

PHYSICAL FUNCTION IN  
TOTAL KNEE ARTHROPLASTY (TKA) PATIENTS

(Summary of Dissertation Studies)

**Study 1:** Validity of CS-PFP10 Test in Unilateral and Bilateral TKA Patients

**Study 2:** Physical Function in TKA Patients

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## ABSTRACT

The general objective of these two studies was to investigate physical function in osteoarthritis (OA) and total knee replacement (TKA) patients. First, a validation study was performed to evaluate the validity of the Continuous Scale Physical Functional Performance (CS-PFP10) test in knee OA awaiting TKA. The CS-PFP10 scores were compared to the Western Ontario and McMaster Universities OA Index (WOMAC), The Knee Society's Clinical Rating System (KSS), and the Short Form 36-item health survey (SF-36) physical function scores. It was hypothesized that at least moderate associations between the CS-PFP10 test scores and the WOMAC, KSS, and SF-36 scores in TKA candidates exist. The results of this study indicated moderate to strong associations between the CS-PFP10 and other physical function scores ( $r=.474$  to  $.598$ ,  $p<.001$ ) showing that the CS-PFP10 is a valid tool for measuring physical function in OA/TKA patients.

The second study was a 12-week prospective study investigating the return of physical function in TKA patients following surgery. We also examined the sensitivity of the CS-PFP10 test to change in TKA patients. The hypotheses of this investigation included that the CS-PFP10 would be sensitive to functional changes in TKA patients and that the magnitude of effect sizes during the initial recovery period following surgery (between 3 and 6 weeks post-op) would be greatest for the CS-PFP10 and the KSS. Finally, we hypothesized that improvements in objective measures of function would not be affected by dispositional optimism, but the subjective measures would be.

Consistent with our hypotheses, the results demonstrated a functional incline over the time course of the study. The effect sizes of the follow-up data suggest that the CS-PFP10 is sensitive in detecting change in function over time, even in a small group of patients. Unexpectedly, the CS-PFP10 indicated an initial drop in physical function immediately after surgery (3 weeks

post), while the other tests did not. These findings indicate that there are differences in perceived and performance-based physical function and could be an indication of the CS-PFP10 being a more sensitive measure of function when compared to the other instruments.

## STUDY 1: VALIDITY OF CS-PFP10 TEST IN UNILATERAL AND BILATERAL TKA PATIENTS

Knee osteoarthritis (OA) accounts for a large percentage of mobility disability in the United States and is one of the most common chronic diseases<sup>1, 2</sup>. It has a significant negative effect on physical function and the ability to perform activities of daily living(ADL)<sup>3</sup>. Traditionally, physical function in these patients has been measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)<sup>4, 5</sup>, the Knee Society Clinical Rating System (KSS),<sup>6</sup> or the Short Form Health Survey (SF-36)<sup>7</sup>. The WOMAC and the SF-36 are subjective survey instruments that rely solely on patient self-reported information, and the KSS contains clinical (objective) and self-report (subjective) items.

There are some known limitations of self-report measures including possible floor and ceiling effects, lack of sensitivity to change, and errors in participant judgment or memory. In addition, the ability and willingness of patients to answer questions correctly and discrepancies between perception and actual ability need to be considered when using self-report measures<sup>8, 9</sup>. Furthermore, studies have shown that OA can lead to increased emotional distress, anxiety, depression, and fatigue. These factors may influence self-perception of function and pain, potentially presenting further limitations with survey-type measures of physical function<sup>10, 6</sup>. Thus, assessing and quantifying the degree of functional disability caused by knee OA solely based on self-report is problematic insofar as the influence of psychosocial factors on self-perceived function is not known and is likely a source of significant random error.

Of the traditional approaches to measuring function in knee OA patients, the KSS is the only one that incorporates some objective items. In addition to self-report items, this assessment includes physician appraisal of knee stability, alignment, and range of motion<sup>11</sup>. Unfortunately, however, knee stability, alignment, and range of motion are more aptly defined as measures of impairment and not measures of functional ability per-se. Thus, valid objective measures of

function for knee OA patients are virtually unavailable. Thus, there has been considerable interest in the development of measures of physical function that can be universally applied across various patient groups with greater specificity and sensitivity in comparison to those instruments that are presently available<sup>10, 12, 26, 38</sup>. Additionally, standardization of measures would allow investigators the opportunity to make comparisons across studies.

In 1996, Cress et al. introduced the Continuous Scale Physical Function Performance test (CS-PFP), which is a collection of 16 items requiring the subject to execute basic and instrumental ADL in a standardized fashion. The CS-PFP was introduced as an option for attaining objective measures of physical function in older adults. More recently Cress et al published a 10-item version of the test (CS-PFP10)<sup>8, 13, 40</sup>. Because the CS-PFP and CS-PFP10 include items that are not based on patients' perception and follows a standardized laboratory set-up and protocol, it is not subject to certain problems inherent in self-report measures such as the SF-36 and WOMAC. The CS-PFP10 has been extensively validated for use in the general population of older adults and has high convergent validity and predictive validity<sup>8, 13, 14</sup>. The tests correlate well with other measures of function and laboratory tests of physical fitness, and discriminates between adults living independently and those living with assistance<sup>8, 13, 14</sup>.

Other advantages of performance-based tests, such as the CS-PFP and CS-PFP10, include that they may be better suited for between-subject comparisons than self-report measures because the basis of comparison is the same<sup>15</sup>. Performance based-tests can also be predictive of future disability and mortality, and provide us information about how a patient may perform in similar tasks during daily activities, which may be different from their perceived functional ability<sup>8</sup>. Thus, the need for examining and refining quantifiable measures of function that are capable of reflecting the OA patient's ability to execute basic and instrumental ADL is apparent.

The CS-PFP10 testing paradigm has been employed in the knee OA population in a few preliminary studies of patients following total knee arthroplasty (TKA), and these were only published as abstracts<sup>16-18</sup>. Petrella et al. measured physical function with the CS-PFP10 in 13 TKA patients that received an early rehabilitation program focusing on functional ROM. The reported mean values for the total CS-PFP10 scores at baseline were 49.2±15 for TKA candidates and 78.7±15 for age-matched controls. Furthermore, the authors report a 19% improvement in functional scores that occurred over the time period between 1- and 3-month post-surgery<sup>17</sup>. Garrison et al.<sup>16, 18</sup>, examined the convergent validity of the CS-PFP10 in TKA patients immediately prior to TKA surgery. Moderate associations between the CS-PFP10 and other commonly used measures of physical function were reported and the largest correlation coefficients were between the CS-PFP10 scores and the KSS function score ( $r = 0.605$ ) and WOMAC Physical Function score ( $r = -0.551$ )<sup>16</sup>. A comparison of functional improvement in CS-PFP10 scores revealed that the percent improvement in scores following TKA reported by Garrison et al. (pre-TKA to 3 months post= 24.7%) were somewhat similar to those reported by Petrella et al. (1 months post TKA to 3 months post = 19%)<sup>17, 18</sup>. The findings from these preliminary studies<sup>16-18</sup> suggest that the CS-PFP10 may be a useful tool for measuring functional performance in the severe OA patients/knee replacement candidates<sup>16, 18</sup>.

### Specific Aims and Hypothesis

The primary purpose of this investigation was to examine the convergent validity of the CS-PFP10 test in a sample of patients with knee OA awaiting TKA including uni- and bilateral TKA candidates. More specifically, the CS-PFP10 scores were compared to the WOMAC, KSS, and the SF-36 physical function scores. The hypothesis of this investigation was that correlation analysis would reveal at least moderate associations between the CS-PFP10 test scores and the WOMAC, KSS, and SF-36 scores in TKA candidates.

## Method

### Participants

A sample of 68 ( $n = 68$ ) TKA candidates were recruited from one orthopaedic clinic with two participating surgeons. The sample included 18 men and 50 women between the ages of 50-85. There were 32 bilateral and 36 unilateral TKA candidates, and TKA candidacy was determined by the examining physician based on several factors including (but not limited to) impaired quality of life, severe knee pain and stiffness that limits the patient's daily activities, limited function or mobility, knee deformity, and failure to obtain pain relief from previous treatment methods.

Prior to enrollment in the study, all candidates received a medical evaluation that included screening for inclusion and exclusion criteria. Inclusion criteria consisted of TKA candidates who were electing to pursue TKA, and who were otherwise apparently healthy or had a diagnosis of stable heart disease (AHA Class A and B and C-stable). Candidates in American Heart Association Class C- unstable or Class D (i.e., symptoms of cardiovascular and/or metabolic disease at rest) were excluded from the study<sup>19</sup>. Patients with other significant comorbidities such as active infection, immunosuppressive disorders, collateral ligament insufficiency (grade 3), posterior cruciate ligament insufficiency (grade two or more), drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson's disease, Multiple Sclerosis, were also excluded from the study. The inclusion and exclusion criteria are described in detail in tables 1. and 2.

