**DIAGNOSTIC ACCURACY OF PATIENT-REPORTED LOWER EXTREMITY PHYSICAL FUNCTION TO DETERMINE SUITABILITY FOR TOTAL KNEE ARTHROPLASTY IN PATIENTS WITH OSTEOARTHRITIS**

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TITLE: Diagnostic Accuracy Of Patient-reported Lower Extremity Physical Function To Determine Suitability For Total Knee Arthroplasty In Patients With Osteoarthritis

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**Abstract**

Knee osteoarthritis (OA) is a debilitating and costly chronic health condition affecting approximately 10% of Canadians. Total Knee Arthroplasty (TKA) is an effective procedure restoring quality of life and providing pain relief for patients with knee OA. The benefits of TKA are well established for patients with knee OA, but determining those who would most benefit is a challenging task. Physical functioning in patients with knee OA has been shown to be a key factor for appropriateness for TKA. The Lower Extremity Functional Scale (LEFS) and the Oxford Knee Score (OKS) are two patient-reported outcome measures (PROMs) measuring physical function that can be utilized to assist health care professionals in determining the need for TKA among this population. The LEFS is a regional PROM consisting of 20 questions asking about activities relating to lower extremity functioning. Questions are scored on a 5-point descriptive scale from 0 (extreme difficulty or unable to perform the activity) to 4 (no difficulty) with a total score of 80. Higher scores represent higher functioning. The OKS is a site-specific PROM that asks questions about pain and function and consists of 12 items ranked on a 5-point descriptive scale. Scores range from 1 to 5 (total score of 60) for each item with lower scores representing higher function.

The purpose of this thesis was to determine the diagnostic accuracy for the LEFS and the OKS for determining appropriateness for TKA in people with primary knee OA. The hypothesis for the current study was that the LEFS would have higher diagnostic accuracy for appropriateness for TKA compared to the OKS. A cross-sectional retrospective study of patients with knee OA attending a Regional Joint Assessment Program (RJAP) from January to September 2013 was conducted. Classification of appropriateness for TKA was determined by the attending orthopedic surgeon’s decision at the end of the assessment. Diagnostic accuracy for the OKS and the LEFS were determined using the area under the curve (AUC) of the receiver operator characteristic (ROC) curve. Cut-off scores were calculated for both outcome measures.

Four hundred and twenty one patients eligible for the study (41.8% males; 66.9 years old) completed the OKS and the LEFS. The diagnostic accuracy for the OKS and the LEFS was determined using the AUC of the ROC curve for each patient-reported measure using Stata ® version 12.1. The cut-off scores were determined as the point on the ROC curve yielding the best sensitivity and specificity for the two outcome measures. The results showed the LEFS did not have higher diagnostic accuracy (LEFS AUC = 0.686 (95% CI = 0.636 – 0.736); OKS AUC = 0.674 (95% CI = 0.623- 0.724)) for determining appropriateness for TKA in patients with primary knee OA in isolation. The best cut-off score for those deemed appropriate for TKA among patients with knee OA was 26 out of 80 LEFS points and 42 points out of 60 OKS points.

The results of this thesis agree with previous research reporting that decision-making regarding the need for TKA in patients with knee OA is multi-factorial. Our data confirm that this decision cannot be based on patient-reported physical function alone. Factors other than or in addition to patient-reported lower limb physical functioning should be considered when determining which patients with knee OA would most benefit from TKA. Further research evaluating these factors is warranted to improve triage services for patients with knee OA most likely to benefit from TKA.

**Dedication**

This thesis is dedicated to my friends and family who have supported my continued education.

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**LIST OF ABBREVIATIONS**

APP – Advanced Physiotherapist Practitioner

ACR – American College of Rheumtaology

AUC – Area under the receiver operator characteristic curve

CI - Confidence interval

EQ-5D - EuroQol Group 5-Dimension Self-Report Questionnaire

ICOAP - Intermittent and Constant Osteoarthritis Pain Measure

JSN – Joint Space Narrowing

LEFS – Lower Extremity Functional Scale

LHIN – Local Health Integrated Network

KOOS – Knee Injury and Osteoarthritis Outcome Scale

KOOS-PS – KOOS Physical Function Short Form

NSAIDs- Non-steroidal anti-inflammatory medications

OA- Osteoarthritis

OARSI- Osteoarthritis Research Society International

OKS – Oxford Knee Score

OMERACT- Outcome Measures in Rheumatoid Arthritis Clinical Trials

PROMs – Patient-Reported Outcome Measures

RJAP – Regional Joint Assessment Program

ROC – Receiver Operator Characteristic

SF-36 – Short Form Health Status Questionnaire

SD- Standard deviation

TKA – Total Knee Arthroplasty

VAS- Visual analog scale

WOMAC- Western Ontario and McMaster Universities osteoarthritis index

χ²- Chi-squared test

**CHAPTER 1: INTRODUCTION**

Osteoarthritis (OA) is a progressively worsening condition affecting approximately 10-15% of the population in Canada (ICES, 2004). Knee OA is the most common type, affecting approximately 6% of people worldwide (Michael et. al., 2010). It is characterized by the loss of articular cartilage and degeneration of the meniscus, but also includes damage to the subchondral bone, as well as ligaments and tendons (Dequeker et. al., 1997 and Felson, 2004; Kazakia et al., 2013).

Radiographic knee OA is defined on the basis of pathophysiological signs present on X-ray including loss of the cartilaginous space, subchondral sclerosis and cysts, and osteophytes (Dahaghin et al., 2005). Although several scoring systems exist, the Kellgren-Lawrence method is the most widely used in research literature (Pereira et al., 2011). It classifies knee OA severity as follows: grade 0, none, representing “no radiographic features of knee OA”; grade 1, doubtful, “doubtful joint space narrowing (JSN) and possible osteophytic lipping’; grade 2, minimal, “presence of definite osteophytes and little/mild JSN”; grade 3, moderate, “definitive moderate osteophytes, definite JSN of at least 50%, sclerosis” and grade 4, severe, “large osteophytes, marked JSN, cysts and sclerosis of subchondral bones” (Kellgren and Lawrence, 1957). Symptomatic knee OA is defined on the basis of symptoms attributable to knee OA including pain, joint stiffness, and loss of function in combination with radiographic evidence of OA (Kopec et al., 2007) or using a diagnostic algorithm that does not require radiographic evidence (Altman et al., 1986). However, not all people with radiographic OA have symptoms (Neogi and Zhang, 2011; Neogi and Zhang, 2013; Pereira et al., 2011).

Prevalence of knee OA varies depending on the definition used, with radiographic knee OA yielding higher estimates compared to symptomatic knee OA (Periera et al., 2011). A systematic review reports that the prevalence of knee OA is higher among women than men, regardless of the definition used (Periera et al., 2011). The rate of physician-diagnosed OA was slightly less than that of self-reported OA in population surveys in British Columbia, Canada in 2001 (Kopec et al., 2007). Predictors of OA onset and progression include aging, obesity and ethnicity with African Americans being more susceptible to progressive knee OA (Kopec et. al., 2013). With the aging population and increasing obesity rates, the prevalence of knee OA is expected to increase (Neogi and Zhang, 2011).

Total knee arthroplasty (TKA) has been used widely as a successful surgical procedure providing high patient satisfaction with respect to reduced pain, and improved overall function and quality of life in those suffering from knee OA (Anderson et. al., 1996; Callahan et. al., 1994; Dieppe et. al., 1999; Hawker et. al., 1998; Norman-Taylor et. al., 1996). Total knee arthroplasty is offered as a last resort when people with severe symptomatic knee OA have failed conservative management and are having daily constant pain that is limiting function and negatively affecting quality of life (Dieppe et. al., 2011; Hawker et. al., 2006; Hawker et. al., 2013). There is no gold standard for assessing physical functioning in patients with knee OA (Dobson et al., 2013). Therefore, a number of different tests of observed and patient-reported physical performance have been used in this population (Bennell et al., 2011). The assessment of functional limitations attributed to knee OA symptoms is important as this is a key factor when determining which patients with knee OA are most likely to benefit from TKA.

The Lower Extremity Functional Scale (LEFS) and the Oxford Knee Score (OKS) are two patient-reported outcome measures (PROMs) used to assess lower extremity physical function. The LEFS has been shown to have high validity for the assessment of lower extremity physical functioning in those who have knee OA (Binkley et al., 1999). The LEFS score showed high convergent validity with the SF-36 physical function domain score. Scores on the LEFS are also highly valid and reliable in the assessment of lower extremity physical functioning after TKA (Stratford et al., 2009). Additionally, recovery curves mapping the LEFS scores following TKA have been constructed (Kennedy et al., 2008). These curves are useful to clinicians to determine the expected recovery for patients after TKA and plan treatments, discharge and timelines for reassessment.

The OKS was initially developed to determine outcomes following TKA (Dawson et al., 1998). The OKS has started to be used to assess people with knee OA in a rehabilitation setting, and recent studies support its reliability and high convergent validity with scores on the physical function subscale of the EuroQol Group 5-Dimension Patient-reported Questionnaire (EQ-5D) and physical function subscale of the Knee injury and Osteoarthritis Outcome Scale (KOOS-PS) (Xie et al., 2011). It has high responsiveness when compared to other measures of health status (SF-36) following TKA (Ko et al., 2013). The recovery curves following TKA based on OKS scores have been mapped for years 1-10 years (Williams et al., 2013).

The purpose of this thesis is to compare the diagnostic accuracy of two patient-reported measures of physical function, the OKS and the LEFS, to classify patients with primary knee OA most likely to benefit from TKA. It is hypothesized that LEFS scores will be able to discriminate patients with knee OA who are deemed appropriate for TKA from those who are not deemed appropriate for TKA better than OKS scores.

The thesis is organized in a traditional format. Chapter 2 provides a review of the literature describing the assessment of physical function in people with knee OA, the utility of PROMs assessing physical function in the clinical decision-making regarding appropriateness for TKA and the basis for the hypothesis and specific research question addressed in this thesis. Chapter 3 describes the methods used in the cross-sectional retrospective chart review conducted to compare the diagnostic accuracy of the OKS and LEFS. Chapter 4 describes the results of the study. The thesis findings are discussed and future directions are provided in Chapter 5.

