Functional and Patient Outcomes following Total Knee Arthroplasty: a multiple-methods approach

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Publication and Presentations

Journal Publications

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2- Does free- living physical activity improve one-year following Total knee arthroplasty in patients with osteoarthritis: A prospective study.
(under Review).

Conference poster presentations:

1- Free-living physical activity at one-year following total knee arthroplasty in patients with osteoarthritis at the International Society for the Measurement of Physical Behaviour (ICAMPAM) conference, June 2019, Maastricht, Netherlands.
2- Functional outcomes after total knee arthroplasty at the Physiotherapy UK 2018 international conference, October, Birmingham, UK.
3- Psychometric analysis of the Arabic version of the Oxford Knee Score for end-stage knee osteoarthritis at the world congress of the Osteoarthritis Research Society International, April 2018, Liverpool, UK.
4- 'Does physical activity change at six months following total knee arthroplasty?' at the British Association for Surgery of the Knee (BASK), March 2018, Leicester, UK.

Abbreviations

OA	Osteoarthritis
NJR	National Joint Registry
TKA	Total knee arthroplasty
PROMs	Patient-reported outcome measures
KOOS	Knee injury and osteoarthritis outcome score
OKS	Oxford Knee Score
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
WHO	World Health Organization
MCID	Minimum clinically important differences
PBOMs	Performance-based outcome measures
OARSI	Osteoarthritis Research Society International
PA	Physical activity
PB	Physical Behaviour
SEBT	Star Excursion Balance Test
UK	United Kingdom
VAS	Visual analogue scale
30sC	30 sec. chair-stand test
SCT	Stair-climb test
TUG	Timed up-and-go test
6MWT	6 min. walking test
UCLA	University of California Los Angeles activity

ABSTRACT

Background and aims: Total knee arthroplasty (TKA) is the gold standard treatment for end-stage knee osteoarthritis. The main outcomes expected are reduced pain and improved function. There is conflicting evidence regarding functional changes post-TKA, which may be due to the nature of the assessment methods used. Commonly, functional changes are measured using Patient Reported Outcome Measures (PROMs) and performance-based measures (PBMs), where under/ overestimation, recall bias and participant research effect cannot be excluded. In addition, satisfaction post-TKA is significantly less than for post-total hip arthroplasty, which emphasises the need for further exploration of the reasons why and propose recommendations to improve it. Furthermore, long-term patient satisfaction and outcomes post-TKA are not predicted. Therefore, the current thesis aims to answer these research questions: Are individuals satisfied following TKA? Can we predict outcomes and satisfaction? What are individuals' experiences? Do they improve their physical behaviour?

Methods: A multiple-methods approach was used to attain the research objectives, using different philosophical traditions (paradigms) to improve the accuracy of the findings and gain a complete picture of outcomes. It provided an opportunity to check outcomes post-TKA using quantitative and qualitative methods and to assess the findings for each method. A retrospective study assessed short- and long-term changes in PROMs to develop a prediction tool for outcomes and satisfaction; a focus-group discussion (FGD) explored, in depth, patients' experiences, satisfaction and expectations post-TKA; and a prospective study assessed free-living physical behaviour (PB) and correlated it with commonly used outcome measures.

Results: PROMs significantly improved and reached a peak post-TKA at one year and remained there for several years, followed by a significant reduction at 10 years. Patients' functional outcomes and satisfaction post-TKA are multifactorial, and the first year is key to long-term outcomes and satisfaction. Patient attitude, sufficient pre-operative education, outcome expectation modification, communication with the surgeon, and patients taking an active role in rehabilitation can all affect post-TKA outcomes and satisfaction. Physical behaviour (PB) improved post-TKA in both volume and pattern six and twelve months post-TKA. OKS score was not correlate or predict the physical activity or satisfaction post-TKA.

Conclusion

The prediction equation developed may help to estimate outcomes and satisfaction, design individual pre-TKA behavioural treatments and modify unrealistic expectations so as to improve outcomes and satisfaction post-TKA, in addition to general education classes to clarify overall experiences, such as: severity of symptoms post-TKA, pain-control options, expected care post-surgery from the surgeon and physiotherapy, possible functional limitations and improvements. There is a clear discordance between PB outcomes and PROMs, this emphasises the need to use objective methods in addition to PROMs, which merely track subjective improvements and may be influenced by recall bias. Although PB improved in terms of stepping, step numbers and patterns, it did not meet physical activity (PA) guideline recommendations. This affirms that arthroplasty alone is unlikely to improve PA and thus educational or behavioural treatments are recommended. Behavioural and motivational classes pre- and following Total Knee Arthroplasty may change sedentary behaviours to meet PA recommendations to improve overall health and enhance satisfaction.

Chapter 1- Introduction

1.0 Introduction

Osteoarthritis (OA) is one of the most prevalent types of musculoskeletal pathology and involves global degeneration of body joints, affecting articular cartilage and other surrounding tissue. It damages cartilage and remodels subarticular bone, with joint ligaments becoming lax, osteophyte formation and a decrease in surrounding muscle strength. The primary symptoms are: joint pain, stiffness and joint-movement limitations, subsequently leading to a progressive reduction in the quality of life through disability (Arden & Nevitt, 2006; Cooper, 2013).

The aetiology of OA is multi-factorial and can be considered the product of an interplay between systemic and local factors. Female gender, advancing age, obesity, knee injury or ligament laxity, repetitive use of joints, bone density and muscle weakness all play roles in osteoarthritic joint development. The knee is one of the joints most commonly affected by OA, second only to the hand. The common classification of OA according to aetiology is: primary (idiopathic) or secondary, due to there being many well-recognised aetiologies, such as metabolic, traumatic or inflammatory disease (Arden & Nevitt, 2006; Blagojevic, Jinks, Jeffery, & Jordan, 2010).

Worldwide, approximately 8 to 15 per cent of the population is affected by OA and around 50 per cent of people aged 75 years and older show severe osteoarthritic radiographic changes (Cross et al., 2014; Rat et al., 2006; Reyes et al., 2016). The 2018 Arthritis Research report estimated that 4.11 million adults (18.2%) aged 45 years and older in the United Kingdom are treated for knee OA and 6 per cent of them have a severe knee condition. In the United Kingdom it is the most common chronic condition within primary care, and by 2030 it is predicted to be the greatest cause of disability in the general population (Blagojevic et al., 2010; Jagger et al., 2006; Zhang & Jordan, 2010).

Estimates of osteoarthritis prevalence vary in different populations, perhaps due to non-standardised diagnostic classifications. Commonly, radiographic diagnoses produce higher estimations than self-reporting patient scales or symptomatic diagnoses. Clinical diagnoses are mainly based on patients' symptoms and clinical examination outcomes (Zhang & Jordan, 2010). According to the National Health and Nutrition Examination Survey, 12.1–16.7 per cent of the population of the United States aged between 45 and 60 years is subsequently clinically diagnosed with joint OA (Lawrence et al., 2008). According to the Kellgren-Lawrence scale, radiological diagnoses identify degenerative changes based on the presence of osteophytes. Radiographically knee OA prevalence in adults aged over 45 years was 9.2 per cent and 27.8 per cent, measured in Framingham and Johnston County,

respectively. For adults over 60 years of age, it was 37.4 per cent. This indicates large variations between the two common methods for knee OA diagnosis in the United States, for example, and further variations exist for other joints and in other countries (Arden & Nevitt, 2006; Cooper, 2013; Lawrence et al., 2008; Zhang & Jordan, 2010).

With an ageing population and increasing obesity, OA has become one of the leading causes of global disability. OA disability is significantly associated with increasing all-cause mortality and serious cardiovascular disease events. According to the World Health Organization, disability is defined as a complex phenomenon that reflects interaction between bodily impairments and consequent effects that result in limiting activity and restricting participation. Globally, hip and knee OA are ranked 11th highest of the 291 conditions contributing to global disability and 38th highest in disability-adjusted life years (DALYs) (Cross et al., 2014, Hoy et al., 2014). Older adults with knee OA perceive high environmental barriers that limit their participation and thus seek ways to lower barriers and minimise disability following serious complications (Cross et al., 2014; Hawker et al., 2014; Vaughan et al., 2017). In comparison with people without OA, individuals with OA over 65 years have an increased risk of hospitalization due to cardiovascular disease of 15–17 per cent. In addition, the prevalence of metabolic syndromes increases to 59 per cent and 20 per cent of them experience depression symptoms (ArthritisResearchUK, 2017; Hawker et al., 2017).

There is a large financial burden on the economy with approximately £205.8 million spent in England in 2016 on joint-disease prescriptions (Arthritis Research UK, 2017). Additionally, individuals diagnosed with OA have a 90 per cent higher risk of work loss due to illness or disability compared to individuals without OA (Sharif et al., 2016), with a third of people with OA taking early retirement or reducing their working hours due to their condition (ArthritisResearchUK, 2017). In a review article on the global economic cost of OA, this showed significant variation in direct and indirect costs on the three continents: Europe, North America and Asia. The estimated direct cost of oral and topical nonsteroidal anti-inflammatory drugs was £25.6 m. and £19.2 m., respectively. More than £3.2 billion was the estimated indirect cost of OA due to loss of economic production. plus £215 million on social services and £43 million on community services for OA (Chen et al.,2012). This highlights the high burden of OA and emphasises the need for effective management to reduce cost and disability of knee OA in the forthcoming decades.

1.1 Management of knee OA

According to the Osteoarthritis Research Society International (OARSI) and the European League Against Rheumatism (EULAR), optimal management for knee OA patients involves a combination of pharmacological and non-pharmacological treatments. As regards non-pharmacological treatment, OARSI and EULAR recommend patient education to enhance self-management and lifestyle changes, regular contact with patients, weight reduction, foot insoles, knee braces, acupuncture and physiotherapy (Fernandes et al., 2013; Jordan et al., 2003; Zhang et al., 2008; Zhang et al., 2007). Established effective physiotherapy interventions include exercise (strengthening, water-based, aerobic) and transcutaneous electrical nerve stimulation (Felson, 2016; Zhang et al., 2008; Zhang et al., 2007). However, if conservative treatment fails to control the symptoms of end-stage OA, surgical intervention is recommended (Zhang et al., 2008; Zhang et al., 2010). One of these treatments is total knee arthroplasty.

Total knee arthroplasty

End-stage knee OA, according to the Kellgren-Lawrence scale of Grade 4, occurs when large osteophytes are present, joint space narrows, with severe sclerosis and definite bone-contour deformity (Cerejo et al., 2002). Individuals with end-stage knee OA complain that pain persists at rest and at night, which may disturb sleep, in addition to a marked and limited range of motion. Pain and limited movement are major sources limiting physical activity and subsequently chronic disability (Heidari, 2011).

Total knee arthroplasty (TKA) surgery was first reported in the 1970s and ’80s (Carr et al., 2012; Tambascia, Vasconcelos, Mello, Teixeira, & Grossi, 2016). When comparing with conservative treatments for end-stage OA, pharmacological treatment is neither clinically effective for pain or pathology progression nor cost-effective. Six months of pharmacological treatment costs around €448 for one patient, which shows the financial impact on society (Turajane, Chaweevanakorn, Sungkhun, Larbphiboonpong, & Wongbunnak, 2012). This agrees with the study by Stan et al. (2015), who assessed the cost-effectiveness of conservative and surgical treatments for late-stage knee OA. Cost-effectiveness analysis examined the ratio of direct costs to associated patient benefits. The median cost-effectiveness ratio per quality-adjusted life year was €1800 for rehabilitation versus €1268 for total knee arthroplasty (Stan et al., 2015).

Thus, TKA is a highly cost-effective intervention to manage end-stage knee OA compared with non-surgical management (Stan, Orban, & Orban, 2015) and lies well within the range

of acceptable cost-effectiveness treatments for other musculoskeletal procedures, such as lumbar spine fusion and discectomy (Losina et al., 2009).

1.2 Increasing burden of global statistics

The amount of TKA operations are steadily increasing in developed countries with an ageing population and increasing obesity; the number of primary knee-replacement procedures recorded by the National Joint Registry (NJR) in 2017 was 102,177, which represents an increase of 3.7 per cent over 2015 and 96.2% of cases involve osteoarthritis. In England and Wales, data analysis by the National Joint Registry (NJR) and the Office of National Statistics suggests that, by 2030, primary TKAs will increase by 117% from the 2012 level. Commonly, 75–85% of patients report satisfaction (either "satisfied" or "very satisfied") with surgery outcomes, while the remaining 15–25% are dissatisfied ("dissatisfied" or "very dissatisfied)(Noble, Conditt, Cook, & Mathis, 2006; National Joint Registry 14th Annual public and patient guide Report 2017). Interestingly, the degree of satisfaction post-TKA is significantly less than for post-total hip arthroplasty, which emphasises the need for further exploration of the reasons for that (Klit, Jacobsen, Rosenlund, Sonne-Holm, & Troelsen, 2014; Neuprez et al., 2016; Noble et.al., 2006). Figure 1-1 shows satisfaction after TKA operations in the UK according to a National Joint Registry public and patient guide report (2017), more than half of them are good but this could be improved on. Variations in patient satisfaction may be due to many factors, such as the methods used to assess outcomes, patients' pre-operative expectations or overall pre-operational status. It is important to understand why there are these varying patient outcomes, as improving these is important. Currently, National Health Service progression reports after TKA are based on patients' report outcomes using Oxford Knee Score, as it convenient for surgeons. The following section summarises the outcome methods used post-TKA, including both their advantages and limitations.

Figure 1-1. Patients Satisfaction after Total Knee Arthroplasty according to National Joint Registry, 14th Annual public and patient guide Report 2017.

1.3 Common evaluation methods post-TKA,

TKA success has traditionally been evaluated from the surgeon's perspective, e.g. the presence of surgical complications or implant survival. This is gradually changing to involve the patient when measuring health outcomes and decision-making processes. Patient-reported outcome measures (PROMs) have evolved in order to better explore patient perspectives by monitoring the quality of care in health organisations and conducting clinical trial outcomes (Hossain, Konan, Patel, Rodriguez-Merchan, & Haddad, 2015). To overcome subjective over/under estimation and recall bias of PROMs, further objective methods are commonly used post-TKA, such as assessments of functional performance, balance and physical activity. Each assessment method will be explored in depth, in the following section, in order to analyse each, one's strengths and limitations and determine the most appropriate options for the current study's objectives.

1.3.1 Patient-reported outcome measures (PROMs)

Generic PROMs, such as short forms (SF-36, SF-12) and the EQ-5D questionnaire, provide crucial global assessments of outcomes post-TKA, rather than specific isolated evaluations of pain, satisfaction or function. Generic PROM methods are limited to assessing the specific details required for various disease populations, which may decrease their sensitivity, maximise ceiling effects and produce type-2 errors in hypothesis testing. Specific PROMs address issues pertinent to health-related quality of life in relation to a specific pathology or intervention in order to improve sensitivity, better detect changes and minimise ceiling effects (Giesinger, Hamilton, Jost, Holzner, & Giesinger, 2014).

The Knee injury and Osteoarthritis Outcome Score (KOOS), Oxford Knee Score (OKS), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) are the PROMs most commonly used for assessment post-TKA ((Mont, Banerjee, Jauregui, Cherian, & Kapadia, 2015).

1.3.2 Functional performance

One of the main outcomes expected post-TKA is improved functional performance, thus the assessment of daily and overall physical activity is essential. With the proportion of young patients undergoing TKA increasing it is also important for assessments to be compatible with a core set of the International Classification of Functioning, Disability and Health definitions of the World Health Organization (Alviar, Olver, Brand, Hale, & Khan, 2011). Also, PROM results cannot exclude subjective over/underestimation due to psychosocial effects or pain from other joints, such as hips or back (Harris et al., 2013; McCambridge, Witton, & Elbourne, 2014; Thumboo, Chew, & Lewin-Koh, 2002). Hence, objective clinical

evaluation methods can minimise patients' subjective over/underestimations of outcomes, though RPE cannot be excluded.

Objective assessment has some advantages over PROMs, such as a lack of ceiling effects and more precision and responsiveness, and it does not require cultural and language adaptation. In contrast, it is costly and sometimes not feasible in clinical practice, thus limited to research centres, where specific in-depth training is needed to minimise technical errors and preserve reliability. In addition, technically, it is only applicable to small groups, in contrast to PROMs. Many reliable objective measurement tools have been used in populations post-TKA, such as video-motion analysis with a force plate, which offers the ultimate functional evaluation, but it is costly and not clinically feasible. (Bolink, van Laarhoven, Lipperts, Heyligers, & Grimm, 2012; Jacobs & Christensen, 2009; Wiik, Manning, Strachan, Amis, & Cobb, 2013). Performance-based outcome measures (PBOMs), a balance test and free-living physical activity accelerometers are clinically feasible and are less costly assessment tools than video-motion analysis to capture functional improvements post-TKA.

1.3.2.1 Performance based outcome measures (PBOMs)

PBOMs are sensitive for detecting change, responsive and have a minimal ceiling effect, as well as being feasible. PROMs and PBOM measurement tools assess different aspects of function post-TKA. PROMs mainly assess patients' functional ability beliefs and experiences, while PBOM measurement tools evaluate patients' actual ability, function and highly correlated with body impairments (Alnahdi, 2014; Skoffer, Dalgas, Mechlenburg, Soballe, & Maribo, 2015). Therefore, to conduct comprehensive functional assessments post-TKA, PROMs, objective functional assessment instruments such as PBOM measurement tools are recommended (Hossain, Patel, Fernandez, Konan, & Haddad, 2013; Tambascia et al., 2016).

Recommended PBOMs are not multi-item, as in real life, which may affect their ecological validity and leave them prone to RPE (Hossain et al., 2013; McCambridge et al., 2014). So, inevitably, other measurements are required to overcome this limitation.

1.3.2.2 Balance

Knee OA affects balance and consequently decreases physical activity (Hinman, Bennell, Metcalf, & Crossley, 2002; Noren, Bogren, Bolin, & Stenstrom, 2001). Instability in end-stage knee OA is one of the main factors that correlate with disability and a high risk of falling (Kauppila et al., 2009; Zasadzka, Borowicz, Roszak, & Pawlaczyk, 2015). Assessing balance improvement post-TKA is essential to capture functional improvements. Dynamic

balance has an advantage over a static based assessment, in that it closely mimics physical activity demand, with the history of falling in the OA population occurs during dynamic activities rather than in a static position.

1.3.3 Assessment of physical activity

Many methods are used to assess physical activity, e.g. direct observation, diaries and questionnaires, though these have subjective limitations and high rates of under/ overestimation. In contrast, objective technology analysis, such as foot switches, optical motion analysis, gait mats and force plates, offer a great degree of accuracy, though they have the limitation of being unsuitable for free-living physical activities assessment and so are primarily for laboratory use. Whilst they can collect objective, valid and reliable data to analyse the quality of movements during assessment time, they cannot capture the actual quantity and quality of daily life movements.

In-between these two methods, accelerometers have the advantage of offering reliable and feasible methods to monitor free-living physical activities without subjective limitations. They are considered expensive in comparison to PROMs but reasonable when compared to laboratory motion-analysis technology. In addition, they compensate for PROMs' limitations, such as subjective and ceiling effects, and capture actual activity based on reliable and valid tools.

Although the main outcomes expected after TKA are reduced pain and improved functional performance, there is limited research on overall free-living physical behaviour (PB) outcomes post-TKA. According to the World Health Organisation, physical activity (PA) is defined as any bodily movement that results in energy expenditure by the skeletal muscles. This includes sport, exercise and other activities, such as playing, walking, doing household chores, gardening and dancing. PA has many positive benefits, such as improved cardio-respiratory fitness and enhanced physical and cognitive function. In addition, it lowers the rates of coronary heart diseases, high blood pressure, stroke, diabetes, colon and breast cancer, depression and the risk of falling (WorldHealthOrganisation, 2016).