**Table 1. Inclusion criteria.**

<b>Inclusion Criteria:</b>
<ul style="list-style-type: none"><li>• Men and Women age 50 to 85.</li><li>• Apparently healthy individuals, and those with stable heart disease (AHA Class A and B).</li></ul> <p><u>Class A:</u> Apparently Healthy Individuals of any age without known heart disease or major risk factors and who have a normal exercise test</p> <p><u>Class B:</u> Documented, stable cardiovascular disease with low risk for vigorous exercise but slightly greater than for apparently healthy individuals. Includes individuals with (1) CAD (MI, CABGS, PTCA, angina pectoris, abnormal exercise test, and abnormal coronary angiograms) whose condition is stable and who have the clinical characteristics outlined below; (2) valvular heart disease; (3) congenital heart disease; (4) cardiomyopathy; and (5) exercise test abnormalities that do not meet the criteria outlined in</p> <p><u>Class C:</u> Clinical characteristics: (1) New York Heart Association (NYHA) class 1 or 2; (2) exercise capacity of &gt;6 METs; (3) no evidence of heart failure; (4) free of ischemia or angina at rest or on the exercise test at or below 6 METs; (5) appropriate rise in systolic blood pressure during exercise; (6) no sequential ectopic ventricular contractions; and (7) ability to satisfactorily self-monitor intensity of activity</p> <ul style="list-style-type: none"><li>• Patient presents with non-inflammatory osteoarthritis and requires a unilateral or bilateral total knee replacement.</li><li>• Patient has moderate to severe pain in affected knee(s).</li><li>• Patient is willing to consent to participate in the study by signing and dating an IRB-approved consent form.</li><li>• Patient plans to be available for follow-up through 3 months postoperative period.</li></ul>

**Table 2 Exclusion Criteria.**

<b>Exclusion Criteria:</b>
<ul style="list-style-type: none"><li>• Patients in American Heart Association Classes D: known to have any of the following will be excluded from the study: A recent significant change in resting ECG, significant valvular heart disease, significant cardiomyopathy, previous episode of ventricular fibrillation or cardiac arrest, complex resting ventricular arrhythmias, significant three-vessel disease, low ejection fraction (&lt;30%), recent complicated myocardial infarction, unstable angina, uncontrolled ventricular dysrhythmia, uncontrolled atrial dysrhythmia, third-degree atrioventricular block, acute congestive heart failure, severe aortic stenosis, suspected or known dissecting aneurysm, active or suspected myocarditis, thrombophlebitis or intracardiac thrombi, recent systemic or pulmonary embolus.</li><li>• Acute infection.</li><li>• Significant emotional distress.</li><li>• Patient known to have insufficient femoral or tibial bone stock resulting from conditions such as cancer, distal femoral/proximal tibial osteotomy, significant osteoporosis or metabolic bone disorders.</li><li>• Patient has failed total or unicondylar knee replacement, or high tibial osteotomy (HTO) of the affected knee.</li><li>• Patient has an active, local infection or systemic infection.</li><li>• Patient has physical, emotional or neurological conditions that would compromise the patient's compliance with postoperative rehabilitation and follow-up (e.g.: drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple sclerosis, etc.).</li><li>• Patient has grade 3 collateral ligament insufficiency.</li><li>• Patient has knee flexion &lt; 90°.</li><li>• Patient has fixed flexion deformity &gt;20°.</li><li>• Patient has posterior cruciate ligament insufficiency of grade two or more.</li><li>• Patient has ipsilateral hip arthritis resulting in any flexion contracture.</li><li>• Patient has lumbar spine disease resulting in significant leg pain.</li><li>• Patient has an immunosuppressive disorder (chronic condition characterized by markedly inhibited ability to respond to antigenic stimuli.) Examples of such conditions include patients who are on immunosuppressive therapy (corticosteroid hormones in large amounts, cytotoxic drugs, antilymphocytic serum or irradiation in large doses), patients with acquired immunodeficiency syndrome (AIDS) or auto-immune diseases (except inflammatory arthritis).</li><li>• Patient is pregnant or plans to become pregnant during the course of the study.</li><li>• Patient has a known sensitivity to materials in the device.</li></ul>

## **Design**

A cross-sectional, correlational research design was employed to examine the relationship between the different instruments used to measure physical function in bilateral and unilateral TKA candidates. We simultaneously measured physical function with the WOMAC, KSS, SF-36, and CS-PFP10 approximately 1-3 weeks prior to surgery. Data were collected at a single location (The American Musculoskeletal Research Institute or AMRI) in Alexandria, LA. Two supporting physicians, Dr. David Pope and Dr. Jeffrey Garrison agreed to support the data collection procedures and provided the TKA candidates for the study.

## **Procedures**

The Institutional Review Board of Louisiana State University approved all procedures described herein. After agreeing to participate in the study, all participants signed an informed consent form. The KSS was conducted by one of the participating clinicians who were trained in obtaining the KSS clinical measurements and followed the KSS assessment protocol. Immediately following this evaluation, TKA candidates who passed the screening and consented to participate in the study completed the SF-36 and WOMAC self-report questionnaires, and performed the CS-PFP10 test. The questionnaires were given to the patient in the clinic by one of two research administrators, who also collected the questionnaires immediately upon their completion.

The same research administrator then conducted the CS-PFP10 test according to the standardized protocol. Heart rate, blood pressure, and ratings of perceived exertion were monitored throughout the CS-PFP10 testing. In addition, the participants were instructed to relate any symptoms of chest pain, dizziness, nausea, fatigue, or otherwise. The CS-PFP10 sessions were conducted by a trained CS-PFP10 technician at a facility that had on-site medical support teams equipped to respond in the event of an emergency. Unpublished data from our

laboratory indicate high inter-rater reliability between these two test administrators on all CS-PFP10 domains and total score ( $n = 13$ ; *intraclass*  $r > 0.90$ ).

## **Instruments**

**Western Ontario and McMaster Universities OA Index.** The Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) is a 24-item self-administered health questionnaire specifically designed for patients with OA of the knee or the hip. The WOMAC includes three scores purported to measure pain, disability and joint stiffness, and physical function. The WOMAC questions are scored on a 5-point Likert scale and the scores are summed for each score. A high WOMAC score indicates a high level of difficulty or disability. The WOMAC has undergone a rigorous validation process and it is widely used in the assessment of patients with hip or knee OA<sup>4, 5, 20, 21</sup>. It is a reliable and responsive tool to measure the outcome of joint replacement when compared to SF-36<sup>20</sup>. The WOMAC requires a license for use and can be obtained at [www.womac.org](http://www.womac.org).

**36-Item Short Form.** The 36-item short form (SF-36) is a 36-item survey designed for use in clinical practice and research to measure self-reported health-related quality of life (HRQL). The SF-36 consists of two sub-scores: the physical component score and mental component score. The two scores are designed to measure eight health concepts: (1) limitations in physical activities, (2) limitations in social activities, (3) limitations in usual role activities, (4) pain, (5) general mental health, (6) limitations because of emotional problems, (7) energy and fatigue (vitality), and (8) general health perceptions<sup>22</sup>. The Physical Functioning (PF), Role-Physical (RP), and Bodily Pain (BP) scores contribute to the Physical Component Summary (PCS). The mental health (MH) and role-emotional (RE) scores contribute to the Mental Component Summary (MCS). Vitality (VT), general health (GH), and social functioning (SF) contribute to both summary scores<sup>23</sup>. The SF-36 is the most widely evaluated generic self-assessment tool in

clinical populations and it has been used in thousands of clinical studies<sup>24</sup>. More detailed information on how to obtain a license is for the SF-36 is available at [www.sf-36.org](http://www.sf-36.org).

**Knee Society Clinical Rating System.** The Knee Society Clinical Rating System (KSS) is a commonly used outcome measure in TKA patients. It is a dual rating system that includes self-reported measures of function and a partially objective knee score for measurement of pain, stability, and range of motion (ROM). The KSS was developed in 1989 to objectively assess the TKA outcomes and to replace the commonly used Hospital for Special Surgery system assessment<sup>6</sup>. The benefits of the KSS are that this measurement system separates knee function from overall function by measuring two distinct parts: Knee Score (pain, ROM, and stability) and Function Score (walking and stair climbing). This enables the knee score to be independent of function and hence not subject to deterioration resulting from other co-morbidities<sup>12</sup>.

The Knee Score of the KSS consists of self-reported pain (50 points) and clinician measured ROM (25 points) and stability (25 points) adding up to 100 points maximum. For the ROM score, the maximum score for arc of movement is achieved at 125° of arc. For the Stability score, the antero-posterior and medio-lateral portions are measured separately. If there are any deficiencies present in flexion contracture, extension lag, or alignment, deductions are made in the scores. The Function Score simply includes self-reported ability to walk (50 points) and climb stairs (50 points). Deductions are made if the patient uses a cane or a crutch. Low scores indicate low levels of physical function.

**Continuous-Scale Physical Functional Performance 10-Item Test.** The Continuous-Scale Physical Functional Performance 10-item Test (CS-PFP10) is a valid, reliable, and sensitive measure of physical function<sup>8,13</sup>. This test is a performance-based functional test battery in which tasks are derived from ordinary ADL. The protocol requires the participant to perform a variety of ADL progressing from low effort to high effort in a standardized fashion. It includes

items such as carrying groceries, stair climbing, sweeping, etc. The tasks are scored on a continuous scale based on time, weight, or distance. The CS-PFP10 scores the tasks in five functional fitness domains including upper body strength, upper body flexibility, lower body strength, balance and coordination, and endurance, as well as calculating a total physical function score. Scores range from 0 to 100 with higher scores representing better physical function.

The CS-PFP10 has high test-retest reliability ( $r = 0.84-0.97$ ) and it is more sensitive for measuring function than some traditional measures such as the SF-36<sup>8</sup>. The CS-PFP10 discriminates between independent-living older adults and those with dependent-care needs<sup>8,14</sup>. Functional performance as measured by the CS-PFP10 has no known ceiling effect and it can be used as a predictor of independence level<sup>25</sup>. Other advantages of the CS-PFP10 include that scoring occurs on a continuous scale, and it is therefore applicable for linear statistical models. Furthermore, the CS-PFP10 provides the investigators with information about various aspects of physical fitness (e.g. lower body strength, muscular endurance, flexibility) as they contribute to physical function.

### **Statistical Analyses**

All statistical analyses were conducted using the SPSS 11.0 (Chicago, IL). Before the analyses, tests for normality and univariate and multivariate outliers were conducted. Descriptive statistics were used to demonstrate the sample characteristics. To test the research hypothesis, partial correlation (controlling for age) was employed to examine the convergent validity of the CS-PFP10 in TKA candidates by comparing the CS-PFP10 subscales and total functional score to the physical function scores of the WOMAC, the KSS, and the SF-36 instruments at baseline (prior to surgery).