**CHAPTER 2:**

**LITERATURE REVIEW: PHYSICAL FUNCTIONING AS A PREDICTOR FOR TKA IN PATIENTS WITH KNEE OA**

**2.1 Knee Osteoarthritis**

Osteoarthritis (OA) is a debilitating condition that can cause pain and functional limitations and lead to extensive health care costs in the developed world. Osteoarthritis of the knee is the most common type of OA, although prevalence estimates vary widely depending on the definition of knee OA used (Periera et al., 2011). Older people (> 65 years) with knee OA reported limitations in physical functioning more than any other health condition (CDC, 2001; Dunlop et al., 2001; Guccione, et al., 1994). The global burden of disease study reported that OA is the eighth leading cause of disability worldwide (Lopez and Murray, 1998). United States census data from people aged 50-84 years were studied to evaluate the quality-adjusted life years lost due to obesity and knee OA (Losina et al., 2011). Approximately 1.9 quality-adjusted life years were estimated to be lost in those with knee OA alone, while quality-adjusted life years lost for obese people with knee OA was estimated at 3.5 (Losina et al., 2011). A recent systematic review reported that work productivity is impacted with strong evidence for absenteeism in those with knee OA (Agaliotis et al, 2014). With increasing obesity rates and an aging population, the burden of knee OA is expected to increase in the near future.

2.1.1 Diagnosis of Knee OA

There are several methods used for diagnosing knee OA. Radiographic knee OA consists of features relating to OA seen on plain radiographs of the knee. It is most commonly defined by the Kellgren-Lawrence Scale which grades the amount of OA radiographically on a 0-4 scale with 0 representing “none” and 4 representing “severe” OA (Kellgren and Lawrence, 1957). Radiographic features of OA include loss of cartilaginous space, subchondral sclerosis, osteophytes and subchondral cysts (Dahaghin et al., 2005). Studies have indicated that prevalence estimates would increase dramatically if the sole method of diagnosing OA was based on radiographs alone, as not all individuals with radiographic knee OA have OA symptoms (Neogi and Zhang, 2013). Although the correlation between radiographic knee OA and knee pain and limitation in physical functioning are low (Jordan, Luta & Renner, 1997) this method does offer early detection of knee OA and may be used to direct treatment toward slowing the progression of knee OA (Busilija et al., 2010). Symptomatic knee OA is often defined as patients having symptoms relating to knee OA including knee pain, joint stiffness, crepitus and musculoskeletal disability relating to knee OA combined with radiographic findings confirming presence of knee OA (Kopec et al., 2007). This definition is important clinically as individuals with symptoms relating to knee OA seek management options. Self-report diagnosis of knee OA offers an inexpensive, easy method that does not require a specialist’s training nor poses additional risks to the general population (Busilija et al., 2010). Typically, most individuals that report having knee OA have been diagnosed previously by a health care professional (Busilija et al., 2010). However, individuals who self-report OA are unclear as to the type of rheumatological condition they have (Rasooly et al., 1995). Prevalence estimates of knee OA vary depending on the definition used with the highest prevalence in population studies using radiographic case definitions while reports of symptomatic and self-report definitions show similar prevalence (Peirera et al., 2011). Clinician-diagnosed knee OA typically combines various definitions of knee OA. The American College of Rheumatology criteria (ACR) for diagnosis of knee OA includes combinations of signs and symptoms for knee OA, radiographic findings, and laboratory findings as shown in Table 1 (Altman et al., 1986).

**Table 1: ACR Criteria for Diagnosis of Knee OA**

|  |  |  |
| --- | --- | --- |
| History and Physical Examination findings | History and Physical Examination and Radiographic findings | History and Physical Examination with Laboratory findings |
| Knee pain and 3 of the following:  a) age >50 years  b) morning stiffness lasting < 30 minutes  c) crepitus throughout range of motion  d) joint line tenderness  e) bony enlargement  f) no palpable warmth of the synovium | Knee pain and 1 of the following:  a) age >50 years  b) morning stiffness lasting < 30 minutes  c) crepitus throughout range of motion and osteophytes | Knee pain and 5 of the following:  a) age >50 years  b) morning stiffness lasting < 30 minutes  c) crepitus throughout range of motion  d) joint line tenderness  e) bony enlargement  f) no palpable warmth of the synovium  g) erthrocyte sedimentation rate (ESR) of < 40mm/hr) rheumatoid factor (RF) <1:40  h) synovial signs of osteoarthritis including clear viscous or white blood cell count of < 2,000 mm­3 |

As clinicians are restricted by time constraints and healthcare costs, using the criteria based on history and physical examination findings alone is a fast and an inexpensive option for diagnosing knee OA. However, the most common method used to diagnose knee OA is based on physical examination findings in combination with radiographs (Swagerty & Hellinger, 2001) as this examination can be completed quickly, and does not require the same level of expertise necessary to complete laboratory tests (Tigges, Sutherland & Manaster, 2000).

2.1.2 Etiology and Risk Factors for Knee OA

2.1.2.1 Etiology and Risk Factors for Onset of Knee OA

The etiology of knee OA is best understood as a problem with joint failure caused by abnormal stresses on the joint. Several biomechanical risk factors for the onset of knee OA have been identified. The knee is susceptible to joint injury and when combined with local factors result in the onset of OA. Local factors include knee joint deformities, malalignment of the knee, and previous injury to the joint. For example, valgus alignment of the knee increases the incidence and risk of lateral compartment knee OA radiographically (Felson et al., 2013) and varus alignment increases the risk for medial compartment structural changes (Sharma et al., 2001). Several studies have identified genes associated with the presence of OA (Valdes and Spector, 2010). Inherited predisposition may include the cartilage’s inability to respond to normal stresses leading to cartilage degeneration as opposed to replenishment (Felson, 2004; Felson 2009). Physiological alteration in the joint may include collagen within cartilage, changes in enzymes within cartilage, variations in cytokines, or growth factors in cartilage and genes that determine structure (Felson, 2004; Felson, 2009). These biomechanical and genetic factors combine to create abnormal stresses that contribute to the risk of developing knee OA.

Risk factors at the whole person level include age, genetics (including family history, gender and ethnicity), and lifestyle factors such as obesity, and previous trauma to the knee. Age is a risk factor for developing knee OA and older joints are less tolerant of mechanical stresses, and high amounts of activities may lead to joint injury (Aigner et al., 2004). Genetic predisposition (having parents or family members with knee OA) has been shown to increase the risk of developing knee OA, especially among those whose parents have multiple joint involvement of OA (Valdes and Spector, 2011; Felson, 2009). Meta-analysis reveals that females have a higher incidence and prevalence of knee OA than males (Srikanth et al., 2005). The Johnston Study and NHANES III study both demonstrated higher radiographic and symptomatic knee OA in African American people compared to Caucasian people (Braga et al., 2009; Dillon et al., 2006), and the NHANES III study showed a similar prevalence between Mexican American and Caucasian sample populations (Dillon et al., 2006). Chinese women from Beijing had a higher prevalence of radiographic knee OA when compared to Caucasian women in the Framingham study (Zhang et al., 2001). Obesity has also been shown to be a primary risk factor in the development of knee OA with high quality cohort studies reporting that people with a body mass index (BMI) considered obese (>30) are 7-8 times more likely to develop knee OA than those with a normal BMI (<25) (Lee and Keen, 2012). Obesity not only increases the mechanical stress across the joint, but also may be an inflammatory risk factor as cytokines in adipose tissue (adipokines) can cause low-grade inflammation in joints (deBoer et al., 2012). Evidence indicates that high-impact activities in older adults leads to a higher incidence of knee OA (McAlindon et al., 1999; Ross et al., 1995). Microtrauma sustained during sporting activities or more frequently, during higher physically demanding jobs can cause joint injury and may lead to knee OA (Cooper et al., 1994; Blagojevic et al., 2010). Joint injury has also been shown to increase the risk of both physician diagnosed (Murphy et al., 2008) and self-reported symptomatic (Blagojevic et al., 2010) knee OA. There is an increase in incidence of knee OA following anterior cruciate ligament injury or meniscal injury (Roos et al., 1995; Lohmander et al., 2004). The risk of radiographic knee OA is 14-fold following meniscal injury and meniscectomy (Roos et al., 1998) and the risk is also increased without menisectomy (Englund et al., 2009) negating previous thoughts that surgery may protect against knee OA (Lohmander et al, 2007). The biomechanical and genetic risk factors creating abnormal stresses in combination with individual risks lead to the onset of knee OA.

2.1.3.2 Risk Factors for Progression of Knee OA

Structural alignment has been shown to increase the progression of knee OA. Malalignment affects the progression of knee OA by increasing stresses on the joint and, when combined with repetitive use or injury, can lead to progression of knee OA (Felson, 2004). Muscle weakness may contribute to knee OA progression as a result of inactivity due to pain, and swelling that causes inhibition of normal protective muscle contractions in the knee joint (Slemenda et al., 1997). On the other hand, stronger quadriceps muscles have been shown to slow the progression for knee OA (Segal et al., 2010). Obesity has also been associated with progression of knee OA with cohort studies showing a risk of 63% in the obese population (United States, aged 60-64 years) compared to 37% in non-obese patients (Holt et al., 2011). Additionally, a randomized controlled study has shown improvement in physical functioning and reduction in pain from knee OA in the Arthritis Diet and Activity Promotion Trial (Messier et al., 2004). Knee joint alignment, muscle weakness and obesity are key factors associated with progression of knee OA, and risk factors for knee OA onset also contribute to disease progression.

2.1.3 Pathophysiology of Knee OA

Osteoarthritis of the knee is a result of the loss of equilibrium between joint tissue formation and degradation causing progressive cartilage matrix destruction (Nuki, 1999). The medial tibiofemoral and patellofemoral joint compartments are most commonly affected (Felson, 2004). Joint destruction involves the thinning or loss of the cartilaginous space and remodeling of bone including subchondral bone loss followed by sclerosis, formation of osteophytes around the joint margins, and bone marrow edema (Nuki, 1999; Felson, 2004; Hunter 2011). There are also changes to the tissues surrounding the joint, including tendon laxity and muscle weakness (Nuki, 1999; Felson, 2004; Hunter, 2011). The synovial lining becomes thickened, there is fibrosis of the joint capsule and the fluid in the joint becomes thinned (Nuki, 1999; Felson, 2004; Hunter, 2011). These changes to the knee joint organ are often associated with an inflammatory response which tips the tissue repair cycle in favour of joint tissue degradation (Dequeker et al., 1997; Nuki, 1999; Felson, 2004; Hunter, 2011).

2.2 Management Options for People with Knee OA

2.2.1 Non-surgical Management Options

Several studies report effectiveness of non-surgical interventions for managing symptomatic knee OA. The Osteoarthritis Research Society International (OARSI) group has recently released new guidelines for the non-surgical management of knee OA (McAlindon et. al., 2014a) Table 2 shows the thirteen recommendations graded as effective from the initial twenty-eight conservative measures evaluated based on quality of evidence reviewed and clinical expertise of the group (McAlindon et al., 2014a).

