RELATIONSHIPS BETWEEN SUBJECTIVE AND OBJECTIVE MEASURES AFTER TOTAL KNEE ARTHROPLASTY

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DECLARATION

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Christy Coyle

November 2012

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ABSTRACT

Total knee arthroplasty (TKA) has proven successful in treating symptomatic arthritis of the knee. Since its development, many and varied outcome measures have been developed to assess outcome. None have been accepted as the universal standard, although some are widely used. Many measures have no data regarding validity, reliability or responsiveness. There is little guidance or consensus in the literature as to which should be used in clinical practice, research or audit. In addition, there is limited research assessing the relationship between subjective clinical outcome scores, patient perceived reports and objective measures such as the timed up and go test (TUG), knee laxity and muscle strength. Establishing relationships between self report and objective measures may aid clinicians in developing more appropriate interventions.

Twenty four patients underwent unilateral TKA and were assessed a mean of 27.5 (SD 11.7) months after surgery. Assessment included four patient reported scores (Knee Outcomes and Osteoarthritis Score, Oxford Knee Score, American Knee Society Score and Short Form 12) and three objective outcome scores (knee laxity, quadriceps muscle strength and timed up and go test (TUG). Significant (<0.05) correlations were demonstrated between the four patient reported scores (r=0.410-0.786) except the MCS portion of the SF12 (r=0.286-0.483).

The TUG was the only objective outcome measure to demonstrate a statistically significant (p=0.0001-0.005) correlation with subjective knee outcome scores (OKS, KOOS and 4 items of the KOOS) (r=-0.557 to -0.770). A patient's ability to walk at a certain pace is correlated with patient satisfaction after TKA. There were no

observed correlations between knee laxity or quadriceps muscle strength with the four subjective knee scores. Therefore for a comprehensive assessment of outcome after TKA, use of a combination of objective and subjective outcome measures is recommended, as they measure different aspects of outcome.

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CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

The knee is a synovial joint connecting the distal end of the femur with the proximal end of the tibia [McMinn et al 1998]. Its functions include the transmission of body weight, shock absorption and the generation of propulsive forces for mobility [Einhorn et al 2007]. Its articulating surfaces are covered with articular cartilage, which has limited ability to maintain its function with increasing age, or heal after trauma, due to its avascular nature [Einhorn et al 2007, Yang et al 2004]. Defects as small as 2mm can lead to the development of osteoarthritis [Yang et al 2004].

Osteoarthritis occurs in 6-12% of the Western population, and will increase even more due to the ageing population [Felson et al 2000]. It can be primary [idiopathic, with no known cause] or secondary to factors such as trauma, infection, meniscal tears or malalignment [Solomon et al 2001]. The knee is the most common joint affected in osteoarthritis [Miller et al 2008]; arthritic disease of the knee joint hindering quality of life in an active ageing population has become increasingly frequent [Hanssen et al 2000]. Symptoms include progressively increasing pain, stiffness, joint deformity and limited range of motion [Solomon et al 2001, Yang et al 2004].

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Non-operative treatments are aimed at reducing pain and slowing progression of disease [Hanssen et al 2000]. These non-operative treatments include simple analgesia, such as anti-inflammatory tablets [Kivitz et al 2002], nutritional supplements such as glucosamine or chondroitin sulfate [Hellio Le Graverand-Gastineau 2009, Lippeiello 2000, Palveka 2002], the use of a walking stick and stress offloading [Hanssen et al 2000], weight loss [Foulsham et al 1981], physiotherapy including quadriceps strengthening [Belleman et al 2005, Hanssen et al 2000], and knee injections with corticosteroid and or hyaluronic acid [Balazs & Delinger 1993]. If persistent pain occurs after exhausting these treatments, surgical intervention may be considered [Ethgen et al 2004, Hanssen et al 2000, Solomon et al 2001].

Surgical options for arthritis of the knee include arthroscopic debridement and lavage [Ethgen et al 2004, Richmond et al 2009, Yang et al 2004], tibial osteotomy to correct deformity producing excessive weight bearing load through one part of the knee [Williams & Devic 2006], knee arthroplasty [Miller et al 2008, Solomon et al 2001, Yang et al 2004] and knee arthrodesis, which is a salvage procedure, as it produces disabling joint immobility [Solomon et al 2001, Yang et al 2004]. Arthroscopy and tibial osteotomy should be considered but are not suitable for the patient with diffuse erosive and degenerative cartilage damage [Belleman et al 2005].

Knee arthroplasty can be either a unicompartmental replacement or a total knee arthroplasty, which may or may not include the patellofemoral joint [Berger et al 2005, Hanssen et al 2000]. Joint arthroplasty is usually reserved for older patients, as there are higher failure rates in the young and middle aged patients due to a higher level of physical activity resulting in wear and loosening of the prosthesis [Ewald & Christie 1987, Hanssen et al 2000, Yang et al 2004].

A total of 269, 266 total knee arthroplasties (TKAs) were performed in Australia in 2010 [National Joint Registry 2010]. Total knee arthroplasty (TKA) is now an accepted treatment in the specialty of orthopaedic surgery [Ethgen et al 2004, Mizner et al 2011, Saleh et al 2005], which has been associated with almost unparalleled success [Bellemans et al 2005, Bellamy et al 1989]. It represents one of the greatest technological achievements in recent decades and provides pain relief and improved function for the symptomatic arthritic knee [Roos et al 2003, Steiner et al 1989]. In the past, the success of TKA has largely been measured through its ability to provide relief of pain; to a considerable extent, it was the only requirement of this procedure as the first generation implants were without precedent [Bellamy et al 1989, Noble et al 2005].

However, during the past three decades, the emphasis has shifted from the era of expansion and technical development to one of assessment and accountability [Bach et al 2001, Bourne 2008, Rodriguez-Merchan 2012, Whitehouse et al 2005]. Rather than comparing a new treatment with no treatment, or looking only at procedural and technical results, investigators are now comparing two efficacious treatments, and measuring the outcome in terms of changes in patient's functional status and well-being [Bourne 2008, Kantz et al 1992, Noble et al 2005].

Other researchers have shown that patients' expectation of orthopaedic treatment is highly variable, and depend on age, diagnosis, severity of disease, culture and lifestyle [Bourne et al 2010, Insall et al 1989], and these goals influence whether the operation is perceived as successful [Bourne et al 2010, Baker et al 2007, Dawson et al 1998]. The patient may hope function will be restored to what it was before the onset of symptoms, but the average patient after TKA is not returned to a normal physical health [Heck et al 1998], or normal knee function [Noble et al 2005].

Variable definitions have been used previously to assess outcome after joint replacement surgery [Ethgen et al 2004, Nestor et al 2010] but to date no consensus has been reached [Amadio 1993, Bourne 2008, Davies et al 2002, Garratt et al 2004, Ghanem 2010, Khanna et al 2011]. The choice of the ideal outcome measure to assess TKA remains a complex issue. Kreibich et al [1996] raised the following questions on this topic: 'Should one be putting more emphasis on the patients' overall improved well-being? Should emphasis be placed on the technical success of the surgery, as it may improve the longevity of the implant? Should one look at financial costs to society?' Research on this topic, however, has proved at best confusing and at worst contradictory [Davies et al 2002, Drake et al 1994, Gartland et al 1998, Garratt et al 2004]. Traditionally, the methods of measuring the outcome of TKA are normally derived from longevity of the implant, and clinical and radiological data which depend on the judgment of the surgeon [Berman et al 1991, Dawson 1998, Ethgen et al 2004]. The concerns of patients and surgeons may differ, however, and methods of recording patients' perception of outcomes are required [Ghanem et al 2010, Hartcourt et al 2001]. Specific patient related factors that determine the success of the TKA remain relatively unknown [Bellamy et al 1988, Jinks et al 2002, Kreibich et al 1996].

There is a multitude of methods for the assessment after TKA [Bourne et al 2008, Davies AP 2002, Ethgen et al 2004, Rodriguez-Merchan 2012]; none have been accepted as the universal standard although some are widely used [Drake et al 1994,

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Garratt et al 2004, Khanna et al 2011]. Both subjective and objective measures are being widely used in the published literature to describe function after TKA [Davies et al 2002, Lamping et al 2001, Mizner et al 2011, Saleh et al 2005]. However; the relationship between objective and subjective outcome measures has only been sparsely investigated [Rossi et al 2006, Silva et al 2003, Weiss et al 2002]. The perception of an individual's functional levels coupled with objective measures of function may provide valuable insight into rehabilitation strategies and outcomes, providing a foundation for evidence based practice [Parent & Moffet 2002]. Establishing relationships between self report and objective measures may aid clinicians in developing more appropriate interventions [Jones et al 2003, Rossie et al 2006, Silva et al 2003]. As more outcome measures for TKA become available, it becomes increasingly important to ensure only valid, responsive and reproducible outcome measures are used in research and clinical practice [Bellamy et al 1988, Wang et al 2010, Whitehouse et al 2005].

1.2 STATEMENT OF THE PROBLEM

TKA is a successful surgical procedure in the treatment of arthritis of the knee. Since its development, many and varied outcome measures have been developed to assess outcome. Many measures that are widely used have no data regarding validity, reliability or responsiveness. There is little guidance or consensus in the literature as to which should be used in clinical practice, research or audit [Rodriguez-Merchan 2012, Khanna et al 2011], and there is little data investigating the correlations of the current measures of outcome [Rossi et al 2006, Silva et al 2003, Weiss et al 2002].

1.3 PURPOSE OF THE STUDY

The aims of this study are:

- 1 To correlate the outcomes of four most commonly used patient-assessed questionnaires used in the assessment of TKA including a dual rating system [The American Knee Society score [KSS]], two validated self-administered questionnaires [the Knee Osteoarthritis Outcomes Score [KOOS] and the Oxford Knee Score [OKS]] and a generic questionnaire [Short Form 12 [SF12] with the physical component score [PCS] and mental component score [MCS]].
- 2 To correlate differences in two objective measures knee laxity and isokinetic muscle strength of the operated lower limb compared with the non operated lower limb at a minimum follow-up of 12 months following TKA.
- **3** To correlate the above subjective and objective outcome measures in the assessment of post-operative function after unilateral TKA.

1.4 SIGNIFICANCE OF THE STUDY

The results of this study will aid clinicians to choose the best method of assessing patients after TKA in clinical practice, audit and research. If patient assessed scores reflect objective outcome, measuring objective data may be deemed unnecessary. Correlations between certain objective measures of outcome and patient reported outcome may highlight areas to focus on during post-operative rehabilitation. Furthermore, the results of this study will contribute to the current knowledge concerning the changes in the operated lower limb after TKA.

1.5 RESEARCH HYPOTHESES

Based on previous research, the following hypotheses are adopted for the present thesis:

- 1 There will be a positive correlation between the OKS and KOOS, the KSS knee and function scores and the PCS portion of the SF12, but not the MCS portion of the SF12
- 2 The operated limb will have a decreased peak torque compared with the non operated limb, but there will be no significant difference in knee laxity between the operated and non operated limb.
- **3** There will be no correlation between knee laxity and patient satisfaction and function after TKA.
- 4 There will be a positive correlation between muscle torque of the operated limb and the OKS, KOOS, KSS pain and function scores and the portion of SF12 related to pain and function [PCS].
- **5** There will be a positive correlation between the TUG and the OKS, KOOS, KSS pain and function scores and the portion of SF12 related to pain and function [PCS].

1.6 LIMITATIONS

- Subjects will be tested at different time intervals following surgery ranging from 12 to 48 months.
- 2 Two different surgeons will be involved in the operations.
- **3** Surgery will be performed with computer aided and without computer aided navigation.

- 4 The control group will be the contralateral non-operated knee of the same subject. It is likely that these knees could be affected by osteoarthritis. Previous research by Felson et al [2000] have demonstrated arthritis in the non-operated limb suggesting that most people in this population group have a knee affected by arthritis.
- 5 There is a multitude of subjective and objective tests available for evaluation of TKA patients. It is out of the realm of this research design to assess all of them; some widely used and some validated tests will be used. These may not necessarily be the most specific or reliable tests.
- 6 Questionnaires by their nature are subjective, and influenced by the presence of an examiner or the patient's 'aim to please'. This, however, is the part of the premise of this research, and is an important part of outcome.
- 7 Bias may be introduced when using instruments for the objective testing i.e. the KT1000, the goniometer and the isokinetic testing, which assesses eccentric and concentric torque development at different speeds.
- 8 With objective testing, the variable of a patient's effort or tendency to 'over perform' or 'under perform', avoidance patterns and compensation mechanisms will be difficult to overcome.
- 9 Patients were recruited from a single praxis. This limits the number of subjects.
 Patients displeased with the treatment may have looked for follow up elsewhere.
 This may cause selection bias towards good outcome.
- 10 Patients were recruited from the orthopaedic outpatients clinic at Rockhampton Base Hospital, which is a regional hospital in Central Queensland. Many patients are elderly and reside over 50km kilometres from the hospital and could

not attend the testing. Subjects therefore cannot be recruited sequentially postoperatively.

- 11 Due to time limitations, it is not possible to assess patients from their preoperative status. Robertsson et al [2001] have found it acceptable to assume patients take their pre-operative condition into account when answering and act as their own comparisons. As this study assesses the correlation between scoring systems and function at a specific moment in time, introduction of bias would be expected to be minimal.
- 12 Technical errors and radiographic findings were not considered in this study and may influence the outcome in some patients.

CHAPTER 2

REVIEW OF THE LITERATURE

2.1 INTRODUCTION

Total knee arthroplasty (TKA) is an orthopaedic technology now widely used in the Western world, which provides relief for the symptomatic arthritic knee. During the last three decades, the era of technological development has expanded into one of assessment and accountability. After the advent of the development of the modern TKA in the 1970's, the market has been flooded with different designs of prostheses, different fixations, different materials for different indications and different patient groups.

To accompany this, there has been an explosion of methods to assess outcome after TKA. With so many different outcome measures available, surgeons, clinicians and researchers find it difficult, if not impossible, to know which prostheses are best for which patients, and what the best methods are to assess function and outcome after TKA. Despite surgical advances, as well as advances in research outcomes, there is a paucity of information about the relationship between objective outcome measures traditionally measured by clinicians, and subjective outcome scores filled out by the patients.

To understand this relationship, it is necessary to outline basic anatomy and biomechanics of the knee joint, as well as the indications for TKA. The reader will better understand the relationship between subjective and objective outcome measures for assessing TKA after further discussion of the history of the surgical techniques and outcome measures of joint replacement for the knee, which has lead us to current day practice. In this review, different types of outcome measures, both subjective and objective, will be outlined, as well as information in the current body of literature on the relationship between the two.

The review of the literature will be structured in the following way:

- 1 Basic anatomy and biomechanics of the knee
- 2 Arthritis of the knee
- 3 Treatment for knee arthritis
- 4 Total knee arthroplasty
- 5 Outcome measures for total knee arthroplasty
- 6 Relationship of outcome measures for total knee arthroplasty

2.2 BASIC ANATOMY AND BIOMECHANICS OF THE KNEE

The knee is a synovial joint connecting the distal end of the femur and the proximal end of the tibia [McMinn et al 1998]. It consists of the medial and lateral tibiofemoral joint, and the patellofemoral joint. It is the largest and most complex joint in the human body [Einhorn et al 2007]. The following paragraphs (2.2.1 to 2.2.5) are adapted from Canale et al [2007], Einhorn et al [2007], Freeman [2001], McMinn et al [1998], Miyamato et al [2009], Ranawat et al [2008], Rohen et al [2002] and Ross & Lamperti [2006].

2.2.1 Osseous anatomy and articular surfaces

The knee is a complex joint, connecting the distal end of the femur with the proximal end of the tibia. The patella, the largest sesamoid bone in the body, articulates with the femur anteriorly (Fig 2.1).

The distal end of the femur consists of two large condyles, the medial and lateral condyles, joined anteriorly by the trochlear surface for articulation with the patella (Fig 2.2) and separated by the deep intercondylar notch posteriorly (behind) (Fig 2.3).

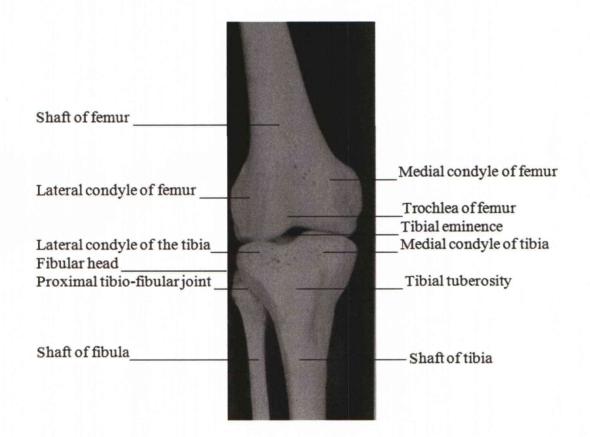


Figure 2.1. Osseous anatomy of the anterior knee joint in the coronal plane (patella removed) [adapted from Rohen et al 2002]

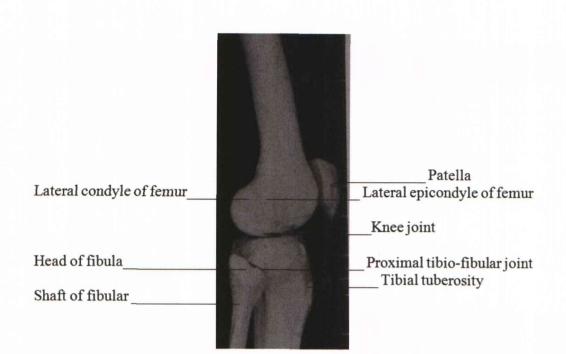
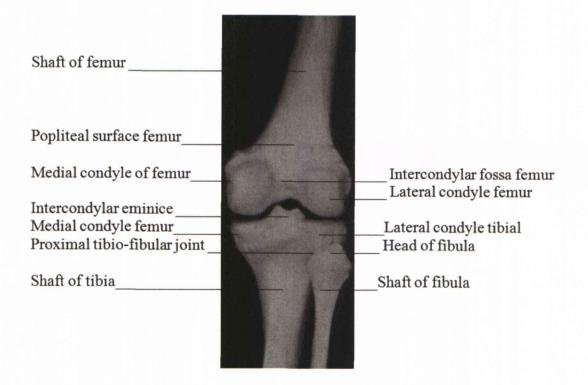
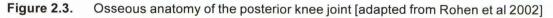


Figure 2.2. Osseous anatomy of the knee joint in the sagittal plane [adapted from Rohen et al 2002]





The distal surface of the medial condyle is narrower and more curved than the lateral condyle for passive rotation of the knee during extension, or the 'screw-home movement'. The upper surface of the tibia, called the tibial plateau, is made up of two separate articular facets. The medial tibial plateau is concave, while the lateral tibial plateau is convex.

The patella is shaped like a rounded triangle, and lies within the quadriceps tendon. It articulates with the surface of the patella. With the quadriceps tendon superiorly and the patellar tendon inferiorly, it forms the extensor mechanism of the knee.

2.2.2 Articular Cartilage

There are two types of cartilage in knee joint: hyaline cartilage, which forms the articular cartilage, and fibrocartilage, which forms the menisci.

The articular surfaces of the femur, the tibial plateau and the undersurface of the patella are covered by articular (hyaline) cartilage. Articular cartilage is tissue that lines synovial joints, and allows low friction movements within synovial joints. With age, chondrocytes lose their ability to main and restore the matrix materials.

2.2.3 Meniscus

The medial and lateral menisci are composed of fibrocartilage and are C-shaped structures (Fig 2.4). The menisci deepen the shallow tibial plateau, prevent the side to side rocking of the femur on the tibia, and act as shock absorbers for the knee. They are avascular except at their attachments peripherally, and receive their nutrition from the surrounding synovial fluid (Fig 2.10). The medial meniscus is more comma shape compared to the lateral meniscus, whereas the lateral meniscus

is truly C-shaped, with its horns closer together. Unlike the medial meniscus, the lateral meniscus has no attachment to its collateral ligament counterpart. The posterior horn of the lateral meniscus receives the insertion of the flat tendon of the upper half of the popliteus muscle. The anterior horns of the two menisci are connected by the transverse ligament, to which the joint capsule is attached.

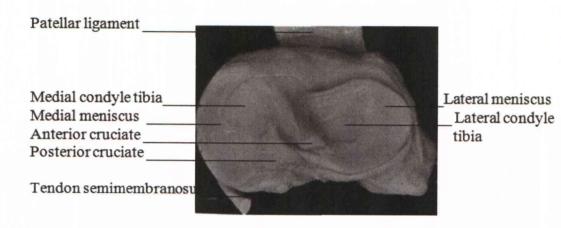


Figure 2.4. The tibial plateau with medial and lateral menisci and cruciate ligaments [adapted from Rohen et al 2002]

2.2.4 Ligaments

The knee ligaments can be classified as extra-capsular and intra-articular, and all act to stabilise the knee joint. The main extra-capsular ligaments are the medial collateral ligament (MCL) and lateral collateral ligaments (LCL). These ligaments provide medial and lateral stability of the knee. The other extra-articular ligaments are the oblique popliteal ligament, and the arcuate popliteal ligament. These will be discussed below.

The medial collateral ligament (MCL) consists of 2 parts: deep and superficial. The superficial part is a broad, flat long band. Its origin is in the medial epicondyle of the

femur and it extends down 12cm to insert into the tibia. The ligament inserts behind the axis of flexion of the femoral condyle and is thus drawn taut by (as well as limits) extension of the knee (Fig 2.5 and 2.6). The deep part lies beneath the superficial part and is attached to the medial meniscus. Biomechanically, the superficial MCL is the primary restraint to valgus stress of the knee, and the deep MCL acts as a secondary stabiliser.

The lateral collateral ligament (LCL) originates from lateral epicondyle and inserts into the head of the fibula. (Fig 2.5 and 2.6) Unlike its medial counterpart, it lies free from the capsule and lateral meniscus. It differs from the MCL in that it is 5 cm long and is round and cord-like; like the MCL, it attaches behind the axis of flexion of the femoral condyle and is drawn taut by (and limits) extension and the terminal 'screw-home' movement. The LCL is the primary static restraint to varus opening of the knee.

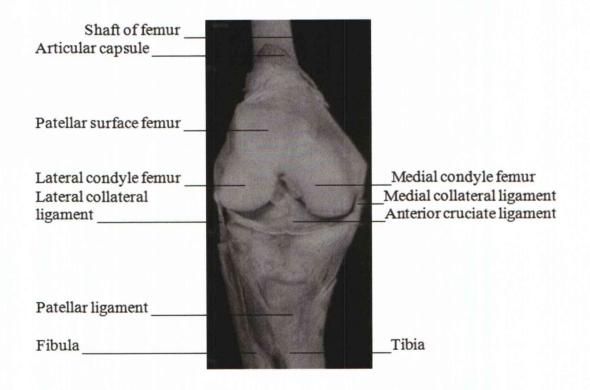


Figure 2.5. Ligaments of the knee [adapted from Rohen et al 2002]

The main intra-articular ligaments are the anterior and posterior cruciate ligaments (ACL and PCL). The cruciate ligaments are named so because they cross each other forming a cross within the femoral notch. They are strong ligaments connecting the femur to the tibia, and are essential for the anteroposterior stability of the knee. They are named for the site of their tibial attachment. The ACL attaches to the anterior tibial plateau in front of the tibial spine to the posterior lateral condyle of the femur and the posterior intercondylar notch. The ACL prevents posterior displacement of the femur on the tibia, and limits extension of the lateral condyle on the femur in the 'screw-home' movement of the femur on the tibia. It is lax when the knee is flexed and taut when the knee is extended. The PCL is attached between the condyles of the posterior tibia to the medial condyle of the femur and the intercondylar notch. The PCL prevents posterior displacement of the femur on the tibia to the medial condyle of the femur and the intercondylar notch.

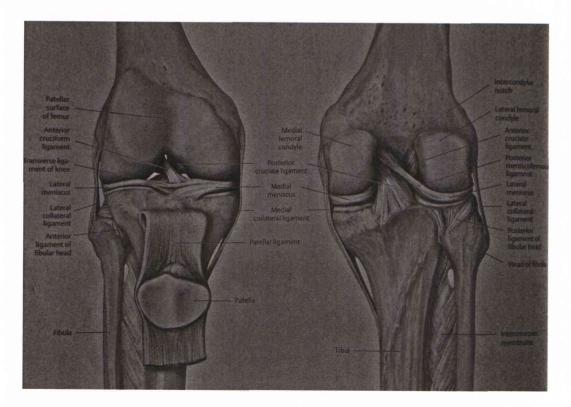


Figure 2.6. Cruciate ligaments of the knee: anterior and posterior views [adapted from Ross and Lamperti 2006]

2.2.5 Posterolateral structures

The posterolateral corner is an important structure in the stability of the knee. It consists of the LCL, the popliteus tendon complex, the posterolateral capsule and the popliteofibular ligament (Fig 2.6 and Fig 2.7). The popliteus muscle slopes up from the popliteal surface of the tibia and inserts on the lateral condyle of the femur. It lies within the capsule of the knee joint, and enters the joint beneath a free edge of the capsule called the arcuate popliteal ligament. Fifty percent of the popliteus muscle continues to form the popliteus tendon. The other fifty percent of the muscle inserts into the lateral meniscus. The oblique popliteal ligament is the lateral expansion from the insertion of one of the hamstring muscles, the semimembranosus muscle, which slopes up to the popliteal surface of the femur. It is a thick strong ligament which blends with the posterolateral capsule of the lateral condyle of the femur. The posterolateral structures function primarily to prevent varus rotation, external tibial rotation and posterior translation of the tibia and femur.

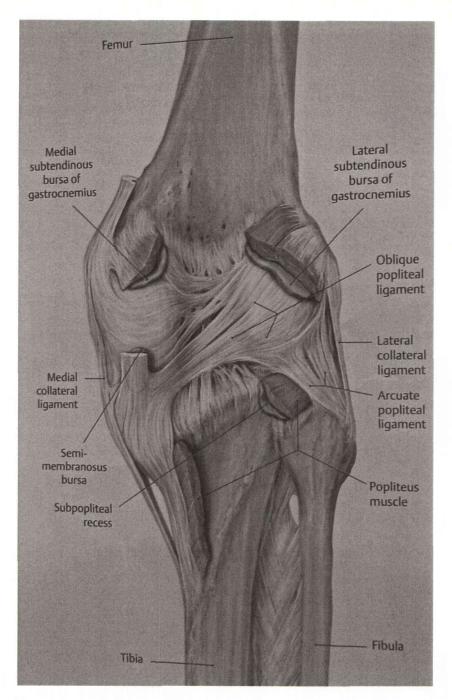


Figure 2.7. Posterior structures of the knee [adapted from Ross and Lamperti 2006]

2.2.6 Muscles

Although many muscles cross the knee joint and are involved in its kinematics, the main two groups are the quadriceps and the hamstrings. These will be discussed below.

2.2.6.1 Anterior muscle group: The quadriceps muscle

The quadriceps muscle is the largest in the body. It is the main extensor of the knee and has four parts: the rectus femoris, the vastus lateralis, the vastus intermedius and vastus medialis, which form a tri-laminar quadriceps tendon and inserts into the patella proximally. Below the patella the capsule is the thick and strong patella ligament, which keeps the patella at a constant distance from the tibia.