## **Results**

Sixty-eight participants met the inclusion criteria for participation in this study; however, after inspection of the data for univariate and multivariate outliers, we excluded four cases from the analysis. Another six participants were eliminated from the sample because of missing or incomplete data. Therefore, findings are presented for 58 patients who were candidates for TKA and elected to pursue a TKA surgery. The patient characteristics are described in Table 3.3 and table 3.4 contains the descriptive characteristics for all variables measured in this study. The age range of the study sample was 50 to 83 years (mean =  $64.9 \pm 9.4$ ). Seventy-four percent of the study sample were female (m = 18, f = 40) and the majority (70%) of this study sample were overweight or obese based on BMI. The mean values for the CS-PFP10 total score, WOMAC Total Score, WOMAC physical function, function score of the KSS, and SF-36 Physical Composite scores were  $38.34 \pm 19.40$ ,  $60.51 \pm 14.41$ ,  $59.43 \pm 16.69$ ,  $39.74 \pm 15.87$ , and  $27.17 \pm 6.41$ , respectively.

**Table 3. Patient Characteristics (Study 1).**

	TKA patients
n	58 (40 female, 18 male; 28 bilateral, 30 unilateral TKA patients )
	Mean $\pm$ Standard Deviation
Age	$64.93 \pm 9.4$
Height (cm)	$167.53 \pm 9.81$
Weight (kg)	$93.74 \pm 16.83$
BMI	$33.69 \pm 6.64$

**Table 4. Descriptive Characteristics, n = 58.**

<u>Instrument/subscore</u>	<u>Mean ± Standard Deviation</u>
CS-PFP10 UBS	39.64±21.89
CS-PFP10 UBF	61.18±18.71
CS-PFP10 LBS	27.54±16.73
CS-PFP10 BAL	36.03±18.99
CS-PFP10 END	35.08±18.59
<b>CS-PFP10 Total</b>	<b>38.34±19.40</b>
WOMAC Pain	60.25±16.99
WOMAC Stiffness	61.85±16.46
WOMAC PF	59.43±16.69
<b>WOMAC Total</b>	<b>60.51±14.41</b>
KSS Knee Score	33.86±18.37
KSS Function Score	39.74±15.87
SF-36 PF	18.45±17.87
SF-36 RP	25.43±23.09
SF-36 BP	22.71±13.94
SF-36 GH	61.31±19.70
SF-36 VT	39.98±20.44
SF-36 SF	46.55±27.18
SF-36 RE	52.58±33.52
SF-36 MH	64.65±21.94
<b>SF-36 MCS</b>	<b>44.65±13.74</b>
<b>SF-36 PCS</b>	<b>27.17±6.41</b>

*CS-PFP10= Continuous Scale Physical Functional Performance*

*UBS = upper body strength score*

*BAL = balance and coordination score*

*UBF = upper body flexibility score*

*END = endurance score*

*LBS = lower body strength score*

*CS-PFP10 Total = total function score*

*KSS = Knee Society Score*

*WOMAC Total = WOMAC Total score*

*PF = SF-36 physical function score*

*RP = SF-36 role physical score*

*BP = SF-36 bodily pain score*

*GH = SF-36 general health score*

*VT = SF-36 vitality score*

*SF = SF-36 social function score*

*RE = SF-36 role emotional score*

*MH = SF-36 mental health score*

*MCS = SF-36 mental component summary*

*PCS = SF-36 physical component summary*

Pearson's product-moment correlation was employed to examine associations among variables and indicated a significant relationship between age and functional measures. All subscales and the total score of the CSPFP-10 had significant associations with age ( $r = -0.315$  to  $0.438$ ,  $p \leq 0.05$ ) Therefore, age was included as a covariate in deriving partial correlation coefficients to describe that associations among CS-PFP10 scores and the other outcomes. The results of the partial correlation are located in table (5).

There were numerous associations between CS-PFP10 subscales and total score with other functional outcomes including the total and physical function subscales of the WOMAC and the KSS. Correlation between the CS-PFP10 and the WOMAC scores were moderate<sup>26</sup> (WOMAC Total Score:  $r = -0.36$ ;  $p = .006$ ; and WOMAC Physical Function-score:  $r = -0.598$ ;  $p < .001$ , respectively). The CS-PFP10 total score also correlated with the KSS Knee Score ( $r = .474$ ,  $p < .001$ ) and the KSS Function Score ( $r = .513$ ,  $p < .001$ ).

Weak associations were detected between the CS-PFP10 and the SF-36 physical function subscales, ( $r = 0.364$ ,  $p = .005$ ) and with some of the other SF-36 subscales. Interestingly, the CS-PFP10 correlated with several sub-components/sub-scores of the SF-36 including components that measured social and emotional well being. These items that positively correlated with the CS-PFP10 included the vitality ( $r = .465$ ,  $p < .001$ ), role physical ( $r = .340$ ,  $p = .049$ ), social functioning ( $r = .4714$ ,  $p < .001$ ), and role emotional ( $r = .522$ ,  $p < .001$ ) components of the SF-36 questionnaire, as well as the mental composite score ( $r = 0.501$ ,  $p < .001$ ) of the SF-36.

**Table 5. Associations among Clinical Function Outcome Measures (expressed as partial correlation Coefficients). \*= $p \leq 0.05$ ; † =  $p \leq 0.01$**

	UBS	UBF	LBS	BAL	END	CSPPF-10	WP	WS	WPF	WOTOT	KS	FKS	SF36-PF	SF36-PCS
UBS	-	.631†	.937†	.881 †	.883†	.924†	-.176	-.114	-.518†	-.315*	.433†	.444†	.381*	.295*
UBF		-	.696 †	.800 †	.784 †	.790†	-.154	-.28	-.448†	-.246	.388*	.366†	.208	.136
LBS			-	.957 †	.954 †	.977†	-.195	-.88	-.539†	-.321*	.424†	.486†	.367*	.255
BAL				-	.997†	.994†	-.240	-.103	-.612†	-.373*	.473†	.521†	.353*	.272*
END					-	.992†	-.245	-.103	-.621†	-.378*	.487†	.530†	.36*	.292*
CSPPF-10						-	-.225	-.99	-.598†	-.360*	.474†	.513†	.364*	.279*
WP							-	.614†	.669†	.889†	-.443†	-.39*	-.028	-.124
WS								-	.521†	.829†	309*	-.266*	-.119	-.194
WPF									-	.852†	-.491†	-.649†	-.439†	-.405†
WTO										-	-.484†	-.508†	-.225	-.279*
KS											-	.442†	.175	.23
FKS												-	.295*	.332*

## Discussion

The aim of this study was to examine the convergent validity of the CS-PFP10 test in uni- and bilateral TKA candidates by comparing the CS-PFP10 to accepted measures of physical function in this population (WOMAC, KSS, and the SF-36 physical function scores). Seventy-four percent of the study patients were female, which is consistent with the general OA population, that is believed to be up to 75% female<sup>27, 28</sup>. Furthermore, the majority of the study patients were obese, which is also a typical characteristic of the knee OA patient population because overweight individuals tend to have a high prevalence of knee OA<sup>29</sup>. Lastly, the age range of the study sample is reasonable given the ages at which the incidence and prevalence of OA of the knee rises and peaks<sup>29, 30</sup>.

The scores obtained from this study correspond with the scores in other studies that have utilized the same instruments in OA patients. For example, the WOMAC Scores in this study were similar to those obtained in a large study ( $n = 862$ ) of OA patients by Lingard et al. in 2001 and 2004 with WOMAC Physical Function Scores of  $46.4 \pm 18.5$  and  $42.3 \pm 19$ , respectively. Furthermore, in 2005, Coleman et al.<sup>31</sup> reported almost identical WOMAC Total Scores of 56.6 in comparison to the mean WOMAC Total Scores in our study (56.4). In addition, the SF-36 Physical Function Scores in this study were similar to other studies examining knee OA patients or TKA candidates. Lingard reported SF-36 Physical Function scores of  $27.4 \pm 20.1$  and  $24.4 \pm 20.2$  in 2001 and 2004, respectively, which compare well with the average SF-36 PF scores in our study ( $20.28 \pm 18.20$ ). Finally, the KSS scores in our study sample were similar to those of reported by Bullens et al. and Lingard et al.<sup>20, 32</sup>.

The CS-PFP10 scores from this study were similar to those in comparison with the data from Cress and Meyer's study in 2003<sup>14</sup>. The mean value for the study sample fell in between the mean

CS-PFP scores for the independent (mean 46.3±16) and dependent (mean 25.7±10) congregate care facility residents in Cress and Meyer's study. The range of values in this study (6.71-81.30) was also similar to the range of values of the above two groups in Cress and Meyer's study (7.0-82.3)<sup>14</sup>. To our knowledge, however, this is the only study that has utilized the CS-PFP10 instrument simultaneously with the KSS, WOMAC, and SF-36 in this population.

Consistent with our hypothesis, the findings from this study reveal several significant associations between the CS-PFP10 test scores and the other assessment tools. In particular, the CS-PFP10 total scores were associated with the KSS knee and knee function scores, the WOMAC physical function and total scores, as well as several SF-36 scores including physical function. Moreover, the domains scores for the CS-PFP10 (upper body strength, upper body flexibility, lower body flexibility, balance/coordination, and endurance) correlated significantly with numerous functional indicators.

The present findings show, that the CS-PFP10 in fact is a valuable tool in measuring physical function in these patients and confirms the convergent validity of the CS-PFP10 test in this patient population. To our knowledge, these are the first published data regarding the validation of the test in this patient population.

The PFP 10 scores were highly correlated with age, whereas the WOMAC and the KSS scores were not in this study sample. The WOMAC, especially the physical function score of WOMAC, generally correlates with age<sup>33-35</sup>. Further, the KSS scores are also found to negatively correlate with increasing age ( $p<0.001$ )<sup>36</sup>.