Table 2: Summary of OARSI Non-surgical Recommendations for People with Knee OA

(McAlindon et al., 2014a)

|  |  |
| --- | --- |
| Core Recommendations for all People with Knee OA | |
| 1) land-based exercises  2) water-based exercise  3) strength training  4) self-management and education  5) weight management | |
| Recommendations for People with Knee OA without co-morbidities | Recommendations for People with Knee OA with co-morbidities |
| 1) biomechanical interventions including custom bracing, knee sleeves and orthotics  2) walking aids – cane  3) capsaicin  4) Oral non-selective NSAIDS  5) Oral cox-2 inhibitors (selective NSAIDS)  6) Acetaminophen (paracetamol)  7) Duloxetine  8) Topical NSAIDS | 1) biomechanical interventions including custom bracing, knee sleeves and orthotics  2) walking aids – cane  3) intra-articular corticosteroid injection  4) Topical NSAIDS |

The group recommended non-surgical treatment for those with co-morbidities, and suggested in a rebuttal comment that each patient with knee OA must be evaluated by their respective physician regarding the appropriate use of medications, as some people with cardiovascular disease or other co-morbid conditions may not be able to take medications recommended in the guideline (McAlindon et. al., 2014b). Other conservative measures that were investigated were deemed uncertain with respect to their effectiveness. These include acupuncture, balneotherapy, transcutaneous electrical nerve stimulation and ultrasound (in those with only knee OA), glucosamine and chondroitin (for symptom relief), hylauronic acid intraarticular injections, oral or transdermal opioids. OARSI indicated that although these measures were deemed uncertain in terms of their effectiveness, it should not detract from their use as management options for knee OA, rather the evidence reviewed did not provide enough strength to make a recommendation for its support (McAlindon et al., 2014a).

2.2.2 Surgical Management Options

If conservative management of knee OA is ineffective, open orthopedic surgery is recommended (McAlindon et al., 2014a). Surgical options are dependent on multiple factors including patient symptoms, degree of knee OA, and patient related factors including patient’s age, co-morbidities, and physical activity levels (Ronn et al., 2011). Radiographic degree of knee OA alone does not indicate the appropriateness for a particular surgical procedure, rather it is the amount of pain and limitations in functioning combined with the radiographic findings that support choosing one surgical intervention over another. The following three types of surgeries for knee OA will be reviewed: arthroscopic surgery, osteotomy, and total knee arthroplasty (TKA).

2.2.3 Arthroscopic Surgery

Arthroscopic surgery is a minimally invasive orthopedic procedure usually performed to repair a torn ligament or meniscus which can be a result of knee OA. A Cochrane review evaluating the effectiveness of arthroscopic surgery for knee OA did not support its use for knee OA (Laupattarakasem et al., 2008). Arthroscopic surgery in more active, younger patients with knee OA has limited benefit although patients with mechanical symptoms due to degenerative meniscal tears may receive benefit (Laupattarakasem et al., 2008). A recent randomized controlled trial evaluating arthroscopic surgery for primary knee OA failed to show effectiveness of the procedure (Sihvonen et al, 2013), endorsing the findings of earlier studies (Moseley et al., 2002; Kirkley et al, 2008). However, the exclusion of patients with mechanical symptoms as well as the small sample size in the study suggests that arthroscopic surgery for specific types of patients, including patients with mechanical symptoms such as locking or catching, warrants consideration (Krych et al., 2014).

2.2.4 Osteotomies

Osteotomies in the knee are suggested for single-compartment OA with varus or valgus deformities (Runn et al., 2011). With the success rates of TKA, osteotomies demonstrated less predictability with respect to outcomes, and were associated with higher complication rates (Runn et al., 2011). However, recent advances in surgical techniques and hardware improvements have revitalized this procedure, especially in younger patients (Lobenhoffer and Agneskirchner, 2003; Staubli et al., 2003; Wagner et al., 2004).

2.1.2.3 Total Knee Arthroplasty

Total knee arthroplasty is a widely recognized successful procedure for the treatment of severe knee OA resulting in improvement of pain, and overall quality of life. (Ethgen, et. al., 2004; Jones et al., 2005; Callahan et al., 1994; Dieppe et al., 1999; Hawker et. al., 1998; Anderson et al., 1996). Higher rates of TKA are seen among people with knee OA who are older and female, reflecting the prevalence of knee OA in the population (Hawker et al., 2000). Utilization rates for TKA for patients with knee OA are a concern since knee OA is not only a leading cause of disability, but also results in extensive healthcare expenditures. Utilization of TKA are higher in the US, while Canada and the United Kingdom show similar utilization rates (Dixon et al., 2004; Dixon et al., 2006; Ackerman et al., 2009). There is disparity in the use of TKA for knee OA in developed countries. In the US, Caucasians are more likely than African American to be considered for TKA (Dieppe et al., 1999). Studies show that those with lower socioeconomic status (SES) in developed countries have a greater need for TKA, yet are less likely to be considered or offered TKA (Yong et al., 2004; Hawker et al., 2002; Rahman, 2011). Variation may also be explained by differences in physicians’ opinion regarding who would most benefit from TKA.

**2.3 Physical Function in Patients with Knee OA**

Physical functioning is defined as the ability to “move around” (Bellamy et. al., 1997) or perform various activities in daily life (Terwee et. al, 2006). Patients with knee OA have demonstrated limitations in physical functioning. Epidemiologic studies showed that persons with radiographic knee OA were more likely to report difficulty with physical functioning, specifically for activities involving mobility and activities of daily living (ADLs) (Guccione et al., 1994; CDC, 1994; Dunlop et al., 2001). Limitations in physical functioning has been shown to be influenced by both the amount of knee OA radiographically and knee pain which suggest that the severity of structural changes and pain are important factors in understanding difficulties with physical functioning in this population (Davis et. al., 1991). Moreover, the presence of co-morbid conditions in patients with knee OA, especially chronic health conditions, such as heart and/or lung disease, and obesity have increased the likelihood of having long-term physical disability (Ettinger, et. al., 1994).

2.3.1 Assessment of Patient-Reported Physical Functioning in Patients with Knee OA

Assessing physical functioning is a complex task as it comprises multiple constructs. Patient-reported outcome measures reflect a person’s perception of their own health status (Carr et. al., 2003) and reports have demonstrated that patients themselves can characterize their own physical function better than health care professionals (VanderZee et. al., 1996). The process for real decision-making in itself is hypothetical as it involves imagining and evaluating hypothetical outcomes, and this is the same process individuals use when making decisions about hypothetical situations. Applied to measures of physical functioning, an individual evaluating their hypothetical ability to complete tasks relating to lower extremity physical function would thus involve the same process of performing the task. These measures are assessed based on what individuals think they can do as opposed to how they function in the real world. Patient-report measures offer an inexpensive, quick, and valid method to assess physical functioning in patients with knee OA.

**2.4 Patient Reported Outcome Measures for Physical Functioning**

2.4.1 Western Ontario and McMaster Arthritis Index (WOMAC)

The WOMAC is a disease-specific patient-reported functional status measure that is used to assess three health concepts, pain, stiffness, and physical function.

2.4.1.1 Development of the WOMAC

The WOMAC was originally developed by Bellamy and colleagues to evaluate the effectiveness of treatments for OA, and has been used extensively to evaluate outcomes for medication effectiveness, and rehabilitation treatments for patients with arthritis (Bellamy et. al., 1986; Bellamy et. al., 1988; Barr et. al, 1994). It was developed from a structured interview in 100 patients with primary OA of the hip and knee, and contains three subscales: Pain (5 items), Stiffness (2 items), and Physical Function (17 items) (Bellamy et al., 1988). It is available in a 5-point descriptive scale (0-4 with adjectives of none, mild, moderate severe and extreme) and a 100 mm VAS with terminal descriptors (no difficulty to extreme difficulty).

2.4.1.2 Psychometric Properties of the WOMAC in Patients with Knee OA

Effect sizes, standardized response means, and mean change response scores demonstrate that the WOMAC is responsive in an arthritis population, and following arthroplasty (McConnell et al., 2001; Stratford et al., 2007; Elrich et al., 2000).It demonstrates adequate to high reliability among the arthritis population (McConnell et al., 2001; Stratford et al., 2007). It has shown adequate construct validity with other health status measures (SF-36 and HAQ), and known group validity as it was able to discriminate between those who were satisfied and those who were not following TKA (Bellamy et al., 1988; Bellamy et al., 1992). It has shown divergent construct validity with low correlations in unrelated dimensions on the SF-36, Doyle, and McMaster Health Index Questionnaire (MHIQ) (Bellamy et al., 1988). The WOMAC was not shown to be superior to the LEFS in patients with knee OA who were wait-listed for TKA (Stratford et al., 2004). A more recent study examining the reliability and responsiveness of the LEFS and WOMAC did not show one measure was superior in patients with knee OA undergoing rehabilitation (Williams et al., 2012).

There was no process used to reduce items at the time the WOMAC was constructed resulting in its lack of factorial validity in that the items found in the pain and physical function sub-scales are evaluating the same health concepts (Kennedy et al., 2003; Geurmazi et al., 2004; Ryser et al., 1999). Specifically, the measure has been shown to have greater difficulty distinguishing between health concepts of pain and physical function (Kennedy et al., 2003; Guermazi et al, 2004; Ryser et al., 1999). The effect of recall bias on long-term responsiveness, and lack of factor and divergent construct validity are two major criticisms specifically related to the WOMAC physical function subscale (Kennedy et. al 2003; Geurmazi et. al. 2004; Ryser et. al., 1999; Terwee et al., 2006). The main barrier to using this instrument in clinical practice is its lack of superiority over other outcome measures that are available at no cost.

2.4.2 Knee Injury and Osteoarthritis Outcome Score (KOOS) and Knee Injury and Osteoarthritis Outcome Score – Physical Function Subscale (KOOS-PS)

2.4.2.1 Development of the KOOS and KOOS-PS

The KOOS was initially developed for use in a more active, younger population with knee injury or OA, and includes a broader range of patient-specific functional abilities using subscales including sport and recreation functioning, and ADLs (Roos et. al., 2008) The questionnaire comprises five domains including pain, symptoms, ADLs (equivalent to the WOMAC physical function subscale), sport and recreation function, and knee-related quality of life. All items are scored from 0 (none/never/not at all) to (extreme(ly)/always/total(ly)) in the domains and the scores totaled. They are transformed to a 0-100 scale with lower scores indicating worsening knee problems. It was developed based on the WOMAC, literature review, and an expert panel (Roos et. al., 1998).

The KOOS-PS was shortened from the original KOOS using Rasch-based item reduction methodology and contains seven items from the ADLs and sport and recreation function subscales from the original KOOS (Perruccio et al., 2008).

2.4.2.2 Psychometric Properties of the KOOS and KOOS-PS in Patients with Knee OA

Scores on the KOOS initially demonstrated high test-retest reliability, and responsiveness in patients following anterior cruciate ligament reconstruction (Roos et. al., 1998). Construct validity in this patient population was supported by expected association with the SF-36 bodily pain and physical functioning subscales (Roos et al., 1998). Face validity of the KOOS was ensured for patients with post-traumatic OA on the basis of a cross-sectional pilot study by having seventy-five people aged 35-76 years with radiographic signs of knee OA and a meniscal injury 20 years previous complete the questionnaires. The initial questionnaires were developed by an expert panel of patients referred for physiotherapy due to knee injuries, orthopedic surgeons and physical therapists from both the United States and Sweden (Roos et al., 1998).

