that individual's second score is 78.9 %LL or higher, as 95% of stable patients would change by less than 8.72%LL. When expressed in centimeters, the average patient in our study has a leg length of approximately 90 cm, and the MDC is approximately 8 cm.

From the previous study on healthy older adults, the reported MDCs were 6.94 and 6.5 %LL for the anterior direction, and 9.69 and 8.85 %LL for the medial direction, on the right and left sides respectively²⁵. Our MDCs were 8.72 %LL for the anterior direction

and 12.42 %LL for the medial direction on the affected leg. This agrees with previous authors' suggestion that MDC values would be higher in patients with knee OA²⁵. The study with healthy recreational athletes reported MDC values ranging from 6.13 to 8.15 %LL for all eight directions, compared to our reported MDC ranges from 7.82 to 16.59 %LL for all directions. The MDC calculations include the SEM, and therefore in comparison to the healthy athlete population, our MDC values will also be higher because our SEM values are higher. As mentioned earlier, this may be a result of only using two test trials on two test occasions instead of three trials and three sessions.

The SEBT demonstrates moderate to excellent reliability on all eight directions and on the composite measure in individuals with knee OA. Combined with the SEM results, we will be able to assess an individual's performance on the SEBT and be confident in the range that their true score falls within. The MDC can also be used to help determine whether a true change has occurred.

5.2 Concurrent Validity

The current results suggest that the observer measurement of reach for all directions is highly correlated to the motion capture measurement on both stance legs. Our results agree with our hypothesis that the observer and motion capture measurement would be highly correlated ($r > 0.75$). This suggests that the observer measurement of reach is valid when compared to the gold standard motion capture measurement of reach. Our results agree with a previous study examining the concurrent validity of motion capture and observer measurement. This previous study only used the anteromedial, medial, and posteromedial directions but found large and significant correlations for all directions⁷⁵. It is important for the observer measurement to agree with the motion capture system to validate the use of the SEBT in a clinical setting. By using measured tape on the ground for all eight directions, the SEBT can be used with confidence in a clinical setting without the need for costly motion capture equipment and the time needed for motion analysis.

5.3 Longitudinal Validity

The current results indicate significant performance improvements of the normalized SEBT on the anterior, medial, posteromedial, posterior, posterolateral and lateral directions on both legs plus the anteromedial direction on the affected leg. Significant improvements were also seen for the composite normalized scores on both legs. This confirms our hypotheses for almost all directions, as we had anticipated a significant improvement in all directions on both legs. No differences were seen for the anterolateral direction on the affected leg and the anteromedial and anterolateral directions on the unaffected leg. This may indicate that these directions are more difficult to improve upon and that a greater improvement of neuromuscular control is needed in order to see a small change in reach. It is also possible that the exercises did not specifically target neuromuscular control needed for that movement.

We had also hypothesized standardized response means greater than 0.4 (a small to moderate effect) for the SEBT measurements. We found SRMs greater than 0.4 for the anterior, anteromedial, medial, posteromedial, posterior, posterolateral, and lateral directions on both legs. The composite normalized reach demonstrated SRMs of 0.78 and 1.00 on the affected and unaffected legs respectively, indicating a medium to large effect. The directions that demonstrated a statistically significant change agree with the hypotheses of SRM greater than 0.4.

When individual patients' improvements are compared to the calculated MDC, the importance of measurement error becomes evident. For example, on the affected leg, depending on the direction, three to seven individuals demonstrated detectable improvements. Only two participants demonstrated a detectable improvement in all eight directions, and one participant demonstrated a detectable deterioration on three directions. On the composite scores, four individuals demonstrated a detectable improvement on the affected leg and seven on the unaffected leg. These results are similar to a previous study in which the significant performance improvements on the anterior and medial directions of the SEBT did not exceed the previously calculated MDC values²⁵. Therefore although we found significant improvements for the group on

several directions and for the composite scores, care is needed to accurately judge changes in an individual patient's change.

We also hypothesized that there would be low-to-moderate correlations between the change in SEBT affected normalized scores and the change in KOOS domains and 40m walk performance. We made these hypotheses because we expected that an improvement on the SEBT would have a low correlation with an improvement on other function tests such as the 40m fast-paced walk. Additionally, we anticipated that these improvements would also show a relationship with improvements on the KOOS, because improvements in neuromuscular control may affect pain, symptoms, function and quality of life. The results indicate support for our hypotheses. There was a moderate relationship between the composite change and the 40m walk performance. There were low correlations for the composite change on the affected leg and the change in pain, symptoms, function in daily living, function in sport and recreation, and knee related quality of life subscales of the KOOS. However, when examining individual reach directions, the anterior, anteromedial, and medial directions demonstrated good correlations with the 40m walk. The anteromedial and medial directions demonstrated low to moderate correlations with all subscales of the KOOS and the 40m walk.