There were limitations of this study, some of which were imposed by the study design. As a result of the number of instruments, many patients expressed dissatisfaction with the amount of time

required for testing. In addition, having expressed dissatisfaction with “too many questionnaires/questions”, some of the patients indicated that they would be unwilling to participate in future follow-up studies. This study is also somewhat limited by its small sample size. However, with the number and nature of significant associations, the inferences of the present investigation do not appear to be influenced by an inability to reject the null hypothesis. The existence of significant positive associations, in spite of the small sample size, is somewhat impressive.

Clearly, there are limitations to all of the instruments used in the study, hence the premise of this study. Using measures that rely on at least in part subjective appraisals of function as a basis for comparison (as is the case with the KSS, WOMAC, and SF-36) allow us to make inferences about the convergent validity of the CS-PFP10, which is a type of “criterion-related” validity. As with all function measures, the lack of a true criterion always imposes some limitation to the generalizability of the data.

While it is impossible to say that the CS-PFP10 is a better estimate of function than the other measures, there are numerous advantages of objective assessments that make the CS-PFP10 attractive. One important strength of objective assessments is that they are often more sensitive to change than subjective instruments. Future investigations should compare the sensitivity of the CS-PFP10 to the other commonly accepted measures so that investigators might be able to employ the most sensitive tools in their clinical outcomes investigations. Furthermore, these findings might be helpful for clinicians and researchers in choosing the appropriate method for measuring physical function in their respective patient populations. Furthermore, the CS-PFP10 gives us information on a variety of fitness domains and is able to point out possible weaknesses of the patients, which the other tests do not. The knowledge gained from the CS-PFP10 test may help clinicians in determining appropriate rehabilitation protocols for patients.

## Conclusion (Study 1)

The data support our hypothesis that the CS-PFP10 scores would be associated with the scores from the other instruments. This finding is important insofar as it suggests that there is convergent validity of the CS-PFP10 for use in the TKA population. As such, it appears that this instrument is capturing the information gained from the other widely accepted outcome measures in the TKA patient population.

The associations between the CS-PFP10 and other functional measures demonstrate that the CS-PFP10 test is a useful and valid measure for quantifying physical function in TKA patients. Information gathered from this study may provide valuable applications for the CS-PFP10 including physical function research, intervention strategies, and program outcome. Continued examination of the CS-PFP10 and other outcomes measurement tools may provide insight into choice of functional assessment instruments when working with OA patients.

## STUDY 2: PHYSICAL FUNCTION IN TKA PATIENTS

Knee osteoarthritis (OA) patients suffer from pain, loss of mobility in joints, muscle weakness, and atrophy as a result of the condition, which all contribute to severe functional limitations in basic and instrumental activities of daily living (ADL)<sup>37, 38</sup>. Thus, OA of the knee causes more functional limitations and disability than any other disease affecting the quality of life of thousands of older adults<sup>3, 39</sup>. As a result of the negative effects of OA, total knee arthroplasty (TKA) may be required, and is often the only effective treatment in reducing joint pain, improving knee function and quality of life in patients with severe knee osteoarthritis (OA)<sup>32</sup>. In order to evaluate the return of physical function and functional independence following TKA, outcomes instruments such as the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC)<sup>4, 5</sup>, the Knee Society Clinical Rating System (KSS)<sup>6</sup> and Short Form Health Survey (SF-36)<sup>7</sup> have frequently been utilized. While the WOMAC and the SF-36 are patient self-report measures, in which the outcome assessment focuses on the perspective of the patient, the KSS includes self-report and clinician based assessments.

Thus, the KSS is a dual rating system and seems to have an advantage as a more well-rounded outcomes tool when compared to the self-report WOMAC and the SF-36<sup>6, 40</sup>. The KSS includes both self-report outcomes and clinician measured appraisals of stability, range of motion, and knee alignment in the assessment, thus reflecting both the patient and physician's perspectives. While the KSS is widely accepted outcomes instrument in OA and TKA patients, it can be argued that the clinical variables measured with the KSS may be better indicators of impairment rather than functional ability. Furthermore, the validity and responsiveness of the KSS has been questioned by some authors, and it has been suggested to be more sensitive to inter-observer bias than, for example, the WOMAC<sup>20, 41</sup>.

In the recent years, the development of universally applicable objective measures of physical function has gained attention of scientists and clinicians because of the known limitations that the currently utilized measures may have in measuring physical function<sup>10, 12, 40</sup>. These known limitations are those often associated with self-report tools and includes possible floor and ceiling effects and lack of sensitivity to change. Discrepancies between perception and actual ability may cause further limitations when using self-report measures<sup>8, 9, 42, 43</sup> and they are also subject to errors in judgment or memory. Furthermore, self-report measures are impacted by some psychosocial parameters such as depression and fatigue<sup>10</sup> and have been linked to dispositional optimism<sup>44, 45</sup> suggesting that responses may also be impacted by a personality trait of dispositional optimism.

Dispositional optimism, considered a stable personality trait over time, can be defined as global positive outcome expectancies and may have an effect on self-reported outcomes<sup>46, 47</sup>. Thus, self-reported functional measures may not reflect accurate changes in function, which further emphasizes the importance of using alternative outcomes instruments in intervention studies. Most clinicians would also agree that it would be beneficial if the approach in measuring clinical outcomes would be standardized, which would offer investigators the advantage of making comparisons across studies<sup>40</sup>.

Nevertheless, it is imperative to continue to identify and improve quantifiable measures of function that mirror the ability of the person to carry out ADLs in TKA patients so that clinicians and scientists can evaluate different treatment outcomes with greater sensitivity and gain information regarding other factors as well. Thus, performance-based tests may be a solution at providing information about the patients' functional status and future disability and mortality. Furthermore, performance-based tests are thought to be a good demonstration of how well or poorly similar tasks are managed at home, and they may be better suited for between-subject comparisons

than self-report because the basis of comparison is the same<sup>15</sup>. Further benefits of using performance-based tests include that the information obtained may present an opportunity for patients to learn that their actual ability may be different from their perceived ability to execute ADLs<sup>8</sup>.

Therefore, regardless of their established reliability and validity, investigators should consider the limitations of the traditionally employed function scales and critical evaluation is needed to prospectively examine the utility of the current instruments and performance based measures of function.

### Specific Aims and Hypotheses

The primary purpose of this study was to examine the return of function and sensitivity of the CS-PFP10 to change in TKA patients from baseline (pre-surgery) to follow-up (3 wks, 6 wks, and 12 wks) by comparing effect sizes of observations.

The hypotheses of this investigation included that: the CS-PFP10 would detect functional changes in TKA patients and that the effect sizes from week 3 to week 6 post-surgery would be greatest for the CS-PFP10 and the KSS compared to the WOMAC Physical Function, the SF-36 Physical Function (PF) subscale, and the SF-36 Physical Component Summary Score (PCS). Finally, we hypothesized that improvements in CS-PFP10 (i.e. objective physical function measure) in TKA patients would be independent of dispositional optimism, as measured with the Life Orientation Test (Revised), but the subjective measures of physical function would not.

### Method

#### **Participants**

Data were collected from a study in which we have a total of 68 patients enrolled currently. The data collection is ongoing, and we have several patients whom we have collected data on visit 1 and

2 (pre-op and 3 wks post), but not yet on visits 3 and 4 (6 and 12 weeks post-operatively). We were able to gather data on  $n = 17$  patients with data on 4 observations (repeated; pre-operative, 3wks post-operative, 6wks post-operative, and 12 wks post-operative). In addition, data were collected on  $n = 30$  participants for whom 3 observations were available. Patients who were candidates for TKA and between the ages of 50-85 were invited to participate in this study. These participants were recruited from one orthopaedic clinic with two participating surgeons. TKA candidacy was determined by the examining physician based on several factors including (but not limited to) impaired quality of life, severe knee pain and stiffness that limits the patient's daily activities, limited function or mobility, knee deformity, and failure to obtain pain relief from previous treatment methods.

Prior to enrollment in the study, all candidates received a medical evaluation, which included screening for inclusion and exclusion criteria (tables 1. and 2.). Inclusion criteria consisted of TKA candidates who were electing to pursue TKA, and who were otherwise apparently healthy or had a diagnosis of stable heart disease (AHA Classes A and B and C-stable). Candidates in American Heart Association Class D (i.e., symptoms of cardiovascular and/or metabolic disease at rest) were excluded from the study<sup>19</sup>. Patients with active infection, immunosuppressive disorders, collateral ligament insufficiency (grade 3), posterior cruciate ligament insufficiency (grade two or more), drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple Sclerosis, were also excluded from the study.

## **Design**

A prospective cohort, pretest-posttest/time-series design was used to test the hypotheses. We simultaneously examined the return to function in patients undergoing simultaneous bilateral TKA or unilateral TKA using the WOMAC, KSS, SF-36, and CS-PFP10 prior to, 3 weeks, 6 weeks, and

12 weeks after surgery. Data were collected in a single location (The American Musculoskeletal Research Institute or AMRI) in Alexandria, LA. Two supporting physicians, Drs. David Pope and Jeffrey Garrison agreed to support the data collection procedures and to provide the investigators with the TKA patients.

## **Procedures**

The study and all procedures were approved by the Institutional Review Board of Louisiana State University and are described here in more detail. All patients whom agreed to participate in the study, signed an informed consent form, and subsequently received a medical examination by one of the participating clinicians. In conjunction with the medical evaluation, the KSS assessment was conducted. The clinicians were trained in obtaining the KSS clinical measurements and followed the KSS assessment protocol. Immediately following this evaluation, TKA candidates who passed the inclusion/exclusion criteria and consented to participating in the study completed the SF-36, WOMAC, and LOT-R self-report questionnaires. Participants were then asked to execute the CS-PFP10 test according to the test protocol. The questionnaires were provided to the patient by one of two research administrators, whom then collected the questionnaires immediately after completion. The same research administrator also conducted the CS-PFP10 test following the standardized protocol. Heart rate and blood pressure were measured before testing, and ratings of perceived exertion were obtained following the CS-PFP10 testing. In addition, the participant was instructed to communicate any symptoms of chest pain, dizziness, nausea, fatigue, or any other abnormal responses to the test administrator. The CS-PFP10 sessions were conducted by trained CS-PFP10 technician at a facility, which had on-site medical support teams equipped to respond in the event of an emergency.

