Reliability and Validity of the Star Excursion Balance Test for Patients with Chronic Patellar Instability

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Abstract

The Star Excursion Balance Test (SEBT) is an eight-direction, maximal-reach balance test whose measurement properties are unknown in participants with chronic patellar instability. We designed an observational study with repeated measures to evaluate the test-retest reliability, cross-sectional and longitudinal construct validity, sensitivity to change and responsiveness of the SEBT in this population. Fifteen patients completed the SEBT and reported outcomes at baseline and two weeks and four patients completed testing three months later at the Fowler Kennedy Sports Medicine Clinic.

Intra-class correlation coefficients (ICC) for the SEBT were fair to good, ranging from 0.66-0.84. The SEBT demonstrates good cross-sectional construct validity and we are unable to comment with certainty on longitudinal construct validity; correlations between SEBT reach distance and patient-reported outcomes showed agreement with our hypotheses in 93 of 126 (74%) and 46 of 108 (43%) directions. These are preliminary results of a larger continuing study; therefore definitive conclusions cannot be made.

Keywords

Star excursion, balance, patella instability, knee, reliability, validity.
Co-Authorship Statement

This study was designed in collaboration with Dr. Dianne Bryant, Dr. Alan Getgood, Greg Alcock and Dr. Jim Dickey. I was responsible for writing the ethics application. I worked with Dr. Bryant and the staff at Empower Health Research Inc. to create the study database. I was responsible for screening patients, recruiting eligible patients and conducting follow-up visits for participating patients. I wrote the original draft of this thesis and Dr. Bryant, Dr. Getgood and Greg Alcock provided me with suggestions and comments to improve the final thesis submission.
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Chapter 1

1 Introduction:

Chronic patellar instability is a symptomatic condition that more commonly affects younger individuals, especially females, following patellar dislocation\textsuperscript{1-4}. Patellar dislocations affect 2.2 - 7 per 100,000 people in the general population, and up to 29 per 100,000 individuals between the ages of 10-19\textsuperscript{2-4}. When the patella dislocates it disengages from the anterior surface of the femur and translates to the lateral side where it can remain locked or spontaneously return to its original position\textsuperscript{1,5,6}. A number of intrinsic (patella alta, greater Q-angle, femoral anteversion, trochlear dysplasia) and extrinsic (family history, young age at time of injury, sports-related injury) risk factors increase the likelihood of recurrent subluxation and dislocation episodes\textsuperscript{4,7-12}. Patellar instability can be managed conservatively with physiotherapy focused on improved patellar tracking via increased VMO and gluteal activity, neuromuscular control and gait biomechanics, however surgical management is an option if conservative treatment fails\textsuperscript{13,14}. Very few studies have thoroughly assessed outcomes such as return to sport and function following conservative or surgical treatment\textsuperscript{15,16}.

Functional tests that assess movement patterns and provide information to clinicians about surrogates for readiness to return to sport and re-injury are becoming increasingly popular in ACL research\textsuperscript{17-20}, however very little has been done toward the development and validation of functional tests for patients with chronic patellar instability.

The Star Excursion Balance Test (SEBT) is a dynamic, maximal reach test involving a series of single-leg squats along eight designated lines radiating from a central point spaced 45° apart\textsuperscript{21,22}. The SEBT has been used predominantly for patients with chronic ankle instability\textsuperscript{23-28} (CAI), though more recent research has expanded to other populations with lower extremity injuries\textsuperscript{29-31}. The SEBT has been shown to be reliable in healthy populations, to differentiate between healthy and injured populations, as well as to predict future injury in healthy athletes\textsuperscript{22}.

To date, no studies have evaluated the measurement properties of the SEBT for patients with chronic patellar instability. Determining the reliability and validity of the SEBT in this
population is a first step toward demonstrating the utility of the SEBT as a functional assessment tool in patients with chronic patellar instability.
Chapter 2

2 Literature Review

2.1.1 Anatomy

2.1.2 The Knee Joint

The knee joint is composed of three bones -- the femur, the tibia and the patella -- and can be divided into two parts: the tibiofemoral joint, which we most commonly refer to as the knee joint, and the patellofemoral joint. The tibiofemoral joint is a hinge-type joint composed of related cruciate ligaments, collateral ligaments and menisci. This joint allows for flexion-extension movements and these motions are combined with gliding and rolling and rotation about a vertical axis. The tibiofemoral joint's stability depends on the strength of surrounding muscles and tendons, as well as the aforementioned ligaments running between the femur and tibia.
2.1.3 The Patellofemoral Joint

The patellofemoral joint is composed of an articulation between the posterior patella -- a triangular-shaped sesamoid bone with a proximal base and distal apex\textsuperscript{33} -- and the anterior, articular surface of the distal femur between the medial and lateral epicondyles\textsuperscript{34}. A broad, high ridge called the trochlear groove forms the lateral edge of the femoral articular surface and provides bony stabilization after the first 30° of knee flexion\textsuperscript{34, 35}. The patella is located in the retinacular layer of the extensor mechanism and is stabilized on the medial and lateral sides by the retinaculum and distally by the extensor mechanism tendons -- the vastus intermedius (VI) at the proximal end and the patellar tendon at the distal pole\textsuperscript{34} -- which encase the patella before
inserting on the tibial tuberosity. Rectus femoris (RF), vastus medialis (VM) and vastus lateralis (VL) are all superficial to VI and terminate in a layer known as the aponeurosis. Oblique fibers of VM and VL, referred to as vastus medialis obliquus (VMO) and vastus lateralis obliquus (VLO) also terminate in the aponeurosis. The aponeurosis, or retinacular layer, is a band of connective tissue that travels over and adheres to the patella, before continuing into the superficial patellar tendon. Vastus lateralis is the largest quadriceps muscle: it makes up over half the quadriceps bulk and inserts 30-40° laterally off the axis of the femur. The patellofemoral ligaments and patellofemoral ligaments add passive support on both the medial and lateral sides of the patella, and the patellofemoral ligaments help anchor the distal femoral origins of the VMO and VLO. The medial patellofemoral ligament (MPFL) is the main passive soft tissue stabilizer against lateral movement of the patella contributing 53-67% of medial soft tissue restraint. The MPFL courses deep to the VM just distal from the adductor tubercle on the femur to the VMO insertion on the superomedial patella.

2.2 Mechanism of Injury

Patellar dislocation most commonly involves the displacement of the patella to the lateral side of the femur. The majority of primary dislocations occur as non-contact injury in the early part of flexion with the tibia in a valgus position. A study by Nikku et al. looked at the mechanism of primary patellar dislocation in 126 patients. They found acute dislocations are more likely to occur while moving into flexion (84%, 102/126) versus extending the knee (8%, 10/126). Of injuries that occur while moving into flexion, significantly more dislocations occurred from an extended start than those that continued flexion from an already bent position. After dislocation, the kneecap can either spontaneously reduce on knee extension or remain locked on the outside of the knee; Nikku et al. also found that spontaneous reduction is more common in skeletally immature females, while skeletally mature men are more likely to need manual reduction of the patella.

2.2.1 Associated Injuries

Lateral dislocation of the patella places significant strain on the medial soft-tissues of the knee. The MPFL is the primary patellar stabilizer on the medial side and often is damaged during a
dislocation. A study by Guerrero et al.\textsuperscript{38} used MRI to examine the knees of 195 individuals who sustained a dislocation with sufficient trauma to cause edema at the medial patella and lateral femoral epicondyle found MPFL tears in 143/195 (74\%) knees.

Osteochondral fractures are also associated with patellar dislocations. Atkin et al.\textsuperscript{2} studied 74 patients who had suffered a first-time dislocation and reported 14 osteochondral fractures (19\%), while Nietosvaara et al.\textsuperscript{39} studied patellar dislocations in children under 16 and found that 28 of 72 knees (39\%) had associated osteochondral fractures. In both studies, fractures occurred on either the medial border of the patella or the lateral femoral condyle\textsuperscript{2,39}. Interestingly, Nietosvaara et al. reported that intra-articular fragments were only discovered in those that had spontaneous reduction of the patella\textsuperscript{39}.

![Figure 2: Skyline view of bilateral MPFL avulsion fractures and laterally subluxed patellas](image)

2.3 Epidemiology

A five-year retrospective study of patellar dislocations that presented to United States emergency department between 2003 and 2008 found that the incidence of patellar dislocations was 2.2 per 100,000\textsuperscript{3} in the general population. An earlier three-year prospective study of patients with a
first-time dislocation estimated the incidence in the general population to be even higher, at 7 per 100,000 per year.\(^2\)

Certain populations are at higher risk of patellar dislocation. Incidence rates increase to between 11.2 and 29 per 100,000 for individuals between the ages of 10 and 19 years\(^3,4\). Higher incidence rates have also been found in younger patients in other parts of the world; the incidence rate of first-time dislocation was 43 per 100,000 in Finnish children under the age of 16. Furthermore, the literature shows 52-72\% of patellar dislocations occur during sports participation\(^1-4\).

### 2.4 Risk Factors for Recurrent Dislocation

Predicting who is likely to experience recurrent patellar dislocations can be difficult, as there are several risk factors that contribute to patellar instability. Recurrent instability episodes are almost seven times higher after a second dislocation and females are more likely to have recurrent instability episodes compared to males\(^4\). Through non-operative management and daily exercises, recurrent instability episodes can be reduced, however the success of non-operative treatment is dependent on the presence of factors that predispose an individual to patella instability in the first place\(^4\).

Risk factors for recurrent dislocation are plentiful and include: younger age at primary dislocation, family history, sports-related injuries, patella alta\(^*\), greater Q-angle\(^†\), femoral anteversion and trochlear dysplasia\(^4,7-10\). Dejour et al. (1994)\(^7\) compared x-ray and computerized topography (CT) scans of 143 knees with patellar instability to 67 contralateral asymptomatic limbs, 190 healthy knee control radiographs and 27 healthy knee control CT scans. They found that four anatomical factors appeared most often in cases of patellar instability: trochlear dysplasia, quadriceps dysplasia, patella alta and TT-TG ratio. Trochlear dysplasia, an abnormally shaped trochlear groove, is present on imaging of 75-85\%\(^7,41\) of knees with patellar instability

\(\text{\textsuperscript{†}Q-angle: the angle between the line of the femur and the line of the tibia. A measure of bony alignment.}\)

\(\text{\textsuperscript{*}Patella alta: a high-riding patella, quantified using an anatomic ratio (e.g. Caton-Dechamps, Insall-Salvati)}\)
compared to only 30% of healthy controls. Furthermore, the knees with patellar instability often had more severe trochlear dysplasia, using the Dejour grading criteria from type A (presence of crossing sign on lateral radiographs) to type D (presence of crossing sign, trochlear spur and double contour on lateral radiographs), compared to healthy knees. A more recent case-control study by Steensen et al. (2015) compared the MRI of 60 participants with recurrent patellar instability to 120 healthy controls. Forty-one of the 60 participants (68.3%) had trochlear dysplasia compared to only seven (5.3%) of the control knees.