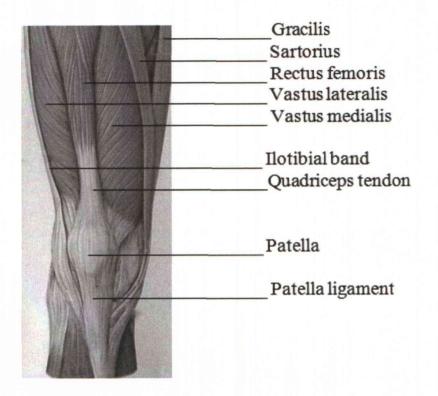


Figure 2.8. Anterior muscles of the knee [adapted from Ross and Lamperti 2006]

2.2.6.2 Posterior muscle group: The hamstring muscles and the popliteus muscle

The hamstring muscles are a large muscle group at the back of the thigh. It consists of three muscles: semimembranosus-, semitendinosus- and biceps femoris muscles. All three muscles originate at the pelvis, and insert into the tibia. They act essentially as flexors of the knee joint, and extensors of the hip joint, which is especially important in walking. The semimembranosus and semitendinosus insert medially, and the biceps femoris inserts laterally. This aids then to rotate the knee in flexion.

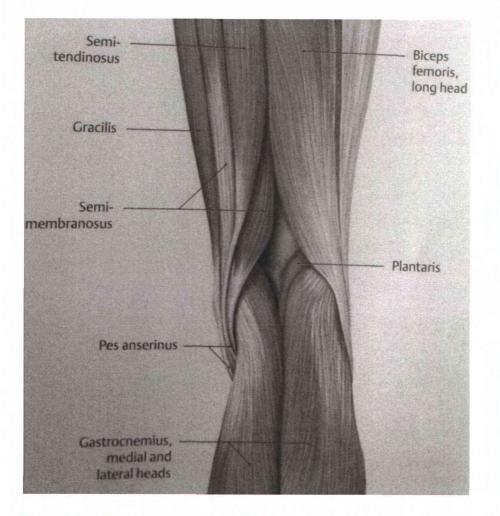


Figure 2.9. Posterior musculature of the knee [adapted from Ross and Lamperti 2006]

2.2.7 Neurovascular supply

The knee joint is supplied by vascular anastomoses around the knee, and the main contributors are the five genicular branches of the popliteal artery. The medial genicular artery supplies the cruciate ligaments. The nerve supply to the knee is various; it includes branches from the femoral, sciatic and obturator nerves. The menisci are almost devoid of sensory fibres, except from the periphery.

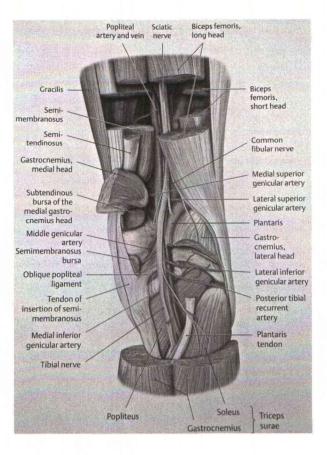


Figure 2.10. Neurovascular structures around the knee [adapted from Ross and Lamperti 2006]

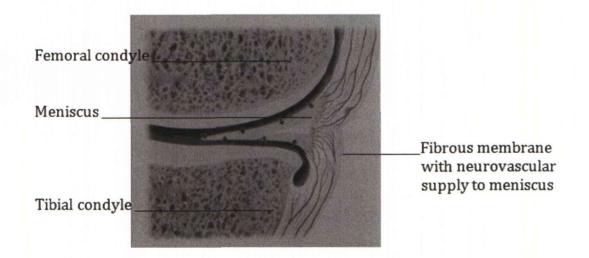


Figure 2.11. Neurovascular supply to the meniscus. Note the fibrous portions of the meniscus adjacent to the capsule peripherally have a rich neurovascular supply. The more central portions are nourished by synovial membrane (arrows).

2.2.8 Biomechanics

In the tibio-femoral joint, motion takes place in three planes: the sagittal plane (flexion-extension), the coronal plane (varus-valgus) and the transverse plane (rotation) [Einhorn et al 2007]. The arc of flexion needed in almost all normal daily activities extends from approximately 20° to 120° of flexion [Freeman 2001, Kauffman et al 2001]. The flexion arc of the knee can be divided into three segments: an arc from -5° to 20°, an arc from 20° to 120°, and an arc from 120° to full flexion [Freeman 2001].

The arc from 20° to -5° of extension is known as the 'screw home' mechanism of the knee [Einhorn 2007, Freeman 2001, McMinn 1998]. During the last 10° of knee extension, extension is resisted by tightening of the posterior capsule, posterior fibres of the PCL, the collateral ligaments, and perhaps most importantly, the ACL [Freeman 2001, McMinn 1998]. The ACL is the first ligament to become taut, and restricts extension of the lateral condyle [McMinn et al 1998]. Because movement of the lateral femoral condyle stops before the medial femoral condyle, the femur internally rotates on the tibia and the medial femoral condyle glides backwards into its own full extension [Einhorn 2007, Freeman 2001, McMinn 1998]. The medial condyle has a longer and more curved articular surface for this purpose [Einhorn 2007, McMinn 1998]. This medial rotation of the femur on the tibia forces the oblique popliteal ligament and collateral ligaments to become taut and limit further rotation.

In the arc from 20° to 120°, the medial femoral condyle does not translate in the antero-posterior direction, but the lateral femoral condyle glides posteriorly, causing external rotation of the femur on the tibia in flexion [Hill et al 2000].

The arc from 120° to full flexion can only be used passively; it requires an external force [ie body weight] to carry the knee into further flexion [Freeman 2001]. Therefore, the arc is only used in squatting and full kneeling [Nakagawa et al 2000].

2.2.9 Arthritis of the knee

Arthritis of the knee affects over one-tenth of the population aged over 55 years and the number and proportion of patients involved may increase as both longevity and body mass index rise [Krishnan et al 2005]. The majority of knee arthritis is degenerative (osteoarthritis), but can also be inflammatory, with rheumatoid arthritis being the most common inflammatory arthritis [Einhorn et al 2007]. 97.1% of TKAs performed in Australia in 2009 was for osteoarthritis (OA) [Australian Orthopaedic Association National Joint Registry 2010]. Arthritis can be unicompartmental, which is characterized by abnormal articular cartilage in the medial or lateral part of the tibiofemoral joint and may then lead to limb malalignment [Iorio & Healy 2003]. The primary goals for treatment of knee arthritis are to relieve pain, delay progression, maintain or improve function, and prevent or correct deformity [Krishnan et al 2005].

2.2.9.1 Osteoarthritis (OA)

Osteoarthritis (OA) is a degenerative disease of synovial joints involving the progressive and focal loss of articular cartilage [Einhorn et al 2007]. Symptoms include pain, decreased range of motion (ROM), knee effusion, crepitus and deformity [Solomon et al 2001]. Radiological imaging to aid with the diagnosis includes radiographs, computerised tomography (CT) and magnetic resonance imaging (MRI) [Chaisson et al 2000]. Various blood tests are currently being

investigated as diagnostic and prognostic factors for osteoarthritis, such as type II collagen degradation product and synthesis markers, cartilage oligomeric matrix protein (COMP), keratan sulphate, hyaluronic acid [Brueyere et al 2003, Peterson et al 1998]; the predictive value of these, however is unproven [Yang et al 2004]. The incidence of OA increases with age, and by the age of 70, everyone will have some form of OA in at least one joint [Solomon et al 2001].

The knee is the commonest of the large joints to be affected by OA [Miller et al 2008]. Most knee OA is idiopathic, and may be bilateral [Yang et al 2004]. OA involves all joint structures, and therefore included in the surgical challenge are ligamentous laxity and joint deformity [Yang et al 2004]. Advanced OA of the medial compartment leads to a varus deformity of the knee, which is the most common deformity [Parkinson & Bhalaik, 2001]. Deformity occurs due to a combination of bone loss and soft tissue contractures [Belleman et al 2005, Iorio & Healy 2003, Parkinson and Bhalaik 2001, Yang et al 2004].

2.2.9.2 Rheumatoid arthritis (RA)

Rheumatoid arthritis (RA) is a systemic, progressive inflammatory disease of synovial joints [Einhorn et al 2007]. It affects more than 1% of the population, and is an autoimmune disease; the incidence is three times higher in women than in men [Solomon et al 2001]. RA usually starts with pain and swelling in small distal joints, and as it progresses, it affects larger joints such as the knee, shoulder and elbow, which is often symmetrical [Solomon et al 2001].

There are three stages of RA: stage one includes pain, swelling, and muscle wasting; stage two progresses to include increasing instability and loss of range of motion;

stage three is characterized by severe pain and disability [Einhorn et al 2007]. In the knee, the commonest deformities are a fixed flexion and or a valgus deformity [Parkinson & Bhalaik 2001].

2.2.10 Summary

The knee joint is a synovial joint in the lower limb, consisting of three articulations. It is covered with protective articular cartilage, which is susceptible to the development of osteoarthritis with age and trauma. Its main movement is the flexion and extension arc, which is controlled largely by the hamstrings and the quadriceps muscle groups, the intra and extra articular ligaments and the bony contours. The anatomy and biomechanics of the native knee is virtually impossible to replicate, which creates difficulty when designing total knee arthroplasty (TKA). The knee can be affected by arthritis, most commonly, osteoarthritis arthritis.

2.3 TREATMENT FOR ARTHRITIS OF THE KNEE

Non operative management is the first step in managing arthritis of the knee, since this may delay or even indefinitely defer the need for surgery [Bellemans et al 2005]. When pain and associated impairment is not controlled satisfactorily with non operative measures, surgical options can be considered [Bellemans et al 2005, Hanssen et al 2000]. In younger patients, TKA is avoided due to higher demands and expectations, and increased likelihood of revision surgery [Hanssen et al 2000].

2.3.1 Non surgical options

Non surgical options include stress off loading orthotics or gait aids such as a walking stick [Bellemans et al 2005, Hanssen et al 2000, Solomon et al 2001], physiotherapy

including quadriceps strengthening [Bellemans et al 2005, Hanssen et al 2000], weight loss [Foulsham et al 1981], and pharmacological treatments [Yang et al 2004]. Medications include analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs ie ibuprofen, Nurofen, Voltaren etc); a serious side effect of these, however, includes upper gastrointestinal bleeding [Kivitz et al 2002]. Newer analgesics called COX-2 inhibitors have shown a decreased rate of gastrointestinal bleeding as well as having a beneficial effect on cartilage matrix metabolism in vitro [El Hajjaji et al 2003]. Nutritional supplements such as glucosamine and chondroitin sulphate may play a part in slowing the progression of disease [Hughes & Carr 2002, Lipiello et al 2000, Palveka et al 2002], and have demonstrated an analgesic and disease modifying effect [Hellio Le Graverand-Gastineau 2009]. Intra articular injections of a synovial fluid component hyaluronic acid aims to decrease synovial viscosity and therefore pain in the knee [Balazs EA & Delinger JL 1993], and has shown positive clinical effects [Richmond et al 2009]. Corticosteroid injections have been used for longer and provide temporary symptomatic relief in some osteoarthritic knees [Richmond et al 2009, Yang et al 2004]. Rheumatoid arthritis can be treated with aggressive medical management, such as nonsteroidal anti-inflammatory drugs (NSAIDs), steroids, methotrexate, and biologic agents [Howe et al 2006].

2.3.2 Surgical options

Persistent pain unresponsive to conservative management is the main indication for surgical intervention; in a number of cases non-arthroplasty surgical alternatives should be considered [Bellemans et al 2005, Ethgen et al 2004]. This is because arthroplasty in the younger patient have higher failure rates due to higher physical activity of the patients, earlier wear and loosening and higher expectations [Hanssen

et al 2000]. Arthroscopic debridement for pain relief of knee OA has been shown to be as efficacious as placebo or physical and medical treatment in two landmark randomized controlled trials [Kirkley et al 2008, Moseley et al 2002]. Arthroscopy is an option patients with primary symptoms and signs of a torn meniscus or loose body [Richmond et al 2009]. Osteotomy of the proximal tibia is used to offload stress in younger patients with unicompartmental osteoarthritis through realignment of deformity [Bellemans et al 2005, Williams & Devic 2006]. Researchers [Grelsamer 1995, Sprenger and Doerzbacher 2003, Williams & Devic 2006, Yasuda et al 1992] agree that outcomes of osteotomy show improved long term results, but disagree on the optimal correction angle. Arthrodesis (knee fusion), is a salvage procedure only [Solomon et al 2001]; despite giving effective pain relief, it is disabling due to immobility of the joint and increased stress on neighbouring joints [Bellemans et al 2005, Parkinson & Bhalaik 2001, Yang et al 2004].

2.3.3 Summary for non TKA management of knee arthritis

The main indication for TKA is severe osteoarthritis of the knee unresponsive to treatment with conservative measures such as gait aids, analgesia or physiotherapy. Other surgical interventions such as HTO for knee OA are usually reserved for younger patients to delay or indefinitely defer the need for TKA. Arthrodesis of the knee is a salvage procedure.

2.4 TOTAL KNEE ARTHROPLASTY

TKA is indicated for patients with intractable pain and significant functional disabilities, who have not had acceptable results from conservative treatments and who are not candidates for other surgical options [Ethgen et al 2004]. Osteoarthritis

(OA) is a degenerative process due to loss of articular cartilage and is the most common indication for TKA. Rheumatoid arthritis is an inflammatory process and can also lead to severe arthritis of the knee requiring TKA. Trauma can be an indication for TKA, either acutely, or as a result of post traumatic arthritis of the knee. TKA in the acute trauma setting would be a rare but sometimes necessary event, where the knee joint cannot be reconstructed acutely [Canale et al 2007]. Trauma may also predispose to OA of the knee, due to damage of the articular cartilage [Yang et al 2004]. TKA is recommended for the older population, and is absolutely contraindicated in the setting of recent or current joint sepsis [Canale et al 2007].

TKA today is one of the most successful procedures in orthopaedic surgery, and numerous successful implant designs are currently in use [Bellemans et al 2005]. The following chapter will document the evolution of TKA, the current designs prostheses available to the orthopaedic surgeon today, as well as the complications that can occur.

2.4.1 History of TKA

As early as 1826, Barton performed a resection arthroplasty of the knee, which resulted in shortening of the limb and re-ankylosis of the joint [Barton JR, 1827]. The first documented interposition knee arthroplasty (involving placing material between the joint surfaces to help prevent re-ankylosis) was documented by Ferguson in 1861 [Ferguson 1861]. After this, many other substances were used, such as pig's bladder [Baer 1921], fascia lata [Putti V 1920], prepatellar bursae [Campbell 1921], and fat [Albee 1928]. Problems encountered with these techniques included limb shortening, infection, a reactive inflammatory response and re-ankylosis [Shetty et al 2003].

In 1938, cobalt chrome (called Vitallium) was used for the first time for joint prostheses; it had excellent wear properties, did not corrode and heralded the age of metallic prostheses [Shetty et al 2003]. After success with total hip replacement in the 1940's, Campbell and Smith Peterson applied this concept to the knee [Campbell 1940, Canale et al 2007, Shetty et al 2003]; they used vitallium plates for an interpostional arthroplasty, which capped the distal femur as a hemiarthroplasty [Canale et al 2007, Shetty et al 2003]. Unfortunately this technique was unsuccessful, as it did not produce significant pain relief [Canale et al 2007].

Over two decades later, Smith-Petersen later introduced a femoral stem with some success in relieving pain [Jones et al 1967]. McKeever and McIntosh were also trialing tibial plateau prostheses, but painful early loosening and unaltered joint surfaces of the arthritic knee joint were a source of persistent pain [Macintosh 1966].

In the 1970's, Insall and his team at the Hospital for Special Surgery designed a tricompartmental total knee replacement with the philosophy that mechanical considerations should outweigh the desire to replicate the normal knee [Canale et al 2007]. This significantly improved survival rates up to 90% at 21 years [Font-Rodriguez et al 1997]. This design was further modified to improve range of motion with a central cam mechanism called the Insall-Burstein posterior cruciate-substituting or posterior stabilising design [Canale et al 2007, Font-Rodriguez et al 1997], which was developed in 1978. Most current total knee designs are derivatives of the Insall-Burstein design, with different modifications over time [Canale et al 2007].



Figure 2.12. Insall-Burstein II posterior-stabilized knee [Canale et al 2007]

Recent technological advances in joint arthroplasty include computer navigation [Chauhan et al 2004, Hoffart et al 2012, Novicoff 2010]; gender specific TKA [Kim et al 2010] and, most recently, custom-fit TKAs [Bali et al 2012, Slover et al 2012].

Computer navigation is digital mapping based on standard anatomical landmarks and kinematic analysis to balance soft tissues [Chauhan et al 2004]. Researchers have found improved alignment when this technology is used for TKA [Chauhan et al 2004, Meikle et al 2001, Novicoff et al 2010, Saragaglia et al 2001], but it remains to be seen whether individual and cumulative improvement will lead to better long term results [Chauhan et al 2004, Novicoff et al 2010]. In a five year prospective controlled trial, Hoffart et al [2012] demonstrated better functional results with navigated TKA compared with conventional TKA at 5 years, but a recent meta analysis [Xie et al 2012] failed to show a difference in functional outcome between navigated TKA and conventional TKA.

Gender specific TKAs were created due to described anatomic differences in the distal femur and trochlear groove dimensions [Johnson et al 2011, Kim et al 2010]. These prostheses provide more options for the surgeon and patient, such as incorporating more sizes, different aspect rations and altered trochlear grooves [Johnson et al 2011], but no benefit from gender-specific TKAs has been shown in early clinical reports [, Johnson et al 2011, Kim et al 2010].

Custom-fit TKAs are a recent development using magnetic resonance imaging (MRI) or computerized tomography (CT) scans to create cutting blocks customized for the individual patient [Slover et al 2012]. The technique was developed to accurately restore the mechanical axis of the arthritic knee, as well as decrease operating time and decrease blood loss and lower the risk of fat embolus intra operatively [Bali et al 2012]. There is limited literature on the subject at present [Bali et al 2012, Slover et al 2012].

2.4.2 Types of implants

There are several different types of arthroplasty for the knee [Canale et al 2007]. Unicompartmental knee arthroplasty (UKA) is an alternative to TKA when only one compartment of the knee (medial or lateral) is damaged [Bellemans et al 2005]. Function is generally better preserved compared with TKA due to preservation of the cruciate ligaments and the other compartment of the knee [Chassin et al 1996], but longevity is not comparable to TKA [Cartier et al 1996, Tabor&Tabor 1998]. UKA has been shown to have a 96% survival rate and 92% satisfaction at ten years [Berger et al 2005].

Current total knee prosthesis designs are unconstrained, constrained non hinged and constrained hinged [Miller et al 2008]; the most commonly used is the unconstrained TKA, which was used by the senior surgeons in our population. In the unconstrained TKA, stability is provided by a combination of the prosthesis design and preservation of the knee ligaments [Canale et al 2007]. In modern day designs, sacrifice of the ACL and/or the PCL is allowed for by the prosthesis; total unrestrained prostheses, where both the ACL and PCL are retained, are rarely used anymore due to poor results [Canale et al 2007]. Increased levels of stability are required in certain circumstances, such as medial collateral ligament deficiency, severe medio-lateral instability, marked bone loss or tumour [Bellemans et al 2005, Canale et al 2007, Miller et al 2008]. Constrained designs, such as implants with fixed hinges, are used in these more complex cases [Bellemans et al 2005, Miller et al 2008].

In TKA, the femoral and tibial articular surfaces are replaced, and sometimes the patella [Bellemans et al 2005, Solomon et al 2001]. The femoral component and tibial baseplate is composed of a metal alloy. A polyethylene liner is placed onto the tibial baseplate [Bellemans et al 2005, Canale et al 2007, Solomon et al 2001]. The components can be cemented or uncemented. Correct placement of the implants in line with the mechanical axis of the lower extremity is essential [Bellemans et al 2005, Canale et al 2007, Miller et al 2008].

2.4.3 Complications following TKA

Complications following TKA can be general or specific to TKA [Solomon et al 1998]. General complications include anaesthetic complications, neurovascular damage and deep vein thrombosis (DVT) and pulmonary embolus (PE) [Einhorn et al 2007, Solomon et al 1998]. In patients without either mechanical or pharmacological prophylaxis after TKA, asymptomatic DVT will develop after 40-60% [Geerts et al 2001], and a fatal PE will develop in 0.5-2% of patients [Einhorn et al 2007, Lieberman and Hsu 2005].

More specific complications include infection, loosening and patellofemoral problems [Canale et al 2007, Solomon et al 1998]. Deep infection occurs in 1-2% of TKA with devastating consequences [Leone and Hanssen et al 2005]. Infection can be superficial or deep, or early, delayed or late; it is treated with antibiotics, debridement, and sometimes joint exchange or arthrodesis, depending on the clinical situation [Einhorn et al 2007, Miller et al 2008]. Loosening can be septic (ie caused by infection) or aseptic (ie caused by osteolysis or wear) and is usually treated with revision surgery replacing the implant with another prosthesis [Einhorn et al 2007, Miller et al 2008, Solomon et al 1998]. Aseptic loosening is the most common cause of failure of total joint replacements [Australian National Joint Registry 2011, Miller et al 2008, Wimhurst 2002]. Patellofemoral problems are common, and can sometimes be treated with revision surgery, especially if the patella has not previously been replaced or if there is patellar misalignment [Miller et al 2008].

2.4.4 Summary of TKA

The development of TKA has evolved since the 1940's with the advent of metallic prostheses. The Insall-Burnstein prostheses in the 1970's provided patients with knee OA excellent relief from their symptoms, and also proved durable. Since then, the market has been flooded with different types and designs of prostheses for TKA, creating an urgent need for good post operative assessment tools. Complications after TKA can be general or specific, and can affect the outcome after surgery.

2.5 OUTCOME MEASURES FOR TKA

There has been a steady increase in the number of TKAs performed in the last ten years, due to the increasing prevalence of knee arthritis secondary to the ageing population, and procedure's proven effectiveness [Badely & Crotty, 1995, McClung et al 2000, Mizner et al 2011]. In Australia, 3102 (7.6%) more primary total knee procedures were performed in 2010 when compared with the previous year [Australian Orthopaedic Association National Joint Registry 2011]. The increase in health care expenditures highlights the need for consistent evaluation of the effectiveness of medical interventions [Hirsch HS 1998]. This evaluation may inform patients, health care providers and researchers of clinical and therapeutic benefits, and improve future management of health care resources [Ritter et al 1997]. Furthermore, patient satisfaction is one of the ultimate goals of all orthopaedic procedures; knowledge of which factors contribute to patient satisfaction can be incorporated in the care for TKA patients [Vissers et al 2010].

It is important to establish a universally acceptable method of measuring the outcome of TKA [Amadio PC 1993, Fuchs et al 2000, Harcourt et al 2001, Konig et

al 1997, Rodriguez-Merchan 2012]. Unfortunately, there is no gold standard within the current body of literature that would aid to select universally accepted outcome tools for TKA [Bach et al 2001, Bourne 2008, Davies et al 2002, Garratt et al 2004, Ghanem 2010, Khanna et al 2011]. The end results of surgical interventions were traditionally assessed through measures of mortality and morbidity rates, operative complications and the lifetime of the prosthesis [Ethgen et al 2004]. However, researchers [Givon et al 1998, Lamping et al 2001, Saleh et al 2005] have suggested that these indicators are not as relevant and may no longer reflect health care efforts or benefits. Other outcomes measures have subsequently been developed to allow investigators and surgeons to quantify preoperative to postoperative improvements in TKA patient health status [Bourne 2008]. This data is generally classified as subjective (patient reported) or objective (performance based and clinical examination) [Mizner et al 2011]. Subjective data measures the effect of the intervention on quality of life and the patient's opinion [Bach et al 2001, Gartland et al 1988, Saleh et al 2005]. Objective data includes longevity of the prosthesis, functional tests and clinical examination [Bach et al 2001, Gartland et al 1988, Saleh et al 2005]. Traditional belief that objective data is more reliable than subjective data is beginning to be dispelled [Liow et al 2000, Rodriguez-Merchan 2012]. A surgeon's technical success may still equal a failure in the patient's perspective if it does not have a significant positive impact on quality of life [Kreibich et al 1996].

2.5.1 Types of outcome measures for TKA

For assessing TKA, outcome tools include: global health questionnaires, disease specific questionnaires, functional outcomes, radiographs and longevity of the

implant, and cost utility assessments [Bourne 2008, Ethgen et al 2004, Nestor et al 2010]. These will be discussed below.

2.5.1.1 Global Health Questionnaires

Global health (or generic) questionnaires are intended for a wider range of health problems, measuring health related quality of life, whereas disease specific questionnaires have been developed for one disease or treatment modality (ie TKA) [Bach et al 2009, Fitzpatrick et al 1992, Kantz et al 1992, Konig et al 1997]. Health related quality of life is a broad concept representing individual responses to the physical, mental and social effects of illness on daily living [Bowling 1992]. When outcomes of TKA are evaluated, numerous factors other than the surgery should be taken into account, such as comorbid conditions, rehabilitation, psychological profile and social factors [Ethgen et al 2004]. If surgeons seek to perceive the broader implications of TKA, then it is necessary to consider outcomes that encompass several dimensions of health [Gartland 1988, Ghanem et al 2010, Murray et al 2007, Rejeski & Shumaker 1994].

Generic health related questionnaires have demonstrated an improved score in patients after TKA in the categories of pain and physical functioning, mental health and social functioning [Aarons et al 1996, Bachmeier et al 2001, Bayley et al 1995, Jones et al 2000, Kiebzak et al 2002, Kirwan et al 1994, Liang et al 1990, Rissanen et al 1997, Ritter et al 1995, Shields et al 1999, Tsuboi et al 1996, Van Essen et al 1998]. Previous investigators [Heck et al 1998, Konig et al 1997] have demonstrated that a decrease in psychological score in a generic questionnaire correlates with a decreased knee score in a condition specific questionnaire. Other researchers [Franklin et al 2008, Heck at al 1998, Jones et al 2005] have described that patients

who were of sound psychological state at the time of surgery were most likely to show improvement in general health post operatively. This could lead to benefits in counselling the patient awaiting TKA with lower mental scores, and a potential trial regarding collaboration with mental health teams and physicians pre-operatively [Heck et al 1998, Kantz et al 1992]. Many experts recommend generic measures be supplemented by knee specific measures to increase specificity in relation to a given disease or intervention [Bach et al 2007, Ethgen et al 2004, Franklin et al 2008, Ghanem et al 2010, Kantz et al 1992].

2.5.1.2 Disease specific questionnaires

It has been suggested that patient based disease specific questionnaires should be the primary outcome in orthopaedic clinical trials [Kettlekamp et al 1975, Roos & Toksvig-Larsen 2003]. Several researchers [Davies AP 2002, Drake et al 1994, Garrett et al 2002, Wang et al 2010] have investigated the available disease specific questionnaires for TKA. The most striking findings were the diversity of system composition [Drake et al 1994]. Pain could accumulate between 7-50% of the total points; stair climbing 4-50%; and range of motion (ROM) 4-30% [Drake et al 1994]. One widely used rating system for TKA was arranged such that a patient could get mild pain at rest, moderate pain on walking, instability of 15° and fixed flexion of 10°, but still able to score 75 points out of a possible 100 and grade of 'good' overall, which would not be acceptable for most orthopaedics surgeons or their patients [Davies RP 2002]. Although the main components of the individual knee rating systems (pain and function) are similar, different definitions and measures existed for each knee instrument [Davies RP 2002, Drake et al 1994, Garrett et al 2004, Wang et al 2010]. Other criticisms of particular types of knee instruments

include: they only focus on short term consequences [Roos and Lohmander 2003]; they do not accurately measure the patients spectrum of range of activities and quality of life [Franklin & Ayers 2008, Saleh et al 2005]; most that are specific for knees are not specific for TKA [Fitzgerald et al 1988, Fitzgerald et al 1992, Lotke and Ecker 1977, Pynsent et al 2005] and most have not been scrutinised for validity, reliability and responsiveness [Amadio PC 1993, Drake et al e1994, Garratt et al 2004, Wang et al 2010, Whitehouse et al 2005]. Other factors to consider are the length of the questionnaire, and available data for a 'normal' population [Dawson et al 1998, Fitzpatrick et al 1992, Paradowski et al 2006]. Short questionnaires have been shown to be as sensitive to important changes as their longer counterparts and are easier to use, which is important for an elderly population [Dawson et al 1998, Fitzpatrick et al 1992, Katz et al 1992]. It is also useful for questionnaires to have data for control groups, as scores for a 'normal' population rarely produce average scores equivalent to best possible scores, and are therefore useful for comparison of age matched populations [Bremner-Smith et al 2004, Jinks et al 2002].

