Reliability, Validity, and Responsiveness of Performance-Based Activity Level Outcome Measures in Patients after Meniscectomy: A Pilot Study

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Abstract
Background: When choosing an outcome measure to evaluate the effect of rehabilitation after an arthroscopic partial meniscectomy, the psychometric properties of that outcome measure and the mechanism of injury should both be considered. However, the psychometric properties of many established performance-based measures have not been studied in this population. The purpose of this study is to establish the reliability, validity, and responsiveness of the Single-Limb Single Hop for Distance (SLHT), Single-Limb Crossover Hop for Distance (CHT), Illinois Agility Test (IAT), Edgren Side Step Test (ESST), and the Stair Measure Test (SMT) in patients who have undergone a meniscectomy.

Study Design: Original Research

Methods: Twenty-six subjects were recruited from an outpatient Physical Therapy (PT) clinic post-arthroscopic partial meniscectomy, 22 of which were able to complete all assessments. Participants completed 8 weeks of PT with assessments within 1 week of surgery and then at 4 and 8 weeks post-surgery. Assessments included evaluations of impairments, activity limitations, and participation restrictions through both self-report measures (International Knee Documentation Committee Form (IKDC) and Tegner Activity Scale (Tegner)) and five performance-based measures (SLHT, CHT, IAT, ESST, SMT). For statistical purposes, patients were divided into two groups: those with degenerative tears and those with non-degenerative tears. Statistical analyses included a calculation of ICC for reliability, Pearson’s correlation coefficient and Spearman’s rank correlation for validity, and effect size, standard error of measurement, and minimal detectable change for responsiveness of the five performance-based outcome measures.

Results: Test-retest reliability was excellent for all performance-based measures and ranged from 0.91 for the ESST to 0.98 for the SMT. A significant negative correlation was found between the IAT (r = -0.46, p = 0.03) and SMT (r = -0.50, p = 0.01) and the IKDC subjective knee evaluation form at 8 weeks post-meniscectomy. The IAT (r = -0.49, p = 0.02) and SMT (r = -0.52, p = 0.009) also moderately negatively correlated with the Tegner while the CHT (r = 0.44, p = 0.03) positively correlated with the Tegner at 8 weeks post-meniscectomy. Small effect sizes were calculated for the SLHT (0.27), the CHT (0.33), and the ESST (0.28), and a moderate effect size was calculated for the IAT (0.59) and SMT (0.51). In the group with non-degenerative tears, performance-based measures were more strongly correlated with the IKDC than in the group with degenerative tears.

Conclusions: All five performance-based outcome measures were reliable and responsive for patient’s post-meniscectomy, but only two were considered valid when compared to both self-report measures.

Level of Evidence: Level 3

Clinical Relevance: All five performance-based tests can be used by PTs to assess changes in patients who have undergone a meniscectomy. The ESST, IAT, and SMT are recommended because they can be used for all patients post-meniscectomy.

Keywords: Edgren side step test; Illinois agility test; single-limb single hop test; single-limb crossover hop test; Stair measure test

Introduction
The menisci serve as shock absorbers and secondary stabilizers, and provide proprioception, joint lubrication, and nutritional support to the articular cartilage, thereby contributing to both load transmission and stability of the knee [1]. Maintenance of these functions is crucial to the overall health and function of the knee joint. Meniscal injury is the second most common injury to the knee, with an incidence of 12% to 14% and a prevalence of 61 cases per 100,000 persons in the United States [2]. The most common procedure following a tear to the meniscus is an arthroscopic partial meniscectomy, approximately 850,000 are performed annually in the United States [2]. Removal of part of the meniscus can cause increased stress on the joint surfaces, altering the biomechanics of the knee, and increasing the risk for impairments, activity limitations, and participation restrictions for the patient [3]. Rehabilitation is the standard of care after a meniscectomy and the main goals of PT are to control the impairments associated with the surgery and to restore function by treating the necessary activity limitations and participation restrictions.

Returning individuals to their premorbid levels of function can be challenging and there is limited evidence from high-quality randomized controlled trials and systematic reviews to support the benefits of PT interventions in these patients [4]. This may, in part, be due to the lack of appropriately chosen outcome measures. Outcome measures capture important information about impairments, activity limitations, and participation restrictions of patients. Physical therapists use this information to evaluate patients, guide treatment, assess change, and determine readiness for discharge. To ensure this evaluation is accurate the outcome measure selected must be appropriate for the population and construct being investigated.