![Lateral knee x-ray illustrating type b trochlear dysplasia](image)

**Figure 3: Lateral knee x-ray illustrating type b trochlear dysplasia**

† Crossing sign: a line represented by the deepest part of the trochlear groove crossing the anterior part of the femoral condyles

§ Trochlear spur: a bump at the top of the trochlear groove that the patella must overcome to articulate with the trochlear groove.

** Double contour: a double line at the anterior part of the femoral condyles, seen if the medial epicondyle is underdeveloped.
Quadriceps dysplasia was measured using patellar tilt\textsuperscript{††}. The mean angle of patellar tilt was significantly higher in the group of patients with patellar instability compared to healthy controls\textsuperscript{7}. Furthermore, contraction of the quadriceps significantly increased the tilt in the group with instability by six degrees, while the mean tilt of the control group only increased by one degree. Using a threshold value of 20\(^{\circ}\) of patellar tilt, 83\% of knees with patellar instability exceeded this value while only 3\% of controls reached that number.

Patellar height can be quantified using numerous ratios, but we use the Caton-Deschamps (CD) ratio. The CD ratio takes the distance from the lowest point on the articulating surface of the patella to the anterior tibial plateau, then divides this distance by the length of the articulating surface of the patella\textsuperscript{10}. A ratio of 0.8 to 1.2 is considered normal, while a ratio of 1.2 or greater indicates patella alta, a condition where the patella sits higher than normal on the femur during extension preventing it from tracking within the groove until deeper in flexion. In the study conducted by Dejour et al., patella alta was identified in 25\% of patients with patellar instability and none of the healthy controls\textsuperscript{7}. Higher prevalence was observed in the study conducted by Steensen et al.,\textsuperscript{12} with 60\% of participants with patellar instability diagnosed with patellar alta, compared to only 21\% of control participants.

\textsuperscript{††} Patellar tilt: the patient lies in supine and the clinician attempts to lift the lateral edge of the patella. Inability to lift the lateral edge indicates tight lateral retinaculum.
Figure 4: Lateral knee radiograph with Caton-Deschamps index of 1.6
Tibial tubercle-Trochlear groove (TT-TG) distance was measured by superimposing CT sections of the tibial tubercle and the trochlea. Lines from the centre of the tibial tubercle and the inferior portion of the trochlear groove were then extended perpendicular to the posterior condylar line. The distance between those two lines represented the TT-TG translation. In the Dejour study, the group with patellar instability had significantly higher TT-TG measurements than the control group. Using a threshold of 20mm, 56% of the knees in the patellar instability group exceeded this value while only 3.5% of the healthy controls and 24% of asymptomatic contralateral knees exceeded this threshold. In the Steensen MRI study, 41.7% of the patellar instability group had an increased TT-TG distance, while only 3.3% of the control group exceeded 20mm.

Anatomical risk factors for patellar instability are much more prevalent in patients suffering from patellar instability compared to healthy controls, and 35 out of 60 (58.3%) knees had multiple risk factors. However, it is possible to possess risk factors and be asymptomatic. Thus, Dejour et al. suggest that for patients with recurrent dislocations, surgery should aim to correct whichever anatomical factors are present.

### 2.5 Clinical Assessment

#### 2.5.1 Patient History

Patient history and clinical assessment are both important for correct diagnosis of patellar instability. When reporting injury history, patients will often complain that the knee gave way and severe pain developed during a twisting or jumping movement. They often describe feeling something move or pop out, with effusion appearing quickly after the injury. The kneecap will either reduce on its own when the knee is extended or require manual relocation. A 2009 study by Nikku et al. found that out of 126 patellar dislocations, 67 (53%) remained locked and had to be manually reduced. Since the presence of risk factors for instability have been shown to be predictive of recurrent dislocation, the history and ultimate treatment recommendations should also assess the presence or absence of both anatomical and environmental risk factors.
2.5.2 Clinical Tests

Clinical tests for patellar instability are used to confirm the dislocation, assess structures around the patella, and estimate the potential for future instability episodes. Many of these diagnostic tests lack evidence to support their sensitivity and specificity for patellar dislocation as they were originally designed for patellofemoral pain syndrome (PFPS) or other ligamentous knee injuries.43

Bassett's sign is the most sensitive test (sensitivity = 0.70) in patients following acute patellar dislocation.44 Clinicians palpate the adductor tubercle, medial retinaculum and medial epicondyle searching for tenderness along the MPFL.43 A positive test indicates disruption of the MPFL.

To administer the apprehension test, the patient lies supine with the knee resting in 30° of flexion.43 The clinician then places one hand on the medial side of the patella and lightly pushes the patella laterally. A positive test reproduces pain, involuntary quadriceps contraction, or a verbal display of apprehension. The sensitivity and specificity of the apprehension test is debated; one study suggests the apprehension test lacks sensitivity (sensitivity = 0.39) for patellar instability. A modified version, called the moving patellar apprehension test, involves two steps. First, the clinician lightly pushes the patella laterally, and flexes the knee to 90° before returning it to extension. Next, the clinician lightly pushes the patella medially and flexes the knee to 90°, before returning it to extension. The test is positive if the patient is apprehensive during step one, but is not apprehensive during step two. The test has demonstrated accuracy (sensitivity = 1.00, specificity = 0.88).

The patellar glide test is used to determine the magnitude of instability and requires the patient to lie supine with the knee relaxed in extension.43 The patella is divided into four quadrants and the clinician manually moves the patella medially and laterally. Movement greater than or equal to three quadrants (greater than half the patellar width) indicates a positive test, suggesting lateral tightness or a lack of medial restraint.
A patellar J-sign is indicative of abnormal tracking of the patella, usually caused by tight lateral structures\textsuperscript{43}. To administer this test, the patient sits on the edge of a bed with the leg fully extended and flexes the knee. The clinician observes the movement of the patella looking for a medial translation in early flexion as the patella engages in the trochlear groove. The test is positive if the clinician observes the patella shift laterally imitating an inverted 'J' pattern as the patient returns to extension.

The Beighton score evaluates hyperextension in both thumbs, fifth digits, elbows and knees, as well as forward flexion in the trunk\textsuperscript{46}. The Beighton score should be assessed if generalized ligament laxity (GLL) is suspected. A positive score indicative of GLL is greater than 4.

### 2.5.3 Imaging

X-Ray is recommended when assessing patients following patellar dislocation to confirm the diagnosis, assess the presence or absence of secondary injuries, and evaluate anatomical factors that contribute to instability and influence the treatment decision\textsuperscript{5, 7, 10, 41, 44, 47}. X-ray can be used to assess patella alta, trochlear dysplasia, patellar tilt and patellar subluxation\textsuperscript{47}. MRI or CT can be used to assess TT-TG distance, but are not necessary as clinicians can likely estimate alignment visually. MRI can also be used to assess osteochondral injuries and potentially the integrity of the medial retinaculum/MPFL.

### 2.6 Conservative vs. Surgical Treatment

There is currently a lack of consensus surrounding operative and non-operative treatment following a first-time patellar dislocation\textsuperscript{13, 14}. Wang et al.\textsuperscript{14} performed a meta-analysis of eight randomized control trials (RCTs) comparing conservative and surgical treatment after first-time patellar dislocation. Although the strength of their conclusions was limited by poor quality RCTs and heterogeneous populations and surgical procedures, they showed that surgery may better reduce the risk of recurrent dislocation; however no differences existed between groups in terms of Kujala Patellofemoral Score (a 13-item patient-reported questionnaire assessing knee function) and patient satisfaction. After their systematic review in 2007, Stefancin and Parker\textsuperscript{13} recommended conservative
treatment following a first-time dislocation, unless any of the following were present: an osteochondral fracture or major chondral damage; substantial disruption of the MPFL; a laterally subluxated patella with normal alignment of the contralateral knee; failure to improve with conservative management accompanied by at least one risk factor for patellar instability; or a recurrent dislocation episode.

2.6.1 Conservative Treatment

The goals of physiotherapy following a patellar dislocation are to reduce swelling, promote VMO and gluteal activity and regain controlled knee flexion\textsuperscript{40}. Electrotherapy and ultrasound can be used to decrease swelling around the patella, while gentle neuromuscular facilitation through hold/relax techniques are recommended two to three weeks post-dislocation. Taping or bracing can be used to stabilize the patella and protect the retinaculum while performing exercises. Improving gait mechanics, foot placement, hip abductor strength and proprioception is imperative, especially in patients with poor alignment or valgus collapse at the knee\textsuperscript{48}. As high as 50\% of patients undergoing conservative management after a first-time dislocation will experience recurrent dislocation\textsuperscript{49, 50}, while up to 70\% will experience ongoing instability without actual dislocation\textsuperscript{9}.

2.6.2 Surgical Treatment

Medial patellofemoral ligament reconstruction is the most common procedure for recurrent patellar instability\textsuperscript{5, 51}. An autograft or allograft is used to reconstruct the MPFL between the superomedial border of the patella and the MPFL insertion just distal to the adductor tubercle on the medial femur\textsuperscript{52}. The goal is to mimic the natural course of the MPFL with similar tension in the graft. A systematic review published in 2012 by Shah et al.\textsuperscript{51} evaluated the outcome following MPFL reconstruction of 629 knee surgeries in 597 patients. Complications of varying severity occurred in 26.1\% of cases, yet the surgery was effective at preventing further instability. Only 3.7\% of individuals experienced further dislocation events while another 8.3\% experienced apprehension, hypermobility or occasional feelings of instability without subluxation.
Further surgical procedures can be performed alongside MPFL reconstruction to correct anatomic anomalies. An excessively flat or convex trochlea can be corrected by trochleoplasty; a difficult procedure to perform whereby the surgeon re-shapes the bony anatomy of the trochlear groove to remove any abnormalities and improve patellar tracking. An excessive TT-TG ratio can be corrected by medializing the tibial tubercle via a tibial tubercle osteotomy (TTO). Excessive patella alta can be corrected by moving the TTO distally and returning the CD ratio to within a normal range of 0.8-1.2. Longo et al (2016) reviewed 14 articles involving 289 participants where MPFL reconstruction was combined with either TTO or trochleoplasty. The authors found similar results in patients who had undergone a combined procedure compared to isolated MPFL reconstruction, with up to 8.8% (25/289) of participants suffering 'functional failure', while up to 40% (116/289) experienced minor complications.