Each research testing session took approximately 1.5 hour with the CS-PFP10 taking

approximately 45 minutes and the questionnaires taking about 30-45 min. Knee replacements were performed by one of two surgeons (in unilateral TKA) or both surgeons simultaneously (in bilateral TKA), within three weeks of the initial/baseline functional testing. All knee compartments were resurfaced to accomplish a traditional cemented TKA. All patients followed a standard protocol for postoperative rehabilitation.

### **Instruments**

Physical function was simultaneously measured in the study sample by four instruments: 1) the Western Ontario and MacMaster University Index (WOMAC), 2) Knee Society Clinical Rating System (KSS), 3) the Short Form 36 (SF-36) and 4) the Continuous Scale Physical Function Performance tests (CS-PFP10). Furthermore, we measured dispositional optimism with the revised Life Orientation Test (LOT-R). A brief description of the functional measurements is provided below as these have been previously described in previous section of this manuscript (Study 1).

**Western Ontario and McMaster Universities OA Index.** The Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) is a self-administered health questionnaire specifically designed for patients with osteoarthritis of the knee or the hip. The WOMAC has 24-items and includes three categories intended to measure pain, disability and joint stiffness, and physical function. The questions are commonly scored on a 5-point Likert scale and the scores are summed for each category. The WOMAC scores express the amount of difficulty or disability so that higher the score, the greater the level of disability. The WOMAC is widely used in the assessment of patients with hip or knee arthritis and is well validated<sup>4, 5, 20, 21</sup>. It has shown to be a reliable assessment and more responsive tool in measuring the outcome of joint replacement when compared to SF-36<sup>20</sup>. The WOMAC is requires a license for use and can be obtained by contacting the author via [www.womac.org](http://www.womac.org).

**36-Item Short Form.** The 36-item short form (SF-36) is the most widely used generic health-survey in clinical populations and has been used in thousands of clinical studies<sup>24</sup>. The SF-36 is a 36-item survey designed for use in clinical practice and research to measure self-reported health-related quality of life (HRQL). The SF-36 is designed to measure eight health concepts: (1) limitations in physical activities, (2) limitations in social activities, (3) limitations in usual role activities, (4) pain, (5) general mental health, (6) limitations because of emotional problems, (7) energy and fatigue (vitality), and (8) general health perceptions<sup>22</sup>. These health concepts contribute to two sub-scores: the physical component score (PCS) and mental component score (MCS). More specifically, the Physical Functioning (PF), Role-Physical (RP), and Bodily Pain (BP) scores factor in to the Physical Component Summary (PCS) and the mental health (MH) and role-emotional (RE) scores contribute to the Mental Component Summary (MCS). Vitality (VT), general health (GH), and social functioning (SF) contribute to both summary scores<sup>23</sup>. The SF-36 questionnaire also requires a license for use and can be obtained by contacting [www.sf-36.org](http://www.sf-36.org) or [www.qualitymetric.com](http://www.qualitymetric.com).

**Knee Society Clinical Rating System.** The Knee Society Clinical Rating System (KSS) is a dual rating system commonly used in both research and clinical practice in OA and total knee replacement patients. It includes two separate scores, the knee score and function score, and includes both self-reported and objective clinical measures. The knee score consists of pain, stability, and range of motion (ROM), and the function score consists of patient self-reported function.

A maximum score of up to 100 points in the Knee Score of the KSS is possible and consists of self-reported pain (50 points) and clinician measured ROM (25 points) and stability (25 points). For the ROM score, the maximum score (25 points) for arc of movement is achieved at 125° of arc. The

KSS Function Score is based on patient's self-reported ability to walk and to climb stairs, in which a use of an assistive device such as a cane or a crutch will lower the score. High scores indicate high levels of physical function.

**Continuous-Scale Physical Functional Performance 10-Item Test.** The Continuous-Scale Physical Functional Performance 10-item Test (CS-PFP10) is a validated, reliable, and sensitive measure of physical function commonly used in older adults<sup>8, 13</sup>. The CS-PFP10 consists of tasks based on ADL and reflects performance based physical function. The test entails that the participant perform a variety of ADL progressing from low effort to high effort in a standardized method. The tasks, such as carrying groceries, stair climbing, and sweeping, are scored on a continuous scale based on time, weight, or distance. Scores range from 0 to 100 with higher scores representing better physical function.

The CS-PFP10 provides a total physical function score as well as valuable information on five functional fitness domains including upper body strength, upper body flexibility, lower body strength, balance and coordination, and endurance. In older adults, the CS-PFP10 is able to differentiate independent-living from those with dependent-care needs based on their functional scores and the scores can be used as predictors for level of independence<sup>8, 14, 25</sup>. The CS-PFP10 is highly reliable and more sensitive in measuring function when compared to some traditional measures such as the SF-36<sup>8</sup>. Finally, the CS-PFP10 is applicable for linear statistical models as it is scored on a continuous scale. More specific description of the CS-PFP10 laboratory and testing set-up and license can be found at the official CS-PFP10 web-site at: <http://www.coe.uga.edu/cs-pfp/overview.html>.

**Life Orientation Test-Revised.** The Life Orientation Test-Revised (LOT-R)<sup>48</sup> is a widely used 10-item self-report measure of dispositional optimism. Dispositional optimism can be defined as

expectations that good things, instead of bad things, will occur<sup>46,47</sup>. The LOT-R includes six main items, which are scored on a Likert-scale. The remaining four items are not included in scoring and used to obscure the intent of this scale. The six “main” items are evenly divided between negatively- and positively-worded items. Participants indicate their degree of agreement with statements such as, "In uncertain times, I usually expect the best," using a response scale ranging from 1 ("strongly disagree") to 4 ("strongly agree"). Negatively worded items are reversed, and a single score is obtained. Total scores ranges from 0 to 24 with higher scores indicating greater optimism and low scores suggesting pessimistic life orientation. Internal consistency of LOT-R total score is estimated at .82 (Cronbach's alpha) and test-retest reliability is adequate ( $r = .79$ )<sup>48</sup>. Scheier and colleagues reported only modest correlations between the LOT-R and measures of neuroticism, self-esteem and trait anxiety (range  $r = -.35$  to  $r = .54$ ) suggesting convergent and discriminant validity of responses to the LOT-R and that LOT-R responses measure a construct distinct from established personality traits<sup>48</sup>. The LOT-R has been used extensively in studies of stress, with college students and with people going through stressful events, such as medical populations facing or recovering from serious diseases or treatments<sup>46-49</sup>.

### **Statistical Analyses**

Before the analyses, tests for normality and univariate and multivariate outliers were conducted. Descriptive statistics are included in table 4. Because the outcomes of subjective/self-report measures may be affected by general outlook or orientation in life, we controlled for dispositional optimism by using the LOT-R score as a covariate in the analyses. To examine the change in function over time in TKA patients, repeated measures analysis of covariance (ANCOVA) with 4 observations (repeated) was employed with baseline LOT-R score as the covariate on  $n = 17$  patients. The four observations were pre-operative, 3wks post-operative, 6wks post-operative, and

12 wks post-operative. In addition, repeated measures ANCOVAs were performed on  $n = 30$  participants for whom 3 observations were available. Least square difference (LSD) pair-wise comparisons were employed to further describe changes in functional scores the four observations. To examine sensitivity to change of the CS-PFP10, KSS, WOMAC, and SF-36 tests, we derived effect sizes between observations (baseline, 3wks, 6wks, 12 wks) as according to the computation of Cohen's  $d$  (where a positive effect size represents improvement). This approach suggests that the effect size is equal to mean score of post test subtracted from mean score of pretest divided by the overall pooled standard deviation ( $d = M_1 - M_2 / \sigma$  where  $\sigma = \sqrt{[\sum (X - M)^2 / N]}$  where  $X$  is the raw score,  $M$  is the mean, and  $N$  is the number of cases). In all cases we will set the Type I error rate at 0.05.

### Results

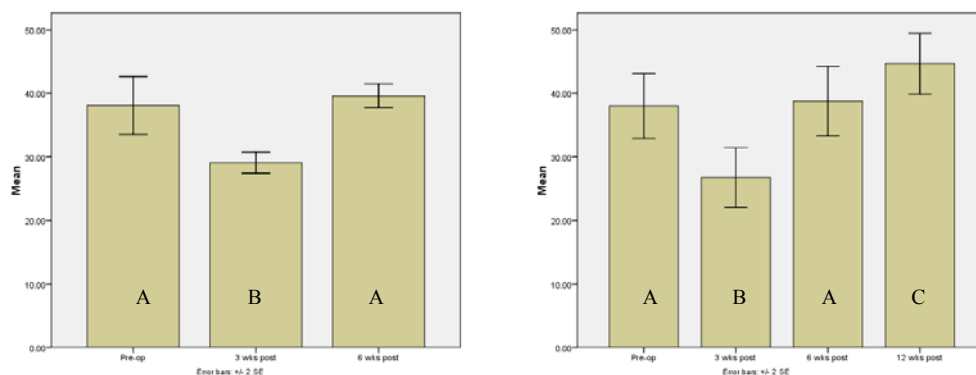
Findings are presented for  $n = 30$  TKA patients, who were observed before, 3 weeks, and 6 weeks after surgery, 17 of whom ( $n=17$ ) who were followed for 12 weeks. The patient characteristics are described in Table 6.

