Western University Scholarship@Western

Electronic Thesis and Dissertation Repository

12-12-2019 9:00 AM

Reliability and Validity of Two Performance-Based Outcome Measures in Rehabilitation Following Total Knee Arthroplasty

Jennifer L. Van Bussel, The University of Western Ontario

Supervisor: Birmingham, Trevor B., *The University of Western Ontario* : Chesworth, Bert M., *The University of Western Ontario* A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences © Jennifer L. Van Bussel 2019

Follow this and additional works at: https://ir.lib.uwo.ca/etd

Part of the Rehabilitation and Therapy Commons

Recommended Citation

Van Bussel, Jennifer L., "Reliability and Validity of Two Performance-Based Outcome Measures in Rehabilitation Following Total Knee Arthroplasty" (2019). *Electronic Thesis and Dissertation Repository*. 6712.

https://ir.lib.uwo.ca/etd/6712

This Dissertation/Thesis is brought to you for free and open access by Scholarship@Western. It has been accepted for inclusion in Electronic Thesis and Dissertation Repository by an authorized administrator of Scholarship@Western. For more information, please contact wlswadmin@uwo.ca.

Abstract

Objectives: Performance-based outcome measures (PBOM) are suggested to evaluate change in function during rehabilitation after total knee arthroplasty (TKA). The purpose of this study was to evaluate the measurement properties of the 30-Second Chair Stand Test (30CST) and 10-Metre Walk Test (10MWT) in patients following TKA.

Methods: Eighty-three patients completed two PBOM on three occasions following surgery. Patients also completed the Western Ontario and McMaster Universities Osteoarthritis Index and Global Rating of Change (GRC).

Results: Intraclass correlation coefficients ranged from 0.82 to 0.96. The standard errors of measurement at 6 and 12 weeks postoperative, respectively, were: $30CST \pm 0.67$ and ± 0.79 , $10MWT \pm 1.05$ and ± 0.57 . Minimal detectable changes (90% confidence level) were: $30CST \pm 1.56$ and ± 1.84 , $10MWT \pm 2.43$ and ± 1.32 . Correlations between change in PBOM and GRC ranged from -0.16 to 0.34.

Conclusions: These results support the reliability, validity and clinical use of the 30CST and 10MWT during rehabilitation following TKA.

Key Words: performance-based outcome measures, rehabilitation, total knee arthroplasty, psychometric measurement properties

Summary for Lay Audience

Rehabilitation is important to achieve optimal results following total knee arthroplasty (TKA). The goal of rehabilitation is to maximize functional independence. One method to assess outcomes is to select appropriate measures that quantify improvements in physical function. Performance-Based Outcome Measures (PBOM) of physical function are more likely to exemplify a change in function than self-report measures alone. This thesis evaluated the measurement properties of the 30-Second Chair Stand Test (30CST) and 10-Metre Walk Test (10MWT) in patients following total knee arthroplasty. The results of the study support the reliability, validity, and clinical use of the 30CST and 10MWT during rehabilitation following surgery. Integrating reliable and valid PBOM into clinical practice is essential for patients, physiotherapists, and surgeons to measure change in function during rehabilitation. This protocol may ultimately assist with clinical decision-making and guide best practice.

Acknowledgements

First, I would like to thank my supervisors Dr. Bert Chesworth and Dr. Trevor Birmingham, your unwavering support and guidance through this process was essential to my success. To my advisory committee members your expertise and contributions to this project is much appreciated.

Patrice Green, your challenge, to turn collection of outcome measures in our clinical practice into a Masters research project was accepted. Thank you to all my colleagues in the Physiotherapy Department at University Hospital for your support and work towards recruitment and data collection.

Mike Lukacs, you have been a great friend during this venture. I appreciate you asking me if I was okay on a regular basis.

To all my family and friends. Each of you has played an important role in completion of this accomplishment. My parents, Vivianne and Denzil Palmer along with my in-laws Cathy and Jim Van Bussel, you have been with me every step of the way and I can't thank you enough.

Most of all, I need to thank my husband Michael Van Bussel. You supported, empowered and motivated me every day. You made me believe the impossible was possible. You are the love of my life and my best friend. To my children Lauren and Luke, I realize all the time dedicated over the past two years to my studies was time spent away from you. Mommy is done; it's time to play!

Table of Contents

Abstractiii
Summary for Lay Audience iv
Acknowledgementsv
Table of Contents
List of Tables
List of Figures x
List of Appendices xi
Chapter 11
Introduction1
Objectives:
Chapter 2
Literature Review
Osteoarthritis
Treatment of Knee Osteoarthritis Including Total Knee Arthroplasty
Total Knee Arthroplasty Rehabilitation Research7
Measurement Properties10
Reliability11
Validity
Standardized Performance-Based Outcome Measures used in Total Knee Arthroplasty14
Reliability of Sit to Stand Test/Walk Tests
<i>Reliability of Performance-Based Outcome Measures in rehabilitation following</i> <i>TKA</i>
Validity of Sit to Stand/Walk Tests
Validity of Performance-Based Outcome Measures in rehabilitation following TKA
Chapter 3
Methods
Study Design
Participants
<i>Testing Procedures</i>

Data Analysis	29
Objective 1 – Test-retest Reliability	30
Objective 2 – Longitudinal Validity	30
Objective 3 – Concurrent Validity	31
Chapter 4	32
Results	32
Objective 1 – Test-retest Reliability	36
Objective 2 – Longitudinal Validity	39
Objective 3 – Concurrent Validity	44
Chapter 5	46
Discussion	46
Limitations	53
Strengths	53
Summary and Recommendations	54
References	55
Appendix A - Letter of Information and Consent	65
Appendix B – Data Collection Form	69
Appendix C – Performance Based Outcome Measures	70
Appendix D – WOMAC	72
Appendix E – Global Rating of Change Scale - Pain	73
Appendix F – Global Rating of Change Scale - Function	74
Appendix G – Ethics Approval	75
Curriculum Vitae	76

List of Tables

Table 1. Patient Characteristics
Table 2. Mean ± Standard Deviation for All Subjects for 30CST, 10MWT, Knee Flexion,WOMACpf and GRCf on Five Separate Test Occasions35
Table 3. Reliability for All Subjects (n=45) Between Test Occasions Two and Three (6Weeks Postoperatively): Mean Difference, Interclass Correlation Coefficients (ICC),Standard Error of Measurement (SEM) Minimal Detectable Change Estimated Using thez Value for 90% Confidence (1.64)
Table 4. Reliability For All Subjects ($n=37$) Between Test Occasions Four and Five (12Weeks Postoperatively): Mean Difference, Intraclass Correlation Coefficients (ICC),Standard Error of Measurement (SEM) Minimal Detectable Change Estimated Using thez Value for 90% Confidence (1.64)
Table 5. Initial to 6 Weeks Postoperative: Mean change scores (scores from trial 2 - trial1) for 30CST and 10MWT and WOMACpf
Table 6. 6 to 12 Weeks Postoperative: Mean change scores (scores from trial 4 - trial 2)for 30CST and 10MWT and WOMACpf40
Table 7. Initial to 12 Weeks Postoperative: Mean change scores (scores from trial 4 -trial 1) for 30CST and 10MWT and WOMACpf
Table 8. Pearson r Values (95%CI) for Correlations Between the 30CST Change Scores,10MWT Change Score, WOMACpf Change Score and GRC Function and Pain FromInitial Testing to 6 Weeks Postoperative41
Table 9. Pearson r Values (95%CI) for Correlations Between the 30CST Change Scores,10MWT Change Score, WOMACpf Change Score and GRC Function and Pain FromInitial Testing to 12 Weeks Postoperative41
Table 10. Pearson r Values (95%CI) for Correlations between 30CST, 10MWT andWOMACpf at Initial Test Occasion
Table 11. Pearson r Values (95%CI) for Correlations between 30CST, 10MWT andWOMACpf at 6 Weeks Postoperative Test Occasion44
Table 12. Pearson r Values (95%CI) for Correlations between 30CST, 10MWT andWOMACpf at 12 Weeks Postoperative Test Occasion

Table 13. Mean ± Standard Deviation of Performance-Based Outcome Measure Sco	ore by
Use of Gait Aid	45

List of Figures

Figure 1 - Schematic Diagram of Study Design
Figure 2 - Enrollment Flow Chart
Figure 3 - Bland-Altman Plot for test-retest agreement of the 10MWT at 6 weeks37
Figure 4 - Bland-Altman Plot for test-retest agreement of the 30CST at 6 weeks
Figure 5 - Bland-Altman Plot for test-retest agreement of the 10MWT at 12 weeks38
Figure 6 - Bland-Altman Plot for test-retest agreement of the 30CST at 12 weeks
Figure 7 - Comparison of Grouped GRC and 30CST change score at 6 weeks
Figure 8 - Comparison of Grouped GRC and 10MWT change score at 6 weeks
Figure 9 - Comparison of Grouped GRC and 30CST change score at 12 weeks
Figure 10 - Comparison of Grouped GRC and 10MWT change score at 12 weeks

List of Appendices

Appendix A - Letter of Information and Consent	65
Appendix B – Data Collection Form	69
Appendix C – Performance Based Outcome Measures	70
Appendix D – Western Ontario and McMaster Universities Osteoarthritis Index	72
Appendix E – Global Rating of Change Scale - Pain	73
Appendix F – Global Rating of Change Scale - Function	74
Appendix G – Ethics Approval	75

Chapter 1

Introduction

According to the Canadian Institute for Health Information, more than 70,000 knee replacements were performed in Canada in 2017-18. Approximately 65,000 were primary replacements. These numbers have increased by 17% in the last 5 years.¹ Similar trends in annual growth in incidence of total knee arthroplasty (TKA) have been observed world-wide.² In 2011, Kurtz et al observed a 27-fold range of TKA utilization rates between 18 different countries, including the United States, Denmark, the Netherlands and Australia. They estimated 1,324,000 primary and revision TKA procedures are completed globally each year, with this number expected to continue to rise.² The 25-year survivorship for total knee arthroplasty is estimated to be 82%.³ Despite overall favourable results many studies estimate that up to 20% of patients are dissatisfied following a total knee arthroplasty. Unfulfilled expectations are strongly associated with poor satisfaction.^{4,5}

Rehabilitation is important to achieve optimal results following total knee arthroplasty. The goals of rehabilitation focus on maximizing functional independence and minimizing complications.⁶ Systematic reviews conclude that no one approach is superior when recommending duration and delivery of care.⁷ One method to assess outcomes is to select appropriate measures that quantify improvements in physical function. Self-report measures are commonly used following surgery due to the ease of administration; however, evidence suggests that these types of measures may fail to capture important functional improvements following TKA. Self-report measures provide an analysis of a patient's perception of their functional abilities. A patient's perception of task importance can influence their response ⁸ along with difficulty separating pain from the ability to perform the activity.⁹ Because of this, performance-based outcome measures (PBOM) of physical function are more likely to exemplify a change in function than self-report measures alone.⁹ Previous research has examined the association between self-report and performance-based measures and found correlations ranging between 0.02 and 0.59.¹⁰

Recommended performance-based measures to assess function in people with hip and knee osteoarthritis, those awaiting joint replacement, and following joint replacement have been outlined by various groups such as The Osteoarthritis Research Society International (OARSI), Rehabilitative Care Alliance (RCA) and various clinical researchers.^{11–13} Although the recommended measures may vary slightly from group to group, they often include a measure of gait speed and lower extremity functional strength and endurance integrated into typical activities relevant to the patient population such as climbing stairs, getting in and out of a chair and walking.

OARSI's recommended minimum set of PBOM include: the 30-second chair stand test, 40 metre fast-paced walk test and stair climb test.¹² Due to the complexity of the 40 metre fast-paced walk test and identified limitations, the 10 metre fast-paced walk test was recognized as an acceptable alternative. These measures focus on a population diagnosed with osteoarthritis (OA), as well as those following joint replacement. The psychometric properties of these measures have been evaluated extensively in those with knee OA who may be awaiting TKA, however, to our knowledge, the reliability and validity has not been examined in the TKA population during postoperative rehabilitation. For this study evaluating measurement properties and establishing point estimates at different points in recovery was an important part of the research design. Change in functional status following TKA is variable and each patient's trajectory is unique. Although potential for recovery following TKA can occur over a 12 month period, the greatest improvement in physical impairments and activity limitations occurs in the first twelve weeks or three months.^{14,15} As the rate of change in function is greater in the initial stage of recovery; we cannot assume that the measurement properties at different time points during this phase are identical.

Integrating reliable and valid PBOMs into clinical practice is essential for patients, physiotherapists, and surgeons to measure change in function during postoperative rehabilitation following TKA and may ultimately assist with clinical decision-making and guide best practice in rehabilitation.

This study will evaluate the measurement properties of the 30-Second Chair Stand Test (30CST) and 10-Metre Walk Test (10MWT) in patients during postoperative rehabilitation following TKA.

Objectives:

- 1) examine test-retest reliability of the 30CST and 10MWT.
- 2) evaluate the longitudinal validity of the 30CST and 10MWT.
- 3) explore the concurrent validity of the 30CST,10MWT and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.

Chapter 2

Literature Review

Osteoarthritis

Osteoarthritis is a common degenerative joint disease. Not only does it target the articular cartilage it also affects the surrounding tissue structures. Chronic low-grade inflammation contributes to the initiation and progression of the disease.^{16,17} Knee OA is characterized by progressive loss and destruction of articular cartilage, thickening of subchondral bone, formation of osteophytes, inflammation of the synovium, degeneration of ligaments and menisci and hypertrophy of the joint capsule leading to loss of normal joint function.^{17,18} The result of this disease can be characterized by joint pain, swelling and stiffness that leads to activity limitations, participation restrictions, sleep interruption, fatigue, depression, anxiety, loss of independence and overall decreased quality of life.¹⁹

OA affects over 250 million people globally or 4% of the world's population. Worldwide estimates are that 9.6% of men and 18% of women over 60 years of age have symptomatic OA.^{19,20} The prevalence of OA continues to increase with age, as does the increase in risk factors for OA such as obesity.^{19,21}

The economic and health burden that OA presents is significant and continues to grow with the aging population and increased demands for effective interventions. Sharif et al.,²² estimate that the total direct cost of OA from 2010 to 2031 in Canada will rise from 2.9 billion to 7.6 billion. These costs include: hospitalization, outpatient services, alternative care/out of pocket, drugs, rehabilitation and side effect of drugs. The size of the working population with OA will also rise leading to increased productivity costs of work loss equaling 17.5 billion.²³

In 2016 OARSI submitted a document to the U.S Food and Drug Administration titled "Osteoarthritis: A Serious Disease".¹⁹ Along with pain, loss of function and increased mortality OA is also associated with increased comorbidity.¹⁹ Cardiovascular disease, diabetes mellitus and hypertension are a few of the more prevalent comorbidities in populations with OA.^{19,24,25} The rationale behind this link may be due to similar risk

factors across the conditions, such as age and obesity and the fact that pain and decreased mobility associated with OA limits a person's ability to self-manage conditions such as diabetes and hypertension as it impacts physical activity levels.^{19,26–29}

Treatment of Knee Osteoarthritis Including Total Knee Arthroplasty

Osteoarthritis is a progressive disease, but it is most definitely not predictable. Systematic reviews and meta-analysis have highlighted prognostic factors that may predict the progression of OA. Patient characteristics included in these predictors were: age, varus alignment, presence of OA in multiple joints, radiographic features and body mass index (BMI). Participation in physical activity was not associated with progression of OA.³⁰

Currently, there is no cure for osteoarthritis. Treatment is targeted at managing symptoms, including pain and loss of function.³¹

Pharmacological interventions such as acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) and intra-articular injections have all been found to be superior to placebo with respect to decreasing pain and improving function.³² Although these treatments may be beneficial in symptom management, the adverse effects associated with these interventions are significant. NSAIDs alone have been shown to increase the risk of serious conditions such as peptic ulcer bleeds, cardiac and kidney disease.^{33–36}

Weight loss has also been determined to be an effective intervention for those with knee OA. A reduction in weight of 5-10% has been associated with a significant decrease in pain and disability.^{37,38} Zheng et al examined the association between an increase in weight and risk of OA. Their systematic review concluded that in an increase in BMI of 5kg/m translated into a 35% increased risk of developing knee OA.³⁹

In 2013, Uthman et al., undertook a systematic review and meta-analysis. Their objective was "To determine whether there is sufficient evidence to conclude that exercise interventions are more effective than no exercise control and to compare the effectiveness of different exercise interventions in relieving pain and improving function in patients with lower limb osteoarthritis." They concluded that enough evidence had been

accumulated to show significant benefit of exercise over no exercise in patients with OA. The authors also concluded that further studies would unlikely change this result. Exercise prescription targeting increase in strength, flexibility and aerobic capacity are likely to provide the most effective results.⁴⁰

In 2015, Fransen et al., completed a Cochrane systematic review concluding, exercise is the only intervention for knee OA whose efficacy is supported by over 50 randomized controlled trials and recommended by several best-practice guidelines.⁴¹

Inclusion of neuromuscular exercises into a comprehensive exercise program with the goal of improved sensorimotor control and functional stabilization of joints has proven to be effective in symptom management in those with OA⁴². These exercises involve multiple joints and muscle groups and are performed in functional weight bearing positions. Emphasis is placed on quality of movement and alignment during the activity.