It may be that an improvement in neuromuscular control may not correlate strongly with improvements in KOOS subscales and the 40m walk because they measure different constructs. It is likely that only a moderate relationship exists between the composite SEBT and the 40m walk test because the 40m walk test is a function test of short walking distances and this may not show significant improvements in time even if neuromuscular control improves. Previous research investigating the effects of neuromuscular exercise on patients with knee OA found a mean improvement of 1.55 seconds (95% CI 0.59, 2.51) on the 20m walk test⁹. In the present study, no significant change was seen on the 40m walk test. The anterior, anteromedial, and medial directions demonstrated the strongest relationships with the 40m walk. It is possible that the muscle activation necessary for the anterior, anteromedial, and medial directions is most similar to that necessary for walking.

Previous research demonstrated significant improvements in muscle strength, KOOS pain and KOOS function in daily living following an exercise program that significantly improved balance on the SEBT²⁵. Although we did not measure muscle strength, our composite results did not demonstrate significant improvements on the KOOS and suggest low correlations between changes in SEBT and changes on the KOOS subscales. However, our baseline KOOS scores for the pain and ADL subscales were higher than the post-test KOOS scores reported previously, indicating that our patients may have had a lesser degree of disability than the population of the previous study. Additionally, previous research has indicated that low correlations are typical between self-report measure and function tests^{51,90,93}. It was suggested that self-report measures and performance measures may assess different aspects of physical function but that they are both important for monitoring patient function⁵¹. Therefore low to moderate correlations ($r=0.24-0.48$) between the change in SEBT and change in KOOS and 40 fast-paced walk test are consistent with previous literature and provide support for the longitudinal validity of the SEBT.

Although significant improvements were only seen in six of the eight directions, at this time we support the inclusion of all eight directions of the SEBT when testing a knee OA population. All directions have adequate reliability and we cannot be conclusive about why changes were not seen in the anteromedial and anterolateral directions. It may be that the exercise program did specifically target the neuromuscular control required for those directions, those directions are the most difficult for demonstrating improvements, or they are the easiest to perform in a knee OA population and therefore are useless for monitoring progress. The composite score may be less responsive than each direction individually because of the noise associated with calculating the mean of eight directions. However, the composite score is reliable and demonstrated a significant improvement following exercise and should therefore be included as a main measure of interest.

5.4 Limitations

A potential limitation in the present study is that test-retest reliability may be affected by diurnal variation if participants were tested at different times during the day. We made an effort to have the two test sessions more than 24 hours apart but within one week to minimize issues with repeated testing, but not all participants attended sessions at the same time of day. As well, participants expressed variations with OA pain and symptoms across visits which may have increased the error associated with a subject's individual scores. Previous literature supports the use of four practice trials and three test trials for the SEBT^{17,24}. However, as the first study to investigate all eight directions of the SEBT in patients with knee OA, we modified the protocol to include one practice trial and two test trials. We did this to limit the physical burden on participants and to ensure they would all be able to complete the test. The average of two trials would better represent the true score than one trial alone.

Data collection is continuing for our longitudinal validity objective. Although the present SRMs and correlations are likely accurate, they may change as more data are added. Therefore, these results should be interpreted with caution as only 21 participants were included in the analyses. Additionally, although knee OA is more common in women, more than three-quarters of our participants were male, which may limit the generalizability of our results. We did not monitor adherence to the exercise program over the course of the twelve weeks and would expect that monitoring adherence may lead to a greater improvement at the final test.

Chapter 6

6 Conclusion

The SEBT has demonstrated suitable measurement properties for use in patients with knee OA focused clinical and research settings. It has good-to-excellent test-retest reliability for all eight SEBT directions and the composite score, similar to previous studies in healthy athletes and adults^{17,25}. The MDC is 8.9 %LL for the composite measure. Excellent correlations between observer and motion capture system measurements suggest high concurrent validity. The SEBT also has reasonable longitudinal validity. Significant improvements were seen in composite scores and most directions on both legs. Improvements in SEBT scores were low-to-moderately correlated with improvements in 40m fast paced walk times and KOOS scores.