A systematic review of the KOOS has demonstrated it has moderate to strong construct validity by expected associations with the SF-36 bodily pain and physical functioning subscales (Peer and Lane, 2013). The KOOS-PS demonstrated expected moderate to strong associations with the WOMAC physical function subscale, fatigue on the Profile of Mood States, Chronic Pain Grade questionnaires and the Hospital Anxiety and Depression Scale (Davis et al., 2009) in patients undergoing TKA for knee OA. The KOOS-PS has acceptable psychometric properties in patients undergoing TKA for knee OA with large effect sizes demonstrating its ability to measure change over time (Peer and Lane, 2013). A strong correlation between scores on the KOOS-PS and the WOMAC pain subscale has been reported consistent with the limitation of the WOMAC with respect to overlapping of the pain and physical functioning subscales (Davis et al., 2009).

2.4.3 Lower Extremity Functional Scale (LEFS)

The LEFS is a region-specific patient-reported measure developed by Binkley et. al. (1999) to measure lower extremity function.

2.4.3.1 Development of the LEFS

The LEFS was developed by asking questions to patients about their lower extremity functioning. Following item reduction and factor analysis, the final questionnaire contained 20 questions about lower extremity functioning, with questions ranked on a 5-point descriptive scale from 0 (extreme difficulty or unable to perform the activity) to 4 (no difficulty) with a total score of 80. Higher scores represent higher functioning. The LEFS questionnaire is found in Appendix 2.

2.4.3.2 Psychometric Properties of the LEFS in Patients with Knee OA

The LEFS has been shown to be highly reliable and valid in a rehabilitation population that included patients with knee OA, and has been used to measure function in the lower extremities before and after hip or knee replacement surgery in people with OA (Yeung et al., 2009; Kennedy et al., 2008). It has also demonstrated responsiveness across both inpatient and outpatient rehabilitation populations with lower extremity dysfunction, including OA (Yeung et al., 2009). The construct convergent and divergent validity are supported by expected associations with physical function subscale and the mental health subscale respectively when compared to the SF-36 health status questionnaire in patients who attended an outpatient rehabilitation program (Binkley et al., 1999). Known group validity has been confirmed through differentiation between patients who required home-care and those who required outpatient services following lower extremity arthroplasty (Stratford et al., 2009). The error associated with an individual score among these specific populations was determined to be +/- 5 LEFS points (Binkley et al., 1999; Stratford et al., 2010; Stratford et al., 2009). The minimally clinical important difference and minimal detectable change have been determined as +/- 9 LEFS points for an individual score among inpatient and outpatient populations, and among those who have had lower extremity joint replacement (Stratford et al., 2000; Stratford et al, 2009). Additionally, recovery curves have been mapped allowing individual comparison of patients who have had TKA to that of the expected recovery (Kennedy et al., 2008). Stratford et. al. (2005) has demonstrated that the LEFS is valid if up to 4 items are missing (as long as no more than 2 missing values are from the same category when the items are ranked from least to most difficult).

2.4.4 Oxford Knee Score (OKS)

The OKS is a site-specific PROM that includes pain and function (Dawson et al., 1998).

2.4.4.1 Development of the OKS

The OKS was initially developed to determine outcomes following TKA, and is widely utilized across Europe (Dawson et al., 1998). It consists of 12 items ranked on a 5-point descriptive scale and scores range from 1 to 5 (total score of 60) with lower scores representing higher function (Dawson et. al., 1998). A more recent scoring system has been suggested, with the scores for each item ranging from 0 to 4 (for a total score of 48) (Murray et al., 2007). A copy of the questionnaire is found in Appendix 3.

2.4.4.2 Psychometric Properties of the OKS in patients with knee OA

Construct convergent validity has been supported in comparison of scores on the OKS with those on the KOOS-PS and the short-form-12 (SF-12) in patients with knee OA undergoing non-operative management (Xie et al., 2011). The OKS also demonstrates convergent construct validity when scores were correlated with scores on the EQ-5D physical function subscale (Xie et al., 2011). However, known group validity was not supported among patients with knee OA (Xie et al., 2011). The MDC90 was +/- 6 OKS points and the MCID was approximately 6 OKS points in patients being treated conservatively for knee OA (Xie et al., 2011). The responsiveness of the OKS was superior to all subscales on the SF-36 in patients undergoing TKA (Ko et al., 2013). The change score determining satisfaction among patients 6 months after TKR was determined to be 11 points (Williams et al., 2013). Long-term mapping of the scores following TKR has been illustrated with the OKS allowing for prediction of functional recovery from years 1-10 (Williams et al., 2013). However, the expected recovery within the first year following TKA has not been mapped using the OKS.

**2.4 Physical Function to determine Appropriateness for TKA in Patients with Knee OA**

There is no standardized method to determine appropriateness for TKA in patients with primary knee OA. Clinical decision-making concerning who will benefit from TKA is a complex task that is not completely understood. To reduce wait times and improve patient outcomes, research has investigated factors contributing to making decisions regarding which patients with knee OA should receive TKA. Referring physicians do not agree on the factors that are important when determining appropriateness for TKA among patients with knee OA (Wright et al., 1995; Coyote et al., 1996; Mamlin et al., 1998; Cross et al., 2006). Even orthopedic surgeons, who are the ultimate decision-makers, do not have complete agreement in determining those who would benefit most from the surgery (Tierney et al., 1994; Mancuso et al., 1996). Several studies have evaluated the agreement of criteria used to determine appropriateness for referral for consideration of TKA among physician groups (Tierney et al., 1994; Coyote et al., 1996; Mamlin et al., 1998). There is also variability in referring physicians’ opinion, as well as orthopedic surgeons’ opinions with respect to the utilization of TKR for knee OA (Wright et al., 1995; Mancuso et al., 1996; Cross et al., 2006). The results of the studies are summarized in Table 3.

Table 3: Agreement Among Physician Groups on Factors Contributing to the Decision to Refer or Recommend TKA for Patients with Knee OA

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Authors | Study Description | Factors suggesting appropriate for TKA | Factors suggesting not appropriate for TKA | Factors of Disagreement (<60% consensus) |
| Tierney  et al.  (1994) | Surveyed all orthopedic surgeons in Indiana | 1) Constant knee pain on weight bearing | 1) Alcohol or drug abuse  2) Major psychiatric disorder  3) Active skin infection | 1) Nursing home resident  2) painful feet  3) patient demands TKA  4) unstable knee  5) severe hip OA |
| Wright et. al. (1995) | Surveyed referring physicians (GPs and rheumatologists) and orthopedic surgeons to ask how specific patient characteristics affected their recommendation for TKA |  | 1) Obesity  2) Peripheral vascular disease  3) isolated patellofemoral  arthritis  4) Alcohol or drug abuse  5) Active skin infection  6) major psyche disorder  7) patient noncompliant  8) age  < 55 years  9) high physical  demands at work  10) septic  arthritis > 1 year ago | 1) Age >80 years old  2) osteoporosis  3) nursing home resident  4) severe hip OA  5) local psoriasis  6) quadriceps lag or weak quadriceps  7) sensation of instability |

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Authors | Study Description | Factors suggesting appropriate for TKA | Factors suggesting not appropriate for TKA | Factors of Disagreement (<60% consensus) |
| Coyote et. al. (1996) | Surveyed rheumatologists and general practitioners (GPs) | **Rheumatologists and GPs**: Pain not responding to drug therapy  **GPs:** Unable to walk a block without pain | **Rheumatologists:** 1) isolated patello-femoral compartment 2) Peripheral vascular disease  3) Active skin infection | **Rheumatologists and GPs**: 1) Noncompliant 2) obese, septic knee > 1 year ago 3) varus or valgus deformity 4) high physically demanding job  **Rheumatologists:** 1) Nursing home  resident 2) patient demands  TKA 3) limited active knee range of motion 4) sensation of knee instability  **GPs:** 1) age < 55 years 2) severe hip OA 3) quadriceps lag 4) weak quadriceps |
| Mancuso et. al. (1996) | Surveyed orthopedic surgeons in New York City regarding candidacy for TKA in patients with knee OA | 1) Severe daily pain  2) rest pain most days during the week  3) Pain on weight bearing  4) destruction of most of the joint space on x-ray  5) functional limitations – unable to walk 3 blocks and difficulty climbing stairs | 1) younger age  2) co-morbidities  3) technical difficulties in performing the surgery  4) lack of motivation  5) Dementia  6) Unrealistic expectations  7) Hostile personality | 1) Age > 80 years  2) weight > 200 lbs (91 kg)  3) wants psychiatric benefit |

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Authors | Study Description | Factors suggesting appropriate for TKA | Factors suggesting not appropriate for TKA | Factors of Disagreement (<60% consensus) |
| Mamlin  et al.  (1998) | Surveyed Family practitioners  and General  internists | 1) Pain despite medications  2) Constant knee pain on weight bearing |  | 1) Septic knee arthritis > 1 year ago  2) no health insurance  3) isolated patellofemoral arthritis  4) patient demands TKA  5) painful feet |
| Cross et. al. (2006) | Surveyed orthopedic surgeons, rheumatologists and primary care physicians | Pain not responding to drug therapy | Having a major psychiatric disorder |  |

Boutron et al. (2008) completed a cross-sectional survey of primary care physicians in France (1471 GPs and 4183 patients with hip or knee OA) evaluating quality of life and disability measures (WOMAC, Lequesne index, SF-36, and a numeric pain scale) to determine need for a referral for consideration of TKA one year after the initial visit to their GP. The results indicated that high levels of disability and pain and low levels of quality of life were factors contributing to the decision to refer a patient to an orthopedic surgeon for consideration of TKA (Boutron et al., 2008). As part of an OARSI/OMERACT initiative, Gossec et al. (2011) studied how factors of pain and disability (measured using the ICOAP, WOMAC, and KOOS-PS) were used by an international group of orthopedic surgeons to determine appropriate candidates for TKA in patients with knee OA. Pain levels were generally higher and patients had more functional limitations, but no specific cut-off scores or pain levels could be determined to identify the patients deemed appropriate for TKA (Gossec et al., 2011). The factors considered when determining referral or recommendation for TKA demonstrate disagreement among the referring physicians as well as orthopedic surgeons. As expected, referring physicians were statistically more likely to refer patients with knee OA to orthopedic surgeons for consultation regarding the need for TKA compared to the surgeons’ opinion about their appropriateness for TKA. It is typical that not all patients would be offered surgery when referred to a specialist.