1.3.4 Patient perspectives of outcomes

Usually, an effective evaluation of a medical intervention depends on our definition of successful treatment in multiple dimensions, such as reducing pain and improving function, or other subjective or objective measures. Other outcome domains, such as emotional and social functioning, patients' expectations, experiences and satisfaction, are difficult to explore fully using quantitative assessment methods. Indeed, Klit et al. (2014) state that PROMs are generic rather than specific, because they do not reflect patients' experiences or

expectations post-TKA (Klit et al., 2014). Hence, outcomes from the patient's perspective are unknown. Further, and potentially crucial to TKR outcomes, are pre-surgery patient-orientated factors that may predict outcomes. Therefore, qualitative assessment methods, such as focus-group discussions with patients, can explore, in depth, both their perceptions and other factors that may affect outcomes (Westby & Backman, 2010; Zacharia, Paul, & Thanveeruddin Sherule, 2016).

1.3.5 Patients' satisfaction

Patient satisfaction post-primary TKA is commonly assessed by asking patients a single question about overall satisfaction with the answer being one of the following four options: (1) on an ordinal 5-point Likert scale (very satisfied, satisfied, neutral, dissatisfied, very dissatisfied), (2) on an ordinal 4-point Likert scale (very satisfied, satisfied, unsure, dissatisfied), (3) on a numeric or VAS-type scale (0–10 or 0–100) (4) or a binary yes/no answer. Other studies have used the 2011 Knee Society Knee Scoring System to assess patient satisfaction, expectations and physical activity or used a questionnaire with four questions where each item is scored on a Likert scale. This four-question questionnaire assesses overall satisfaction, satisfaction with pain relief, housework capability and recreational activity satisfaction. There is no consensus regarding the best method to evaluate patients' satisfaction post-TKA (Choi & Ra, 2016; Kahlenberg et al., 2018).

To gain an overall picture of patients' recovery post-TKA, different measures and outcomes have been utilised, including both subjective and objective measurements tools as well as patients' concerns and experiences, using qualitative methods. The multiple-methods approach provides a richness of understanding of patient's views, which may cover quantitative methods' gaps and limitations to improve healthcare services and patients' satisfaction rate in addition to its provision of adequate numbers for the statistical analysis of the outcomes (Beaton & Clark, 2009). Thus, this may help us understand the interaction between components of the International Classification of Functioning, Disability and Health (ICF) on patients' activities (Fig 1-2). Understanding the effect value of each component may help to improve both function and patient satisfaction post-TKA.

Within this thesis, three studies have been undertaken which assess functional outcomes post-TKA. The short and long-term outcomes, satisfaction post-TKA and personal factors that may affect that are assessed in a retrospective study (chapter 4). Patients' experiences, concerns, satisfaction and expectations post-TKA are explored in more depth in a qualitative study in Chapter 5. In Chapter 6, the body's function and activity as well as personal factors

are assessed through a prospective study using both subjective and objective methods, as per recommendations made by other studies in the literature. The outcomes from two knee arthroplasty approaches are explored by comparing outcomes post-TKA in UK and Middle Eastern populations. More details of the outcome measurement tools used in the post-TKA literature review as well as both the objects and methods of each study will be discussed in the following chapters.

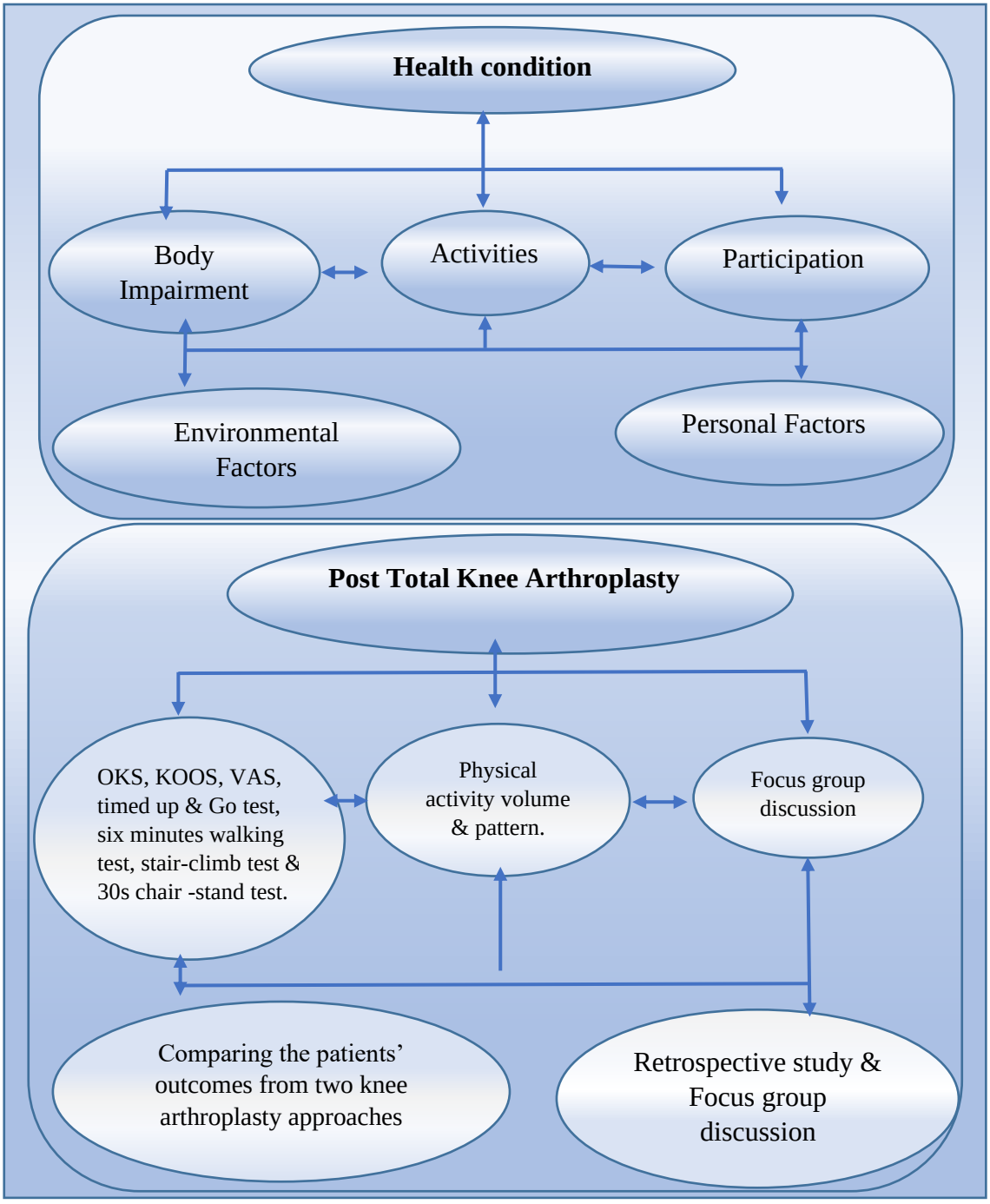

Figure 1-2. Interaction between the International Classification of Functioning, Disability and Health's (ICF) components.

Chapter 2 – Literature Review

2.0 Introduction

This review chapter is devoted to reviewing the available evidence relating to commonly methods used to measure functional outcomes and satisfaction following TKA, in addition to the strengths and weaknesses of each tool. This work is primarily undertaken to refine the research objectives and develop an inclusive methodology. The following systematic review sets out to answer the following research questions: What are the existing evidence, recommendations and gaps regarding outcome measurement tools post-TKA, such as: patients-reported outcome measurements (PROMs), functional performance, balance, physical behaviour changes, patients' experiences, patients' satisfaction and factors that influence/ predict outcomes post-TKA. Although 3- dimensional motion analysis is the gold standard to assess gait improvements post-TKA, the current study setting was hospital-based, and the main limitation of 3-dimentional motion analysis is that it is laboratory-based. So, it is not feasible for the current study.

The chapter is divided into three main sections: general research strategy, literature review and gaps in the literature. The first section clarifies the research strategy used, the inclusion and exclusion criteria for current systematic review, and the paper-quality assessment tools used. There is also a brief summary of research results for all outcome measurements following total knee arthroplasty (TKA). The second section of the chapter includes full details of the literature review for five common outcome-measurement tools used for evaluating patients following TKA: (1) patient-reported outcome measures (PROMs); (2) patient-performance and balance outcomes; (3) physical-behaviour assessment; (4) patients' concerns and experiences; and (5) patients' satisfaction. Section Three summarises gaps in the literature of post-TKA assessments tools, and examines the rationale, objective, research question and hypotheses.

2.1 General search strategy

In accordance with PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines to pursue the objectives of the study, a systematic review of the literature was conducted electronically, making use of several medical databases including: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline/ PubMed, PEDro, Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), ProQuest, TRIP and Google Scholar in two stages (from 2004 to the present to ensure we covered more than a decade in the reviews. In 2004, the first annual report of the joint's registry for England and Wales, which handles data analysis of knee and hip replacements

procedures, was published and thus is a sensible starting point. To define the search strategy, the PICO (Population, Intervention, Comparison and Outcome) framework was used. In the first stage, the keywords and terms used were:

Post primary total knee arthroplasty OR post primary total knee replacement OR TKA OR TKR	AND patient-reported outcome measures OR functional outcomes measures OR PROMs OR scoring
	AND performance-based test OR physical function performance test OR measuring functional improvement OR objective outcome measurement.
	AND balance OR dynamic balance OR star excursion balance test
	AND physical activity OR activity levels OR participation in physical activities OR direct measurement of movement OR accelerometer.
	AND focus group discussion OR FGD OR group discussion OR in-depth group interviews.
	AND Satisfaction

The search was limited to research published in English between 2004 to present for human adult participants and with full access to articles. Unpublished studies were not included because they are rarely peer-reviewed.

Studies were included if they satisfied: any study methodology-measuring outcomes post-primary TKA in terms of patient-reported outcome measures or satisfaction solely or in combined with patient performance-based tests, physical-activity measuring devices, and focus-group interventions. Specific inclusion and exclusion criteria for patient-reported outcome measures are clarified in each section separately.

Exclusion criteria

- Post-traumatic and revision TKA outcome measurements.
- Unicompartmental knee-replacement outcome measurements.
- TKR in pathological groups, such as neurological disorders (stroke, Parkinson's disease etc.), haemophilia and psychological pathologies.
- The presence of major postoperative complications, such as infection, fracture, acute myocardial infarction, stroke, pulmonary embolism or deep-vein thrombosis.
- Post-TKA outcomes based on implant survival, surgical techniques, complications, engineering metallurgic issues and radiographic or any other outcomes not patient generated.

Articles' titles and abstracts were screened to exclude non-matching criteria. Then, the remaining full texts of studies were filtered to exclude papers that did not meet the inclusion criteria. Reference management software (Endnote X7) was used to merge results and remove duplicates.

2.1.1 Quality of the included studies and Risk of methodology bias Critical appraisal

The methodological quality of the studies was appraised using CASP (Critical Appraisal Skills Programme) and a suitable study-design tools checklist (CASP, 2007) according to two independent reviewers.

The CASP tool assesses three main aspects of a research paper: the validity of a study, the quality of the reported results and the value of the conclusions drawn. The CASP checklist is summarised in a table for each study design individually. Positive items (YES) were calculated to estimate the total CASP score and thus assess the study's internal validity and bias potential. A study with a high positive (YES) score was considered to have low bias risk and a study with one or more key domains with a negative scored (NO) was considered to have high bias risk and so its conclusion was interpreted carefully.

2.2 Literature review

This section concludes the available evidence, recommendations and gaps regarding outcome measurement tools post-TKA, starting with patient-reported outcome measurements (PROMs); then a functional performance test, balance and physical behaviour changes post-TKA; followed by patients' experiences and satisfaction post-TKA; and finally, the factors that influence/ predict outcomes post-TKA. Each outcome measure was assessed independently. A PRISMA search strategy was used to devise a transparent article-selection process, which is summarised in Flow Diagram 2-1 for all outcome measurements post-TKA.

2.2.1 Patient-reported outcome measures (PROMs)

In 2009, the NHS (National Health Service) gave prominence to patients' views about their health by implementing a PROM (Patient Reported Outcome Measures) programme for all patients undergoing four types of elective surgery. Before and after knee and hip arthroplasty, varicose-vein and hernia-repair surgery. PROMs' information is used for health prognoses, to evaluate NHS patients' health outcomes and reward good performance. PROMs' main aim is to assess patients' health at various points in time and estimate health changes, their use is not to measure patients' experiences or satisfaction with health-service providers. PROMs are further used in the NHS to inform patients about well-performing hospitals and as part of performance discussions between management teams and clinicians, which may help with decision-making in the case of service expansion or new service implementation (Barham & Devlin, 2010; Drife, 2010).

PROMs Search results

Various valid and reliable patient-reported outcome measurement scales are used following TKA, mainly to assess pain, function and physical activity. A PRISMA search strategy was summarised in Flow Diagram 2-1 for the first stage. After electronic filtration of a first-stage search to restrict the results to articles in English, about humans and with full access produced for 2004 to present, 831 articles were identified. After title-screening and duplicate exclusion, 48 studies satisfied the inclusion criteria clarified in the previous general search strategy section. Abstract screening for 11 papers satisfied the eligibility criteria and these were included in the review (six systematic reviews, four cohort studies, and one International Society of Arthroplasty Registries (ISAR) committee's survey report). The remaining 37 papers were excluded, 16 papers were excluded as the full text not available, 6 papers used PROMs to assess patients on a waiting list before TKA without post-surgery assessment, 5 articles were about PROMs cross-cultural adaptation on OA patients pre-TKA, 2 papers used only generic PROMs, 5 papers were about unicompartmental knee operations and 3 papers on revision surgery (Figure 2-2).

Six systematic reviews and four prospective cohort studies, as well as a committee survey report from ISAR (International Society of Arthroplasty Registries), reached comparable conclusions; KOOS, OKS and WOMAC are the PROMs most commonly used and recommended for assessment post-TKA (Alnahdi, 2014; Alviar et al. 2011; Collins, Misra, Felson, Crossley, & Roos, 2011; Dowsey & Choong, 2013; Hamilton, Gaston, & Simpson, 2012; Hossain et al., 2015; Kauppila et al., 2011; Khanna, Singh, Pomeroy, & Gioe, 2011; Mizner et al., 2011; Ramkumar, Harris, & Noble, 2015; Rolfson et al., 2016).

Critical appraisal assessments of these systematic review studies and a summary are presented in Tables 2-1 and 2-2, respectively. The same for cohort observational studies is presented in Tables 2-3 and 2-4, respectively. Apart from the study by Alviar et al. (2011), none of the other six reviews included assessment the quality of included papers, which may increase the risk of results bias. No review considers all the confounding factors that may affect PROM outcomes post-TKA in their results analyses, nor do they discuss possible explanations for variations and similarities in their results or state them precisely. All the included cohort studies were prospective, which may increase the risk of bias due to unclear subject-selection procedures and differential loss of follow-up, no studies consider possible confounding factors while assessing patient outcomes, such as patient expectations, experience or physical activity level recovery, in the study design or results analysis.

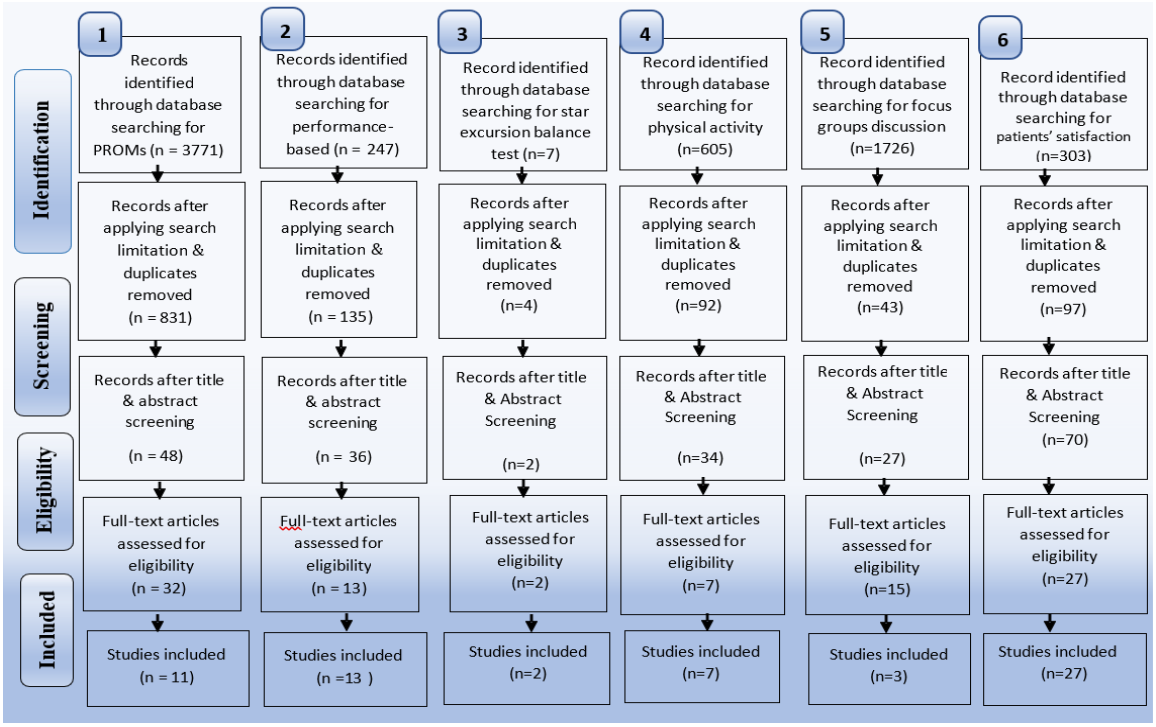

Figure 2- 1. PRISMA 2009 Flow Diagram

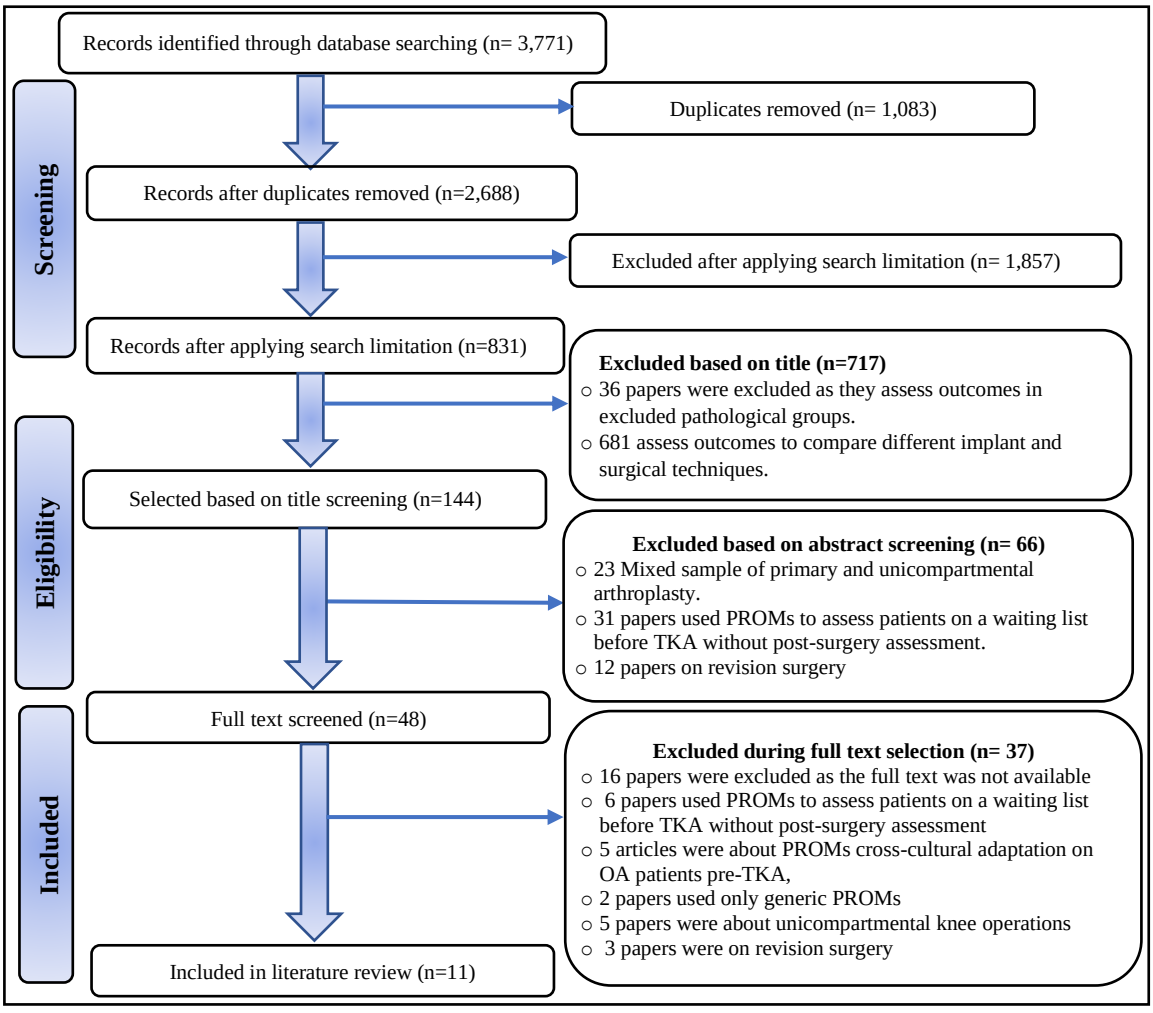

Figure 2- 2. PRISMA 2009 Flow Diagram for Patients Reported Outcome Measures Post-Total knee arthroplasty.