2.6.3 Summary

Conservative treatment is currently recommended after first-time patellar dislocations, however it could be as many as 50% of patients will experience a recurrent dislocation. Studies comparing conservative treatment to surgical treatment after a first-time dislocation have shown patients are less likely to re-dislocate after surgery; however patient satisfaction between the groups did not differ. Isolated MPFL reconstruction and MPFL reconstruction coupled with bony procedures to correct anatomical abnormalities appear to be effective procedures that produce low re-dislocation rates. Future research should involve high-level controlled trials, as current evidence is limited by retrospective and non-randomized study designs.

2.7 Return to Sport

While the frequency of re-dislocation is low for those that do undergo surgery, the actual goal of surgical treatment is for patients to return to a similar or higher level of activity following rehabilitation. Non-operative and post-surgical rehabilitation for chronic patellar instability share the following goals; no pain, no effusion, no instability, full range of motion, symmetrical strength and dynamic stability. Fisher et al. (2010) performed a systematic review to determine the efficacy of return to sport after MPFL
reconstruction, reporting that the published studies were of poor methodological quality and often did not evaluate return to sport. These limitations meant that they were unable to make conclusions about its effectiveness.

A more recent cohort study by Ambrozic and Novak looked at return to sport following MPFL reconstruction at a mean follow up of six years post-surgery. The authors found that of the 26 participants who played sports prior to the surgery, 23 participants (88.5%) had returned to sport post-surgery. Sixteen (69.4%) of these participants were able to return to the same or higher level of sport.

Functional tests are becoming more prominent in return to sport decision making, led by ACL research. Unfortunately, literature examining functional tests in patients with patellar instability is currently lacking. One such test that is recommended for evaluation of limb stability during rehabilitation for patients with patellar instability is the Star Excursion Balance Test (SEBT).

### 2.8 Star Excursion Balance Test (SEBT)

The SEBT is a standing, single-leg, maximal-reach test performed in eight directions along designated lines. The lines extend from a centre point and are spaced 45 degrees apart. The lines are labelled anterior (ANT), anteromedial (AM), medial (MED), posteromedial (PM), posterior (POS), posterolateral (PL), lateral (LAT) and anterolateral (AL) in relation to the stance foot. The stance limb is placed with the middle of the foot on the centre of the star facing in the anterior direction, with the non-stance limb beside it. The non-stance limb is then used to reach out and tap the line as far away as possible while keeping all the weight on the stance limb, after which it is returned to the starting position in bilateral stance. Any loss of balance or movement of the stance foot voids the attempt and that direction must be re-attempted. One complete trial involves reaching in all eight directions with both limbs. The outcome scores are the reach distances in each direction, with a higher score indicating further reach. Reach distances are normalized using limb length to control for variation due to height differences. Limb length is measured from the anterior superior iliac spine of the hip to
the medial malleolus of the ipsilateral leg and is recorded prior to the first time performing the star excursion.

2.8.1 Modified Three-Direction SEBT

Currently, it is recommended participants complete four practice trials for each SEBT direction on both limbs to account for practice effects and achieve the desired measurement reliability. The amount of time required to perform these practice trials is a concern for clinicians operating with time constraints in the clinical setting. Previous authors have attempted to reduce the amount of time the SEBT protocol currently takes, and successfully demonstrated similar reliability using four practice trials instead of six\textsuperscript{58-60}.

Factor analysis of SEBT reach distances in a study comparing participants with chronic ankle instability (CAI) to healthy participants found that the eight reach directions were redundant and certain directions were highly correlated\textsuperscript{23}. Hertel suggested the posterior-medial direction of the SEBT was highly indicative of performance in all directions in both healthy participants and participants with CAI. A 2008 kinematic study of SEBT performance could help explain this redundancy: hip flexion and knee flexion are responsible for 62-95\% of the variance in reach performance on the SEBT\textsuperscript{61}. One change to streamline the testing protocol involved moving to a modified three-direction SEBT\textsuperscript{62,63} -- which utilizes only the ANT, PM and PL directions -- or the similarly designed Y-balance test\textsuperscript{64-66}. However, this redundancy was determined using only patients with CAI, and different injured populations have demonstrated important reach deficits on other directions of the SEBT\textsuperscript{30}. Important information may be missed by generically reducing the SEBT to these three directions in injured populations that have not yet been thoroughly studied.

2.9 Reliability of the SEBT

Previous research has demonstrated good to excellent reliability for the SEBT in studies of healthy participants. Kinzey and Armstrong (1998)\textsuperscript{67} were the first to evaluate the reliability of the SEBT in assessing dynamic balance. They tested 20 healthy participants
aged 18-35 on two separate occasions one week apart. Participants reached only in the anterior-medial (AM) and posterior-medial (PM) directions with each foot, completing five reaches in one direction before moving onto the next arm of the star. The SEBT showed moderate to strong reliability in these directions, yielding intra-class correlation (ICC) values of 0.87 on the left AM/PM reaches, 0.82 in the right PM direction and 0.67 for the right AM reach. They suggested that participants complete six practice trials to increase the reliability of the reach measurements.

Hertel, Miller and Denegar (2000)\textsuperscript{68} estimated the intra- and inter-rater reliability of the SEBT for all eight directions using 16 healthy participants with an average age of 21.3 years. Participants performed testing on two separate days one week apart. At each visit participants performed three trials of the eight-direction SEBT with each leg in every direction as measured by examiner one, before taking a rest and repeating the testing protocol again for a different examiner. The SEBT showed good to strong intra-rater reliability in all directions: examiner one’s ICC values ranged from 0.78-0.96 for both days while the second examiner’s ICC values ranged from 0.82-0.96. Inter-tester ICC values were slightly lower on day one, ranging from 0.35-0.84, before increasing to 0.81-0.93 on day two. The longest reach distances occurred during trials seven to nine, which the authors attributed to participants needing a number of trials to learn optimal reach movements. Hertel, Miller and Denegar\textsuperscript{68} agreed with Kinzey and Armstrong’s\textsuperscript{67} recommendation of six practice trials to account for these learning effects.

A 2006 study that included 235 high school basketball players and the ability of the SEBT to predict injury also included a pilot study for reliability of the three direction SEBT\textsuperscript{63}. In the pilot portion of the study, 14 participants were tested during the preseason to examine intra-rater reliability and 20 participants performed the SEBT again at the end of the season to estimate test-retest reliability. Participants performed six practice trials in each of the three directions before completing three scored trials; the greatest reach distance of the three attempts was recorded as the score for that direction. Participants were tested, given a five minute rest, then tested again. The intra-rater reliability ICC values for all three directions ranged from 0.84-0.87. The test-retest reliability time
interval before and after the season was larger than other studies and still returned strong ICC values ranging from 0.89-0.93.

Munro and Herrington (2010) estimated the test-retest reliability of normalized SEBT scores in a study of 22 healthy participants with an average age of 22.5 years. Participants performed the eight-direction SEBT on two testing days one week apart at the same time of day. Reach direction and stance leg order were randomized for each subject prior to the trial. Participants completed seven trials in each direction on the original leg before taking a one minute rest and repeating the trials with the contra-lateral leg. Reach distances stabilized by the fourth trial, therefore trials five to seven were used to measure test-retest reliability. ICC values were high, ranging from 0.84-0.92 for each direction. Additionally, they estimated the smallest detectable change of the SEBT to be approximately 5-7cm.

In 2014, Hyong and Kim further examined the intra- and inter-rater reliability of the SEBT in a study of 67 healthy participants. The testing protocol was identical to the Plisky study done in 2006; participants performed six practice trials before completing three scored trials, two scored by rater 'A' and one scored by raters 'B' and 'C'. The SEBT showed high intra- and inter-rater reliability with ICC scores ranging from 0.88-0.93, and 0.83-0.93, respectively.

2.9.1 Summary
Reliability of the SEBT has been studied thoroughly in healthy individuals. Four to six practice trials are recommended to account for learning effects. No authors have estimated the reliability of the SEBT in injured populations.

2.10 Known Groups Validity of the SEBT
When the SEBT has been used in injured populations research has focused on the ability to differentiate between injured and uninjured limbs of participants with injuries between injured and healthy controls.
2.10.1 Ankle Injuries

The SEBT has primarily been used to study participants with ankle sprains and chronic ankle instability (CAI)\textsuperscript{23-27}. In 2002, Olmsted et al.\textsuperscript{24} compared 20 participants with CAI to 20 healthy, matched (by gender, sport and position) controls at one time point on the eight-direction SEBT. Participants with CAI demonstrated significant reach deficits in the L and AL directions compared to other axes of the SEBT, as well as deficits when compared to their own healthy limb (78.6cm versus 81.2 cm) and the matched limb of healthy controls (78.6cm versus 82.8cm). A 2004 study by Gribble et al.\textsuperscript{25} expanded on this research using 14 participants with CAI and 16 healthy controls. The authors had participants perform five trials of a modified three-direction SEBT (ANT, MED, and POS), and added a fatigue factor to four of the five trials. Gribble et al. observed that the group with CAI demonstrated significant reach deficits in all three directions on the injured limb compared to both their non-injured side and healthy controls. These differences ranged from 3-5% of normalized reach distance. In 2006, Hertel had 48 participants with unilateral CAI perform the eight-direction SEBT and compared them to 39 healthy controls\textsuperscript{23}. Although the main purpose of their study was to evaluate the redundancy of the eight-direction SEBT, however they did note significant reach deficits for the CAI group in the AM, MED and PM directions compared to their healthy limb and the matched limb of healthy controls.