Although there is no real consensus on who should be referred or would most benefit from TKA, limited physical functioning is globally recognized as an important criteria for recommending TKA to patients with knee OA. Gossec et. al. (2011) was not able to determine cut-off scores for the PROMs used to assess physical functioning (WOMAC and KOOS-PS) that could be used to determine whether TKA was required. However, other PROMs measuring physical function were not tested and may show higher diagnostic accuracy. The lack of factorial validity of the WOMAC, KOOS, and KOOS-PS in patients with knee OA suggest that perhaps other PROMs may be more suitable for determining appropriateness for TKA for this population.

The LEFS and OKS are used pre-operatively to assist in determining physical functioning in patients with knee OA at a regional assessment program. Clinically PROMs are a quick method that can be used to provide health care practitioners with information about functioning saving time and allowing for higher volumes of patients to be seen. It would be helpful if these PROMs can assist with determining those who would most benefit from TKA by determining their diagnostic accuracy and cut-off scores. Given that there is no gold standard to assess physical functioning in this patient population, and that physical function is a determining factor in considering whether a patient with knee OA is appropriate for TKA, it was questioned if one of these outcome measures would be a better predictor of patients deemed appropriate for TKA.

**2.5 Thesis Objectives**

The objectives of this thesis are to 1) compare the diagnostic accuracy of two outcome measures, the Oxford Knee Scale (OKS) and the Lower Extremity Functional Scale (LEFS) for TKA in patients with primary knee OA and 2) determine cut-off scores to predict those who are appropriate for TKA in patients with primary knee OA. The hypothesis of the study is that the LEFS will be a better predictor of those deemed appropriate for TKA in patients with primary knee OA. The study includes a retrospective cross-sectional review of patients attending a Regional Joint Assessment Program designed to help manage patients with knee OA and to identify those who are no longer coping and most likely to benefit from TKA. Previous research has shown that the LEFS is a valid and reliable tool in patients across the spectrum of knee OA as a measure of physical functioning. In contrast, the OKS has been studied primarily in patients at end-stage knee OA undergoing TKA and less evidence is available validating its use in patients with knee OA who are being treated conservatively.

**CHAPTER 3:**

**STUDY METHODS**

**3.1 Study Design and Ethics**

A cross-sectional retrospective chart review of patients with knee OA attending a Regional Joint Assessment Program for initial surgical consultation was conducted. Approval for the study protocol was obtained from the Hamilton Integrated Research Ethics Board of HHS and McMaster University.

**3.2 Study Database**

The medical records contain data for people with hip and knee problems assessed at an Ontario Regional Joint Assessment Program (RJAP), a Local Health Integrated Network (LHIN-4)-wide program developed to reduce surgical wait times for patients requiring hip or knee arthroplasty. Patients are referred to the program directly from their family physicians or other physicians such as rheumatologists or sports medicine physicians. Also, patients may be referred to a specific orthopedic surgeon participating in the program. Initial assessments are completed by an advanced physiotherapist practitioner (APP) at various outpatient orthopedic clinics across LHIN-4. The LEFS and the OKS are mailed out to patients up to 2 weeks prior to their appointment time. If patients arrive for their assessment without the questionnaires completed, they are asked to complete them in the waiting room. The decision for TKA is based on various criteria including pain and physical functioning, age, disease severity, physical examination, and conservative measures trialed. Each case is reviewed with the attending orthopedic surgeon, and treatment plan discussed with the patient. Patients learn the outcome of their suitability for arthroplasty or an intermediary surgical procedure immediately at the end of the assessment from the surgeon. The outcome of the assessment was recorded in the study database and extracted from the patients’ medical record. Non-surgical patients are provided with recommendations regarding conservative measures for managing their hip or knee problem. Dictated consultation notes summarizing the initial assessment are recorded in the hospital electronic system.

For the current study, data for patients attending a single RJAP site (Hamilton Health Sciences – Juravinski Hospital) for an initial assessment between January 1, 2013 and September 30, 2013 were reviewed for eligibility. The medical records for the Hamilton Health Sciences – Jurivinski Hospital RJAP site was chosen for review due to the high volumes of patients referred and joint replacements performed - approximately 1700 annually. Responses to each questionnaire item on the LEFS and OKS were recorded in the study database. Data extracted included age, gender, co-morbid conditions, duration of OA symptoms, conservative treatments trialed, knee OA severity, and pain scores. The appropriateness for TKA was recorded as yes/no.

**3.3 Inclusion Criteria**

Inclusion criteria were participants who had a primary diagnosis of knee OA and were 50 years of age or older at the time of the initial assessment and completed both the OKS and LEFS questionnaires. Up to 4 missing items on the LEFS were acceptable if 2 or fewer items were missing from the same category (Stratford et al., 2005). Missing responses were imputed according to the method described by Stratford et. al., (2005) to calculate the total score. According to Murray et. al., (2007) if one or two items are missing on the OKS, the total score may still be valid. However, there is no published literature available reporting on the validity of the OKS using these methods to handle missing data or for inputting unanswered items. For the current study, participants were included if there was no missing data on the OKS.

**3.4 Exclusion Criteria**

Patients were excluded from the study if they had a primary diagnosis other than knee OA (e.g. inflammatory arthropathy, osteonecrosis, or soft tissue injury not related to OA), had a previous joint replacement in the knee of interest, were not medically stable for surgery, or had primary hip OA that was worse radiographically and functionally than the knee OA based on physical assessment. It was expected that the function and symptoms associated with the above conditions would not be similar to those with primary knee OA.

**3.5 Demographics**

The following demographics were extracted from the health records: age (years), gender (M/F), co-morbid health conditions (frequency of neurological, cardiovascular, musculoskeletal and reported as percentages) time since knee OA diagnosis (years), knee OA severity based on diagnosis at the end of the assessment, and conservative interventions trialed (counted as yes/no and reported as percentages). For patients with bilateral knee pain, the data for the most painful knee were used. The first question on the OKS was extracted to quantify pain intensity (see Appendix 3). The conservative measures were counted as yes/no, and the percentages were reported.

**3.6 Classification of Appropriateness for TKA**

In the current study suitability for TKA is defined according to two groups: ‘appropriate for TKA’ versus ‘not yet ready for TKA’. Patients deemed ‘appropriate for TKA’ at the end of the assessment but decided not to proceed with surgery were coded as ‘appropriate for TKA’.

**3.7 Statistical Analysis**

3.7.1 Sample Size Calculation

The sample size was calculated based on the formulas provided by Hanley and McNeill (1982,1983) as shown in Appendix 1 to test the hypothesis that the LEFS scores would be a better predictor of suitability for TKA than the OKS scores. The sample size estimate was determined to be 450 participants based on the prevalence of patients deemed appropriate for TKA (41% appropriate for TKA) and a correlation of 0.79 for scores on the LEFS and OKS on preliminary analysis of data extracted for 161 eligible patients attending the RJAP during the first quarter of 2013.

3.7.2 Patient Characteristics

Descriptive statistics and inferential statistics were computed using Stata 12.1 statistical software. The median scores on the OKS and LEFS and age were compared using non-parametric tests between the ‘appropriate for TKA’ and the ‘not ready for TKA’ groups. The proportions were calculated for age, gender, OA severity, symptom duration, co-morbid conditions and conservative measures trialed. The conservative interventions trialed, knee OA severity, and pain scores for each group (appropriate for TKA and not yet ready for TKA) were compared using a χ2 test (Fisher’s exact test when less than 5 patients had trialed the intervention). The level of significance was set at 0.05. Quality checking of the extracted data entered ensured against missing or implausible values.

3.7.3 Receiver Operator Characteristic Analysis

Receiver operator characteristic (ROC) curves were constructed and the area under the curve (AUC) and confidence intervals (Streiner and Cairney, 2007) were computed using Stata 12.1 statistical software to determine the ability of scores on the LEFS and OKS to discriminate between the two groups. For each measure, various cut-points were plotted according to the sensitivity (true positives along the y-axis) against 1-specificity (false positives on the x-axis). AUC falls between 0 to 1 and is interpreted as follows: AUC ranging between 0.8 to 1 represents excellent diagnostic accuracy; 0.7 to 0.8 represents moderate accuracy; 0.5-0.7 represents poor diagnostic accuracy (Streiner and Cairney, 2007). The AUC for the LEFS and the OKS were compared using a z-test to determine statistical significance. The level of significance was set at 0.05.

3.7.4 Calculation of Cut-off Scores

To determine the best cut-off scores for correctly identifying candidates for TKA, the point closest to the top left-hand corner of the ROC curve (most true positives and fewest false positives) was calculated mathematically for the LEFS and the OKS separately.

**CHAPTER 4:**

**STUDY RESULTS**

**4.1 Study Flow Diagram and Patient Characteristics**

Figure 1 illustrates the study flow diagram. Of the 984 patients with knee OA attending the RJAP for an initial assessment during the study period, data for 421 patients were admitted to the study based on eligibility criteria.



Figure 1. Study Flow Diagram

The sample characteristics are summarized in Table 4. Most of the patients in the study were women. The “appropriate for TKA” group was statistically older (p<0.001) compared to the “not ready for TKA” group. The LEFS and OKS median scores were statistically different between the two groups (p<0.001), representing higher functioning in the “not ready for TKA” group. The ‘appropriate for TKA’ group had statistically significant higher severity of knee OA determined by the assessment (p <0.001), and reported pain as ‘severe’ (p = 0.01) compared to the ‘not yet ready for TKA’ group. The ‘not yet ready for TKA” group had significantly higher pain scores in the ‘very mild’ (p=0.01) and ‘mild’ (p<0.001) categories compared to the ‘appropriate for TKA’ group. However, both groups had the majority of patients that rated their pain level as ‘moderate’. The duration of knee OA was not consistently recorded in the patient health record leading to missing data. Co-morbid conditions are listed in Table 5.

The conservative interventions trialed by the sample are listed in Table 6. The χ2 analysis showed that more people deemed appropriate for TKA had tried analgesics (p = 0.006), cortisone injections (p<0.001), viscosupplementation injections (p = 0.03), a home exercise program (p = 0.02), and gait aids (p = 0.019) compared to those not yet ready for TKA. Those not yet ready for TKA were more likely to have tried acupuncture compared to those appropriate for TKA (p = 0.004). There were no between-group differences in the use of the other conservative interventions.