There is overall agreement that the challenge for any rating system of TKA is to objectively assess the function of the knee independently of the overall function of the patient, which may be limited by something entirely different [Dawson et al 2006, Insall et al 1989, Ghanem et al 2010, Konig et al 1997, Whiteouse et al 2005]. The rationale of a dual rating system is to eliminate the impact of increasing age or co-morbidities leading to deteriorated global scores although the knee itself remains unchanged [Insall et al 1989, Konig et al 1997]. As an example, one of the most widely used questionnaires for TKA is the American Knee Society Score (KSS) [Insall et al 1989]. This is a dual rating system; the aim is to differentiate the status of the knee from general function (stair climbing, walking etc), which can be affected by other patient comorbidities such as age or other medical conditions [Brinker et al 1997]. The two scores of the KSS, the knee score and the function score, are not meant to be added together [Apley AG 1990]. Several widely used patient based knee instruments include clinical examination indicators (such as range of motion (ROM), quadriceps strength and knee alignment) in their assessment [Davies et al 2002, Drake et al 1994, Hofmann et al 2001, Insall et al 1989]. This is to provide a more comprehensive picture of TKA outcome, rather than just the patient's opinion [Lamping et al 2001].

This design, however, precludes the use of the KSS in postal audits and research; this places a heavy burden on time, money and resources [Fitzgerald et al 1992, Khanna et al 2011, Konig et al 1997, Medalla et al 2009, Whitehouse et al 2005]. Clinical indicators have also proven to be less reliable than patient assessment [Fitzgerald et al 1992, Garratt et al 2004, Gartland et al 1988, Kantz et al 1988, Lamping et al 2001, Laporte et al 1985, Liow et al 2003, Roos & Toksvig-Larsen 2003, Saleh et al 2005, Schal et al 1999, Whitehouse et al 2005]. Furthermore the proportional reliance on subjective and objective data differs, and such a variation may affect the responsiveness as well as the reliability of the scores [Lamping et al 2001]. It is now widely accepted that clinical trials should incorporate the patients' views about outcome [Bourne 2008, Ethgen et al 2004, Garratt et al 2004, Gartland et al 1988, Kantz et al 1992, Lamping et al 2001, Saleh et al 2005]. For these reasons, subjective patient based questionnaires to evaluate TKA have been recently intensively promoted in orthopaedic research and audit [Ethgen et al 2004, Roos & Toksvig-Larsen 2003]. More recently, however, Mizner et al [2011] has

demonstrated that patient report fails to capture acute functional declines after TKA, and may over state the long term functional improvement.

2.5.1.3 Functional Outcomes

TKA effectively relieves pain but improvement in physical function varies post operatively [Franklin et al 2008]. Despite excellent imaging and surgical technique, an estimated 15-30% of patients report minimal functional improvement at 6-12 months [Ayers et al 2005], while another 10% report functional gains up to three times the national average [Jones et al 2005]. This post TKA functional variation is not explained by persistent knee pain or poor pre operative function [Ayers et al 2005, Franklin et al 2008, Jones et al 2005].

Function is consistent with the descriptions of Bellamy [2000]; 'the ability to move around", and Terwee et al [2006]: 'the ability to perform daily activities". Historically, self-reports of physical function have been preferred over performance based assessments [Bellamy et al 1997]. Conversely, there has been a growing body of evidence demonstrating self reports of physical function provide inaccurate representations of the true ability of patients [Bellamy et al 1988, Mizner et al 2011, Stratford & Kennedy 2004]. Some researchers [Kennedy et al 2005, Silva et al 2003, Stratford et al 2009] advocate using objective measures to assess outcome and document change in function over time, arguing that improving knee function is a premier issue in TKA patients. Disability from arthritis of the knee is produced by pain, limited ROM, deformity, instability and poor mobility, which can all be measured objectively, excluding pain [Collopy et al 1977]. Although the past three decades have seen a considerable development and evaluation in subjective outcomes research [Lamping et al 2001, Visser et al 2010, Wang et al 2010], these advances have not been paralleled to the same extent in objective performance measures [Harding et al 1988, Kennedy et al 2005, Visser et al 2010].

2.5.1.4 Radiographs

Aseptic loosening is the most common cause of failure of total joint replacements [Australian National Joint Registry 2010, Baker et al 2012, Miller et al 2008, Wimhurst 2002]; 30.7% of the TKAs revised in Australia in 2010 were for aseptic loosening [Australian Orthopaedic Association National Joint Registry 2011]. This is in comparison to other causes of revision, including infection (22.2%), patellofemoral pain (13.5%), pain (9.0%) and instability (5.8%) [Australian Orthopaedic Association National Joint Registry 2010]. The precise pathogenesis of aseptic loosening remains controversial, and is thought to include prosthetic migration, joint fluid pressure, but mainly, host response to particulate debris [Naudie et al 2007, Wimhurst 2002]. Factors that can contribute to this process include increased activity affecting loads placed on a TKA over time [Naudie et al 2007], polyethylene structure and thickness [Einhorn et al 2007, Miller et al 2008, Naudie & Rorabeck 2004] and component design [Canale et al 2007, Einhorn et al 2007, Naudie et al 2007, Wimhurst JA 2002] and alignment and soft tissue balancing of the knee [Canale et al 2007, Naudie et al 2007]. The early metal and polyethylene prostheses wore out quickly due to implant design and polyethylene problems [Canale et al 2007, Miller et al 2008]. In 1969, a 10 year follow up of one of the early designs found a 42% revision rate [Platt & Pepler 1969]. One of the longest follow up studies of more modern TKAs shows a 90% survival rate at 21 years [Font-Rodriguez et al 1997].

Aseptic loosening around a TKA can usually be visualized on xrays as radiolucency [Naudie et al 2007]. Osteolysis (dissolution of bone) can occur as a response to periprosthetic particulate debris that results from and is dependent on material type as well as particle size, shape, and amount [Tsao et al 2008]. Particulate debris from polyethylene implants plays an important role in the development of periprosthetic osteolysis and total joint replacement failure [McCalden et al 2005]. Usually, patients early in the evolution of osteolysis are asymptomatic and the amount of wear and bone resorption is limited [Naudie et al 2007]. The rate of progression of an osteolytic lesion varies, but most progress with time [Naudie & Rorabeck 2004]. It is advisable to replace those implants in patients who are symptomatic or who have rapidly increasing lesions or have other causative factors such as malalignment or instability [Naudie et al 2007].

Investigators [Bach et al 2009, Lotke et al 1977] have found a high correlation between clinical results and radiographs after TKA. Lotke et al [1977] investigated 70 TKAs and found those with good radiographic alignment had better clinical results. Bach et al [2009)] found a significant correlation between the extent of radiolucent lines of the tibial component and generic health related quality of life questionnaires but not with the American Knee Society Score (KSS) or alignment of the TKA. In contrast, other researchers [Bullens et al 2001, Ecker et al 1987] could not demonstrate a significant correlation between the occurrence of thin radiolucent lines and clinical results.

2.5.1.5 Cost Utility Assessments

TKA has been found to be a cost effective procedure and compares favourably with other medical and surgical interventions [Kaper & Bourne 2001, Laupaucis et al 1994, Lavernia et al 1997]. To measure this, the cost to quality adjusted life year (QALY) is used, but can be difficult to perform as it requires accurate costing data combined with a perceived change in outcome [Sackett et al 1996]. Investigators [Kaper & Bourne 2001, Laupaucis et al 1994, Lavernia et al 1997] have found that cost to QALY is less for TKA than for other common medical and surgical interventions such as heart transplants and coronary artery bypass. TKA has proved itself worthy of funding from governments and health related administrations [Kaper & Bourne 2001, Laupaucis et al 1994, Lavernia et al 1997].

2.5.1.6 Summary outcome measures after TKA

Since the success of TKA, there has been a multitude of assessment tools developed available to clinicians and researchers, including generic and disease specific questionnaires, functional outcomes and imaging, longevity and cost utility. The lack of consensus or a gold standard has served to complicate research regarding outcome after TKA.

2.5.2 The Outcomes Movement: validity, reliability and responsiveness

Healthcare providers need to know how good an intervention such as TKA is, and whether it is cost effective [Bourne RB 2008, Ethgen et al 2004]. The application of outcomes data to TKA will foster continuous quality improvement in surgical techniques, implant selection and patient care [Bourne RB 2008]. Because TKA is a high volume, high cost medical intervention, it is not surprising that there has been an explosion in the number of assessment methods for TKA in the last three decades

[Bach et al 2001, Bourne RB 2008, Davies AP 2002, Garratt et al 2001, Konig et al 1997, Rodriguez-Merchan 2012, Whitehouse et al 2005].

Researchers [Brinker et al 1997, Drake et al 1994, Garratt et al 2004, Gollehon et al 1987, Whitehouse et al 2005] agree that growth in the number of assessment instruments confuse results of outcome after TKA. The plethora of available methods has led to a lack of standardisation and limits ability to generalise findings [Brinker et al 1997, Drake et al 1994, Fuchs et al 2000, Garratt et al 2004, Gollehon at el 1987, Rossi & Hansson 2004, Whitehouse et al 2005]. A large variety of scores with different designs make comparisons between different patient groups, different implants or different surgical techniques impossible [Bach et al 2001, Fuchs et al 2001, Garratt et al 2004, Konig et al 1997]. Investigators [Aglietti et al 1984, Bach et al 2001, Goldman et al 1996, Haas et al 1995, Konig et al 1997, Liow et al 2000, Mont et al 1998, Shih et al 1993, Tankersely & Hungerford et al 1995] have attempted to allow for comparison in studies using different knee instruments by designating a numerical score into a category (ie excellent, good, fair, poor) but this is not a scientific method [Gartland 1988]. Bach et al [2001] demonstrated considerable disagreement between observers when this oversimplification was applied.

The relatively new field of health measurement, or the Outcomes Movement, has been developed specifically in response to the need for rigorous measurement of patient based outcomes in evaluating healthcare [Lamping et al 2001]. The shift in emphasis to patient based outcomes in evaluating healthcare has been vigorously promoted in research during the Outcomes Movement in the last three decades [Frater and Sheldon 1993, Hammermeister et al 1995, Wang et al 2010]. Measures are only considered scientifically acceptable after they have been subjected to a comprehensive series of tests to demonstrate that they are reliable, valid and responsive [Bourne RB 2008, Lamping et al 2001, Pynsent PB 2001, Robertsson et al 2001, Rodriguez-Merchan 2012, Roos & Toksvig-Larsen 2003, Wang et al 2010, Whitehouse et al 2005]. These three properties are often used in scrutinizing outcome measures for TKA [Bemben et al 2003, Garrett et al 2004, Johanson et al 2004, Kennedy et al 2005, Rossi et al 2006, Saleh et al 2005, Wang et al 2010] and will be discussed below.

Validity can be difficult to both define and assess [Brinker et al 1997, Pynsent PB 2001]. It reflects the extent to which the instrument measures what it is purported to measure [Garratt et al 2004, Wang et al 2010]. Validation is difficult with patient assessed questionnaires as they are measuring an inherently subjective phenomenon [Fitzpatrick et al 1992]. Outcome measures can be validated through content validity, construct validity and concurrent validity [Bellamy & Campbell 1989, Johanson et al 2004, Pynsent PB 2001, Wang et al 2010]. Content validity examines the ability of the instrument to measure all aspects of the condition for which it was designed, so that it is applicable to all patients with that condition [Dawson et al 1998, Pynsent PB 2001]. An increase in the content will tend to decrease the reliability, but this must be viewed as secondary in importance to validity [Pynsnet PB 20010]. Face validity is an example of content validity [Wang et al 2010]; does the instrument 'look like' it measures what it purports to measure, and does it cover the full range of relevant topics [Fitzpatrick et al 1992, Johanson et al 2004]? Face validity can be achieved by involving a wide range of people in the development of instruments: doctors, nurses, patients, social scientists etc., who can confirm face validity [Fizpatrick et al 1992, Guyatt et al 1986, Johanson et al 2004]. Content and

face validation are no longer considered adequate as the only tests of validity [Bellamy and Campbell 1989]. Construct validity measures the extent to which a measure corresponds to theoretical concepts concerning the area of interest [Dawson et al 1998, Johanson et al 2004, Pynsent PB 2001]; for example, a measure of lower limb function may be expected to change with age. Concurrent (also known as criterion) validity measures the correlation of scores or results with an existing 'gold standard' [Wang et al 2010]; if no such entity exists, it is compared with external criteria known or believed to measure the attribute, such as existing instruments or functional tests [Bellamy et al 1989, Ghanem et al 2010, Johanson et al 2004, Pysnent PB 2001]. The Outcomes Movement has shown patients as an important part of the validation process [Fitzpatrick et al 1998, Garratt et al 2004, Lamping et al 2001]. Research in many areas of medicine and surgery has demonstrated that patients can give reliable information about their health status and benefits of treatment, and the goals of the patient are increasingly being recognized to influence the success of the surgery [Dawson et al 1998, Fitzpatrick et al 1992, Hawker et al 1998, Saleh et al 2005]. Research findings are now considered to be incomplete unless the patients' views of treatment are formally assessed [Amadio PC 1993, Garratt et al 2004].

Reliability refers to the ability of the questionnaire to consistently produce the same score on repeated use under the same conditions [Dawson et al 1998, Fitzpatrick et al 1992, Kreibich et al 1996, Pynsent PB 2001, Robertsson and Dunbar 2001], as well as the random error of an instrument [Wang et al 2010]. For example, research often tests the reliability of a questionnaire by re-testing the same subjects on a different day [Bellamy & Campbell 1989, Pynsnet PB 2001].

Responsiveness reflects the ability of a measure to capture clinically meaningful changes in a patient's state over time [Johanson 2004, Robertsson & Dunbar 2001, Roos and Toksvig-Larsen 2003, Wang et al 2010]. Responsiveness and sensitivity are similar: sensitivity measures the ability of an instrument to measure *any* change [Fortin et al 1995, Liang et al 2002], whereas responsiveness measures only clinically significant change [Johanson 2004]. A more responsive test would theoretically be able to identify more subtle changes in patient status [Kreibich et al 1996]. If a small change must be detected, and the outcome measure is only moderately reliable, large numbers of patients are required [Pynsnet 2001]. The responsiveness of an instrument can be decreased in several ways: items which are not relevant to the disease or treatment; items which are static over time; items which are subject to floor or ceiling effects (i.e. if the satisfaction is so high there is no further scope to register) and categories which are too broad [Fitzpatrick et al 1992]. The specificity of a score influences its responsiveness, which is the most important aspect in relation to prospective outcome studies [Murray et al 2007].

It is also important to remember that validity, reliability and responsiveness are context specific attributes; an instrument or performance measure that has demonstrated satisfactory measurement properties in one population is not necessarily appropriate for use in other populations [Fitzpatrick et al 1998, Garratt et al 2004]. Therefore, not only do these outcome measures need rigorous testing, but they need to be tested in the TKA population in a certain cultural group [Garratt et al 2004]. The specificity of a knee rating scale influences its responsiveness, which is the most important aspect in relation to prospective outcome studies [Murray 2007].

Orthopaedic research has come under some scrutiny in recent years; orthopaedic outcome measures have been criticized for their lack of validity, reliability and responsiveness [Amadio PC 1993, Bourne et al 2010, Drake et al 1994, Fuchs et al 2000, Garratt et al 2004, Whitehouse et al 2005]. As TKA becomes more widely utilized, it becomes increasingly important to ensure only valid, responsive and reproducible outcome measures are used in research and clinical practice [Bellamy et al 1988, Relman AS 1988, Whitehouse et al 2005]. The use of unvalidated questionnaires to evaluate patient based outcomes in clinical research can no longer be justified [Lamping et al 2001].

2.5.2.1 Summary of the Outcomes Movement

The Outcomes Movement has seen a shift of emphasis in the last few decades to patient based outcome measures. Assessment tools for outcome after TKA are now only considered scientifically acceptable if they are reliable, valid and responsive.

2.5.3 Knee Rating Systems

It is well known that the concerns and priorities of patients differ from those of the surgeons [Bourne et al 2010, Ghanem et al 2010, Hartcourt et al 2001]. It seems surgeons are more satisfied with the results of TKA than patients [Bourne et al 2010, Bullens et al 2001]. Every orthopaedic surgeon will have treated patients who clinically and radiologically appear to have the perfect knee replacement and yet remain unsatisfied [Amadio PC 1993, Saleh et al 2005]. For this reason, subjective patient based questionnaires to evaluate surgical outcomes have been intensively promoted in orthopaedic research and audit [Ghanem et al 2010, Roos & Toksvig-Larsen 2003]. In several comparative studies of patient based questionnaires for

TKA [Davies AP 2002, Drake et al 1994, Garrett et al 2004], the most widely used was the American Knee Society Score (KSS), and the most recommended was the Oxford Knee Score (OKS) and the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) or the Knee Injury and Osteoarthritis Outcomes Score (KOOS). The KOOS contains the entirety of the WOMAC. Generic rating scores recommended were the SF36 and its shorter, validated form, the SF12 [Davies AP 2002, Garrett et al 2004].

2.5.3.1 Oxford Knee Score

Dawson et al [1998] developed the Oxford Knee Score (OKS), and it was validated at its conception. The authors selected 20 patients on the waiting list for TKA from the orthopaedic outpatient department, and interviewed them regarding quality of life with regard to their knee [Dawson et al 1998]. The authors then drafted a questionnaire and tested this questionnaire on 20 new patients who commented and included any other problems. Modifications were then made and this procedure was repeated in a further two series to produce the final questionnaire. The final version consists of twelve items, each with a score of one to five: pain; difficulty washing and drying self; difficulty getting in and out the car/public transport; walking duration; pain on standing; limp; ability to kneel; night pain; interference with work; giving way; ability to do shopping and ability to descend stairs (Appendix V).

This questionnaire was then tested in a prospective study to determine if it had a high completion rate, internal consistency, reproducibility, content validity, construct validity and responsiveness on 117 consecutive patients [Dawson et al 1998]. The OKS was found to have a very high completion rate pre and post operatively; pre-operatively, all twelve items were answered by every patient. This has been reproduced in other studies when compared with other measures of health status [Dawson et al 1998, Dunbar et al 2001, Medulla et al 2009]. The OKS was shown to have high internal consistency and reproducibility, and moderate correlations with both components of the KSS and the physical function and pain for the SF36 [Dawson et al 1998]. The effect size for the OKS was larger than any other individual parts of the SF36 and showed the most responsiveness of all three questionnaires, which is in keeping with other studies [Lingard et al 2001, Liow et al 2003, Katz et al 1992, Robertsson and Dunbar 2001, Roos & Toksvig-Larsen 2003].

The use of the Oxford Knee Score, since its development over ten years ago, has slowly increased. It is now used not only in research and audit but also in National Joint Registries, including those of England, New Zealand and Sweden [Murray et al 2007].

The OKS has received commendation for its reliability, validity and responsiveness [Davies AP 2002, Dunbar et al 2001, Hasballa et al 2003, Garratt et al 2004], as well as its practicality and high completion rate when compared with other highly used questionnaires such as the KSS [Davies AP 2002, Garratt et al 2004, Liow et al 2002] WOMAC [Dunbar et al 2001], and the British Orthopaedic Association Score [Liow et al 2002]. It has been shown to have good reliability and a good coverage of thresholds [Conaghan et al 2007, Ko et al 2009]. An additional advantage is that it can be completed by post, thereby avoiding inconvenience and cost [Murray et al 2007]. In a review of knee specific questionnaires, Davies AP [2002] described the OKS as 'a genuine attempt to create a new tool for the assessment of TKA outcomes'; it appears to offer a number of advantages and generates scores that allow comparisons between different patient groups and different regimens.

Harcourt et al [2001] drew attention to the problem of specificity of the knee score when lumbar spine and hip morbidity co-exist. The OKS was shown to be highly sensitive but not specific, partly due to the "function" questions and partly due to "referred pain" to the knee [Harcourt et al 2001]. To avoid this problem, Konig et al [1997] suggested that the knee and functional ratings should be divided into separate scores for pain and function, similar to a dual rating system. Pysent et al [2005] suggested excluding any OKS questionnaire with two or more omitted questions. Pysent [2005] discovered that patients could not kneel before TKA, and are unable to kneel afterwards, which partly contributed to the higher steady state for the postoperative OKS scores.

Whitehouse et al [2005] found a similar problem of kneeling in her postal audit using the OKS pre and post TKA. It was therefore difficult for patients to get a perfect score of twelve. Other criticisms included: item 4 (walking time) had a significantly higher frequency of missing responses when compared to the other items (likely due to ambiguous wording); and there is no allowance in the OKS for comorbid conditions.

2.5.3.2 Knee Osteoarthritis Outcomes Score (KOOS)

Roos et al [1995] developed the Knee and Osteoarthritis Outcome Score (KOOS) (Appendix VI). The American-English and Swedish versions were developed simultaneously [Roos et al 1998], and is now also available in German [Kessler et al 2003]. The KOOS is a knee specific instrument, which assesses patients' views on their knee and associated quality of life. It contains 42 items in 5 separately scored subscales: pain, other knee symptoms, function in daily living (ADL), function in Sport and Recreation (Sport/Rec), and knee related quality of life. It has been

modified to assess other lower limb problems: foot and ankle (FAOS) [Roos et al 2001]; the hip (HOOS) [Nilsdotter et al 2003]; rheumatoid arthritis (RAOS) [Bremander et al 2003]. It was developed as an extension of the WOMAC Osteoarthritis Index and contains the full and original version [Roos et al 1999].

The KOOS was validated throughout its development, involving a literature review, an expert panel and a pilot study including 75 patients [Roos & Lohmander 2003]. The KOOS has been validated in several different populations including 18-46 year olds undergoing ACL reconstruction [Roos et al 1998], subjects aged 16-79 post knee arthroscopy [Roos et al 1998b], patients aged 38 to 76 who had undergone meniscectomy 16 years previously [Roos et al 1999], and TKA patients [Roos & Toksvig-Larsen 2003].

A Likert scale is used to score the KOOS and all items have five possible answers scored from zero (no problems) to four (extreme problems). Each of the five scores is calculated as the sum of the items included and scores are then transformed to zero to one hundred (0-100) scale with zero (0) representing extreme knee problems and one hundred (100) representing no knee problems. An aggregate score is not calculated as the KOOS is designed for analysis of each subscale separately.

The WOMAC was developed for the elderly population with OA whereas the KOOS developed for younger/more active patients due to the increasing interest to investigate the early treatment of OA [Roos et al 1998, Roos et al 1999]. Roos et al [2003] sent 125 patients the KOOS, SF36 and a questionnaire on background function pre and post TKA. Two different random selected subsets of patients were sent the KOOS two weeks apart. The response rate was up to 92% and few individual items were missing at baseline except for the item sport and recreation;

74% of items for this subscale were missing. Greater than 90% reported that improvement in four subscales pain, symptoms, activities of daily living (ADL) and knee related quality of life. Fifty-one percent reported that the subscale Sport and Recreation function extremely or very important when deciding to have their knee operated on. The Sport and Recreation subscale is not incorporated in the WOMAC and reflects higher demands of physical activity of older patients compared with some decades ago. Higher responsiveness was observed for KOOS when compared with the WOMAC. The authors discussed that a disadvantage of the KOOS is the increased number of items when compared with the WOMAC (42 compared with 24) resulting in a larger burden for patient, especially if multiple instruments are used concurrently [Roos & Toksvig-Larsen 2003]; other investigators [Perruccio et al 2008, Ryser et al 1999, Sun et al 1997] have shared this concern.

Paradowski et al [2006] aimed to establish a population based reference data for the KOOS. The KOOS was sent to 840 persons aged 18-84 years in Sweden. The response rate was 68% of subjects. As would be predicted, more difficulty was seen in the older age groups for ADL function, sports and recreation and knee related QOL. Paradowski et al [2006] found functional difficulties increased with age, supporting previous studies in the population and in knee OA patients [Jinks et al 2002, Bremner-Smith 2004, Brinker et al 1997, Riter et al 2004]. The decline in function with older age groups was more apparent for the subscale Sport and Recreation function compared with ADL. This investigator highlights that the KOOS acts like a dual rating system. The instrument was never meant to generate a total score, and thus each section can be looked at individually [Roos & Lohmander 2003]. Like the KSS

function score, the sports and recreation subscale for the KOOS is sensitive to patient factors other than the knee such as age [Paradowski et al 2006].

Despite concerns with the number of items [Sun et al 1997, Ryser et al 1999], the KOOS has proved to be valid, reliable and responsive for TKA patients [Roos & Toksvig-Larsen 2003], and has been recommended in recent reviews of patient based questionnaires for TKA outcomes [Garratt et al 2004, Rodriguez-Merchan et al 2012, Wang et al 2010].

2.5.3.3 American Knee Society Score (KSS)

The American Knee Society Score (KSS) (Appendix VII) was created by the American Knee Society and published by Insall et al [1989]. The Knee Society aimed to create a new rating system for TKA assessment to supersede the ageing but widely used Hospital for Special Surgery Rating System (which Insall also helped to create in 1976). The authors noticed that the HSS lacked in two areas:

- 1 It was created in a time where knee arthroplasty was just being developed, and as a result the expectations were lower.
- 2 Because the HSS incorporated a functional component, the score tended to deteriorate as the patient aged, although knee score remained unchanged [Davies 2002].

The Knee Society then decided by consensus to separate the knee and the functional assessment [Insall et al 1989]; the end result was the American Knee Society Score (KSS) (Appendix VII). A patient categorisation system is included in the KSS to identify those patients whose function may be undermined by factors other than the knee in question: A: No substantial disease in the contralateral knee; B: Substantial

arthrosis; C: Multiple joint involvement or generalised disability [Liow et al 2000]. The Knee score is comprised of pain (50 points), range of motion (25 points, with a maximum of 125 degrees), and stability, measuring antero-posterior and mediolateral stability separately (25 points each). Deductions are made for flexion contracture, extension lag, and alignment. The Function score is comprised of walking distance (50 points), and stair climbing (50 points) with deductions for using a walking aid.

Since its development, the KSS has been consistently criticised for the lack of validation at its origin [Davie 2002, Drake et al 1994, Garratt et al 2004, Ghanem et al 2010, Lingard et al 2001]. Despite these concerns, the KSS has been widely accepted as an objective measure of knee status in patients undergoing TKA [Drake et al 1994, Davies AP 2002, Ghanem et al 2010]. It has also been used to evaluate construct validity of other outcome scales [Dawson et al 1998]. The KSS is currently undergoing an update, including validation, to include objective and functional assessments to better reflect patient outcome after TKA [Ghanem et al 2010].

The reliability of the KSS is not optimal [Khanna et al 2011, Liow et al 2000]. Liow et al [2000] investigated the reliability of the KSS and then compared it with the reliability of the British Orthopaedic Association score and the OKS in later research [Liow et al 2002]. Six observers of mixed experience assessed 29 patients at least two hours apart. The BOAS had higher reliability when compared to the KSS but was less responsive. For the KSS, there was significant disagreement on stability, ROM and extension lag, and the agreement for mediolateral stability was no greater than expected by chance; it had the lowest reliability of the three instruments. Bach et al [2001] also compared the reliability of the KSS knee and function scores with two experienced orthopaedic surgeons and found the KSS knee score to have the lowest reliability of four knee specific instruments (the Hungerford score, the HSS, the KSS and the Bristol score).