The Clinical Practice Guidelines (CPGs) for meniscal lesions recommend that clinicians use easily reproducible PT performance measures to assess activity limitations and participation restrictions associated with patients’ knee pain and mobility impairments and to assess changes in level of function [4]. Performance-Based Outcome Measures (PBMs) are frequently used in the clinical setting, but are less frequently reported in the literature. PBMs allow clinicians an opportunity to observe movements, thereby providing objective information that self-report outcome measures alone may not be able to capture. This provides PTs with additional information on the...
impairments leading to activity limitations and participation restrictions that can help guide their plan of care [4].

The CPGs recommend the following performance measures: the single-limb hop test, 6-minute walk test, timed up-and-go test, and stair measure test for the assessment of individuals with meniscal lesions, however, these performance measures have only been validated in patients with anterior cruciate ligament tears and those who have undergone total joint arthroplasties [4], not in patients who have meniscus tears or who have recently undergone a meniscectomy [5-7].

The purpose of this study was to examine the psychometric properties of five PBMs for patients after arthroscopic partial meniscectomy. Three of the PBMs were recommended by CPGs, the SLHT, the CHT, and the SMT [5-7]. The remaining two examined in this study, the ESST and the IAT, were not addressed by CPGs but were included because they are reliable measures of multi-directional movements related to the lower limbs and are safe and feasible for patients in the various stages of meniscectomy recovery [8].

This study provides information on the reliability, validity and responsiveness of five PBMs for patients after arthroscopic partial meniscectomy. Additionally, it suggests that difference outcome measures should be used based on two subpopulations of patients with meniscus tears, patients with degenerative tears and patients with non-degenerative tears.

Methods

Sample and recruitment

A convenience sample of 26 patients was recruited from the University of Miami Hospital’s sports medicine clinic. Male and female patients who underwent a partial meniscectomy and were between the ages of 18 and 60 years were included in this study. Professional athletes, patients with bilateral injuries, and patients with neurological or musculoskeletal pathologies that limited the immobility were excluded from this study. The principal investigator recruited participants during their initial PT visit, which was scheduled within 1 week of arthroscopic partial meniscectomy. The purpose and the design of the study were explained to potential participants and those who agreed to participate signed an informed consent form.

Subjects were categorized into two groups based on review of the arthroscopic images by the sports medicine physician. Eleven individuals were categorized as having a Degenerative Meniscus (DM) tears and were able to complete at PBMs while 10 were categorized with a Non-Degenerative Meniscus (NDM) tears and were able to complete all PBMs. Three patients either had significant difficulty or could not complete the hop tests (SLHT and CHT) and one patient experienced back pain and therefore this score was eliminated from the analyses. Two other patients could not complete the tests because they feared pain in their knees. These patients were included, but received a score of zero for the hop tests (SLHT and CHT).

This study was approved by the University of Miami’s Human Subjects Research Institutional Review Board.

Procedure

Subjects received PT 3x/week for 8 weeks and assessments were performed at initial PT evaluation, at 4 weeks post-meniscectomy, and at 8 weeks post-meniscectomy. The initial assessment included measurements of impairments and the completion of the following self-report measures, the demographic, current health assessment form, and subjective knee evaluation form of the IKDC and the Tegner Activity Scale. The 4 and 8-week assessments included at PT re-assessment, which included impairments, documentation of the same self-report measures and assessment of all five PBMs.

Data collection and scoring

The standardized versions of the SLHT, CHT, and SMT were administered as described in the CPGs and are further outlined in Figure 1. Image to represent the Single-Limb Single Hop Test for Distance (SLHT), Figure 2. Image to represent the single-limb Crossover Hop Test for Distance (CHT), and Figure 3. Image to represent the Stair Measure Test (SMT). The IAT and ESST were also administered based on previous research on injured servicemen. 8 The details are outlined in Figure 3. Image to represent the Edgren Side Step Test (ESST) and Figure 4. Image to represent the Illinois Agility Test (IAT) [19]. Test administration is also described in the above figures and includes the criteria for not successfully completing a trial.

Prior to completing each PBM, subjects completed a 10-minute warm-up on a stationary bike followed by the administration of the five PBMs in the following order: SLHT, CHT, IAT, ESST, and SMT. Three trials of each test were performed with the first trial considered a practice trial.

Subjects were instructed to hop as far as they could while still landing safely. Prior to completing each PBM, subjects completed a 10-minute warm-up on a stationary bike followed by the administration of the five PBMs in the following order: SLHT, CHT, IAT, ESST, and SMT. Three trials of each test were performed with the first trial considered the practice trial.

Figure 1: Image to represent the Single-Limb Single Hop Test for Distance (SLHT).

Figure 2: Image to represent the single-limb crossover hop test for distance (CHT).