KOOS, OKS and WOMAC are the PROMs most commonly used for assessment post-TKA despite their limitations in terms of comprehensive assessment of patients post-TKA, such as expectations, satisfaction, function and quality of life (Mont et al., 2015) (see Table 2-5). They also have limitations in terms of assessing specific essential activities of daily life, such as driving. These activities become essential for patient satisfaction post-TKA as there is an increase in young patients undergoing the surgery. This is a crucial source of type 2 error that may maximise the ceiling effect and give false negative results (Hossain et al., 2015). It is therefore hard to conclude that there is one best or gold standard for specific PROMs for patients post-TKA from the available evidence. In the following section, in-depth analysis explores the recommended PROMs (KOOS, OKS, WOMAC) validity, reliability and responsiveness, with details of the function-assessment strengths and limitations of each one, which may indicate suitable specific outcome measures for the current study and appropriate additional outcome measures that can compensate for the limitations and capture outcomes post-TKA across a broader spectrum.

Table 2-1. Critical Appraisal Skills Program (CASP) for Patients-reported Outcome Measures for systematic review papers.

CASP	Criteria	Hossain et al. 2015	Ramkumar et al. 2015	Alnahdi 2014	Dowsey et al. 2013	Collins et al. 2011	Alviar et al. 2011
Validity of results	Population defined	YES	YES	YES	YES	YES	YES
	Intervention described	YES	YES	YES	YES	YES	YES
	Study design	YES	YES	YES	YES	YES	YES
	Outcome defined	YES	YES	YES	YES	YES	YES
	Addresses the reviews question	YES	YES	YES	YES	YES	YES
	Selects an appropriate study design	YES	YES	YES	YES	YES	YES
	Relevant studies included (contact with experts, unpublished, not in English)	NO	NO	NO	NO	NO	NO
	Assesses the quality of included studies	NO	NO	NO	NO	NO	YES
	Discusses the results: variation, combined	YES	YES	NO	NO	NO	NO
Results	Clearly states the results	YES	YES	NO	NO	YES	YES
	Results expressed numerically or as odds ratios	NO	NO	NO	NO	YES	YES
	Precision of results (confidence interval)	NO	NO	NO	NO	YES	NO
Results	Results applicable to local population	YES	YES	YES	YES	YES	YES
	Considers all outcomes	YES	NO	NO	NO	NO	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES	YES
	Relevant to present evidence base	YES	YES	YES	YES	YES	YES
	Total score	12/16 75%	11/16 68%	9/16 56%	9/16 56%	12/16 75%	13/16 81%

Table 2-2. Characteristics and results of Patient-reported Outcome Measures, Systematic Review Studies (1/2)

Research title	Author	Subject	Results
Patient-reported outcome measures in arthroplasty registries	Rolfson et al. 2016 survey	Survey of 41 ISAR member registries	The most common generic PROMs used were the EuroQol 5-dimension health outcome survey (EQ-5D) and the Short Form-12 health survey (SF- 12), or the similar Veterans RAND 12-item health survey (VR-12). The most common specific PROMs were Hip/Knee disability and Osteoarthritis Outcome Score (HOOS) /(KOOS), Oxford Hip/knee Score (OHS)/(OKS), WOMAC and University of California at Los Angeles Activity Score (UCLA).
Assessment of outcomes after total knee Arthroplasty – are we there yet?	Hossain et al. 2015 Review article	Strengths & limitations of assessment methods, PROMs. Objective assessment. Interoperation of outcomes.	PROMs will continue to play a prominent role in assessing performance and determining the comparative effectiveness of different treatments for arthroplasty. KOOS, OKS, WOMAC: have limitations in assessing recreational and another ADL. Activity extension PROMs are required to minimize the celling effect. New scale: forgotten joint score, TK function, HAAS.
Measures of Knee Function review	Collins et al. 2011 Review	9 reported outcomes: IKDS, KOOS, KOOS-PS, KOOS-ADL, LKSS, OKS & WOMAC	IKDS: knee pathology. KOOS: young/middle age post trauma/ OA. KOOS-PS: OA. KOOS-ADL: young & old undergoing all pathologies. OKS: post-TKR WOMAC; knee & hip OA. ARS: sport with knee disorders. LKSS: instability. Internal & intra- reliability, validity. With consideration of reliability, validity, ceiling/ floor effect and effect size, no gold standard measure for knee function.

Table 2-2. Characteristics and results of Patient-reported Outcomes Measures, Systematic Review Studies (2/2)

Research title	Author	Subject	Results
Patient-reported outcome measures after total knee arthroplasty review	Ramkumar et al. 2015 review	38 articles 47 PROMS post-surgery	Only 6 of 38 surveys acknowledge all gold standard psychometric properties: OKS, KSS, KOOS, WOMAC. KSS, OKS: shorter than KOOS, WOMAC (33 vs 42 items). OKS, KSS: general level of pain (OKS: entirely patient driven/ KSS component completion by surgeon) KOOS: emphasis on sport, recreation, quality of life.
Utility of Outcome Measures in Total Knee Replacement Surgery	Dowsey et al. 2013 review article	OKS, KOOS, WOMAC, KSS	Outcomes captured post-TKA depend on many factors, such as score used, analysis of scores and timing used post-surgery.
Outcome measures capturing ICF domains in patients with TKA	AlNahdi et al. 2014 review article	Review article up to March 2014	Pain (VAS/ NVAS), ROM (joint mobility), Muscle performance (quads, abd.), Self-reported activity: WOMAC, LEFS, KOOS. Performance-based measures of activity: 30s chair-stand test, 40m fast-paced walk test, stair-climb test, 6-min. walk test, TUG test had strengths & limitations.
Do the patient-reported outcome measures used in assessing rehabilitation outcomes after hip and TKA capture issues relevant to patients?	Alviar et al. 2011 review article	Compare the contents of PROMs with International Classification of Functioning Disabilities and Health	All tools cover general mobility but lack driving, assisting others, interpersonal relationships and community life. Majority do not address environmental factors, such as having the support of family members, neighbors and health workers. Balance between complexity and simplicity is essential.

Table 2-3. Critical Appraisal Skills Program (CASP) for Patient- reported Outcome Measures for Cohort Papers.

CASP	Criterion	Hamilton 2012	Khanna 2011	Mizner 2011	Kauppila 2011
Validity of results	Study design	YES	YES	YES	YES
	Population defined	YES	YES	YES	YES
	Risk factors exposed/ described	YES	YES	YES	YES
	Outcomes defined	YES	YES	YES	YES
	Clear detection of beneficial/ harmful effects	NA	NA	NA	NA
	Represents a defined population	YES	YES	YES	YES
	Includes all prospective population without bias in selection	YES	No	No	YES
	Uses subjective/ objective measures	YES	YES	YES	YES
	Uses valid measures	YES	YES	YES	No
	All subjects have the same exposure procedure	YES	YES	YES	YES
	Establishes a reliable system to detect all cases	YES	YES	YES	YES
	Subjects/ assessors blinded	NA	YES	NO	YES
	Identifies important confounding factors	NO	NO	NO	YES
	Consider confounding factors in the design/ analysis	YES	NO	NO	YES
	Enough follow-up length	YES	YES	YES	YES
	Follow-up of subjects sufficient	YES	YES	NO	NO
The results	Bottom line of results	YES	YES	YES	YES
	Reports rates/ proportions	NO	YES	NO	YES
	Strength of association/ RR	NO	NA	YES	NO
	Absolute risk reduction/ ARR	NO	NA	NO	NO
	Confidence-interval range	YES	YES	YES	YES
	The effects of bias, chance and confounding factors have been minimised in the results.	YES	NO	NO	NO
	Reliable methods/ study design	YES	YES	YES	YES
Results value	Results applicable to local population	YES	YES	YES	NO
	Cohort design appropriate to answer the research question	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES
	Relevant to present evidence base?	YES	YES	YES	YES
	Supported by stronger evidence, more than recommendations	NO	NO	NO	NO
	Total score	23/28 82%	23/28 82%	19/28 68%	21/28 75%

Table 2-4. Characteristics and results of Patient-reported Outcomes Measures for Observational Cohort Studies.

Research title	Author/ study type	Subjects	Methods	Results
Comparative outcomes of total hip and knee arthroplasty: a prospective cohort	Hamilton et al. 2012 prospective cohort study	1,410 THA 1,244 TKA	Cohort study 2006–2008 OKS, SF-12, satisfaction pre-, 6 and 12 months	Mean pre-operative OKS scores were strong predictors of post-operation OKS Age, gender &general health does not influence the results. Regression modelling was not able to predict individual outcomes
Comparison of patient-reported and clinician-Assessed outcomes following total-knee arthroplasty	Khanna et al. 2011 cohort study	140 pt. post TKA follow-up Compare pt. assessments and three clinicians' assessments	Patient self-assessment via mailed, American Knee Society (AKS), Oxford Knee Score, ROM photographs and goniometer with instructions	AKS pain scores 4 points worse than clinicians', AKS function scores 10 points worse while OKS scores were similar. ROM may be reasonably self-assessed by comparison with photographs. Follow-up post-TKA used patient-reported measures, thus alleviating the burden of clinic visits yet maintaining contact.
Measuring Functional Improvement After TKA Requires Both Performance-Based and Patient-Report Assessments	Mizner et al. 2011 Prospective cohort	100 (52M, 48F) TKA 3 measurement periods (before, post-surgery 1 & 12 months)	PROM (SF-36, KOS). Performance-based measures (PBMs)of activity (TUG, SC.6MWT) physical impairment measures (pain, knee girth, knee ROM, quad. Strength).	PBMs & impairment decrease initially post OR and then increase in the long term. PBMs showed greater response than PROM. PROM showed NO response early and excellent in the long-term. Patient perception fails to capture acute functional decline post TKA & may overstate in the long term. Sig. relationships exist between physical impairments & PROMs & PBMs Pain is the strongest relation of all impairments at all stages
Outcomes of primary total-knee arthroplasty: impact of patient-relevant factors on self-reported function and quality of life	KAUPPILA et al. 2011 prospective	88 included (75 completed the study) 1-year follow up post-TKA	Pre-assessment and 1-year post-TKA Comorbid questions, Surgical background, Radiographs, WOMAC, HRQOL by 15D AROM	Low 15D pre-TKA, pain post-TKA, higher age and pre-pulmonary disease decrease the possibility to reach HRQOL of general population. More severe pain pre-TKA associated with higher recovery rate. Osteoporosis, male, poor contralateral knee function and higher age associated with lower degree of improvement. Outcomes of TKA: the impact of patient-relevant factors on self-reported function and quality of life.

Table 2-5. Commonly used Patient-reported Outcome Measures post-total knee arthroplasty in all included studies.

Study type	Study authors	Osteoarthritis Outcome Score (KOOS)	Oxford Knee Scale (OKS)	Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)	University of California at Los Angeles Activity Score (UCLA)	New Knee Society Score (KSS)
Systematic review	Rolfson et al. 2016	√	√	√	√	
	Hossain et al. 2015	√	√	√		
	Collins et al. 2011	√	√	√		
	Ramkumar et al. 2015	√	√	√		√
	Dowsey et al. 2013	√	√	√		√
	Alnahdi et al. 2014	√		√		
	Alviar et al. 2011	√	√	√		
Observational Cohort	Hamilton et al. 2012		√			
	Khanna et al. 2011		√			
	Mizner et al. 2011	√				
	Kauppila et al. 2011			√		

During the second stage of the patient-reported outcome measures literature search these keywords were used:

Post primary total knee arthroplasty OR post primary total knee replacement OR TKA OR TKR	AND Knee injury and osteoarthritis outcome score OR KOOS AND reliability OR validity OR responsiveness OR Sensitivity OR measurement properties
	AND Oxford Knee Score OR OKS AND reliability OR validity OR responsiveness OR sensitivity OR measurement properties
	AND Western Ontario and McMaster Universities Arthritis Index OR WOMAC AND reliability OR validity OR responsiveness OR sensitivity OR measurement properties.

Studies were included if they satisfied the following:

Any study assessing the measurement properties of Knee injury and Osteoarthritis Outcome Score (KOOS) or Oxford Knee Score (OKS) or Western Ontario and McMaster Universities Arthritis Index (WOMAC) in patients undergoing TKA at any point in time post-TKA for adult subjects, without any limitation regarding publication date, in order to explore original developments in PROMs.

Exclusion criteria:

All cross-cultural translation and validation not in English or Arabic was excluded.

Validation or reliability evaluations of other pathology subjects, rather than post-TKA, were excluded. Thus, post-knee injuries, ACL and knee OA studies were excluded. A PRISMA search strategy was summarised in Flow Diagram 2-3 for the second stage.

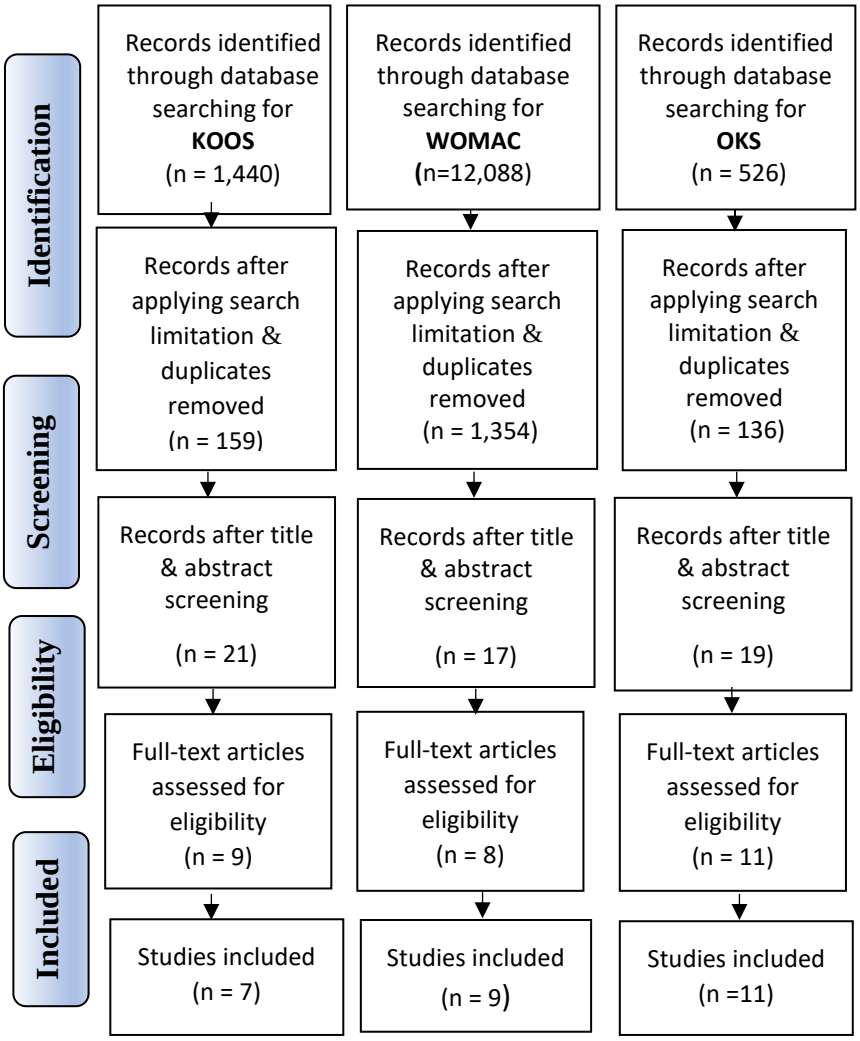

Figure 2-3. PRISMA Flow Diagram for Common Patients Reported Outcome Measures.

2.2.1.1 Knee Injury and Osteoarthritis Outcome Score (KOOS)

KOOS is an extension of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), which has remained unchanged since 1998. The main purpose of KOOS is to measure the short- and long-term follow-up of patients' opinions about their knee and accompanying problems, with good coverage of function in terms of joint mobility, stability, stiffness, sensations of pain, activities of daily living, sport, recreation and knee-related quality of life, as the intended population is the young and middle-aged with post-knee injuries or trauma and patients with knee osteoarthritis. The primary strong point for KOOS is a short function score which covers functional requirement assessment suitable for active participants while minimising the ceiling effect (Collins et al., 2011; Peer & Lane, 2013; Roos, Roos, Lohmander, Ekdahl, & Beynnon, 1998).

It contains 42 items across five subscales: severity and frequency of pain during daily functional activities; severity of knee symptoms such as stiffness, range of motion, clicking, grinding, catching, hang-up and swelling; experiencing difficulty in activities of daily living; experiencing difficulty in sport and recreation; and, finally, knee-related quality of life (Collins et al., 2011; Peer & Lane, 2013; Roos, Roos, Lohmander, Ekdahl, & Beynnon, 1998).

The main objectives of this search were to explore original studies of KOOS development and other studies assessing the reliability, validity and responsiveness post-TKA were included. After title-screening and duplicate exclusion, 21 studies satisfied the inclusion criteria clarified in the previous section. Abstract screening for 7 papers satisfied the eligibility criteria and these were included in the review. The remaining 14 papers were excluded because: for 5 papers the full text was not available, and 9 papers examined KOOS along with other knee injuries (Figure 2-4). Two studies in Arabic were analysed, although they assessed patients diagnosed with knee osteoarthritis, anterior cruciate ligament and meniscus injuries. The quality of all six included studies was assessed according to CASP and the results are summarised in Table 2-6, while their full characteristics and results are presented in Table 2-7.