Lingard et al [2001] aimed to validate the KSS by comparing results and responsiveness with the SF36 and the WOMAC in a large multi-centre trial on a TKA population. The KSS knee score was responsive for assessing the results of TKA, but the KSS function score was not. The KSS and WOMAC pain scores were more responsive than the SF36. Kreibich et al [1996] discovered a similar result. The KSS knee score and function score had consistently low internal consistency (a measure of reliability). WOMAC pain and function scores and SF36 bodily pain score and physical function scores had significantly stronger correlations when compared with the KSS.

Recently, Medulla et al [2009] reported a good correlation between the KSS Knee and Function Score and the OKS at two years post operatively; this decreased at five to ten years post operatively, but there was still a statistically significant correlation.

The need for a dual rating system was explored by Konig et al [1997], who followed up 276 TKA patients for 2-5 years with the KSS knee and function scores and compared them in a longitudinal study. Considerable gain in knee and functional rating was obtained post-operatively, but at two years the knee score reached a plateau while the function score started to decline, vindicating the original authors [Insall et al 1989]. This has been reproduced by other authors [Benjamin et al 2003, Bremner-Smith et al 2004, Medulla et al 2009], up to ten years post operatively. In his review of patient based questionnaires for TKA, Davies AP [2002] advocated this instrument as being concise and easy to use, representing a clear attempt to separate function of the TKA from overall patient function.

2.5.3.4 Short Form 12

The main generic health instrument used in clinical trials at the present time is the Short Form 36 (SF36). This is a thirty six (36) item health survey that measures the following eight (8) areas of health:

1 Limitations in physical functioning due to health

- 2 Limitations in social activities due to physical or emotional health
- 3 Limitations in usual role activities due to physical health
- 4 Limitations in usual role activities due to personal or emotional problems
- 5 General mental health (psychological distress and well being)
- **6** Vitality (energy and fatigue)
- 7 Bodily pain
- 8 Perceptions of health in general

Scores range from 0-100, with 100 being the most healthy score. It has been validated in several populations, including clinical indicators as presence and absence of disease, severity within disease category, and changes in disease related symptoms over time. It has proved to be reliable in chronic and general disease populations [McHorney et al 1992, Nelson et al 1990, Sterward et al 1988, Sterward et al 1989, Ware et al 1993].

The short form 12 (SF12) (Appendix VIII) was created from original authors of the SF36. They found twelve SF-36 items and improved scoring algorithms reproduced at least 90% of the variance in the physical and mental health summary measures in both general and patient populations [Ware et al 1996]. The SF12 was validated at its creation, and was found to be comparable in reliability and responsiveness to the SF36 [Ware et al 1996].

One of the major benefits of the additional use of a generic questionnaire is the patient's psychological status can be assessed pre and post operatively [Ghanem et al 2010, Heck et al 1998]. Investigators have shown that a decrease in psychological score in a generic questionnaire correlates with a decreased knee score in a condition specific questionnaire [Heck et al 1998, Konig et al 1997, Smith et al 1992]. Other researchers [Bayley et al 1995, Jones et al 2000, Liang et al 1990, McGuigan et al 1995, Rissanen et al 1996, Ritter et al 1995, Van Essen et al 1998] have shown an improvement in mental health and social functioning scores after TKA.

Heck et al [1998] showed that patients most likely to show improvement in general health were of sound psychological state at the time of surgery; the use of generic tools will improve the likelihood of identification of this pre-operative risk factor, which then leads onto benefits in pre-operative counselling for the patient with mental dysfunction and the collaboration with the mental health team [Heck et al 1998, Konig et al 1997]. Konig et al [1997] suggested that psychological factors should be included in a knee specific instrument due to this potential and yet unexplored influence [Smith et al 1992].

2.5.3.5 Summary of knee rating systems

Subjective patient based questionnaires have been intensively promoted in orthopaedic research and audit. In several comparative studies of patient based questionnaires for TKA, the most widely used was the American Knee Society Score (KSS), and the most recommended, due to their responsiveness, reliability and validity, was the Oxford Knee Score (OKS) and the WOMAC or the KOOS; recommended generic scores included the SF36 or SF12.

2.5.4 Relationships between knee rating scales

Since the advent of the outcomes movement, there has been little research in the way of correlations between the patient's perception of health to performance indicators, which were previously an important measure of outcome [Finch et al 1998, Rossi et al 2006, Silva et al 2003]. TKA has been found to effectively relieve pain, but improvement in physical function varies after the procedure independent of type of prostheses, surgical technique, and pain [Franklin et al 2008]. An estimated 15-30% of patients report minimal functional improvement twelve months after TKA, whereas another 10% report functional gains up to three times aged matched controls [Ayers et al 2005, Jones et al 2005]. Ayers et al [2005] but could not find a cause for this variation in function in 165 patients with unilateral TKA. Jones et al [2005] could not identify a clear patient-related or peri-operative factor that would predict improvement in function. The perception of an individual's functional levels coupled with objective measures of function may provide valuable insight into rehabilitation strategies and outcomes, providing a foundation for evidence based practice [Nagi 1991, Rossi et al 2006]. Patients within two years post operatively after TKA report difficulty in completing more challenging activities such as stair climbing, heavy domestic duties or demanding tasks such as squatting [Jones et al 2003, Rissanen et al 1996, Weiss et al 2002]. Establishing relationships between self-report and objective measures has high priority among researchers in rehabilitation and may aid clinicians in developing more appropriate interventions [Rossi et al 2006].

Recent cross sectional studies have shown that prominent self report measures of physical function correlate more highly with pain than with objective performance

tests in patients with knee OA [Maly et al 2006, Terwee et al 2006]. Only a moderate correlation exists between self report and performance measures [Cress et al 1995, Finch et al 1998], Maly et al 2006, Terwee et al 2006].

Maly et al [2006] reported a stronger correlation between WOMAC physical function and WOMAC pain score than between WOMAC physical function and a 6 minute walk test. Terwee et al [2006] had similar findings in his OA knee population, showing a stronger correlation between WOMAC pain and physical functioning scores than between WOMAC physical functioning scores and 23 performance knee tests, including walking, stair climbing, sitting, rising, lifting, carrying etc. Stratford et al [2009] attempted to devise a method that allows the assessment of a measure's ability to assess change in the lower limb function independent of pain in TKA patients. He concluded that validation studies of outcome measures must rigorously challenge the measures abilities to assess what they profess to measure. 'Given performance measures may be considered a criterion standard against which self report measures can be compared' [Stratford et al 2009]. Researchers [Kennedy et al 2002, Rossi et al 2006, Stratford et al 2009] suggest that a comprehensive assessment should include both types of measures.

Medalla et al [2009] investigated the OKS as a tool to indicate whether patients after TKA needed clinical review. They estimated that for the 63 065 TKAs in 2006 performed in the United Kingdom, formal reviews of these patients would cost 4.22 million pounds at each time point, and that most patients would present with well functioning knees and require no intervention [Medalla et al 2009]. They found that the OKS correlated well with the Knee Score of the KSS at two years post operatively, and postulated that all TKA patients should complete the OKS at two

years, and those scoring less than 24 should not attend the outpatients department. Only with further research correlating objective and subjective outcome measures for TKA should this method be implemented.

2.5.5 Objective outcome measures

Several authors [Ghandi et al 2009, Kennedy et al 2005, Silva et al 2003 Stevens-Lapsley et al 2011, Stratford et al 2010] advocate using objective measures to assess outcome and document change over time, as improving knee function is a premier issue in TKA patients. Recently, researchers [Mizner et al 2011, Stevens-Lapsley et al 2011, Stratford et al 2010] have demonstrated that dependence on patient based questionnaires alone in the peri-operative period after TKA will result in an overestimation of their function. They recommend both patient self report and objective outcome measures when assessing patients after TKA, as they provide different and complementary information. Ghandi et al [2009] emphasizes the importance of using both assessment tools, as self report assess a long term perception of a patient's abilities post operatively, whereas performance based measures only capture 'a snap shot'.

Although pain cannot be measured directly, investigators [Murray et al 1983, Rossi et al 2004] identify functional outcomes are an indirect measure of pain. Murray et al [1983] showed pain improvement paralleled improvement in functional outcome in the early post operative phase of TKA. Mizner et al [2011] suggested patients post TKA have difficulty discriminating pain from their ability to perform functional tasks.

TKA patients have self reported difficulty participating in heavy domestic duties and difficult tasks such as stair climbing [Hidling et al 1997, Weiss et al 2002]. Weiss et al [2002] developed a questionnaire to investigate important activities limiting patients at least one year after TKA. Forty percent of patients considered squatting to be important, and 75% reported some limitation during squatting. It appears that more demanding tasks, such as those that involve many muscle groups and joints to complete motion, are perceived as difficult after TKA [Jones et al 2003, Rossi & Hasson 2004 Weiss et al 2002], and the TKA population has decreased function in these tasks when compared to a control population [Noble et al 2005].

Walsh et al [1998] reported that half of TKA patients are slower in ascending and descending stairs when compared with age and gender matched subjects. Jesevar et al [1993] evaluated lower limb kinematics during stair negotiation 12-19 months after TKA, and showed it was a more demanding task when compared with healthy controls. Ouellet & Moffet [2002] demonstrated that TKA patients were 58% slower in completing a timed walking test (the Timed Up and Go (TUG)) when compared with age matched controls.

There are many and varied objective methods of assessing outcome following TKA. These include range of motion and knee stability [Aglietti et al 1984, Gore et al 1986, Insall et al 1989, Murray et al 1983, Nestor et al 2010, Rossi et al 2011]. radiological imaging [Aglietti et al 1984, Bach et al 2009, Gore et al 1986, Lotke et al 1977, Nestor et al 2010, Steiner et al 1989], muscle strength testing [Berman et al 1991, Collopy et al 1977, Huang et al 1996, Mizner et al 2011, Murray et al 1993, Rossi et al 2011, Schroer et al 2010, Silva et al 2003, Stevens-Lapsley et al 2010], knee laxity [Matsuda et al 1999, White et al 1991], gait analysis [Berman et al 1991,

Collopy et al 1977, Gore et al 1986, Jolles et al 2012, Steiner et al 1989], gait velocity [Bourne RB 2008, Jolles et al 2012, Kennedy et al 2005, Kreibich et al 1996, Mizner et al 2011, Rossi et al 2006, Stratford et al 2009], and other functional testing such as stair climbing [Bourne RB 2008, Kennedy et al 2005, Kreibich et al 1996, Mizner et al 2011, Stratford et al 2009]. Like subjective outcome measures, validation, reliability and responsiveness of objective outcome measures are often overlooked [Harding et al 1988, Kennedy et al 2005, Mathias et al 1986]. The multitudes of varied assessments make comparison in research difficult [Bach et al 2001, Fuchs et al 2001, König et al 1997]. Researchers [Matsuda & Ishii 2004, Mizner et al 2011, Rossi et al 2006] suggested patient report measures of activity have poor concurrent validity with performance base measures, but what specific functional tasks most manifest this lack of correlation are not known [Mizner et al 2011]. It is important to evaluate quadriceps strength as knee extensor function after unilateral TKA is related to load-bearing during functional tasks [Rossi et al 2011].

2.5.5.1 Muscle strength of quadriceps and hamstrings muscles

The quadriceps and hamstrings muscles control active movement of the knee joint [McMinn RMH 1998]. Knee strength is an important factor in the clinical outcome after TKA, but little data exist on the relationship between knee strength after TKA to patient characteristics outcomes measures [Silva et al 2003]. Arthritis of the knee can cause muscle atrophy and muscle strength imbalance [Hsieh et al 1987, Rossi et al 2011]. Patients with TKA often show muscle weakness before or early in the postoperative period [Berman et al 1991, Hsieh et al 1987, Nestor et al 2010, Rossi et al 2011, Stevens-Lapsely et al 2010]. Postulated reasons for this weakness include the result of muscle atrophy caused by disuse before the TKA that cannot be

recovered post-operatively [Schroer et al 2011, Silva et al 2003], volitional muscle activation [Saleh et al 2010], surgical technique, [Stevens-Lapsley et al 2010], implant design [Green & Schurman 2008, Huang et al 1996] and post-operative rehabilitation [Greene & Schurman 2008]. Muscle strength testing in the post operative period allows the surgeon to prescribe adequate rehabilitation such as quadriceps or hamstrings muscle strengthening [Berman et al 1991]. A dynamometer can measure muscle strength and provide objective measures of knee function. This instrument is commonly used to assess knee strength in athletic training and rehabilitation of knee injuries [Silva et al 2003].

2.5.5.1.1 Measuring muscle strength

To understand muscle strength and exercise, simple biomechanical principles and definitions will be discussed below. Force is defined by the production of motion in a body. Torque is a rotatory force [Einhorn et al 2007]. Resistance is force acting in opposition to a contracting muscle. It will cause tension to develop in the muscle [Hislop et al 1967]. The physical agent or act of applying resistance is called the load. The force and torque a muscle can generate at the joint is a product of the tension that the contracting muscle can develop [Hislop et al 1967].

Strength may be defined as the ability of muscle to exert force [Berman et al 1991] and can be measured isotonically, isometrically, or isokinetically [Kramer et al 1990, Lord et al 1992]. Isotonic exercise involves muscular contractions against a mechanical system providing a constant load [Kramer et al 1990, Lord et al 1992]. Although the load is constant, the resistance has its greatest mechanical advantage on the muscle at extremes of the range. Therefore the lever is most efficient at mid range. Isometric exercise denotes muscular contraction against a load which is

basically immovable [Kramer et al 1990, Lord et al 1992]. Maximum loading can be developed but only in one position with no physical work being performed [Lord et al 1992].

Isokinetic exercise results from control of speed [Bemben et al 1993, Hislop et al 1967, Moffrold et al 1969]. An external device is used to hold the speed of body movements to constant rates irrespective of the magnitude of forces generated by the participating muscles [Moffrold et al 1969]. In conventional exercise, energy is only partially absorbed and the remainder is dissipated with accelerations in the exercise motion. In isokinetic exercise, energy cannot be dissipated by acceleration because this is mechanically prevented by the device [Lord et al 1992]. Therefore energy is always proportional to the magnitude of muscular force [Kramer et al 1990]. In an isokinetic system, increasing the force of muscular contraction does not change the angular velocity of contraction, but is translated into increased torque [Kramer et al 1992].

2.5.5.1.2 Reliability of the isokinetic devices

The reliability of isokinetic devices have been measured in several studies [Bemben at al 1993, Harding et al 1988, Montgomery et al 1989]. The stability of torque during repeated isokinetic testing has been found to be in agreement with previous studies that used isolated concentric knee extensions [Harding et al 1988, Montgomery et al 1989]. It has been demonstrated that increasing the number of repetitions of continuous flexion/extension cycles of the knee and decreasing the velocity in healthy subjects increases the reliability [Harding et al 1988, Montgomery et al 1989, Bemben at al 1993].

Using the Biodex B-2000 Isokinetic dynamometer, researchers have demonstrated that although reliability decreases as angular velocity increases, the study data produced at rates up to four hundred and fifty degrees per second (450°/s) were still acceptable [Bemben et al 1993, Wilk et al 1988]. The angle of peak torque is speed specific but not sport or leg dominant specific [Bemben et al 1993]. The Biodex 2000 has proven to be simple and reproducible [Berman et al 1991].

2.5.5.1.3 Muscle strength in TKA patients

Since the development of TKA, quadriceps weakness is a feature of the operated leg up to two years post operatively [Berman et al 1999, Collopy et al 1977, Jevesar et al 1993, Lorentzen et al 1999, Rossi et al 2004, Steiner et al 1989, Walsh et al 1998], and recovery of muscle strength and function to normal levels is rare [Stevens-Lapsley 2010]. The loss of quadriceps strength after TKA is a result of preexisting quadriceps weakness [Berman et al 1991, Fisher 1993, Hsieh et al 1987], surgical trauma during TKA [Stevens-Lapsley et al 2010] and age related limitations in recovery of muscle function [Greene and Schurman 2008, Stevens-Lapsley et al 2010]. Early in the evolution of TKA, Collopy et al [1977] used isometric testing on the first twenty TKAs at their hospital to show that there was profound weakness of the quadriceps which tended to improve up to twelve months post operatively, the length of their follow up. Gore et al [1986] used isometric strength to show that extensor strength was significantly better two years post operatively when compared with pre operatively, whereas flexor (hamstring) muscle strength remained the same as the non-operated side, similar to Steiner's et al findings [Steiner et al 1989]. In patients with unilateral TKA, it is reported improvements in muscle strength continued up to one year post operatively, but never reached their pre operative level

(61 to 80% of the non operated side) [Anchuela et al 2001, Berman et al 1991, Lorentzen et al 1999, Rossi et al 2004, Walsh et al 1998, Stevens-Lapsley et al 2010]. Bemben et al [1991] demonstrated that peak torque levels for hamstring muscle strength reached the level of the non operated leg within twelve months, whereas levels for the quadriceps continued to increase even up to two years.

Researchers [Fuchs et al 2000, Huang et al 1996, Lord et al 1992, Silva et al 2003, Stevens-Lapsley et al 2010] comparing muscle strength in subjects post TKA with aged matched controls agree that extensor muscle strength is significantly decreased (50 to 63 percent) when compared with age matched controls up to ten years post operatively.

2.5.5.2 Timed up and go (TUG)

Walking ability is a crucial component of lower extremity function [Kennedy et al 2002]. The importance of walking speed in older adults is well recognized because of its implications to independent living [Bohannon et al 1996]. Timed walk tests and assessment of demanding tasks indicate that individuals take longer to complete these tasks years after TKA when compared with individuals of a similar age [Ouellet et al 2002, Walsh et al 1998]. Walking velocity has been used to assess patients after TKA in a non standardised fashion [Gore et al 1986, Kettlekamp et al 1975]. Surprisingly, few studies have used timed tests such as the timed up and go (TUG) to assess overall functional mobility after TKA [Gore et al 1986, Kennedy et al 2002, Ouellet et al 2002, Rossi et al 2006]. Investigating mobility after TKA may provide clinicians with important information that could assist in the development of future interventions [Rossi et al 2006]. A criticism of these timed walking tests is

that walking velocity is affected by other factors than TKA, such as patient comorbidities affecting mobility [Gore et al 1986].

The timed up and go measures (in seconds) the time taken by an individual to stand up from a standard arm chair, walk a distance of three metres (3m), turn and walk back to chair and sit down again [Podsiadlo et al 1991]. The original authors [Mathias et al 1986] devised the test but rather than timing the patients, they classified risk of falling on a scale of one to five. Podsiadlo et al [1991] revised the test so it was timed and then validated the new TUG and assessed it for reliability. They concluded that the TUG is a simple, practical, reliable performance test of physical mobility, which is in agreement with other authors [Kennedy et al 2005, Rossi et al 2006]. Responsiveness of the TUG has also been proven in the TKA population [Ghandi et al 2009, Mizner et al 2011, Kennedy et al 2005, Stevens-Lapsley et al 2011].

The TUG was originally developed to easily evaluate the risk of falls using balance and basic functional mobility [Kennedy et al 2005], as it has been shown to correlate with such measures [Podsiadlo et al 1991]. The scope of its usefulness has been widened to include patients post total hip and total knee arthroplasty [Mathias et al 1986]. Studies indicate that cut off scores between ten to thirteen seconds as indicating the demarcation point at higher risk of falling [Shumway-Cook et al 2000, Trueblood et al 2001]. Results of the TUG combined with measures of perceived abilities will provide a greater understanding of overall disability [Rossi et al 2006, Stevens-Lapsley et al 2011, Stratford et al 2009].

Researchers [Berman et al 1991, Collopy et al 1977, Ghandi et al 2009, Mizner et al 2011, Murray et al 1983, Steiner et al 1989, Stevens-Lapsley et al 2011, Stratford et al 2009] have used velocity as a measure of outcome after TKA, but these results are

difficult to compare due to a lack of standardisation. Rossi et al [2006] compared eleven patients post TKA with aged matched controls using TUG and a validated knee specific questionnaire (WOMAC). The TKA group (10-26 months post operation) were 28% slower when compared with gender and age matched controls, and correlated with the WOMAC with the physical function domains. The authors concluded that TUG provides quantifiable objective information that documents mobility post TKA [Rossi et al 2006].

Kennedy et al [2005] tested the responsiveness of the TUG in the THA and TKA population, and compared it with other functional walking tests: self paced walking test (SPWT) which involves walking forty metres (40m) as fast as possible; stair climbing test (ST) where the patient ascends and descends nine steps, and the six minute walk test (6MWT) which involves the patient covering as much ground as possible in six minutes. They found the TUG was less reliable than the other three tests (ICC 0.75 for TUG compared with 0.9 to 0.94 when compared with the 6MWT, ST and SPWT), but some patients were unable to complete the ST or 6MWT in their first post operative session (with 15 days post operation). They found all four measures to be responsive when assessing TKA patients from pre- to post-surgery and in the period of a median of 38 days post operatively.

2.5.5.3 Knee laxity

Static stability of the knee and normal motion of the joint both depend on complex interactions between the surrounding ligaments [Gollehon et al 1987]. In section 2.1, the important role of the ACL and PCL for knee stability was already highlighted.

It is not clear how much sagittal laxity is acceptable after TKA [Jones et al 2006]. The amount of AP laxity required for good ROM and function continues to be debated [Seon et al 2010]. Moderate laxity may give increased ROM and improved functional results compared with a knee that is too tight [Kuster et al 2004, Warren et al 1994]. Too much laxity, however, may lead to instability, poor function, pain and early failure [Dejour et al 1999, Jones et al 2006, Waslewski et al 1998]. Antero-posterior displacement of the knee is therefore considered one of the most important indices for assessing surgical outcome after TKA [Schuster et al 2011]. Researchers [Jones et al 2006, Matsuda & Ishii et al 2004, Schuster et al 2011, Seon et al 2010] report factors that may influence the sagittal laxity after TKA are: the decision to retain or substitute the PCL, the functional status of the PCL if retained, the geometry of the prosthesis, the bone cuts including the posterior tibial slope

The KT1000 knee arthrometer (MEDmetric, San Diego, California) has been used in many knee laxity studies, and is a simple and portable instrument [Daniel et al 1985, Forster et al 1989, Malcolm et al 1985, Sherman et al 1987]. The arthrometer measures the relative motion between a patella pad and tibial tuberosity pad (fig 2.11).



Figure 2.13. KT 2000 (Used manually without computer software acts as KT 1000)

The reliability of the KT1000 knee arthrometer (MEDmetric, San Diego, California) has been tested on native knees in vivo and in vitro [Daniel et al 1985]. Several investigators [Forster et al 1989, Sernet et al 2007, Torzilli et al 1991] have questioned the reliability of the KT arthrometer. It has demonstrated a high subject variation between tests [Torzilli et al 1991] and can be affected by examiner factors [Sernert et al 2007]. Investigators have shown poor inter-tester reliability but high intra-tester reliability [Fiebert et al.1994, Forster et al 1989, Myrer et al. 1996]. Experienced clinicians have been shown to achieve more reproducible results [Berry et al 1999, Forster et al 1989, Jonsson et al 1982]. Important considerations to improve reproducibility include neutral rotation of the knee [Fiebert et al. 1994], direct placement over the joint line and direction of the displacement forces anteriorly [Kowalk et al. 1993].

Investigators [Matsuda et al 1999, White et al 1991, Rajgopal et al 2011] have assessed stability of the knee after TKA in vivo using a KT arthrometer. White et al [1991] assessed knee laxity in 70 knee arthroplasties using KT1000, including 19 unicompartmental and 43 total Oxford prostheses and eight posterior stabilised TKAs. Anterior displacement was measured using KT1000, with a single blinded investigator. They found significant differences in laxity between the ACL retained and ACL absent knees for all Oxford TKAs, but the observed differences were not statistically significant for the subset unicompartmental knee replacements, posterior stabilised knees and the control group. However, within the group with increased laxity, there was a wide variation which lead the authors to suggest the secondary constraints control sagittal plane laxity in the absence of the ACL. TKAs with greater laxity had greater incidence of late failure (six months to ten years), and suggested that this was probably due to eccentric loading or increased muscle force to control unstable knees. An unconstrained knee prosthesis depends on the integrity of the soft tissues for stability, and the ACL is an important constraint upon the anterior subluxation of the tibia [Matsuda et al 1999, White et al 1991]. Matsuda et al [1999] assessed 19 PCL retaining TKAs in 14 patients. They defined TKAs that had a smaller laxity in 75° of flexion as PCL functioning knees and TKAs that had a larger

laxity in 75° of flexion as PCL non functioning knees, based on the results of a cadaveric knee kinematics study [Matsuda et al 1997]. At final follow up, the KSS score of the PCL functioning TKAs was significantly higher than that of the PC non functioning knees. Rajgopal et al [2011] assessed the posterior laxity of 52 PCL retaining TKA's in situ after 11 years. They demonstrated that a posterior laxity of 5-10mm had no adverse effect on the functioning of the knee. An MRI of the knees confirmed an intact PCL in 45 knees.

2.5.5.4 Summary of objective outcome measures

Improving knee function is one of the premier issues in TKA patients, and may be an indirect measure of pain. Patients after TKA have difficulty in participating in more demanding tasks when compared to a normal control population. There are many objective methods of assessing outcome after TKA, including clinical parameters, muscle strength, gait velocity tests such as the TUG, and knee laxity.

2.6 RELATIONSHIPS BETWEEN SUBJECTIVE AND OBJECTIVE OUTCOME MEASURES

2.6.1 Subjective measures and muscle strength

Gore et al [1989] assessed 34 males with 39 TKAs, and compared tests of functional performance pre-operatively, and at six, twelve and 24 months post operatively (including ROM, extensor lag, weight distribution between feet during one minute of standing, cane/crutch force during walking, and isokinetic strength of knee and extensor muscles) with the Hospital for Special Surgery (HSS) knee questionnaire and an xray rating scale. The post operative score of the HSS was found to correlate significantly with almost all objective measures of function as well as with subjective ratings of pain, but not with the xray score. Berman et al [1991] found there was no statistical correlation between HSS with isokinetic strength or gait after TKA.

Silva et al [2003] compared knee strength in TKA patients with a control group and correlated these to patient variables and clinical outcomes. Fifty two control knees in 31 patients and 32 TKAs in 19 patients were assessed with isometric muscle testing and the KSS. On average, women and obese subjects had lower peak torque values,

and the control group had (21.2%) less peak torque than TKA subjects. Only quadriceps strength and the KSS function score correlated.

Mizner et al [2011] assessed 100 patients 2 weeks preoperatively and 1month and 12 months post operatively after unilateral TKA. They demonstrated a statistically significant correlation between isometric quadriceps strength and the Knee Outcome Survey-Activities of Daily Living Scale (KOS-ADL).

2.6.2 Subjective measures and knee laxity

Researchers have attempted to relate the laxity of a TKA to functional outcome or ROM [Dejour et al 1999, Warren et al 1994, Matsuda et al 1999, Matsuda & Ishii 2004, Rajgopal et al 2011]. Dejour et al [1999] compared PCL retaining prosthesis with PCL sacrificing prosthesis at 3-4 years using clinical examination and xray. They found a significant correlation between 10mm of anterior translation with worse KSS function scores. Matsuda & Ishii [2004] looked at the difference in AP laxity between fixed bearing and mobile bearing knees using the KT2000. They found an increase in AP laxity for mobile bearing knees, but this had no correlation with HSS scores.

2.6.3 Subjective measures and TUG

Kreibich et al [1996] compared responsiveness of six methods of assessment three and six months post TKA in 68 patients. The methods of assessment were KSS, WOMAC, SF36, a 6 minute walk test (6MWT), a 30 second stair climb and a time trade off test, which is a visual aid comparing different QOL factors. All of the outcome measures were responsive, the most responsive being the WOMAC and KSS, and the least being the time trade off test [Kreibich et al 1996]. Rossi et al [2006] selected eleven TKA patients with no pain on walking or using aids up to two years post operatively, and compared them with an age and sex matched control group using the WOMAC and the TUG. The TUG was significantly correlated (p<0.5) with the aggregate WOMAC score and physical function subscale but not with the subscales of symptoms (including pain and stiffness). The authors concluded that the TUG provides quantifiable information on overall mobility and when results of this test are combined with measures of perceived abilities, a greater understanding of overall disability will be achieved.