Figure 3: Image to represent the Edgren Side Step Test (ESST).

Figure 4: Image to represent the Illinois Agility Test (IAT) [19].
Three trials were performed with a 30 second rest break in between. Experienced pain greater than 6/10 during the course otherwise disqualified if they failed to run the course as instructed or if they time to complete each trial was recorded in seconds. Subjects were forward and back while weaving in and out of 4 cones, and finally the course by moving forward then back to the start line, then forward and back while weaving in and out of 4 cones, and finally by moving straight forward and back again to the finish line. The time to complete each trial was recorded in seconds. Subjects were disqualified if they failed to run the course as instructed or if they experienced pain greater than 6/10 during the course other wise three trials were performed with a 30 second rest break in between.

Data reduction: reliability, validity and responsiveness

Power analyses for correlations with an alpha level of 0.05 and a one-tailed hypothesis revealed that to avoid type I and type II errors, a sample size of 13 and 16 patients, respectively, was required to achieve an r = 0.70.

Week 4 was chosen to analyze test-retest reliability because more score variability was expected at this time point than at week 8, when patients are expected to have returned to their prior levels of function. As the first trial for each test was used as a practice trial, the second and third trials for each individual PBM were used to assess function.

To assess criterion validity, patient scores on the PBMs at week eight were compared to scores on the IKDC subjective knee valuation form and the Tegner. Week 8 was chosen as the most appropriate week to collect representative PBM scores because it allowed for the most healing time after surgery.

Responsiveness to change was assessed using scores for all PBMs at weeks four and eight. Three responsiveness measures were calculated: effect size, Standard Error of Measurement (SEM), and Minimal Detectable Change (MDC). Effect size provides information about whether the PBMs can detect the real change occurring between weeks four and eight. SEM and MDC represent the amount of error attributed to measurement error and the magnitude of change that exceeds random variability, respectively. MDC identifies the magnitude of change required to exceed both measurement error and random error, whereas the SEM identifies the magnitude of change required to exceed measurement error only. For the PBMs to be characterized as responsive to change, the change in scores measured between weeks four and eight must be greater than the SEM or, more conservatively, the MDC.

Statistical analyses

Statistical analyses were conducted using SAS for Windows, version 9.4.
9.2. Test-retest reliability was determined for each measure at week four using the second and third trial for each patient. The ICC was calculated and a value greater than 0.70 was considered acceptable [13].

Construct validity was investigated by calculating the ICCs for each PBM and the IKDC subjective evaluation form and the Tegner using scores from each patient’s week eight assessment. Pearson’s correlation coefficient and Spearman’s rank correlation were used to compare the PBMs to the IKDC subjective evaluation form and the Tegner, respectively. The same analyses were also used to compare the scores of patients with DM and NDM tears.

Responsiveness assesses an instrument’s ability to measure change over the course of treatment. Responsiveness to change was assessed for all PBMs between four and eight weeks. Effect size was calculated as follows: $ES = (\text{mean postoperative score at week 8} - \text{mean postoperative score at week 4})/\text{Standard Deviation (SD) of postoperative score at week 4}$. Small effects were considered to be greater than 0.20, moderate effects were considered to be greater than 0.50, and large effects were considered to be greater than 0.80. The SEM was calculated as follows: $SEM = SD \times \sqrt{1-R}$ where $R$ is the reliability. The MDC was calculated using the following equation: $\text{MDC} = (z\text{-score(95% CI)} \times SEM) / \sqrt{2.14}$.

**Results**

**Table 1:** Demographic information for patients after meniscectomy. Twenty-six patients were included in this study (22 men and 4 women; 39.7±12 [SD] years) with ages ranging from 21 to 60 years old. Power analysis for a sample size of 26 and a correlation coefficient of 0.70 revealed this study had 98% power.

**Reliability**

**Table 2:** Test-retest reliability for the SLHT, CHT, ESST, IAT, and SMT assessed at 4-weeks post-meniscectomy shows the ICCs and 95% confidence intervals for each PBM. Test-retest reliability was found to be excellent for all and ranged from 0.91 for the ESST to 0.98 for the SMT.

Validity For the SLHT, CHT, and ESST, a higher score is indicative of better performance. The IAT and SMT are timed tests and therefore lower scores (in seconds) are indicative of better performance.