There is no universal gold standard for patient-reported outcome measures to explore construct validity. KOOS was originally validated for knee injuries and shows moderate correlation with SF-36 scales as they have similar structures: r= 0.57 for sport, r=0.47 for recreation and r=0.46 for pain. Test-retest reliability is high for all items, the correlation coefficient for pain is 0.85, for knee symptoms it is 0.93, for daily living activities 0.75, for recreation and sport 0.81 and for knee-related quality of life 0.86. KOOS shows significant

changes over time post-operation at 3, 6 and 12 months in all scores (Friedman's test P< 0.02), and the effect size is high at > 0.8 for all subscales, especially for sport, recreation and knee-related quality of life (Roos et al., 1998).

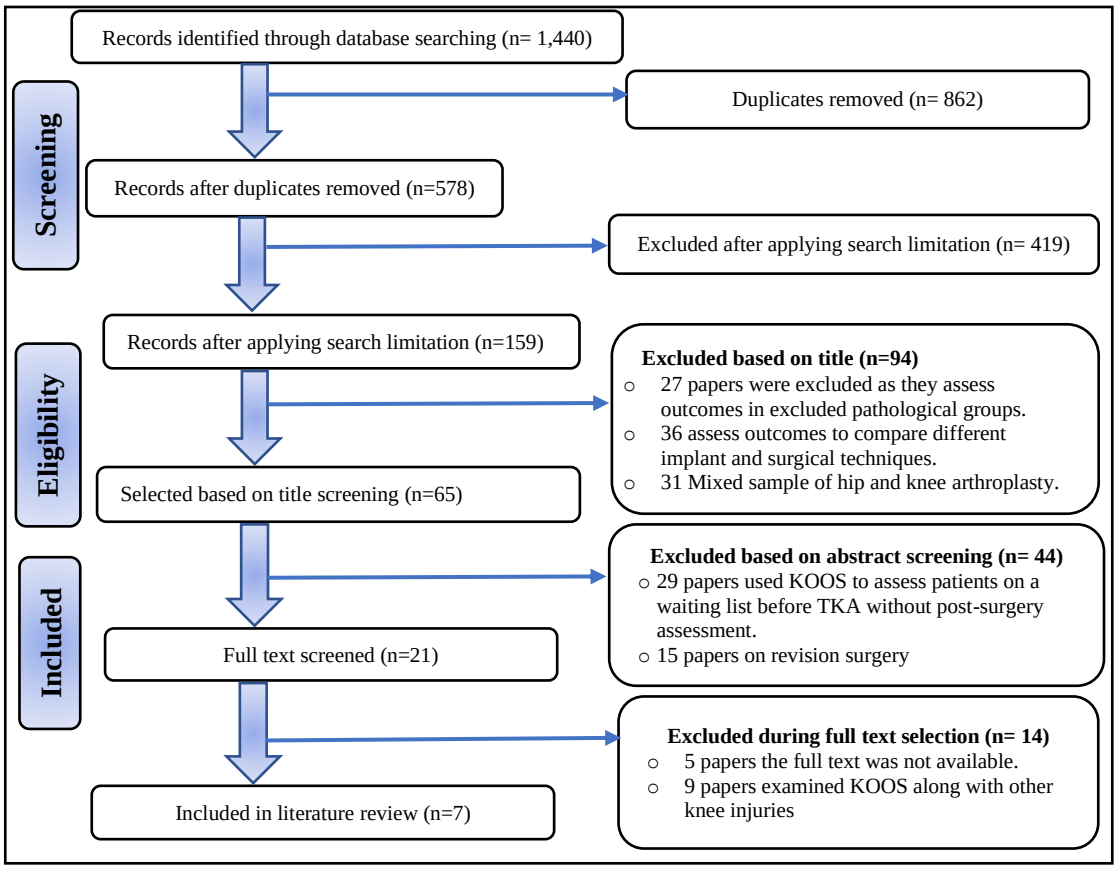

Figure 2- 4. PRISMA Flow Diagram for Knee Injury and Osteoarthritis Outcome Score (KOOS) Post-Total knee arthroplasty.

The reliability and validity of KOOS with post-TKA populations were evaluated by Roos & Toksvig-Larsen (2003), where the study found good reliability and validity. ICC was more than 0.75 for all sub-scores and had a moderate correlation with SF-36. The knee-related quality of life subscale showed a maximum response with effect sizes of 2.86 and 3.54 at 6 and 12 months, respectively. Pain was the second response, with effect sizes of 2.28 and 2.55 at 6 and 12 months, respectively. A possible ceiling effect post-TKR at 6 months for the pain and sport subscale was in the acceptable range. However, at post-12 months the range reached 22% on the pain subscale.

A Japanese retrospective correlation study of KOOS used the Knee Society Score (KSS), Japanese Orthopaedic Association (JOA) score and X-ray findings as objective measures. The study concluded that there was a significant correlation between KOOS scores and all scores on KSS and JOA. There was a strong correlation between KOOS ADL, function KSS

scores and surgeons' satisfaction, but weak correlation between KOOS QOL, radiological findings, JOA and KSS. These results highlight the need to use other outcome measures to assess patients' QOL and satisfaction post-TKA, in addition to the available PROMs (Sasaki et al., 2014).

The short physical function of KOOS (KOOS-PS) contains only seven items to assess function but shows similar validity and responsiveness to the 17 function items of the WOMAC scale and good internal consistency (Davis et al., 2009). KOOS-PS assesses patients post-TKA with the same quality as WOMAC, but without redundant items (Ryser, Wright, Aeschlimann, Mariacher-Gehler, & Stucki, 1999).

The Arabic version of KOOS is a valid and reliable PROM to measure physical function for post-anterior cruciate ligament (ACL) knee injuries and in knee osteoarthritis patients (Almangoush et al., 2013; Torad, El Kader, Saleh, & Torad, 2015). However, no previous study has explored the Arabic version's validity, reliability and responsiveness for patients post-TKA.

In conclusion, KOOS is a valid, reliable and responsive assessment tool for patients post-TKA, it has certain advantages over WOMAC and OKS, especially in groups with high physical activity expectations and younger subjects. It also evaluates knee-related quality of life, which is a crucial issue for the majority of patients post-TKA, something not covered by WOMAC or OKS (Roos & Toksvig-Larsen, 2003). Most of the subjects in all three studies were females and their ages ranged from 43 to 82 years; it was concluded that the results indicate that KOOS has sufficient validity and reliability post-TKA. Special consideration is required if KOOS is used for a 12-month follow-up as the ceiling effect reaches 22% on the pain scale and 17% for quality of life, which are above the acceptable ceiling effect percentage of 15% (Terwee et al., 2007). Hence it is recommended to use other measurement scales for patient quality of life and expectations, rather than KOOS (Sasaki et al., 2014).

Table 2- 6. Critical Appraisal Skills Program (CASP) for Knee Injury and Osteoarthritis Outcome Score (KOOS) reliability and validity studies.

CASP	Criterion	Roos et al. 1998	Roos et al. 2003	Sasaki et al. 2014	Davis et al. 2009	Almangoush et al. 2013	Torad et al. 2015
Validity of results	Population defined	YES	YES	YES	YES	YES	YES
	Intervention described	YES	YES	YES	YES	YES	YES
	Study design	YES	YES	YES	YES	YES	YES
	Outcome defined	YES	YES	YES	YES	YES	YES
	Patient randomization (recruitment)	NO	YES	YES	NO	NO	NO
	Researchers/ assessors blinded	NO	NO	NO	NO	NO	YES
	Similar group baseline	NO	NO	YES	NO	NO	NO
	Equal intervention	YES	YES	NO	YES	NO	YES
	All subjects accounted for in conclusion	YES	YES	YES	YES	YES	YES
Results	Clearly defined outcomes	YES	YES	YES	YES	YES	YES
	Non-selective reporting of outcomes	YES	YES	YES	YES	YES	YES
	Appropriate statistical methods	YES	YES	YES	YES	YES	YES
	Statistically significance reported	YES	YES	YES	YES	YES	YES
Results value	Inferential statistics employed	YES	YES	YES	YES	YES	YES
	Generalizability	YES	YES	YES	YES	YES	YES
	Confidence intervals presented	YES	YES	YES	YES	YES	YES
	Clinical relevance defined	YES	YES	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES	YES
	Relevant to present evidence base?	YES	YES	YES	YES	YES	YES
	Total score	16/19 84%	17/19 89%	17/19 %89	16/19 84%	15/19 79%	17/19 %89

Table 2-7. Characteristics and results of Reliability and Validity Studies for Osteoarthritis Outcome Score (KOOS) – (1/2).

Research Title	Author	Subjects	Methods	Results
Knee Injury and Osteoarthritis Outcome Score Development of a Self-Administered Outcome Measure	Roos et al. 1998	21 post ACL and meniscus repairs (9 males, 12 females) Ages 18–46 years	Test-retest reliability Correlation with SF-36	High reliability for all subscales; ICC for pain .85, symptoms .93, ADL .75, sport .81 and quality of life .86. High correlation between SF and KOOS for all scores. ADL r=.57, sport r=.47, pain r=.46. Low correlation with mental scores (convergent validity). High effect size > .8 for all scales with significant changes post-operation.
Knee Injury and Osteoarthritis Outcome Score (KOOS) – validation and comparison with WOMAC in total knee replacement	Roos et al. 2003	105 post-TKA (6–12 months) Ages 43–86 years 39 males and 66 females	Prospective evaluation of test-retest reliability and validity	ICC for 54 pt. 0.75 with no significant changes between two measures. Construct validity shows high correlation between KOOS & SF36. Rs=.62 pain, .48 ADL. Low correlation with mental scores (convergent validity). Responsiveness: significant improvement p<.001, effect size for quality of life 2.86–3.54 at 6/12 months, respectively; pain 2.28–2.55 at 6/12 months, respectively; sport 1.18–1.08 at 6/12 months, respectively. No floor effect pre-TKA, but ceiling effects at: 6 months: 15% pain score, 16% sport; 12 months: 22% pain, 17% quality of life.
Relationship between patient-based outcome scores and conventional objective outcome scales in post-operative TKA patients	Sasaki et al. 2014	130 patients post-TKA (16 males, 114 females) 91.4% post-primary TKA 74.0±8.0 years old	Retrospective study 2002–2010 Correlation study	KOOS subscale significantly correlated with all the objective scales of Japanese Orthopedic Association scores and KSS. KOOS ADL strongly correlated with surgeons' satisfaction, KSS function score, CC= .80–.83. Strong correlation between KSS and KOOS pain score, CC=.68. Moderate correlation between KSS and KOOS symptoms, sport and QOL. Weak correlation between KOOS and surgeons' satisfaction, CC 188–.32. It is recommended to use other types of outcome measurements with objective conventional scales to explore QOL and patients' satisfaction.

Table 2-7. Characteristics and results of Reliability and Validity Studies for Osteoarthritis Outcome Score (KOOS) – (2/2)

Research Title	Author	Subjects	Methods	Results
Comparative validity and responsiveness of HOOS-PS and KOOS-PS to WOMAC physical function subscale in total joint replacement for osteoarthritis	A. Davis et al. 2009	Post THA & TKA TKA =248 Mean age 64.5 years 63% female	Internal consistency of KOOS-PS. Construct validity & responsiveness compared to WOMAC.	Cronbach's alpha = .89, which indicates a homogeneous construct and good internal consistency. Correlation with physical functions r=.90, with physical function exclusion r=.85, which indicates similar construct validity & responsiveness to WOMAC's 17 function items. Short physical function KOOS is a short homogenous scale with a similar construct validity and responsiveness to 17 items of WOMAC
Cross-cultural adaptation, reliability, internal consistency and validation of Arabic version of the Knee injury and Osteoarthritis Outcome Score (KOOS) for Egyptian patients with knee injuries	Almangoush et al. 2013	129 patients diagnosed with ACL injury, meniscus & both. 99 males, 30 females Mean age 30.8 years	Translation, cross-cultural adaptation, reliability & validity assessment of Arabic version	Reliable and valid in ACL, meniscus injury Cronbach's alpha coefficients of .80 and .95, ICC= .88–.96 Construct validity with higher correlation, similar constructs to KOOS subscale, RAND-36 and VAS. Only a 3.1% ceiling effect on ADL scale & a 1.6% floor effect on sport/ recreation scale. Recommendation for Arabic version: validation with greater age range and other pathologies.
Validity and reliability of the Arabic version of KOOS-physical function short form in knee osteoarthritic patients	Torad et.al 2015	69 patients diagnosed with knee OA. 52 females 17 males Mixed unilateral & bilateral knee OA	Translation, reliability & validity assessment of Arabic version	Index of content validity 97.14% – excellent content validity Good test re-test internal consistency with Cronbach's alpha of .848. Good test re-test internal consistency, Spearman's correlation coefficients 0.7–0.9

2.2.1.2 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

WOMAC is one of the commonly used specific PROMs for lower-limb dysfunction in osteoarthritis, it has been used for over 30 years, with different patient pathologies, to evaluate changes in patients' status post-therapeutic intervention. Originally, it assessed pain, joint stiffness and physical function in hip/knee osteoarthritis patients. Pain, stiffness and physical function subscales assess 24 items: five items assess pain during daily activity (standing, walking, climbing stairs, sitting and lying in bed) and two items assess joint stiffness. The physical functions covered by the remaining 17 items include stair use, sit-to-stand, standing, walking, getting in/out of a car, shopping, putting on/ taking off socks, getting out of bed, bending, lying in bed, getting in/ out of a bath, sitting, getting on/ off a toilet, heavy and light household duties. It has validated paper, telephone and electronic versions (Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988).

It was originally validated for knee and hip osteoarthritis patients within a double blinded randomized study investigating the effects of two different types of anti-rheumatic drugs on osteoarthritis hip/ knee patients. The pain, stiffness and physical functions fulfil the criteria required for content, construct and face validity. WOMAC is a reliable and responsive specific PROM in osteoarthritis. Cronbach's alpha for pain, stiffness and function were, respectively, 0.86–0.89, 0.90–0.91 and 0.90. The test-retest reliability with a one-week interval was 0.68 for both pain and function and 0.48 for stiffness (Bellamy et.al. 1988).

According to the search keywords used, the main concerns were specific PROMs post-TKA and original studies of WOMAC's development, other studies assessing its reliability, validity and responsiveness with patient's post-TKA were included (Figure 2-2). The search keywords explored studies assessing the entire criteria of WOMAC with post-TKA populations; minimal important changes and relations with other measurements tools were included too. After title-screening and duplicate exclusion, 17 studies satisfied the inclusion criteria clarified in the previous section; 3 studies were excluded as the full text was not available; 5 papers used WOMAC to assess patients on a waiting list before TKA without post-surgery assessment; the remaining 9 papers satisfied the eligibility criteria and were included in the review (Figure 2-5). The quality of all nine studies included was assessed according to CASP and is summarised in Table 2-8 for cohort studies, Table 2-9 for systematic reviews and Table 2-10 for clinical study designs. The full characteristics and results are summarised in Table 2-11.

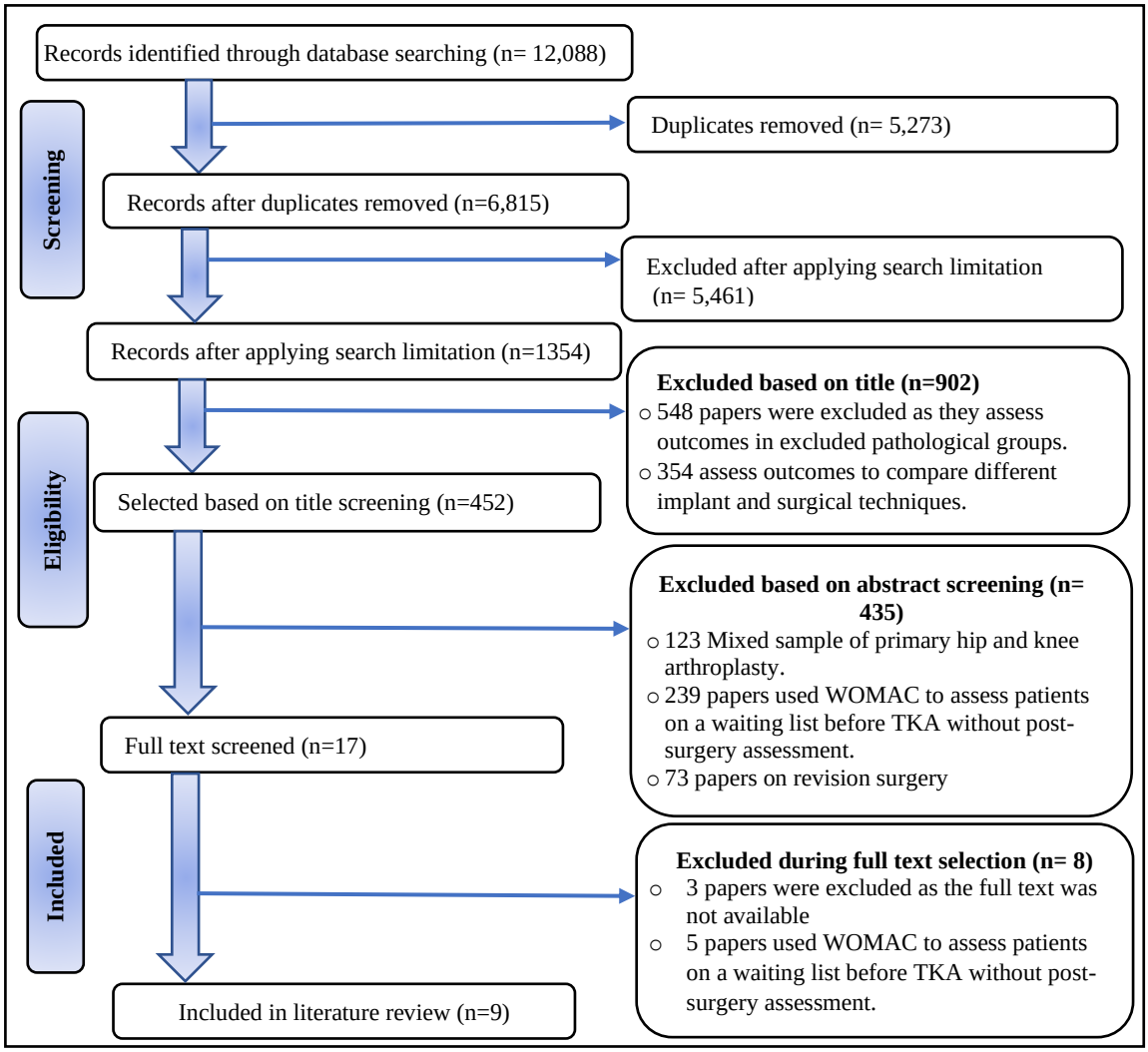

Figure 2- 5. PRISMA Flow Diagram for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Post-Total knee arthroplasty.