First line and second line treatments including: education, exercise, weight control, medication, assistive devices and physiotherapy are all effective management strategies for those with knee OA.^{31,43} For many, this is all that will be required to control symptoms and maintain function. For those who continue to experience significant pain, loss of function and decreased quality of life, a total knee replacement can be a beneficial and cost-effective treatment for end-stage OA.¹⁵ Appropriateness of surgery must take into consideration the patient's current state, disease progression and expected benefit from the proposed surgery.

According to the Canadian Institute for Health Information, more than 70,000 knee replacements were performed in Canada in 2017-18. Approximately 65, 00 were primary replacements. These numbers have increased by 17% in the last 5 years.¹ The 25-year survivorship for total knee arthroplasty is estimated to be 82%.³ Despite overall favourable results many studies estimate that up to 20% of patients are dissatisfied following a total knee arthroplasty. Unfulfilled expectations are strongly associated with poor satisfaction.^{4,5} Identifying gaps in expectations would enable clinicians to provide better preoperative education to help patients develop realistic expectations for recovery which may improve outcomes.

Total Knee Arthroplasty Rehabilitation Research

Defining optimal rehabilitation following total knee arthroplasty continues to be an ongoing challenge for researchers and clinicians alike. As different measures of outcome are utilized; when comparing one treatment protocol to another it can be difficult to integrate the results and come to an agreed upon best practice guideline. Patient factors, such as expectations, pre-operative function and comorbidities also need to be considered when establishing a treatment plan and delivery of care. It is reported that functional improvements can continue to be observed for up to one year following TKA, however many rehabilitation programs do not follow patients past the twelve-week mark.^{44–46}

Westby et al.,⁴⁷ led a group of 42 experts, including clinicians, researchers and patients through a Delphi process to reach a consensus on best practices for post-acute rehabilitation following total knee arthroplasty. Consensus was reached on recommendations such as: patients should be offered structured-post acute rehabilitation, the rehabilitation should be offered by trained professionals and care should be under direct health professional supervision. Recommended interventions included: therapeutic and functional exercise, gait training, cardiovascular training, thermal modalities, manual therapy and patient education. Consensus was not reached when it came to number of weeks of treatment, frequency of visits and overall number of treatment sessions. It was agreed, by 97%, that body structures and function outcomes be routinely assessed. Recommendations for appropriate tools to assess these outcomes were also highlighted. Timed walk, single leg static balance, repeated stands and timed stair climb were included in the performance based outcome measures. The WOMAC, Lower Extremity Functional Scale (LEFS) and Numeric Pain Rating Scale (NPRS) were among the self-report measures agreed to be the best to use.

The Rehabilitative Care Alliance in Ontario, funded by the 14 Local Health Integrated Networks (LHIN), created a best practice framework outlining recommended ambulatory rehabilitation care for patients with primary total knee replacement. The group advocated for rehabilitation to be initiated within 7 days of discharge. Duration of treatment would depend on achievement of goals and plateaus but exercises to achieve range of motion (ROM) and function throughout the first 12 weeks following surgery should be provided

with a frequency of 2-3 times per week. It was stated that regarding function, ROM and health-related quality of life, group-based therapy models provided similar outcomes to 1:1 therapy. In planning for discharge, patients are to be provided with a home program and education in a continuing program in the community. To measure progress, ROM, strength and gait speed are to be assessed along with one self-report measure and at least one performance-based outcome measure.¹³

Buker et al.,⁴⁸ conducted a prospective randomized trial comparing supervised physiotherapy and a standardized home program on functional status in 34 patients following a total knee arthroplasty. The WOMAC was used for assessment of physical function. Secondary measures included pain on a visual analog scale, ROM, Beck Depression Inventory Scale and the Short Form 36 (SF36) to assess overall quality of life. The study found no difference between the two groups with respect to functional status. No performance-based measures were included for the assessment of functional status.

Bruun-Olsen et al.,⁴⁹ conducted a randomized controlled trail (RCT) to compare the immediate and long-term effects of a walking-skill program and usual physiotherapy care in 57 patients following primary total knee arthroplasty. The walking-skill group program included functional training in weight-bearing positions and participating in activities such as, climbing stairs, walking at different speeds and maneuvering around and over obstacles. The usual physiotherapy care included ROM and strength exercises mostly performed in sitting, with little emphasis on a functional component. Both groups received 12 supervised sessions over the course of 6 weeks. Outcome measures included: the 6 minute walk test (6MWT), timed stair climbing, timed stands, figure-of-eight test, index of muscle function, active knee ROM, Knee Injury and Osteoarthritis Outcome Score and self-efficacy score. The results reported a significant difference between groups favoring the walking-skills group with respect to the primary outcome measure of the 6MWT. This difference was noted at all testing time points which included 9 months after the intervention ended, at 12 months following surgery.

Harmer et al.,⁵⁰ conducted a RCT comparing land-based versus water-based rehabilitation

in 102 patients following total knee arthroplasty. Groups were compared at 8 and 26 weeks following surgery using the 6MWT, stair climbing power and WOMAC. Pain was recorded on VAS along with passive knee ROM and knee edema. All outcomes improved in both groups over time. Although there was a statistically significant difference, favouring the water-based group in stair climbing power, WOMAC stiffness, WOMAC function and knee edema, these were felt to not be clinically important differences. This would lead us to conclude that both land-based and water-based rehabilitation provides comparable improvements following TKA.

In recent years two systematic reviews have examined exercise after TKA. In 2013, Pozzi et al.,⁵¹ published a systematic review of 19 controlled trials identifying four categories of post-operative intervention of importance to discuss: strengthening exercises, aquatic therapy, balance training and clinical environment. The authors provided recommendations for optimal outpatient physiotherapy protocols based on their findings. Based on the literature it is recommended that strengthening and functional exercises, both land-based or water-based are appropriate. Rehabilitation performed in a clinic may provide the best long-term outcomes. Studies that conclude that outpatient physiotherapy does not offer long-term benefit often used inadequate methodology to support their results. There was some agreement that alternate forms of rehabilitation, such as home based or telerehabilitation can provide improved outcomes for those who may not be able to access outpatient rehabilitation facilities. Consistently it was noted that "usual care" or "standard physical therapy" often lacked the detail surrounding treatment parameters making it difficult to compare treatment groups. With each study established measures were used to assess change in selected outcomes. Performancebased measures such as the timed up and go (TUG), stair climb test, 6MWT, gait speed, and 30CST were often used to evaluate functional change. The WOMAC, Oxford Knee Score and SF-36 provided information regarding self-reported change.

In 2015, Artz et al.,⁵² completed a systematic review and meta-analysis exploring the effectiveness of physiotherapy exercise following total knee replacement. The review included 18 randomized control trials with a total of 1739 patients following TKA. Outcomes measures used included both performance-based and self-report measures of

function similar to the Pozzi et al.,⁵¹ systematic review. Of note, 11 of the 18 RCTs were used in both papers. Results of the meta-analysis were reported as standardized mean differences (SMD). Overall, compared to those receiving minimal physiotherapy, those provided with physiotherapy exercises had improved physical function at 3 to 4 months with a SMD of -0.37 (95% confidence interval (CI) -0.62 to -0.12) concluding that those who received physiotherapy exercises had a greater improvement in physical function than those who received minimal or no physiotherapy exercise.

After review of the literature it is clear that although there are some common themes highlighted in research, there is still no clear formula when it comes to rehabilitation following TKA. Patient and environmental factors are essential to consider when establishing a treatment plan.

Many studies have integrated both self-report and performance-based measures into their outcomes, including the 30CST and gait speed, allowing them to capture perceived and true functional change when comparing groups. There continues to be a growing body of evidence that self-report measures are influenced by the patient's experience during activities, such as increased pain or rate of perceived exertion and therefore can provide an imprecise representation of their true functional capacity.^{53,54} Therefore, in addition to self-report measures, performance-based measures are essential to use when measuring functional improvement following TKA.^{8,9,53,55}

Measurement Properties

When selecting outcome measures to evaluate functional change, it is crucial that the measure possess adequate measurement properties. Acceptable reliability, validity and ability to detect change are required in order to provide accurate and meaningful results. To be useful outcome measures should allow for improvement and deterioration in a patient's functional status to be revealed.⁵⁶

Reliability

A reliable measure must possess precision, or the ability to provide consistent values for repeated measurements with minimal error in measurement. It must also be able to differentiate between individuals who are being measured with the tool. With this in mind reliability is often communicated as relative reliability or absolute reliability.

Relative reliability allows us to explore the measure's ability to differentiate between individuals. Relative reliability is calculated as the ratio of the true variance to the total variance. The true variance can also be termed as between-patient variance. The total variance is the sum of the true variance and the error variance, or within-patient difference.⁵⁶ Relative reliability is expressed with an Intraclass Correlation Coefficient (ICC) with values varying from 0.00-1.00. An ICC closer to 1.00 indicates higher reliability. Portney and Watkins suggest that values less than 0.50 reflect poor reliability, 0.50 to 0.75 suggest moderate reliability and ICC values greater than 0.75 reflect good reliability.⁵⁷ Similarly, Fleiss describes values from 0.40 to 0.75 as fair to good.⁵⁸ When evaluating relative reliability the ICC is the superior coefficient to use rather than Pearson product moment correlation. Association between two sets of data determines correlation. Pearson's can tell us how the scores vary together, but does not provide information on the agreement between the score.⁵⁶

Absolute reliability interprets the error associated with an individual's score at a single point in time. The measurement error is reported in the same units as the original measurement unlike the ICC. This is often expressed as the standard error of measurement (SEM). The SEM is calculated as standard deviation(SD) $\sqrt{(1-ICC)}$. In order to establish if true change has occurred in a score rather than change due to error in measurement the Minimal Detectable Change (MDC) can be calculated using the SEM. Calculating an estimate of the Minimal Detectable Change at 90% confidence level (MDC90) is achieved by multiplying the SEM by $\sqrt{2}$ and the *z* value for 90% confidence (1.64).⁵⁷

Validity

Validity refers to the extent that a measure actually measures what it is intended to measure. A valid measure also allows us to make inferences from test scores that may assist us in clinical decision-making. Portney and Watkins state that a measure may be used for discriminative, evaluative or predictive purposes. Is the measure able to discriminate among individuals with and without a condition or trait? Can the measure evaluate change between two test occasions? Finally, can we make predictions surrounding prognosis or function based on a measures score? These are related to the validity of a measure.⁵⁷

When examining validity, the magnitude and direction of the relationship between two measures is often studied using correlation analysis. When evaluating continuous interval or ratio data the most common measure of correlation is the Pearson product moment correlation (r). If the data being analyzed is ranked or ordinal a Spearman rank correlation co-efficient is used (rs). Correlation values are reported from 0.00 (no correlation) to 1.00 (perfect correlation).⁵⁷ Portney and Watkins suggest, "correlations ranging from 0.00 to 0.25 suggest little or no relationship; those from 0.25 to 0.50 suggest a fair degree of relationship; values of 0.50 to 0.75 are moderate to good; and values above 0.75 are considered good to excellent".⁵⁷ The direction of the relationship between the two measures will be represented by a + or - sign. For example, if one variable increases as does the other a positive (+) correlation occurs. If one variable increases while the other decreases a negative (-) correlation will be reported.

Four types of validity are described in the literature: face validity, content validity, criterion validity and construct validity.⁵⁶

Face validity indicates that a test appears to test what it is supposed to. This is the least rigorous form of validity and is often established through observation.

Content validity refers to the extent that the measure incorporates a comprehensive sample of items with respect to what is being evaluated. For example, if lower extremity

function is the topic of interest, the measure should encompass multiple tasks that relate to the lower extremity.

Criterion validity is the most objective approach to validity. It examines the measure's ability to predict results obtained using another measure. The measure being examined is compared to a gold standard or established measure that is already validated. The scores on the two measures can then be correlated to each other to determine if the new measure could be used as an alternate for the other validated measure it is tested against. Criterion validity can be divided into concurrent validity and predictive validity. Concurrent validity is studied when the two measures are administered at approximately the same time. Prescriptive validity evaluates a measure's ability to predict a future criterion score or outcome.

Construct validity is applied in the absence of a gold standard. Here theories are formulated and validity is evaluated based on the extent to which the measure produces results in line with the proposed theories. Within the confines of construct validity also discussed is cross-sectional and longitudinal validity, convergent and discriminant validity, known-groups validity, sensitivity to change and responsiveness.

Cross-sectional validity⁴⁸ evaluates two measures administered at a single point in time and the association, or correlation between the scores on that one occasion. Longitudinal validity examines the association between the change score of the validated measure and the change score of the new measure being studied. Convergent validity indicates that two measures that are thought to test the same thing should provide similar results and be highly correlated. Measures that test different attributes should yield low correlation or different results indicating adequate discriminant validity. Known-groups validity examines two or more distinct groups. It is anticipated that the measure will be able to distinguish between groups that possess a certain attribute or level of attribute.

Longitudinal validity describes the extent to which a measure evaluates constructs related to change. Sensitivity to change is the often simply referred to as the ability of a measure to detect change over time. Coefficients used to express sensitivity to change can include Effect Size (ES) and Standardized Response Mean (SRM). ES is calculated by dividing

the mean change score by the standard deviation of the baseline score. Cohen describes interpretations of ES as scores below 0.2 are small, 0.5 is considered moderate and 0.8 is considered large.⁵⁶ SRM is calculated by dividing the mean change by the standard deviation of the change scores. A SRM > 1 indicates that the change could be detected over the variability.⁵⁶ Responsiveness is the ability of a measure to detect clinically meaningful change over time. Liang states "sensitivity to change is a necessary but insufficient condition for responsiveness". What constitutes a clinically important change can vary depending on the situation and the interpretation of the individual.⁵⁹

Standardized Performance-Based Outcome Measures used in Total Knee Arthroplasty

Performance-based outcome measures play an important role in measuring functional change and outcome following TKA. The relationship between a patient's self-efficacy in performance of function and these measures is strong and mitigates the individual's inability to discriminate between pain and their ability to perform the task that can often be associated with self-report measures of function.^{9,53,60}

Recommended performance-based measures to assess function in people with hip and knee osteoarthritis, those awaiting joint replacement and following joint replacement have been outlined by various groups such as The Osteoarthritis Research Society International (OARSI), Rehabilitative Care Alliance (RCA) and various clinical researchers.^{11–13} Although the recommended measures may vary slightly from group to group, they often include a measure of gait speed and lower extremity functional strength and endurance integrated into typical activities relevant to the patient population such as climbing stairs, getting in and out of a chair and walking.

Groups such as OARSI and the RCA, recommend a minimum set of self-reported outcome measures and PBOM. These measures focus on a population diagnosed with osteoarthritis (OA), as well as those following joint replacement. Although the psychometric properties of these measures have been evaluated extensively in those with knee OA who may be awaiting TKA, to our knowledge, the reliability and validity has not been examined in the TKA population during postoperative rehabilitation. Dobson et al¹² proposed a recommended set of performance-based measures to use in people diagnosed with hip and knee osteoarthritis or following joint replacement. A survey of experts and systematic review facilitated the process and measures were selected based on their measurement-property evidence, feasibility of the test, scoring method and expert consensus. This process resulted in a recommended set of performance-based measures including: the 30CST, 40 m Fast-paced Walk Test (40FPWT), Stair Climb Test, TUG and 6 Minute Walk Test (6MWT). The first three of the mentioned tests were recommended as a minimum core set. As a follow up to these recommendations, due to the complex nature administering the 40FPWT and scoring the 11 Step Stair Climb Test, the 10 Metre Fast-paced Walk Test and 20-second stair climb test were suggested as alternatives.⁶¹

The Total Joint Arthroplasty and Outcome Measures (TJAOM) Knowledge Translation Taskforce, led by Dr. Marie Westby, has created a toolkit to provide clinicians with outcome measures for use along the continuum of care for patients before and after arthroplasty.¹¹ Prior to the creation of this toolkit McAuley et al.,⁶² surveyed Canadian Physiotherapists about their experience using outcome measures in total hip and knee arthroplasty patients. Familiarity with tests, current use and potential for future use were explored. A secondary aim of the study was to understand clinical issues and barriers to using outcome measures in various practice settings. A majority of the respondents reported using more than one outcome measure. Familiarity was greatest with the TUG, Single Leg Stance Test and 6MWT followed by the Sit to Stand Test and Walking Speed Test. Beliefs regarding value of using a standardized tool, varying patient populations, phase of recovery, care setting and availability of tools were all noted as concerns and potential barriers to implementing appropriate outcome measures into their current practice.