Parent & Moffet [2002] compared the 6 minute walk test (6MWT), gait speed, stair ascent time with the WOMAC difficulty subscale and SF-36 role-physical and physical functioning subscale scores at time intervals pre and post operatively. For all intervals, the WOMAC difficulty subscale was the most responsive questionnaire and the 6-minute gait test was the most responsive locomotor test. Stair ascent duration was the least responsive measure.

Mizner et al [2011] also assessed the responsiveness of both patient report and performance based outcome measures both pre and post operatively in unilateral TKA patients. They demonstrated that performance based measures (TUG, 6 minute walk test, stair climbing test) had greater responsiveness during the acute stages after surgery than the patient reported questionnaire (Knee Outcome Surgery-Activities of Daily Living scale (KOS-ADLS). All performance based measures underwent a considerable decline from 2 weeks pre operatively to 1 month; however the scores on the KOS-ADL failed to show worsening. Mizner et al [2011] concluded that patients tended to overestimate their outcome in functional ability. Other researchers agree with this result. Using SF36, WOMAC and TUG to assess

patients in the pre and early post operative period, researchers [Ghandi et al 2009, Stevens-Lapsley et al 2011, Stratford et al 2009] have confirmed that patients tend to overestimate their functional ability post operatively, due to improvement in pain. They demonstrated different trajectories in TUG and patient report in the early post operative period.

2.6.4 Summary of the relationship between outcome measures

Despite excellent advances in prostheses and surgical technique of TKA, function still remains less than aged matched populations, and a substantial variation occurs in improvement in self reported function after TKA which cannot be explained by pain. Reports of correlation between muscle strength, knee laxity and timed walking tests such as the timed up and go with knee rating scores post TKA remains scarce and conflicting. A comprehensive assessment should include both types of measures.

2.7 CONCLUSION

The knee joint is a complex synovial joint of the lower limb. Damage to its protective articular cartilage over time can lead to the development of osteoarthritis. Its complex anatomy and biomechanics are virtually impossible to replicate; therefore designing TKA has historically been a complex task.

TKA is one of the most successful procedures in orthopaedic surgery, and numerous implants are currently in use. The incidence of knee OA is increasing with our ageing population, as is the need for TKA. There has been a steady increase in the number of TKA performed in the last two decades. With this has grown a multitude

of assessment tools available to measure outcome after TKA. These include patient based generic and disease specific questionnaires, and functional outcomes.

Unfortunately, the growth of these outcome measures had lead to a lack of consensus or gold standard of which to use. Research regarding outcome after TKA now lacks uniformity or order, due to the lack of ability to analyse or compare results. Researchers agree that any outcome measure used should be comprehensively tested for validity, responsiveness and reliability.

Patient based questionnaires have proven to be an effective way of assessing outcome after TKA, and are promoted in orthopaedic research and audit. Functional outcomes have also been recommended, as function in TKA patients has found to be less than their aged matched counterparts.

Correlating subjective and objective outcome after TKA is one method of assessing patient needs after TKA. By utilising the most widely used and most recommended patient based questionnaires and correlating them with several functional tests, this research aims to validate outcome measures already in use, as well as highlighting specific rehabilitation needs after TKA that are important to the patient.

CHAPTER 3

MATERIALS AND METHODS

3.1 SUBJECTS

Subjects were recruited from the Department of Orthopaedics Outpatient Department at Rockhampton Base Hospital. This clinic caters for most of the public subjects in the wider Central Queensland catchment area requiring total joint arthroplasty.

Referrals to this clinic are largely through the General Practitioner of the subject. The average time from referral to be seen is six months and the average time on the waiting list for a joint replacement is six months.

Ethical clearance was obtained from both the Human Ethics Research Review Panel at Central Queensland University and Rockhampton Health District (Appendix I, II). Subjects who agreed to participate in the research and fulfilled the selection criteria were handed a Form of Disclosure (Appendix III) and signed an institutionally approved Informed Consent Form (Appendix IV). All testing was conducted according to the statement on Human Experimentation (National Health and Medical Research Council, 1992). All subjects were examined by one of two orthopaedic surgeons working in the department (EH and MR), who then placed the subject on the waiting list and would perform the surgery. During this waiting period, subjects were encouraged to remain active and aim for a health body mass index. No referral to physiotherapy was initiated due to the nature of the project; however, if a subject elected to be treated by a private physiotherapist in the pre-operative interval, the treating surgeon did not discourage it. Regular analgesics for pain control was encouraged and supervised by the General Practitioner.

Operating notes and medical files of all subjects were screened using the following inclusion and exclusion criteria:

3.1.1 Inclusion Criteria

- 1 Patients who were able to give independent consent
- 2 Patients who had a unilateral TKA for osteoarthritis of the knee at least 12 months prior at Rockhampton Base Hospital by a senior surgeon (EH or MR)
- 3 No history of surgery or trauma to the contra-lateral lower extremity in the past 12 months

3.1.2 Exclusion Criteria

- 1 Medical conditions that prevent subjects to adequately mobilise
 - **a** Acute and chronic cardiac conditions resulting in shortness of breath at rest and during minor exertion (<20 steps)
 - **b** Acute and chronic respiratory conditions
 - c Acute renal failure

- d Uncontrolled diabetes mellitus
- e Hypertension > 180 systolic and > 100 diastolic
- f Postural hypotension with increased risk of falling
- g Surgery to lower limb in the past year
- **h** Surgery to upper limb in the past year with limited ability to support/mobilise with aids
- i Previous CVA with residual deficits affecting mobility
- **j** Acute psychiatric conditions
- 2 Surgical conditions
 - a Previous knee replacement
 - **b** Total hip replacement
- 3 Other
 - a Subject refusal
 - **b** Surgeon's assessment subject is not able to participate

3.1.3 Surgical procedure

Subjects were scheduled by the hospital's elective surgery coordinator. On the day of surgery, subjects were taken into the operating room and anaesthetised using a spinal or a general anaesthetic. Intravenous prophylactic antibiotics were given, and then tourniquet was inflated to 300mmHg. A single midline incision was made from the distal femur to the tibial tuberosity. Using standard techniques, a midline parapatellar arthrotomy was made, and the patellar was everted laterally (Fig 3.1). The anterior cruciate ligament and medial and lateral menisci were excised. The posterior cruciate ligament was retained.

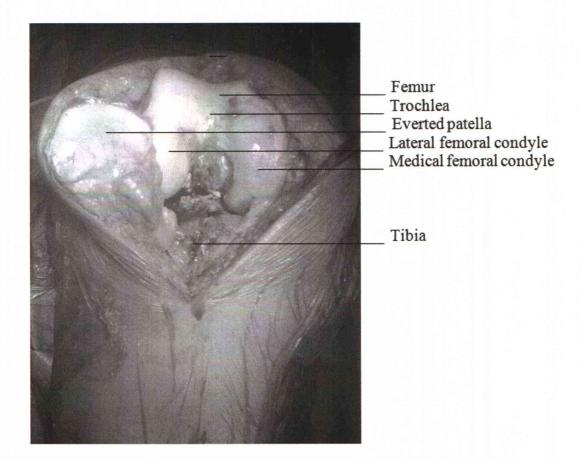


Figure 3.1. Exposure of knee joint during TKA

The femur was sized and cut either using computer assisted navigation or an instrumented guide. The tibia was then cut using computer assisted navigation or and instrumented guide. A cutting block was used to perform the tibial cut, and this was then rechecked. The soft tissue was balanced and an appropriately sized prosthesis was selected and trialed. The bone was washed and prepared, and the definitive prostheses were then cemented onto the bone.

All subjects had a Duracon [®] Cruciate Retaining Total Knee Replacement (Fig 3.2). Both the femoral and tibial components were cemented. Ten of the TKA's were performed using computer aided navigation (EH), which involves digitally mapping landmarks to assist in soft tissue balancing of the knee.



Figure 3.2. Duracon ® Total Knee Replacement

The arthrotomy was closed, and the wound was closed in layers. Routine compression dressings were placed prior to the tourniquet being deflated.

Post-operatively, the subjects had routine thromboembolic prophylaxis and intravenous antibiotics. Subjects had Xrays and commenced mobilization with physiotherapy. Dressings were debulked on day 2, and further flexion was allowed. Physiotherapy continued during the inpatient stay working on mobility, quadriceps strength and range of motion. Subjects were discharged when they were safe mobilizing alone and had a flexion rage of at least 90°. They had a 2 week would check and an outpatient department check with their surgeon (EH or MR) and an xray at 6 weeks, 3 months, 6 months, 12 months and then yearly after this.

3.1.4 Sample size

The number of subjects selected for analysis in the present study was based upon the method described by Bach & Sharpe [1989]. Sample size was calculated on the basis of achieving clinically significant changes in angle-specific isokinetic knee extensor strength through the ROM. Westing et al [1988] demonstrated that the method error and standard deviation for this measure is approximately 8% and 13 Nm, respectively.

A power calculation for sample size was performed based on Wilk's study [Wilk et al. 1994]. Selecting an alpha level of 0.05 and power of 80%, 23 complete datasets were needed to achieve adequate statistical power.

3.2 EXPERIMENTAL DESIGN AND PROCEDURE

Subjects attended the Human Movements Laboratory on an allocated day. All subjects were offered an introductory familiarization session on a day prior to their testing day. After initial introductions, details of subjects demographic details, weight and height, were collected. The subjects were assessed using a number of techniques described below.

3.2.1 Knee rating systems

Subjective responses of TKA subjects were derived using the Oxford Knee Score (OKS), the Knee Outcomes Osteoarthritis Score (KOOS), the Short Form 12 (SF12) and the Knee Society Clinical Rating System (KSS). The OKS and SF12 were sent as postal questionnaires. The KOOS and KSS were completed during the testing session. After completing the written questionnaires, all participants were

interviewed to assess any problems or inconsistencies encountered in responding to the questions within each of the scoring systems. After answering all questionnaires, subjects were then put through the objective testing.

3.2.1.1 The Oxford Knee Score (OKS)

The Oxford Knee Score (Appendix V) consists of twelve items, each with a score of one to five (from worst to best): pain; difficulty washing and drying self; difficulty getting in and out the car/public transport; walking duration; pain on standing; limp; ability to kneel; night pain; interference with work; giving way; ability to do shopping and ability to descend stairs. This was sent as a postal questionnaire.

3.2.1.2 Knee Outcomes Osteoarthritis Score (KOOS)

The Knee Osteoarthritis Outcomes Score (Appendix VI) is a knee specific subject based questionnaire, which assesses subjects' views on their knee and associated quality of life. It contains 42 items in 5 separately scored subscales: pain, other knee symptoms, function in daily living (ADL), function in Sport and Recreation (Sport/Rec), and knee related quality of life. Each of the 42 items has an option of a score of 1-5.

3.2.1.3 The Knee Society Score (KSS)

The Knee Society Clinical Rating System (Appendix VII) categorises subjects to identify those subjects whose function may be undermined by factors other than the knee in question:

- 1 No substantial disease in the contralateral knee
- 2 Substantial arthrosis
- 3 Multiple joint involvement or generalised disability [Liow 2000]

It assesses subjects by two scores: the Knee score and the Function score. The Knee score is comprised of pain (50 points), range of motion (25 points with a maximum of 125 degrees) and stability, measuring antero-posterior and mediolateral stability separately (25 points). Deductions are made for flexion contracture, extension lag, and alignment. The Function score is comprised of walking distance (50 points), and stair climbing (50 points) with deductions for using a walking aid.

The clinical examination was performed by one investigator (CC) who was experienced in orthopaedic examination:

- 1 Range of motion (ROM): ROM was measured using a goniometer on the lateral aspect of knee from full passive extension to full passive flexion. The centre of the goniometer was placed at the tibiofemoral articulation, with arm following the line of the femur and the other following the line of the tibia.
- 2 Antero-posterior displacement: The investigator massaged the subject's hamstrings to help in relaxation, and then sat on the foot with the subject's permission with the knee flexed at 90°. The investigator then drew the tibia anteriorly on the femur and estimated this displacement in millimetres (mm). Similar posterior displacement of the tibia on the femur was measured using the same methodology.
- 3 Mediolateral displacement: The subjects' lower limb was held under the investigator's axilla and supported with one hand while the other hand applied valgus and varus stress to the knee at 30 degrees of knee flexion. The displacement is measured in mm and added to correlate to a score.

- 4 Flexion contracture: The subject was asked to straighten both knees flat on the bed, and passive extension or the lack thereof was measured on the operated leg with the goniometer.
- 5 Extension lag: If full extension was not achieved actively, the investigator gently passively extended the affected knee. The difference between active and passive extension was measured in degrees and correlated to a score.
- 6 Alignment: The angle between a line between the anterior superior iliac spine and the centre of the patella and a line between the centre of the patella and the centre of the ankle will be measured in degrees and correlated to a score.

3.2.1.4 Short-Form 12 (SF12)

The short form 12 (SF12) (Appendix VIII) was created from the SF36. It consists of twelve SF-36 items and improved scoring algorithms. It is then calculated into the Physical Component Score (PCS) and Mental Component Score (MSC) as described by Ware et al [1995]. This was sent as a postal questionnaire.

3.2.2 Relationship between outcome scores

Relationships between all rating scores were correlated using statistical analysis as described below (Section 3.4 Statistical Analysis).

3.2.3 Objective testing

Testing was performed at the University's gait laboratory in a specific order with each subject to reproduce equal conditions for each subject and time interval in order to reduce measurement bias. Objective testing was performed in accordance with the flow chart on page 92.

3.2.3.1 Muscle torque

Muscle strength was assessed using a BiodexTM Isokinetic Dynamometer (System 3 BIODEXTM, Shirley, New York). Isokinetic eccentric strength was tested at 120 deg/sec. Both the involved and non-involved leg were tested to calculate symmetry indices. The non-involved leg was tested first. Each session began with a practice test of 3 trials. Changing the BiodexTM attachments to the contralateral extremity resulted in a short break within strength testing. The subjects performed 3 trials at 120 deg/sec with a 30 second rest period between each.

Each subject was asked to sit on the testing bench of the BiodexTM Isokinetic Dynamometer. The backrest was declined 15 degrees from vertical. Subjects were secured to the testing chair with shoulder, hip and thigh velcro straps to prevent counter-movement. The chair was orientated in a direction which allows flexion or extension to be achieved (Figure 3.4). The rotational axis of the dynamometer was aligned with the rotational axis (transepicondylar axis) of the knee. This axis was determined by palpating the lateral and medial epicondyle of the measured knee with the knee in 90 degrees of flexion. Once the position was confirmed, the test leg was secured to the lever arm with velcro straps 5-10 cm proximal to the medial malleolus.

Following a five minute break, the isokinetic eccentric testing was then performed. The subject remained positioned and secured as described above. Peak muscle torque was assessed at 120 deg/sec. Subjects performed three sub maximal knee extension and flexion repetitions at the selected speed. These trials served both as

warm-up and familiarization exercises. Each subject then performed one set of three maximal extension and flexion repetitions. Verbal encouragement served to facilitate maximum performance. A 30 second rest interval between all sets was permitted to avoid fatigue. A rest interval between three to five minutes was permitted before testing commenced on the involved extremity.



Figure 3.3. BiodexTM muscle dynamometer in use

3.2.3.2 Knee Laxity

Subjects were tested according to the Reference, Maintenance and User's Guide for the Knee Ligament Arthrometer [Daniel 1993]. One investigator (CC) who was experienced in using the KT1000 arthrometer tested all subjects. Subjects were placed on the bed with one pillow, with the thigh and foot support placed as per protocol to position both lower limbs in the same degree of flexion and rotation, with the knee flexed to $20\pm5^{\circ}$ (Fig 3.3). The thigh strap was placed and tightened around both thighs. The non operated knee was tested first, and then the operated knee.

The KT1000 arthrometer was placed on the anterior aspect of the leg held on with 2 circumferential Velcro straps. An arrow at the level of the joint aided positioning; the calf was then gently oscillated to relax the muscles. The patella was stabilized by constant pressure directed posteriorly by the investigator on the patella sensor pad. The dial was zeroed by repeated anterior and posterior force on the force handle with the other hand until the displacement dial returned to the same position. An upward force was then applied through the handle. The audiotone signaled when a 15lb and 20lb force was applied; the displacement was read in mm from the dial indicator. This was repeated with a force directed posteriorly with a 20lb force. Readings were only accepted if the indicator needle returned to zero when tension in the handle was released. This was repeated a total of three times and the score was averaged.

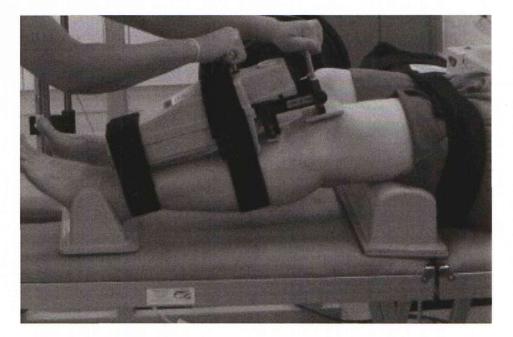


Figure 3.4. KT1000 dynamometer in use

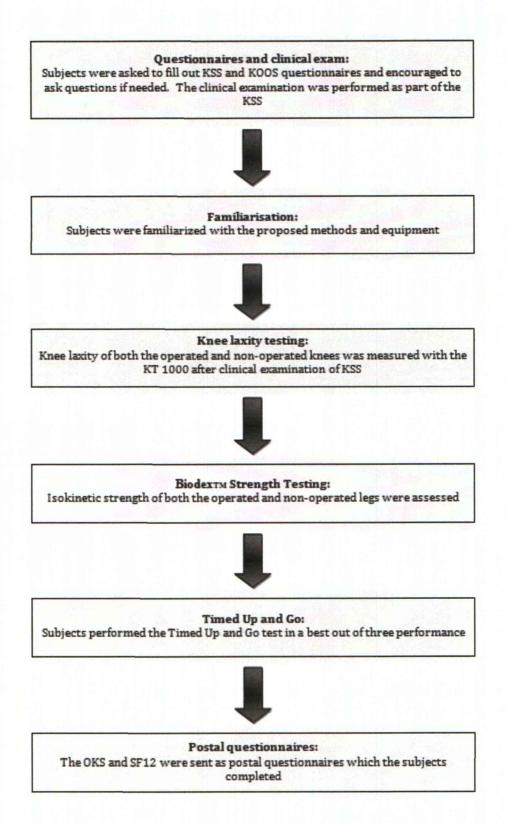
3.2.3.3 Timed Up and Go (TUG)

Reliable measures of functional outcome are essential when documenting the outcome of surgical intervention and rehabilitation [Brosky et al. 1999]. The timed up and go test has been previously used in elderly subjects post surgically as an objective assessment of knee function [Gore et al 1986, Ouellet et al 2002, Walsh et al 1998]. Functional testing was conducted at the Central Queensland University Human Performance Laboratory on a cemented non-slip surface.

Subjects were rested for 5 minutes after the BiodexTM testing prior to performing the TUG. Subjects were asked to rise comfortably from a chair, walk as fast as they could at a comfortable pace without running for a distance of three meters then return to a sitting position in the chair. The investigator (CC) demonstrated this. Subjects were allowed to use walking devices normally used for mobilizing. Subjects completed this task 3 times with a rest period of 30 seconds between. During each trial they received verbal encouragements to facilitate maximum walking speed. This was repeated three times and the shortest time was used.

3.2.4 TESTING SESSION FLOW CHART

The flow chart below summaries the order of testing for the subjects.



3.3 DATA MEASURES

3.3.1 Subjects

Body mass (kg), height (cm), age and sex and time from surgery were recorded and included in the analysis.

3.3.2 Knee Rating Systems

Subjective responses pertaining to knee function of the operated knee after TKA were derived using the Oxford Knee Score, the Knee Osteoarthritis Outcomes Score, the Knee Society Clinical Rating System.

The Oxford Knee Score (OKS) as mentioned above has 12 items for which the best score was 12 (the best outcome gave a point of one) and the worst score was a maximum of 60 (the worst outcome gave a point of five).

The Knee Osteoarthritis Outcomes Score (KOOS) as mentioned above had five subscales with a different number of items in each. Each item had a maximum of 4 points and a minimum score of 0. These were then added and a score out of 100 was generated for each subscale, with 100 being the best outcome, and 0 being the worst outcome, as per the original authors (Roos et al 2003). The subscales were not designed to be added together.

The Knee Society Clinical Rating Scale (KSS) was designed as two different scores. The Knee Score is made up of pain, range of motion and stability, with a maximum of 125 points. The Function score is comprised of walking distance, stair climbing and walking aids, with a maximum of 100 points. The SF12 is divided into Physical Component Score (PCS) and Mental Component Score (MCS) with a maximum score of 100 points each.

3.3.3 Objective testing

For isokinetic muscle strength, the peak torque (Nm/kg) generated by the muscles of the non-involved and involved limbs were calculated from the three best trials for each leg.

For knee laxity using the KT1000 arthrometer, the three measurements obtained from the non-operated and then the operated knees (in mm) was averaged. This number was then used for correlation.

The best of the three trials (in seconds) for the TUG was used.

3.4 STATISTICAL ANALYSIS

Descriptive statistics including the mean and standard deviation (SD) were calculated to summarise the data. Correlational analyses were then performed to examine the relationships among the knee rating scales, among the objective measures, and between the knee rating scales and objective measures. All scores and measures were correlated using Pearson product moment correlation coefficient. The lower 1-sided 95% confidence interval was calculated for each correlation coefficient. A level of significance of p < 0.05 was selected in all analyses to limit the chance of Type I error to 5%. In accordance with O'Keefe [2003] alpha level correction using Bonferroni or other such adjustments was not conducted so as to maintain statistical power. It is recognised that, whilst all the variables were carefully chosen, they are numerous and hence there is an increased risk of Type I

error. However, the cost of incurring a Type 1 error was deemed minimal and therefore appropriate given the exploratory nature of the study.

All analyses were conducted using SPSS (Version 12.0.1; Chicago, IL) for Windows.

3.5 DATA SECURITY

In accordance with the Data Security Policy at Central Queensland University, the following steps were applied to ensure data security.

- 1 Once each testing session was completed, all data were backed up to a secure network server. Access to the network is password protected.
- 2 All data was backed up to the principle investigator's personal computer hard drive. Access to this computer is password protected.
- 3 All questionnaire responses placed in a filing cabinet, which was locked with a key.

CHAPTER 4

RESULTS

The present project aimed to compare knee rating outcome scores, knee laxity, muscular strength and TUG. A large quantity of data was collected. Only significant and relevant results in relation to the purposes of this project are reported.

4.1 **DEMOGRAPHICS**

Twenty four subjects with a mean age of 68.0 ± 6.88 (range 54-80) years were included in the study. There were 13 males with a mean age of 65.5 ± 5.08 (range 54-80) and 11 females with a mean age of 68.72 ± 8.26 (range 62-77) years. The mean body mass index (BMI) of the subjects (weight (kg) /(height (m))²) was 31.5 ± 5.88 (range 19.8-42.1).

The average time from surgery was 27.5 ± 11.7 (12-58) months. Senior orthopaedic consultants (EH or MR) operated on all subjects. All patients had a cemented Duracon Total Knee Replacement ten of which were navigated (all EH).

Due to missing data, two subjects did not have results for the SF12. Two subjects were unable to complete the OKS. Subjects were not contactable to complete the questionnaires. One subject was unable to complete the Biodex muscle testing due

to being unwell. Therefore only 22 subjects completed the SF12 and OKS and Biodex muscle testing

4.2 KNEE RATING SYSTEMS

This section outlines the mean results of the Oxford Knee Score, the five subscales of the Knee Injury and Osteoarthritis Outcomes Score, the two subscales of the Knee Society Clinical Rating Score and the Short Form 12 including standard deviations and confidence intervals. The results are shown as mean total scores. Table 4.1 summarises the results for all outcome scores.

Knee Rating Score	Score	Standard Deviation	Confidence Interval
OKS	23.1	10.9	4.6
KOOS symptoms	80.2	17.3	6.9
KOOS pain	79.7	19.8	7.9
KOOS ADL	78.8	19.9	7.94
KOOS sports	39.6	33.8	13.5
KOOS QOL	63.2	30.9	12.4
KSS Knee	75.1	19.41	7.69
KSS Function	65.38	17.69	7.08
SF12 PCS	37.89	10.46	4.37
SF12 MCS	51.24	10.72	4.47

Table 4.1.	Knee Rating Systems Scores
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4.2.1 The Oxford Knee Score (OKS)

The mean total score for the OKS was 23.1 ± 19 (range 13 to 53).

4.2.2 The Knee Injury and Osteoarthritis Outcomes Score (KOOS)

The mean total score for the Symptoms Subscale was 80.2 ± 17.3 (range 35.7 to 100). The mean total score for the Pain Subscale was 79.7 ± 19.8 (range 27.8 to 100). The mean total score for the Activities of Daily Living subscale was 78.7 ± 19.9 (range 48.3 to 100). The mean total score for the Sports and Recreation subscale was 39.6 ± 33.8 (range 0-100). The mean total score for the Quality of Life subscale was 63.2 ± 30.9 (range 12.5 to 100).

4.2.3 The Knee Society Score (KSS)

The mean total score for the KSS Knee score was 75.1 ± 19.41 (range 33 to 100). The mean total score of the KSS Function scores was 65.38 ± 17.69 (45 to 100).

4.2.4 The Short Form 12 (SF12)

The mean PCS score for the SF12 was 37.89 ± 10.46 (range 22.6 to 57.2). The mean MCS score for the SF12 was 51.2 ± 10.7 (range 27 to 63.1).

4.3 RELATIONSHIP BETWEEN OUTCOME SCORES

This section outlines the relationships between scores used in this research:

Oxford Knee Score (OKS), Knee Injury and Osteoarthritis Outcome Score (KOOS), the American Knee Society Score (KSS) and the Short Form 12 Physical Component Score (PCS) and Mental Component Score (MCS). Table 4.2 summarises the results of the relationships between outcome scores.

Table 4.2. Relationships between outcome scores

Knee Scores	Pearson Correlation	p-levels	Critical R value
OKS-KOOS symptoms	654**	.001	.423(r20)
OKS-KOOS pain	707**	.000	.423(r20)
OKS-KOOS ADL	783**	.000	.423(r20)
OKS-KOOS sports	558**	.005	.423(r20)
OKS-KOOS QOL	786**	.000	.423(r20)
OKS-KSS Knee	740**	.000	.423(r20)
OKS-KSS Function	366	.078	.423(r20)
OKS-PCS	528*	.008	.433(r19)
OKS-MCS	455*	.025	.433(r19)
KSS Knee-KOOS symptoms	.774**	.000	.404(r22)
KSS Knee-KOOS pain	.737**	.000	.404(r22)
KSS Knee-KOOS ADL	.672**	.000	.404(r22)
KSS Knee-KOOS sports	.521*	.009	.404(r22)
KSS Knee-KOOS QOL	.715**	.000	.404(r22)
KSS Knee-KSS Function	.550**	.005	.404(r22)
KSS Knee-PCS	.496*	.014	.413 (r21)
KSS Knee-MCS	.286	.209	.413 (r21)
KSS Function-KOOS symptoms	.448*	.028	.404(r22)
KSS Function-KOOS pain	.460*	.024	.404(r22)
KSS Function-KOOS ADL	.560**	.004	.404(r22)
KSS Function-KOOS sports	.449*	.028	.404(r22)
KSS Function-KOOS QOL	.474*	.019	.404(r22)
KSS Function-PCS	.692**	.000	.413 (r21)
KSS Function-MCS	.431*	.036	.413 (r21)
PCS-KOOS symptoms	.362	.082	.413 (r21)
PCS-KOOS pain	.362	0.82	.413 (r21)
PCS-KOOS ADL	.501*	.013	.413 (r21)
PCS-KOOS sports	.665**	.000	.413 (r21)
PCS-KOOS QOL	.485*	.016	.413 (r21)
PCS-MCS	.410*	.047	.413 (r21)
MCS-KOOS symptoms	.162	.450	.413 (r21)
MCS-KOOS pain	.334	.110	.413 (r21)
MCS-KOOS ADL	.598**	.002	.413 (r21)
MCS-KOOS sports	.456*	.025	.413 (r21)
MCS-KOOS QOL	.483*	.017	.413 (r21)

4.3.1 Oxford Knee Score (OKS) relationships

Strong and significant correlations (r=0.528-0.786, p=0.0001-0.005) between OKS and the other scoring systems (all five items of the KOOS, KSS function SF12 PCS) were observed. There were no correlations between the OKS and the KSS function score, and only a moderate correlation between the OKS and PCS (r=.528, p=.008) and MCS (r=.455, p=0.025).