The validity and reliability of WOMAC with post-TKA populations were confirmed in the Swedish and German versions only. The Swedish version was used on 3,600 patient's post-TKA and assessed the validity, reliability and responsiveness of WOMAC, Lequesne and Oxford. The results showed no differences in the response rate, but the completed questionnaire was highest for Oxford at 89.4%, with WOMAC at 83%. WOMAC took the longest time to complete at an average 11.7 minutes. The ceiling effect for WOMAC was highest at 18.3% and 0.8% for floor effect. Reliability for pain, stiffness and physical functions was, respectively, 0.95, 0.90 and 0.92 (Dunbar, Robertsson, Ryd, & Lidgren, 2001). A German study concluded that WOMAC had a global effect size of 2.25–2.34. The explanation for the inferior response of WOMAC was the low sensitivity of a stiffness sub-scale. WOMAC's pain and function was more responsive than the Lequesne scale (Theiler et al., 1999).

The relative efficiency (RE) of WOMAC with a post-TKA population was assessed and compared with the Health Assessment Questionnaire (HAQ) and Arthritis Impact Measurement Scale (AIMS). The results indicated that WOMAC was more efficient for assessing physical function and pain than HAQ. AIMS was more efficient for assessing pain. The RE of WOMAC versus AIMS was greater for physical function (1.75) and less for the pain subscale (0.80). The RE of WOMAC versus HAQ was greater for both pain and physical function (1.59–1.13) (Griffiths et al., 1995).

In contrast, a recent study compared WOMAC's responsiveness with specific and generic PROMs and the results showed that specific PROMs were more responsive than generic ones post-TKA. WOMAC is not recommended post-TKA as its stiffness subscale shows the worst effect size and standardized response mean at the baseline and until 24 months' follow-up. WOMAC's stiffness ceiling effect was 14.6%, 29%, 51%, 64% and 39% at the baseline, 2, 6, 12 and 24 months post-TKA, respectively (Giesinger et al., 2014). The correlation coefficient results between SF-36 and WOMAC post-TKA for pain, physical function and overall score were 0.55, 0.50 and 0.55, respectively (Bombardier et al., 1995), which are below the acceptable value for ICC (Terwee et al., 2007).

A systematic review by (McConnell, Kolopack, & Davis, 2001) did not include any studies assessing WOMAC's reliability for a post-TKA population; however, construct validity showed moderate to strong correlation with other measurements post-TKA (SF-36, Nottingham Health Profile function scale, range of motion, radiology Kellgren rating) and their disability scales. The effect size post-TKA was large, 0.95–41 for pain, 0.88–24 for stiffness and 1.01–23.9 for function. The standardized mean response range was 0.63–1.99 (McConnell et al., 2001). Minimal clinically important differences (MCIDs) were around 15 points for WOMAC post-TKA and minimal detectable change (MDC) ranged from 13.11 for function to 29.12 for stiffness (Escobar et al., 2007). An updated systematic review assessed the measurement properties of WOMAC with a post-TKA population; it found acceptable ≥ .70 internal consistency reliability for pain and stiffness, and excellent ≥ .90-.95 functional internal consistency. Test-retest reliability was acceptable for pain and function but weak for stiffness. There was a high unacceptable floor effect for pain and stiffness of 20–26% (Gandek, 2015).

In conclusion, WOMAC shows moderate to strong validity and excellent physical function internal consistency with a large effect size. It has acceptable pain and stiffness internal consistency but weak stiffness test-retest reliability. The low sensitivity of WOMAC's stiffness subscale reduces the overall standardized response mean. The ceiling effect was

higher than the acceptable percentage of 15% (Terwee et al., 2007) at 6, 12 and 24 months (Dunbar et al., 2001; Gandek, 2015; Giesinger et al., 2014). These weaknesses in WOMAC's tools for a post-TKA population are enough to exclude it as an option for assessment tools in the current study.

Table 2-8. Critical Appraisal Skills Program (CASP) for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) cohort studies.

CASP	Criterion	Dunbar et al. 2001	Stucki et al 1998	Bombardier et al. 1995	Giesinger et al. 2013	Escobar et al. 2006
Validity of results	Study design	YES	YES	YES	YES	YES
	Population defined	YES	YES	YES	YES	YES
	Risk factors exposed/described	YES	YES	YES	YES	YES
	Outcomes defined	YES	YES	YES	YES	YES
	Clear detection of beneficial/harmful effects	YES	YES	YES	YES	YES
	Represents a defined population	YES	NO	YES	YES	NO
	Includes all the prospective population without bias	YES	NO	YES	NO	NO
	Uses subjective/objective measurements	YES	YES	YES	YES	YES
	Uses valid measurements	NO	YES	YES	YES	YES
	All subjects use the same exposure procedure	NO	NO	NO	YES	YES
	Establishes a reliable system to detect all cases	YES	NO	NO	NO	NO
	Subjects/assessors blinded	NO	NO	NO	NO	NO
	Identifies important confounding factors	NO	NO	NO	NO	NO
	Considers confounding factors in the analysis	NO	NO	NO	NO	NO
	Sufficient follow-up length	YES	YES	NO	YES	YES
	Follow-up complete for enough subjects	YES	NO	YES	YES	YES
Results	Bottom-line of results	YES	YES	YES	YES	YES
	Reports rates/proportions	NO	NO	NO	NO	NO
	Strength of association RR	NO	NO	NO	NO	NO
	Absolute risk reduction ARR	NO	NO	NO	NO	NO
	Confidence-interval range	YES	YES	YES	NO	YES
	The effects of bias, chance and confounding factors have been minimised in the results.	YES	NO	NO	NO	YES
	Reliable methods/ study design	YES	YES	YES	YES	YES
Results value	Results applicable to local population?	YES	YES	YES	YES	YES
	Cohort design is appropriate to answer the question	YES	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES
	Relevant to present evidence base?	YES	YES	YES	YES	YES
	Supported by evidence, more than recommendation	NO	NO	NO	NO	NO
	Total score	19/28 68%	15/28 53%	17/28 61%	17/28 61%	18/28 64%

Table 2-9. Critical Appraisal Skills Program (CASP) for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) systematic review studies.

CASP	Criterion	McCONNELL et.al 2001	Gandek et.al 2015
Validity of result	Population defined	YES	YES
	Intervention described	YES	YES
	Study design	YES	YES
	Outcome defined	YES	YES
	Addresses the research question	YES	YES
	Selects an appropriate study design	YES	YES
	Relevant studies included (contact with experts, unpublished, non-English)	NO	NO
	Assesses the quality of included studies	NO	YES
	Discusses results, variations/combined	NO	NO
Results	Clearly states the results	YES	YES
	Results expressed (numerically, odds ratios)	YES	YES
	Precision of results (confidence interval)	YES	YES
Results value	Results applicable to local population	YES	YES
	Considers all outcomes	YES	YES
	Are the benefits worth the cost?	YES	YES
	Relevance to present evidence base	NO	NO
	Total score	12/16, 75%	13/16, 81%

Table 2-10. Critical Appraisal Skills Program (CASP) for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) clinical studies.

CPSP	Criteria	Theiler et al. 1999	Griffiths et al. 1995
Validity of results	Population defined	YES	YES
	Intervention described	YES	YES
	Study design	YES	YES
	Outcome defined	YES	YES
	Patient randomization (recruitment)	NO	NO
	Researchers/assessors blinded	NO	NO
	Similar group baseline	NO	NO
	Equal intervention	NO	YES
	All subjects accounted for in the conclusion	NO	YES
Results	Clearly defined outcomes	YES	YES
	Non-selective reporting of outcomes	YES	YES
	Appropriate statistical methods	YES	YES
	Statistically significance reported	YES	YES
Results value	Inferential statistics employed	YES	YES
	Generalizability	YES	YES
	Confidence intervals presented	NO	NO
	Clinical relevance defined	YES	YES
	Are the benefits worth the cost?	YES	YES
	Relevant to present evidence base	YES	YES
	Total score	13/19, 68%	15/19, 79%

Table 2-11. Characteristics and results of Reliability and Validity Studies for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (1/3).

Research title	Author	Subjects	Methods	Results
Appropriate questionnaires for knee Arthroplasty	Dunbar et al. 2001	3,052 patients post-TKA Ages 57–94 years, 2,511 were females	Prospective study assessing the reliability and validity of specific PROMs (Lequesne, Oxford-12 and WOMAC)	No difference in response rate. Complete questionnaires were highest for Oxford at 89.4%, then WOMAC at 83%. WOMAC took the longest time to complete at 11.7 minutes, 95% CI 11–12.4. WOMAC had the highest ceiling effect at 18.3%, floor effect slightly higher than the others at 0.8%. WOMAC ICCs were 0.95 for pain, 0.90 for stiffness and .92 for function.
Superior responsiveness of the seven pain function sections of WOMAC as compared to the Lequesne-algofunctional Index	Theiler et al. 1999	43 baselines, both hip and knee, Complete, only 13 patients post-TKA. Mean age 68 years, 60% females	Correlation study of German version of WOMAC and self-administered Lequesne OA index Post-TKA & -THA follow-up for 1 year	Pain section was more responsive than others. WOMAC stiffness scale was less responsive than others. WOMAC's pain & function scales more responsive than Lequesne. WOMAC's effect size was 2.25, standardized response mean was 2.34. Lequesne effect size was 2.35, standardized response mean was 1.96. Explanation for the inferior response of WOMAC was the low sensitivity of the stiffness sub-scale.
The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): A Review of Its Utility and Measurement Properties	McConnell et al. 2001	43 articles measuring patient's post-arthroplasty, drug therapy, other surgical and non-surgical interventions	Review article evaluates the reliability, validity and responsiveness of WOMAC with four different knee pathologies	No included study assesses reliability post-TKA. 4 studies with OA and one post-total hip arthroplasty. It met the minimum standard and had low reliability for stiffness. Construct validity showed moderate to strong correlation with other measurements post-TKA (SF-36, Nottingham Health Profile function scale, range of motion, radiology Kellgren rating). 6 studies estimate a large effect size post-TKA. The range for pain was 0.95-41, for stiffness 0.88–24 and for function 1.01–23.9. Standardized response mean range was 0.63–1.99.

Table 2-11. Characteristics and results of Reliability and Validity Studies for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (2/3)

Research Title	Author	Subjects	Methods	Results
Comparison of a Generic and a Disease-Specific Measure of Pain and Physical Function After TKA	Bombardier et al. 1995	Included 826 patients post-TKA. Ages 67–99 years, 71% females 2–7 years post-TKA	Retrospective survey to assess the reliability and validity of WOMAC and SF-36	The correlation coefficients for pain and function and overall scores of SF-36 and WOMAC were 0.55, 0.50 and 0.55, respectively. This indicates that SF36 and WOMAC have similar dimensions but WOMAC measures a different aspect of outcomes when compared with generic SF-36.
A Comparative Study of the Relative Efficiency of WOMAC, AIMS & HAQ Instruments in Evaluating the Outcome of TKA	Griffiths et al. 1995	21 patients evaluated pre-/ 6 months post-TKA. Mean age 65 years, 50% females	Compared the relative efficiency (RE) of WOMAC, Health Assessment Questionnaire (HAQ)&Arthritis Impact Measurement Scale (AIMS)	The RE of WOMAC versus AIMS was greater for physical function (1.75) and less for the pain subscale (0.80). The RE of WOMAC versus HAQ was greater for both pain and physical function (1.59–1.13). WOMAC was more efficient for assessing physical function and pain than HAQ. AIMS was more efficient for assessing pain.
Comparative responsiveness of outcome measures for total knee arthroplasty	Giesinger et al. 2013	98 patients Mean age 68.1 years. 49% female	Prospective study assessment at five time points: pre- & 2, 6, 12, 24 months post-TKA. Compares responsiveness of WOMAC, Forgotten Joint Score (FJS-12), EQ-5D, Knee Social Score (KSS) and range of motion (ROM)	Pre-operative to 2 months: effect size (ES) -1.50. Standardized response means (SRMs) were highest for pain -1.18, and function -0.9. Baseline WOMAC stiffness floor effect was 12.4% and 14.6% ceiling effect. 2 months post-TKA, ceiling effect was 29%. 2–6 months, small ES and SRMs, WOMAC stiffness ceiling effect was 51.6%. 6–12 months: WOMAC stiffness performed the worst for ES & SRM. Ceiling effect was 64.4%. 12-24 months: WOMAC total score shows best SRM, at 0.31. Stiffness ceiling effect was 39.6%. Specific PROMs were more responsive than generic ones post-TKA. FJS was the most responsive tool in the current study, better than WOMAC & KSS.

Table 2-11. Characteristics and results of Reliability and Validity Studies for Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (3/3)

Research Title	Author	Subjects	Methods	Results
Measurement Properties of the Western Ontario and McMaster Universities Osteoarthritis Index: A Systematic Review	Gandek et al. 2015	76 articles, 6 of them TKA	Review articles for WOMAC's measurement properties	Acceptable ≥ .70 internal consistency for pain and stiffness, excellent ≥ .90-.95 functional internal consistency. Test-retest reliability acceptable for pain and function, weak for stiffness. High unacceptable ceiling effect for pain and stiffness 20–26%.
Responsiveness and clinically important differences for WOMAC and SF-36 after total knee replacement	Escobar et al. 2006	823 patients included after operations and only 364 complete the 2-year follow-up Mean age 71 years 75% females	Prospective study to evaluate responsiveness, minimal clinically important differences (MCIDs) and minimal detectable change (MDC)	6 months post-TKA: 27 for stiffness, 31 for pain. 6–24 months: WOMAC improved by 2–6 points. MCID ranged from 14.52 for stiffness and 22.87 for pain. MDC ranged from 13.11 for function to 29.12 for stiffness. In general, MICD post-TKA was around 15 in WOMAC.

2.2.1.3 Oxford Knee Score (OKS)

A final version of a 12-item questionnaire was developed to assess patients post-TKA after interviews with patients undergoing joint replacement and a multiple drafting process to identify their experiences and problems post-TKA since 1998. The main objective of the questionnaire was to measure the patients' perspective on outcomes post-TKA in a short, reliable, practical and valid way with good sensitivity to important clinical changes. The questionnaire elicited data on recall symptoms in the previous four weeks. It assessed the severity of pain and the ability to engage in the basic daily activities of living, such as personal hygiene, use of transportation, ability to walk pain-free, sit-to-stand movement, limping due to knee pain, kneeling, bed mobility and pain, housework, general stability, shopping and use of stairs (Dawson, Fitzpatrick, Murray, & Carr, 1998; Murray et al., 2007). The OKS score has been approved as a specific PROM to evaluate performance and for audit purposes post-TKA in England and Wales (Clement, MacDonald, Patton, & Burnett, 2015).

According to the search keywords used, the main concerns were specific PROMs post-TKA, original studies on OKS development, other studies assessing its reliability, validity and responsiveness, with patients post-TKA included. The search keywords explore studies assessing all the criteria of OKS with a post-TKA population, such as minimal important changes and gender differences; relations to other measurements tools were included too. After abstract-screening and duplication exclusion, 19 studies satisfied the inclusion criteria clarified in the previous section; 11 papers satisfied the eligibility criteria and were included in the review, while 4 studies were excluded as the full text was not available; 3 papers used OKS to assess patients on a waiting list before TKA without post-surgery assessment; and one paper on revision surgery (Figure 2-6). The quality of all eleven included studies was assessed according to CASP, the original study and the two Arabic translation were a clinical trial are summarised in Table 2-12; the other eight were cohort studies and are analysed in Table 2-13. The full characteristics and results are summarised in Table 2-14.

The original paper by Dawson et al., (1998) assessed OKS validity, reliability and responsiveness for post-TKA patients. The construct validity showed a moderate correlation with the American Knee Society (AKS) and significant agreement with SF-36 and the Stanford Health Assessment Questionnaire (HAQ) for pain and function items. Internal consistency based on Cronbach's alpha was 0.87 pre-operation and 0.93 six months post-

TKA. The test re-test correlation score was r=0.92 and Bland & Altman showed 89% for score differences between 0 ± 4 points. Interestingly, the effect size was larger than SF-36 at 2.19.

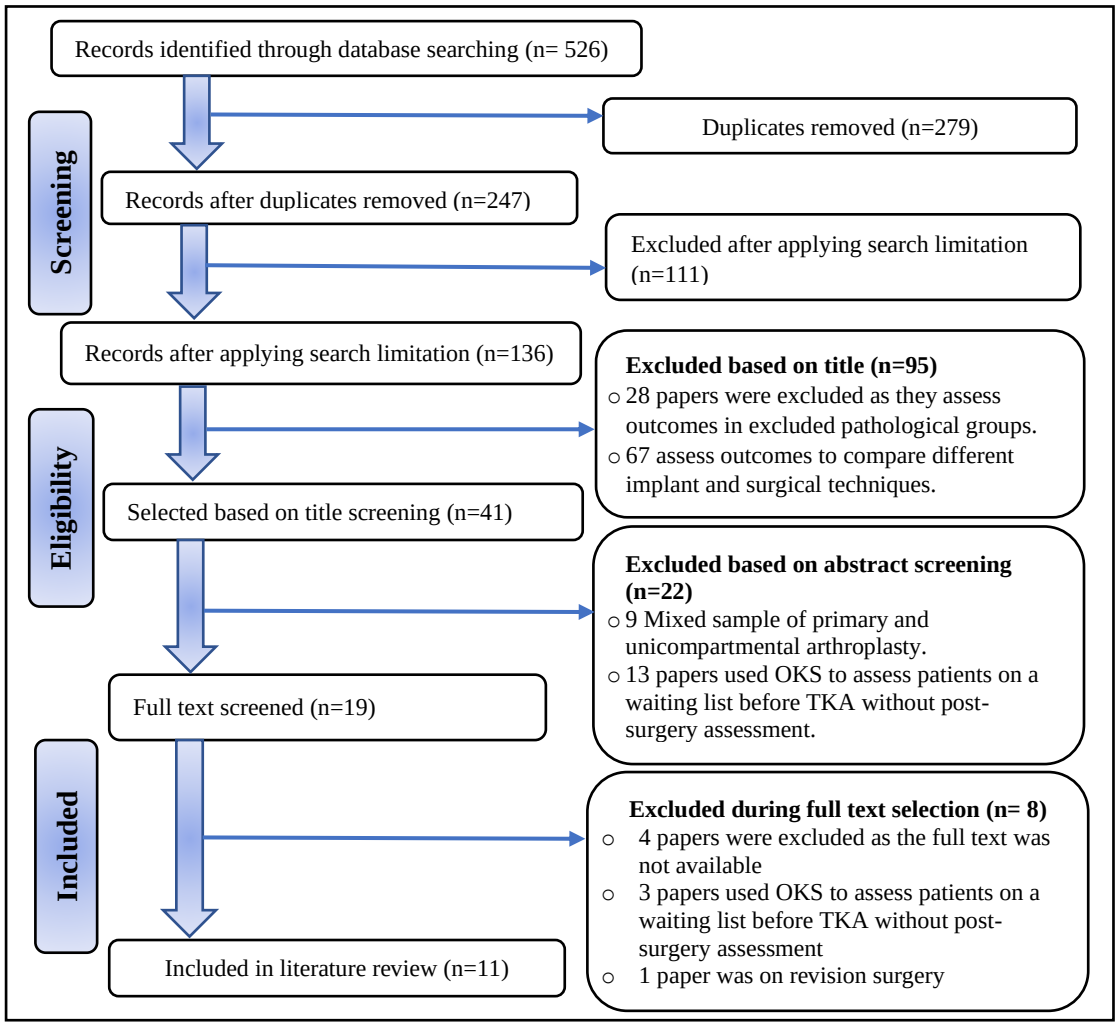

Figure 2- 6. PRISMA Flow Diagram for Oxford Knee Score (OKS) Post-Total knee arthroplasty.