6.1 Future Directions

Although the present study suggests that all eight directions of the SEBT are reliable and valid, future research may benefit from investigating the lower limb kinematics and muscle activation during each direction of the test in patients with knee OA. This would further our understanding of the neuromuscular control needed for each direction and may assist with identifying the most important aspects of the tests, and/or eliminating unnecessary test directions to decrease the time burden of the test. Future investigations may also benefit from a larger and more diverse sample of individuals with knee OA to determine if measurement properties differ among different subgroups of patients.

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Appendices

Appendix A. Letter of Information and Consent



LETTER OF INFORMATION AND CONSENT
Primary Investigator: Trevor Birmingham PhD
Co-Investigators: Lauren Kanko MSc Candidate, Dr. JR Giffin,
Kirstie Gillanders, Kirsten Lemmon, Ryan Chan, Mike Postic

Project Title: Validity and Reliability of the Star Excursion Balance Test for Patients with Knee Osteoarthritis

Principal Investigator: Dr. Trevor Birmingham PhD, Professor, Faculty of Health Sciences, School of Physical Therapy, Elborn College



Introduction

You are being asked to participate in this research study about the measurement properties of the star excursion balance test (SEBT). This is a test of single leg standing balance test and postural control. You are being asked to participate because you meet the inclusion criteria for the study and have knee osteoarthritis (OA). We are evaluating the measurement properties of the SEBT to help validate its use in clinical and research settings for people with knee OA.

Why is the study being done?

Osteoarthritis, often simply termed "OA", is a common musculoskeletal condition that causes substantial pain and disability. It frequently affects the knees. Exercise programs that focus on neuromuscular control of the knee have been shown to provide improvements for patients. However, there is no widely accepted, simple-to-use clinical tool to monitor progress in improving postural control specific to patients with knee OA.

The purpose of this study is to investigate the measurement properties of the star excursion balance test (SEBT) in patients with knee OA. We will test the longitudinal validity of the SEBT (i.e. its ability to detect change) following 12 weeks of completing balancing exercises (at home), the test-retest reliability of the SEBT measurements completed within one week, and the concurrent validity of the SEBT measurements made by the observer and by sophisticated cameras (a motion capture system located in a biomechanics lab, only for the London sub-group).

What are the study procedures?

You will be asked to perform the SEBT on each leg during either two or three testing sessions, depending on where you live. The study will take place in the following locations, with 35 participants being recruited in London and an additional 25 participants being recruited from the other clinics.

- a. Wolf Orthopaedic Biomechanics Laboratory, Fowler Kennedy Sport Medicine Clinic (UWO) - London
- b. Barrhaven Physiotherapy – Ottawa Physiotherapy and Sport Clinics
- c. Momentum Physiotherapy – Gloucester
- d. Amped Sports Lab and Ice Complex – Ottawa
- e. Evolution Physiotherapy - Kanata
- f. Kinatex Physimed – Ville saint Laurent
- g. Paramount Physiotherapy and Sports Injuries Clinic - Brampton

Participants living in London are asked to complete three testing sessions, two within one week, and one 12 weeks later. Participants in London will complete one in the biomechanics lab and the other two in the physiotherapy clinic. Participants living in the other locations are asked to complete the same testing in their respective clinics. In all cases, participants will be shown balancing exercises (similar to the SEBT components) to practice at home during the 12 weeks between testing. During this time, you may also be performing strengthening exercises and other postural control exercises suggested by your physiotherapist. If so, we ask that you also practice the SEBT exercises that will be shown to you.

Each testing session will take approximately 30 minutes. The first two sessions will be separated by at least 24 hours, but by no more than one week. The third session will be 12 weeks later.

On each test session, you will complete the SEBT. It includes a star of eight lines taped to the ground at 45 degree angles. You will stand in the centre of the star on one leg, reach as far as possible in each direction of the star with your non-weightbearing leg, perform a light tap on the ground, and return your leg to the centre. You will perform one practice trial in each of the eight directions of the star for each stance leg. You will then perform two test trials consecutively in each direction on your unaffected leg (less symptomatic leg). The two test trials will then be repeated in each direction on your affected leg. The SEBT will be followed by the 40m fast paced walk test, during which you will walk along a 10m space back and forth four times as fast as you can without running. This will be repeated at your last visit.

If you are located in London, one of the testing sessions will take place in the Wolf Orthopaedic Biomechanics Laboratory. Reflective markers (like small glow-in-the-dark balls) will be attached to your body (i.e. feet, ankles, calves, knees, thighs, hips, back, scapula, shoulders, elbows, and wrists) to record your movements while you complete

the SEBT. These markers are identified by the cameras to track your movements and will be compared to the observer's measurements.