The recommendations outlined in the TJAOM tool kit included outcome measures to be used along the total joint arthroplasty continuum: Pre-operative, Acute, Post-acute and Active Living. Pre-operative was defined as moderate to advanced OA. Acute is during the hospital stay. Post-acute refers to the outpatient/home therapy setting and active living would be defined as 1 year following surgery and onwards. With the exception of

the acute phase, the recommended performance-based outcome measure included: 30CST, Gait speed (self-selected), Stair climb test, Single leg stance test (30 seconds), 6MWT, TUG and functional reach.

Sit to stand and walking tests have been used and are recommended to measure performance in both patients with OA who may be awaiting joint replacement and those following joint replacement surgery.^{9,53,63,64} Not only can these measures be used to track progress with functional change, they may also assist in clinical decision making, goal setting and communication with both patients and other health care providers.⁶²

Reliability of Sit to Stand Test/Walk Tests

Gill et al.,⁶³ investigated the intra-rater and inter-rater reliability of the 50-foot Timed Walk (50FTW) and 30CST in patients awaiting total hip or total knee replacement. Eighty-two subjects who were participating in a 6-week exercise program were recruited. Measurements were collected at baseline, 7 weeks and 15 weeks. During each testing occasion, four trials of the 50FWT and two trials of the 30CST were completed, as the 30CST may be more likely to exacerbate pain. The study also explored if a practice effect may be responsible for improved performance. ICC (1,1) was calculated for each testing occasion and resulted in ICCs for the 50FTW ranging from 0.93 (95%CI 0.91 to 0.96) to 0.97 (95% CI 0.96 to 0.98). The SEM was 1.32 seconds and the MDC90% was calculated to be 3.08 seconds. These were calculated from the baseline assessment scores. It was noted by comparing mean scores that the first trial of the 50FWT was slower than subsequent trials. Results were similar for the 30CST with results ranging from 0.95 (95% CI 0.93 to 0.97) to 0.98 (95% CI 0.97 to 0.99). For baseline scores the SEM was 0.70 stands and the MDC90% was 1.64 stands. As the SEM and MDC90% were calculated from baseline scores, we are unaware if these are similar when repeated after an intervention has taken place. The authors concluded that the 50FWT and the 30CST could be reliable measures in those awaiting joint replacement. They did note that a practice trial should be administered when first introducing the test as significant differences were noted between trial one and trial two. These stabilized for the remainder of the 50FWT trials, but we are unsure if the same would hold true for the 30CST as only two trials were completed due to concerns of increasing pain. The protocols described in this study were used in the study completed for this thesis.

Fransen et al.,⁶⁵ examined 41 patients with knee osteoarthritis. Each patient performed a walk test over a course of 8 metres. Five trials were completed at a self-selected pace that individuals considered normal, followed by five trials at a self-selected pace that individuals considered fast. A rest period of 45-60 seconds was provided between each trial. A total of three test occasions were completed at one week intervals. Results showed that the ICC (2,1) were consistently high ranging from 0.90 to 0.98 with the lower boundaries of the 95%CI ranging from 0.84 to 0.96. The authors noted superior test-retest reliability in the fast-self-selected walking speed as compared to the normal self-selected speed. The SEM 90%CI was calculated as +/-0.12 m/s. Similar to other studies they noted that there was a learning curve and a practice trial allows for familiarization where stability between the second and third trials was achieved.

Kennedy et al.,⁵⁵ examined the reliability and sensitivity to change of the 6MWT, TUG, Stair Climb Test and a Fast Self-Paced Walk Test (SPWT) in patients with hip and knee osteoarthritis who went on to have a total hip or total knee arthroplasty. Test-retest reliability (ICC (2,1)) was assessed in 21 patients at three time points prior to surgery. Subjects were required to walk two lengths of a 20 metre course (excluding turns) and given the instruction "walk as quickly as you can without overexerting yourself". The median time between the first and second test occasions was 91 days and between the first and third test occasions was 178 days. The authors felt that time between testing sessions was acceptable to establish test-retest reliability as previous literature had suggested that the amount of functional change while someone was on the waitlist is minimal. The estimated reliability was calculated as ICC = 0.91 (95% CI 0.81 to 0.97), SEM 1.73 (95% CI 1.39 to 2.29) confidence in score 90% = +/- 2.86sec and MDC90% = 4.04 seconds. In conclusion, the authors felt that the measure met the requisite standards for acceptable reliability for making decisions at the individual patient levels. It must be noted that no test-retest reliability analysis was completed following surgery and the sample size used for the analysis was quite small. Responsiveness of the measure will be discussed in a future section.

Perera et al.,⁶⁶ examined 692 participants enrolled in three different studies. The three data sets were used and analyzed. Gait speed was calculated in meters/second and distance covered in the different studies ranged from 10 feet to 10 metres. Test-retest reliability estimates were calculated from a subsample of subjects from the studies and used to calculate the SEM. ICC values were not reported. SEM results varied from 0.04m/s for a 10 metre distance to 0.10 m/s for a distance of 10 feet. Meaningful change was then estimated using both an anchor-based and distribution-based method. The overall recommendations outlined a change of 0.05 m/s and 0.10 m/s were required to meet a small and substantial meaningful change with a 10 m gait speed test.

Barthuly et al.,⁶⁷ highlighted that restoration of walking is a primary concern for those undergoing short-term rehabilitation. Relevance to community ambulation, incident health events and mortality has led many to recommend gait speed as a clinical vital sign. 136 patients admitted for short-term rehabilitation participated in a prospective observational study. Participants were tested on admission, the following day and prior to discharge (mean of 15.1 days). Gait speed was assessed over a 5.2 m course with time beginning after a 1 m distance allotted for acceleration. ICC was estimated at 0.932 (95%CI 0.906 to 0.951). The SEM was calculated as 0.05 m/s and the associated MDC95% was 0.13 m/s. The authors concluded that results were consistent with previous studies.

Davey et al.,⁶⁸ looked to estimate the test-retest reliability of a number of functional and self-report measures in 21 elderly subjects with hip and knee osteoarthritis. The participants were part of a larger RCT to determine the cost-effectiveness of water therapy for those with OA. The walking test required subjects to ambulate over a distance of 8 feet with an additional 2 feet at either end. Individuals were asked to walk "at their own pace". Two trials were allowed with the faster of the two being noted. The measures were repeated on two occasions less than a week apart. The study looked to estimate test-retest reliability to determine the degree to which the same result can be obtained with repeat measurements. The SEM was estimated to provide information as to how useful a measure may be for monitoring change in performance and the variation that might be expected for a measure. Test-retest correlations were estimated using

Pearson's correlation co-efficient and reported as r = 0.90. SEM was reported as 0.12 seconds (95%CI -0.07 to 0.29). MDC90% was not reported. One concern is using Pearson coefficient rather than an Interclass Correlation Coefficient to estimate reliability. As mentioned previously, Pearson does not take differences between score into account, only how they vary to each other. This may lead to an overestimation of agreement.

Dobson et al.,⁶¹ set out to evaluate the reliability and measurement error of the OARSI recommended performance-based tests of physical function in 51 people with hip and knee osteoarthritis. The performance-based measures included the 40FPWT, 10FPWT and 30CST. Relative reliability was calculated using ICCs and absolute reliability was estimated using SEM and MDC. Participants completed the measures on two test occasions, one-week apart. Within-rater reliability was calculated using an ICC (2,1) and between-rater using an ICC (1,1).

For the 40FPWT the ICC (1,1) for the 40FPWT was 0.96 (95%CI 0.93 to 0.98) and SEM 0.06 m/s (95%CI 0.05 to 0.08). The ICC (2,1) was estimated as 0.92 (95%CI 0.82 to 0.96) and SEM 0.07 m/s (95%CI 0.06 to 0.09). MDC90% was estimated as 0.19 m/s. Results for the 10FPWT ICC (1,1) was 0.91 (95%CI 0.83 to 0.95) and ICC (2,1) was 0.88 (95%CI 0.80 to 0.93). SEM was 0.10 m/s (95%CI 0.09 to 0.13). MDC90% was estimated as 0.28 m/s. The 30CST measured in number of stands was estimated as 0.86 (95%CI 0.77 to 0.92) with an SEM of 1.0 (95%CI 0.8 to 1.3) and within-rater as 0.85 (95%CI 0.67 to 0.93) with an SEM of 0.9 (95%CI 0.7 to 1.1). MDC90% was estimated at 2.0 stands.

The authors concluded that sufficiently small measurement error associated with the tests indicate these tests are appropriate for measuring change in those with hip and knee OA. The results also indicate that the 10FPWT is an acceptable alternative to the 40FPWT.

Marks,⁶⁹ evaluated the reliability of the 13 m walk test in 15 females with knee OA. Subjects completed two trials of the test with a 2 minute rest period in between. The same protocol was carried out 1 week later with no intervention in between. Results concluded ICCs for the tests conducted within and across sessions were 0.98, 0.99, 0.88 and 0.80, respectively. 95%CI was not reported. The average SEM across sessions was 1.06 seconds. MDC 90% was not reported. In contrast to other studies, Marks reported that there were no systematic learning curve or fatigue effects with repeated testing. The author did admit that a larger sample size would be ideal in further studies.

Jones et al.,⁷⁰ evaluated the 30CST as a measure of lower body strength in communityresiding older adults. 76 community-dwelling older adults completed two 30CST and two maximum leg-press tests; these were repeated 2 to 5 days later. The authors were interested in the 30CST as an alternative to other sit to stand tests that required an individual to complete a minimum amount of sit to stands. It was observed that a number of older adults could not complete the minimum number of stands required for the test, which resulted in a floor effect. A floor effect results when a subject cannot reach the minimum requirements of a test.^{71,72} Test-retest ICC for the 30CST was estimated at 0.89 (95%CI 0.79-0.93). The authors noted that all participants were able to complete the 30CST with scores ranging from 2 to a maximum of 21. They concluded that the 30CST had the capability of assessing a wider range of ability levels and did not demonstrate the same floor effect that other tests that required a minimum number of stands had previously in the literature.

Wright et al.,⁷³ assessed patients with a diagnosis of hip or knee OA, who were part of a larger trial, in an effort to estimate reliability of the 40FPWT, TUG, 30CST and 20-cm Step Test. Two different raters tested participants, one week apart, prior to any intervention. ICC (2,1) was calculated for the 40FPWT as 0.95 (95%CI 0.90 to 0.98) with an SEM of 1.00 m/s. The ICC for the 30CST was estimated as 0.81 (95%CI 0.63 to 0.91) with a SEM of 1.27 stands. The authors indicated that 33 patients were required for the reliability assessment. Unfortunately, this was not achieved and may have impacted the significance of the results.

Tolk et al.,⁷⁴ conducted a prospective cohort study to investigate the reliability, validity and responsiveness of the OARSI core set of performance-based outcome measures that include the 30CST, 40FPWT and Stair Climb Test. Participants included 85 patients with knee OA who were awaiting TKA. Measures were collected pre-operatively and 12

months following surgery. Test-retest calculations were obtained pre-operatively with a 30-minute rest period between testing sessions. Appropriate test-retest reliability was found for all three tests. For the 30 CST an estimated ICC of 0.90 (95%CI 0.68 to 0.96), SEM 0.85 stands and smallest detectable change (SDC = $1.96 \times \sqrt{2} \times SEM$) of 2.4 stands was reported. The 40FPWT yielded a similar ICC of 0.93 (95%CI 0.85 to 0.96), SEM 0.10 m/s and SDC of 0.27 m/s.

Reliability of Performance-Based Outcome Measures in rehabilitation following TKA

The relative and absolute reliability of sit to stand and walk tests has been established for a number of different types of tests and suggests good to excellent reliability. When exploring reliability of these performance-based outcome measures, many studies have included patients with hip and knee OA who may or may not be awaiting total joint arthroplasty. Those studies that included patients who underwent TKA calculated reliability in testing sessions that occurred prior to surgery. To our knowledge, there are no reports to date of relative or absolute reliability estimates calculated during rehabilitation following TKA. As well, the MDC90% that has been reported has been at a single time point prior to surgery. In order to accurately estimate the relative and absolute reliability, along with the MDC90% at various time points in rehabilitation following TKA these performance-based outcome measures need to be examined in the desired population at the appropriate time points following surgery.

Validity of Sit to Stand/Walk Test

Using a head-to-head comparison design, Gill et al.,⁶⁴ assessed and compared the validity of six physical function measures in 82 people awaiting TKA or THA. The measures examined included the WOMAC physical function (WOMAC*pf*) scale, SF-36 Physical Component Summary Scale, Patient Specific Functional Scale, 30CST and 50-foot timed walk. Validity was explored by assessing convergent validity, discriminative validity, known-groups validity and responsiveness. Spearman's rho correlation coefficients were calculated when investigating convergent and discriminative validity. The 30CST had moderately high correlations with the 50-foot walk test ($\rho = 0.64$) and WOMAC*pf* ($\rho =$ 0.62). The correlation between the 50-foot walk test and WOMAC*pf* was moderately

correlated ($\rho = 0.42$). All three of the mentioned tests had evidence of known-groups validity and were able to distinguish between subjects who were using a gait aid and those who were not. Standardized response means (SRM) of 0.2, 0.5 and 0.8 have been interpreted to represent small, moderate and large responsiveness to change.⁷⁵ The 30CST had large responsiveness (0.84, 95%CI 0.61 to 1.07) while the 50-foot walk test (0.45, 95%CI 0.22 to 0.68) and WOMAC*pf* (0.70, 95%CI 0.47 to 0.93) had a more moderate response.

Jones et al.,⁷⁰ conducted a study to examine the validity of the 30CST as a measure of lower body strength in adults over the age of 60. A moderately high correlation was found between the 30CST and weight-adjusted leg press (r = 0.77, 95%CI 0.64 to 0.85). It was also observed that the 30CST could discriminate between age groups and levels of physical activity.

Wright et al.,⁷³ compared three methodological approaches to establishing the major clinically important improvement (MCII) of four tests, including the 30CST and 40SPWT. Three anchor-based approaches were used in patients with hip OA. An anchor-based approach compares changes in the outcome measures' score to an external standard; often used is the Global Rating of Change (GRC). The authors selected a GRC score of greater than +5 to represent an important change. Patients who indicated a major improvement had statistically significant greater improvements in the 40 SPWT and 30CST. When comparing the three methodological approaches, the MCII for the 30CST varied from 2.0 to 2.6 stands and the 40SPWT from 0.2 to 0.3 m/s.

French et al.,⁷⁶ conducted a study to compare the responsiveness of two self-report measures and three performance-based measures in patients with knee OA after physiotherapy. Both the WOMAC and timed-stand-test were included in their investigation. The timed-stand-test change score was significantly different (p<0.002) indicating the result of the outcome was different following intervention. An SRM of 0.39 and ES of 0.36 demonstrated a small effect size based on Cohen's criteria.

Marks,⁶⁹ conducted an observational study to investigate the validity of the 13-m walk test in 15 patients with knee OA. A positive correlation (r = 0.66) was found between the

walk test and the functional handicap scores on the Lequesne Index of Severity for Knee OA. No relationship was identified between the walk test and age, weight or height.

In 2003, Stratford et al.,⁷⁷ conducted an observational study of 93 patients awaiting total hip or knee arthroplasty. The authors explored the correlation between the Lower Extremity Functional Scale (LEFS), the self-paced walk test (SPW) (2 lengths of a 20m indoor course), TUG and stair test. A significant correlation was reported between the LEFS and self-paced walk test (r = 0.44, 95%CI 0.26 to 0.59). To further investigate the content validity of the timed tests, the LEFS walk items were correlated with the SPW. This yielded similar results r = 0.47 (95%CI 0.29 to 0.61). Performance-based measure outcomes are reported in time and do not take into account pain or perceived exertion. Following the completion of the performance-based measure, participants were asked to rate their pain when performing the test and their rate of perceived exertion. When the time, pain and exertion scores were pooled for the SPW test, the correlation with the LEFS was significantly greater, r = 0.59 (95%CI 0.44 to 0.71). The authors concluded that adding pain and exertion domains would heighten the content validity of the performance-based test.

Kennedy et al.,⁵⁵ conducted an observational evaluating the sensitivity to change of four performance-based measures following total hip and knee arthroplasty. Two time points following surgery were to be explored to assess the ability of the measures to detect change, both deterioration and improvement. Participants were evaluated pre-operatively, within 15 days post-operatively and a minimum of 20 days occurred between the second and third testing session. SRM for the self-paced walk test was estimated at - 0.89 (95%CI -1.42 to -0.68) between the pre-operative and first post-operative testing session. The negative score was associated with deterioration in function, which would be expected so soon after surgery. The SRM during the post-operative phase was reported as 0.79 (95%CI 0.66 to 1.45).

Barthuly et al.,⁶⁷ conducted a prospective observational study involving patients admitted to short-term rehabilitation following an acute-care hospitalization. The majority of subjects had undergone total knee arthroplasty. Gait speed was measured at a

comfortable speed over 5.2 m and measured at baseline, 2 days later and just prior to discharge. The mean time between admission and discharge was 15.1 days. ES estimation for gait speed was 1.11 and SRM was 1.25. Minimal clinically important difference (MCID) was also explored and was reported between 0.10 m/s and 0.18 m/s depending on the anchor used to establish significant change.