Two studies have looked at the effect of rehabilitation programs on SEBT performance in participants with CAI\textsuperscript{26, 27}; both studies were randomized trials involving a four-week comprehensive rehabilitation program. Participants completed trials of the SEBT before and after completion of the rehabilitation program. Hale et al. enrolled 29 participants with CAI (16 were randomized to a rehab intervention group, 13 were randomized to a control group) and 19 healthy controls\textsuperscript{26}. At baseline, there were no differences in the eight SEBT reach distances between the CAI-rehab group, the CAI-control group or the healthy group on both the involved and uninvolved limbs; however patients with CAI demonstrated significant reach deficits between their own involved and uninvolved limb in the PM, PL and LAT directions. SEBT scores did not significantly change over the four-week period in the CAI control group (ICC = 0.80-0.93) or the healthy participants;
however the CAI rehab group did demonstrate significant SEBT reach change scores, as well as significant improvement compared to their control and healthy counterparts in the PM, PL and LAT directions (evidence of known groups construct validity). Lee et al. enrolled 18 male participants with CAI and randomized nine to the intervention group and nine to the control group\textsuperscript{27}. The SEBT reach distances of both groups increased over the four week period, but the intervention group improved significantly more than the control group in the AM, POS, PL, LAT and AL directions. There were no significant differences between the groups for the uninvolved limb.

2.10.2 Knee Injuries

Three studies have examined the performance of the SEBT in populations with knee injuries\textsuperscript{30, 31, 62}. In 2010, Aminaka and Gribble performed a study comparing 20 participants with patellofemoral pain syndrome (PFPS) to 20 healthy controls \textsuperscript{31}. Participants performed six practice tests in the ANT direction only, before completing three trials with or without patellar taping. Participants then rested for five minutes and completed three more trials with the other taping condition. Participants with PFPS showed no differences in the taped condition (PFPS: 63.5\% +/- 1.3 vs. Control: 64.8\% +/- 1.3) and slight deficits in the non-taped (PFPS: 62.8\% +/- 1.2 vs. Control: 65.6\% +/- 1.2\%) condition. The clinical importance of this small observed difference in the non-taped condition is unknown.

Several studies have observed SEBT performance in participants following anterior cruciate ligament injury. A study of 25 participants who were ACL-deficient compared the performance of the injured limb to that of their non-injured limb and healthy matched controls\textsuperscript{30}. All participants had suffered a non-contact injury and ranged from five to 24 months post-injury. The ACL-deficient group demonstrated significant reach deficits compared to the control group on both limbs; the ACL-deficit group scored worse in the ANT, LAT, PM and MED directions on their injured limb, as well as the LAT and MED directions of their non-injured limb. No significant differences were found within the ACL-deficient group when comparing their own injured limb to their own non-injured limbs. Dynamic postural control appears to be affected by ACL deficiency; however the authors noted that deficits on the non-injured limb could be a sign that postural control
deficits may pre-dispose to ACL injury. In 2013, Delahunt et al.\textsuperscript{69} investigated dynamic postural control in 14 women who had experienced non-contact ACL tears and undergone reconstruction. The participants were 10 months to six years (mean 2.8 years) from surgery and had returned to full sport participation. They were compared to 17 healthy, matched controls on the three-direction SEBT. The group who had undergone ACL-reconstruction had significant reach deficits in the PM (96.06% +/- 7.56% vs. 105.06% +/- 7.68%) and PL (89.53% +/- 7.42% vs. 98.87 +/- 8.59%) directions compared to the healthy controls. It is difficult to determine the clinical significance of these differences as confidence intervals did overlap.

Clagg et al. (2015)\textsuperscript{62} studied 66 participants at the time they were cleared to return to sport post-ACL reconstruction, comparing them to 47 healthy controls. Participants were deemed ready to return to sport if they had completed a rehabilitation program, been cleared to return to all athletic activities and were interested in resuming pivoting and cutting sports. Participants were, on average, 17 years old and 6.7 months post-surgery. The study was cross-sectional and compared performance on the modified three-direction SEBT to isokinetic strength and surgical procedure. Patients who had undergone ACL reconstruction demonstrated significant reach deficits in the ANT direction for both the injured and non-injured limbs compared to controls. No differences existed in the PM or PL directions. Hip abductor strength was weakly correlated with performance in all three reach directions ($r = 0.28-0.41$) on the injured side, as was quadriceps and hamstring strength for the PL direction ($r = 0.28-0.29$).

2.11 Predictive Validity of the SEBT

The SEBT has also been used as a predictive tool in sports participants and has demonstrated the ability to predict lower extremity injury in case-control and cohort studies of healthy, athletic populations over the course of a year\textsuperscript{63, 66, 70, 71}. Reach deficits, quantified in different ways depending on the study, put healthy individuals at a higher risk of ankle sprains.

A prospective cohort of 235 high school basketball players who were tested prior to the season found that a difference in ANT reach distance greater than four centimeters
between the right and left legs was predictive of ankle sprain. In another study involving 121 recreational athletes who were tested prior to the season, decreased performance in the PL direction of the SEBT was the second highest predictor of ankle sprains trailing only a history of sprains. Participants that reached less than 80cm on the PL direction of the SEBT had a 48% greater risk of suffering an ankle sprain than those that reached further than 80cm.

A pilot study involving 59 American football players had participants complete the SEBT prior to the season, before following them for a year; six players suffered non-contact lower-body injuries that season. Analysis showed a composite score below 89.6% of limb length had a positive likelihood ratio of 3.5, increasing the risk of injury during a football season from 37.7% to 68.1%, but the pilot study was limited by a small sample size. Gribble et al. expanded on football research in 2016 using a prospective cohort of 539 high school and college players. Participants completed the SEBT and Functional Movement Screen (FMS) in the pre-season and were followed for a year with the authors observing for lateral ankle sprains. Participants were excluded if they suffered any other injuries that season. The 54 participants who suffered ankle sprains scored worse on the ANT direction of the SEBT (65.51% +/- 7.90%) compared to the non-injured athletes (69.67% +/- 7.60%) at baseline testing, and had nearly three times higher odds of suffering a lateral ankle sprain.

The three-direction SEBT has also shown predictive validity in injured patients after a first time-lateral ankle sprain (LAS). Out of 70 participants with LAS, 28 (40%) presented with CAI at one year post-injury. Decreased reach distance in the POS direction at six months post-injury was significant and contributed to a regression model that was 75% sensitive and 91% specific for CAI in this sample. Participants with CAI reached approximately 7.5cm less in the posterior direction compared to those that coped with LAS.

2.12 Summary

The SEBT has good to excellent reliability after four practice trials in healthy participants, the ability to detect reach deficits in participants with a variety of ankle and
knee injuries, and the ability to predict future injury. However, no studies have examined the measurement properties of the SEBT in participants with chronic patellar instability.
Chapter 3

3 Objectives

Our objective was to evaluate the measurement properties of the SEBT in patients with chronic patellar instability. Specifically, we will evaluate test-retest reliability, cross-sectional and longitudinal construct validity, sensitivity to change, and responsiveness.
Chapter 4

4 Methodology

This was a prospective, observational cohort study with repeated measures.

4.1 Institutional Approval

Local ethics approval was obtained from the Western University Health Sciences Research Ethics Board (HSREB) following a delegated review for the use of human participants (REB file number: 106806) (Appendix A).

4.2 Eligibility Requirements

Participants were eligible to participate in the study if they: (A) had experienced two or more patellar instability episodes; (B) were candidates for surgery; and (C) were between the ages of 15 and 50 years.

Participants were excluded if they: (1) had undergone previous surgery; (2) had a vestibular disorder, concussion, or lower extremity injury other than patellar instability within the last three months; (3) did not speak, read or understand English; (4) had a cognitive impairment or psychiatric illness that precluded informed consent or rendered the patient unable to complete questionnaires; (5) incompetency or unwillingness to provide informed consent; or (6) had no fixed address or no means of contact and were not available for the two year follow-up period.

4.3 Subject Recruitment

Participants were recruited from the clinics and wait lists of four orthopaedic surgeons at the Fowler Kennedy Sport Medicine Clinic in London, Ontario Canada.

4.4 Outcome Measures

Participants were assessed at screening (T1), two weeks post-screening (T2), three months post-screening (T3), and six months (T4) and 24 months (T5) post-operatively. Our primary outcome measure was normalized reach distance for all eight directions of
the SEBT. Our secondary outcome measures included the Banff Patella Instability Instrument (BPII), the Kujala Patellofemoral Score (KPS), the Lower Extremity Functional Scale (LEFS), the Short Form-12 Health Survey (SF-12), the Marx Activity Rating Scale, the Fear Avoidance Beliefs Questionnaire (FABQ), the Generalized Self-Efficacy questionnaire (GSE), and the 4-Item Pain Intensity Measure (P4).

Participants completed all 10 questionnaires and performed the SEBT trials at each visit. A global rating of change scale was completed at T2, T3, T4, and T5.

4.4.1 Primary Outcome Measure

4.4.1.1 SEBT Normalized Reach Distance

Our primary outcome was normalized reach distance in each of the eight directions on the SEBT. The eight reach directions were labeled anterior (ANT), anterior medial (AM), medial (MED), posterior medial (PM), posterior (POS), posterior lateral (PL), lateral (LAT) and anterior lateral (AL) with regards to the stance foot. We normalized reach distance using leg length to remove significant differences between genders\(^{57}\). We measured limb length from the anterior superior iliac spine to the medial malleolus on the right leg. Following the protocol suggested by Robinson and Gribble\(^{58}\), participants performed four practice reaches along each direction, first on the non-injured stance limb followed by the injured stance limb. Participants then performed three scored trials in all directions for each limb starting with the non-injured limb.

For each trial of the SEBT, participants placed their stance foot in the centre of the star with the non-stance foot beside it (see Figure 2). Participants reached in the indicated direction using the non-stance foot, tapping the toe as far along the line as possible before returning to the two-foot starting position. If the participant lost their balance or transferred any weight to the non-stance foot at anytime during the excursion the trial was discarded and repeated. Participants reached in the anterior direction first, performed three trials along that vector, and then progressed to the next line medially with regards to the stance foot. Participants performed all trials with the healthy stance limb before repeating the procedure on the injured stance leg.
4.4.2 Secondary Outcomes

4.4.2.1 Kujala Patellofemoral Score (KPS)

The Kujala Patellofemoral Score (KPS) is a 13-question patient-reported questionnaire where a high score of 100 indicates high functional ability. Patients are given 3-5 possible responses per question and each question is scored out of 5 or 10. The KPS has been shown to differentiate between anterior knee pain and other conditions of the knee. It demonstrated internal consistency, test-retest reliability and correlated with other knee-specific questionnaires\(^72\).