**Table 6. Patient Characteristics (Study 2).**

TKA	female, male
n=30 (obs1,2,3)	23 female, 7 male
n=17 (obs 1,2,3,4)	14 female, 3 male
	Mean $\pm$ Standard Deviation
Age	66.60 $\pm$ 9.93
Height (cm)	166.73 $\pm$ 8.00
Weight (kg)	93.25 $\pm$ 16.02
BMI	33.69 $\pm$ 6.26

Repeated measures ANOVA consistently revealed main effects of time on all functional measures, regardless of whether using three or four observations. However, including LOT-R as a covariate in the analyses reduced the statistical power, resulting in no significant main effects of time. Because of the significant main effects of the ANOVAS, and the poor power with the ANCOVAS, we elected to perform follow-up LSD pair-wise comparisons. With respect to CS-PFP10, significant changes from baseline to 3 weeks, between 3 and 6 weeks post-op, and a further change from 6 weeks to 12 weeks post-op,  $F(3,51) = 19.59, p < 0.001$ , were detected.

However, baseline and 6-wk scores were not significantly different. Figures 1. and 2. illustrate the changes in total CS-PFP10 scores over the course of the study. A somewhat unexpected finding was the initial drop after surgery (at 3 wks post) in physical function below baseline (pre-op) levels, detected by the CS-PFP10 at 3-weeks after surgery.



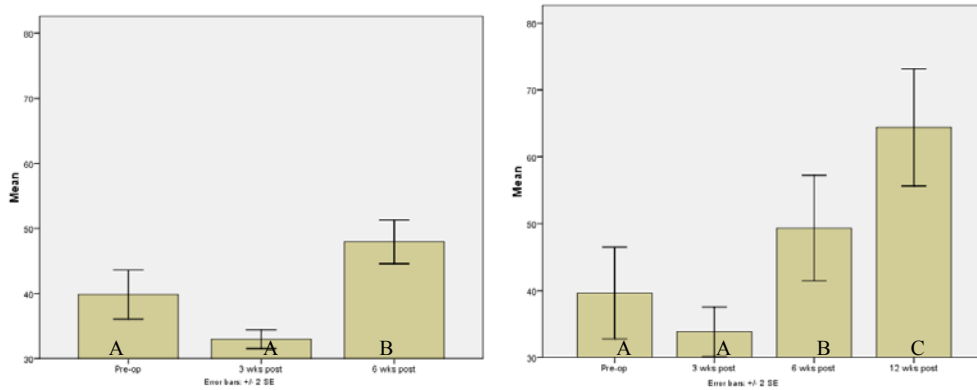
**Figures 1. and 2. CS-PFP10 Scores in TKA patients (n=30 and n=17, respectively).**

*The bars that share a different letter, are different from each other ( $p < 0.05$ ).*

Pair wise comparisons also reveal a general improvement in KSS function scores over 3 observations (n=30) and over 4 observations (n=17) (figures 3. and 4.). The mean score for KSS Function at baseline was  $39.57 \pm 15.07$  and significant improvements in scores were detected between 3 weeks and 6 wks post-operatively (ES=0.81), baseline (pre-op) and 6 weeks and 12

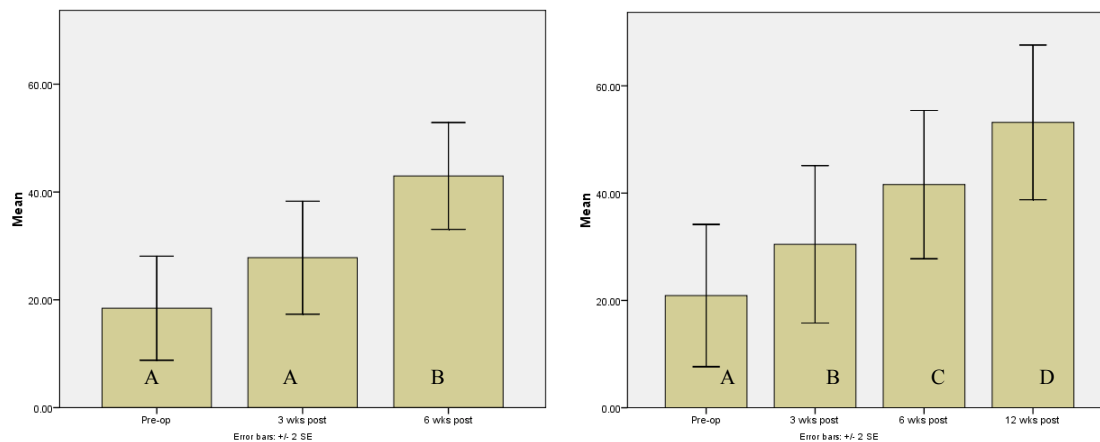
weeks after surgery (ES=0.62 and 1.29, respectively),  $F(3,51) = 20.9, p < 0.001$ . The Largest effect in KSS Function was detected between 3 weeks and 12 weeks post-TKA with an ES of 1.56.

However, there were no significant differences between baseline and 3 weeks post-op.



**Figures 3. and 4. KSS Function Scores in TKA patients (n=30 and n=17, respectively).** The bars that share a different letter, are different from each other ( $p < 0.05$ ).

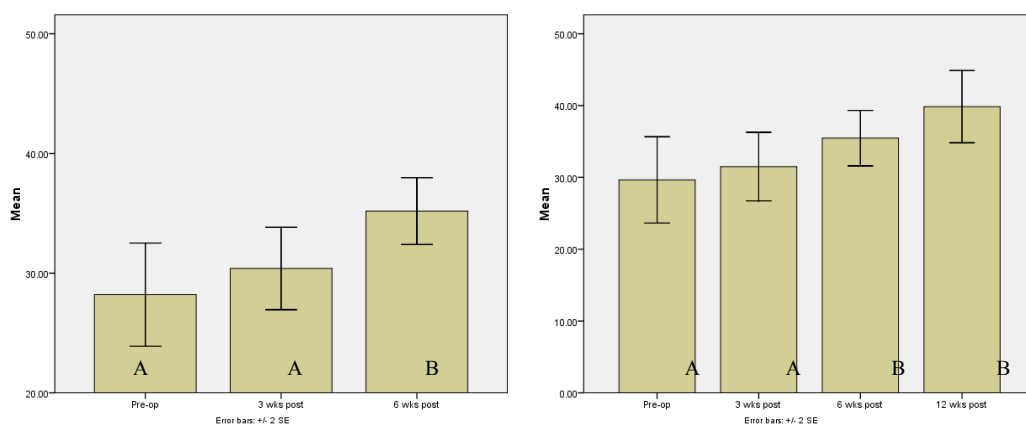
Pair wise comparisons reveal that the SF-36 Physical Function scores improved from before TKA to 3, 6, and 12-week follow-up scores, and between 3 weeks, 6 weeks, and 12 weeks as well,  $F(3,51) = 14.59, p < 0.05$  (Table 6. and Figures 5. and 6.). Largest improvements in SF-36 PF scores were noted between the baseline SF-36 scores and 12 weeks post-operatively with an ES of 1.51.



**Figures 5. and 6. SF-36 Physical Function Scores in TKA patients (n=30 and n=17, respectively).** The bars that share a different letter, are different from each other ( $p < 0.05$ ).

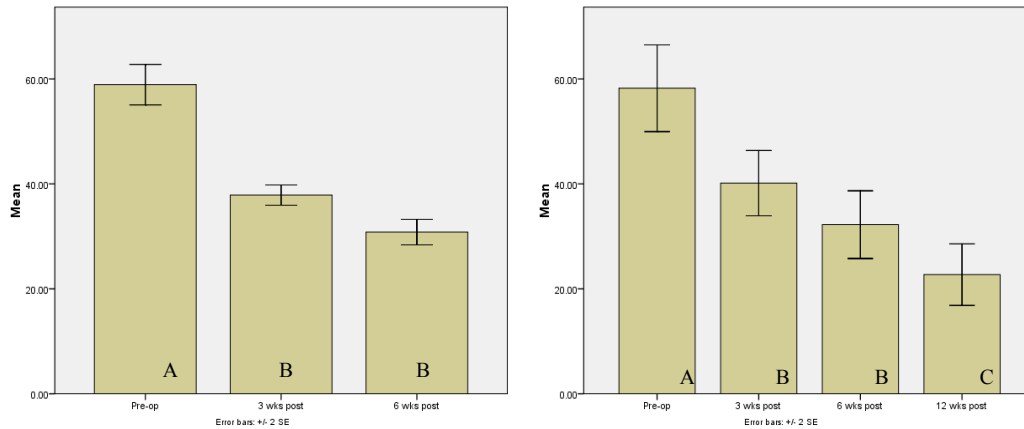
SF-36 Physical Composite Score (PCS) also demonstrated similar gradual improvement from

baseline (pre-op) to 12-weeks after TKA,  $F(3,48) = 10.21$ ,  $p < 0.001$ , (figures 7. and 8.). However, the baseline (pre-op) values were different from 6-and 12-week scores, but not 3-week scores. There were significant differences between 3 and 6-weeks, as well as between 3- and 12-weeks (see table 6. and figures 7. and 8.).



**Figures 7. and 8. SF-36 PCS Scores in TKA patients (n=30 and n=17, respectively).**  
*The bars that share a different letter, are different from each other ( $p < 0.05$ ).*

With respect to WOMAC, pair wise comparisons indicate that the patients reported significant improvement in physical function (demonstrated as reductions in WOMAC physical function scores) from pre-operative observation to all post-operative observations (3 weeks, 6weeks, and 12 weeks following surgery) with the greatest ES between baseline (pre-operative observation) and 12 weeks post-operative observation (ES=2.03),  $F(3,51) = 23.08$ ,  $p < 0.05$ . The effect sizes for change in function from baseline to 3 weeks, 6 weeks to 12 weeks, and from baseline to 6 and 12 weeks are presented in table 6.



**Figures 9. and 10. WOMAC Physical Function Scores in TKA patients (n=30 and n=17, respectively).**

*The bars that share a different letter, are different from each other ( $p < 0.05$ ).*

The ANCOVAS revealed no significant time by LOT-R interactions on any functional indicators. The average LOT-R score at baseline (pre-op) was  $17.77 \pm 4.64$ , and there were no change ( $p < 0.05$ ) in the LOT-R scores between any of the four observations over time (pre-op, 3wks, 6wks, and 12 wks post-op). Furthermore, there were no significant associations between the LOT-R scores (at baseline) and the functional measures (CS-PFP10 total, KSS function, WOMAC function, SF-36 physical function, or SF-36 physical composite score).