You will also fill out the Knee Injury and Osteoarthritis Outcome Score (KOOS) and a Global Rating of Change score (GRC) at your first and last visit.

Are there any discomforts or risks associated with testing?

You may experience mild muscle soreness associated with physiotherapy and balance testing, but the potential duration of discomfort should be brief and would be similar to what patients experience with typical daily activities.

Benefits

You may not receive direct benefit from being in this study. Information learned from this study may help lead to improved treatment of knee osteoarthritis in the future.

Voluntary Participation

Your participation in this study is voluntary. You may decide to not participate in this study, withdraw consent, and/or withdraw your data from the study at any time. You may leave the study at any time without affecting your care. There will be no direct compensation for your participation in this study.

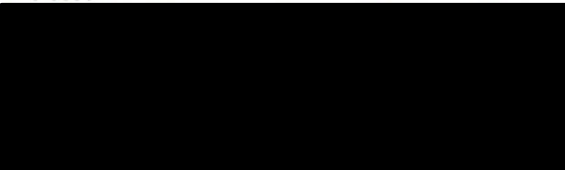
Confidentiality

Participant information will be kept private and only study investigators will have access to this information. Research data will be kept on a password protected computer and in locked cabinets in a secure lab and office. When the results are reported, individual records will be coded or results will be reported as group data. Data will be kept for five years. The Western University Health Sciences Research Ethics Board may require access to study records for quality assurance purposes.

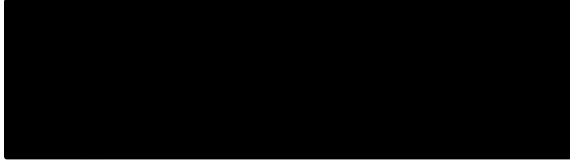
Questions about the Study

If you have any questions or concerns about the study, you may contact:

Dr. Trevor Birmingham PhD
Professor



Lauren Kanko BSc
MSc Graduate Student



If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics [redacted]



Thank you.



Trevor Birmingham

Appendix B. Ethics Approval Notice



Research Ethics

Western University Health Science Research Ethics Board HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Trevor Birmingham
Department & Institution: Health Sciences/Physical Therapy, Western University

Review Type: Delegated
HSREB File Number: 108555
Study Title: Validity and Reliability of the Star Excursion Balance Test for Patients with Knee Osteoarthritis

HSREB Initial Approval Date: January 27, 2017
HSREB Expiry Date: January 27, 2018

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Western University Protocol		2016/12/07
Letter of Information & Consent		2016/12/07
Recruitment Items	Poster	2016/12/07
Data Collection Form/Case Report Form	GRC - Received 2016/12/07	2016/12/07

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics Officer, on behalf of Dr. Joseph Gilbert, HSREB Chair

Curriculum Vitae

Lauren Kanko MSc Candidate

EDUCATION

- 2015-2017
(In progress) Master of Science, Kinesiology, Integrative Biosciences
Western University, London ON
Collaborative Program in Musculoskeletal Health Research
Supervisor: Dr. Trevor Birmingham
- 2011-2015 Bachelor of Science Honours, Specialization Kinesiology
Queen's University, Kingston ON

HONOURS & AWARDS

- 2015-2017 Western Graduate Research Scholarship
- 2015-2017 Collaborative Program for Musculoskeletal Health
Research Trainee Award
- 2011-2015 Queen's University Dean's Honour List
- 2011 Queen's University Excellence Scholarship

RELATED EXPERIENCE

- 2015-2017 Wolf Orthopaedic Biomechanics Laboratory
Western University, London ON
Research Student
- 2015-2017 Teaching Assistant, Western University
KIN2241 Biomechanics

Professor: Dr. Tom Jenkyn

KIN3353 Biomechanical Analysis of Human Locomotion

Professor: Dr. Volker Nolte

KIN1080 Introduction to Psychomotor Behavior

Professor: Dr. Matthew Heath

PRESENTATIONS

Poster Presentation

London Health Research Day 2017

Validity and Reliability of the Star Excursion Balance Test in Patients with Knee Osteoarthritis

Poster Presentation

Faculty of Health Sciences Research Day 2016

Validity, Test-Retest Reliability, and Sensitivity to Change of the Star Excursion Balance Test for Patients with Knee Osteoarthritis Undergoing Rehabilitation

Oral Presentation

Kinesiology Graduate Student Research Symposium 2016

Validity, Test-Retest Reliability and Sensitivity to Change of the Star Excursion Balance Test for Patients with Knee Osteoarthritis: A Study Proposal