A cross-cultural adaptation study by Alghadir et al. (2017) assessed the Arabic version of OKS, and found acceptable psychometric properties in that version, as well as significant correlation with WOMAC. The study was limited to male patients with a low mean age (Alghadir, Al-Eisa, & Anwer, 2017). The other paper that assessed the Arabic version of OKS, by Ahmed et al. (2019), was a mixture of knee pathology (30 subjects for anterior cruciate ligament reconstruction, 20 subjects for partial meniscectomy, 20 subjects for high tibial osteotomy, and only 30 subjects for total knee arthroplasty), so it is hard to isolate their knee arthroplasty findings as they encountered different problems (Ahmed, Said, Ramadan,

& El-Assal, 2019). Neither Arabic study assessed the responsiveness following TKA, or ceiling and floor effects, which are important to assess the sensitivity of the version to detect changes post-TKA and exclude type-2 errors from the conclusion (Giesinger et al., 2014).

The OKS ceiling effect post-TKA was assessed by (Marx et al., 2005) in a prospective cohort study of 58 patients post-TKA at 6- and 12-months follow-up. The results show that the percentage of patients receiving a score of 100 or equivalent (that is, a maximum or near-maximum score) was 5% (3 out of 58) and 7% (3 out of 46) at 6 and 12 months, respectively. Patients receiving a score of 100–95 or equivalent equated to 14% (8 out of 58) and 22% (10 out of 46) at 6 and 12 months, respectively.

OKS score has the advantage of accurate estimation of clinical, meaningful or minimal important changes (MIC) for each different study design. The MIC in one group as a cohort study or changes at the individual patient level over time were estimated using anchor-based methods, with 9 points for cohort change and 7 points for individual change. Minimal important difference (MID) detected difference changes between two groups in a clinical trial where there were 5-point changes (Beard et al., 2015). Agreement for post-TKA and MID between 4 and 5 points was concluded by Clement, MacDonald, & Simpson, (2014), even with different methodologies. Clement et al. (2014) used triangulation methods with multiple anchor questions to estimate MID, in addition to validating the correlation with patient satisfaction, functional recovery and pain relief. A study by Beard et al. (2015) estimated MID based on distribution-based methods using particular sample statistical characteristics to determine effect size, minimal detectable changes (MDC) and standard error of measurement. Although these studies differ in their methodologies, they draw the same MID score conclusion.

A retrospective study with an 8-year follow-up of 4,186 patients post-TKA concluded there was no further variation in OKS score after 0.9 years. This can be used as preoperative patient education to clarify the estimated time progression post-TKA. However, this curve timing requires further validation as patient inclusion was not represent as a consecutive series of patients post-TKA. This is because institutional policy does not routinely review patients post-TKA after one year unless they have a problem or complain about the replaced knee, which may affect their conclusion (Matharu, McBryde, Robb, & Pynsent, 2014).

Although all the included studies had more female than male subjects – it is in the nature of the disease that more females are affected by OA than males – this did not affect the results or conclusions, as no differences were found between them in terms of outcomes in the

medium term (two years). A prospective cohort study by Gen et al. (2015) with a two-year follow-up compared the differences between 71 males and 112 female aged-matched patients post-primary TKA using OKS and other outcome measures (knee range of motion, knee society score and SF-36). Although the females pre-TKA had higher body mass indices and poorer knee-flexion ranges of motion, the results for outcomes measures showed no significant differences between the two groups at a two-year follow-up (Gen, Bin Abd Razak, Chi, & Chye, 2015).

The relationship between patient-reported outcomes using OKS and other performance-based measures improves as patients report pain relief over time post-TKA. So, pain is a dominant factor that explains OKS variation in the first year post-TKA. The agreement between OKS and other objective performance measures, such as functional tasks, range of motion and muscle strength, improved with time from 35% pre-TKA to 62% at 12 months post-TKA (Hamilton et al., 2012).

In contrast, OKS post-TKA shows a moderate association with patient satisfaction (CI 0.45–0.60). The absolute change threshold was 11 points or more for all satisfied patients six months post-TKA, but further validation is required with a longer follow-up period before generalisation of this threshold can be used (Judge et al., 2012).

Post-TKA, OKS score's advantage is that it may be used to predict patients' expectations for achievement. However, some pre-operational expectations may require modification to improve patients' satisfaction post-TKA. Ten out of 17 patients' common preoperative expectations were significantly associated with poorer symptoms and worse OKS, although these expectations differed according to patient's age, gender and severity of symptoms pre-operation. A common expectation was an improved ability to walk, while common male patients' expectations were improved ability to straighten their legs, squat and kneel, and participate in sexual activity. In terms of an age effect on expectations, older patients expected they would not need a walking stick post-TKA. In contrast, younger patients' expectations included a return to employment, sport, recreation and sexual activity (Clement et al., 2015).

In conclusion, with OKS's valid, reliable and responsive assessment tools for the period post-TKA, it has advantages over WOMAC and KOOS, as it simple and short. As a PROM main concern is to explore outcomes from the patients' perspective, OKS has the advantage of offering clear MIC and MID values for all types of study and is designed to ensure that results are recognised by patients, in addition to statistical differences, and this may improve

the power calculation. The ceiling effect is more than acceptable at 12 months follow-up, as is KOOS (Terwee et al., 2007). In contrast, OKS do not assess knee-related quality of life and recreation as KOOS does. The available Arabic version of OKS is limited to only male patients with a low mean age and without responsiveness post TKA. So, a further examination of older individuals over a longer period post-TKA and of females is needed.

Table 2-12. Critical Appraisal Skills Program (CASP) for Oxford Knee Score (OKS) reliability and validity study.

CAPS	Criterion	Dawson et al. 1998	Alghdir et al. 2017	Ahmed et.al 2019
Validity of result	Population defined	Yes	Yes	Yes
	Intervention described	Yes	Yes	Yes
	Study design	Yes	Yes	Yes
	Outcome defined	Yes	Yes	Yes
	Patient randomization (recruitment)	No	No	No
	Researchers/assessors blinded	No	No	No
	Similar group baseline	No	NA	NA
	Equal intervention	Yes	Yes	Yes
	All subjects accounted for in conclusion	No	Yes	No
The results	Clearly defined outcomes	Yes	Yes	Yes
	Non-selective reporting of outcomes	Yes	Yes	Yes
	Appropriate statistical methods	Yes	Yes	Yes
	Statistical significance reported	Yes	Yes	No
Results value	Inferential statistics employed	Yes	Yes	Yes
	Generalizability	Yes	No	No
	Confidence intervals presented	Yes	Yes	NA
	Clinical relevance defined	Yes	Yes	Yes
	Are the benefits worth the cost?	Yes	Yes	Yes
	Relevant to present evidence base	Yes	Yes	Yes
	Total score	15/19, 79%	16/19, 84%	14/19, 74%

Table 2-13. Critical Appraisal Skills Program (CASP) for Oxford Knee Score (OKS) cohort studies.

CASP	Criteria	Beard et al. 2015	Marx et al. 2005	Clement et al. 2014	Clement et al. 2015	Hamilton et al. 2012	Matharu et al. 2014	Gen et al. 2015	Judge et al. 2012
Validity of results	Study design	YES	YES	YES	YES	YES	YES	YES	YES
	Population defined	YES	YES	YES	YES	YES	YES	YES	YES
	Risk factors exposed/described	YES	YES	YES	YES	YES	YES	YES	YES
	Outcomes defined	YES	YES	YES	YES	YES	YES	YES	YES
	Clear detection of beneficial/harmful effects	YES	YES	YES	YES	YES	YES	YES	YES
	Represents a defined population	YES	YES	YES	YES	YES	YES	YES	YES
	Includes all prospective population without bias	YES	NO	YES	YES	YES	NO	YES	YES
	Uses subjective/objective measurements	YES	YES	YES	YES	YES	YES	YES	YES
	Uses valid measurements	YES	YES	YES	YES	YES	YES	YES	YES
	All subjects use same exposure procedure	NO	NO	YES	YES	NO	NO	YES	NO
	Establishes reliable system for detecting all cases	NO	YES	YES	YES	YES	NO	YES	NO
	Subjects/assessors blinded	NO	NO	NO	NO	NO	NO	NO	NO
	Identifies important confounding factors	NO	NO	NO	NO	NO	NO	NO	NO
	Considers confounding factors in the analysis	NO	NO	NO	NO	NO	NO	NO	NO
	Sufficient follow-up length	NO	YES	YES	YES	YES	YES	YES	NO
	Follow-up sufficient	YES	YES	YES	YES	YES	YES	YES	YES
Results	Bottom line of results	YES	YES	YES	YES	YES	YES	YES	YES
	Reports rates/proportions	NO	NO	NO	YES	NO	NO	NO	YES
	Strength of association RR	NO	NO	NO	NO	NO	NO	NO	NO
	Absolute risk reduction ARR	NO	NO	NO	NO	NO	NO	NO	YES
	Confidence-interval range	YES	NO	YES	YES	NO	NO	NO	YES
	The effects of bias, chance and confounding factors have been minimised in the results.	YES	YES	YES	YES	YES	NO	YES	YES
	Reliable methods/ study design	YES	YES	YES	YES	YES	NO	YES	YES
Results value	Results applicable to local population	YES	YES	YES	YES	YES	YES	YES	YES
	Cohort design is appropriate	YES	YES	YES	YES	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES	YES	YES	YES
	Relevant to present evidence base	YES	YES	YES	YES	YES	YES	YES	YES
	Supported by evidence, more than recommendation	YES	NO	YES	NO	NO	NO	NO	YES
	Total score	19/28 68%	18/28 64%	22/28 78%	22/28 78%	19/28 68%	15/28 54%	20/28 71%	21/28 75%

Table 2-14. Characteristics and results of Reliability and Validity Studies for Oxford Knee Score (OKS) (1/3).

Research Title	Author	Subjects	Methods	Results
Questionnaire on the perceptions of patients about total knee replacement	Dawson et al. 1998	66 females. 51 males. Age range 46–89 years. 86% primary knee arthritis, 8% secondary arthritis	Reliability, validity and responsiveness assessments of new OKS score	Cronbach's alpha to assess internal consistency was .87 pre-TKA and .93 6 months post-TKA. Test-retest to assess reproducibility in terms of total score correlation r=.92. p<0001, and Bland & Altman showed 89% of score differences between 0 ±4 points. Construct validity showed moderate correlation pre-TKA with American Knee Society AKS. Significant agreement with SF-36 & HAQ. The effect size was larger than SF-36 at 2.19.
Cross-cultural adaptation and psychometric analysis of the Arabic version of the Oxford Knee Score in adult male with knee osteoarthritis	Alghadir et.al 2017	97 males (age 57.55 ± 11.49 years) with knee OA	Reliability, validity assessments of Arabic translated version	Reliability and internal consistency were high with an ICC of 0.97, and the Cronbach's alpha coefficient of 0.987, respectively. A significant relationship between the OKS-Ar and the WOMAC and VAS scores confirmed the construct validity ($p < 0.001$).
Arabic translation and validation of three knee scores, Lysholm Knee Score (LKS), Oxford Knee Score (OKS), and International Knee Documentation Committee Subjective Knee Form (IKDC)	Ahmed et.al. 2019	100 patients with knee problems; ligamentous injuries, meniscus injuries, and osteoarthritis age (18-70 years).	Reliability, validity assessments of Arabic translated version	OKS reliability was good 0.85. The Cronbach's ά was excellent 0.90 Construct validity was high 0.91

Table 2-14. Characteristics and results of Reliability and Validity Studies for Oxford Knee Score (OKS) (2/3)

Research title	Author	Subjects	Methods	Results
Meaningful changes for Oxford hip and knee scores after joint-replacement surgery	Beard et al. 2015	94,502: only 60% of them completed both pre-/ post-OKS. 94,015 completed a global assessment. 55.5% were females.	Retrospective study estimated minimal important changes (MIC) and minimal important differences (MID) Pre-/ 6 months post-TKA	Anchor-based methods estimated MIC for single groups, such as cohorts and individual patients post-TKA. MIC for cohort study = 9 points, for individual level = 7 points. Distribution-based methods estimated MID between two groups, such as a clinical trial. MID for two groups estimated post-TKA= 5 points.
Measuring improvement following total hip and knee arthroplasty using patient-based measures of outcomes	Marx et al. 2005	58 post-primary TKA 42–90 years 62% were female	Prospective study using MODEMS, WOMAC and OKS	Descriptive analysis without a power calculation. Majority of patients 12 months post-TKA felt their knee was normal and gave a score of 100. Minority of them responded 'knee could be better and there is room for improvement', which indicates the presence of a ceiling effect. The percentages of patients giving a score of 100 or equivalent at 6 and 12 months, respectively, were 5% and 7%. The percentages of patient giving a score of 95–100 or equivalent at 6 and 12 months, respectively, were 14 % and 22%.
Minimal clinically important differences in the Oxford Knee Score and Short Form-12 score after TKA	Clement et al. 2014	505 post primary TKA 210 males 295 females Ages 39–91 years	Retrospective cohort study to estimate minimal clinical important differences in MCID	Minimal clinical important differences (MICD) for OKS power the study and ensure the results are recognised by patients, in addition to highlighting statistical differences. Significant improvements in both OKS and SF-12 at one year. Increased level of satisfaction with pain relief and function correlated with OKS improvement. MICD for OKS and SF-12 4–5 points for both pain relief and function.
An analysis of Oxford hip and knee scores following primary hip and knee replacement performed at a specialist center	Matharu et al. 2014	4,186 patients post-TKA 61% females Av. age 69.2 years	Retrospective assessment of post-primary TKA data OKS 1997–2001 pre-/ post-surgery	The median time for absolute OKS changes post-TKA at which there was no further variation was 0.9 years. The plot changes can be used as a performance monitor for surgeons and as pre-operation education for patients to modify their expectations. The plot produced requires validation before use. Limitations of the study were inconclusive patient inclusion and the presence of only descriptive analysis.

Table 2-14. Characteristics and results of Reliability and Validity Studies for Oxford Knee Score (OKS) (3/3)

Research Title	Author	Subjects	Methods	Results
No gender-based differences in outcomes after conventional TKA in Asians	Gen et al. 2015	Age-matched 217 post-TKA 106 males 111 females 2006–2011	Prospective assessment of gender effect on short-term outcomes	Preoperatively, the female group's average body mass index was higher and knee-flexion range was poorer than the male group. Two years post-TKA there were no significant differences between male & female groups in any outcome measures (knee range of motion, knee society score, SF36 and OKS)
Is patient reporting of physical function accurate following total knee replacement	Hamilton et al. 2012	183 primary TKA 71 males 112 females Ages 46–92 years. Assessed pre-TKA and at 6, 26 and 52 weeks	Prospective correlation study between OKS and numerical scale functional based outcomes, ROM and strength.	All variables significantly improved over time, except that knee flexion reduced post-TKA until 6 weeks. Moderate correlation between OKS and function at 12 months (.49). Strong correlation between OKS and pain (0.7–.65). Poor correlation between knee flexion and function (0.25). Pain was the dominant factor that explained OKS variation over time. The agreement between direct assessment and OKS improved over time, from 35% pre-TKA to 62% 12 months post.
Post-operative Oxford Knee Score can be used to indicate whether patient expectations have been achieved after primary total knee arthroplasty	Clement et al. 2014	322 TKA 128 males (37–89 years) 194 females (33–91 years)	Prospective study to explore threshold values in OKS post-TKA to achieve patients' expectations and satisfaction	OKS mean pre-TKA was 19.1 and post-TKA 35.0, a significant improvement. A common pre-TKA expectation was improved ability to walk. Males more likely to expect to straighten their leg, improved ability to squat, kneel and participate in sexual activity. Older patients' expectation was not needing a stick for walking. Younger patients' expectations were a return to employment, sport & recreation and sexual activity. 10/17 expectations associated with significantly lower symptoms of worse OKS. Expectations differed according to patient gender, age and severity of symptoms. OKS may be used to predict patients' expectations of achievement.
Interpretation of patient-reported outcomes for hip and knee replacement surgery	Judge et al. 2012	Primary TKA =1,784 2004–2009 Age 17–96 years 62% female	Pre- & 6 months post, TKA & OKS correlation with patients' satisfaction	OKS improved from 19.9 to 34.5 post-TKA. 1591/1784 (89.2%) responses satisfied. Moderate association between OKS score and satisfaction score, P=0.57, 95%, CI 0.45–0.60. Absolute change P=0.49, 95%, CI 0.46–0.53. OKS threshold absolute change of 11 points or more satisfied.

2.2.1.4 Overall summary of Patient-reported outcome measures:

In general, assessments of PROMs post-TKA focus on symptoms, function, activity and participation, with limitations in terms of receiving competent care from family, neighbours and healthcare workers, and intimate relationships. In a population younger than 65 years, driving, a return to work and hobbies are limited in all of them.

Function and environmental assessment depth differ according to the age of the population post-TKA, as those older than 65 years may require further assessments of mental and physical endurance. A younger population needs more in-depth assessment for a return to work, driving, recreation and sport activity. That may be why there is no available gold standard that covers all the gaps and is suitable for broad age requirements post-TKA, with a suitable balance between complexity and simplicity.

In conclusion, both KOOS and OKS show good reliability, validity and responsiveness with a post-TKA population. Both have similar values for ceiling effect in a 12-month follow-up. The OKS has the advantage that it is simple and short, has better reliability scores with TKA patients, clear MIDC values and clear outcome categories (see Table 2-15). In contrast, KOOS has the advantage of being more suitable for young patients to assess, in sufficient depth, function, sport, recreation and knee-related quality of life. In terms of the quality of the items to assess symptoms and functional recovery post-TKA, the three commonly used PROMs are compared in depth in Table 2-16. A balance between complexity, the ability to assess items and maintain sufficient measurement properties is required to achieve comprehensive, valid and reliable outcomes post-TKA.

So, the current study used OKS as a main PROM as it is simple for patients and has good measurement properties, the KOOS was used a secondary PROM to assess the correlation between the two Arabic versions. The knee quality of life will be assessed in more depth with focus-group interventions, with more than the four questions in KOOS. Physical function activity will be assessed with objective, valid and reliable methods using a physical activity accelerometer to estimate comprehensive outcomes post-TKA with the minimum limitations possible.

Table 2-15. The measurement criteria for WOMAC, KOOS and OKS for post TKR population.