**Table 3:** Correlations between SLHT, CHT, ESST, IAT, and SMT and the full scale IKDC and the Tegner assessed at 8-weeks post-meniscectomy shows the Pearson-Spearman correlation coefficient for each performance-based measure. A significant negative correlation was found between the IAT ($r = -0.46, p = 0.03$) and SMT ($r = -0.50, p = 0.01$) and the IKDC subjective knee evaluation form at eight weeks post-meniscectomy. Patients with higher scores on the IKDC subjective knee evaluation form tended to have significantly faster scores on the IAT and SMT.

The IAT ($r = -0.49, p = 0.02$) and SMT ($r = -0.52, p = 0.009$) also moderately negatively correlated with the Tegner. Patients that reported higher activity levels on the Tegner hopped further and were able to complete agility activities and climb the stairs in less time. Additionally, CHT ($r = 0.44, p = 0.03$) positively correlated with the Tegner at 8 weeks post-meniscectomy.

**Table 4:** Correlations between SLHT, CHT, ESST, IAT, and SMT and the self-report measures (Tegner, IKDC: Sport activities and function sub-sections) assessed at 8-weeks post-meniscectomy for subjects with DM and NDM tears. Subjects with DM and NDM show the correlation coefficient ($r$) for each functional performance test compared to the IKDC subjective knee evaluation form subcategories and the Tegner at week eight post-meniscectomy. The IAT ($r = -0.54, p = 0.01$), ESST ($r = 0.49, p = 0.02$), and SMT ($r = -0.61, p = 0.002$) were moderately positively correlated with the sport activities sub-section of the IKDC subjective knee evaluation format week eight post-meniscectomy. The same measures were also moderately correlated with IKDC function subcategory.

Table 4 also compares the R-values for the PBMs compared to the IKDC subjective knee evaluation form subcategories and the Tegner between patients with DM and those with NDM tears. In the group with NDM tears, PBMs were more strongly correlated with IKDC subjective knee evaluation form values than in the group with DM tears. No statistically significant differences were found between patients with NDM tears and those with DM tears when comparing PBMs and the Tegner.

**Responsiveness**

The effect size, SEM, and MDC for all PBM scores between weeks four and eight are shown in Table 5. Responsiveness statistics for the SLHT, CHT, ESST, IAT, and SMT calculated from 4-weeks to 8-weeks post-meniscectomy. Small effect sizes were calculated for the SLHT (0.27), the CHT (0.33), and the ESST (0.28), and a moderate effect size was calculated for the IAT (0.59) and SMT (0.51). The SEMs demonstrate that a change of 0.35 inches (0.89 cm) and 0.99 inches (2.51 cm) were required to exceed measurement error for the SLHT and CHT, respectively. For the IAT and SMT, a change of 0.93 seconds and 0.44 seconds, respectively, were required to exceed measurement error. A change of 1.49 m on the ESST was required to exceed measurement error. As expected, the MDC values were similar to, but higher than the SEM values.

**Discussion**

Outcome measures are important tools for guiding clinical decision making and treatment planning, and must be chosen with skill and understanding. However, the psychometrics of many performance-based measures have not been studied in patients who have undergone a partial meniscectomy, making it difficult to choose the optimal outcome measure for this population. In addition to first considering the psychometric properties of an outcome measure, clinicians must also consider the relevance of the outcome measure to the population being investigated and the safety, feasibility, and ease of performing each measure during multiple phases of recovery, especially in post-operative patients.

The results of this study indicate that five PBMs, SLHT, CHT, IAT, ESST, and SMT, are reliable and responsive to change, making them appropriate to use in clinical settings with patients who have undergone a meniscectomy. The results also suggest that the utility of these measures may differ in people with DM versus NDM tears. Additionally, only certain measures (IAT and SMT) consistently showed good validity.
making these measures better at measuring activity limitations in this population. These same measures may also be more appropriate than others may for assessing the different types of meniscus tears, acute versus chronic. The current CPGs for meniscal lesions recommend use of the SLHT, CHT, and SMT, but do not consider the other valid measures (IAT and ESST) [4].

Although the SLHT and CHT are reliable measures, they are not valid for all patients with meniscus tears. These PBM's may be more appropriate for patients with NDM tears than patients with DM tears may. By contrast, the IAT, ESST, and SMT are appropriate for patients with all types of meniscus tears.

The SLHT and CHT measure the ability of the patient to hop. Hopping is a higher-level ballistic activity that requires good strength, stability, neuromuscular control, and proprioceptive function of the knee [12]. However, these hop tests may not be appropriate and safe for patients with all types of meniscus tears. Hopping is a specialized activity that may be more important for younger patients or patients returning to high-level sports than for older non-sporting patients. Hopping may no longer be a functional task for patients with DM tears, nor may it be appropriate for patients with Osteoarthritis (OA). Patients with acute/tramautic meniscus tears may be accustomed to hopping and may need to return to hopping after surgery. This should be considered when choosing this measure as an assessment tool for patients after meniscectomy.