## Discussion

The purpose of this study was to test the hypotheses that physical function will improve over time and that effect sizes would be stronger with KSS and CS-PFP10 when compared to WOMAC and SF-36. The characteristics of the current study's population, of which 75% were female, were consistent with the general OA population demographics<sup>27, 28</sup>. Furthermore, the majority of the study patients were either overweight or obese, with an average BMI of  $33.69 \pm 6.25$  (range 22.88 to 47.93), which corresponds with the typical knee OA patient as obesity is a major contributor to the high prevalence of condition<sup>29</sup>. Lastly, the age range of the study sample is similar to the age at

which knee OA is most likely to peak<sup>29,30</sup>.

The scores of physical function were as expected as measured by the KSS, WOMAC, and the SF-36. The mean CS-PFP10 score from the current study fell in between the mean CS-PFP scores for the independent (mean 46.3±16) and dependent (mean 25.7±10) congregate care facility residents in Cress and Meyer's study in 2003<sup>14</sup>. The range of values in the current study (6.71-81.30) was also very similar to the range of CS-PFP10 values in Cress and Meyer's study (7.0-82.3)<sup>14</sup>. It is reported though that majority of older adults over the age of 60 have some degree of OA. To our knowledge, there is only one study that has implemented the CS-PFP10 test in TKA patient population<sup>17</sup>.

The CS-PFP10 scores in the current study were lower than those reported in the one study that has utilized the CS-PFP10 in the TKA population<sup>17</sup>. Petrella's study design varied in comparison to the current study in at least the recruitment approach of the patients. We recruited all consecutive TKA candidates who qualified for the study (based on the inclusion and exclusion criteria) in a clinic setting with the help of the participating physicians. In Petrella's study, recruitment was conducted via mail outs, which may have resulted in different demographic and functional characteristics of the patients volunteering to participate. In our study, at baseline (pre-op), many patients had low level of physical function and well below the threshold of functional level of independence (as defined by Cress & Meyer<sup>14</sup>). Thus, these low functioning patients may have not been as likely to respond to a mail out compared to recruitment in clinic setting, because of the extra burden and effort it would have required them to go for functional testing.

**Table 7. Mean Values and Effect Sizes for Functional Outcomes in TKA patients.**

	Baseline <sup>a</sup>	3 wk post <sup>a</sup>	6-wk post <sup>a</sup>	12-wk post <sup>a</sup>	ES <sup>b</sup> 0-3 wks	ES <sup>b</sup> 3-6 wks	ES <sup>b</sup> 6-12 wks	ES <sup>b</sup> 0-6 wks	ES <sup>b</sup> 0-12 wks	ES <sup>b</sup> 3-12 wks
CS-PFP10 n=30	34.90±13.72	29.45±10.23	39.74± 11.63	-	0.42	0.91	-	0.35	-	-
CS-PFP10 n=17	37.90±11.14	27.29±9.99	39.36±11.71	45.19±10.15	.95	1.03	0.50	0.12	0.65	1.76
KSS Func. n=30	39.57±15.07	35.86±7.48	51.64±19.35	-	0.25	0.81	-	0.62	-	-
KSS Func. n=17	39.71±14.99	34.64±7.24	49.19±17.32	64.41±19.14	0.34	0.84	0.80	0.55	1.29	1.56
KSS KS n=29	33.35±16.51	62.84±11.15	61.59±13.04	-	1.79	0.09	-	1.71	-	-
KSS KS n=17	36.47±16.29	60.48±10.99	56.89±13.25	72.81±11.56	1.47	0.27	1.20	1.25	2.23	1.06
WOM pf n=30	60.32±15.51	38.11±11.97	31.21±15.20	-	1.43	0.45	-	1.87	-	-
WOM pf n=17	58.80±17.89	40.77±13.32	32.66±13.98	23.17±12.65	1.01	0.58	0.67	1.46	1.99	1.32
SF-36 pf n=29	20.17±21.89	28.77±17.24	40.97±16.78	-	0.39	0.71	-	0.95	-	-
SF-36 pf n=17	18.23±18.87	30.40±20.63	40.15±19.13	51.47±21.92	0.59	0.47	0.51	1.14	1.51	0.96
SF-36 PCS n=28	27.88±8.43	30.39±5.54	36.15±5.24	-	0.30	1.04	-	0.98	-	-
SF-36 PCS n=17	27.99±8.66	31.06±6.77	35.83±5.81	39.33±7.87	0.35	0.71	0.45	0.91	1.31	1.05

<sup>a</sup> values for Baseline, 3, 6, and 12 weeks post TKA are Mean ±S.D.

<sup>b</sup> ES = effect size; computation of effect size is described in method section.

CS-PFP10 = CS-PFP10 total function score, KSS Func. =KSS physical function score. WOM pf = WOMAC physical function score; KSS KS = KSS knee score

Furthermore, in the current study, functional testing was coordinated so that it was conducted the same day, time, and at the same location, than the participant's doctor's appointment, thus further lessening the burden on the patient. Therefore, we speculate/suggest that there may have been a selection bias in Petrella's study to select out the least functional patients from their study sample. As a result of the approach to recruitment in the current study, we may have captured a more complete representation of the TKA candidates including the poorest functioning patients. Furthermore, especially at 3 wks post, when the patients were at very low levels of function and were experiencing high levels of pain, swelling, and fatigue as a result of the TKA surgery, it would have been very difficult to get these patients to come in if it wasn't for the doctor's appointment they had to come.

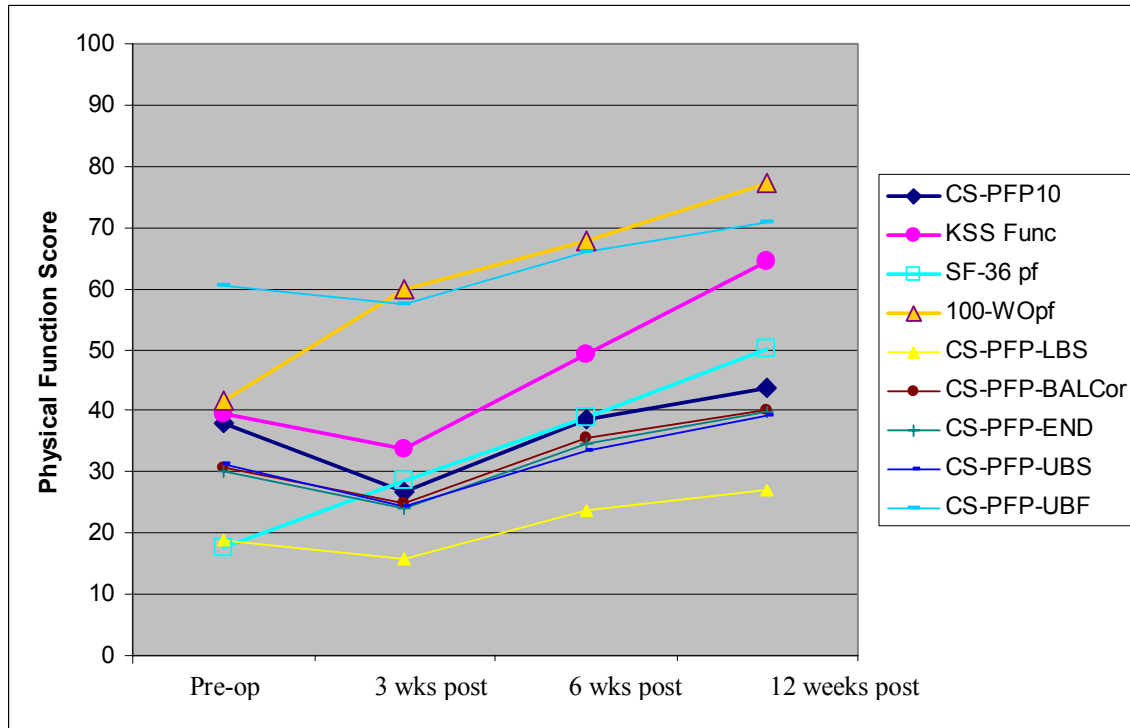
The results from this study are similar to studies that have utilized the same outcome instruments in end stage OA patients/TKA candidates. The WOMAC Scores in this study were similar to those obtained in a large study ( $n = 862$ ) of OA patients by Lingard et al. in 2001 and 2004 with baseline WOMAC Physical Function Scores of  $46.4 \pm 18.5$  and  $42.3 \pm 19$ , respectively. Lingard et al.'s study did not, however, report any follow-up observations until 12 months after TKA. Furthermore, almost identical WOMAC Total Scores of 56.6 were reported by Coleman et al. in comparison to the mean WOMAC Total Scores in our study (56.4) in 2005<sup>31</sup>. In addition, Lingard et al. reported SF-36 Physical Function scores very similar to ours ( $20.28 \pm 18.20$ ) in 2001 and 2004<sup>20, 50</sup>. Finally, the baseline KSS scores in our study sample were similar to those of reported by Bullens et al. and Lingard et al<sup>20, 32</sup>. Furthermore, Konig et al. reported similar KSS Function and Knee Scores at pre-op and at 12-weeks following TKA when compared to the current study<sup>51</sup>. Lastly, the optimism/pessimism expressed as LOT-R scores were similar to the normative LOT-R scores reported by Scheier et al<sup>48</sup>.