Criterion	WOMAC	KOOS	OKS
Length	24 items: 5 pain, 2 stiffness, 17 function (14).	Length 42 items: 9 pain, 5 symptoms, 17 ADL difficulty, 5 sport, recreation and quality of life (5).	Short, 12 items: 5 pain, 7 function (4).
Origin date	1982 for lower limbs dysfunction in OA	1998 evaluation for knee injury & OA (5).	1998 for TKA outcome (4).
Validity for TKA	Construct validity showed moderate to strong correlation with other measurements post-TKA (SF36, Nottingham health profile function scale, range of motion, radiology Kellgren rating) and disability scale (9).	Construct validity shows high correlation between KOOS & SF36. Rs=.62 pain, .48 ADL. Low correlation with mental scores (convergent validity) (7).	Construct validity shows moderate correlation pre-TKA with American knee society (AKS); significant agreement with SF36 & HAQ (4).
Sensitivity/ responsiveness	Response rate at one year 90% Effect size 2.25 (8).	Significant improvement, p<.001, effect size for quality of life 2.86–3.54 at 6/12 months, pain 2.28–2.55 at 6/12 months, sport 1.18–1.08 at 6/12 months, respectively (7).	Effect size 2.19, larger than SF36 (4).
Reliability for TKA	Acceptable ≥ .70 internal reliability for pain and stiffness, excellent ≥ .90-.95 for function. Test-retest reliability acceptable for pain and function, weak for stiffness (11). Correlation coefficients for pain, function and overall score 0.55, 0.50 and 0.55, respectively (13).	ICC post-TKA 0.75 with no significant changes between two measures (7).	Internal consistency: Cronbach's alpha .87 pre-TKA and .93 6 months post. Test-retest: r=.92, ± 0–4 points of differences (4).
Time required	11 minutes.	10 minutes (5).	5 minutes.
Accepted missing values	Not more than 5 pain, 2 stiffness, 4 function (14).	Two–six items and substituted by average value for dimensions (6) (7).	2 items.
Outcome categories	Improvement in pain & function ≥ 50% & absolute change ≥ 20. Responder if pain/ function/ global ≥ 20%, absolute ≥ 10.	0–100: 0 extreme knee problems, 100 no knee problems.	Excellent >41, Good 34–41, Fair 27–33, Poor < 27. (4).
MCID*	15 points (14).	8–10 points (5).	5 points for 2 groups' estimations, 9,7 points for cohorts & individuals (2,12).
Floor effect	14%.	48% for sport & recreation section (1,7)	7% (1), no effect (15)
Ceiling effect	**6 MONTHS:** 27% for pain, 51% for stiffness (10); **12 MONTHS:** 17% quality of life, 30% pain, 64% stiffness (10).	**6 MONTHS:** 15% for pain, 16% for sport, **12 MONTHS:** 22% pain & 17% for quality of life (1, 7).	**6 MONTHS:** 5–14%; **12 MONTHS:** 7–22% (1), no effect (15).

* MCID = Minimum clinically important differences, WOMAC =Western Ontario and McMaster Universities osteoarthritis index, KOOS = Knee injury and Osteoarthritis Outcome Score, OKS = Oxford Knee Score, 1 = Dowsey & Choong, 2013, 2= Beard et al., 2015, 3 = Murray et al., 2007, 4 = Dawson, Fitzpatrick, Murray, & Carr, 1998, 5 = Peer & Lane, 2013, 6 = Roos, Roos, Lohmander, Ekdahl, & Beynnon, 1998, 7 = Roos & Toksvig-Larsen, 2003, 8 = Theiler et al., 1999, 9 = McConnell, Kolopack, & Davis, 2001, 10 = Giesinger, Hamilton, Jost, Holzner, & Giesinger, 2014, 11 = Gandek, 2015), 12 = Clement, MacDonald, & Simpson, 2014, 13 = Bombardier et al., 1995, 14= Dunbar, Robertsson, Ryd, & Lidgren, 2001, 15= Harris et al., 2015.

Table 2-16. Symptoms, ADL, sport and quality of life assessment in three common patient-report outcome measures.

Function		WOMAC	KOOS	OKS
ADL & SYMPOTOMS	Frequency of pain	No	Yes	No
	Intensity of pain	Yes	Yes	Yes
	Patient hygiene & washing	No	No	Yes
	Bed mobility	Yes	Yes	Yes
	Sitting	Yes	Yes	No
	Standing from chair	Yes	Yes	Yes
	Standing	Yes	Yes	No
	Get in/out of car or public transportation	Yes	Yes	Yes
	Walking on a flat surface	Yes	Yes	Yes
	Duration of walking pain-free	No	Yes	Yes
	Walking aids used	No	No	No
	Walking aids (type, reason, ability to walk and stand with or without).	No	No	No
	Knee gives way	No	No	Yes
	Stairs	Yes	Yes	Yes
	Limping	No	No	Yes
	Kneeling	No	Yes	Yes
	Squatting	No	Yes	No
	Housework	Yes	Yes	Yes
	Heavy housework	Yes	Yes	No
	Household shopping	Yes	Yes	Yes
	Getting in/out of a bath	Yes	Yes	No
	Getting on/off a toilet	Yes	Yes	No
	Bending to floor	Yes	Yes	No
	Putting on socks	Yes	Yes	No
	Stiffness (morning/later in the day)	Yes	Yes	No
	Swelling, clicking or catching	No	Yes	No
	Knee full extension/flexion	No	Yes	No
	Antero-posterior/ mediolateral stability	No	No	No
	Contracture/ lag /varus or valgus	No	No	No
Sport	Turning on affected knee	No	Yes	No
	Running	No	Yes	No
	Jumping	No	Yes	No
	Walking on an uneven surface	No	No	No
quality of life	Aware of knee problem	No	Yes	No
	Lifestyle modification	No	Yes	No
	Lack of confidence	No	Yes	No
	General difficulties	No	Yes	No
	Expectations and satisfaction (pain, ADL and sport)	No	No	No
	Total	16/38	29/38	12/38

2.2.2 Patients performance-based outcome

As mentioned in the previous PROM section, there is value in assessing the patient's perspective post-TKA using PROM as valid, reliable and feasible methodology. However, limitations due to subjective under/over estimation of results and ceiling effects cannot be excluded. The patient's perspective fails to capture functional ability, especially in the acute stage post-TKA, and overestimates long-term functional outcome improvements (Mizner et al., 2011). A further objective measurement methodology is recommended to complement PROM and overcome this limitation via more precision and responsiveness to explore global outcome changes post-TKA. Performance-based outcome measures (PBOMs) offer more objective functional assessment, but these are not enough post-TKA as they do not take into account patients' perceptions of recovery. According to the Osteoarthritis Research Society International (OARSI), a set of PBOMs to assess outcomes post-arthroplasty is recommended. A total of 138 experienced clinicians and researchers from 16 countries reached a consensus and incorporated five tests recommended for individuals diagnosed with hip or knee OA and following joint replacement. These are: 30 s chair-stand test (30 s CT), 40 m fast-paced walk test (40 m FPWT), a stair-climb test (SCT), timed up-and-go test (TUG) and 6 m walk test (6MWT) (Dobson et al., 2013).

To capture health-related domains, according to the International Classification of Functioning Disability and Health (ICF) recommendation, assessment should include body-structure impairments, such as pain, swelling and muscle strength, function and activity limitations and participation restrictions. PBOMs assess function and activity limitation domains to identify a wider outcome spectrum post-TKA according, to World Health Organisation recommendations (Alnahdi, 2014). In addition, functional assessment demands post-TKA are likely to increase as TKA is being applied to younger populations than before and their functional requirements and abilities are higher than those of older patients (Boonstra, De Waal Malefijt, & Verdonschot, 2008). In accordance with PRISMA, a systematic review of patient performance-based literature was conducted electronically according to the search strategy explained in section one.

Inclusion criteria: Any study measuring function post-primary TKA with any performance-based test.

Exclusion criteria; Any study analysing movement and function post-TKA in a laboratory environment. Studies assessing functional performance using any kind of self-reporting scale or questionnaire. Studies assessing functional performance only before TKA.

Search results

A PRISMA search strategy was used to devise a transparent article-selection process, this is summarised in Flow Diagram 2-7. After electronic filtration of a first-stage search to restrict the results to articles in English, about humans and with full access produced between 2004 to present, around 135 articles were identified. After title-screening and duplication exclusion, 36 studies satisfied the inclusion criteria; 6 studies were excluded as the full text was not available; 13 papers were excluded as they assessed osteoarthritis patients before TKA without post-TKA measurements; and 4 papers on revision surgery. Abstract screening found that 13 papers satisfied the eligibility criteria assessing PBOMs post-TKA, these are included and summarised in Table 2-17. Six studies explore the correlation between PBOMs and other outcomes post-TKA. Five studies assess the psychometric properties of PBOMs in a post-TKA population. The last two are systematic reviews about PBOM use post-TKA. The first part explored PBOMs used to assess functional outcomes post-TKA, the second part assessed their psychometric properties. The quality of all the studies according to the Critical Appraisal Skills Program (CASP) is clarified in Table 2-18.

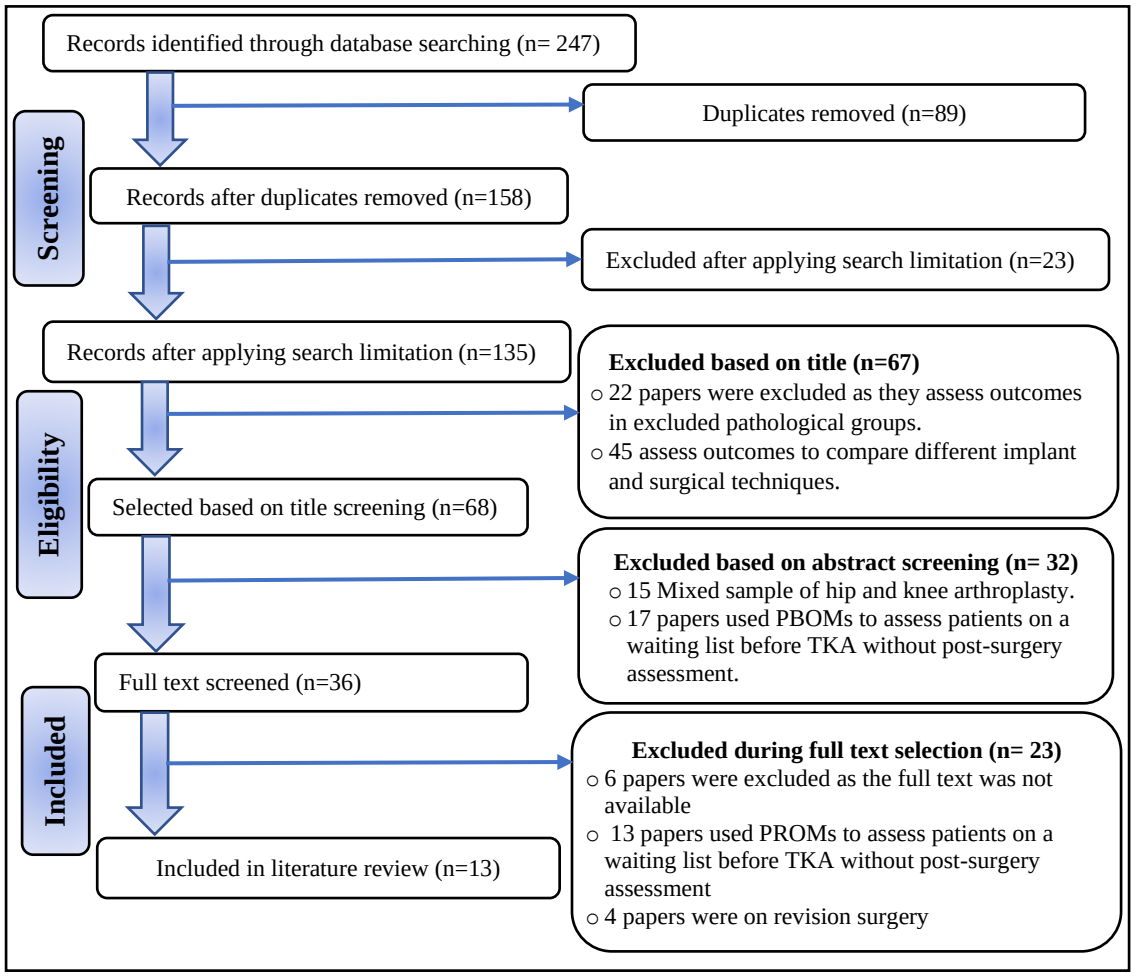

Figure 2-7. PRISMA Flow diagram for Performance Based Outcome Measures.

The study by Stevens-Lapsley et al. (2011) notes the importance of including PBOMs to assess outcomes post-TKA and does not solely rely on PROMs (KOOS) as their outcomes do not reflect each other. There is no correlation between PBOMs and pain, although pain closely parallels PROMs. That may indicate that each method explores a different domain of patient recovery post-TKA and different methods are essential to capture functional limitations (Stevens-Lapsley, Schenkman, & Dayton, 2011). In agreement, the study by Mizner et al. (2011) notes the failure of patient perception to capture functional changes in the acute stage post-TKA. All the studies found PBOMs (TUG, SCT AND 6MWT) decreased one-month post-surgery, then improved over the longer term, as seen in 12-month assessments. The PROMs (Short Form-36 Health Questionnaire & Knee Outcome Survey Activities of the Daily Living Scale) were variable, with no to little response one-month post-TKA, but with excellent long-term responsiveness (Mizner et al., 2011). So, to assess function post-TKA it is essential to use both PROMs and PBOMs.

A sit to stand performance test (STS), one of the recommended PBOMs, had the ability to identify patients with substantial improvements in gait patterns, while using KOOS as a PROM could not differentiate between patients improving in their functional performance and those not doing so. Those patients who improved post-TKA in their performance of STS for more than 2.5 s showed significant improvements in the gait Deviation Index for kinematics and kinetics (Naili et al., 2016). This agrees with the results obtained by Boonstra et al. (2008), where the STS test correlated with biomechanical knee function changes and is a valid tool to discriminate between healthy individuals and patients post-TKA. In addition, a timed up and go (TUG) test is valid to detect patient changes via quick global functional assessments post-TKA (Boonstra et al., 2008).

There was good correlation between muscle strength and PBOMs in a post-TKA population. Extensor and flexor muscle strength correlates with three PBOMs for patients scheduled for TKA. The best correlation was with a 30 s chair stand test (30s CT), then a timed up and Go (TUG) test and a walking test. There was however no correlation between muscle strength and 6 MWT or KOOS (Skoffer et al., 2015). Leg-press power shows an association with a 30 s chair stand test and a 10-metre fast walking test in post-TKA patients (Aalund, Larsen, Hansen, & Bandholm, 2013).

In summary, PBOMs are simple and feasible functional tests able to capture different aspects of patient function, they differ from PROMs and do not require any cultural adaptation. An STS test seems to follow kinematic and kinetic improvements post-TKA. TUG, a valid quick

functional assessment tool, 30s CT, timed up and Go and walking showed good correlation with knee extensor and flexor muscle strength.

PBOM psychometric properties in arthroplasty populations have been evaluated by many separate studies. A study by Kennedy et al. (2005) concluded that 6MWT, SCT and FPWT are reliable responsive tools to detect patient improvements or deterioration post-arthroplasty, even in the early postoperative period. The ICC value for 6MWT was 0.94 (0.88, 0.98), for TUG 0.75 (0.51, 0.89), for ST 0.90 (0.79, 0.96) and for SPWT 0.91 (0.81, 0.97) (Kennedy, Stratford, Wessel, Gollish, & Penney, 2005). A randomized controlled study concluded that there was a valid minimal important improvement threshold for a 6MWT test of 26 weeks post-TKA, i.e. 26–55 metres based on a triangulation method (Naylor, Mills, Buhagiar, Fortunato, & Wright, 2016). Excellent reliability concluded for both a 50-foot walk test (50 FWT) and a 30-second chair stand test (30 CST) in patients having undergone TKA (Unver, Kalkan, Yuksel, Kahraman, & Karatosun, 2015).

The interrater reliability and validity of a stair descent, and ascent test were assessed by Almeida et al. (2010); their study showed good reliability, with ICC=0.94 for both ascending and descending, with minimum detectable changes, which is useful for clinical use. The test correlated with knee flexion range of motion while there was no correlation with extension (Almeida, Schroeder, Gil, Fitzgerald, & Piva, 2010).

A study by Hossain et al. (2013) concluded that PBOMs are a reliable way to assess functional changes in musculoskeletal function post-TKA. Although including PBOM tests is advanced and may be suitable for young patients with an active life style, the study recommends a combination of the following 12 tests: timed horizontal leg hold (quadriceps endurance test); timed single leg stance (balance and proprioception test); timed 10 m walk; stride length; cadence and step length (measured during a 10 m walking test); timed 10 step stair climb; timed get up and go test (TGUG); single hop distance; triple hop distance and timed 6 m hop; a kneeling test. The results show that 26% of patients were unable to do a single hop test and 16% a triple hop test. The study's sample ages were however young for a control group at 21–64 years, and for TKA 42–85 years. In addition, a set of 12 PBOM tests is not practical for daily clinical work as they require plenty of time and space (Hossain et al., 2013).

In summary, four of the five PBOM tests recommended by OARSI show excellent to good psychometric properties with a post-TKA population, as summarised in Table 2-19. All four tests will be included in the current study, i.e. 30s CST, SCT, TUGT and 6MWT (Ko, Naylor, Harris, Crosbie, & Yeo, 2013).

Table 2-17. Characteristics and results of Patients' Performance Based Outcome Measures Post Total Knee Arthroplasty studies (1/4).

Research Title	Author	Subjects	Method	Results
Comparison of Self-Reported Knee Injury and Osteoarthritis Outcome Score with Performance Measures in Patients After TKA	Stevens-Lapsley 2011	39 participants (17 men and 22 women; mean age, 64.0 ± 8.2y	Prospective, randomized using KOOS - SF-36 SCT, TUG & 6MW tests Quadriceps Strength Pre-& 1–6 months post	1-month post-TKA; KOOS ADL, Pain & QoL improve significantly. SCT, TUG & 6MW declined. 3–6 months post-TKA; KOOS improve on all 5 subscales. SCT, TUG & 6MW improved. KOOS pain strongly correlated with KOOS ADL scores but not with 6 MWT.
Measuring Functional Improvement After Total Knee Arthroplasty Requires Both Performance-Based and Patient-Report Assessments	Mizner et al. 2011	100 patients scheduled for unilateral TKA Measured before, 1–12 months post-TKA	Short Form-36 Health Questionnaire & Knee Outcome Survey of Activities of Daily Living Scale. Timed Up and GO test Stair Climbing test 6 -minute walk test knee girth, ROM and strength	All physical performance measures decreased initially after surgery then increased in the long term. Patient-report measures were variable, with no to small response early on, but excellent long-term responsiveness. The perceived function did not follow the same trend, and some showed an increase immediately after surgery. Patient perception fails to capture acute functional decline after TKA and may overstate long-term functional improvement with surgery.
Deficits in functional performance and gait one year after total knee arthroplasty despite improved self-reported function	Naili 2016	28 patients with knee OA, mean age of 66 years, 25 age- and gender-matched controls participated	3-dimensional gait analysis to measure kinematic and kinetic gait deviations, respectively. Five Times Sit-to-Stand (5STS) test, KOOS, at baseline prior to surgery and 1 year after TKA.	Kinetic gait deviations of both operated and non-operated limb persisted post-TKA. Kinematic gait patterns were comparable to controls. 5 STS & KOOS improved significantly post-TKA but did not match the control group. Good 5STS group shows significant improvements in Gait Deviation Index for kinematics and kinetics. Based on changes in 5STS performance, we could identify patients with substantial improvements in gait patterns, while self-reported measures of function could not.

Table 2-17. Characteristics and results of patients' Performance Based Outcome Measurements post-total knee arthroplasty studies (2/4).