Borjesson et al.,⁷⁸ set out to identify the most discriminative walking speed to be used when evaluating patients with knee osteoarthritis following unicompartmental knee arthroplasty or high tibial osteotomy. 54 individuals walked a 5 m distance, with 3 m of walkway at each end to allow for acceleration and deceleration. The distance was completed with walks at slow, normal and fast speeds. The first test occasion occurred prior to surgery and the second, one-year following surgery. During each testing session, two trials were completed with the second trial used for the calculation. Responsiveness was calculated as ES, SRM and relative efficiency. Relative efficiency was estimated with t-statistic*fastpace*/t-statistic*normalpace*). All subjects with unilateral knee OA had a significant (p<0.001) improvement in their walking speed from pre-surgery to post-surgery. ES ranged from 0.34 to 0.58 and SRM varied from 0.49 to 0.71. For both ES and SRM the slow walking had the highest values.

Tolk et al., examined the construct validity and responsiveness of the OARSI core set of performance-based outcome measures.⁷⁴ Creating predefined hypotheses assessed both properties. Measures would be assumed valid and responsive if at least 75% of the hypotheses were confirmed. Based on this evaluation procedure it was determined that none of the tests met the construct validity criteria and only the 40FPWT was considered to be responsive. When reviewing each hypothesis, it is observed that correlation between the performance-based and self-report measures varied between -0.25 and 0.35. Change scores and analysis of responsiveness between the anchor-question using a GRC and the change score on the self-report-measure of function ranged between -0.22 and 0.43. The authors concluded that the performance-based measures were not valid or responsive and therefore do not justify their use in clinical practice. A statement like this needs careful consideration, as it was the predefined hypotheses that determined the

validity and responsiveness. Had other parameters been used the results and conclusion may have differed greatly.

Validity of Performance-Based Outcome Measures in rehabilitation following TKA

It appears that there is at best a moderate association between self-report and performance-based measures, including sit to stand and walk tests. The two can be considered complementary, but do not measure the same construct. Stratford et al⁵⁴ concluded that performance-based measures may be more sensitive to change than selfreport measures. Based on the above literature review, it also appears that inquiry into the psychometric properties of sit to stand and walk tests has not been evaluated previously in post-operative arthroplasty populations (i.e., TKA and THA). Furthermore, to our knowledge, previous studies have not investigated the longitudinal and concurrent validity of the 30CST and 10MWT during rehabilitation following TKA. As previously mentioned, it has been recommended that these outcome measures should be used in clinical practice^{7,9,11,12,62}, and thus requires normative data to ensure optimization of clinical outcomes. Normative data has been established for the 30CST and 10MWT in community dwelling adult populations,^{70,79,80} and could provide a benchmark for recovery from arthroplasty procedures. Establishing these measurement properties in this population is essential to help determine functional change and may assist in identifying superior treatment pathways.

Chapter 3

Methods

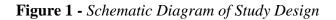
Study Design

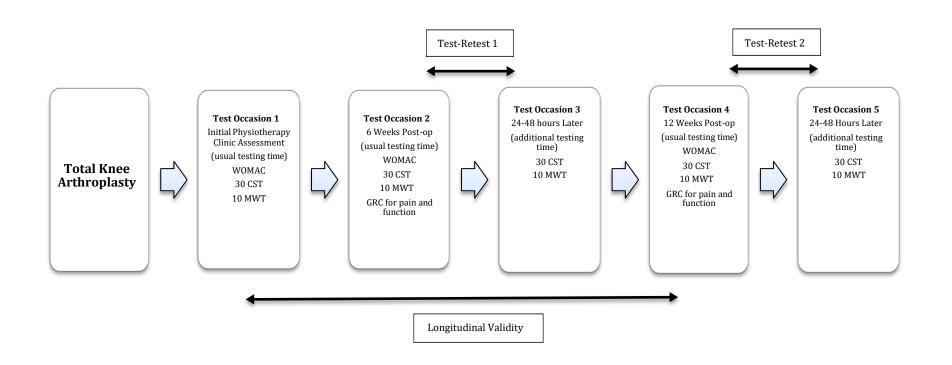
The study design was prospective and observational with repeated measures. Patients performed the 30CST and 10MWT and completed the WOMAC and the Global Rating of Change (GRC) questionnaires on three occasions. The initial testing occasion was during their initial assessment at the LHSC-UH Physiotherapy Clinic (approximately four weeks following surgery). The second and third occasions were at six weeks and twelve weeks following surgery respectively. This was the usual standard of care for all TKA patients referred to our facility. From these time points we were able to evaluate longitudinal validity. In order to evaluate test-retest reliability, a subgroup of patients completed one or two additional testing session and repeated the two PBOMs 24 to 48 hours following their six-week and twelve-week postoperative testing (Figure 1).

Participants

We recruited patients between the ages of 45 and 88 years. All patients had undergone a unilateral primary total knee arthroplasty (TKA) resulting from end stage osteoarthritis (OA) as determined by the treating surgeon at London Health Sciences Centre – University Hospital (LHSC-UH). All patients were recruited from the Physiotherapy Clinic at LHSC-UH.

Patients were excluded if they had undergone a revision TKA, bilateral TKA or unicompartmental TKA. Patients with rheumatoid arthritis, diagnosed neurological movement disorder or concurrent musculoskeletal condition (e.g. back, hip or ankle injury) leaving them unable to complete performance-based outcome measures (PBOM), were also excluded. Patients were required to understand, read and write in English to complete study questionnaires. The institution's ethics board review board approved the study and all participants provided informed consent prior to participation. The study





Letter of Information and Ethics Approval Notice are provided in Appendices A and G respectively.

Sample size was based on our primary responsiveness analysis which calculated the correlation between the GRC and the two PBOMs as this required the largest sample size. Considering an alpha of $\alpha = 0.05$ and an expected Pearson's *r* of 0.6 with a 95% CI width of 0.3, we required a minimum sample size of 74 patients with complete data.⁸¹ In order to account for a potential loss to follow-up rate of 20% we planned to recruit 89 patients. We ensured that at least 30 patients participated in the reliability testing, providing the ability to estimate an ICC of at least 0.85 with 95% CI width of 0.2.⁸²

Testing Procedures

The testing procedures were identical on each test session. LHSC-UH Physiotherapy Clinic clinical staff administered testing. All staff received training on test administration and utilized identical protocols and equipment. The primary study assessor assessed them for competency.

On the initial test occasion, the investigator collected demographic data from the patients and entered it into the data collection form (Appendix B). On the three standard test occasions, patients completed the Western Ontario and McMaster Universities Osteoarthritis Index (Appendix D), a condition-specific self-report questionnaire designed for patients with hip and knee OA. The questionnaire consists of 24 questions across three categories: pain, stiffness and physical function. Individuals are asked to rate their level of difficulty on a five-point scale with 0 = None, and 4 = Extremely. The total score is out of 96, with higher scores indicating greater difficulty. The WOMAC's reliability and validity are well established in hip and knee OA.⁸³ Subsequent to the initial test occasion, patients also completed two GRC questionnaires. The GRC scale is used to quantify a patient's improvement or deterioration over time.⁸⁴ Patients were asked two questions, "*With respect to your joint replacement surgery, how would you rate your pain (1) or function (2) now, compared to when you first started physiotherapy here at University Hospital?*" The GRC utilized in this study was a 15-point adjectival scale ranging from -7 (a very great deal worse) to +7 (a very great deal better). A score of 0

indicates the same, or no change. Other responses were scored as follows: a tiny bit better/worse, almost the same = 1; a little bit better/worse = 2; somewhat better/worse = 3, moderately better/worse = 4; a good deal better/worse = 5; a great deal better/worse = 6; a very great deal better/worse = 7 (Appendices E and F). The test administrator also measured active knee range of motion and recorded if a gait aid was required during each testing occasion.

The two PBOM were administered according to adapted protocols outlined by Gill et al.⁶³ and Tilson et al.⁸⁵ The tests included the 10 Metre Walk Test (10MWT) and the 30 Chair Stand Test (30CST). Each patient completed the WOMAC and GRC prior to the PBOMs. The two PBOMs were completed in the same order, as listed above, at each test occasion.

The 10MWT required the subject to walk as fast as they can, safely, over a total distance of 14 metres. The walking course was set up in a hallway and included a 2 m distance at the beginning and end to allow for warm up and slow down. The 10 m in between was used for the speed measurement. Subjects were allowed to use their appropriate gait aid, which the assessor noted. Two trials were conducted, with a short rest period between as required (Appendix C).

The 30CST was performed following the 10MWT. A chair with a 17-inch seat height and no armrests was placed against the wall. Patients were instructed to stand fully up and fully down without using their hands and were given 30 seconds to complete as many repetitions as possible. Each subject was allowed one trial sit to stand prior to the test beginning (Appendix C). The same stopwatch was used for both tests and during all test occasions.

<u>Data Analysis</u>

All statistics were calculated using IBM SPSS Statistics version 25. Descriptive statistics, including mean and standard deviation of the sample were calculated. On each test occasion, the 10MWT scores were recorded in absolute time (in seconds) and were

calculated as the mean of the two-recorded trials. The 30CST scores were recorded as an absolute number.

Objective 1 – Test-retest Reliability

10MWT and 30CST scores from occasions: 2 and 3, and, 4 and 5 were compared using a series of paired t-tests.

Test-retest reliability was assessed using values obtained from test occasions 2 and 3 (6 weeks postoperatively) and test occasions 4 and 5 (12 weeks postoperatively). Relative reliability was estimated using Intraclass Correlation Coefficients (ICC) with a two-way random model for consistency. Absolute reliability was estimated using the Standard Error of Measurement (SEM). SEM was calculated as the standard deviation (SD) $\sqrt{(1-ICC)}$. The SEM was also used to calculate an estimate of the Minimal Detectable Change at 90% confidence level (MDC90), by multiplying the SEM by $\sqrt{2}$ and the *z* value for 90% confidence (1.64). Lastly, we created Bland and Altman plots for the two performance-based outcome measures at both 6 and 12 weeks postoperatively (Figures 3-6).

Objective 2 – Longitudinal Validity

Longitudinal validity and sensitivity to change were evaluated using the change scores between test occasions: 1 and 2 (initial to 6 weeks postoperative), 1 and 4 (initial to 12 weeks postoperative) and 2 and 4 (6 weeks postoperative to 12 weeks postoperative).

Pearson correlation coefficients (r) were used to determine the association between the change in each performance-based measure, the GRC pain and function, and change in WOMAC physical function subscale.

The ability to detect change was expressed by calculating both the standardized response mean (SRM) and effect size (ES). The SRM was calculated by dividing the mean of the change scores by the standard deviation of the change scores. The ES was calculated by dividing the mean of the change scores by the standard deviation of the baseline score. Specifically, when calculating the ES for initial to 6 weeks post-op and initial to 12 weeks post-op, the SD from the initial score was used. When calculating the ES from 6-12 weeks post op, the SD of the score at 6-weeks was used. These values assist in evaluating how well a measure can distinguish "signal" from "noise".

Objective 3 – Concurrent Validity

In order to explore concurrent validity of the 10MWT, 30CST and WOMAC physical function subscale, Pearson's *r* was also calculated.

Finally, known-groups validity was investigated by comparing scores on each of the performance-based measures for individuals who walked with a gait aid versus those who walked without a gait aid. A statically significant difference using an independent t-test identifies that known-groups validity is achieved.

Chapter 4

Results

Eighty-five patients we approached as potential participants. Those who did not enter the study had undergone revision surgery (1) or were unwilling to participate (1). Eighty-three participants were entered into the study (Figure 2.). Complete data were collected on 80 patients.

During the study two patients did not attend their twelve-week testing sessions. Multiple attempts were made to contact the patients to schedule an appointment however we were unsuccessful. One subject was excluded in the sensitivity to change portion of the study as she had a respiratory infection and could not complete the 30CST. The final sample consisted of eighty-one patients who attended testing session at all three time points (initial visit, six weeks and twelve weeks postoperative). Forty-five patients completed a second testing session 24-48 hours following the six-week testing and thirty-seven patients completed a second testing session 24 to 48 hours following the twelve-week testing session to evaluate test-retest reliability of the two PBOMs.

Figure 2 - Enrollment Flow Chart

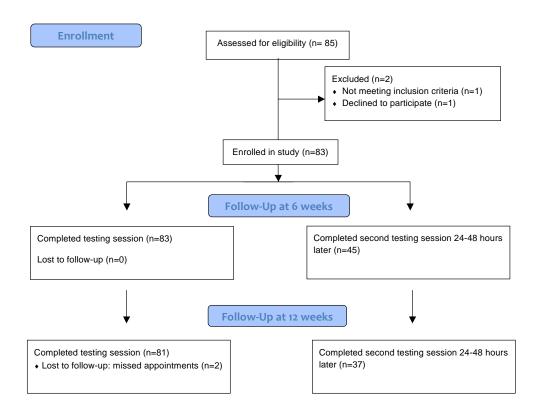


Figure 2. Enrollment flow chart

A summary of patient characteristics is outlined below (Table 1) including; age, height, weight, BMI, length of postoperative stay in hospital, number of comorbidities, number of home care visits, days from surgery to initial testing and use of gait aid at during initial testing session.

	Female Subjects	Male Subjects	Total
Sample size (n)	52	31	83
Age (y)	67.6 ± 8.8	69.5 ± 8.5	68.3 ±8.7
Height (m)	1.62 ± 0.07	1.75 ± 0.08	1.67 ± 0.10
Weight (kg)	89.8 ± 19.9	96.4 ± 16.0	92.3 ± 18.7
Body mass index	34.01 ± 6.45	31.38 ± 4.20	33.02 ± 5.83
Length of stay (days)	2.48 ± 1.04	2.10 ± 0.91	2.34 ± 1.00
Co-morbidities (n)	2.50 ± 1.50	1.68 ± 1.14	2.19 ± 1.43
Home care visits (n)	3.63 ± 1.1	3.65 ± 0.8	3.64 ± 1.0
Days from surgery (days)	29.87 ± 5.77	28.45 ± 5.12	29.24 ± 5.55
Gait aid at initial testing (n)	38	21	59

 Table 1. Patient Characteristics

Mean \pm Standard Deviation

A summary of statistics for the 30CST scores, 10MWT scores, knee flexion range of motion in degrees, WOMAC physical function (WOMAC*pf*) scores and Global Rating of Change function (GRC*f*) on all test occasion are below in Table 2.

Test	Initial Testing	6-wk Postop	6-wk re-test	12-wk Postop	12-wk re-test
Ν	83	83	45	81	37
30CST (n)	4.2 ± 3.9	8.7 ± 3.9	9.2 ± 3.5	12.2 ± 3.76	12.8 ± 2.9
10MWT (s)	14.88 ± 9.32	10.45 ± 2.95	9.97 ± 2.2	8.30 ± 1.96	8.12 ± 1.61
Knee Flexion (°)	100.6 ± 15.2	112.6 ± 11.5	-	120.8 ± 8.32	-
WOMACpf	33.4 ± 13.6	24.66 ± 12.4	-	16.28 ±12.1	-
GRCf	-	4.4 ± 2.1	-	5.77 ± 1.1	-

Table 2. Mean ± Standard Deviation for All Subjects for 30CST, 10MWT, Knee Flexion,WOMACpf and GRCf on Five Separate Test Occasions

For all tests completed, paired t-tests determined that all the scores on each test occasion were significantly different.

For the 30CST there was a significant difference in all scores between all test occasions (p < 0.001), this included a significant difference between test occasions 2 and 3, and 4 and 5, which were collected to establish test-retest reliability.

The results of the 10MWT were similar in that scores between all test occasions were significantly different. The difference between the scores obtained on the first and second test occasion was significant with p < 0.01. Between score differences on test occasion 1 and 3 were p < 0.005. For the remainder of the scores, the comparison between test occasions 2-3, 3-4 and 4-5 were significantly different (p < 0.001).

Objective 1 – Test-retest Reliability

Reliability statistics for the 30CST and 10MWT are outline in Tables 3 and 4. These values were calculated at both 6 weeks and 12 weeks post op.