Table 4: Patient Characteristics

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Characteristics** | **Total Sample (n=421)** | **Appropriate for TKA (n=175)** | **Not ready for TKA (n=246)** |
| Age (years) (SD) | 66.9 (9.5) | 69.6 (9.7) | 65.0 (8.8) |
| Male/Female | 41.8%/58.2% | 40.0%/60.0% | 43.1%/56.9% |
| LEFS scores  Max score =80  (higher scores= higher function) | Median = 27  Min = 0  Max = 80 | Median = 23  Min = 0  Max = 72 | Median 33  Min = 0  Max = 80 |
| OKS scores  Max score = 60  (higher scores = lower function) | Median = 40  Min = 13  Max = 58 | Median = 42  Min = 21  Max = 57 | Median = 38  Min = 13  Max = 58 |
| Pain Scores 1 |  |  |  |
| None | 1.0% | 0.0% | 1.6% |
| Very Mild\* | 3.3% | 0.6% | 5.3% |
| Mild\* | 10.7% | 2.9% | 16.2% |
| Moderate | 52.3% | 53.7% | 51.2% |
| Severe\* | 32.8% | 42.9% | 25.6% |
| Severity of OA2 |  |  |  |
| Mild\* | 9.0% | 0.0% | 15.4% |
| Mild-moderate\* | 6.2% | 0.0% | 10.6% |
| Moderate\* | 16.3% | 4.0% | 25.2% |
| Moderate-severe\* | 13.8% | 6.3% | 19.1% |
| Severe\* | 54.4% | 89.7% | 29.1% |
| OA symptom duration | (n = 342) | (n=133) | (n=209) |
| <1 year | 22.2% | 7.5% | 31.6% |
| 2-5 years | 45.0% | 47.4% | 43.5% |
| 6-10 years | 19.6% | 28.6% | 13.9% |
| >10 years | 13.4% | 17.3% | 11.0% |

1 OKS-question 1 2 Determined based on radiographic findings and clinical examination

\*statistically significant

Table 5: Co-morbid Conditions

|  |  |  |  |
| --- | --- | --- | --- |
| **Co-morbid Condition** | **Total Sample (n=421)** | **Appropriate for TKA (n=175)** | **Not ready for TKA (n=246)** |
| Resp and CV | 49.6% | 54.4% | 45.5% |
| MSK | 16.4% | 16.0% | 16.7% |
| Neuro | 2.9% | 4.6% | 1.6% |
| Prior Knee Surgery | 21.9% | 26.9% | 18.3% |
| Obesity | 14.7% | 10.9% | 17.5% |
| Mental Health | 3.3% | 4.6% | 2.4% |
| Osteoporosis | 7.6% | 6.3% | 8.5% |

Table 6: Conservative Interventions Trialed

|  |  |  |  |
| --- | --- | --- | --- |
| **Conservative Intervention** | **Total Sample (n=421)** | **Appropriate for TKA (n=175)** | **Not ready for TKA (n=246)** |
| Analgesics\* | 46.6% | 56.7% | 39.4% |
| NSAIDS | 48.0% | 49.1% | 47.2% |
| Cortisone Injections\* | 27.6% | 37.7% | 20.3% |
| Viscosupplementation\* | 7.1% | 10.2% | 4.9% |
| Brace/Sleeve | 27.8% | 27.4% | 28.0% |
| Formal Physiotherapy | 21.1% | 19.4% | 22.4% |
| Home Exercise\* | 7.8% | 11.4% | 5.2% |
| Aquatic Exercises | 5.2% | 5.7% | 4.9% |
| Weight Loss | 6.9% | 2.3% | 7.3% |
| Thermal Therapy | 6.4% | 8.6% | 9.3% |
| Accupuncture\* | 0.7% | 0.6% | 0.8% |
| Topical Creams | 16.6% | 16.0% | 17.1% |
| **Conservative Intervention** | **Total Sample (n=421)** | **Appropriate for TKA (n=175)** | **Not ready for TKA (n=246)** |
| Joint Supplements | 9.3% | 8.6% | 9.8% |
| Gait aids\* | 2.4% | 4.6% | 0.8% |
| Other | 5.0% | 5.7% | 4.5% |

\*Indicates statistical significance

**4.2 ROC Analysis**

The diagnostic accuracy of the LEFS for TKA in patients with knee OA was not superior to the OKS (p = 0.18).

Figure 2 illustrates the ROC characteristics for the LEFS. The AUC was 0.686 (95% CI = 0.636 – 0.736) for LEFS. The best cut-off scores on the LEFS for discriminating between patients deemed ready for TKA and those not yet ready for TKA was 26 out of 80 points. The cut-off score for the LEFS for appropriateness for TKA had a sensitivity of 0.62 and a specificity of 0.65. This cut-point correctly identified 63.4% of the patients deemed appropriate for TKA. The positive predictive value (PPV) was 55.4% and the negative predictive value (NPV) was 70.4% for the LEFS in our sample population.

Figure 3 illustrates the ROC curve characteristics for the OKS. The AUC was 0.674 (95% CI = 0.623- 0.724) for the OKS. The best cut-off score on the OKS for discriminating between patients deemed appropriate for TKA and those not yet ready for TKA was 42 out of 60 points. This cut-off score has a sensitivity of 0.57 and specificity of 0.67. It correctly identified 62.3% of the patients deemed appropriate for TKA. The PPV of the OKS was 68.9% and the NPV was 66.3%.

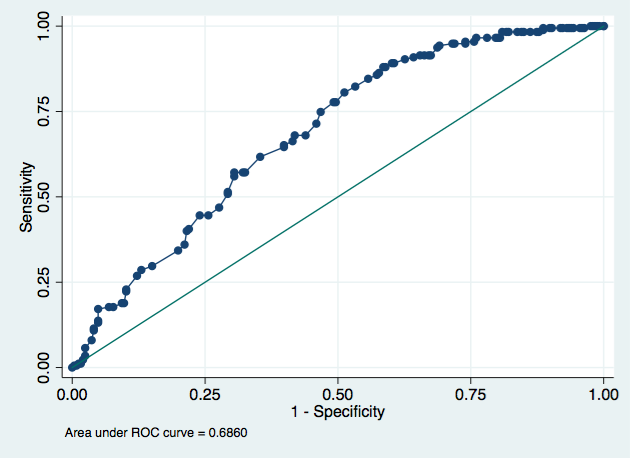


Figure 2: ROC curve for the LEFS

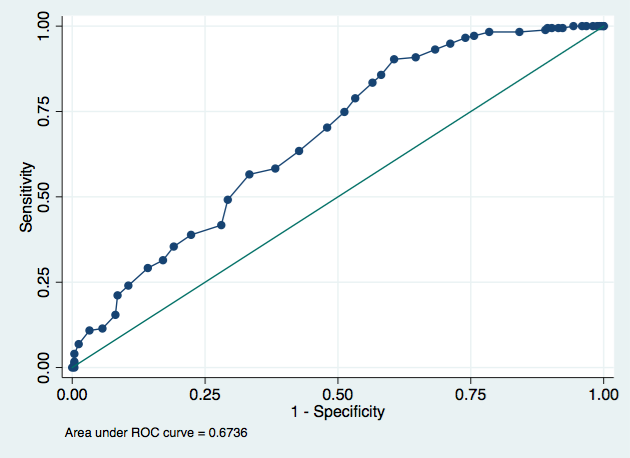


Figure 3: ROC curve for the OKS

**CHAPTER 5: DISCUSSION AND CONCLUSIONS**

**5.1 Discussion**

The overall goal of this thesis was to determine if suitability for TKA could be predicted on the basis of scores on PROMs currently used in our Joint Assessment Program to quantify lower extremity physical functioning in people with primary knee OA. The main objective of the study was to determine if the diagnostic accuracy of the LEFS was superior to the OKS in determining suitability for TKA in patients with primary knee OA. Diagnostic accuracy was poor for both outcome measures and the LEFS was not superior to the OKS. The study results show that the individual LEFS and OKS scores have insufficient diagnostic accuracy to determine suitable candidates for TKA in our sample. The second objective was to determine best LEFS and the OKS cut-off scores for determining those appropriate for TKA among patients with primary knee OA. The cut-off score was 26 out of 80 points on the LEFS and 42 out of 60 points on the OKS. Both PROMs had higher specificity than sensitivity (based on the best cut-points determined in this study). Therefore, the LEFS and OKS are most useful for identifying those with scores indicative of better function who not yet ready for TKA in our sample population. However, the number of people with scores indicative of better function who are appropriate for TKA is high given the moderate specificity of both PROMs. In other patient populations this may not be the same unless the prevalence is similar to ours. Most of the patients seen for initial consultation are deemed not yet ready for TKA at our center, and this prevalence may be different compared to other joint assessment centers. The predictive values of the LEFS and OKS indicate that in our sample population the LEFS is better at determining those patients with better function who are not yet ready for TKA.

The diagnostic accuracy of the LEFS was expected to be superior to that of the OKS as the LEFS has been validated in patients across the spectrum of knee OA compared to the OKS (Yeung et al., 2009). The OKS has primarily been used to evaluate outcomes after TKA (Dawson et al., 1998; Ko et al, 2013; Williams et al., 2013). Research on the OKS across the spectrum of OA is currently limited, with the results demonstrating that it does not have sufficient validity in a rehabilitation population of patients with knee OA (Xie et al., 2011). It would be expected that an outcome measure that has been used across the spectrum on knee OA would better discriminate patients assessed at the RJAP. However the study hypothesis was not supported. These outcome measures were developed to assess change over time, and not all outcome measures are intended to be used as diagnostic tests. Other PROMs or combinations of PROMs may demonstrate higher diagnostic accuracy in those with knee OA who are deemed appropriate for TKA.

Patient-reported outcome measures alone have not been shown to be accurate in determining physical functioning in patients who have knee OA (Stratford et al., 2006). Pain and physical function have been shown to be correlated in patients with knee OA (Kavchak et. al, 2012; Nebel et al., 2009; Riddle and Stratford, 2013; Zifchock et .al, 2011). The OKS score incorporates both pain and function constructs and the diagnostic accuracy was no different than for the LEFS. On the other hand, physical performance measures have been shown to better predict some aspects of physical functioning than patient-reported measures (Terwee et. al, 2006). Maly et al. (2006) reported that patient-reported measures of physical functioning are strongly correlated to pain in patients with knee OA. Terwee et. al. (2006) concluded that patient-reported measures of physical functioning are more affected by pain compared to performance-based instruments, and suggest that patient-reported measures are less valid when they have a high correlation to pain among the knee OA population. This finding was demonstrated empirically in a study of people with hip and knee OA who had recently undergone joint replacements in which post-operative patient-reported physical functioning was superior to performance on mobility tests administered at that time (Stratford et al., 2010). Other studies have indicated that patient reported and physical performance outcome measures are measuring different aspects of physical functioning (Stratford and Kennedy, 2006; Terwee et. al, 2006) and using both types of measures will provide a more comprehensive assessment of physical functioning (Dobson et al., 2012; Dobson et al., 2013). Further investigation is warranted to determine if a combination of scores on both patient-reported and performance-based measures of lower extremity functional disability may provide better diagnostic accuracy for determining appropriateness for TKA.