4.3.2 Knee Society Score (KSS) relationships

Strong and highly significant correlations (r=0521-0.774, p=0.0001-0.005) between the KSS knee scores and other scoring systems (the OKS, four items of the KOOS, the KSS function scores). No correlation was observed between the KSS Knee and MCS, and only a moderate correlation between the KSS knee and PCS (r=.496, p=.014) and the KSS knee and KOOS sports (r=0.521, p=0.009).

Strong and highly significant correlations between the KSS function and KOOS ADL (r=0.56, p=0.004) and PCS (r=0.692, p=0.000) and OKS and KSS knee were observed. Only moderate correlations between the KSS function and the other four items of the KOOS and the MCS were observed (r=0.431-0.474, p=0.019-0.-36).

4.3.3 Knee Injury and Osteoarthritis Outcomes Score (KOOS) relationships

Strong and highly significant relationships were observed between all five items of the KOOS and the OKS (r=-0.558 to -0.786, p=0.000-0.005).

Strong and highly significant correlations were observed between four items of the KOOS and the KSS Function score (r=0.448-0.474, p=0.019-0.028). Strong and

highly significant correlations between the KSS function and KOOS ADL (r=.560, p=0.004). Only a moderate correlation was observed between the KSS knee and KOOS sports score (r=0.521, p=0.009) and no correlations were observed between the KSS Knee and other four KOOS sub scores.

Strong and highly significant correlations between the PCS and the KOOS sports (r=0.665, p=0.000) were observed. Moderate correlations were observed between the PCS and KOOS ADL and KOOS QOL scores (r=0.485-0.501, p=0.013-0.016). There were no observed correlations between PCS and KOOS symptoms and KOOS pain scores. There was a strong and highly significant correlation between the MCS and KOOS ADL score (r=0.598, p=0.002). There were moderate correlations between the MCS and KOOS goal scores (r=0.456-0.483, p=0.17-0.025). There were no observed correlations between the MCS and KOOS symptoms.

4.3.4 Short Form 12 (SF12) relationships

Strong and highly significant correlations between the PCS and the KSS function and KOOS sports (r=0.665, p=0.000) were observed. There were no observed correlations between PCS and KOOS symptoms and KOOS pain, and moderate correlations (r=0.410-0.528, p=0.008-0.047) between PCS and the OKS, KSS knee, KOOS ADL and KOOS QOL, and MCS.

There was a strong and highly significant correlation between the MCS and KOOS ADL (r=0.598, p=0.002). There were moderate correlations between the MCS and OKS, KSS function, KOOS sports and KOOS QOL (r=0.431-0.483, p=0.17-0.036).

There were no observed correlations between the MCS and KSS knee, KOOS pain and KOOS symptoms.

4.4 OBJECTIVE OUTCOME MEASURES

This section outlines the mean results of the isokinetic muscle strength for the operated and non-operated lower limbs, knee laxity for the operated and non-operated limbs, and the Timed Up and Go. The results are divided into mean total scores, and differences between the limbs. Table 4.3 summarises the results for all objective measures.

Objective measure	Score	Standard Deviation	Confidence Interval
Muscle torque (O) (Nm/kg)	113.01	9.04	3.69
Muscle torque (NO) (Nm/kg)	113.69	8.37	3.42
Muscle torque symmetry index	1.00	0.15	0.06
Knee laxity (O) (mm)	3.83	2.03	1.5
Knee laxity (NO) (mm)	4.13	2.15	1.65
Knee laxity difference (mm)	1.96	1.27	0.51
TUG (s)	7.89	2.66	1.06

Table 4.3. Objective measures

4.4.1 Muscle torque

Isokinetic peak torque (Nm/kg) was measured at 120 deg/sec. The mean peak torque for the operated leg was 113.01Nm/kg \pm 9.04 (range 102.88-123.82), and for the non-operated leg was 113.69Nm/kg \pm 8.37 (range 102.38-123.43). The symmetry index was 1 \pm 0.15. There was no significant (p=0.08) difference between the values for the operated and non-operated legs.

4.4.2 Knee laxity

The mean total laxity (mm) for the operated knee was 3.83 ± 2.03 (range 1.07-8.00) and the mean total laxity for the non-operated knee was 4.12 ± 2.15 (range 1.4-10.83). There was no significant difference between the values of the operated and non-operated knees (p=0.08).

4.4.3 Time Up and Go (TUG)

The mean TUG times (seconds) was 7.89 ± 2.66 (range 5.3 to 17.4).

4.4.4 Relationship between objective outcome measures

This section outlines the relationships between objective outcome measures. No significant correlations were observed between knee laxity of the operated and non-operated knees, or knee laxity and the TUG. Table 4.4 shows the relationships between objective outcome measures.

Table 4.4.	Relationship between objective outcome measures
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Objective tests	Pearson Correlation	p-levels	Critical R value
Muscle torque (O)-muscle torque (NO)	-0.281	0.097	0.413(r21)
Muscle torque (O)-knee laxity (O)	-0.275	0.102	0.413(r21)
Muscle torque (O)-TUG	-0.178	0.209	0.413(r21)
Knee laxity (O)-Knee laxity (NO)	0.364	0.080	0.404(r22)
Knee laxity (O)-TUG	0.263	0.215	0.404(r22)

4.5 RELATIONSHIP BETWEEN SUBJECTIVE AND OBJECTIVE OUTCOME MEASURES

This section describes the relationships between subjective and objective outcome measures.

4.5.1 Muscle torque relationships

Table 4.5 summarizes the relationship between muscle torque and outcome scores.

Table 4.5.	Relationship between muscle torque and outcome scores
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Knee Scores	Pearson Correlation	p-levels	Critical R value
OKS-muscle torque (O)	-0.333	0.065	.423(r20)
KSS Knee- muscle torque (O)	0.196	0.185	.404(r22)
KSS Function-muscle torque (O)	-0.041	0.426	.404(r22)
KOOS symptoms-muscle torque (O)	0.044	0.422	.404(r22)
KOOS pain-muscle torque (O)	0.029	0.447	.404(r22)
KOOS ADL-muscle torque (O)	0.182	0.203	.404(r22)
KOOS sports-muscle torque (O)	-0.040	0.427	.404(r22)
KOOS QOL-muscle torque (O)	0.003	0.494	.404(r22)
PCS-muscle torque (O)	0.115	0.310	.413 (r21)
MCS- muscle torque (O)	0.416	0.030	.413 (r21)

There were no observed correlations between muscle torque of the operated knee and outcome scores. Only 22 subjects were able to complete the Biodex testing, which means these values were underpowered.

4.5.2 Knee laxity relationships

Table 4.6 summarizes the relationship between knee laxity of the operated knee and outcome scores.

Table 4.6.	Relationship between knee laxity	and outcome scores
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Knee Scores	Pearson Correlation	p-levels	Critical R value
OKS-knee laxity (O)	.236	.267	.423(r20)
KSS Knee- knee laxity (O)	203	.340	.404(r22)
KSS Function-knee laxity (O)	083	.699	.404(r22)
KOOS symptoms-knee laxity (O)	354	.090	.404(r22)
KOOS pain-knee laxity (O)	344	.100	.404(r22)
KOOS ADL-knee laxity (O)	393	.058	.404(r22)
KOOS sports-knee laxity (O)	178	.404	.404(r22)
KOOS QOL-knee laxity (O)	307	.144	.404(r22)
PCS-knee laxity (O)	.029	.892	.413 (r21)
MCS-knee laxity (O)	495*	.014	.413 (r21)

No observed correlations were found between knee laxity of the operated knee and knee rating scores. Only 22 subjects completed the OKS and SF12, which means these scores were underpowered.

4.5.3 TUG relationships

Table 4.7 summarizes the relationship between TUG and outcome scores.

 Table 4.7.
 Relationship between TUG and outcome scores

Knee Scores	Pearson Correlation	p-levels	Critical R value
OKS-TUG	.651**	.001	.404(r22)
KSS Knee-TUG	770**	.000	.404(r22)
KSS Function-TUG	513*	.010	.404(r22)
KOOS symptoms-TUG	680**	.000	.404(r22)
KOOS pain-TUG	679**	.000	.404(r22)
KOOS ADL-TUG	723**	.000	.404(r22)
KOOS sports-TUG	557**	.004	.404(r22)
KOOS QOL-TUG	686**	.000	.404(r22)
PCS-TUG	392	.058	.413 (r21)
MCS-TUG	424*	.039	.413 (r21)

Strong and highly significant correlations (r=-.557 to -.770, p=0.0001-0.005) were observed between TUG and the knee rating scores (OKS, KSS knee and 4 items of the KOOS). Moderate correlations were observed between TUG and KSS function (r=-.513, p=0.10) and MCS (r=-.424, p=0.39).

CHAPTER 5

DISCUSSION

The purpose of this study was to investigate relationships between commonly used knee rating scales and objective outcome measures in patients after TKA. Patients from the shared practice of two orthopaedic surgeons were recruited and tested a minimum of one year post TKA. The contralateral knee was used as a control. To minimize bias, other patient comorbidities that would affect the lower limb or comprehension of rating scales were excluded.

5.1 **DEMOGRAPHICS**

TKA is an operation usually reserved for the older population, as osteoarthritis progresses with age [Einhorn et al 2007, Solomon et al 2009]. The mean age of the subjects in this research was 68 ± 6.88 (range 54-80) years. There were 13 males with a mean age of 65.5 ± 5.08 (range 54-80) and 11 females with a mean age of 68.72 ± 8.26 (range 62-77) years. In a large prospective study involving 1141 patients over two years, Scott et al [2010] used the OKS and SF12 to assess patient satisfaction before and after TKA. Their mean age was 70.1 years, and 45% of the population was men. Franklin et al [2008] collected demographic data from the US National Joint Registry from 2000 to 2005. Of the 8050 patients with TKA in their analysis, 66% were female and the average age was 69 ± 10 years. Medalla et al [2009] asked 190 patients to complete OKS and KSS questionnaires after TKA. Forty one percent of their population was men, and the average age was 71.6 years. Bourne et al [2010] assessed 1703 patients one year after primary TKA with the WOMAC questionnaire, and the enrolled cohort had a mean age of 69 ± 9 years with 60% being female.

Gender ratio and age distribution were therefore comparable to other recent studies assessing objective measures after TKA [Bourne et al 2010, Franklin et al 2008, Medalla et al 2009, Rossi et al 2006, Scott et al 2010].

The mean BMI of subjects in the present research was 31.5 ± 5.88 (range 19.8-42.1). Franklin et al [2008] collected data for 8050 patients from the US joint registry over 5 years. The average BMI in their population was 32 ± 7.1 . Bourne et al [2010] prospectively reviewed satisfaction in 1703 patients undergoing TKA from the Ontario Joint Replacement Registry. The average BMI was 32 ± 6 . Mizner et al [2011] assessed 100 patients pre and post TKA with patient outcome scores and functional tests. The mean BMI was 30.8 ± 4 . The BMI in the current population group was also comparable to other research [Bourne et al 2010, Franklin et al 2008, Kennedy et al 2002, Mizner et al 2011, Saleh et al 2005]. According to guidelines from the National Institute of Health [2009] this is classed as obese. The population group investigated in the current research confirms that obesity is a risk factor for developing osteoarthritis of the knee [Foulsham et al 1981, Solomon et al 2001].

In the current research, ten of the TKA's were navigated. Computer navigation uses digital mapping of standard anatomical landmarks so that kinematic analysis can optimise soft tissue tensioning during TKA [Chauhan et al 2004, Novicoff et al

2010, Pang et al 2011]. Researchers [Chauhan et al 2004, Meikle et al 2001, Novicoff et al 2010, Saragaglia et al 2001] have reported improved alignment when using this technology for TKA. Chauhan et al [2004] randomized 70 patients to either conventional or computer assisted TKA. They reported a statistically significant improvement in the alignment of TKA's using navigation on CT. A meta analysis by Novicoff et al [2010] reported improvement in alignment of TKA when using computer assisted surgery. Hoffart et al [2012] alternately allocated 195 patients to either conventional surgery or navigation for TKA and reported better functional outcome in the navigation group using the KSS (p=0.008). However, Xie et al [2012] performed a meta analysis of 21 randomised controlled trials and failed to demonstrate improved function post-operatively in the navigation population. It is unclear if improved alignment will lead to better long term results [Novicoff et al 2010, Xie et al 2012]. Therefore, as navigation leads to improved alignment only and not clinical outcome in the short term, [Xie et al 2012], it is unlikely any difference between the two groups would have influenced the results of the current research.

The subjects in our research were at least 12 months post surgery (mean 27.5 \pm 11.7). During the development of the early TKA prostheses, Murray et al [1983] observed most improvement after surgery occurred 12 months up post- operatively in 21 patients. Mizner et al [2011] states that patient outcomes do not stabilize until at least six months post-operatively. They demonstrated considerable improvement in both patient reported and performance-based outcomes from one month pre-operatively to 12 months post-operatively. Schroer et al [2010] demonstrated statistically significant increases in quadriceps strength after TKA up to one year

post-operatively. Researchers [Khanna et al 2011, Mizner et al 2011, Murray et al 1983, Schroer et al 2010, Walsh et al 1998] have tested subjective and objective outcomes after TKA after a minimum of 12 months. The testing interval employed by the present research is therefore well supported by the published literature [Murray et al 1983, Mizner et al 2011] and allows comparison with previous investigations.

Considering the above, the present research was comparable to other research using functional tests after unilateral TKA [Bourne et al 2010, Franklin et al 2008, Kennedy et al 2002, Medalla et al 2009, Rossi et al 2006, Saleh et al 2005, Scott et al 2010].

5.2 KNEE RATING SYSTEMS

5.2.1 The Oxford Knee Score (OKS)

The mean OKS score in the current research was 23.1 ± 19 (range 13 to 53), where 12 was the best outcome possible and 60 was the worst.

Other researchers [Baker et al 2007, Dawson et al 1998, Pysent et al 2005, Medalla et al 2009, Whitehouse et al 2005] have reported similar scores post TKA. Baker et al [2007] reported a mean OKS score of 25.0 in 8231 patients from the National Joint Registry of Wales and England, up to 2 years after unilateral TKA. The authors suggested this could be a national benchmark. Whitehouse et al [2005] performed a postal audit to 856 patients up to 5 years after unilateral TKA. Their response rate was 89.1% with a completed questionnaire rate of 81.1%. Their mean OKS score was 26.5. Medalla et al [2009] investigated whether patient self assessment was a viable alternative to clinical review after TKA. Using the OKS in

195 patients at two years post- operatively, they demonstrated a mean OKS score of 25.77. Fifty percent of patients had a score lower than 24 at two years post-operatively, which dropped to 30% at 10 years. Impellizzeri et al [2011] asked 100 patients undergoing TKA to complete 4 questionnaires pre and 6 months post-operatively. Their mean OKS score at 6 months was 26.1.

The current result of a mean score of 23.1 is comparable to previous results. The lower mean score in the present research when compared with researchers [Baker et al 2007, Impellizzeri et al 2011, Medalla et al 2009, Whitehouse et al 2005, ,] may reflect variables such as a different population group (rural Queensland Australia). In addition to this, the current research reflects a population a mean of 12 months post TKA (mean 27.5 \pm 11.7). As discussed in chapter 5.1, other researchers [Mizner et al 2011, Murray et al 1982, Schroer et al 2010] have observed peak patient function and patient perceived satisfaction at 12 months post-operatively. This may be reflected in the current mean OKS score. Only 21 subjects had a compete set of results for muscle torque, due to 3 patients being unable to complete one of either the Biodex, SF12 and OKS. However the inability to test muscle strength in these three patients would not have influenced the OKS scores at all but could potentially result in reduced power when using the OKS for correlation analysis.

5.2.2 The Knee Osteoarthritis Outcomes Score (KOOS)

The KOOS scores in the present research were as follows: The mean total score for the Symptoms Subscale was 80.2 ± 17.3 (range 35.7 to 100). The mean total score for the Pain Subscale was 79.7 ± 19.8 (range 27.8 to 100). The mean total score for

the Activities of Daily Living subscale was 78.7 ± 19.9 (range 48.3 to 100). The mean total score for the Sports and Recreation subscale was 39.6 ± 33.8 (range 0-100). The mean total score for the Quality of Life subscale was 63.2 ± 30.9 (range 12.5 to 100).

Bullens et al [2001] followed up 108 patients and compared the KSS with the WOMAC. The KOOS contains the full version of the WOMAC, with 2 added subsections (Sports and Quality of Life) [Roos et al 1999]. They reported lower Pain, Symptoms and ADL scores with the WOMAC (mean values: pain 78.4, symptoms 68.4, ADL 62.9), but their time to follow up was much longer (a mean of 4.9 years). Bourne et al [2010] prospectively collected data from 1703 primary TKA patients one year post-operatively using the WOMAC. They demonstrated similar values for Pain, Symptoms and ADLs to the current research (mean values: Pain 86 \pm 16.3, Symptoms 79.4 \pm 19.7, ADL 80.9 \pm 17.7). Nilsdotter et al [2009] investigated KOOS scores of 125 consecutive patients after primary TKA in their institution. At 12 months post-operatively, mean scores for the KOOS similar to the current research: (mean values: pain 82, symptoms 80, ADL 82, sports of 42 and OOL 70). Stevens-Lapsley et al [2011] assessed patients six months after unilateral TKA with KOOS. They demonstrated results similar to the current research (mean values: pain 81, symptoms 72, ADL 88, sports 51 and QOL 67). The lower value for the Symptoms category in these results may reflect the shorter follow up time. However, the Sports value was higher than the current research (51 versus 39.6 for the current research), which may reflect their stricter exclusion criteria (healthier subjects were involved in their research). The current population reflects a TKA population with a mean age of 68 ± 6.88 (range 54-80) years; the Sports subsection

may not be relevant for such an elderly age group. However, inclusion of the Sports subsection increases the responsiveness of the KOOS.

The KOOS scores in the current research are similar to previous KOOS and WOMAC scores [Bourne et al 2010, Lingard et al 2001, Nilsdotter 2009, Roos & Toksvig Larsen 2003, Stevens-Lapsley et al 2011] and therefore confirms that the population and outcome as demonstrated by the current project is comparable to these above mentioned studies.

5.2.3 The Knee Society Score (KSS)

In the current research, the mean total score for the KSS Knee score was 75.1 \pm 19.41 (range 33 to 100), and the mean total score of the KSS Function scores was 65.38 \pm 17.69 (45 to 100).

Previous investigators [Bach et al 2002, Bach et al 2009, Bullens et al 2001, Jones et al 2006, Konig et al 1997, Lingard et al 2001, Medalla et al 2009, Warren et al 1994] have demonstrated a wide variation in the KSS Knee and Function scores after TKA. In a large, multi-centre trial, Lingard et al [2001] reviewed 697 patients 12 months post-operatively after unilateral TKA. The mean KSS Knee score was 87.4, and the mean KSS Function score was 62.6. The elevated value of the KSS Knee score when compared with other values in the literature may be due to a heterogeneous group of assessors. Meijerink et al [2011] used the KSS to assess patients randomized to either the CKS TKA or the PFC TKA. In their population of 77 patients, they demonstrated a lower KSS knee and Function score in the CKS TKA population (KSS knee score 80 and KSS Function score 55) when compared with the PFC TKA (KSS knee score 88 and KSS function score 65). Medalla et al

[2009] reported that the KSS acts as a dual rating score. They assessed 55 patients pre-operatively and at two, five and ten years; although the KSS Function score decreased from 71 at two years post-operatively to 56 at ten years, the KSS Knee score remained the same with a score of 81 at two years to 80 at ten years.

The scores for the KSS Function score in previous research ranged from 50 to 71 and the KSS knee score range from 56 to 88. This wide range possibly reflects the reported poor reliability of the KSS [Bach et al 2002, Khanna et al 2011, Liow et al 2003]. Bach et al [2002] compared the inter-observer reliability of the KSS Knee and Function scores with the Bristol Knee score and the HSS scores. They reported an inter-observer correlation coefficient (ICC) of 0.48 for the KSS knee score, which indicated a poor inter-observer reliability when compared with the Bristol knee score (ICC=0.84), the HSS (ICC = 0.82) and the KSS function score (ICC=0.78). This indicated demonstrated poor inherent reliability of the KSS.

Given these caveats, the results of the KSS need to be interpreted with caution. However, as the KSS is the most commonly knee score currently used for outcome analysis, it was included as an outcome measure to be able to compare the results of the current project to these of other researchers.

5.2.4 The Short Form 12 (SF12)

The current research demonstrated the mean PCS score for the SF12 was 37.89 ± 10.46 (range 22.6 to 57.2), and mean MCS score for the SF12 was 51.2 ± 10.7 (range 27 to 63.1).

PCS and MCS scores of the SF12 in the current research are similar to previous research in TKA patients [Franklin et al 2008, Jones et al 2006, Heck et al 1998,

Impellizzeri et al 2010, Marx et al 2005, Scott et al 2010, Williams et al 2012]. Williams et al [2012] reviewed the mental component of the SF12 in patients after TKA (including UKA and revision TKA) 12 months post- operatively. The mean SF12 MCS score was 53.1 ±10 (17-68). Unfortunately, outcome after primary TKA was not separated from outcome after revision surgery. Scott et al [2010] studied 1141 consecutive patients 12 months post TKA and observed SF12 scores similar to the current research in the satisfied cohort (PCS = 40.5 ± 10 , MCS = 53.2 ± 9.4), and lower scores in the dissatisfied cohort (PCS = 32.0 ± 7.1 , MCS= 44.4 ± 12.3). The current research reported results comparable with research demonstrating satisfaction. Only 22 patients completed the SF12, and therefore the results of the present research are potentially underpowered. The Short Form 12 (SF 12) measures both physical and mental health as a more general questionnaire [Ware et al 1996]. One of the major benefits of the additional use of a generic questionnaire is the patient's psychological status can be assessed pre and post operatively [Ghanem et al 2010, Heck et al 1998]. One of its main benefits of this generic tool is the identification of patients with pre-operative mental dysfunction. The score also provides information about improvement in mental health and social functioning scores following surgery. Given that the results of the current research are similar and comparable to previous studies [Franklin et al 2008, Jones et al 2006, Heck et al 1998, Impellizzeri et al 2010, Marx et al 2005, Scott et al 2010, Williams et al 2012] in addition to the overall satisfaction of the patients, it is unlikely that this potential lack in power is clinically relevant.

In summary, the results in the current research for the four rating scores are comparable to other research in the same time frame post-operatively. The KSS

Knee and Function score are within the reported range. However, the results should be viewed with caution, due to the inherent poor reliability of the score, reflected by the wide range of scores in previously published literature.

5.3 RELATIONSHIP BETWEEN OUTCOME SCORES

The relationship between the four knee rating systems has been previously assessed by a other researchers [Bullens et al 2001, Dawson et al 1998, Lingard et al 2001, Kantz et al 1999, Kreibich et al 1996, Impellizzeri et al 2010, Medalla et al 2009, Roos et al 2003].

5.3.1 Oxford Knee Score (OKS) relationships

In the current research, the OKS had strong and highly significant correlations with all 5 items of the KOOS and the KSS function score (r=0.528-0.786, p=0.0001-0.005).

Dawson et al [1998] validated the OKS at its creation, finding significant (p<0.01) and strong correlations with the KSS knee (r= -0.47) and function scores (r= -0.54) and SF36 scores (r=-0.19 to -0.78). Similar to the results of the present research, Dawson et al [1998] reported strong correlations with the physical questions but only moderate correlations with the mental questions. Medalla et al [2009] demonstrated the OKS correlated with the KSS knee (r=-0.52) and function score (r=-0.58) up to 10 years post-operatively. In the current study, the OKS had strong and highly significant correlations with the KSS knee score, but not the KSS function score. This may be due to a ceiling effect for both the OKS and the KSS function score as the satisfaction was very high in the population of the current

research. It may also be due to the reported decreased reliability and responsiveness of the KSS [Liow et al 2003, Khanna et al 2011]. The OKS has been shown to have greater responsiveness than the SF36 and KSS for TKA patients [Dawson et al 1998, Liow et al 2003]. Liow et al [2003] assessed 29 TKA patients pre and postoperatively, with the OKS, KSS and British Orthopaedic Association Scores (BOAS) and demonstrated the OKS had the greatest responsiveness and greatest reliability of the three scores. Due to its relative simplicity and smaller number of items when compared with the KOOS, and ability to be completed by post, unlike the KSS, the recommendations from the current research would give preference to the OKS to assess patient perceived outcome after TKA.

5.3.2 Knee Society Score (KSS) relationships

The current research demonstrated that the KSS knee score correlated strongly and significantly with the OKS, four items of the KOOS, the KSS function scores (r=0521-0.774, p=0.0001-0.005), and the KSS Function score correlated strongly with the KOOS ADL score (r=0.56, p=0.004) and the PCS of the SF12 (r=0.692, p=0.000). Although widely used, the KSS was not validated at its creation [Ghanem et al 2010, Insall et al 1989]. Several researchers have attempted to validate the KSS [Kreibich et al 1996, Lingard et al 2001, Liow et al 2003]. Lingard et al [2001] reported the KSS pain score to have significant (p<0.001) and moderate correlations with the WOMAC (KOOS) pain score (r=0.44), and the KSS function score (r=0.76) and WOMAC function score (r=0.58). The current research confirmed these findings.

The KSS is a responsive measure in the TKA population [Kreibich et al 1996, Lingard et al 2001] but has poor internal consistency [Lingard et al 2001, Liow et al 2003], and poor reliability [Liow et al 2003]. The KSS is currently undergoing an update including validation to better reflect patient outcome after TKA [Ghanem et al 2010].

5.3.3 Knee Osteoarthritis and Outcomes Score (KOOS) relationships

In the current research, all five items of the KOOS had strong and highly significant correlations with the OKS and the KSS function score (r=0.528-0.786, p=0.0001-0.005). The PCS of the SF12 correlated strongly with the ADL question (r=0.501, p=0.13) and sport (r=0.665, p=0.000) questions. Interestingly, the MCS correlated strongly with the ADL question (r=0.598, p=0.002), but not at all with pain and symptoms, indicating patients rank being independent important.

Roos et al [2003] established correlations between the KOOS and the SF36 items in the TKA population, and the correlations were higher between similar constructs: bodily pain versus pain (r=0.62), and physical function versus activities of daily living (r=0.48). The current research confirmed the findings of Roos et al [2003]. The items of the KOOS correlated higher with similar constructs of the other questionnaires. MCS of the SF12 in the current research did not demonstrate strong correlations with the physical subscales of the KOOS, indicating that they measure different aspects of outcome after TKA.