Table 3. Reliability for All Subjects (n=45) Between Test Occasions Two and Three (6 Weeks Postoperatively): Mean Difference, Interclass Correlation Coefficients (ICC), Standard Error of Measurement (SEM) Minimal Detectable Change Estimated Using the z Value for 90% Confidence (1.64)

Test	Mean Difference (95%CI)	ICC (95%CI)	SEM (95%CI)	MDC90
30CST	-0.91 (-1.20 to -0.62)	0.96 (0.93 to 0.98)	±0.67 (0.57 to 0.87)	±1.56
10MWT	1.04 (0.50 to 1.49)	0.82 (0.70 to 0.90)	±1.05 (0.88 to 1.34)	±2.43

Table 4. Reliability for All Subjects (n=37) Between Test Occasions Four and Five (12 Weeks Postoperatively): Mean Difference, Intraclass Correlation Coefficients (ICC), Standard Error of Measurement (SEM) Minimal Detectable Change Estimated Using the z Value for 90% Confidence (1.64)

Test	Mean Difference (95%CI)	ICC (95%CI)	SEM (95%CI)	MDC90
30CST	-0.97 (-1.35 to -0.59)	0.93 (0.86 to 0.96)	±0.79 (0.66 to 1.05)	±1.84
10MWT	0.53 (0.26 to 0.80)	0.89 (0.80 to 0.94)	±0.57 (0.47 to 0.75)	±1.32

For the 30CST at 6 weeks postoperatively the ICC (0.96, 95%CI 0.93 to 0.98) and SEM (\pm 0.67, 95%CI 0.57 to 0.87) indicated acceptable reliability. The same is true for 12 weeks postoperatively where the ICC (0.93, 95%CI 0.86 to 0.96) and SEM (\pm 0.79, 95%CI 0.66 to 1.05) also confirmed adequate reliability. The minimal detectable change, at the 90% confidence interval, was 1.56 stands and 1.84 stands at 6 and 12 weeks following surgery respectively.

For the 10MWT at 6 weeks postoperatively the ICC (0.82, 95%CI 0.70 to 0.90) and SEM (± 1.05 , 95%CI 0.88 to 1.34) were also satisfactory. The same can be said at 12 weeks postoperatively with the ICC (0.89, 95%CI 0.80 to 0.94) and SEM (± 0.57 , 95%CI 0.47 to 0.75). The minimal detectable change, at the 90% confidence interval, was 2.43 seconds and 1.32 seconds at 6 and 12 weeks following surgery respectively.

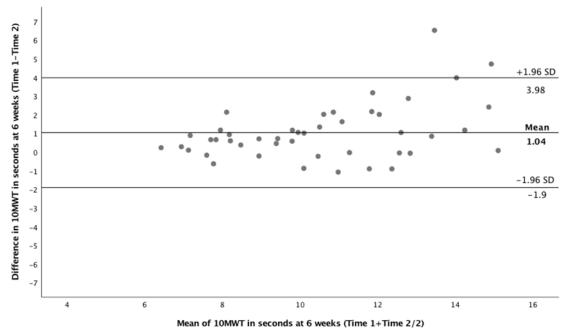


Figure 3 – Bland-Altman plot for test-retest agreement of the 10MWT at 6 weeks

Figure 3. Bland-Altman plot for test-retest agreement of the 10MWT at 6 weeks

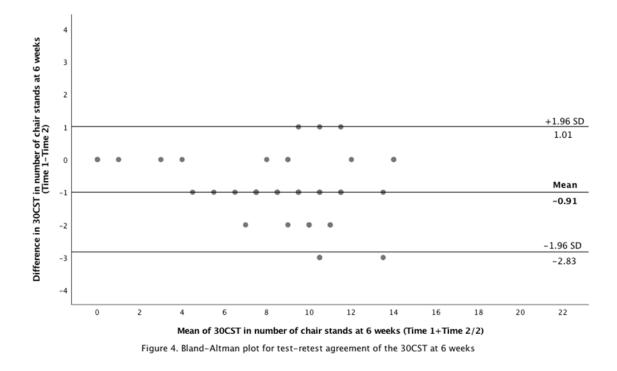


Figure 4 – Bland-Altman plot for test-retest agreement of the 30SCST at 6 weeks

Figure 5 – Bland-Altman plot for test-retest agreement of the 10MWT at 12 weeks

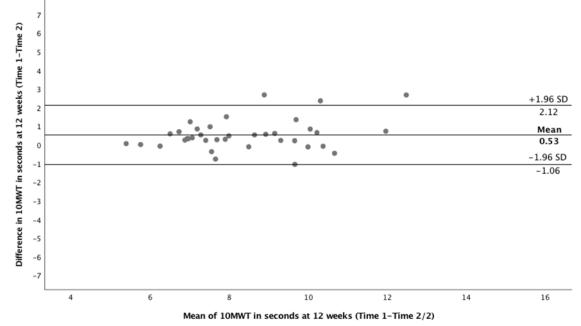


Figure 5. Bland-Altman plot for test-retest agreement of the 10MWT at 12 weeks

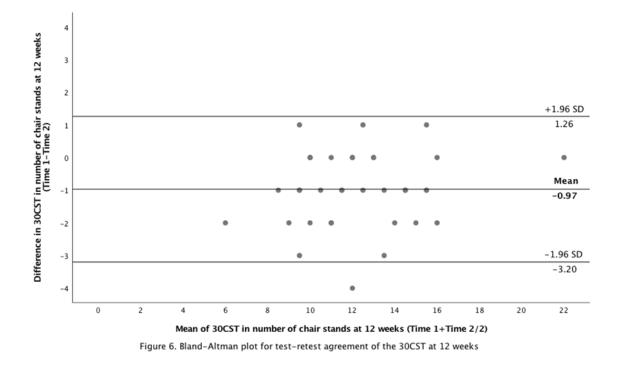


Figure 6 – Bland-Altman plot for test-retest agreement of the 30CST at 12 weeks

Objective 2 – Longitudinal Validity

When comparing the 30CST and 10MWT scores from initial to 6 weeks following surgery to 12 weeks following surgery, there was an improvement in each performance-based measure as the time from surgery increased. The same was observed with the WOMAC*pf* scores.

Change scores, SRMs and ES for the 30CST, 10MWT and WOMAC*pf* from initial visit to 6 weeks postoperative and initial visit to12 weeks postoperative are summarized in Table 5-7. For each time interval, the 30CST had the greatest SRM followed by the WOMAC*pf* than the 10MWT. For the 30CST, from initial to 6 weeks postoperative, the SRM (1.94) and ES (1.16) indicated that the performance-based outcome measures are sensitive to clinical change. The results were similar from initial to 12 weeks postoperative with an SRM 1.94 and ES 2.07.

Table 5. Initial to 6 Weeks Postoperative: Mean change scores (scores from trial 2 - trial1) for 30CST and 10MWT and WOMACpf

Test	Mean change score (95% CI)	SRM	ES
30CST	4.55 (3.70 to 5.30)	1.30	1.16
10MWT	4.42 (2.71 to 6.13)	0.56	0.48
WOMACpf	8.69 (6.29 to 11.08)	0.79	0.64

•

Table 6. 6 to 12 Weeks Postoperative: Mean change scores (scores from trial 4 - trial 2)for 30CST and 10MWT and WOMACpf

Test	Mean change score (95% CI)	SRM	ES
30CST	3.54 (2.85 to 4.22)	1.14	0.90
10MWT	2.17 (1.71 to 2.62)	1.06	0.74
WOMAC	8.06 (5.88 to 10.25)	0.82	0.65

Table 7. Initial to 12 Weeks Postoperative: Mean change scores (scores from trial 4 -trial 1) for 30CST and 10MWT and WOMACpf

Test	Mean change score (95% CI)	SRM	ES
30CST	8.12 (7.20 to 9.05)	1.94	2.07
10MWT	6.65 (4.74 to 8.58)	0.77	0.71
WOMACpf	16.67 (14.14 to 19.19)	1.46	1.23

Pearson correlation coefficients (r) were calculated to explore the association between the change scores on the two performance-based outcome measures, change score of the WOMAC*pf* and the GRC*f*. Values were calculated for changes between initial testing and 6 weeks postoperative and initial testing and 12 weeks postoperative. Correlations between the two performance-based tests and self-report measures ranged from -0.16 to 0.34. The strongest association was between the 30CST and GRC*f* at both time frames. Results are summarized in Tables 8-9 below.

Table 8. Pearson r Values (95%CI) for Correlations Between the 30CST Change Scores,10MWT Change Score, WOMACpf Change Score and GRC Function and Pain fromInitial Testing to 6 Weeks Postoperative

Test	Global Rating of Change Function	Global Rating of Change Pain	WOMAC <i>pf</i> Change Score
30CST	0.34 (0.13 to 0.52)	0.28 (0.07 to 0.47)	0.22 (0 to 0.42)
10MWT	0.05 (-0.17 to 0.26)	0.03 (-0.19 to 0.24)	0.22 (0 to 0.42)
WOMACpf	-0.10 (-0.31 to 0.12)	0.07 (-0.15 to 0.28)	-

Table 9. Pearson r Values (95%CI) for Correlations Between the 30CST Change Scores,10MWT Change Score, WOMACpf Change Score and GRC Function and Pain fromInitial Testing to 12 Weeks Postoperative

Test	Global Rating of Change Function	Global Rating of Change Pain	WOMAC <i>pf</i> Change Score
30CST	0.25 (0.03 to 0.45)	0.23 (0.01 to 0.43)	0.15 (-0.07 to 0.36)
10MWT	-0.16(-0.37 to 0.06)	-0.01(-0.23 to 0.21)	0.11 (-0.11 to 0.32)
WOMACpf	0.07 (-0.15 to 0.28)	0.22 (0.002 to 0.42)	-

The GRC*f* responses were then grouped into 0 (0-1 no change), 1 (2-3 little change), 2 (4-5 moderate change) and 3 (6-7 large change) and presented using a stem and leaf plot (Figures 3-6). On observation, we see that those who felt they had a greater improvement in function also had a greater change in their performance on a functional test demonstrating responsiveness. Association between the 10MWT and self-report measures was not as strong.

Figure 7 - Comparison of Grouped GRC and 30CST change score at 6 weeks

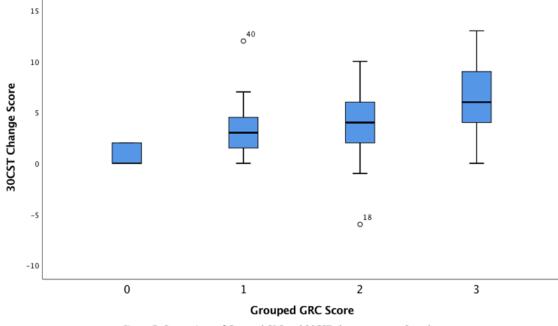


Figure 7. Comparison of Grouped GRC and 30CST change score at 6 weeks

Figure 8 - Comparison of Grouped GRC and 10MWT change score at 6 weeks

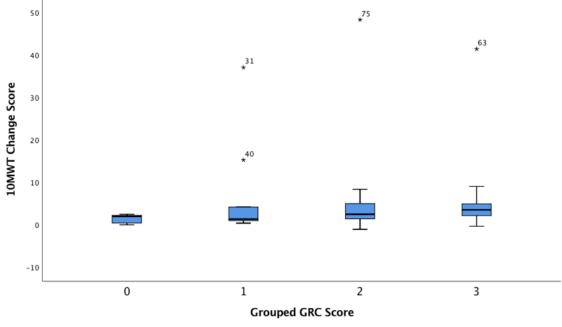


Figure 8. Comparison of Grouped GRC and 10MWT change score at 6 weeks

Figure 9 - Comparison of Grouped GRC and 30CST change score at 12 weeks

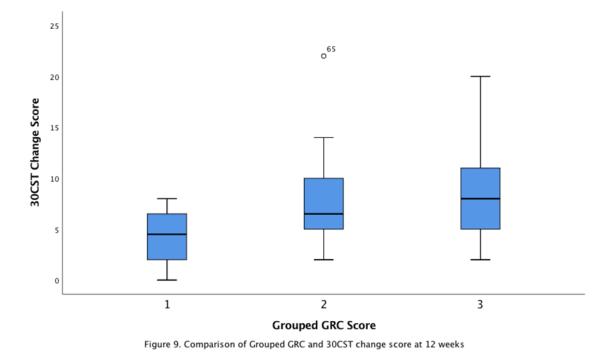


Figure 10 - Comparison of Grouped GRC and 10MWT change score at 12 weeks

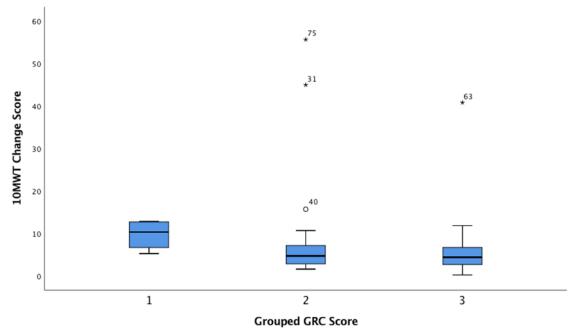


Figure 10. Comparison of Grouped GRC and 10MWT change score at 12 weeks

Objective 3 – Concurrent Validity

Correlations were then examined between the 30CST, 10MWT and WOMAC*pf* at each of the three testing time points and summarized in Tables 10-12 below. Similar to the association in change score, the correlations at one time point between the two performance-based measures and the WOMAC*pf* score ranged between -0.05 and -0.33 for the 30CST and 0.21 to 0.27 for the 10MWT. Association was greater between the 30CST and WOMAC*pf* scores at initial testing and 12 weeks post op than the 10MWT and WOMAC*pf* score. The 10MWT had a greater association with the WOMAC*pf* score at six weeks postoperative. The association between the two performance-based outcome measures increased the further out from surgery and ranged from -0.34 to -0.57.

Table 10. Pearson r Values (95%CI) for Correlations between 30CST, 10MWT andWOMACpf at Initial Test Occasion

Test	WOMACpf	30CST	10MWT
30CST	-0.33 (-0.51 to -0.12)	-	-0.34 (-0.52 to -0.13)
10MWT	0.22 (0.01 to 0.42)	-0.34 (-0.52 to -0.13)	-
WOMACpf	_	-0.33 (-0.51 to -0.12)	0.22 (0 to 0.42)

Table 11. Pearson r Values (95%CI) for Correlations between 30CST, 10MWT andWOMACpf at 6 Weeks Postoperative Test Occasion

Test	WOMACpf	30CST	10MWT
30CST	-0.05 (-0.26 to 0.17)	-	-0.47 (-0.62 to -0.28)
10MWT	0.27 (0.06 to 0.46)	-0.47 (-0.62 to -0.28)	-
WOMACpf	-	-0.05 (-0.26 to 0.17)	0.27 (0.06 to 0.46)

Table 12. Pearson r Values (95%CI) for Correlations between 30CST, 10MWT andWOMACpf at 12 Weeks Postoperative Test Occasion

Test	WOMACpf	30CST	10MWT
30CST	-0.16 (-0.37 to 0.06)	-	-0.57 (-0.70 to -0.40)
10MWT	0.21 (-0.01 to 0.41)	-0.57 (-0.70 to -0.40)	-
WOMACpf	_	-0.16 (-0.37 to 0.06)	0.21 (-0.01 to 0.41)

Known-groups validity was examined to help establish if the two performance-based outcome measures could differentiate between those who were using a gait aid or not while completing the functional test. At all three testing occasions the mean scores between those with a gait aid and those without were all significantly different indicating the functional tests could differentiate between the two groups (Table 13).

Table 13. Mean ± Standard Deviation of Performance-Based Outcome Measure Score byUse of Gait Aid

	Gait Aid (n)	No Gait Aid (n)
10MWT Score (s)		
Initial	16.81 ± 10.40 (59)	10.12 ± 1.90 (24)
6 Week Post Op	12.50 ± 3.03 (32)	9.17 ± 2.05 (51)
12 Week Post Op	10.60 ± 1.71 (15)	7.75 ± 1.61 (66)
30CST Score (n)		
Initial	3.39 ± 3.41 (59)	6.04 ± 4.51 (24)
6 Week Post Op	7.00 ± 3.93 (32)	9.78 ± 3.60 (51)
12 Week Post Op	10.00 ± 4.00 (15)	12.69 ± 3.55 (66)

Chapter 5

Discussion

This study evaluated the measurement properties of the 30CST and 10MWT in patients during the first 12 weeks of postoperative rehabilitation following TKA. Through this study we were able to determine that these performance-based outcome measures can be used as standardized outcome measures in those following TKA. The test-retest reliability of the two measures is adequate as the presented ICC values are well above the accepted value of 0.70^{74} . Estimates of measurement error and minimal detectable change in these scores are also provided for both the 6 and 12 week intervals following surgery which can assist clinicians in determining if a true change has occurred with respect to their patient's functional status. Not only can these measurements be considered reliable, but they are also sensitive to change as indicated by the change in scores over time and calculated standardized response mean and effect size. Correlations between the change scores on the two performance-based outcome measures and self-report measures, including the WOMACpf and GRCf show that those who felt they had a greater improvement in function also had a greater change in their performance on a functional test. When evaluating the correlation between the WOMACpf and the two performancebased measures at a single time point the association is low to moderate at best, concluding that both self-report measures and performance- based measures are required to capture the overall function of those following TKA.

The ICC's reported in this study suggest not only adequate, but excellent relative reliability and signify that the 30CST and 10MWT are suitable for differentiating between patients during rehabilitation following TKA. For test-retest reliability the current study's findings are similar to those ICC values published in previous research. ICCs for the 30CST ranged from 0.93 to 0.96 depending on the time of evaluation during rehabilitation, either 6 weeks or 12 weeks postoperatively. Gill et al.,⁶³ reported ICCs from 0.95 to 0.98 for those with knee osteoarthritis awaiting TKA. The ICC's reported in the present study were higher than those reported by Dobson et al.,⁸⁶ and Tolk et al.,⁷⁴

(0.85 to 0.90). Again, populations observed in these studies were those with osteoarthritis who may or may not be awaiting arthroplasty surgery.