Our study results are supported by the study by Gossec et al. (2011). In that international cross-sectional study, pain assessed using the Intermittent and Constant Osteoarthritis Pain (ICOAP) patient-reported questionnaire and lower extremity functional disability assessed by the Hip/Knee Injury and Osteoarthritis Outcome Score – physical function short form (HOOS-PS/KOOS-PS) patient-reported questionnaires did not predict the orthopedic surgeon’s decision regarding patients’ suitability for total joint replacement (TJR). The AUC curves constructed for pain and function separately did not demonstrate sufficient diagnostic accuracy for recommending TJR in their population and therefore the researchers combined pain and function to determine the diagnostic accuracy of the combined scores. Even after stratifying for radiographic severity, cut-points could not be determined as the combined score did not have suitable diagnostic accuracy. Gossec et al. (2006) also concluded that duration of OA symptoms was an important factor indicating appropriateness for TJR. The duration of OA symptoms was not consistently reported in the clinical health record and therefore conclusions regarding the importance of this factor’s contribution for determining appropriateness for TKA cannot be determined in our study. However, conservative treatments trialed nor other factors considered to be involved with determining appropriateness for TJA were evaluated in that international study, and other studies indicate there are many other factors that are strong determinants of surgery (Hadorn and Holmes, 1997; Conner-Spady et al, 2004; Escobar et al., 2003). Furthermore, tools developed to prioritize those patients with OA who are most likely to benefit from TKA have utilized a multitude of factors that do not only include physical functioning, but also consider other patients characteristics including patients’ age, pain levels, radiographic severity of knee OA, exhaustion of conservative measures, especially the use of pain medications, and clinical examination findings including knee joint deformities, ROM, muscle strength, and joint instability. Appendix 4 summarizes the priority tools and the potential factors indicating appropriateness for TKA among the knee OA population. Although the commonality among the priority tools suggested that functional disability is a key determinant of appropriateness for TKA in patients with primary knee OA, other factors including age, severity of knee pain, radiographic severity of knee OA, exhaustion of non-surgical measures and clinical findings such as deformities, limitations in range of motion of the knee, and instability require further testing and may provide higher diagnostic accuracy for determining appropriateness for TKA in patients with knee OA. In our sample population, the patient characteristics in the ‘appropriate for TKA’ group included more severe knee OA, determined at the end of the clinical assessment (incorporating physical examination with history and symptoms), use of analgesics, and cortisone injections for pain relief when compared to the ‘not yet ready for TKA’ group. Knee pain of moderate intensity was similarly reported in the two groups, also found in Gossec et al. (2006). The characteristics in our sample are similar to characteristics used in the priority tools, and are in agreement with the results of Gossec et al. (2006). Overall, there are many individual patient characteristics to consider when determining appropriateness for TKA. Patients’ perceptions of their own candidacy for TKA have been well documented in the literature. A summary of studies outlining patients’ beliefs about their candidacy for TKA is summarized in Table 7 (Hawker et al., 2006; O’Neill et al., 2007; Frankel et al., 2012).

Table 7: Patient Perceptions of Appropriateness for TKA



|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author** | **Study Description** | **Factors suggesting Appropriate for TKA** | **Factors suggesting not appropriate for TKA** | **Comments** |
| Hawker et. al. (2006) | Prospective evaluation of patients’ perceptions of TKA candidacy | 1) Largest predictor reaching significance was willingness of the patient to consider the surgery  2) Patients had higher WOMAC scores  3) older patients had higher ratios for TKA  4) better health (using the SF-36)  5) higher education (after adjusting for willingness to consider surgery) |  | 1) unwillingness to proceed with TKR was accounted for by misconceptions regarding indications for TKA including patients’ lack of awareness of the severity of pain and limitations required for TKA  2) patients with lower SES had higher perceived risks of TKA  3) being both female and having a lower SES were less likely to have received a recommendation from family or friends to consider TKA |
| O’Neill et. al. (2007) | Meta-analysis of ten qualitative studies regarding the decision-making process for TKA in patients with knee OA | 1) more severe daily pain relating to arthritis (as opposed to a normal process of aging)  2) The relationship with health care professionals - patients often put trust in the surgeons and nurses, and rely on their expert opinion of their candidacy for the surgery, and to provide education  3) benefits outweigh risk of surgery  4) patients expectations that TKA would reduce pain and improve physical functioning | 1) others were “worse off”  2) unwilling to accept the risk of surgery  3) patients were able to rely on conservative measures to alleviate their pain | 1) patients have a poor attitude toward TKA |

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author | Study Description | Factors suggesting Appropriate for TKA | Factors suggesting not appropriate for TKA | Comments |
| Frankel et. al. (2012) | Qualitative analysis of patient perceptions of appropriateness for joint replacement surgery | 1) pain intensity, its impact on physical functioning, and ability to cope  2) being “bad enough” against their own markers of pain and functioning  3) “being ready” psychologically for the surgery and rehabilitation  4) having a positive attitude toward TKA  5) referring physician’s opinion as well as orthpaedic surgeon’s opinion including the findings on physical examination combined with radiographic severity  6) =>70 years were more accepting of the physician’s opinion candidacy for surgery  4) benefits of TKA outweighing the risks, especially with respect to employment, burden on others and their own ability to function as caregivers | 1) those who had a “bad attitude”  2) not willing to have surgery due to the anaesthetic, or the lengthy rehabilitation course |  |

These studies indicate that although patients may have severe knee OA both radiographically and symptomatically, they may not be willing to undergo surgery due to their perceptions about their need for TKA, especially if their perception is that the risks outweigh benefits of surgery. This was accounted for in our study as patients who were deemed appropriate for TKA at the end of the assessment but chose not to be wait-listed were deemed ‘appropriate for TKA’. The qualitative analyses support that there is more than limitations in physical functioning that determines appropriateness for TKA in patients with knee OA including patients’ perceptions of their readiness for undergoing surgery.

The capacity to benefit framework created by Dieppe proposes a method for decision making for joint arthroplasty in patients with osteoarthritis (Dieppe, 2011). Specifically, the decision to consider the benefit of TKA for patients with knee OA is determined by disease-related factors: 1) the state of the knee and the risk of continuing on non-operatively and 2) the impact of the disease on quality of life factors (Dieppe et .al, 2011). The treatment-related factors include the benefits of TKA considering co-morbidities and balancing risk/benefits while considering the benefits of non-surgical options including patient preferences (Dieppe et al., 2011). Dieppe’s framework provides a structured guideline for health care professionals of factors to consider when determining appropriateness for TKA in patients with knee OA. In our study, the capacity to benefit framework was utilized during the assessment of the patient to assist in determining appropriateness for TKA. For example, radiographic severity of knee OA is one component when making a determination about progression of the disease state. The state of disease and its impact on the patient is considered during the assessment. The results of the study indicated that those deemed ‘appropriate for TKA’ showed “severe” or “moderate to severe” compared those ‘not yet ready for TKA’. Physical functioning as measured by the LEFS and OKS is only one component in the ‘disease related factors’ of Dieppe’s framework, and physical functioning outcome measures alone do not show the complete impact of knee OA on an individual’s overall ability to function in daily life, or to participate in societal activities. The sample characteristics of the population studied demonstrated group differences in the conservative measures trialed indicating that it may be a contributing factor in determining appropriateness for TKA.

5.1.1 Limitations

This thesis presents results that must be interpreted in the context of the study limitations. The target sample size was not achieved in the study period set due to the number of people who did not complete the OKS and/or the LEFS. Seventy-eight percent of the patients attending the RJAP site during the study period for initial assessment completed both questionnaires. As there is no method available to correct for missing data on the OKS and maintain validity, completion of this outcome measure was a limiting factor for admission to the study. The authors were contacted and suggested that the OKS is valid if no more than 2 items are missing, and that these items can be imputed using the average of the total score for individual patients. Also, if there are multiple responses checked, the one corresponding with worsening pain or functional status should be used. However, as there is no published research supporting the validity of the OKS with missing items or items imputed, for our study if items were missing, or there were multiple responses recorded, the OKS was not used. Potential reasons why the questionnaires were incomplete could be due to interpretability of the questions, relevance of the questions or uncertainty regarding whether the questionnaires would be useful to the attending surgeon. In addition, the validity of administering the LEFS and OKS through postal mail has not been determined and may have contributed to the rates of missing responses. Thus, results may differ if those patients who did not complete the PROMS were included. Furthermore, extending the study period to cover all 4 quarters would take into account any seasonal effects on scores. Given the variability in the process of deciding appropriateness for TKA, the findings may differ in people who are being assessed at different Joint Assessment Programs, different RJAP sites, or other clinical settings and thus limits the generalizability of the study results to other patient populations. Another important limitation to consider is that diagnostic accuracy of the LEFS and OKS were determined on the basis of the clinical judgement of suitability for TKA. It is unknown if those deemed appropriate for TKA truly benefited from the surgery or if some deemed not yet ready required a TKA. In the absence of a criterion standard for determining who will benefit from TKA, classification by the orthopaedic surgeon served as a surrogate. Additionally, as the APPs may use the total scores on the LEFS and OKS to assist the surgeon in making the decision regarding suitability for TKA the estimated diagnostic accuracy of these measures may be inflated.

**5.2 Conclusions**

The LEFS and OKS did not have sufficient diagnostic accuracy alone to determine appropriateness for TKA in patients with primary knee OA. Determining suitability for TKA in patients with knee OA is a complex decision completed on an individual basis and the degree to which scores on the LEFS and OKS enter into this decision requires further study. This thesis provides new knowledge around the diagnostic accuracy of the LEFS and OKS, two outcome measures commonly used to assess physical function in the OA population. It provides support that the LEFS and OKS alone do not provide sufficient diagnostic accuracy for appropriateness for TKA in the OA population. Further research is needed to assess the impact of adding physical performance measures to determine diagnostic accuracy for classifying people with knee OA as ‘appropriate for TKA’ versus ‘not yet ready for TKA’. Additional studies evaluating the clinical utility of the priority tools and capacity to benefit framework that account for multiple patient factors including limitations in physical functioning and patient perceptions may lead to better selection of patients appropriate for TKA in patients with primary knee OA.