5.3.4 Short Form 12 (SF12) relationships

In the current research, there are strong correlations between the OKS and the PCS of the SF12. Strong and highly significant correlations between the PCS and the KSS function and KOOS sports (r=0.665, p=0.000) were also observed. Impellizzeri et al [2010] established significant (p<0.001) and strong correlations between the SF12 PCS (r=-0.05) and OKS but not the SF12 MCS (r=-0.17). This concurs with Lingard et al [2001] and Roos et al [2003], who demonstrated strong correlations between the SF36 Function score and the KSS Function score [Lingard et al 2001] and the KOOS pain and ADL subscores [Roos et al 2003]. These relationships have been discussed in the previous sections 5.3.1 to 5.3.3

There was a strong and highly significant correlation between the MCS and KOOS ADL (r=0.598, p=0.002). Similar to other researchers [Impellizzeri et al 2010, Lingard et al 2001, Roos et al 2003], the current research failed to demonstrate strong correlations between the MCS of the SF12 and the knee rating questionnaires.

Based on these findings, the first hypothesis that there will be a positive correlation between the OKS, KOOS, KSS knee and function scores and PCS portion of the SF12, but not the MCS portion of the SF12, is accepted. The rating scores in the current research, with the exception of the SF12 MCS, correlated strongly and significantly. Despite its previous lack of credible validation, the KSS knee and Function score correlated strongly with the validated scores (SF12, all 5 items of the KOOS and the OKS). It still remains subject to the assessor due to its poor reliability [Bach et al 2002, Liow et al 2000, Schal et al 1999] and the clinical examination aspect of the Knee Score can create financial and labour burdens

[Fitzgerald et al 1992, Kochan et al 1984, Konig et al 1997, Medalla et al 2009, Whitehouse et al 2005].

In contrast to the KSS, the OKS and the KOOS were both validated at conception. The OKS is a reliable, responsive instrument [Lingard et al 2001, Liow et al 2003, Katz et al 1992, Robertsson and Dunbar 2001, Roos & Toksvig-Larsen 2003], and is widely commended [Davies AP 2002, Dunbar et al 2001, Hasballa et al 2003, Garratt et al 2004]. It is well validated and researched and is now used as an outcome tool within several joint registries worldwide [Murray et al 2007]. Researchers have raised concerns with the number of items (Sun et al 1997, Ryser et al 1999]. The OKS has been shown to have a higher completion rate in postal audit when compared with the WOMAC [Dunbar et al 2001]. As the current research established that the OKS has strong correlations with the KOOS and KSS Knee and Function Score, the OKS is recommended, as it measures similar aspects of outcome but is more cost effective and easier to complete.

5.4 **OBJECTIVE OUTCOME MEASURES**

Muscle torque, knee laxity and the timed up and go (TUG) have previously been used to assess subjects after TKA in recent literature [Jones et al 2006, Matsuda and Ishii et al 2004, Nestor et al 2010, Rossi et al 2006, Rossi et al 2011, Schroer et al 2010, Schuster et al 2011, Stevens-Lapsley et al 2011, Matsuda & Ishii 2004].

5.4.1 Muscle torque

The results of the present research demonstrated the mean peak torque for the operated leg was 113.01 Nm/kg (102.88-123.99), and for the non-operated leg was

113.68 Nm/kg (102.38-123.43). There was no significant difference between the values for the operated and non-operated legs.

There is a wide variation in values for isokinetic muscle strength after TKA in the literature [Berman et al 1991, Collopy et al 1977, Fuchs et al 2000, Gore et al 1986, Huang et al 1996, Rossi et al 2011, Schroer et al 2010, Visser et al 2010, Walsh et al 1998]. These range from peak torques of 51.5 Nm/kg to 109 Nm/kg. Walsh et al [1998] assessed 29 patients 12 months after TKA with the LIDO dynamometer, at 120 deg/sec. Their mean peak torque in the TKA patients was 57.8 Nm for women, and 90 Nm for men. Quadriceps torque was less than the 'healthy' control group, with 80 Nm for women and 115.02 Nm for men. Fuchs et al [2000] assessed the peak isokinetic quadriceps torque in 19 TKA patients a mean of 24.6±16.7 (range 4-80) months post-operatively, and compared their results with 22 'healthy volunteers'. They used the Cybex 6000 dynamometer at 60°/sec and 180°/sec. Their mean maximum peak quadriceps torque at 60° was 87.43Nm for TKA men and 43.6 Nm for TKA women versus 148.36Nm for control men and 116.41 for control women, which was a statistically significant difference (p<0.05). Rossi et al [2011] compared peak isokinetic quadriceps torque after bilateral simultaneous TKA in eight patients. They used the Cybex dynamometer at 60°/sec and demonstrated a mean of 106.65Nm at 12 months post-operatively. Kim et al [2010] randomized 50 patients to either a standard approach or muscle sparing approach, which protects the extensor mechanism of the knee. At 12 months post-operatively, their mean peak isokinetic extensor torque for the standard group was 53.9 ± 12 Nm and 65.9 ± 16.3 Nm for the muscle sparing group, which reached statistical significance (p=0.037).

Our results were amongst the highest peak torques post TKA. As discussed above, this may be due to different angles and speeds of measurement, different dynamometers, different prostheses, different population groups and different periods of time post surgery. Investigators [Berman et al 1991, Murray et al 1982, Saleh et al 2010] have demonstrated that quadriceps strength post TKA continues to improve up to two years post-operatively. Our research was conducted at an average of 30.6 months after surgery. Patients that volunteer for research may be healthier than those that decline; this may also attribute to the high values of peak torque. Researchers have also demonstrated that men have higher peak quadriceps torque post TKA than women [Fuchs et al 2000, Walsh et al 2010]. The population in the current research included 13 men and 11 women which may have attributed to the higher torque values. In addition, our population was in rural Australia, which is not comparable to other research.

The current research failed to demonstrate a significant difference in peak torque between the operated and non-operated limbs, using the non-operated limb as a control. The second hypothesis that the operated limb will have a decreased peak torque when compared with the non-operated limb can not be accepted based on the current findings. Previously, researchers [Berman et al 1991, Lorentzen et al 1999] have demonstrated lower peak quadriceps torque when compared with the nonoperated side; unfortunately, only descriptive statistics were used and statistically significant findings were not included in the analysis. Improved surgical techniques, implant designs and more aggressive physiotherapy in the last 10 years may have increased muscle strength post TKA. More recently, Schroer et al [2010] observed that peak isokinetic quadriceps torque of the operated and non-operated knees was equivalent (p=0.81) at one year post TKA, using a muscle sparing approach. They attribute this result to their surgical approach; however Nestor et al [2010] demonstrated no improvement in quadriceps strength at 12 weeks after TKA when comparing a standard and muscle sparing approach in a randomized controlled trial. In contrast, Kim et al [2010] did find a significant (p=0.037) difference between muscle sparing and standard approaches at 12 months in their randomized controlled trial. It has therefore not been established whether quadriceps torque at one year post TKA is affected when compared with the contralateral side.

Isokinetic peak torque (Nm/kg) was measured at 120 deg/sec. In the current research, elderly subjects had difficulty with testing at lower speeds. One subject failed to achieve 3 trials at 120 deg/sec, and the results were not included in this project. Other researchers [Huang et al 1996, Walsh et al 1998] testing isokinetic muscle strength after TKA have also used this protocol. Isokinetic muscle strength after TKA have also used this protocol. Isokinetic muscle strength at 60 deg/sec has also been tested [Fuchs et al 2000, Nestor et al 2010, Rossi et al 2011, Schroer et al 2010]. This was not possible in the elderly population of the current research. Walsh et al [1998] demonstrated more work was needed with isokinetic strength testing at speeds lower than 120 deg/sec. Nestor et al [2010] discussed that in the TKA population, slower speeds increase joint compressive loads and are difficult for subjects to complete.

Jevsevar et al [1993] suggested it may not be appropriate to use the contralateral non-operated knee for comparison, as it may be affected by OA or reduced activity. Volunteers that act as controls are often healthier than the average population [Fuchs et al 2000, Walsh et al 1998]; therefore, volunteers may act as a better control group than the contralateral limb, as was used in the current research. It can be argued,

however, that OA affects up to 12% of the population, and even more of the older population [Felson et al 2000], and age matched volunteers may also have OA in the affected knee. Using the contralateral limb controls for other variables; walking ability which influences isokinetic strength and endurance, confidence, familiarity with the testing device, and enthusiasm.

5.4.2 Knee laxity

In the current research, mean total laxity with the knee at 20 ± 5 degrees of flexion using a 20 lb force both anteriorly and posteriorly was measured as 3.83 ± 2.03 mm for the operated knee and 4.12 ± 2.15 mm for the non-operated knee. There was no significant difference between the operated and non-operated knees. The research hypothesis that there will be no significant difference in knee laxity between the operated and non-operated limb is supported by the current results.

It is unclear how much sagittal laxity is acceptable after TKA [Jones et al 2006]. Jones et al [2006] assessed knee laxity in TKA patients a minimum of five years post-operatively, using a KT1000. They assessed the knees at 80° of flexion using a 20lb force, and then at 30° of flexion using a 30lb force anteriorly and a 20lb force posteriorly. At 30°, they established a combined laxity of 7.3mm of in the whole population. This laxity is greater than the results in the current research, which may be due to using higher forces, a longer time after surgery, and different prostheses. Matsuda and Ishii et al [2004] assessed 60 TKA's at 30° and 90° of flexion using a Telos arthrometer and 150N (33lb) of force. Again, they reported higher laxity (9.8mm for posterior cruciate ligament sacrificing TKAs) but this may reflect a different arthrometer and a higher force. Seon et al [2010] also used the Telos

arthrometer to assess 55 TKA patients; however they used a 9kg load with the knee flexed to 90° and the patient in the lateral decubitus position for stress lateral radiographs. Schuster et al [2011] used the Rolimeter arthrometer at 25° and 90° of flexion pre- operatively, intra-operatively (under spinal anaesthesiae) and at follow up. All patient groups had higher knee laxity pre and intra-operatively. Mean laxity at follow up was 4.6±2.1 mm at follow up at 25°. Although similar to the current research, it is difficult to compare the results. Other researchers have used different arthrometers, higher forces, different types of prostheses and different degrees of flexion.

The protocol described by Daniel et al [1985] was used in the present research. White et al [1991] used the same protocol but measured anterior laxity only and confirmed the current results and demonstrated no significant difference between the operated and non-operated knees.

Researchers [Daniel et al 1985, Malcolm et al 1985, Sherman et al 1987] have established the reliability and responsiveness of the KT1000 arthrometer. Other investigators have questioned its reliability, which can be affected by inexperience of the examiner [Berry et al 1999, Forster et al 1989, Jonsson et al 1982], incorrect rotation of the knee [Fiebert et al. 1994], or incorrect use of the instrument [Kowalk et al 1993]. Testing in the present research involved one investigator [CC], experienced in orthopaedic examination, testing each knee with three trials. The three trials for each value were averaged. The average variation for all trials in this research was 0.34mm. Jones et al [2005] suggested that total AP laxity should be used, which was used in the present research.

5.4.3 Timed Up and Go (TUG)

In the present study, the mean of the fastest TUG times was 7.89±2.66 seconds. All subjects in the current research were able to complete the TUG.

Kennedy et al [2005] tested the reliability of the TUG during the peri-operative period for THA and TKA patients. They tested then retested arthroplasty patients pre-operatively, and reported the TUG as reliable for group application. The TUG was compared with three other walking tests and was the least reliable of the four. Some subjects, however, were unable to complete two of the assessment measures (6MWT and SCT), whereas all subjects could complete the TUG. Mizner et al [2011] confirmed the TUG subject to a ceiling effect when compared with the 6MWT and SCT, due to its lower demand. However, both researchers [Kennedy et al 2005, Mizner et al 2011] agree that the TUG is responsive in the assessment of TKA patients.

Researchers [Freter et al 2000, Kennedy et al 2005, Ouellet & Moffet 2002, Parent & Moffet 2002, Rossi et al 2006] agree that the TUG has not been commonly used to assess overall function in TKA patients. Rossi et al [2006] assessed 11 patients 10 to 26 months after TKA, and compared their TUG time with age matched controls. The TKA population was slower when compared to age and sex related counterparts. The mean fastest TUG time in the TKA population was 7.3 seconds, which is comparable to the current research. Mizner et al [2011] used three functional tests, including the TUG, to longitudinally assess patients after TUG periopoeratively. The TUG was more responsive than patient based questionnaires (including the SF 36), and the mean fastest TUG at 12 months post-operatively was similar to the current research (7.9 seconds SD 1.8). Stevens-Lapsley et al [2011]

reported a mean fastest TUG time of 7.92 seconds (SD 0.41) in 59 subjects 6 months after unilateral TKA. Results of previous research using TUG at 12 months post TKA is comparable to the current results.

5.5 RELATIONSHIP BETWEEN KNEE RATING SCORES AND OBJECTIVE OUTCOME MEASURES

Relationships between objective measures and subjective assessment of symptoms and function after TKA have not been established yet [Silva et al 2003, Rossi et al 2006, Walsh et al 1998]. Rating scales such as the OKS, KSS and WOMAC are the main tools used to report outcome after TKA [Garratt et al 2004, Kreibich et al 1996]. It therefore remains to be investigated whether these rating scales provide information reflecting subjective and objective performance-based measures for patients after TKA [Fuchs et al 2000]. Establishing relationships between self report and objective measures has high priority among researchers in rehabilitation after TKA [Rossi et al 2006].

5.5.1 Muscle torque relationships

In the current research, there were no observed correlations between peak muscle torque and the knee rating scores. Early researchers [Aglieti et al 1984, Berman et al 1991, Gore et al 1986], used the Hospital for Special Surgery Score (HSS) and muscle strength to evaluate their early results. Gore et al [1986] demonstrated the post-operative HSS score correlated with muscle strength. The outcome of these early studies can not be compared to the current research because the HSS is an unvalidated knee rating score, and the prostheses used by Gore et al [1986] were first generation TKA's with a different design.

The relationship between muscle strength and subjective knee rating scores has been investigated more recently with varying results. Silva et al [2003] selected a population of 19 patients with 32 'clinically well functioning TKAs', at a minimum of 2 years after surgery (mean 2.8 years). Isometric peak quadriceps and hamstrings torque was tested using a LIDO dynamometer. Using this protocol Silva et al [2003] demonstrated a positive correlation (r=0.57, p=0.04, r2 = 0.349) between isometric peak quadriceps torque and the KSS function score.

Mizner et al [2011] also demonstrated a weak correlation between isometric quadriceps strength of the involved limb and a knee rating score KOS-ADL both pre-operatively (r=0.28. p<0.05, r2=0.195) and one year post- operatively (r=0.26, p<0.05, r2 = 0.195), but not at one month post-operatively. There was no correlation between the peak muscle torque and KOS-ADL at one month post operatively, as muscle strength weakened and the KOS ADL improved from pre-operatively.

Fuchs et al [2000] compared peak quadriceps torque in 22 TKA patients with the HSS score and the SF36 4-80 months post TKA. They demonstrated statistically significant but low correlation coefficients between isokinetic quadriceps peak torque and the HSS overall score (r=0.669), the SF 36 physical functioning score (r=0.619), the SF36 physical role limitations (r=0.576) and the SF 36 bodily pain score (r=0.641) where the critical r value was 0.456. Unfortunately, the HSS is not a validated score, they failed to describe their recruitment procedure and their population group was heterogeneous (4 months to 6.7 years post-operatively). They concluded that isokinetic testing is 'irreplaceable' in assessing muscle strength, as clinical and quality of life scores are incapable of predicting muscle strength in TKA. They advised testing both pre and post-operatively. In contrast, Visser et al

[2010] assessed quadriceps muscle strength in 45 TKA patients with a Microget hand-held dynamometer 6 months post-operatively, and reported no correlation with patient satisfaction (p=0.15). Unfortunately they did not describe their methodology further, and did not state the type of muscle strength tested.

In the current research, there were no observed correlations between peak muscle torque and the knee rating scores. Based on these findings, the study hypothesis that there will be a correlation between muscle torque and knee rating scores can not be supported. Although other researchers demonstrating a relationship between peak quadriceps torque and scores of patient based outcome measures, a closer inspection of methodology makes comparison with the current results difficult. Silva et al (2003) used only well functioning TKA's in their research, and did not state how their patient population was recruited. Additionally, the correlation was moderate (r=0.57, p=0.04, r2 = 0.349) and isometric peak torque was used. Mizner et al [2011] also evaluated peak isometric strength, which is not comparable to isokinetic muscle strength, which was used in the current research. Isometric exercise denotes muscular contraction against an immovable load [Lord et al 1992], whereas isokinetic exercise measures energy proportional to the magnitude of muscular force [Kramer et al 1990] controlled by the Biodex device. The results of these two different types of strength measurement are not comparable.

Another reason for the lack of correlation is that the only 21 subjects completed the Biodex, OKS and SF12. An a-priori power calculation was performed for this project and based on Wilk's data [Wilk et al. 1994]. To achieve sufficient power (80%), 23 complete datasets were needed and hence the results for the relationships between scores and strength may be underpowered. Wilk [1994] investigated the

relationship between a subjective knee score (pain, swelling, giving way), hopping tests and isokinetic strength. He noted a positive correlation between isokinetic knee extension peak torque and subjective knee scores and the three hopping tests (r=0.48-.49) but could not demonstrate any significant correlations for isokinetic test results for the knee flexors, isokinetic strength and subjective knee score. As a consequence the results of the present research may be underpowered. However a post-hoc comparison using the correlation coefficient between OKS and muscle torque from the present research revealed statistical power of 0.86.

5.5.2 Knee laxity relationships

In the current research, there were no observed correlations between knee laxity and the knee rating scores. A moderate correlation (r=-.495, p=0.039) between knee laxity of the operated knee and MCS was observed.

Jones et al [2006] predicted that moderate knee laxity post TKA may improve functional results due to better ROM, but too much laxity may lead to instability, poor function and early failure. Dejour et al [1999] could not identify a relationship between knee laxity after TKA and the WOMAC, KSS or SF12. Similarly, Warren et al [1994] could not find any association between AP laxity and patients satisfaction or pain relief using the KSS, although laxity below 5mm lead to a restricted passive ROM.

More recently, Seon et al [2010] used the Telos arthrometer and stress radiographs to correlate mean AP laxity with the HSS and WOMAC scores. They arbitrarily divided the groups into stable (AP translation <10mm) and unstable (AP translation >10mm). They reported no differences in either groups with regard to the HSS and

WOMAC total score, but the stable group had a better WOMAC function score (p=0.011).

Other researchers did not report a relationship between MCS of the SF12 and knee laxity. Therefore, the moderate correlation demonstrated in the current research seem anomalous, and perhaps due to chance. In addition, the current research failed to demonstrate a correlation between the KOOS/WOMAC function (ADL) score and mean total laxity (r=-0.197, p=0.355). This may be due to the fact that all subjects in the current research had a mean total laxity below 5mm, and therefore were classed as 'stable' according to Seon et al [2010]. There was no association between knee laxity and self reported function. Based on these observations, the hypothesis that there will be no correlation between knee laxity and patient satisfaction and function after TKA is supported. A further study would need to be designed with higher numbers to investigate an association between knee laxity, function, symptoms and early failure.

5.5.3 TUG relationships

Strong and highly significant correlations between the TUG and knee rating scores (OKS, KSS knee scores and 4 items of the KOOS) were observed (r=-0.720 to 0.557, p=0.0001 to 0.005). In addition, moderate correlations were observed between TUG and KSS function (r=-.513, p=0.10) and MCS (r=-.424, p=0.39). These correlations would suggest that walking ability and speed are important to the patient, and possibly representative of their pain and individual function levels.

Walking velocity has been shown to have a relationship with knee rating scores and patient satisfaction after TKA [Gore et al 1986, Rossi et al 2006]. This confirms the

results of the present research. Rossi et al [2006] reported statistically significant (p<0.05) correlations between the TUG and the aggregate WOMAC score (r=0.59, $r^{2}=0.553$) and the physical function score (r=0.63, $r^{2}=0.553$) at 10-26 months postoperatively. Other researchers (Ghandi et al 2009, Mizner et al 2011, Stevens-Lapsley et al 2011, Stratford et al 2009) have reported poor concurrent validity between patient reported and performance based measures in the pre and short term post-operative time period after TKA. Mizner et al [2011] compared walking tests (6MWT, SCT and TUG), and isometric muscle strength, with a knee specific auestionnaire and the SF36. Patient based questionnaires tended to overestimate the actual short-term and long-term changes in physical function. Stratford et al [2010] assessed 85 hip and knee arthroplasty patients pre and up to 13 weeks postoperatively, using patient based questionnaires (WOMAC and Lower Extremity Functional Scale (LEFS)) and walking tests (TUG, and 6MWT). They demonstrated that self report and physical function do not have the same trajectory in the early post-operative period, and concluded that 'dependence on self-report alone will result in an overestimation of the ability of patients to move around post arthroplasty'. Ghandi et al [2009] also demonstrated similar results using the TUG, WOMAC and SF-36 to assess 142 TKA and 58 THA patients peri-operatively. Stevens-Lapsley et al [2011] used the SF36, KOOS, isometric muscle strength and walking tests including the 6MWT, SCT and TUG to assess patients pre and up to 12 months post-operatively after TKA. They reported only the KOOS Sport and Recreation scale did not over report physical function post-operatively. They concluded that 'both sets of tools provide different and complementary information regarding outcomes after TKA; therefore neither should be used in isolation.' It is important to note that these researchers (Ghandi et al 2009, Mizner et al 2011,

Stevens-Lapsley et al 2011, Stratford et al 2010) assessed patients in longitudinal studies during the early peri-operative period. The current research assessed subjects at a point in time over 12 months post-operatively.

Therefore, the hypothesis that there will be a positive correlation between the TUG and the OKS, KOOS, KSS knee and function scores and SF12 PCS was partly supported by the current research. The TUG did not correlate with the SF12 PCS, and only moderately with the KSS Function score and KOOS sports score. The TUG is a walking test only, and is subject to ceiling effects; therefore, it may fail to reflect difficulties with heavier tasks, such as heavy lifting or stair climbing, as measured by the KOOS Sports and Recreation and KSS Function scores. Although such activities are not common in the older arthroplasty population, Williams et al [2012] demonstrated younger more active patients could return to sporting activities post-operatively.

5.5.4 Limitations

Many factors may play a role when analyzing the outcomes of knee rating systems. Bias can potentially be introduced by obtaining the score through an interview process. Researchers [Bullens et al 2001, Hoeher et al 1997, Khanna et al 2011, Morris et al 1993] reported higher scores if patients were interviewed and the investigator was involved in administering the questionnaire rather than selfadministered. They suggested that self-administered questionnaires should be used in order to avoid interview bias. In the current research, KSS was the only score that was achieved via interview rather than being self-administered. However, the researcher was available if the subjects had questions for the other rating scores, which may have introduced bias.

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A second factor is the lack of pre-operative data; this was not a longitudinal study. Scott et al [2010] demonstrated improvement in pain relief to be a strong predictor of satisfaction, and other researchers [Bourne et al 2010, Baker et al 2007, Fisher et al 2007] have demonstrated other pre-operative factors influencing outcome after TKA. Murray et al [2007] suggested that the change in scores should be analysed in addition to the post-operative score. Judge et al [2011], however, demonstrated that there was no predictive value of pre operative hip and knee questionnaires in relation to post-operative patient satisfaction. Robertsson et al [2001] stated that when the pre-operative status has not been recorded, patients could be assumed to take their pre-operative condition into account when answering and act as their own comparisons. All knee scoring systems produced scores comparable to previous longitudinal research reporting on satisfaction after TKA.

The third factor which influences the outcome of knee rating systems, is the interpretation of the different scoring systems described above. All four scoring systems seem to measure different aspects of subjective patient satisfaction and physical function, and some generate multiple scores, while others generate one score to encompass all aspects. This makes comparison difficult. For example, clinical parameters measured in the KSS are not measured at all in the other scores. The MCS of the SF12 is not considered in the other knee scores. The Sports and Recreation subscale of the KOOS is not represented in the other scores. It has been generally recommended in the literature [Bach et al 2007, Ethgen et al 2004, Franklin et al 2008, Ghanem et al 2010] that both generic and condition specific instruments should be used in research in order to evaluate different aspects of patient health, as long as these instruments are valid, responsive and reliable.

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A limitation of the current research was that not all subjects completed all questionnaires or functional testing. Only 22 subjects completed the SF12 and OKS, and one subject was unable to complete the Biodex muscle testing. The power calculation for sample size performed demonstrated that 23 complete databases were needed to achieve adequate statistical power, with an alpha level of 0.05 and power of 80%. Therefore, data for the SF12 and OKS are potentially underpowered, and therefore the non-significant results for these values should be interpreted with caution.

The results of the current research suggest that commonly used knee outcome rating scales do not correlate well with muscle strength or knee laxity, but they do correlate significantly with the TUG. Therefore, knee outcome scores used without functional assessment are not sufficient to comprehensively assess results of TKA. From the present data the TUG is the most important in patient satisfaction and function after TKA of the three objective measures tested. This may be pertinent in post-operative rehabilitation, as the ability to walk at a certain pace correlates with post-operative satisfaction for the patient.

CHAPTER 6

SUMMARY AND CONCLUSIONS

6.1 SUMMARY

The purposes of this study were:

- 1 To correlate the outcomes of four commonly used patient based questionnaires used in the assessment of TKA including a dual rating system [The American Knee Society score [KSS]], two validated self-administered questionnaires [the Knee Osteoarthritis Outcomes Score [KOOS] and the Oxford Knee Score [OKS]] and a generic questionnaire [Short Form 12 [SF12] with the physical component score [PCS] and mental component score [MCS]].
- 2 To correlate differences in two objective measures of the operated lower limb compared with the non-operated lower limb [knee laxity and isokinetic muscle strength] at least 12 months post TKA.
- **3** To correlate the above subjective and objective outcome measures in the assessment of post-operative function after unilateral TKA.

From the purposes, several hypotheses were developed:

HYPOTHESIS 1: There will be a positive correlation between the OKS and KOOS, the KSS knee and function scores and the PCS portion of the SF12 PCS, but not the MCS portion of the SF12.

Previous research [Bullens et al 2001, Dawson et al 1998, Lingard et al 2001, Kantz et al 1999, Kreibich et al 1996, Impellizzeri et al 2010, Medalla et al 2009, Roos et al 2003] has examined the relationship between knee rating systems with conflicting results. The results of the current research observed strong correlations [r=0.410-0.786] between the four examined and commonly used rating scales (OKS, KOOS, KSS and PCS portion of the SF12). The MCS portion of the SF12 demonstrated weaker correlations with the other knee rating scores (r=0.286-0.483), except for the KOOS ADL (r=0.598), which demonstrated a strong and highly significant correlation.

Based on the above findings, the first hypothesis that the OKS, KOOS, KSS Knee and Function scores and PCS portion of the KOOS have a positive correlation but not the MCS portion of the SF12 was accepted. However, the current research demonstrated a strong and highly significant correlation between the MCS of the SF12 and the KOOS ADL.

HYPOTHESIS 2: The operated limb will have a decreased peak torque when compared with the non-operated limb, but there will be no significant difference in knee laxity between the operated and non-operated limb.

Researchers commonly evaluate outcome after TKA using peak isokinetic muscle torque [Bemben et al 1991, Fuchs et al 2000, Gore et al 1986, Huang et al 1996, Nestor et al 2010, Rossi et al 2011, Schroer et al 2010, Walsh et al 1998] and knee

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laxity [Dejour et al 1999, Jones et al 2006, Kuster et al 2004, Matsuda & Ishii et al 2004, Schuster et al 2011, Seon et al 2010, Waslewski et al 1998]. Previous research [Berman et al 1991, Lorentzen et al 1999] has demonstrated lower peak torque when compared with the non-operated extremity. Recently, Schroer et al [2010] demonstrated no significant difference in peak isokinetic quadriceps torque of the operated and non-operated knees at one year post TKA. White et al [1991] used the same protocol as the current research [Daniel et al 1985] but measured anterior laxity only. They reported no significant difference between the operated and non-operated knees.