Figure 5: Depiction of the SEBT for the left stance leg.
4.4.2.2 Banff Patellar Instability Instrument (BPII)

The Banff Patella Instability Instrument (BPII) is a patient-reported outcome measure designed specifically for a population with patellar instability. There are 32 total questions split into five domains that query physical symptoms, occupational concerns, recreational activities, lifestyle, and social and emotional aspects. Each item has one 100 mm visual analogue scale response option, with labeled anchors at 0 mm (e.g., extremely difficult) and 100 mm (e.g., not difficult at all). Scores are calculated by converting the average of each of the five domain scores to a total average score out of 100% where 100% represents the best possible score. It has been shown to have construct and content validity (83-100%), as well as internal consistency and reliability (test-retest ICC of 0.98) in all populations across the patellar instability disease spectrum both pre- and post-op\textsuperscript{73}.

4.4.2.3 Lower Extremity Functional Scale (LEFS)

The Lower Extremity Functional Score (LEFS) is a self-report functional measure for patients with lower extremity orthopedic conditions. This scale consists of 20 functional items with five response options each ranging from zero (extreme difficulty) to four (no difficulty). The total possible score of 80 indicates a high functional level. The scale has shown excellent test-retest reliability ($r=0.94$) and demonstrated construct validity with the SF-36\textsuperscript{74}. A patient's LEFS score has an error of five points, and both the minimal detectable change (MDC) and minimally clinically important difference (MCID) were found to be nine points\textsuperscript{74}. The scale is one page in length and can be completed by most patients in less than two minutes.

4.4.2.4 Marx Activity Rating Scale

The Marx Activity Scale is a four-item activity rating scale developed by Marx et al.\textsuperscript{75} The patient is asked to rate how often they were able to perform each activity (e.g. running, cutting, decelerating, and pivoting) in their most healthy and active state. The patient is provided with five categories of frequency of each functional activity, ranging from less than one time in a month to four or more times in a week. One point is allocated for each category of frequency and a maximum score of 16 points can be awarded. It has demonstrated high reliability and validity in patients with disorders of the knee\textsuperscript{75}. 
4.4.2.5 4-Item Pain Intensity Measure (P4)

The 4-Item Pain Intensity Measure (P4) is a four-item questionnaire created by Spadoni et al\textsuperscript{76} that evaluates the level of pain present for a patient over the past two days. The patient is to report the level of pain they experience in the morning, afternoon, evening and during activity. Each item has ten response options ranging from 0 (no pain) to 10 (pain as bad as it can be). The patient’s score is calculated by adding the score from each item, to give a possible maximum score of 40. The P4 has been shown to be a valid and reliable instrument for assessing change in pain intensity\textsuperscript{77}.

4.4.2.6 Short-Form Health Survey (SF-12)

The 12-item Short Form Health Survey (SF-12) is an abbreviated 12 question general health scale that evaluates domains of physical and mental health through summary scores. The SF-12 is scored separately for physical and mental health sections with each section ranging from 0 (low level of health) and 100 (high level of health) and has proved valid in a wide variety of populations and contexts\textsuperscript{78}.

4.4.2.7 Generalized Self-Efficacy Scale (GSE)

The General Self-Efficacy Scale (GSE) is a self-reported questionnaire designed to measure an individual's self-efficacy and self-belief in their ability to complete tasks and overcome obstacles\textsuperscript{79}. There are 10 items each scored from 1 (low self-efficacy) to 4 (high self-efficacy). The overall score is calculated by summing the scores from all 10 questions to provide a total between 10 and 40. Criterion-related validity has been shown to correlate with both negative and positive factors for various domains of perceived self-efficacy\textsuperscript{79}.

4.4.2.8 Fear Avoidance Beliefs Questionnaire (FABQ)

The Fear Avoidance Beliefs Questionnaire (FABQ) is broken up into a physical activity (FABQPA) and a work (FABQW) subscale. The FABQPA is out of 24 possible points while the FABQW consists of 42 possible points. For both scales a high score represents increased fear of performing the activity. Originally designed for low back pain\textsuperscript{80}, the FABQ has shown to produce similar results when modified for different anatomical
regions of the body, including the lower extremity\textsuperscript{81}. We have modified the FABQ by replacing any reference to the back with the knee instead.

4.4.2.9 Pain Catastrophizing Scale (PCS)

The Pain Catastrophizing Scale (PCS) is a 13 item questionnaire where each item is scored from 0 (not at all) to 4 (all the time). The PCS total score is out of 52 and is calculated by summing the responses to all 13 questions. Its multi-dimensional approach to catastrophization and connection to pain is well-supported by research and it can be completed in several minutes making it useful in clinical practice\textsuperscript{82}.

4.4.2.10 Global Rating of Change Questionnaire (GRC)

The Global Rating of Change (GRC) is a 15 point scale ranging from -7 (much worse) to +7 (much better). It is used to measure the patient's self-reported estimate of progress compared to an initial level of health. Strong correlations have been found between GRC scales and improvement on outcome questionnaires and are used to demonstrate patient-important changes\textsuperscript{83}.

4.5 Sample Size

The primary outcome of this study was test-retest reliability of the SEBT over a two week interval. We used a one-sided confidence interval parameter estimate with a lower confidence interval of 0.1, an expected ICC of 0.85 and $\alpha = 0.05$\textsuperscript{84}. The required sample size based on the chosen values was 36 participants and, after accounting for a drop-out rate of 25%, we decided to recruit 45 participants.

4.6 Statistical Analysis

All data analyses were performed using IBM SPSS Statistics version 22 (IBM Corp., Armonk, NY)\textsuperscript{85}.

4.6.1 Test-Retest Reliability

We hypothesized that the SEBT would have an intra-class correlation coefficient (ICC) of at least 0.85 over a two week interval. We analyzed test-retest reliability using the
SEBT scores for all eight directions from T1 and T2. We used an ICC(2,1) to estimate absolute agreement and the standard error of measurement (SEM) to estimate the error around an individual score. ICC scores were interpreted according to Coppieters et al\textsuperscript{86}: $<0.40 = \text{poor}, 0.40-0.70 = \text{fair}, 0.70-0.90 = \text{good}, >0.90 = \text{excellent}$. We provided the 95% CI around both parameter estimates.

### 4.6.2 Cross-Sectional Construct Validity

We hypothesized the magnitude of the association between the SEBT measurements, patient characteristics and other measures of function and pain at T2 using Cohen's interpretations for 'r' (Table 1). If the participant did not complete T2 we substituted their measurements from T1. We also indicated the expected direction of the association as either positive or negative. We decided to classify the tool as having excellent cross-sectional construct validity if greater than 75% of the hypotheses were supported by our data (i.e. within one classification of magnitude and identical in direction)\textsuperscript{87}. We used Spearman's rho for dichotomous outcomes and Pearson's r for continuous outcomes.

### Table 1: Hypotheses about the magnitude and direction of the association between the SEBT and other outcome measures to evaluate cross-sectional construct validity

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*Pearson' r magnitude values: L=large = \(>0.5\), \(M=\)medium = \(0.3-0.5\), \(S=\)small = \(0.1-0.3\), \(T=\)trivial=\(<0.1\)
4.6.3 Longitudinal Construct Validity

We hypothesized the magnitude of the association between the change in SEBT, change in patient characteristics like fear avoidance and the change in function and pain outcomes using Cohen's interpretations for 'r' (Table 2). We also indicated the expected direction of the association as either positive or negative. We collected data at T1 and T3. We used Pearson's r to estimate the magnitude of the association between the change in outcome score and the change in SEBT score. We decided to classify the tool as having longitudinal construct validity if greater than 75% of the hypotheses were supported by our data (i.e. within one classification of magnitude and identical in direction)\textsuperscript{87}. We also evaluated longitudinal construct validity by grouping the mean SEBT change score for participants who rated themselves as 0 (no change), 2/3 (minimal change), 4/5 (moderate change) or 6/7 (large change) on the GRC where we expected to observe an incremental increase in the magnitude of the change score in SEBT as participants indicated greater improvement.

Table 2: Hypotheses about the magnitude and direction of the association between the SEBT and other outcome measures to assess longitudinal construct validity

<table>
<thead>
<tr>
<th>Change in... (T3-T1)</th>
<th>ANT</th>
<th>AM</th>
<th>MED</th>
<th>PM</th>
<th>POS</th>
<th>PL</th>
<th>LAT</th>
<th>AL</th>
<th>Injured to Uninjured Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPII</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
</tr>
<tr>
<td>KPS</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
</tr>
<tr>
<td>LEFS</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
<td>L+</td>
</tr>
<tr>
<td>MARX</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
</tr>
<tr>
<td>PCS</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
</tr>
<tr>
<td>P4</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
</tr>
<tr>
<td>P4 Post-SEBT</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
<td>L-</td>
</tr>
<tr>
<td>GSE</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
<td>S+</td>
</tr>
<tr>
<td>SF-12 Mental</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
</tr>
<tr>
<td>SF-12 Physical</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
<td>M+</td>
</tr>
<tr>
<td>FABQ-PA</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
</tr>
<tr>
<td>FABQ-W</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
<td>T</td>
</tr>
</tbody>
</table>

*Pearson' r magnitude values: L=large = >0.5, M=medium = 0.3-0.5, S=small = 0.1-0.3, T=trivial = <0.1*
4.7 Sensitivity to Change

We analyzed sensitivity to change by calculating the change in mean SEBT scores from T1 to T3. We then calculated the standardized response mean (SRM) by taking the average difference between the two means, and dividing those by the standard deviation of the change. We used an SEM equation to calculate the minimal detectable change (MDC) at 95% confidence.

4.7.1 Responsiveness

We used an anchor-based approach to analyze responsiveness. We took participants who indicated a two (a little better or a little worse, but large enough to be important) on the GRC and considered them as experiencing a minimally clinically important change (MCID). We repeated this analysis for changes from T1 to T4 and for changes from T3 to T4 as the MCID may change over time and across interventions.
Chapter 5

5 Results

5.1 Participant Demographics

Fifteen participants were enrolled in the study at the time of analysis and twelve participants had completed both the registration and two-week visit. Four participants had completed the three month visit. Baseline demographic characteristics are displayed below (Table 3).