Relative reliability for the 10MWT was estimated from 0.82 to 0.89; this was established by using the mean of the two trials during each testing session. Estimated values were slightly lower than those reported in the literature. Previous research has examined a variety of gait speed tests using different distances and protocols. Using the 50FWT and a protocol that the current study was modeled after, Gill et al.,⁶³ estimated ICCs ranging from 0.93 to 0.97. The protocol used by Fransen et a.,1⁶⁵ required each participant to walk a course of 8 metres. ICCs were consistently high ranging from 0.90 to 0.98.

Each of these studies allowed for four to five trials of the walk test and noted a significant difference in the first and second test trials which stabilized for the remainder of the trials indicating a learning curve was probable and a practice trial should be allowed. In our study a significant difference was found between all test occasions, including those used to establish test-retest reliability. Perhaps allowing for a practice trial and using values once scores had stabilized would have changed this. As well, our population was in the initial stages of rehabilitation following TKA, not those with osteoarthritis awaiting a TKA; this could also contribute to the difference in scores. We would assume that patients would remain stable between testing sessions, but other confounding factors, such as pain management and other activities completed that day may influence their test score.

Similarly, published values for the SEM and MDC90, measuring absolute reliability have been estimated using individuals with knee osteoarthritis. To our knowledge no studies have explored these measurement properties in those during rehabilitation following TKA. These values are reported in a measure's scale points and allow a clinician to estimate the reliability of the measurements they take. As patients following TKA may improve differently depending on the stage of recovery they are in, it is important that absolute reliability values be estimated at these different time points to accurately interpret the results.

Previous research has estimated the SEM for the 30CST to be from 0.70 to 1.27 stands^{61,63,73,74} and the MDC90 to be from 1.64 to 2.4 stands.^{61,63,73,74} At 6 weeks postoperative our study reported the SEM for the 30CST to be 0.67 and at 12 weeks postoperative the SEM was calculated to be 0.79. Based on the estimated error in the 30CST at 6 weeks postoperative (SEM x $1.96 = \pm 1.31$), a clinician can be 95% confident that a measured value of 8 stands could vary from 6.7 to 9.3 stands, simply due to measurement error. At the 12 week postoperative mark (SEM x $1.96 = \pm 1.55$) this same score could vary from 6.5 to 9.6 stands. With the calculated MDC90, 90% of stable patients would change less than 1.56 stands at 6 weeks and 1.84 stands at 12 weeks following surgery.

Comparing this study's findings for the 10MWT to the literature is somewhat more difficult as measures of gait speed are often varied with respect to distance walked, selected pace and reported scale values (seconds versus m/s). If we compare our results to the protocol our study was modeled after, Gill et al.,⁶³ report the SEM and MDC90 for the 50FWT to be 1.32 seconds and 3.08 seconds respectively. The subjects in this study were awaiting a total hip or knee replacement and participating in a six-week exercise program prior to surgery. Values were estimated from baseline scores and not following the intervention. We estimated the SEM to be 1.05 seconds at 6-weeks post op and 0.57 at 12 weeks postoperative. Based on an estimated error in the 10MWT at 6 weeks postoperative (SEM x 1.96 = ± 2.06), a clinician can be 95% confident that a measured value of 10.56 seconds could vary from 8.50 to 12.62 seconds, due solely to measurement error. At the 12 week mark (SEM x 1.96 = ± 1.12) this same score could vary from 9.44 to 11.68 seconds. Furthermore, with a calculated of MDC90 of 2.43 seconds at 6 weeks and 1.32 seconds at 12 weeks, 90% of stable patients would change by less than 2.43 or 1.32 seconds.

When comparing the results of the two tests we observed that the MDC90 for the 10MWT decreased over time whereas the opposite occurred for the 30CST. This may be due to the greater variability in scores during the 10MWT observed during the earlier stages of recovery due to use of a gait aid, effect of surgery on ambulation and other contributing impairments to gait.

Using established performance-based measures, which have adequate reliability is essential; however, in clinical practice using a measure that is able to detect change in an individual makes the measure's use clinically relevant. Change scores, standardized response means, and effect size were calculated to explore the sensitivity to change of the 30CST and 10MWT.

For the 10MWT effect size ranged between 0.48 to 0.74, which as described by Cohen indicates a moderate to large effect.⁵⁶ Standardized response mean values were calculated from 0.56 to 1.06, which again can be considered moderate to high. The highest values were obtained between measurements taken at the 6 week and 12 week mark indicating that at different times the ability of the 10MWT to detect change is better. These findings are similar to Borjesson et al.,⁷⁸ who evaluated 54 individuals following unicompartmental knee arthroplasty prior to surgery and at one year post-operatively. ES ranged from 0.34 to 0.58 and SRM from 0.49 to 0.71. The ability to detect change was best when a slow gait speed was used; this may help direct selection of a test when considering fast-paced versus self-paced walk test.

A similar trend was found with the 30CST where ES and SRM ranged from 0.90 to 2.07 and 1.14 to 1.94 respectively. In the case of the 30CST the highest values obtained were between measurements taken at initial testing and 12 weeks postoperative. Values for both measures were lower in the period evaluating change between initial testing and 6 weeks postoperative, this may have been due to the little time that was allotted for change to occur. The mean time in days between initial testing and 6-week testing was 14.77 days (SD \pm 6.1) with the number of days ranging from 5 to 35 days. The interquartile range during this period was 7 days. The ability to detect change in a shorter period of time would be more challenging than given a sufficient amount of time when we would expect a change to occur.

Overall the 30CST was able to detect change better than the 10MWT between all time points. Gill et al.,⁶⁴ reported a similar trend with the 30CST demonstrating a large responsiveness (0.84) compared to the moderate result (0.45) from the 50FPWT. This

finding may help clinical decision-making when selecting an outcome measure to be used in clinical practice. Not only is the 30CST easier to administer than the 10MWT, but its superior ability to detect change may make it the test of choice if their time for collecting measures is a factor.

Our validity results agree with previous reports that performance-based measures and self-report measures are, at best, moderately correlated⁵⁷ When exploring change scores between the initial and 6-week testing, correlations between the change in the 30CST and GRC*f* (r = 0.34) and WOMAC*pf* (r = 0.22) indicated that the change in ability to sit to stand is only fairly⁵⁷ associated with perceived change in function. The correlation was similar when change scores between initial and 12-week testing were examined; GRC*f* (r = 0.25) and WOMAC*pf* (r = 0.15).

Correlation between the 10MWT change score and GRC*f* (r = 0.05) and WOMAC*pf* change score (r = 0.22) at 6- weeks and GRC*f* (r = -0.16) and WOMAC*pf* change score (r = 0.11) were significantly less than the 30CST. The GRC is commonly used in musculoskeletal research to identify and quantify a patient's change over time; however the GRC places a significant cognitive demand on the patient⁸⁴, in our case to remember what they were like when they first began physiotherapy at University Hospital. The GRC scale used in this study was a 15 adjectival scale ranging from -7 (a very great deal worse) to +7 (a very great deal better). To evaluate responsiveness, we grouped the responses where those answering 0-1 indicated no change, 2-3 was a small amount of change, 4-5 and moderate amount of change and 6-7 a large amount of change. The results were then analyzed using a stem and leaf plot. From this we can visualize that those who felt that they had a greater change in function also had a greater change score on both the 30CST and 10MWT. The exception was with the 10MWT at 12 weeks which could be associated with a potential ceiling effect.

Correlation at a single time point between the WOMAC*pf* and 30CST ranged from -0.05 to -0.33. For the 10MWT values were fairly consistent over the three test occasions (r = 0.21 to 0.27). These findings are similar to Tolk et al.,⁷⁴ yet compared to other studies where the performance-based measures were correlated to self-report measures of outcome^{64,69,77} the correlation is lower. One reason for this may be the difference in the

population that our study was exploring the measurement properties in. Previous literature tended to focus on those with osteoarthritis awaiting TKA where individuals may have been more stable and homogeneous. Their perceived function and influence of pain on perceived function would be very different than an individual who had just undergone joint replacement surgery. Those studies that did include postoperative patients evaluated them at time points outside of the first three months in rehabilitation.⁷⁸

Establishing measurement properties in performance-based outcome measures is important but it is only the first step. Encouraging utilization and assisting in interpreting results to drive clinical decision-making is key to ensure translation of research into practice. The potential clinical use is demonstrated in the following example:

Your patient is a 71-year-old male who underwent a right total knee arthroplasty 3 months ago. Six weeks ago, you evaluated his lower extremity strength and gait speed using the 30CST and 10MWT. He was able to complete 9 stands in 30 seconds and the mean score of his two trials on the 10MWT was 11.62 seconds. Following this you implemented a progressive strengthening and walking program as he is planning on returning to golf as soon as he is able to. Both you and the patient would like to evaluate whether his strength and gait speed have changed over the six weeks of training. You repeat the tests and today he is able to complete 15 stands and walk the 10-metre course in 7.01 seconds.

• What is the patient's level of functional performance today?

The patient's 30CST is 15 stands, and you can be 95% confident that the true number of stands lies between 13.5 and 16.5 stands. The patient's 10MWT was completed in 7.01 seconds. You can be 95% confident that the true time is between 5.89 and 8.13 seconds (see Table 4).

• Has the patient's functional performance truly improved over the past 6 weeks of training?

You know that 90% of stable patients would be expected to change by less than 1.84 stands and 1.32 seconds. As his 30CST improved by 6 stands and his 10MWT improved by 4.61 seconds, you can be confident he has truly improved (see Table 4).

• How would your assessment change if you wanted to use a performance-based measure, but you have a busy day in clinic and cannot afford the time required to administer both tests?

Overall the 30CST had the highest relative reliability and high sensitivity to change (SRM = 1.14, ES = 0.90) between 6 and 12 weeks following surgery. The SRM and MDC90 were only slightly higher for the 30CST than the 10MWT at the three-month time point. Correlation to the GRC*f* and WOMAC*pf* were low for both the 30CST and 10MWT, to note the correlation between the two performance-based measures at 3 months was considered moderate (-0.57). If a clinician had to pick one test to complete, the 30CST may be the best option. This test also requires less time to complete and set up is more amenable to limited space.

The objectives of this study were to examine the test retest reliability, longitudinal validity and concurrent validity of the 30CST and 10MWT in patients following TKA. This was accomplished, as the relative reliability and absolute reliability were determined at two time points along with the SRM and ES. Further support for using these performance-based measures was provided by revealing low to moderate correlations to the GRC*f* and WOMAC*pf*. The results suggest that using these two performance-based measures is appropriate for those undergoing rehabilitation following total knee arthroplasty.

Limitations

The limitations of the study are as follows:

- Patients were completing rehabilitation at the same centre; however, specific interventions would be based on the patient's individual situation and therapist treatment philosophies. The variation in treatment may impact the level and pace of improvement. For example, if patient A had been introduced to the sit test in week 1 of treatment as an exercise vs. patient B who had not been introduced to sit to as an exercise until week 6, the level of improvement would vary possibly due to familiarity of the exercise.
- 2) There was some variation in the time when participants entered the study (i.e. their first postoperative physical therapy assessment). The mean (SD) time from surgery to first physical therapy visit was 29.24 (±5.55) days. The 6-week and 12-week assessments were based on the time from surgery.

Strengths

- The study met the required sample size to explore both our validity and reliability objectives. Only two subjects were lost to follow up.
- The demographics of the sample suggest the results are generalizable to those who have undergone a unilateral TKA and are appropriate for those who are undergoing rehabilitation following TKA.
- 3) The study evaluated the measurement properties and established point estimates and described the MDC90 for the two PBOM at both 6 weeks and 12 weeks following TKA. This will allow clinicians to be confident in their interpretation of results during testing sessions at different time points in recovery.

Summary and Recommendations

- Both performance-based outcome measures are feasible and easy to administer. Compared to other recommended tests (40MFWT, Stair Climb Test), these require little equipment and time to administer. These measures capture aspects of function that are important for individuals following TKA and assist both clinician and patient in realizing change has occurred and not just relying on selfreport and impairment measures which may not fully capture functional change.
- 2) This study explored the measurement properties of the tests in the first 12 weeks following TKA. There is a need to continue to measure these tests further out in the recovery process. This may also assist in implementation of rehabilitation guidelines where discharge from physiotherapy was based more on function than time.

References

- 1. Hip and knee replacements in Canada: CJRR report | CIHI. https://www.cihi.ca/en/hip-and-knee-replacements-in-canada-cjrr-report-0. Accessed September 4, 2019.
- Kurtz SM, Ong KL, Lau E, et al. International survey of primary and revision total knee replacement. *Int Orthop.* 2011;35(12):1783-1789. doi:10.1007/s00264-011-1235-5
- Evans JT, Walker RW, Evans JP, Blom AW, Sayers A, Whitehouse MR. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *Lancet*. 2019;393(10172):655-663. doi:10.1016/S0140-6736(18)32531-5
- 4. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KDJ. Patient satisfaction after total knee arthroplasty: Who is satisfied and who is not? *Clin Orthop Relat Res.* 2010;468(1):57-63. doi:10.1007/s11999-009-1119-9
- Tilbury C, Haanstra TM, Leichtenberg CS, et al. Primary Arthroplasty Unfulfilled Expectations After Total Hip and Knee Arthroplasty Surgery: There Is a Need for Better Preoperative Patient Information and Education. *J Arthroplasty*. 2016;31(10):2139-2145. doi:10.1016/j.arth.2016.02.061
- 6. Imada A, Nelms N, Halsey D, Blankstein M. Physical therapists collect different outcome measures after total joint arthroplasty as compared to most orthopaedic surgeons: a New England study. *Arthroplast Today*. 2018;4(1):113-117. doi:10.1016/j.artd.2017.08.003
- Westby MD, Brittain A, Backman CL. Expert Consensus on Best Practices for Post-Acute Rehabilitation After Total Hip and Knee Arthroplasty: A Canada and United States Delphi Study. *Arthritis Care Res (Hoboken)*. 2014. doi:10.1002/acr.22164
- 8. Stevens-Lapsley JE, Schenkman ML, Dayton MR. Comparison of Self-Reported Knee Injury and Osteoarthritis Outcome Score to Performance Measures in Patients After Total Knee Arthroplasty. *PM&R*. 2011;3(6):541-549. doi:10.1016/j.pmrj.2011.03.002

- Mizner RL, Petterson SC, Clements KE, Zeni JA, Irrgang JJ, Snyder-Mackler L. Measuring Functional Improvement After Total Knee Arthroplasty Requires Both Performance-Based and Patient-Report Assessments. *J Arthroplasty*. 2011;26(5):728-737. doi:10.1016/j.arth.2010.06.004
- Kennedy D, Stratford PW, C Pagura SM, Walsh M, Woodhouse LJ. Comparison of Gender and Group Differences in Self-Report and Physical Performance Measures in Total Hip and Knee Arthroplasty Candidates. *J Arthroplasty*. 2002;17(1):70-77. doi:10.1054/arth.2002.29324
- Force TKTT. Total Joint Arthroplasty and Outcome Measures (TJAOM) Toolkit / Department of Physical Therapy.; 2016. https://physicaltherapy.med.ubc.ca/physical-therapy-knowledge-broker/total-jointarthroplasty-and-outcome-measures-tjaom-toolkit/. Accessed September 4, 2019.
- Dobson F, Hinman RS, Roos EM, et al. OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. *Osteoarthr Cartil.* 2013;21(8):1042-1052. doi:10.1016/j.joca.2013.05.002
- 13. Health Quality Ontario. *Rehabilitative Care Alliance: Rehabilitative Care Best Practices for Patients with Primary Hip & Knee Replacement.*; 2017. doi:10.1002/14651858.CD004957.pub3
- 14. Davis AM, Perruccio A V., Ibrahim S, et al. The trajectory of recovery and the inter-relationships of symptoms, activity and participation in the first year following total hip and knee replacement. *Osteoarthr Cartil*. 2011;19(12):1413-1421. doi:10.1016/j.joca.2011.08.007
- 15. Kennedy DM, Stratford PW, Riddle DL, Hanna SE, Gollish JD. Assessing Recovery and Establishing Prognosis Following Total Knee Arthroplasty Background and Purpose. *Phys Ther*. 2008;88(1):22-32. www.ptjournal.org. Accessed August 12, 2019.
- 16. Malfait AM. Osteoarthritis year in review 2015: biology. *Osteoarthr Cartil.* 2016;24(1):21-26. doi:10.1016/j.joca.2015.09.010
- 17. Chen D, Shen J, Zhao W, et al. Osteoarthritis: toward a comprehensive understanding of pathological mechanism. *Bone Res.* 2017;5:16044. doi:10.1038/boneres.2016.44