Consistent with our hypothesis, the ANOVAS and follow-up pair-wise comparisons demonstrate a functional improvement over the 12 weeks following TKA. In general, while the results of the ANOVAS suggest main effects of time, however, there appear to be some differences in the direction of changes and the magnitude of effect sizes according to the functional outcome. Furthermore, the absence of a time by Life Orientation score interaction suggests no significant influence of dispositional optimism on the effect of time for this group of TKA patients. Furthermore, the CS-PFP10 demonstrated a largest ES between the early post-op period (from 3 weeks to 6 weeks post-op;  $ES=1.03$ ). Effect sizes are generally considered as "small,  $d = .2$ ," "medium,  $d = .5$ ," and "large,  $d = .8$ "<sup>26</sup>. Unexpectedly, however, we observed an initial decrease in physical function at 3wks post-op as defined by scores on the CS-PFP10 test. This unique finding gives us some insight on physical function (or limitations) in the immediate post-operative period following TKA, which is not well documented. Thus, the 3, 6- and 12-week follow-up data suggest that the CS-PFP10 is sensitive in detecting change in function over time, even among small groups of patients.

Interestingly, none of the other measures detected the decline in function at 3 weeks after TKA. The SF-36 PF and WOMAC demonstrated a consistent increase from baseline to 12-weeks post surgery. The differences in perceived physical function and performance based physical function are interesting. From these findings, one might hypothesize that the objective instrument was more inclined to detect the the decrement in performance because it is measuring true function, whereas psychological factors may have affected the subjective instruments. Thus, this difference in results with different instruments may be explained by the fact that the patients expected their function to incline as a result of TKA, which affected their perception of physical

function. This data may also be an indication of the CS-PFP10 being a more sensitive measure of function when compared to the other instruments.

**Figure 11. Physical Function Scores in TKA Patients**



We tested these hypotheses by including LOT-R as a covariate. While this measure of dispositional optimism did not interact with time, the interaction term approached significance for the WOMAC scores ( $p = 0.16$ ). This paired with power  $< 0.50$  makes it difficult to rule out the possibility that optimism was in fact influence at least the WOMAC scores. Therefore, the possibility that the improvement in WOMAC scores are reflecting psychological benefits more so than actual functional improvements is worth of further investigation.

Finally, we hypothesized that the effect sizes to detect change in function, in particular from weeks 3 to 6 post op, would be strongest for the CS-PFP10 and the KSS. The results of the study support this hypothesis. However, the PCS scores across 28 patients for whom three observations were available are at least as impressive. Further, the ES for the CS-PFP10 from weeks 3 to 12

post op, are the largest (ES=1.76). This reflects the instrument's sensitivity to the initial drop in functional scores (at 3-weeks post) followed by incline, which the other instruments failed to observe. These data in general support the inclusion of objective measures of function in evaluating the efficacy of TKA.

Limitations of this study include non-randomized study design and lack of multi-center data. As with any non-randomized study design, selection bias is always a risk. We tried minimizing selection bias by enrolling all consecutive patients whom consented to participation and fit the inclusion criteria. Further limitations of this study include a small sample size and a relatively short follow-up (12 weeks) after surgery. Another limitation in the current study was that we had no control over the type and compliance of the post-operative rehabilitation, and what kind of contribution this had on return to function. Future studies should include a long-term follow-up visits, such as 1- and 2-year follow-up, and a greater sample size. Strengths of the study include that it utilized both self-report and performance based, as well as clinician report outcomes instruments. This allows as non-biased view of the patients' physical functional performance as possible.

Thus, it appears that the CS-PFP10 can detect small changes in physical function and therefore could be applied to studies where change in function is an important consideration. Such applications include comparing the functional outcomes of different surgical approaches, implants, or rehabilitation protocols. Other more subjective or generic measures might be limited by floor and ceiling effects, whereas the CS-PFP10 might be able to give us information not limited by these effects. The clinical relevance of these findings is applicable in outcomes instrument selection. It may be reasoned that the CS-PFP10 used together with the KSS would give clinicians and researchers sensitive and well rounded information and reflect both

performance based physical function as well as perceived physical function along with the clinical measures gained from the Knee Score of KSS. However, more research is needed to confirm this observation.

Finally, the data reveal that CS-PFP10 is sensitive to detect change particularly following the initial three to six weeks post-TKA. Furthermore, the other clinical assessments utilized in this study did not appear to be measuring small changes in function. Thus, it would be critical that clinicians and scientists use objective, performance-based instruments, such as the CS-PFP10, to examine function, if detecting small changes in function is important, especially during the first 3 weeks following surgery. Thus, future research should focus on examining group differences, the early post-op period, and investigating predictors of physical function.

## CONCLUSION

The general objective of these studies was to investigate physical function in osteoarthritis (OA) and total knee replacement (TKA) patients. Two studies were conducted to achieve this objective:

- First, a validation study was performed to evaluate the validity of the CS-PFP10 test in OA patients.
- The second study was a 12-week prospective study (study 2) investigating the return of physical function in TKA patients. We also examined the sensitivity of the CS-PFP10 test to change in TKA patients.

The primary purpose of Study 1 was to examine the convergent validity of the CS-PFP10 test in a sample of patients with knee OA awaiting TKA. The CS-PFP10 scores were compared to the WOMAC, KSS, and the SF-36 physical function scores. The hypothesis of this investigation was that correlation analysis would reveal at least moderate associations between the CS-PFP10 test scores and the WOMAC, KSS, and SF-36 scores in TKA candidates.

The results of this study indicated moderate association associations between the CS-PFP10 and WOMAC physical function ( $r=.598$ ,  $p<.001$ ), the KSS Physical Function ( $r=.513$ ,  $p<.001$ ), and KSS Knee Scores ( $r=.474$ ,  $p<.001$ )<sup>26</sup>. Further, weak associations were found between the CS-PFP10 and SF-36 Physical Function, Physical Composite Score, and WOMAC total score. The findings from this study show that the CS-PFP10 is a valid tool for measuring physical function in OA/TKA patients.

The main purpose of study 2 was to investigate the return of function in TKA patients following surgery. Further, sensitivity of the CS-PFP10 to change in TKA patients was examined. The hypotheses of this investigation included that the CS-PFP10 would be sensitive to

functional changes in TKA patients and that the magnitude of effect sizes during the initial recovery period following surgery (between 3 and 6 weeks post-op) would be greatest for the CS-PFP10 and the KSS. Additionally, examining the extent of functional improvements in TKA patients following surgery was exploratory and the investigation was merely conducted to provide a basis for future research. Finally, we hypothesized that improvements in CS-PFP10 in TKA patients would not be affected by dispositional optimism, but the subjective measures of physical function would be.

Consistent with our hypotheses, the results demonstrated a functional incline over the time course of the study. The effect sizes of the follow-up data suggest that the CS-PFP10 is sensitive in detecting change in function over time, even in a small group of patients. We also found an unexpected yet interesting finding, which indicated an initial drop in physical function immediately after surgery (3 weeks post). Furthermore, the only instrument that was able to show this decline was the CS-PFP10 test. The SF-36 PF and WOMAC demonstrated a consistent improvement in function from baseline to 12-weeks post surgery. These findings indicate that there are differences in perceived physical function and performance-based physical function. While the patients' performance based function actually declined, the self-reported function improved. This data may also be an indication of the CS-PFP10 being a more sensitive measure of function when compared to the other instruments.

Although this research improves upon the limitations of previous research, which commonly have utilized only self-reported outcome instruments, some limitations are still present. First, one of the major limitations of these studies includes the difficulty of recruiting participants, thus yielding a small sample size. In comparison, if the same study was conducted at a multi-center trial, a larger sample size would be possible along with a greater geographic variation in the

study sample. Therefore, the generalizability of this data may be limited and larger studies are necessary to draw any firm conclusions.

We recruited all consecutive TKA candidates, who fit the inclusion criteria, in a clinic setting with the assistance of the physicians. This brings us to one of the strengths of the studies including the support from the participating clinic and physicians. This, we believe, was a crucial factor in being able to recruit a sample of patients whose functional levels ranged from very low to high. It is important to include the lowest functioning patients in research studies, so that we have a better understanding of the disability levels of the severe OA patients/TKA candidates. If the patients would have been recruited by other means, it may be likely that the lowest functioning patients would have been selected out simply because of their inability to come for testing sessions.

Another limitation of these studies included long patient visits (1.5 hours/observation) putting a burden on the patient, and might affect the long-term participation rate. Thus, this must be taken into consideration in planning future studies by limiting the number of instruments used. Yet, a variety of instruments utilized, including subjective and objective, and perception- and performance-based measures of physical function, can also represent strength of the studies. By utilizing a variety of instruments, we ensured a well-rounded data set that included all important aspects of patient's recovery.

It has been demonstrated that the CS-PFP10 is sensitive to changes in physical function, even in small study samples. Therefore, the CS-PFP10 could be utilized in future studies in which change in function is an important factor to assess such as when comparing the functional outcomes of different surgical approaches, implants, or rehabilitation protocols. Other measurement tools that are more subjective or generic might not be able to detect these changes

and be limited by floor and ceiling effects. The clinical application of this information is important, as it may help researchers and physicians in choosing the appropriate tool in measuring outcomes. It may be reasoned that the ideal outcome instrument combination in studies when sensitivity of the instrument is important would include the CS-PFP10 and the KSS. This would allow clinicians and researchers to sensitively collect comprehensive information that reflects performance-based and perceived physical function along with the clinical measures gained from the Knee Score of KSS. However, more research is needed to confirm this observation.

Future research should include the use of objective, performance-based instruments, such as the CS-PFP10, to examine function, when designing studies in which detecting small changes in function is important, especially during the first 3 weeks following surgery. Moreover, future research should focus on examining if group differences in performance-based physical function in this population exist, and whether activity levels of the patient affect the rate of functional recovery following TKA. Additionally, investigating the effects of exercise interventions implemented before the TKA or following the initial standard physical therapy regimen on the functional abilities of patients would be interesting. Especially now that we have some indication of an instrument, that sensitively detects changes in physical function in the early post-op period, researchers should focus on what factors make a difference in terms of function early on in the recovery. Finally, investigating predictors of physical function in the TKA population would be a worthwhile effort for investigators.

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