Table 3: Baseline demographics for participants completing the SEBT

<table>
<thead>
<tr>
<th>Demographic Characteristic</th>
<th>Participants (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Mean Age (yrs) ± SD</td>
<td>21.1 ± 5.3</td>
</tr>
<tr>
<td>Mean Height (cm) ± SD</td>
<td>176.1 ± 10.0</td>
</tr>
<tr>
<td>Mean Weight (kg) ± SD</td>
<td>78.91 ± 15.0</td>
</tr>
<tr>
<td>Mean BMI (kg/m$^2$) ± SD</td>
<td>25.4 ± 4.1</td>
</tr>
<tr>
<td>Dominant Limb, Right (%)</td>
<td>12 (80)</td>
</tr>
<tr>
<td>Injured Limb, n (%)</td>
<td></td>
</tr>
<tr>
<td>Dominant</td>
<td>8 (53.3%)</td>
</tr>
<tr>
<td>Non-dominant</td>
<td>7 (46.7%)</td>
</tr>
<tr>
<td>Mechanism of First Dislocation, n (%)</td>
<td></td>
</tr>
<tr>
<td>Contact</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Non-Contact</td>
<td>9 (60)</td>
</tr>
<tr>
<td>Mean # of dislocations ± SD</td>
<td>8 ± 8.4</td>
</tr>
<tr>
<td>Frequency of giving away episodes, n (%)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>Weekly</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Monthly</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Never</td>
<td>1 (6.7)</td>
</tr>
</tbody>
</table>

Abbreviations: SD = standard deviation, BMI = body mass index

5.2 Reliability

5.2.1 Test-Retest Reliability

Three participants were unable to return to the clinic for their two-week appointment because they were unwilling to travel the distance to the clinic. Therefore, the SEBT
scores of 12 participants were used to assess test-retest reliability. The SEBT demonstrated fair (r = 0.40-0.70) or good reliability (r > 0.70) in all directions. The SEM, calculated to assess the error in the original measurement units, ranged from approximately 4% to 7.5% of leg length for all directions (Table 4).

Table 4: Mean scores, ICC(2,1) and SEM values for the eight-direction SEBT over a two week interval for participants with chronic patellar instability

<table>
<thead>
<tr>
<th>SEBT Direction</th>
<th>Mean ± SD</th>
<th>ICC (Lower 95% CI)</th>
<th>SEM (Upper 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANT</td>
<td>77.6 ± 10.2</td>
<td>0.75 (0.20)</td>
<td>4.91 (8.78)</td>
</tr>
<tr>
<td>AM</td>
<td>80.3 ± 9.8</td>
<td>0.82 (0.38)</td>
<td>4.01 (7.44)</td>
</tr>
<tr>
<td>MED</td>
<td>84.0 ± 9.7</td>
<td>0.77 (0.25)</td>
<td>4.71 (8.50)</td>
</tr>
<tr>
<td>PM</td>
<td>88.0 ± 11.8</td>
<td>0.73 (0.15)</td>
<td>5.89 (10.45)</td>
</tr>
<tr>
<td>POS</td>
<td>86.5 ± 14.0</td>
<td>0.80 (0.33)</td>
<td>6.20 (11.34)</td>
</tr>
<tr>
<td>PL</td>
<td>76.1 ± 12.8</td>
<td>0.74 (0.17)</td>
<td>6.38 (11.40)</td>
</tr>
<tr>
<td>LAT</td>
<td>62.9 ± 13.7</td>
<td>0.66 (0.01)</td>
<td>7.40 (12.63)</td>
</tr>
<tr>
<td>AL</td>
<td>69.7 ± 9.11</td>
<td>0.66 (0.01)</td>
<td>5.39 (9.19)</td>
</tr>
</tbody>
</table>

Abbreviations: SD= standard deviation, CI = confidence interval, SEM = standard error of the measurement.

5.3 Validity

5.3.1 Cross-Sectional Construct Validity

A total of 15 SEBT scores and questionnaire results were analyzed for this outcome. Agreement between the a priori hypotheses and the experimental correlations between SEBT reach distance and the outcome measures are presented below (Table 5).

Table 5: Correlations between SEBT scores and other outcome measures to evaluate cross-sectional construct validity and agreement with a priori hypotheses.
5.3.2 Longitudinal Construct Validity

Four participants completed the three month visit and the associated questionnaires at the time of data analysis. Correlation between SEBT change scores and patient-reported outcome change scores are illustrated below, along with agreement between the correlations and a priori hypotheses (Table 6).

Table 6: Association between SEBT change scores and other outcome measures change scores from T3 to T1 and agreement with a priori hypotheses

<table>
<thead>
<tr>
<th>Change in... (T3-T1)</th>
<th>A</th>
<th>AM</th>
<th>M</th>
<th>PM</th>
<th>P</th>
<th>PL</th>
<th>L</th>
<th>AL</th>
<th>Injured to Uninjured Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPII</td>
<td>0.80*</td>
<td>0.80*</td>
<td>0.40↑</td>
<td>0.80*</td>
<td>0.80*</td>
<td>0.80*</td>
<td>1.00*</td>
<td>0.40↑</td>
<td>0.80*</td>
</tr>
<tr>
<td>KPS</td>
<td>0.40↑</td>
<td>0.40↑</td>
<td>0.60*</td>
<td>0.60*</td>
<td>0.60*</td>
<td>0.60*</td>
<td>0.80*</td>
<td>0.80*</td>
<td>0.00↑↑</td>
</tr>
<tr>
<td>LEFS</td>
<td>0.63*</td>
<td>0.63*</td>
<td>0.74*</td>
<td>0.74*</td>
<td>0.74*</td>
<td>0.74*</td>
<td>0.95*</td>
<td>0.21↑</td>
<td>0.63*</td>
</tr>
<tr>
<td>MARX</td>
<td>-0.32↑</td>
<td>-0.32↑</td>
<td>-0.63↑</td>
<td>0.63↑</td>
<td>0.63↑</td>
<td>0.63↑</td>
<td>0.32↑</td>
<td>0.32↑</td>
<td>-0.32↑</td>
</tr>
<tr>
<td>PCS</td>
<td>-0.11↑</td>
<td>-0.11↑</td>
<td>0.21↑</td>
<td>0.63↑</td>
<td>0.63↑</td>
<td>0.63↑</td>
<td>0.11↑</td>
<td>0.95↑</td>
<td>-0.11↑</td>
</tr>
<tr>
<td>P4</td>
<td>0.87↑↑↑↑↑↑</td>
<td>0.10↑↑↑↑↑↑</td>
<td>0.20↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.30↑↑↑↑↑↑</td>
<td>0.10↑↑↑↑↑↑</td>
</tr>
<tr>
<td>P4 Post-Activity</td>
<td>-0.20↑↑↑↑</td>
<td>-0.21↑↑↑↑</td>
<td>-0.05↑↑↑↑↑↑</td>
<td>0.15↑↑↑↑↑↑</td>
<td>0.15↑↑↑↑↑↑</td>
<td>0.15↑↑↑↑↑↑</td>
<td>-0.10↑↑↑↑↑↑</td>
<td>0.31↑↑↑↑↑↑</td>
<td>-0.21↑↑↑↑↑↑</td>
</tr>
<tr>
<td>GSE</td>
<td>-0.40↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.80↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.80↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
</tr>
<tr>
<td>SF-12 Mental</td>
<td>0.80↑↑</td>
<td>0.80↑↑↑↑↑↑</td>
<td>0.66↑↑↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>0.40*</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>0.80↑↑↑↑↑↑</td>
</tr>
<tr>
<td>SF-12 Physical</td>
<td>0.40*</td>
<td>0.40*</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>0.60↑↑↑↑↑↑</td>
<td>0.60↑↑↑↑↑↑</td>
<td>0.60↑↑↑↑↑↑</td>
<td>0.80↑↑↑↑↑↑</td>
<td>0.00↑↑↑↑↑↑</td>
<td>0.40*</td>
</tr>
<tr>
<td>FABQ-PA</td>
<td>0.80↑↑↑↑↑↑</td>
<td>0.80↑↑↑↑↑↑</td>
<td>0.60↑↑↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>0.80↑↑↑↑↑↑</td>
</tr>
<tr>
<td>FABQ-W</td>
<td>-0.40↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.80↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
<td>-0.20↑↑↑↑↑↑</td>
<td>-0.80↑↑↑↑↑↑</td>
<td>-0.40↑↑↑↑↑↑</td>
</tr>
</tbody>
</table>

* Pearson’s r magnitude values: large = >0.5, medium = 0.3-0.5, small = 0.1-0.3, trivial = <0.1  
  * = correlation agreed with the hypothesis  
  ↑ = correlation was one category higher than expected from the hypothesis  
  ↓ = correlation was one category lower than expected from the hypothesis
5.4 Sensitivity to Change

The SRM of the SEBT from T3 to T1 ranged from 0.22 to 0.81 for all directions. The SRM in the ANT, AM, POS, and AL directions demonstrates a small effect size (0.2-0.5) while the MED, PM, PL and LAT effect sizes are moderate (0.5-0.8) according to Cohen. We consider the ANT, PL, LAT and AL directions to be the most relevant directions for change for patients with patellar instability. The SRM's for these directions were 0.35, 0.80, 0.54 and 0.36 respectively. The MDC\textsubscript{95} of the SEBT ranged from approximately 11\% to 20.5\% of leg length in each direction (Table 7). The MDC\textsubscript{95} for the ANT, PL, LAT and AL directions are 13.6\%, 17.7\%, 20.5\% and 14.9\% respectively.