- Loeser RF, Olex AL, McNulty MA, et al. Disease Progression and Phasic Changes in Gene Expression in a Mouse Model of Osteoarthritis. Rannou F, ed. *PLoS One*. 2013;8(1):e54633. doi:10.1371/journal.pone.0054633
- March L, Cross M, Arden N, Hawker G. Osteoarthritis: A Serious Disease.;
 2016:1-103. https://www.oarsi.org/sites/default/files/docs/2016/oarsi_white_paper_oa_serious_ disease_121416_1.pdf.
- 20. WHO | Chronic rheumatic conditions. *WHO*. 2016. https://www.who.int/chp/topics/rheumatic/en/. Accessed September 4, 2019.
- 21. Dekker J, Van Dijk GM, Veenhof C. Risk factors for functional decline in osteoarthritis of the hip or knee. *Curr Opin Rheumatol*. 2009;21(5):520-524. doi:10.1097/BOR.0b013e32832e6eaa
- Sharif B, Kopec J, Bansback N, et al. Projecting the direct cost burden of osteoarthritis in Canada using a microsimulation model. *Osteoarthr Cartil*. 2015;23(10):1654-1663. doi:10.1016/j.joca.2015.05.029
- 23. Sharif B, Garner R, Hennessy D, Sanmartin C, Flanagan WM, Marshall DA. Productivity costs of work loss associated with osteoarthritis in Canada from 2010 to 2031. *Osteoarthr Cartil*. 2017;25(2):249-258. doi:10.1016/j.joca.2016.09.011
- 24. Rahman MM, Kopec JA, Cibere J, Goldsmith CH, Anis AH. The relationship between osteoarthritis and cardiovascular disease in a population health survey: a cross-sectional study. *BMJ*. 2013;3(5):e002624. doi:10.1136/bmjopen-2013
- 25. Rahman MM, Cibere J, Anis AH, Goldsmith CH, Kopec JA. Risk of Type 2 Diabetes among Osteoarthritis Patients in a Prospective Longitudinal Study. *Int J Rheumatol.* November 2014. doi:10.1155/2014/620920
- 26. Reeuwijk KG, de Rooij M, van Dijk GM, Veenhof C, Steultjens MP, Dekker J. Osteoarthritis of the hip or knee: which coexisting disorders are disabling? *Clin Rheumatol*. 2010;29(7):739-747. doi:10.1007/s10067-010-1392-8
- Gad B V., Higuera CA, Klika AK, Elsharkawy KA, Barsoum WK. Validity of Patient-Reported Comorbidities Before Total Knee and Hip Arthroplasty in Patients Older Than 65 years. *J Arthroplasty*. 2012;27(10):1750-1756. doi:10.1016/J.ARTH.2012.05.005

- 28. Gore M, Tai K-S, Sadosky A, Leslie D, Stacey BR. Clinical comorbidities, treatment patterns, and direct medical costs of patients with osteoarthritis in usual care: a retrospective claims database analysis. *J Med Econ*. 2011;14(4):497-507. doi:10.3111/13696998.2011.594347
- 29. Nielen MM, van Sijl AM, Peters MJ, Verheij RA, Schellevis FG, Nurmohamed MT. Cardiovascular disease prevalence in patients with inflammatory arthritis, diabetes mellitus and osteoarthritis: a cross-sectional study in primary care. *BMC Musculoskelet Disord*. 2012;13(1):150. doi:10.1186/1471-2474-13-150
- 30. Chapple CM, Nicholson H, Baxter GD, Abbott JH. Patient characteristics that predict progression of knee osteoarthritis: A systematic review of prognostic studies. *Arthritis Care Res.* 2011;63(8):1115-1125. doi:10.1002/acr.20492
- McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the nonsurgical management of knee osteoarthritis. *Osteoarthr Cartil*. 2014;22(3):363-388. doi:10.1016/j.joca.2014.01.003
- 32. Bannuru RR, Schmid CH, Kent DM, Vaysbrot EE, Wong JB, McAlindon TE. Comparative Effectiveness of Pharmacologic Interventions for Knee Osteoarthritis. *Ann Intern Med.* 2015;162(1):46. doi:10.7326/m14-1231
- 33. Lanza FL, Chan FKL, Quigley EMM, et al. Guidelines for prevention of NSAIDrelated ulcer complications. *Am J Gastroenterol*. 2009;104(3):728-738. doi:10.1038/ajg.2009.115
- 34. Hsu CC, Wang H, Hsu YH, et al. Use of Nonsteroidal Anti-Inflammatory Drugs and Risk of Chronic Kidney Disease in Subjects with Hypertension: Nationwide Longitudinal Cohort Study. *Hypertension*. 2015;66(3):524-533. doi:10.1161/HYPERTENSIONAHA.114.05105
- Liu G, Yan Y-P, Zheng X-X, et al. Meta-Analysis of Nonsteroidal Anti-Inflammatory Drug Use and Risk of Atrial Fibrillation. *Am J Cardiol*. 2014;114(10):1523-1529. https://linkinghub.elsevier.com/retrieve/pii/S0002914914017093. Accessed August 11, 2019.
- 36. Trelle S, Reichenbach S, Wandel S, et al. Cardiovascular safety of non-steroidal anti-inflammatory drugs: Network meta-analysis. *BMJ*. 2011;342:c7056. doi:10.1136/bmj.c7086

- 37. Messier SP, Mihalko SL, Legault C, et al. Effects of intensive diet and exercise on knee joint loads, inflammation, and clinical outcomes among overweight and obese adults with knee osteoarthritis: The IDEA randomized clinical trial. *JAMA J Am Med Assoc.* 2013;310(12):1263-1273. doi:10.1001/jama.2013.277669
- 38. Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and metaanalysis. *Ann Rheum Dis.* 2007;66(4):433-439. doi:10.1136/ard.2006.065904
- 39. Zheng H, Chen C. Body mass index and risk of knee osteoarthritis: systematic review and meta-analysis of prospective studies. *BMJ*. 2015;5(12):e007568. doi:10.1136/bmjopen-2014-007568
- 40. Uthman OA, Van Der Windt DA, Jordan JL, et al. Exercise for lower limb osteoarthritis: Systematic review incorporating trial sequential analysis and network meta-analysis. *Br J Sports Med.* 2014;48(21):1579. doi:10.1136/bjsports-2014-5555rep
- 41. Fransen M, Mcconnell S, Harmer AR, et al. Exercise for osteoarthritis of the knee: a Cochrane systematic review. *Br J Sports Med.* 2015;49(24):1554-1557. doi:10.1136/bjsports-2015-095424
- 42. Ageberg E, Roos EM. Neuromuscular Exercise as Treatment of Degenerative Knee Disease. *Exerc Sport Sci Rev.* 2015;43(1):14-22. www.acsm-essr.org. Accessed August 11, 2019.
- 43. Roos EM, Juhl CB. Osteoarthritis 2012 year in review: rehabilitation and outcomes. *Osteoarthr Cartil*. 2012;20(12):1477-1483. doi:10.1016/j.joca.2012.08.028
- 44. Petterson SC, Mizner RL, Stevens JE, et al. Improved function from progressive strengthening interventions after total knee arthroplasty: A randomized clinical trial with an imbedded prospective cohort. *Arthritis Care Res.* 2009;61(2):174-183. doi:10.1002/art.24167
- 45. Feng JE, Novikov D, Anoushiravani AA, Schwarzkopf R. Total knee arthroplasty: improving outcomes with a multidisciplinary approach. *J Multidiscip Healthc*. 2018:11-63. doi:10.2147/JMDH.S140550

- 46. Minns Lowe CJ, Barker KL, Dewey M, Sackley CM. Effectiveness of physiotherapy exercise after knee arthroplasty for osteoarthritis: Systematic review and meta-analysis of randomised controlled trials. *Br Med J*. 2007;335(7624):812-815. doi:10.1136/bmj.39311.460093.BE
- 47. Westby MD, Brittain A, Backman CL. Expert consensus on best practices for postacute rehabilitation after total hip and knee arthroplasty: A Canada and United States Delphi study. *Arthritis Care Res.* 2014. doi:10.1002/acr.22164
- Büker N, Akkaya S, Akkaya N, et al. Comparison of Effects of Supervised Physiotherapy and a Standardized Home Program on Functional Status in Patients with Total Knee Arthroplasty: A Prospective Study. *J Phys Ther Sci.* 2014;26(10):1531-1536. doi:10.1589/jpts.26.1531
- 49. Bruun-Olsen V, Heiberg KE, Wahl AK, Mengshoel AM. The immediate and longterm effects of a walking-skill program compared to usual physiotherapy care in patients who have undergone total knee arthroplasty (TKA): A randomized controlled trial. *Disabil Rehabil*. 2013;35(23):2008-2015. doi:10.3109/09638288.2013.770084
- 50. Harmer AR, Naylor JM, Crosbie J, Russell T. Land-based versus water-based rehabilitation following total knee replacement: A randomized, single-blind trial. *Arthritis Care Res.* 2009;61(2):184-191. doi:10.1002/art.24420
- 51. Pozzi F, Snyder-Mackler L, Zeni J. Physical exercise after knee arthroplasty: a systematic review of controlled trials. *Eur J Phys Rehabil Med.* 2013;49(6):877.
- 52. Artz N, Elvers KT, Lowe CM, Sackley C, Jepson P, Beswick AD. Effectiveness of physiotherapy exercise following total knee replacement: systematic review and meta-analysis. *BMC Musculoskelet Disord*. 2015;16(1):15. doi:10.1186/s12891-015-0469-6
- 53. Stratford PW, Kennedy DM. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. *J Clin Epidemiol*. 2006;59(2):160-167. doi:10.1016/j.jclinepi.2005.07.012
- 54. Stratford PW, Kennedy DM, Riddle DL. New study design evaluated the validity of measures to assess change after hip or knee arthroplasty. *J Clin Epidemiol*. 2009;62(3):347-352. doi:10.1016/j.jclinepi.2008.06.008

- 55. Kennedy DM, Stratford PW, Wessel J, Gollish JD, Penney D. Assessing stability and change of four performance measures: A longitudinal study evaluating outcome following total hip and knee arthroplasty. *BMC Musculoskelet Disord*. 2005;6. doi:10.1186/1471-2474-6-3
- 56. Finch E, Canadian Physiotherapy Association. Physical Rehabilitation Outcome Measures : A Guide to Enhanced Clinical Decision Making. BC Decker; 2002. https://books.google.ca/books/about/Physical_Rehabilitation_Outcome_Measures. html?id=_2aJPgAACAAJ&redir_esc=y. Accessed September 4, 2019.
- 57. Portney, L.G. and Watkins, M.P. (2000) Foundations of clinical research: Applications to practice. 2nd Edition, Prentice Hall Health USR.
- 58. Fleiss JL. The Design and Analysis of Clinical Experiments. New York: John Wiley & Sons; 1986.
- 59. Liang MH. Longitudinal construct validity: Establishment of clinical meaning in patient evaluative instruments. *Med Care*. 2000;38(9 SUPPL. 2):84-90.
- 60. Hossain FS, Konan S, Patel S, Rodriguez-Merchan EC, Haddad FS. The assessment of outcome after total knee arthroplasty: are we there yet? *Bone Joint J*. 2015;97-B(1):3-9. doi:10.1302/0301-620X.97B1.34434
- 61. Dobson F, Hinman RS, Hall M, et al. Reliability and measurement error of the Osteoarthritis Research Society International (OARSI) recommended performance-based tests of physical function in people with hip and knee osteoarthritis. *Osteoarthr Cartil*. 2017;25(11):1792-1786. doi:10.1016/j.joca.2017.06.006
- 62. McAuley C, Hoens A, Troughton D, Field R, Duggan M, Reid W. A Survey of Physiotherapists' Experience Using Outcome Measures in Total Hip and Knee Arthroplasty. *Physiother Canada*. 2014;66(3):274-285. doi:10.3138/ptc.2013-34
- 63. Gill S, McBurney H. Reliability of performance-based measures in people awaiting joint replacement surgery of the hip or knee. *Physiother Res Int.* 2008. doi:10.1002/pri.411
- 64. Gill SD, De Morton NA, Mc Burney H. An investigation of the validity of six measures of physical function in people awaiting joint replacement surgery of the hip or knee. *Clin Rehabil.* 2012;26(10):945-951. doi:10.1177/0269215511434993

- Fransen, M, Crosbie, J, Edmonds J. Reliability of Gait Measurements in People With Osteoarthritis of the Knee. *Phys Ther*. 1997;77(9):944-953. https://academic.oup.com/ptj/article-abstract/77/9/944/2633206. Accessed August 24, 2019.
- 66. Perera S, Mody SH, Woodman RC, Studenski SA. Meaningful change and responsiveness in common physical performance measures in older adults. *J Am Geriatr Soc.* 2006;54(5):743-749. doi:10.1111/j.1532-5415.2006.00701.x
- 67. Barthuly AM, Bohannon RW, Gorack W. Gait speed is a responsive measure of physical performance for patients undergoing short-term rehabilitation. *Gait Posture*. 2012;36(1):61-64. doi:10.1016/j.gaitpost.2012.01.002
- 68. Davey RC, Edwards SM, Cochrane T. Test-retest reliability of lower extremity functional and self-reported measures in elderly with osteoarthritis. *Adv Physiother*. 2003;5(4):155-160. doi:10.1080/1403819038190310017075
- 69. Marks R. Reliability and validity of self-paced walking time measures for knee osteoarthritis. *Arthritis Rheum*. 1994;7(1):50-53. doi:10.1002/art.1790070111
- 70. Jones J, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. *Res Q Exerc Sport Jun.* 1999;70(2).
- 71. Guralnik JM, Simonsick EM, Ferrucci L, et al. A Short Physical Performance Battery Assessing Lower Extremity Function: Association With Self-Reported Disability and Prediction of Mortality and Nursing Home Admission. *J Gerontol*. 1994;49(2):M85-M94. doi:10.1093/geronj/49.2.M85
- 72. Csuka M, McCarty DJ. Simple method for measurement of lower extremity muscle strength. *Am J Med.* 1985;78(1):77-81. doi:10.1016/0002-9343(85)90465-6
- 73. Wright AA, Cook CE, Baxter GD, Dockerty JD, Abbott JH. A Comparison of 3 Methodological Approaches to Defining Major Clinically Important Improvement of 4 Performance Measures in Patients With Hip Osteoarthritis. *J Orthop Sport Phys Ther.* 2011. doi:10.2519/jospt.2011.3515

- 74. Tolk JJ, Janssen RPAA, Prinsen CACC, et al. The OARSI core set of performance-based measures for knee osteoarthritis is reliable but not valid and responsive. *Knee Surgery, Sport Traumatol Arthrosc.* 2017;27(9):1-12. doi:10.1007/s00167-017-4789-y
- 75. Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. *J Clin Epidemiol*. 2000;53(5):459-468. doi:10.1016/S0895-4356(99)00206-1
- 76. French HP, Fitzpatrick M, Fitzgerald O. Responsiveness of physical function outcomes following physiotherapy intervention for osteoarthritis of the knee: an outcome comparison study. *Physiotherapy*. 2011;97:302-308. doi:10.1016/j.physio.2011.08.004
- 77. Stratford PW, Kennedy D, Pagura SMC, Gollish JD. The relationship between self-report and performance-related measures: Questioning the content validity of timed tests. *Arthritis Rheum.* 2003;49(4):535-540. doi:10.1002/art.11196
- 78. Börjesson, Margareta, Weidenheim, Lars, Elfving, Britt, Olsson E. Tests of walking ability at different speeds in patients with knee osteoarthritis. *Physiother Res Int*. 2007;12(2):115-121. doi:10.1002/pri
- 79. Rikli R, Activity CJ-J of aging and physical, 1999 U. Functional fitness normative scores for community-residing older adults, ages 60-94. *J Aging Phys Act*. 1999;7:162-181. http://hdcs.fullerton.edu/csa/Research/documents/RikliJones1999FunctionalFitness NormativeScores_000.pdf. Accessed September 4, 2019.
- 80. Bohannon RW, Williams Andrews A. Normal walking speed: a descriptive metaanalysis. *Physiotherapy*. 2011;97(3):182-189. doi:10.1016/J.PHYSIO.2010.12.004
- 81. Bonett DG, Wright TA. Sample size requirements for estimating Pearson, Kendall and Spearman correlations. *Psychometrika*. 2000;65(1):23-28. doi:10.1007/BF02294183
- 82. Bonett DG. Sample size requirements for estimating intraclass correlations with desired precision. *Stat Med.* 2002;21(9):1331-1335. doi:10.1002/sim.1108

- McConnell S, Kolopack P, Davis AM. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): a review of its utility and measurement properties. *Arthritis Rheum*. 2001;45(5):453-461. doi:10.1002/1529-0131(200110)45:5<453::aid-art365>3.0.co;2-w
- Kamper SJ, Maher CG, Mackay G. Global Rating of Change Scales: A Review of Strengths and Weaknesses and Considerations for Design. *J Man Manip Ther*. 2009;17(3):163-170. doi:10.1179/jmt.2009.17.3.163
- 85. Tilson JK, Sullivan KJ, Cen SY, et al. Meaningful Gait Speed Improvement During the First 60 Days Poststroke: Minimal Clinically Important Difference. *Phys Ther*. 2010;90(2):196-208. www.ptjournal.org.
- 86. Dobson F, Hinman RSS, Hall M, Terwee CBB, Roos EMM, Bennell KLL. Measurement properties of performance-based measures to assess physical function in hip and knee osteoarthritis: A systematic review. *Osteoarthr Cartil.* 2012;20(12):1548-1562. doi:10.1016/j.joca.2012.08.015

Appendix A - Letter of Information and Consent

Reliability and Validity of Two Performance Based Outcome Measures in Rehabilitation Following Total Knee Arthroplasty

You are being invited to voluntary participate in this research study as you have recently had a total knee replacement at London Health Science Centre – University Hospital.