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**APPENDIX**

1. Sample Size Calculation

Hanley and McNeill (1982,1983)

n = [(Zα\* sqrt{2V1}) + (Zβ \*sqrt {V1+V2})]2/δ

Zalpha = 1.645 for 5% one-sided test of significance

Z beta = 1.645 for 95% power

V1 = Q1 + Q2 – 2 θ12

V2 = Q1 + Q2 – 2 θ22

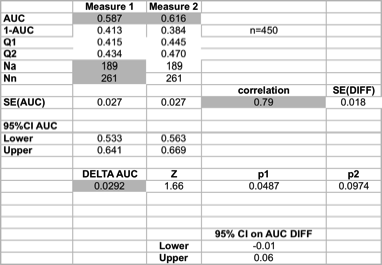
δ = θ2-θ1

Q1 = θ/(2-θ)

Q2 = 2θ2 / (1+θ)

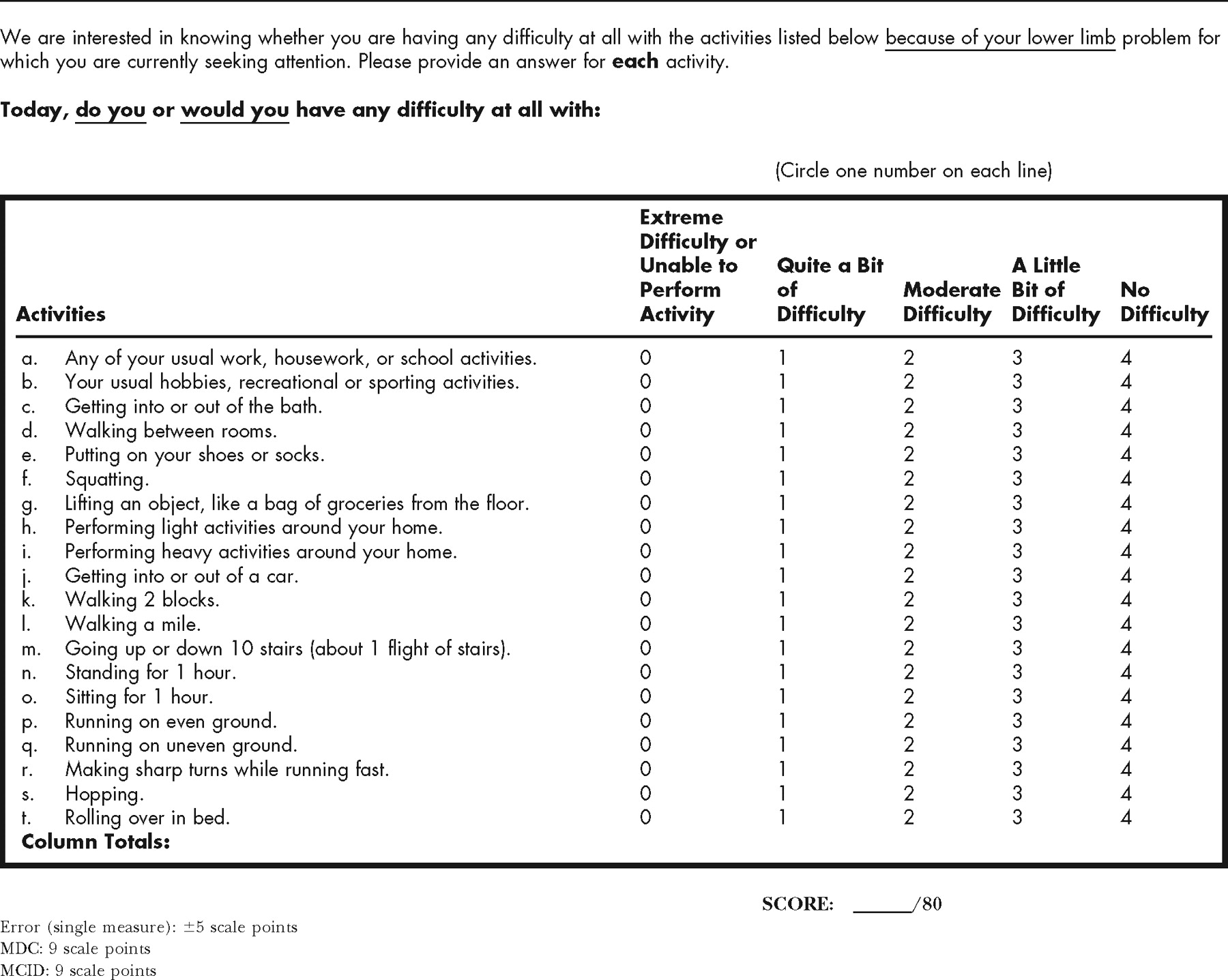
θ = true area

SE (diff) = sqrt [(SE12 +SE22)-(2rSE1SE2)] Critical z = AUC(diff)/SE(diff)



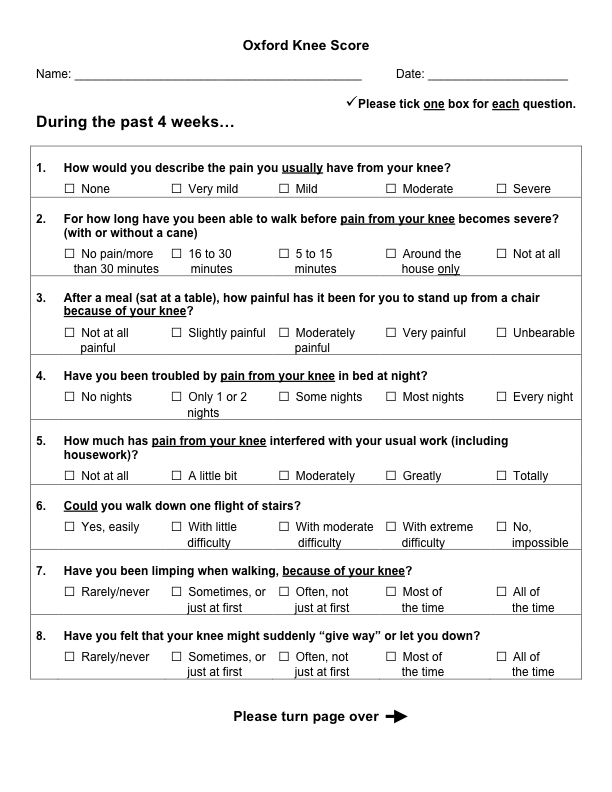
2. Lower Extremity Functional Scale

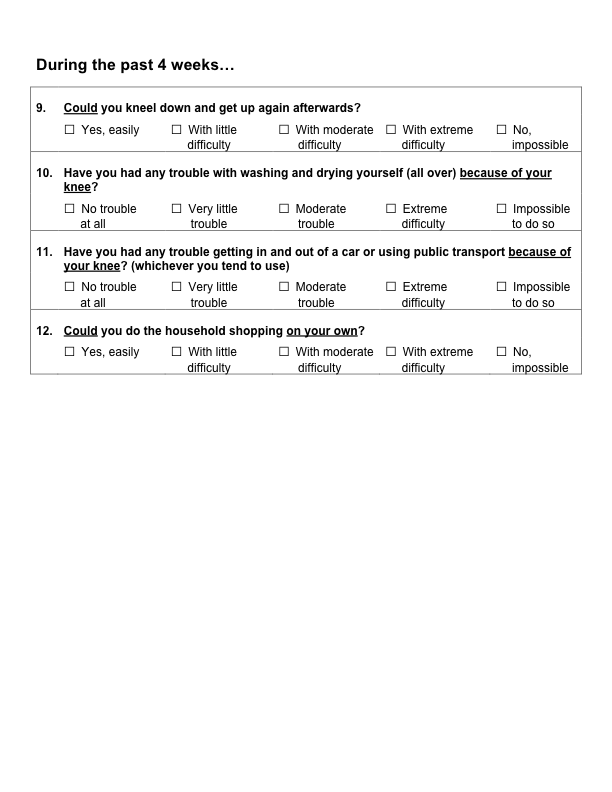
(Binkley et al., 1999)



3. Oxford Knee Score

(Dawson et al., 1998)





4. Consensus Statements and Priority Tools for Appropriateness for TKA in Patients with Knee OA

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|  |  |  |  |
| --- | --- | --- | --- |
| Study | Study Description | Factors suggesting appropriate for TKA | Comments |
| NIH Consensus Statement on Total Knee Replacement (2003) | A panel in the United States representing various fields including orthopaedics, rheumatology, internal medicine, nursing, physical therapy, rehabilitation, biostatistics, epidemiology, and health services research, as well as a TKR patient reviewed the medical literature and an extensive bibliography of total knee replacement research papers, prepared by the National Library of Medicine to develop a statement regarding appropriateness and effectiveness of TKA. | 1) radiographic evidence of joint destruction  2) moderate to severe pain not relieved by non-surgical management treatments  3) significant functional limitations limiting quality of life | 1) Orthopaedic surgeon discussing the benefits and risks of the surgery with patients  2) patients younger than 55 years or greater than 75 years should be considered for TKR, but issues of premature loosening (as related to younger patients who potentially put higher demands on their prosthesis) and perioperative complications and rates (in those who are older as they may present with more comorbid conditions) be discussed |
| Escobar et. al., 2003 | Various clinical scenarios were created and evaluated using the RAND method including age, localization of the area affected, physical findings, namely mobility and stability of the joint, symptoms (degree of pain and physical functioning), and radiographic evidence of knee OA | A classification tree (only considering those who did not have prior surgical intervention) was developed and tested to determine if their method of correctly determining those appropriate for TKR was effective | Patients with prior surgical management of the affected knee (e.g. arthroscopic surgery were excluded from the study) which limits the applicability of the tool as previous knee surgery is a risk factor for developing and progression of knee OA |

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| --- | --- | --- | --- |
| Study | Study Description | Factors suggesting appropriate for TKA | Comments |
| Quintana et. al., 2006 | Utilized the priority criteria developed by Escobar et al. (2003) to determine its validity for appropriatness for TKA | 1) Higher improvements on the domains of the WOMAC and SF-36 (used to measure physical function and health status) in those deemed appropriate for TKA  more severe 2) symptomatic OA and moderate to severe radiographic findings were the factors that explained most of the variability of appropriateness as determined by panelists |  |
| Naylor and Williams, 1996 | A decision tree was developed to determine appropriateness for TKR in patients with knee OA in Ontario, Canada using the RAND method of determining the priority and criteria for TKA among orthoopaedic surgeons | 1) Pain at rest  2) Problems in work or caregiving  3) Pain with ADLs |  |
| Hadorn and Holmes, 1997 | National criteria was developed In New Zealand for assessing the priority given to patients for medical and surgical procedures to ensure fairness and equitable process, as well as to allow comparison between hospitals and to integrate social values and provide a framework for acceptable waiting times for patients receiving those procedures, including TKA | Social factors influencing priority for TKA were discussed including age, work status, caregivers or loss of own independence, and time spent on the waiting list | Social factors should have less weight in making the decision for TKR compared to clinical factors of radiographic findings, and physical examination |

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| --- | --- | --- | --- |
| Study | Study Description | Factors suggesting appropriate for TKA | Comments |
| Conner-Spady et. al. 2004 | Evaluated the validity of the tool developed by Naylor and Williams (1996) to determine priority for TKA | Validation of the priority tool was demonstrated.  The WOMAC was used to evaluate physical functioning and those with lower physical functioning were appropriate for TKA |  |
| Löfvendahl et. al., 2010 | Indication criteria for patients scheduled for TKA due to knee OA in orthpaedic clinics across Sweden were compared. A Swedish priority criteria tool was developed based on the tool used in Canada with some minor changes. | All patients considered for TKA had severe knee OA clinically and radiographically; patient-reported difficulty with pain at rest, walking and limitations in activities of daily life were found to be statistically significant factors among those who had TKA |  |