The IAT was developed as a test of motor ability, particularly running and dodging agility in healthy individuals [8,15,16]. It is a measure of multi-directional (lateral, sagittal, and transverse) agility that emphasizes the ability to accelerate and decelerate when performing a variety of maneuvers [17]. These activities are functionally important for younger patients who are trying to return to sporting activities after a meniscectomy. The IAT can be easily modified to allow the patient to walk through the course, making it a more appropriate and safe test for patients with DM tears. The ability for this modification makes it more relevant to an older, less active population who do not plan to return to jogging, and still allows for a comparison of activity limitation before and at the end of an episode of care. The IAT simultaneously measures a wide range of movements with minimal equipment and set-up in a short period of time and is therefore a valuable and clinically friendly outcome measure.

The ESST was developed to assess an individual's agility in the lateral direction [18]. Lateral mobility is an important function for all patients after meniscectomy, especially patients who are returning to a sport. Lateral movements are more difficult for patients with DM tears because they are likely to have some form of OA associated with their meniscus tear. However, patients can move through this test as slowly as necessary, which makes it a safe and feasible test for all patients after undergoing a meniscectomy. The ESST provides valuable information to clinicians and is easily reproducible.

Table 3: Correlations between SLHT, CHT, ESST, IAT and SMT and the full scale IKDC and the Tegner assessed at 8-weeks post-meniscectomy.

Table 4: Correlations between SLHT, CHT, ESST, IAT and SMT and the self-report measures (Tegner, IKDC: Sport activities and function sections) assessed at 8-weeks post-meniscectomy for subjects with DM and NDM.

Table 5: Responsiveness statistics for the SLHT, CHT, ESST, IAT and SMT calculated from 4-weeks to 8-weeks post-meniscectomy.
The SMT is an outcome measure that assesses the ability to climb stairs. Although this test does not measure multiple planes of motion, it does measure an activity that is necessary and appropriate for all individuals. The SMT is a timed test and therefore patients can complete it at whatever speed they feel comfortable. This test is also easily modified by using a handrail for safety. Use of the SMT has been validated in patients after hip and knee replacement surgeries, and as evidenced by this research, the SMT is a valid performance-based activity limitation measure for use in patients who have undergone a meniscectomy.

Limitations and Future Research Considerations

This study was limited by a small sample size. The current data is being used as a pilot study to recruit a larger cohort, which will lead to a more significant representation of this research. Another limitation of this study was the gender distribution, which was not representative of the 2.5:1 ratio of men to women who experience meniscus tears [3]. The sample recruited consisted of 22 women and 4 men for a ratio of 1:5.5 men to women, the exact opposite of the target population. Further research should therefore include a better representation of the target population. There was also significant variability between patients with a DM and NDM tears; even within these groups, there was significant variability and additional research should evaluate additional subcategories of each group. Finally, most PT clinics have a number of physical therapists that evaluate and treat patients at different times. It would be beneficial to examine inter-rater reliability of these measures.

Conclusion

The psychometric properties of many PBM have not been studied in patients who have undergone partial meniscectomy and consideration of the mechanism of injury is important in determining the utility of a PBM. The results of this study indicate that five PBMs, SLHT, CHT, IAT, ESST, and SMT, are reliable and responsive to change. Only two PBMs (IAT and SMT) were valid against both the Tegner and IKDC subjective knee evaluation form and therefore can be used to assess activity limitations in patients after arthroscopic partial meniscectomy. The current CPG for meniscallesions recommends the SLHT, CHT, and SMT, but excludes measures of multi-directional movement such as the ESST and IAT. Results from this study indicate that the SLHT and CHT may not be the most appropriate tests for patients with meniscus tears, especially those that are degenerative. The ESST, IAT, and SMT, however, seem to be safe and feasible for all patients after partial meniscectomy. Although more research is needed to investigate the selection of measures for patients with DM versus NDM tears. The PBMs examined in this study are appropriate to use during rehabilitation to assess changes in level of function for people undergoing partial meniscectomy, and can be used with confidence by clinicians working in clinical and research settings.

With the growing emphasis on outcomes-based reimbursement, research on the effectiveness of rehabilitation interventions is imperative and currently research focused on patients who have undergone partial meniscectomy is lacking. Outcome measures should be used to measure the impact of PT on health outcomes relevant to the patient, and should be specific and appropriate to the population being investigated [4]. This work adds to the body of knowledge related to appropriate outcome measures for use in this population.

References