This letter of information describes the research study and your role as a participant. The purpose of this letter is to provide you with information required for you to make an informed decision regarding participation in this research. Please read this form carefully. Do not hesitate to ask anything about the information provided. The study supervisor, Dr. Trevor Birmingham, or co-investigator, Jen Van Bussel describe the study and answer any questions you may have. This project is part of the requirements of a Master of Science degree for Jen Van Bussel, who will be collecting the data.

Study Purpose

The purpose of this study is to determine the reliability (precision) and validity (accuracy) of the 30 Second Chair Stand Test (30 CST) and 10 Metre Walk Test (10 MWT) during rehabilitation in patients following total knee arthroplasty (TKA). Using reliable and valid outcome measures during rehabilitation will help evaluate improvements in physical function and assist in making decision regarding treatment.

Procedure

If you choose to participate in the study, you will be asked to fill out the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and complete the 30 CST and 10 MWT as part of your standard physiotherapy assessment today. These measures, along with the Global Rating of Change (GRC) will be repeated as part of a standard assessment during your scheduled follow-up visits with your physiotherapist at 6 weeks and 12 weeks following surgery. Study participation involves you attending two extra sessions where you will be asked to repeat the 30 CST and 10 MWT. These sessions will occur 24-48 hours after your 6-week and 12-week physiotherapy follow-up visit. These sessions will take approximately 10 minutes of your time to complete.

<u>Risks</u>

The perceived risks of participation are minimal. As with any test of physical function that requires you to be standing or walking there is a risk of falling. Allowing you to use any gait aid you require during the 10 MWT will control this risk. Furthermore, during the 30 CST and 10 MWT the tester will remain in close proximity to you to provide assistance if required.

Completion of the 30 CST and 10 MWT may cause a temporary increase in symptoms, which is similar to the risk associated with any physiotherapy session. You are in complete control of all aspects of these tests, and may stop at any point if you choose.

Personal data will be gathered for this study. There is a risk for breaching confidentiality of this information; however procedures are set in place to minimize this risk (see below).

Benefits and Compensation

There are no direct benefits to you as a result of participation in this study. Participation in this study may help physiotherapists in the future select reliable and valid outcome measures to use during rehabilitation following TKA. In turn this will help future patients, physiotherapists and surgeons measure true functional change and assist in clinical decision making.

Reimbursement

You will be reimbursed for parking expenses accrued during the five session, as outlined above, when testing will occur.

Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate or discontinue your participation at any time without affecting the medical care being provided to you in any way. Should you choose to withdraw, information collected will only be done as part of your standard assessment and not used in this study. The deidentified data you have contributed to that point may be used to help answer our research question.

Confidentiality

Your confidentiality will be respected. You will be given an identification number, by your physiotherapist, to use with your data collection forms. All information collected for this study will be kept confidential and identified by this number. All information collected will be stored in a locked cabinet and entered onto a secure password protected server at University Hospital. A list linking your identification number with your name will be kept on a secure password protected server at University Hospital. All information will be kept in a secure and confidential location for a minimum of 15 years.

The results of this study may be used in presentations or published in a peer reviewed scientific journal. Only group averages will be reported and your name and identity will not be disclosed.

Qualified representatives of the Lawson Quality Assurance Education Program may look at your medical/clinical study records at the site where those records are held, for quality

assurance (to check that the information collected for the study is correct and follows proper laws and guidelines).

You will be given a copy of this letter of information and consent form once it has been signed. You do not waive any legal rights by signing the consent form. Representatives of the University of Western Ontario Health Sciences Research Ethics Board my contact you or require access to your study-related records to monitor the conduct of the research.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Experience Office at LHSC. or access the online form at: https://apps.lhsc.on.ca/?q=forms/patient-experiencecontact-form.

We thank you in advance for considering participation in this study.

Sincerely,

Dr. Trevor Birmingham PT, PhD

Consent Form

Reliability and Validity of Two Performance Based Outcome Measures in Rehabilitation Following Total Knee Arthroplasty

I have read the letter of information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant name (print)

Participant signature

Person obtaining consent (print)

Signature of person obtaining consent

Date

Date

Appendix B – Data Collection Form

DATA COLLECTION FORM London Health Sciences Centre Reliability and Validity of Two Performance Ba Outcome Measures in Rehabilitation Following Knee Arthroplasty	ssed Total	(M/F)(m)(kg)	
Key: WOMAC = The Western Ontario and McM GRC Scale = Global Rating of Change S	Scale		
Date of Surgery:	Date o Number o	f Inpatient Discharge: _	(YYYYMWDD)
Initial Physiotherapy Assessment Post-Oper	ative Week #	Outcome Measure	5
Date (ҮҮҮҮ ммлоо):			STREAM: 1 2 3
Gait Aid (yes/no and type)			
WOMAC Total Score Pain Score Stiffness Score Physical Function Score 10 Metre Walk Test (seconds) 30 Second Chair Stand Test Knee Range of Motion (degrees) Numeric Pain Rating Scale Post-Operative Week #6 Outcome Measures Oatt Aid WOMAC Total Score Pain Score Pain Score Stiffness Score Physical Function Score 10 Metre Walk Test 30 Second Chair Stand Test Gait Aid WOMAC Total Score Physical Function Score 10 Metre Walk Test 30 Second Chair Stand Test GRC Scale - Function GRC Scale - Pain			STREAM: 1 2 3
Knee Range of Motion			
Post-Operative Week #12 Outcome Measures			1
	1		STREAM. 1 2 2
Date (үүүүлммлоо): Gait Aid			STREAM: 1 2 3
WOMAC Total Score Pain Score Stiffness Score Physical Function Score 10 Metre Walk Test 30 Second Chair Stand Test GRC Scale - Function GRC Scale - Pain Knee Range of Motion			
Comments:			

Version 26,06/2018

Appendix C – Performance Based Outcome Measures

Performance – Based Outcome Measures of Function

30 Second Chair Stand Test (30 CST)

The 30 CST assesses functional lower extremity strength and dynamic balance through an evaluation of the ability to rise from a chair and sit back down repeatedly over 30 seconds (Bennell, 2011). The test is easy to administer and requires the use of a stopwatch and straight back chair with a 17-inch seat height without arms. The test has demonstrated both reliability and validity in those awaiting joint replacement surgery of the hip or knee (Gill 2008; 2012).

10 Metre Walk Test (10 MWT)

A self-paced walk test is used in many groups, including those with hip and knee OA. Gait speed has been established as a responsive and predictive measure for multiple patient populations (Bennell, 2011). The test requires the participant to walk as fast as they can, safely, over a distance of 10 metres. Gait aids may be used as required during the test and use will be noted by the tester.

Protocol for the 30 Second Chair Stand Test

Patient Set Up

- 1. Use a chair with a 17-inch seat height.
- 2. Place the chair against a wall to prevent it from moving.
- 3. Sit the patient comfortably in the middle of the chair.
- 4. Allow the patient to position their feet where they are comfortable.
- 5. Ask them to cross their arms across their chest.

Instructions to Patient

- 1. "This test looks at how many times you can stand and sit from a chair in 30 seconds."
- 2. "If you do not fully stand or sit down so that your bottom touches the seat, that repetition will not be counted."
- 3. Demonstrate movement.
- 4. Allow one practice stand by the patient.
- 5. "When I say "GO", I want you to stand up and sit down as many times as you can in 30 seconds."
- 6. "If you have pain that becomes too uncomfortable, you are allowed to stop the test."
- 7. "Do you understand what you need to do?"
- 8. "Are you ready?"
- 9. "Ready, set GO."

General Guidelines

- 1. If the patient is more than halfway up at the end of 30 seconds, it counts as a full stand.
- 2. Do not offer any encouragement before or after each test other than "well done".
- 3. If the patient expresses concern about performing a task, tell them to "do the best that you can".

(Adapted from: Gill and McBurney, 2008, p.151)

Protocol for the 10 Metre Walk Test

Patient Set Up

- 1. Mark out a 14-metre walkway with lines at 0m, 2m, 12m and 14m.
- 2. Instruct the patient to stand with toes touching the line at the 0m mark.

Instructions to Patient

- 1. "I am going to time how fast you can walk 10 metres"
- 2. "I want you to go as fast as you can safely walk. You will walk from the yellow line to the other yellow line at the end of the walkway."
- 3. Demonstrate the test and show the patient where the end line is.
- 4. "I want you to start when I say "GO", and I will give you a "Ready, Set, GO""
- 5. "If you have pain that becomes too uncomfortable, you are allowed to stop the test"
- 6. "Do you understand what you need to do?"
- 7. "Are you ready?"
- 8. "Ready, set, GO"

General Guidelines

- 1. Timing: start the stopwatch as the first part of the patient's trunk or foot crosses the 2m-mark. This allows for acceleration of gait speed to occur prior to time starting. Stop the stopwatch as the first part of their trunk or foot crosses the 12m-mark. This will eliminate the effect of deceleration on test results.
- 2. Walk a pace behind the patient to avoid influencing pace but be close enough to ensure safety.
- 3. The patient can use their usual and most appropriate gait aid.
- 4. Do not offer any encouragement before or after the test other than "well done".
- 5. If a patient expresses concern about performing the task, tell them to "do their best".

(Adapted from: Gill and McBurney, 2008, p.151)

Appendix D – WOMAC

The Western Ontario and McMaster U	Iniversities Osteoarthritis Index (WOMAC)
------------------------------------	-------------------------------------	--------

Instructions: Please	e rate the followi	ng activities in ea	ach category acco	ording to the following scale of
difficulty:				

0 = None 1 = Slight 2 = Moderate 3 = Very 4 = Extremely

Circle one number	for each activity		
Pain	1. Walking		01234
	2. Stair Climbing		01234
	3. Nocturnal		01234
	4. Rest		01234
	5. Weight Bearing		01234
Stiffness	1. Morning stiffness		01234
	2. Stiffness occurring later in the da	iy	01234
Physical Function	1. Descending stairs		01234
	2. Ascending stairs		01234
	3. Rising from sitting		01234
	4. Standing		01234
	5. Bending to floor		01234
	6. Walking on flat surface		01234
	7. Getting in / out of car		01234
	8. Going shopping		01234
	9. Putting on socks		01234
	10. Lying in bed		01234
	11. Taking off socks		01234
	12. Rising from bed		01234
	13. Getting in / out of bath		01234
	14. Sitting		01234
	15. Getting on / off toilet		01234
	16. Heavy domestic duties		01234
	17. Light domestic duties		01234
Pain Score:	/20	Stiffness Score: _	/8
Physical Fu	nction Score:/68	Total Score:	/96%

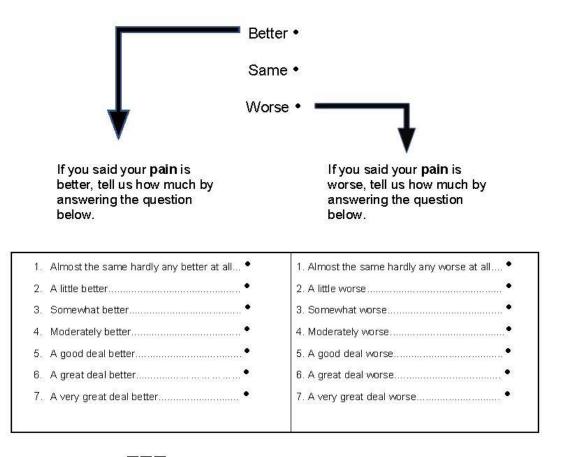
Study ID Number

May 2018, Version 1

Appendix E – Global Rating of Change Scale - Pain

Global Rating of Change Scale - PAIN

With respect to your joint replacement surgery, how would you describe your *pain* now compared to when you first started physiotherapy here at University Hospital?



Study ID Number

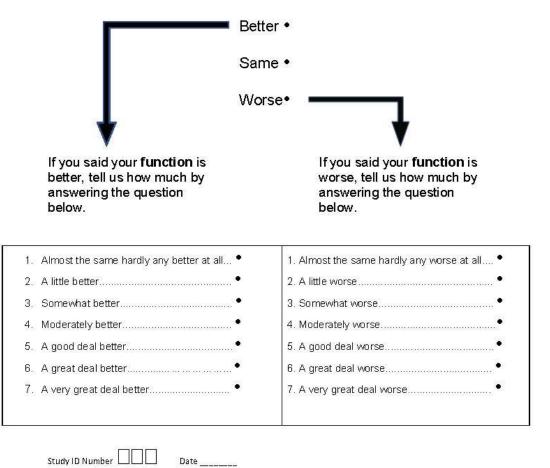
Date _____

May 2018, Version 1

Appendix F – Global Rating of Change Scale - Function

Global Rating of Change Scale - FUNCTION

With respect to your joint replacement surgery, how would you describe your *function* now compared to when you first started physiotherapy here at University Hospital?



Study ID Number

May 2018, Version 1

Appendix G – Ethics Approval



Date: 2 July 2018

To: Dr. Trevor Birmingham

Project ID: 111857

Study Title: Reliability and Validity of Two Performance Based Outcome Measures in Rehabilitation Following Total Knee Arthroplasty

Application Type: HSREB Initial Application

Review Type: Delegated

Full Board Reporting Date: 17July2018

Date Approval Issued: 02/Jul/2018 15:09

REB Approval Expiry Date: 02/Jul/2019

Dear Dr. Trevor Birmingham

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

Document Type	Document Date	Document Version
Other Data Collection Instruments	26/Jun/2018	2
Paper Survey	01/May/2018	1
Paper Survey	01/May/2018	1
Written Consent/Assent	26/Jun/2018	2
Protocol	01/May/2018	1
Paper Survey	01/May/2018	1
	Other Data Collection Instruments Paper Survey Paper Survey Written Consent/Assent Protocol	Date Other Data Collection 26/Jun/2018 Instruments Paper Survey 01/May/2018 01/May/2018 Paper Survey 01/May/2018 Written Consent/Assent 26/Jun/2018 Protocol 01/May/2018

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Nicola Geoghegan-Morphet, Ethics Officer on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).

Page 1 of 2

Curriculum Vitae

Academic Background:

2019	Master of Science (Physical Therapy) Western University London, Ontario, Canada
2010	Diploma of Advanced Manual and Manipulative Physiotherapy Canadian Physiotherapy Association – Orthopaedic Division Toronto, Ontario, Canada
2006	Diploma of Intermediate Manual and Manipulative Physiotherapy Canadian Physiotherapy Association – Orthopaedic Division Toronto, Ontario, Canada
2001	Bachelor of Science (Physical Therapy with Distinction) The University of Western Ontario London, Ontario, Canada
1998	Bachelor of Science (Exercise Science with Distinction) Specialization in Athletic Therapy Concordia University Montreal, Quebec, Canada
Honours and Award	s:
2017-18	UWO Health Sciences Teaching Excellence Recognition
2003	Silver Quill Award Canadian - Physiotherapy Association
2001	Ann Collins Whitmore Award - Physiotherapy Foundation of Canada
2001	Barbara Edwardson Orthopaedic Award
Related Work Expen	rience:
2019 – present	Advanced Practice Provider

2019 – přesení	SW LHIN Musculoskeletal Rapid Access Clinic – Hip and Knee London Health Sciences Centre
2012 - 2019	Physiotherapist London Health Sciences Centre – Surgical Care Program

2004 - 2012	Physiotherapist Fowler Kennedy Sport Medicine Clinic
2006 - 2007	Independent Consultant Physiomed Health
2001-2004	Clinic Manager and Physiotherapist – Argyle and Strathroy Clinics - Spine and Joint Physiotherapy Centre

Related Teaching Experience:

2013 - present	Lecturer Western University
2010 - present	Instructor and Mentor Canadian Physiotherapy Association – Orthopaedic Division
2007 - 2008	Orthopaedic Residency/Fellowship Program Faculty <i>Brooks Rehabilitation</i> Jacksonville, Florida, USA

Publications:

Palmer, J. L., Young, S., Fox, E., Lindsay, D. & Vandervoort, A. A. (2003). Senior Recreational golfers: A survey of musculoskeletal conditions, playing characteristics, and warm-up patterns. *Physiotherapy Canada*, 55(2) 79-85.