Table 7: Standardized response mean and minimal detectable change for each direction of the SEBT

<table>
<thead>
<tr>
<th></th>
<th>*ANT</th>
<th>AM</th>
<th>MED</th>
<th>PM</th>
<th>POS</th>
<th>*PL</th>
<th>*LAT</th>
<th>*AL</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRM\textsubscript{T3-T1}</td>
<td>0.35</td>
<td>0.22</td>
<td>0.75</td>
<td>0.71</td>
<td>0.48</td>
<td>0.80</td>
<td>0.54</td>
<td>0.36</td>
</tr>
<tr>
<td>MDC\textsubscript{95} (%)</td>
<td>13.6</td>
<td>11.1</td>
<td>13.1</td>
<td>16.3</td>
<td>17.2</td>
<td>17.7</td>
<td>20.5</td>
<td>14.9</td>
</tr>
</tbody>
</table>

\textit{SRM} = Standardized response mean between T3 and T1
\textit{MDC} = minimal detectable change at a 95\% confidence interval
* indicates directions we consider most relevant to change

5.5 Responsiveness

Four participants completed the three month visit and indicated their level of change on a GRC scale. Three participants did not change or considered their change to be insignificant, and their SEBT change scores varied from 3.7 to 22.3\%. We consider the ANT, PL, LAT and AL directions to the most relevant to responsiveness and participant scores changed by 3.7\%, 16.3\%, 22.3\% and 12.0\% in these directions. One participant felt they improved by a moderate or good amount that was enough to be considered improvement (4 or 5), and their SEBT scores changed by 0 to 8\%, including 0\%, 8\%, 5\% and 3\% in the ANT, PL, LAT and AL directions. One participant indicated they were a great or very great deal better (6-7), and their SEBT scores changed by 5 to 20\% in each direction, including 12\%, 15\%, 20\% and 5\% in the ANT, PL, LAT and AL directions. No patients indicated they were a little or somewhat better, but enough to be important (2-3) and as a result we were unable to calculate a MCID at this time (Table 8).
Table 8: Mean change scores in SEBT reach distance grouped according to patient-indicated level of change

<table>
<thead>
<tr>
<th></th>
<th>Global Rating of Change Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-1</td>
</tr>
<tr>
<td>SEBT</td>
<td></td>
</tr>
<tr>
<td>*ANT</td>
<td>3.7%</td>
</tr>
<tr>
<td>AM</td>
<td>3.7%</td>
</tr>
<tr>
<td>MED</td>
<td>13.0%</td>
</tr>
<tr>
<td>PM</td>
<td>14.0%</td>
</tr>
<tr>
<td>POS</td>
<td>13.3%</td>
</tr>
<tr>
<td>*PL</td>
<td>16.3%</td>
</tr>
<tr>
<td>*LAT</td>
<td>22.3%</td>
</tr>
<tr>
<td>*AL</td>
<td>12.0%</td>
</tr>
</tbody>
</table>

*Indicates directions we consider most relevant to change
Chapter 6

6 Discussion

Reliability of the SEBT has been thoroughly reported in healthy participants, however because it is a functional test, the parameters of the test must be explored within each disease population in order for clinicians to gain meaningful information about the disease and improvement or worsening of the condition. Currently, most reliability and validity studies for the SEBT are interpreted from healthy participants or injured participants with CAI. This study evaluates measurement properties regarding reliability and validity for patients with chronic patellar instability and reports population-specific reliability, error, and change scores.

We found the test-retest reliability of the SEBT was fair to good for all directions, with ICC's ranging from 0.66 to 0.83, however these values are lower than we expected and lower than the ICC's of 0.84-0.92 that have been found in previous research using four practice trials in healthy participants\(^6^0\). It is not surprising that reliability of the SEBT is lower for injured participants, as the SEBT is a near-maximal reach balance test where participants are encouraged to reach as far as possible along each line without losing their balance. Injured participants may be hesitant to approach their maximum reach distance because of their injury, fear avoidance, or onset of symptoms. ICC's for participants with chronic patellar instability were lowest in the LAT and AL direction (0.66), both of which require the participant to flex the knee and reach the contralateral limb around and behind the stance limb, a combination of movements that has components of the injury mechanism and produces discomfort and apprehension. Secondly, the majority of patients reached a greater distance during the second session, which may be an effect of learning and/or confidence\(^6^8\), which may be amplified in a participant who has additional apprehension from being injured. Thirdly, our test-retest interval was two weeks due to our participant population and the nature of our clinic. This is larger than those found in previous studies which examined intra-rater reliability\(^6^8\) and between-test reliability measured three times each one week apart\(^6^0\). Any number of these factors may contribute to a lower reliability in this study.
The SEM provides a standard deviation of the measurement error that reflects the reliability of the response.\textsuperscript{86} For test-retest reliability, these values represent the range that the true score can be expected to be found within when re-testing participants on the SEBT. Clinicians use this value to determine how confident they can be that the participant's achieved score resembles a true score. Our SEM values ranged from 4.01 to 7.40\% for all directions, with upper 95\% CIs for each direction ranging from 7.86 to 14.50\%. The error measurements for our study are high compared to studies of healthy individuals, where the SEM ranged from 3.19 to 4.96\%.\textsuperscript{59} SEM is directly related to the standard deviation and reliability. This may explain why our error is larger than previous studies. Our values tell the clinician that for a participant with a leg length of 90cm, reach distance has an error as high as ± 3.6-6.7 cm, and that they can expect, with 95\% confidence, that upon re-testing, the participant's score will fall somewhere within this interval of ± 7.1-13.1cm.

The agreement between our hypotheses for cross-sectional construct validity for the SEBT and patient-reported outcome measures was good, as 93 of 126 correlations (74\%) are within one category of our \textit{a priori} hypotheses. The most important outcomes for patients and their clinicians involve relevant functional questions such as items found within patella and lower extremity-specific outcomes like the BPII, KPS and LEFS, which makes them suitable tools against which to measure the convergent validity of the SEBT. If the SEBT is measuring what we intend it to measure, participants who score higher on the SEBT should also score highly on outcomes regarding disease-specific patient-reported function at the same time point; 22 of our 27 hypotheses (82\%) are within one category of what we predicted, demonstrating medium or large correlations with SEBT reach distance. Pain scores (P4, P4 post-activity, PCS) also demonstrate strong agreement with our hypotheses, scoring within one category in 25 of 27 (93\%) directions.

Outcomes measuring general health and activity (SF-12 PCS, MARX) had excellent agreement with our hypotheses (17 of 18 predictions, 94\%), while aspects of mental health (GSE, SF-12 MCS, FABQPA, FABQW) only matched our correlations in 9 of 36 (25\%) directions. Demographic characteristics (age and sex) showed little to no
agreement with our hypotheses, only agreeing in 7 of 18 directions. Normalizing SEBT reach distances by height or leg length has previously been shown to eliminate differences between sexes\textsuperscript{57} and we based our hypotheses regarding sex on these trends; however in our sample males were generally older and experienced less frequent giving away episodes than females. This increased impairment in younger, female participants may be reflected in reach distance, and could explain why older participants and male participants achieved longer reach distances compared to our younger, female participants.

Our results for longitudinal construct validity are severely underpowered, which may help to explain our results. We made 108 hypotheses for longitudinal construct validity and found agreement with 46 (43\%). Patella and lower extremity-specific questionnaires (BPII, KPS, LEFS) show the strongest agreement, with 23 of 27 (85\%) within one category of our predicted result. Those three outcomes ask detailed questions about lower extremity function and are expected to correlate highly if the SEBT is able to measure relevant change undergone by participants with patellar instability. In longitudinal studies of participants with CAI, SEBT change disease-specific outcome scores, like the Cumberland Ankle Instability Tool (CAIT)\textsuperscript{89} and foot/ankle disability index (FADI)\textsuperscript{26, 27} increased significantly alongside increases in SEBT scores.

Pain scores (PCS, P4, P4-post) agree poorly for longitudinal change, with just 7 of 27 (26\%) being within one category of our a priori hypotheses. Changes in the SF-12 PCS, a general health questionnaire, agree with 7 of 9 hypotheses while changes in the MARX, an activity questionnaire, meet our hypotheses in 0 of 9 directions. Mental change scores (GSE, SF-12 MCS, FABQPA and FABQW) also demonstrate poor agreement with our predictions agreeing in 9 of 36 directions (25\%).

The SRM is an effect size representing mean change scores between T3 and T1 in each direction relative to the standard deviation of those change scores\textsuperscript{86}. Clinicians interpret scores greater than one as important change, yet the change scores for this study never exceeded that value; our SRM values are small (0.2-0.5) to moderate (0.5-0.8) in all directions. The MDC is presented in the original units and is the amount a participant's
scores must change for a clinician to be 95% confident that the change is real and not due to random chance\textsuperscript{86}. The MDC's for the SEBT range from 11.1-20.5\% in all directions for our study. Previous test-retest reliability studies of healthy participants have produced smallest detectable distance (SDD) values ranging from 6.13-8.15. A 20.5\% (approximately 18.5cm for an individual with a leg length of 90cm) increase or decrease represents a massive value needed for an individual to declare themselves changed, especially compared to the 8.15\% (7.3cm) reported for healthy individuals. The MDC is directly related to the SEM and as a result, the MDC is larger in directions with wider error values. Increasing sample size and reliability would provide us with greater confidence as to the reliability of the SEBT for participants with chronic patellar instability.

6.1 Limitations

The most obvious limitation of this study was the small sample size. At the time this thesis was written, only twelve participants, one-third of our \textit{a priori} sample size, had reached the two week time point; however, recruitment will continue in the future until the study is adequately powered.

Secondly, we were limited by the nature of our clinic. Our study was designed to recruit a cohort of patients that have already suffered an injury and been referred to our clinic. We are unable to statistically control for variability between participants prior to their first patellar dislocation. Our study also did not assess any participant biomechanics or movement patterns while performing the SEBT preventing us from determining why participants may be limited overall or in certain directions.

Lastly, we may have been limited by the number of outcomes we used and the threshold method we applied to assess validity of the SEBT. Including outcomes that have demonstrated validity and reliability in populations with chronic patellar instability is crucial to assessing the validity of our test; predicting how these constructs will correlate with SEBT performance is rather straight-forward as all the domains they assess are related to and important to function in those affected by patellar instability. It is much more difficult to assess and predict how outcomes that explore constructs not directly
related to the symptoms and limitations of the disease will correlate with performance on a balance test. Outcomes included assessing mental aspects of health may have made our constructs more robust, yet they showed much lower agreement with our hypotheses than the questionnaires assessing physical health and function because predicting how they would correlate was much more difficult.
Chapter 7

7 Conclusion

We found the SEBT to have fair to good reliability (0.66-0.82) in each direction for participants with chronic patellar instability. The SEBT currently shows good cross-sectional construct validity agreeing with 93 of our 126 hypotheses (74%), though it does fall below our original threshold of 75%. We are unable to make conclusions about longitudinal construct validity in this population until we recruit a larger sample size.

7.1 Future Direction

For this study, recruitment will continue until we reach the original sample size of 36 participants. The larger sample size will provide more accurate estimates of reliability, validity, responsiveness and sensitivity to change for participants with chronic patellar instability.