In the current project, the symmetry index for isokinetic peak torque at 120° /sec was 1 ± 0.15 . Significant difference between the values for the operated and non-operated knees for peak isokinetic muscle torque (p=0.080) or knee laxity (p=0.080) was not demonstrated.

Based on the above findings, the first part of the second hypothesis that the operated limb will have a decreased peak torque when compared with the non-operated limb was rejected. However, the second part of the hypothesis, that there will be no significant difference in knee laxity between the operated and non-operated limb was accepted.

HYPOTHESIS 3: There will be no correlation between knee laxity and patient satisfaction and function after TKA.

Previous research [Dejour et al 1999, Jones et al 2006, Warren et al 1994] has previously failed to demonstrate a correlation between knee laxity and patient satisfaction and function after TKA. The results of the current research demonstrate a weak negative correlation between the MCS of the SF12 and knee laxity (r=0.495, p=0.14). This was thought to most likely be due to chance, as it could 138 not be explained, and was not similar with the other results of the current research. No other observed correlations were demonstrated between knee laxity of the operated knee and knee rating scores (r=-0.354 to 0.029).

Based on the above findings, the third hypothesis that there will be no correlation between knee laxity and patient satisfaction and function after TKA was accepted.

HYPOTHESIS 4: There will be a positive correlation between muscle torque of the operated limb and the OKS, KOOS, KSS knee and function scores and the portion of SF12 related to pain and function [PCS].

Research [Fuchs et al 2000, Mizner et al 2011, Silva et al 2003, Visser et al 2010] has reported varying results of the relationship between peak muscle torque and subjective knee rating scores after TKA. The current research failed to report a correlation between peak muscle torque of the operated knee after TKA and the commonly used knee rating scores. Only 21 subjects had a compete set of results for muscle torque, due to 3 patients being unable to complete one of either the Biodex, SF12 and OKS. The power calculation for sample size performed demonstrated that 23 complete databases were needed to achieve adequate statistical power, with an alpha level of 0.05 and power of 80%. Therefore, data for the Biodex, SF12 and OKS are potentially underpowered, and therefore the non-significant results for these values should be interpreted with caution. However, a post- hoc comparison using the correlation coefficient between OKS and muscle torque demonstrated a statistical power of 0.86 in the present research.

Therefore, the fourth hypothesis that there will be a positive relationship between muscle torque of the operated limb and the knee rating scores was rejected.

HYPOTHESIS 5: There will be a positive correlation between the TUG and the OKS, KOOS, KSS knee and function scores and the portion of SF12 related to pain and function [PCS].

Previous research [Gore et al 1986, Rossi et al 2006] has reported a positive relationship between walking velocity and knee rating scores in the late post operative period after TKA (after six months). Other researchers [Ghandi et al 2009, Mizner et al 2011, Stevens-Lapsley et al 2011, Stratford et al 2009] have reported that self report and walking tests do not have the same trajectory in the early post operative period. The present research observed strong and highly significant correlations between the TUG and the OKS, KSS knee score and 4 items of the KOOS. The TUG did not correlate with the SF12 PCS, and only moderately with the KSS Function score and KOOS sports score. This may be due to the TUG being subject to ceiling effects, as it is a walking test only. Therefore it may fail to reflect difficulties with heavier tasks, such as heavy lifting or stair climbing, as measured by the KOOS Sports and Recreation and KSS Function scores.

Thus, the fifth hypothesis that there will be a positive correlation between the TUG and the OKS, KOOS and KSS knee score was accepted. However, the TUG did not correlate with the SF12 PCS, and had only moderate correlations with the KSS Function score and KOOS sports score (r=-0.513-(-0.424)).

6.2 CONCLUSION

A number of significant findings were identified in the present research. Firstly, strong correlations were observed between the four examined and commonly used rating scales (OKS, KOOS, KSS and PCS portion of the SF12), but not the MCS portion of the SF12. The strongest predictors of the OKS were the 5 items of the

KOOS and the KSS knee score. Therefore, based on the current research, the OKS is recommended for large scale audit and research due to its validity, simplicity and ability to be posted. The KOOS is recommended when increased responsiveness is required, such as research comparing two different prostheses. Previous investigators have advised to combine at least two of the scoring systems to collect sufficient information. Based on the current results, the MCS portion of the SF12 measures different aspects of outcome after TKA, and the SF12 is recommended in conjunction with a knee specific questionnaire.

Secondly, the TUG is most suited to provide an indication of objective performance in patients post TKA. Thirdly, outcome rating scales do not appear to correlate with strength and knee laxity. This finding suggests outcome rating scales are not suited to assess outcome after TKA by themselves.

In summary, for a comprehensive assessment of outcome after TKA, the present research findings suggest the use of a combination of objective and subjective outcome measures. Subjective rating scales should include at least one validated knee specific questionnaire and a validated generic questionnaire. Based on the current research, the OKS and SF12 are recommended in a clinical setting for the subjective component, as they are validated and reliable, and short and easy to complete. For more comprehensive assessment, the KOOS is also validated but more responsive for purposes for research. These should be used in combination with the TUG as the objective component.

6.3 LIMITATIONS

There are several limitations with the current research. Ten of the TKA's were performed using navigation. Researchers [Chauhan et al 2004, Meikle et al 2001,

Novicoff et al 2010, Saragaglia et al 2001] have reported improved alignment when using this technology for TKA, but there is controversy as to whether this leads to improved function [Hoffart et al 2012, Xie et al 2012].

Patients were recruited from the orthopaedic outpatients clinic at Rockhampton Base Hospital, which is a regional hospital in Central Queensland. Many patients are elderly and reside over 50 kilometres from the hospital and could not attend the testing. Subjects therefore could not be recruited sequentially post operatively. In addition, two different surgeons were involved in the surgery, which potentially introduced bias.

The assessment of relationships between subjective rating outcome scores, knee laxity, the TUG and muscle strength was based on the inclusion of 23 subjects only. Only 22 subjects completed the SF12 and OKS, and one subject was unable to complete the muscle testing. The small sample size may have resulted in a Type II error and lack of power. The demonstrated strong and significant correlations (r=0.76-0.99) between the OKS and other rating scales (r=0.528-0.786), the SF12 and knee rating scales, (r=0.410-0.665) and the OKS and the TUG (r=0.651) are a powerful argument that this potential limitation may not be valid at all.

6.4 **RECOMMENDATIONS FOR FUTURE RESEARCH**

Based on the findings of the current thesis, directions for further research include:

1 A longitudinal study including pre operative data is needed to investigate the responsiveness and early peri-operative relationships of the subjective and objective outcome measures in the present research.

- 2 Given the limited follow-up period of the present study, a longer term study is needed to investigate whether relationships between knee rating scores and isokinetic peak torque, knee laxity and the Timed Up and Go remain in the longer term.
- **3** Whilst muscle strength and knee laxity have not been identified as important factors in self reported patient satisfaction, future research might determine whether alternative objective outcome measures such as gait analysis, x-rays, and other functional tests such as stair climbing and heavy lifting play a role in self reported outcome.
- 4 Establishing relationships between self report and objective measures has high priority among researchers in rehabilitation after TKA. Future research should evaluate the effect of different rehabilitation programs on knee kinematics and kinetics after TKA.

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APPENDIX I

ETHICS APPROVAL FROM CENTRAL QUEENSLAND UNIVERSITY MEMORANDUM

From the Office of Research Secretary, Human Research Ethics Committee Ph: 07 4923 2603 Fax: 07 4923 2600 Email: ethics@cqu.edu.au

19 October 2006

Dr Christy Coyle School of Health & Human Performance Building 77 CQU

Dear Dr Coyle

HUMAN RESEARCH ETHICS COMMITTEE ETHICAL APPROVAL -PROJECT: H06/02-15, postoperative function following total knee arthroplasty: an investigation incorporating tibial acceleration profiles, gait analysis, strength assessment, viscoelastic properties and outcome scores.

The Human Research Ethics Committee is an approved institutional ethics committee constituted in accord with guidelines formulated by the National Health and Medical Research Council (NHMRC) and governed by policies and procedures consistent with principles as contained in publications such as the joint Australian Vice-Chancellors' Committee and NHMRC *Statement and Guidelines on Research Practice*.

On 19 October 2006, the Chair of the Human Research Ethics Committee of the Central Queensland University acknowledged that you have complied with the conditions placed on the project, 'Postoperative function following total knee arthroplasty: an investigation incorporating tibial acceleration profiles, gait analysis,

strength assessment, viscoelastic properties and outcome scores' (Project Number H06/02-15).

The period of ethics approval is 16 October 2006 to 31 December 2007. The approval number is H06/02-15; please quote this number in all dealings with the Committee.

The standard conditions of approval for this research project are that:

- **a** you conduct the research project strictly in accordance with the proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee;
- **b** you report immediately anything which may warrant review of ethics approval of the project, including:
 - i serious or unexpected adverse effects on participants;
 - ii proposed changes in the protocol;
 - iii unforeseen events that might affect continued ethical acceptability of the project; (A written report detailing the adverse occurrence or unforeseen event must be submitted to the Committee Chair within one working day after the event.)
- c you provide the Human Research Ethics Committee with a written "Annual Report" by no later than 28 February each calendar year and "Final Report" by no later than one (1) month after the approval expiry date; (A copy of the reporting proformas may be obtained from the Human Research Ethics Committee Secretary, Sharyn Hsueh please contact at the telephone or email given on the first page.)
- **d** if the research project is discontinued, you advise the Committee in writing within five (5) working days of the discontinuation;
- e you make submission to the Human Research Ethics Committee for approval of any proposed variations or modifications to the approved project before making any such changes;
- **f** you comply with each and all of the above conditions of approval and any additional conditions or any modification of conditions which may be made subsequently by the Human Research Ethics Committee;
- **g** you advise the Human Research Ethics Committee (email: *ethics@cqu.edu.au*) immediately if any complaints are made, or expressions of concern are raised, in relation to the project.

Please note that failure to comply with the conditions of approval and the *National Statement on Ethical Conduct in Research Involving Humans* may result in withdrawal of approval for the project.

You are required to advise the Secretary in writing within five (5) working days if this project does not proceed for any reason. In the event that you require an extension of ethics approval for this project, please make written application in advance of the end-date of this approval. The research cannot continue beyond the end date of approval unless the Committee has granted an extension of ethics approval. Extensions of approval cannot be granted retrospectively. Should you need an extension but not apply for this before the end-date of the approval then a full new application for approval must be submitted to the Secretary for the Committee to consider.

The Human Research Ethics Committee wishes to support researchers in achieving positive research outcomes. If you have issues where the Human Research Ethics Committee may be of assistance or have any queries in relation to this approval please do not hesitate to contact the Secretary, Sharyn Hsueh or myself.

Yours sincerely,

Associate Professor Ken Purnell Chair, Human Research Ethics Committee Cc: Project File Prof Erik Hohmann, Dr Adam Bryant (Supervisors)

Application Category: A

APPENDIX II

FORM OF DISCLOSURE



Central Queensland UNIVERSITY

INFORMATION SHEET

Postoperative function following total knee arthroplasty: An investigation incorporating tibial acceleration profiles, gait analysis, strength assessment, viscoelastic properties and outcome scores

Investigator

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Dr Adam Bryant Ph.D.

Centre for Health, Exercise and Sports Medicine School of Physiotherapy Faculty of Medicine, Dentistry and Health Sciences University of Melbourne Telephone (03) 83 44 4137 Email *albryant@unimelb.edu.au*

Dear _____

You are invited to participate in a study to investigate gender differences in different parameters of the lower limb. The following pages will provide you with information outlining the background of the study, the adopted procedures and any possible risks or side effects associated with the study. Please feel free to discuss your involvement in this study with your investigator at any stage.

Introduction

Total knee arthroplasty is a surgical procedure that is the primary end stage treatment for ostcoarthritis of the knee. There are several questionnaires that are used to assess outcomes after surgery. It is important to ensure that these questionnaires correlate with objective function of the operated lower limb after surgery. It is also important to assess how having a total knee replacement changes the function of the operated lower limb. Currently there are few studies that correlate scores of a questionnaire widely used to assess function after total knee replacement (Knee Society Score) with objective function of the operated lower limb after total knee replacement (Knee arthroplasty.

Purpose

The purpose of this study is:

- 1 To assess subjective function in the operated lower limb after total knee replacement by using two (2) questionnaires (Knee Society Score and Knee and Osteoarthritis Outcome Score)
- 2 To assess objective function in the operated lower limb after total knee replacement by using tests in the laboratory (muscle strength, muscle stiffness, knee laxity, timed walking, tibial acceleration and EMG)
- **3** To compare subjective and objective function in the operated lower limb after total knee replacement

Procedure

You will be required to attend one (1) testing session at the Human Performance Laboratory at Central Queensland University lasting approximately 2-3 hours.

Prior to your participation in the study you will be required to complete a Short Form 12 Questionnaire (SF-12) and sign an informed consent form. You will undergo a familiarisation session where the equipment and procedures used in the study will be explained to you.

During each laboratory session you will undergo the following tests:

- 1 Answer two (2) questionnaires ((Knee Society Score and Knee and Osteoarthritis Outcome Score)
- 2 Assessment of knee joint laxity. This will be assessed using a KT-2000[™] knee arthrometer. This device measures the movement about the knee joint when a pressure is applied. You will be lying on the bench with the legs supported. The device is strapped to one knee and pressure applied. A computer will record the measurement. Both knees will be tested.
- 3 Maximal hamstrings/quadriceps strength. You will be seated and strapped into a testing chair with a non-stretch strap attached to your ankle. This strap will also be attached to a force measuring device via a high tension wire and secured to a bracket mounted on the wall. In the testing position, your leg will be almost completely extended and from this position you will be required to pull back and push out against the strap as hard and as fast as possible for five (5) seconds. This will be repeated three (3) times with a one (1) minute rest interval between trials. Both legs will be tested.
- 4 Assessment of tibial acceleration. We will measure the forces that your body exerts on the ground as you walk over a force place. An accelerometer will be placed on you shin bone to measure the "shocks" during walking.
- 5 Gait analysis. You will walk a distance of five (5) metres as fast as you can. In addition three (3) electrodes (stickers) will be placed on the back and front of your thigh and ankle to measure muscle electrical activity during walking.
- 6 Timed walking distance. As you are walking the above five (5) metres, you will be timed as you walk through a light gate.

Risks

During the study, you will be asked to exert maximal effort. Some discomfort is expected. However you will be allowed to warm up prior to undertaking this test. Following each testing session, you will be offered information to assist recovery. Furthermore, a familiarisation session will be offered prior to the commencement of the study to introduce testing staff and equipment. Therefore the risk to you is minimal. You will have been pre-screened to ensure that you do not have any existing medical or musculoskeletal conditions that may indicate that you should not

undertake maximal exercise. If health risk factors are found to exist which may affect your health or contra-indicate exercise participation, then you will be referred to a medical doctor.

Outcomes

This research will form the major part of a Masters degree and the results will be included in a final thesis. It is expected that the results of this study will be published in peer-reviewed sports science and medical journals. Your anonymity is assured via the procedures outlined in the consent form. If the investigator requires consent for additional use not covered in the current informed consent document, she will contact each participant by mail to obtain written informed consent for the proposed use.

Data will be stored for five (5) years in accordance with the Central Queensland University Code of Conduct.

APPENDIX III

INFORMED CONSENT FORM

Confidentiality

There will be the strictest confidentiality regarding the results of this study. Your name will not appear in publications associated with this research. Your results will be provided to you in both written and verbal form. No one else will be given your results unless you request it.

Throughout the course of the proposed research program, you are free to withdraw at any time for whatever reason.

Enquiries

Any enquiries or concerns about the proposed research can be directed to the researcher by ringing 0402 528339, by email at *chycoyle@yahoo.com*, or by writing to Dr Christy Coyle, School of Health and Human Performance, Central Queensland University, North Rockhampton 4702.

Freedom to Withdraw

I have read the above information. The nature, the demands, risks and benefits of the project have been explained to me. I knowingly assume the risks involved, and understand that I may withdraw my consent and discontinue participation at any time without penalty or loss of benefit to myself. In signing this consent form I am not waiving my legal claims, rights or remedies. A copy of the consent form will be given to me.

NAME:

SIGNATURE:

DATE:

CONTACT DETAILS:

I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised and have witnessed the above signature. I have also provided the participant a copy of this signed consent document.

NAME:	
SIGNATURE:	
DATE:	

Please contact Central Queensland University's Research Service Office (phone: 4930-9828) should there be any concerns about the nature and/or conduct of this research project.

APPENDIX IV

OXFORD KNEE SCORE

PROBLEMS WITH YOUR KNEE

Tick one box for every question

- **1 During the past 4 weeks....**How would you describe the pain you usually have from your knee?
 - □ None
 - □ Very mild
 - □ Mild
 - \square Moderate
 - □ Severe
- **2 During the past 4 weeks....** Have you had any trouble with washing and drying yourself (all over) because of your knee?
 - \Box No trouble at all
 - \Box Very little trouble
 - \Box Moderate trouble
 - □ Extreme difficulty
 - \Box Impossible to do
- **3** During the past 4 weeks.... Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use)
 - \Box No trouble at all
 - \Box Very little trouble
 - \Box Moderate trouble
 - □ Extreme difficulty
 - \Box Impossible to do

- **4 During the past 4 weeks....** For how long have you been able to walk before pain from your knee becomes *severe*? (with or without a stick)
 - □ No pain/More than 30 minutes
 - \Box Very little pain/16 to 30 minutes
 - \Box Mild pain/5 to 15 minutes
 - \Box Around the house only
 - □ Pain severe when walking
- **5 During the past 4 weeks....** After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?
 - □ Not at all painful
 - □ Slightly painful
 - □ Moderately painful
 - □ Very painful
 - □ Unbearable
- **6 During the past 4 weeks....** Have you been limping when walking, because of your knee?
 - □ Yes, Easily
 - \Box Only 1 or 2 nights
 - \Box Some nights
 - \Box Most nights
 - \Box Every night

7 During the past 4 weeks.... Could you kneel down and get up again afterwards?

- \Box Yes, Easily
- □ With little difficulty
- \Box With moderate difficulty
- \Box With extreme difficulty
- \Box No, impossible

- 8 **During the past 4 weeks....** Have you been troubled by pain from your knee in bed at night?
 - \Box No nights
 - \Box Only 1 or 2 nights
 - \Box Some nights
 - \Box Most nights
 - □ Every night
- **9 During the past 4 weeks....** How much has pain from your knee interfered with your usual work (including housework)?
 - \Box Not at all
 - \Box A little bit
 - □ Moderately
 - □ Greatly
 - □ Totally
- **10 During the past 4 weeks....** Have you felt that your knee might suddenly 'give way' or let you down?
 - □ Rarely/never
 - □ Sometimes, or just at first
 - □ Often, not just at first
 - \Box Most of the time
 - \Box All of the time

11 During the past 4 weeks.... Could you do the household shopping on your own?

- □ Yes, Easily
- □ With little difficulty
- □ With moderate difficulty
- □ With extreme difficulty
- □ No, impossible

12 During the past 4 weeks.... Could you walk down one flight of stairs?

- □ Yes, Easily
- □ With little difficulty
- □ With moderate difficulty
- □ With extreme difficulty
- \Box No, impossible

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APPENDIX V

KNEE OSTEOARTHRITIS OUTCOMES SCORE

KOOS KNEE SURVEY

Today's date:____/___/____Date of birth:____/____/

Name: ______

Instructions

This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to do your usual activities.

Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms

These questions should be answered thinking of your knee symptoms during the last week.

1 Do you have swelling in your knee?

 \Box Never \Box Rarely \Box Sometimes \Box Often \Box Always

2 Do you feel grinding, hear clicking or any other type of noise when your knee moves?

 \Box Never \Box Rarely \Box Sometimes \Box Often \Box Always

3	Does your	knee catch	or hang up w	hen moving?	•	
	□ Never	□ Rarely	🗆 Someti	mes 🗆 Oft	en 🛛 Always	
4	Can you st	traighten yo	our knee fully	?		
	□ Never	□ Rarely	□ Someti	mes 🗆 Oft	en 🗆 Always	
5	Can you b	end your kr	nee fully?			
	□ Never	🗇 Rarely	🗆 Someti	mes 🛛 Oft	en 🗆 Always	
Sti	iffness					
exp	perienced du	iring the last	week in your	knee. Stiffnes	iffness you have is is a sensation of ye your knee joint.	
1	How sever	e is your kn	iee joint stiffr	ness after firs	t wakening in the	morning?
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme	
2	How seven day?	re is your k	nee stiffness	after sitting,	lying or resting	later in the
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme	
Pa	in					
1	How often	do you exp	erience knee	pain?		
	□ Never	□ Month	ly 🗆 Week	tly 🗆 Daily	y 🗆 Always	
	What amo following d	-	e pain have y	ou experienc	ed the last week	during the
2	Twisting/p	oivoting on y	your knee			
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme	
3	Straighten	ing knee fu	lly			
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme	
4	Bending k	nee fully				
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme	
5	Walking o	n flat surfac	ce			
	□ None		□ Moderate	□ Severe	□ Extreme	
6	Going up o	or down stai	irs			

	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
7	At night v	vhile in bed			
	□ None	\Box Mild	□ Moderate	□ Severe	□ Extreme
8	Sitting or l	lying			
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
9	Standing u	pright			
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your knee.

1 Descending stai	rs
-------------------	----

	□ None	□ Mild	□ Moderate	□ Severe	Extreme
2	Ascending	stairs			,
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
			ving activities pl e last week due 1		the degree of difficulty you
3	Rising from	m sitting			
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
4	Standing				
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
5	Bending to	o floor/pick	up an object		
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
6	Walking o	on flat surfa	ice		
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
7	Getting in	/out of car			
	□ None	🗆 Mild	□ Moderate	□ Severe	□ Extreme

8	Going sho	pping			
	□ None	\square Mild	□ Moderate	□ Severe	□ Extreme
9	Putting on	socks/stoc	kings		
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
10	Rising fro	m bed			
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
11	Taking of	f socks/stoc	kings		
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
12	Lying in b	ed (turning	g over, maintaiı	ning knee pos	sition)
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
13	Getting in	/out of batl	h _.		
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
14	Sitting				
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
15	Getting on	off toilet			
	🗋 None	□ Mild	□ Moderate	□ Severe	□ Extreme
	For each of	f the follow	ing activities ple	ase indicate th	he degree of difficulty you
	have exper	ienced in th	e last week due	to your knee.	
16	Heavy don	nestic duties	s (moving heavy	boxes, scrubl	oing floors, etc)
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme
17	Light dome	estic duties	(cooking, dustin	g, etc)	
	□ None	□ Mild	□ Moderate	□ Severe	□ Extreme

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the last week due to your knee.

1	Squatting					
	□ None	□ Mild	□ Moderate	□ Severe	□ Extre	eme
2	Running					
	□ None	□ Mild	□ Moderate	□ Severe	🗆 Extra	eme
3	Jumping					
	□ None	□ Mild	□ Moderate	□ Severe	🗆 Extra	eme
4	Twisting/p	oivoting on	your injured k	knee		
	□ None	□ Mild	□ Moderate	□ Severe	□ Extre	eme
5	Kneeling					
	□ None	□ Mild	□ Moderate	□ Severe	□ Extre	eme
Qı	uality of L	ife				
1	How often	are you av	vare of your k	nee problem?		
	□ Never	□ Month	nly 🗆 Week	ly 🛛 Daily	□ Con	stantly
2	Have you to your kn	•	our life style t	o avoid poten	tially daı	naging activities
	□ Not at a	all 🗆 Mi	ldly 🛛 Mod	erately 🗆 S	everely	□ Totally
3	How much	n are you tr	oubled with la	ck of confide	nce in yo	ur knee?
	□ Not at a	all 🗆 Mi	ldly 🛛 Mod	erately 🗆 S	everely	□ Extremely
4	In general	, how mucl	h difficulty do	you have with	ı your kn	ee?
	□ Not at a	all 🗆 Mi	ldly 🛛 Mod	erately 🗆 S	everely	□ Extremely

Thank you very much for completing all the questions in this questionnaire.

APPENDIX VI

AMERICAN KNEE SOCIETY SCORE

Patient category

- A. Unilateral or bilateral (opposite knee successfully replaced)
- B. Unilateral, other knee symptomatic
- C. Multiple arthritis or medical infirmity

Objective Scoring

Pain	Points
None	50
Mild or occasional	45
Stairs only	40
Walking & stairs	30
Moderate	
Occasional	20
Continual	10
Severe	0

Range of motion

 $(5^{\circ} = 1 \text{ point}) 25$

Stability Anteroposterior

<5 mm 10 5-10 mm 5 10 mm 0

Mediolateral

<5° 15 6° -9° 10 10° -14° 5 15° 0

Flexion contracture

5° -10° -2 10° -15° -5 16° -20° -10 >20° -15

Extension lag

<10° -5 10° -20° -10 >20° -15

Alignment

5° -10° 0 0° -4° 3 points each dègree 11° -15° 3 points each degree

Functional Scoring

Walking	50
Unlimited	40
>10 blocks	30
5-10 blocks	20
<5 blocks	10
Housebound	0

Stairs

Normal up & down	50
Normal up, down with rail	40
Up & down with rail	30
Up with rail; unable down	15
Unable	0

Functional Deductions

Cane	-5
Two canes	-10
Crutches or walker	-20
Other	20

Knee Score

(If total is a minus number, score is 0)

APPENDIX VII

SHORT FORM 12

SF12 - Health

The following questions ask you for your views about your health. Please try to answer the questions as accurately as you can.

QUESTION 1: In general would you say your health is:

- 1 Excellent
- 2 Very good
- 3 Good
- 4 Fair
- 5 Poor
- 6 Don't know

QUESTION 2: Does your health now limit you a lot, limit you a little, or not limit you at all?

- 1 Yes, limited a lot
- 2 Yes, limited a little
- 3 No, not limited at all
- 4 Don't know

QUESTION 3: Climbing stairs. Does your health now limit you a lot, limit you a little, or not limit you at all ?

- 1 Yes, limited a lot
- 2 Yes, limited a little
- 3 No, not limited at all
- 4 Don't know
- **5** Question 4:

QUESTION 4: During the <u>past month</u>, have you accomplished less than you would like as a result of your physical health?

1 Yes

2 No

QUESTION 5: During the past month, were you limited in the kind of work or other regular activities you do as a result of your physical health?

1 Yes

2 No

QUESTION 6: During the past month, have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?

1 Yes

2 No

QUESTION 7: During the past month, did you not do work or other regular activities as carefully as usual as result of any emotional problems, such as feeling depressed or anxious?

1 Yes

2 No

QUESTION 8: During the past month, how much did pain interfere with your normal work, including both work outside the home and housework? Did it **interfere:**

1 Not at all

2 A little bit

3 Moderately

4 Quite a bit

5 Extremely

QUESTION 9: During the past month, how much of the time has your physical health or emotional problems interfered with your social activities like visiting friends or relatives? Has it interfered-

- 1 All of the time
- 2 Most of the time
- 3 Some of the time
- 4 A little of the time
- 5 Or none of the time

QUESTION 10: How much of the time during the past month have you felt calm and peaceful:

- 1 All of the time
- 2 Most of the time
- 3 A good bit of the time
- 4 Some of the time
- 5 A little of the time
- 6 None of the time

QUESTION 11: How much of the time during the past month did you have a lot of energy?

- 1 All of the time
- 2 Most of the time
- 3 A good bit of the time
- 4 Some of the time
- 5 A little of the time
- 6 None of the time

QUESTION 12: How much of the time during the past month have you felt downhearted and blue?

- 1 All of the time
- 2 Most of the time
- 3 A good bit of the time
- 4 Some of the time
- 5 A little of the time
- 6 None of the time