Future research should attempt to provide more information about the SEBT for participants with patellar instability and should expand on the promising relationship between SEBT scores and patient-reported lower-extremity outcome measures. A study following participants after an acute patellar dislocation may help identify sub-groups that respond well to conservative treatment versus those that will eventually require surgery to manage instability (discriminative properties). An appropriately powered study could also create sub-groups for anatomical risk factors (patella alta, trochlear dysplasia, increased TT-TG ratio, etc.) and determine whether a relationship exists between the presence or absence of these conditions and reach distance.

Future studies should also compare pre- and post-op SEBT scores for participants who undergo surgery for patellar instability. Changes in reach distance, SEBT shape/area, and related outcome measures may help clinicians' evaluate whether the procedure restores more normal mechanics and function. Sub-groups could be established based on the procedures performed to determine if addressing certain anatomical risk factors was related to change in reach scores later on. Future studies could also consider adding a
biomechanics component and a matched, healthy control group. Comparing reach distances and movement patterns for patients with patellar instability to healthy controls could help clinicians quantify and describe any deficits or limitations experienced by the population being treated.

Future research should also attempt to evaluate the measurement properties of the SEBT in other injured populations. The medium to high correlations between SEBT scores and patient-reported outcomes such as the LEFS and the P4 may already have value to clinicians. The LEFS and P4 are not patella-specific; patients are asked to evaluate general lower extremity limitations and pain, and clinicians may find this relationship exists in other injured populations they treat. Bundling the SEBT and these patient-reported measures may assist clinicians in delivering evidence-based clinical decision making, however these relationships will first need to be studied in the populations being treated.
References


26. Hale SA, Hertel J and Olmsted-Kramer LC. The effect of a 4-week comprehensive rehabilitation program on postural control and lower extremity function in


Appendices
Appendix A: Western Research Ethics Approval

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

Principal Investigator: Dr. Alan Gettuso
Department & Institution: Schulich School of Medicine and Dentistry/Surgery, Western University

Review Type: Delegated
HSREB File Number: 106806
Study Title: Reliability and validity parameters of the star excursion for patients with chronic patellar instability
Sponsor:

HSREB Initial Approval Date: August 19, 2015
HSREB Expiry Date: August 19, 2016

Documents Approved and/or Received for Information:

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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 GCP), 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.

Western University, Research, Support Services Bldg., Rm. 5350
London, ON, Canada N6A 1W9 1.519.855.3038 1.519.850.2466 www.uwo.ca/research/ethics
Appendix B: Letter of Information and Consent

LETTER OF INFORMATION

Title of Research:
Reliability and Validity Parameters of the Star Excursion Balance Test for Patients with Chronic Patellar Instability

Lead Researchers:
Dr. Alan Getgood - Principal Investigator
Fowler Kennedy Sport Medicine Clinic, Western University

Greg Alcock, MSc(PT), BA Hons(PE), FCAMPT
Fowler Kennedy Sport Medicine Clinic

Dr. Jim Dickey, PhD
School of Kinesiology, Western University

Information:
You are being invited to participate in a research study because your surgeon has determined that you have chronic patellar instability and you are a candidate for surgery. The purpose of this letter is to provide you with information required for you to make an informed decision regarding participation in this research.

The purpose of this study is to validate the Star Excursion Balance Test (SEBT) in a population with chronic patellar instability. The SEBT is a standing, single-leg, maximal-reach test performed in 8 directions along designated lines. The lines extend from a centre point and are spaced 45° apart creating a star-like shape. The SEBT has primarily been used with ankle sprains and chronic ankle instability, and studies have shown it is a useful tool for tracking return to sport and predicting injuries. Studies in patients with knee injuries have shown promising results and more studies are needed to determine the effectiveness of the SEBT in populations with these various injuries. Experts have suggested using the SEBT in non-operative management and post-surgical rehabilitation of chronic patellar instability to help clinicians determine when it is safe for patients to return to activity. This study is designed to follow patients being treated for chronic patellar instability to estimate the validity and reliability of the SEBT in this population. We will recruit 150 patients from the Fowler Kennedy Sport Medicine Clinic to participate in this study.
Eligibility:
To participate in this study you must be between the ages of 15 and 50. You must be diagnosed with chronic patellar instability and selected as a candidate for surgery by your surgeon. You cannot have had previous surgeries on the lower extremity. You cannot have been diagnosed with vestibular disorder, cerebral concussion or a lower extremity injury other than patellar instability within the last three months. If you are currently participating in another research study, you must inform your surgeon and the research assistant.

Explanation of the Study Procedures:
Non-operative treatment and surgical treatment have the same goal; to prevent dislocation events by increasing the stability of the knee cap. Patients are prescribed bracing and physiotherapy to strengthen structures around the knee prior to surgery and this study will not change the pre-operative or operative care prescribed to you by the surgeon. The SEBT and questionnaires in this study are not standard of care, and are for the purpose of this research project. The SEBT is a clinical test similar to the exercises you will do during rehabilitation; we are asking you to complete the SEBT and related questionnaires at various time points throughout your recovery to help us develop it as a functional tool for assessing the rehabilitation of patients with chronic patellar instability.

Description of the Study:
The total time commitment of the study is three years. There are 5 visits total and each visit will take approximately 50 minutes of your time. After the initial visit you will be asked to visit the clinic for appointments 2 weeks and 3 months later for the purpose of the research study. You will then have surgery, after which you will be asked to book appointments at 6 months and 2 years post-surgery; these visits coincide with standard of care follow-up visits with your surgeon.

At each visit you will be asked to complete 10 questionnaires, perform four trials of the SEBT for each leg, then complete a short pain scale. Completing the questionnaires will take approximately 25-30 minutes of your time. The questionnaires ask questions about your ability to function, participate in sports, your quality of life, your general health, how you cope with pain, coping strategies and whether your symptoms have changed. Performing one complete SEBT trial involves measuring your reach distance in eight different directions for each leg. Completing all four trials of the SEBT will take you approximately 20-25 minutes. At 12 and 18 months you will also be asked to report the amount of time you were at risk of re-injury (i.e. participation in sports) and any adverse events you have experienced since the surgery; you will be able to report these using online questionnaires and will not have to visit the clinic at these time points for the study.

Alternatives to Participation:
If you do not choose to participate in this study, you will receive the same physical therapy, bracing and operative treatments but you will not complete questionnaires or the SEBT.

Risks:
You could fall, injure or re-injure yourself while performing tests, however, the risks are no greater than those encountered with typical rehabilitation protocols. There are no other known health risks associated with this study.

Benefits:
There are no direct benefits to you for participating in this study; however your participation will...
help inform surgeons and physiotherapists as to when patients with chronic patellar instability are ready to return to activity.

**Cost/Compensation:**
You will not be compensated for your participation in this study.

**Voluntary Participation:**
Your participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care or academic status. Should you choose to withdraw from this study, we will keep all data obtained up to the point that you chose to withdraw.

Participation in this study does not prevent you from participating in any other research studies at the present time or future. If you are participating in another research study, we ask that you please inform us of your participation. You do not waive any legal rights by signing the consent form.

**Confidentiality:**
All information will be kept confidential to the best of our ability. The companies that take care of the research databases are EmPower Health Research (www.empowerhealthresearch.ca) and Ortech (www.ortechsystems.com). Your identifying information (name, phone number, email address, date of birth) is being collected as part of your participation in this study. Your data is protected by a username and password. It travels in a scrambled format to servers (storage computer) that are located in Montreal, Quebec, Canada (EmPower) and London, Ontario Canada (Ortech). The companies that house the servers for EmPower (Netelligent) and Ortech (Start Communications) are professional companies with extremely high standards of physical and virtual security. We want to let you know however, that even with this high level of security, there is always a remote chance that your information could be accessed or “hacked” by someone who is not supposed to have your information. The chance that this information will be accidentally released is small. In any publication, presentation or report, your name will not be used and any information that discloses your identity will not be released or published.

Study data will be kept for five years. Representatives of The University of Western Ontario Health Sciences Research Ethics Board and representatives of the Lawson Quality Assurance Education Program may contact you or require access to your study-related records to monitor the conduct of the research.

**Questions:**
If you have questions about the conduct of the study or your rights as a research participant, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute [519] 667-6649. If you have questions or concerns about your surgery or physiotherapy, please contact your orthopaedic surgeon or physiotherapist. If you have any questions about this research, please contact Andrew Firth at [519] 661-2111 ext. 87505 or afirth5@uwo.ca or your orthopaedic surgeon.
This letter is yours to keep.

Sincerely,

Dr. Alan Getgood, MD
Dr. Dianne Bryant, PhD
Greg Alcock, FCAMPT
Dr. Jim Dickey, PhD
Andrew Firth, MSc (can.)
Codie Primeau, MSc (can.)
CONSENT FORM

Title of Research:

I have read the letter of information, have had the nature of the study explained to me, and I agree to participate in the study. All questions have been answered to my satisfaction. I will receive a copy of the Letter of Information and this signed consent form.

___________________________      ___________________________     ___________________
Printed Name of the Participant                   Signature of the Participant                                 Date

___________________________      ___________________________     ___________________
Printed Name of the Parent or Legally Authorized Representative (if required) Signature of the Parent or Legally Authorized Representative (if required) Date

___________________________      ___________________________     ___________________
Printed Name of the Person Responsible for Obtaining Informed Consent Signature of the Person Responsible for Obtaining Informed Consent Date
Appendix C: Image Permissions

Figure 2: Extensor Mechanism Anatomy from Flandry and Hommel., Normal Anatomy and Biomechanics of the Knee, Sports Med Arthrosc, 2011. 19(2); p82-92.

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TERMS AND CONDITIONS

Jul 26, 2016
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Author of this Wolters Kluwer article
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Validity and Reliability of the Star Excursion Balance Test for Chronic Patellar Instability
Expected completion date Aug 2016
Estimated size(pages) 60
Requestor Location Andrew D Firth
## Curriculum Vitae

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FHS Research Day, Western University, 2016

Oral Presentation: Reliability and Validity Parameters of the Star Excursion Balance Test for Patients with Chronic Patellar Instability
Bodies of Knowledge Conference, University of Toronto, 2015

Oral Presentation: Reliability and Validity Parameters of the Star Excursion Balance Test for Patients with Chronic Patellar Instability
FHS Research Day, Western University, 2015