Research Title	Author	Subjects	Methods	Results
How to quantify knee function after total knee arthroplasty?	Boonstra et al. 2008	28 measured 16 months post-TKA and 31 healthy subjects.	WOMAC, Knee Society score & performance-based tests (sit-to-stand movement and timed-up-and-go) were used to assess which of these are selective and valid to measure knee function.	The sit-to-stand movement and timed-up-and-go tests were both selective and functionally content valid. The timed-up-and-go test can be used for a quick initial assessment of global function and the sit-to-stand movement as a more biomechanical instrument identifying how the knee function of the patient is affected.
Functional performance is associated with both knee extensor & flexor strength in patients scheduled for total knee arthroplasty	Skoffer 2015	Fifty-nine patients, mean age 70.4 years, 6 weeks before TKA.	Associations between muscle strength, measured functional performance (30 s chair-stand test, timed Up-and-Go, 6MWT and 10 m walking test) and PROM (KOOS).	Knee extensor & flexor associate with PBOM, 30 s chair-stand test better than timed Up-and-Go and walking tests. No correlation between 6MWT & muscle strength. No correlation between PBOM & KOOS. KOOS correlates with pain.
Normalised Knee-Extension Strength or Leg-Press Power After Fast-Track TKA Associated with Performance-Based and Self-Reported Function?	Aalund et al. 2013	39 unilateral TKA	Correlation study between isometric knee extension, leg press power, 30 s chair-stand test, 10 m walking test WOMAC and OKS scale	Leg-press power correlates with both 30 s chair-stand test, 10 m walking test (WOMAC) and OKS scale, more than isometric knee extension. This may be due to it being a closed kinetic-chain task, such as walking or rising from a chair.
A performance-based patient outcome score for active patients following TKA	Hossain et al. 2012	50 healthy and 50 patients who underwent TKA	Timed horizontal leg hold; Timed single leg stance; Timed 10 m walk; Stride length; Cadence & Step length; Timed 10 step stair; Timed get up and go test; Single hop distance; Triple hop distance, Timed 6 m hop; Kneeling test.	The study's performance-based knee function score is a reliable dimension-specific tool to detect change in musculoskeletal function after TKA. It complements existing self-reported outcome tools and facilitates a comprehensive assessment of patients following TKA.

Table 2-17. Characteristics and results of patient's Performance Based Outcome Measurements post-total knee arthroplasty studies (3/4).

Research Title	Author	Subjects	Methods	Results
Assessing stability and change of four performance measures' outcomes post JA	Kennedy et al. 2005	81 post TKA	6 MWT TUG Stair measure Fast self-paced walk test SPWT	6MWT, ST, SPWT Test retest reliable to detect deterioration & improvement post TJA. ICC 6MWT 0.94, TUG 0.75, ST 0.90 and SPWT 0.91. Standardized response means varied from .79 to 1.98.
Minimal important improvement thresholds for a six-minute walk test on a knee	Naylor et al. 2016	158 patients post-TKA	6 MWT pre- and 10, 26 weeks post-TKA and patients' perceived improvement in mobility post-surgery on a 7-point transition scale.	A valid threshold of improvement for 6MWT can only be proposed for changes identified from baseline to 26 weeks post-surgery. A true minimal or greater threshold of meaningful improvement following surgery is likely within the ranges proposed by the triangulation of all four methods, i.e. 26 to 55 m.
Reliability of the 50-Foot walk test and 30-second chair stand test in Total Knee Arthroplasty	Unver et al. 2015	33 patients at least 6 months post-bilateral TKA	Test re-test reliability study to assess the 50-Foot Walk Test (50 FWT) and 30-second Chair Stand Test (30 CST) in patients who have undergone TKA.	The 50 FWT and 30 CST showed excellent reliability. ICC for 50 FWT and 30 CST were 0.97 and 0.92, respectively.
Interrater Reliability and Validity of the Stair Ascend/ Descend Test in Subjects with Total Knee Arthroplasty	Almeida et al. 2010	43 patients post unilateral TKA (2–6 months)	Interrater Reliability of stair test, two raters measured the time for patients' performance: one standing at top to record STUp and one at the bottom to record STTotal.	STTotal and STUp have good interrater reliability and minimum detectable changes that are adequate for clinical use, ICC=0.94. Standard errors of measurement were 1.14 seconds and .82 seconds, and minimum detectable changes associated with a 90% confidence interval were 2.6 seconds and 1.9 seconds, respectively. Correlates with knee flexion ROM but not extension.

Table 2-17. Characteristics and results of patients' Performance Based Outcome Measurements post-total knee arthroplasty studies (4/4).

Research Title	Author	Subjects	Methods & Conclusion
Outcome measures capturing ICF domains in patients with total knee arthroplasty	Alnahdi et al. 2014	Review article up to March 2014	Pain (VAS/NVAS), KOOS, WOMAC, ROM (joint mobility), Muscle performance (quads. abd.). **Self-report activity limitation:** ✓ WOMAC, LEFS, KOOS **Performance-based measures of activity limitation:** ✓ 30 s chair stand test. ✓ 40 m fast paced walk test ✓ Stair climb test ✓ 6 m walk test ✓ TUG test
OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis	Dobson 2013	An international, multidisciplinary expert advisory group was established to guide the study. Potential tests for consideration in the recommended set were identified via a survey of selected experts and through a systematic review of the measurement properties for performance-based tests.	Consensus incorporated the opinions of 138 experienced clinicians and researchers from 16 countries. The five tests recommended by the advisory group and endorsed by the Osteoarthritis Research Society International (OARSI) were: ✓30 s chair-stand test, ✓40 m fast-paced walk test, ✓stair-climb test, ✓ timed up-and-go test ✓ 6 m walk test. The first three were recommended as the minimal core set of Performance-based tests for hip or knee OA.

Table 2-18. Critical Appraisal Skills Program (CASP) for Patients' Performance Based Outcome Measures Post Total Knee Arthroplasty.

CASP section	Criterion	Stevens-Lapsley 2011	Mizner et al. 2011	Naili 2016	Boonstra 2008	Skoffer 2015	Aalund et al. 2013	Hossain et al 2012	Kennedy et al. 2005	Naylor 2016	Unver et al. 2015	Almeida 2010
Validity of results	Population defined	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Intervention described	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Study design	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Outcome defined	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Patient randomization (recruitment)	YES	NO	NO	NO	YES	NO	NO	NO	YES	NO	YES
	Researchers/assessors blinded	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	Similar group baseline	NO	YES	YES	NO	YES	YES	NO	YES	YES	YES	YES
	Equal intervention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	All subjects accounted for in conclusion	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES
The results	Clearly defined outcomes	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Non-selective reporting of outcomes	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Appropriate statistical methods	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Statistical significance reported	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Results' value	Inferential statistics employed	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES
	Generalizability	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES
	Confidence intervals presented	NO	YES	NO	NO	NO	NO	YES	YES	YES	YES	YES
	Clinical relevance defined	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Relevant to present evidence base	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Total score	16/19 84%	17/19 89%	16/19 84%	15/19 79%	17/19 89%	14/19 74%	15/19 79%	17/19 89%	18/19 95%	17/19 89%	18/19 95%

Table 2-19. Measurements Criteria for recommended Performance -Based test by Osteoarthritis Research Society International (OARSI).

	30 s chair-stand test	40 m fast-paced walk test	stair-climb test	timed up-and-go test	6 m walk test
Reliability and validity with TKA* patients	Excellent reliability ICC= 0.92 (2)	NAD	Reliable to detect deterioration & improvement ICC = 0.90 (7)	Valid & quick initial assessment of global function (6). Reliable to detect deterioration & improvement ICC = 0.75 (7)	Reliable to detect deterioration & improvement ICC = 0.94 (7)
Correlation with muscle strength	Good correlation with knee extensor & flexor muscle strength (3). Correlates with leg press strength (4)	NAD	NAD	Good correlation with knee extensor & flexor muscle strength (3).	No correlation between 6MWT & muscle strength (3).
Correlation with knee range of motion	NAD	NAD	Correlates with knee flexion but not with extension (10)	NAD	NAD
Correlation with PROMS	No correlation with KOOS (3)	NAD	NAD	No correlation with KOOS (3)	No correlation with KOOS (3)
Responsiveness	NAD	NAD	Highly responsive in early stage 1-month post-TKA & long-term after 12 months (5).	Highly responsive in early stage 1-month post-TKA & long-term after 12 months (5).	Highly responsive in early stage 1-month post-TKA & long-term after 12 months (5).
minimum detectable change	1.64 repetition (11)	NAD	2.6–1.9 seconds (10), 5.49 (7)	0.79 seconds (5) - 2.49 seconds (11).	26–55 metres (9)

TKA = Total knee arthroplasty. NAD = No Available Data. (1) (Dobson et al., 2013), (2) (Unver, Kalkan, Yuksel, Kahraman, & Karatosun, 2015), (3) (Skoffer, Dalgas, Mechlenburg, Soballe, & Maribo, 2015), (4) (Aalund, Larsen, Hansen, & Bandholm, 2013), (5) (Mizner et al., 2011), (6) (Boonstra, De Waal Malefijt, & Verdonschot, 2008), (7) (Kennedy, Stratford, Wessel, Gollish, & Penney, 2005), (8)(Naili et al., 2016), (9) (Naylor, Mills, Buhagiar, Fortunato, & Wright, 2016), (10) (Almeida, Schroeder, Gil, Fitzgerald, & Piva, 2010), (11) (Alnahdi, 2014).

2.2.3 Balance tests

Peripheral joint arthritis affects balance and consequently decreases physical activity (Hinman et al., 2002; Noren et al., 2001). Instability in end-stage knee OA is one of the main factors that correlate with disability and a high risk of falling (Kauppila et al., 2009; Zasadzka et al., 2015). Assessing balance improvement post-TKA is essential to capture functional improvements. A dynamic balance assessment has an advantage over a static one, in that it closely mimics physical activity demand, better than a static one, and the history of falling in the OA population accrues during activity rather than in a static position.

Dynamic balance in individuals with OA is commonly assessed using a step test (Hinman et al., 2002; Hinman, Heywood, & Day, 2007; Lim, Hinman, Wrigley, Sharma, & Bennell, 2008). The individual is asked to stand on the test leg in front of a 15 cm high step and then asked to take steps with the other leg for 15 seconds, meanwhile the assessor records the number of steps taken during that time interval. The test only assesses dynamic balance in one direction, which does not reflect daily activity balance requirements and muscular endurance may affect the test performance. A study by Hinman et al. (2002) found dynamic balance reductions in knee OA patients compared with healthy subjects using a step test. This was a randomised control study to assess balance and muscle strength improvements in OA patients before and after aquatic balance and strengthening exercises using a step test. No immediate effect of intervention on step test performance was found; however, after six weeks, balance performance significantly improved. This may have been due to improvements in endurance, rather than balance (Hinman et al., 2002).

Dynamic balance may be assessed with another test, i.e. the Star Excursion Balance Test (SEBT). In a SEBT, the individual stands in the centre of the grid and is instructed to stand on the affected or operated leg while reaching out as far as possible in one of the three directions with the other lower extremities, and then returns that leg to the centre. The assessor measures the reach distance in each direction, in centimetres, and then normalises the average of the three trials to leg length (Coughlan, Fullam, Delahunt, Gissane, & Caulfield, 2012; Fullam, Caulfield, Coughlan, & Delahunt, 2014). Thus, this test assesses balance in multiple directions, which may better mimic daily life activity requirements, and it has excellent inter-rater reliability for healthy participants. Originally, the test was across eight reaching directions, but this demonstrated redundancy and led to developing the Y Balance test with just three reaching directions (Hertel, Braham, Hale, & Olmsted-Kramer, 2006; Robinson & Gribble, 2008). Therefore, a Y balance test with anterior, posteromedial and posterolateral directions was recommended as quadriceps and abductor muscle

weakness have been shown to impair the proprioception and activation pattern in elderly participants with knee OA (Hortobagyi, Garry, Holbert, & Devita, 2004).

SEBT is a valid and reliable method to differentiate pathologies in lower limbs, such as chronic ankle instability, anterior cruciate ligament reconstruction and patellofemoral pain syndrome. It has the ability to detect changes due to external influences, such as taping, bracing, orthoses and induced fatigue (Gribble, Hertel, & Plisky, 2012; Hyong & Kim, 2014; Plisky, Rauh, Kaminski, & Underwood, 2006).

A PRISMA search strategy was used to devise a transparent article-selection process, this is summarised in Flow Diagram 2-8. After electronic filtration of a first-stage search to restrict the results to articles in English, about humans and with full access produced between 2004 to present, around 7 articles were identified. After title-screening and duplication exclusion, 4 studies satisfied the inclusion criteria, 2 studies were excluded as they used SEBT along with other knee injuries. The remaining two studies used SEBT with knee OA patients, one assessed reliability with early to moderate knee OA and responsiveness after an exercise programme. SEBT showed excellent psychometric properties in early and moderate stages of knee OA (Kanko et al., 2019). The other study by Al-Khlaifat et al. (2016) found significant improvements in dynamic balance after six weeks of training for knee OA patients, which indicates good sensitivity to detect improvements after an exercise programme (Al-Khlaifat, Herrington, Tyson, Hammond, & Jones, 2016). Interestingly, no studies have assessed dynamic balance post-TKA using SEBT or a reliability study with individuals with end-stage OA.

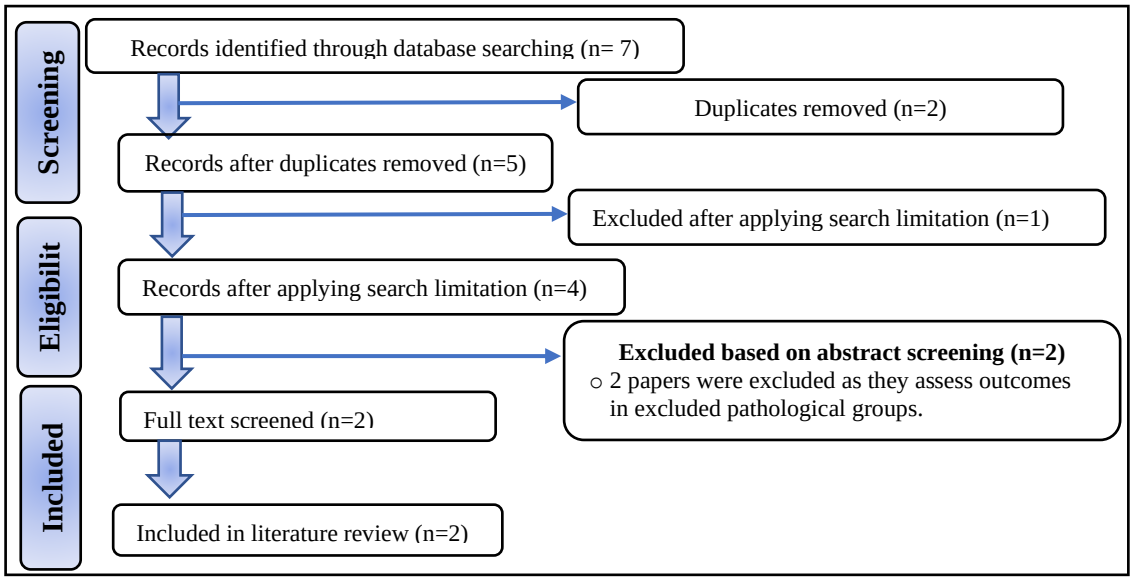

Figure 2- 8. PRISMA Flow diagram for Star Excursion Balance Test (SEBT)

2.2.4 Physical Behaviour outcome

As in the previous section, it concludes by noting the advantages of OKS although it is limited in assessing function and sport. So, the current study will use OKS as a PROM as it simple for patients and has good measurement properties, plus an accelerometer to compensate its limitations and assess physical activity using valid, reliable and objective methods to estimate comprehensive outcomes post-TKA, with as few limitations as possible. The main outcome expected after TKA is reduced pain and improved functional performance. There is limited research on free-living Physical Activity (PA) outcomes post-TKA. According to the World Health Organization, PA is defined as any bodily movement that results in energy expenditure by the skeletal muscles. This includes sport, exercise and other activities, such as playing, walking, doing household chores, gardening and dancing. At least 150 minutes of moderate PA is recommended per week for adults over 18 years of age. For adult aged 65 and above, PA at least three times per week is essential to improve balance activity and prevent falls. PA has many positive benefits, such as improved cardio-respiratory fitness and enhanced physical and cognitive function. In addition, it lowers the rates of coronary heart disease, high blood pressure, stroke, diabetes, colon and breast cancer, depression and the risk of falling (WorldHealthOrganisation, 2016).

Interestingly, free-living PA is not commonly measured by the National Health Service (NHS) in the UK post-TKA and reports are mainly based on PROMs. This may be due to healthcare professionals assuming that PA performance will recover to that associated with good long-term health. However, there is emerging evidence in the present literature that this is not the case (Harding, Holland, Delany, & Hinman, 2014; Kahn & Schwarzkopf, 2015; Vissers, Bussmann, de Groot, Verhaar, & Reijman, 2013). It is important to have a clear understanding of PA engagement post-TKA to see if free-living PA levels are suitable for the maintenance of good long-term health according to World Health Organization recommendations.

Accelerometers have the advantage of offering free-living reliable, feasible and environmentally constrained methods to monitor PA without subjective limitations and reasonable cost when compared to laboratory motion-analysis technology (Granat, 2012). The accelerometer was invented in the early 1950s to monitor movements, but its high cost limited it use until the 1970s. Advances in science and technology saw a resurgence in the use of accelerometers at more reasonable prices. It uses a movement monitor with semiconductor strain-gauge elements to detect body-segment movement. A portable waist data device records data through a cable (Morris, 1973). The rate and intensity of body

movements in three planes (anterior-posterior, mediolateral and vertical) are monitored through measurements of acceleration along a sensitive axis. An accelerometer has the advantages of detecting the intensity and frequency of movements better than a pedometer or actometers. Integrated microelectromechanical systems (iMEMSs) boost the performance of accelerometers, improve their quality and reliability and reduce their size and cost. In conclusion, the accelerometer has the advantage of being small in size and making a continuous record of movements, both quality and quantity, that is consistent with good reliability and cost (Godfrey, Conway, Meagher, & G, 2008).

Commonly, studies that utilise an accelerometer find that PA remains either as before surgery or diminishes. In contrast, studies that utilize PROMs as self-reporting to evaluate PA post-TKA show that patients perceive themselves to be more physically active (Kahn & Schwarzkopf, 2015). This discrepancy in PA outcomes post-TKA may be due to differences in assessments methods and the nature of PA. PA outcome measures are not uniform and are deeply stratified, e.g. number of steps, time spent sitting, standing or stepping, cycles per min. or energy expenditure, which require different methods to capture each outcome and its progression. It is hard to capture PA accurately and analyse its quality and quantity as it is affected by many factors, including mechanical, physiological and psychological (Godfrey et al., 2008; Paxton, Melanson, Stevens-Lapsley, & Christiansen, 2015).

In accordance with PRISMA, a systematic review of physical activity literature was conducted electronically according to search strategy in section one.

Inclusion criteria: Any study measuring physical activity post-primary TKA with any continuous objective methods.

Exclusion criteria: Any study analysing movement's post-TKA in a laboratory environment or with a pedometer, or for less than 24 hours as this does not capture real life function. Studies assessing physical activity only before TKA and comparing it with healthy people. Studies assessing physical activity using any kind of self-reporting scale or questionnaire.

Search results: A PRISMA search strategy was used to devise a transparent article-selection process, which is summarised in Flow Diagram 2-9 after electronic filtration of a first-stage search to restrict the results to articles in English, about humans and with full access produced between 2004 to present, around 92 articles were identified. After title-screening and duplication exclusion, 34 studies satisfied the inclusion criteria; 27 studies were excluded, 11 papers measured PA using an activity scale questionnaire without

objective tools, 9 studies used pedometers to measure the number of steps only, 4 papers were in a laboratory environment for one day and 3 studies compared the physical activity of patients with end-stage knee OA with healthy individuals. Full-text screening found that seven papers satisfied the eligibility criteria, these are included and summarised in Table 2-20. Seven studies assessed physical activity post-TKA utilising different types of accelerometers. Two studies used activPAL, two used ActiGraph 1GT1M, one used StepWatch Activity Monitor (SAM), one study used an Activity Monitor (AM) accelerometer, and the last study used hardware introduced by Morlock et al. (2015).

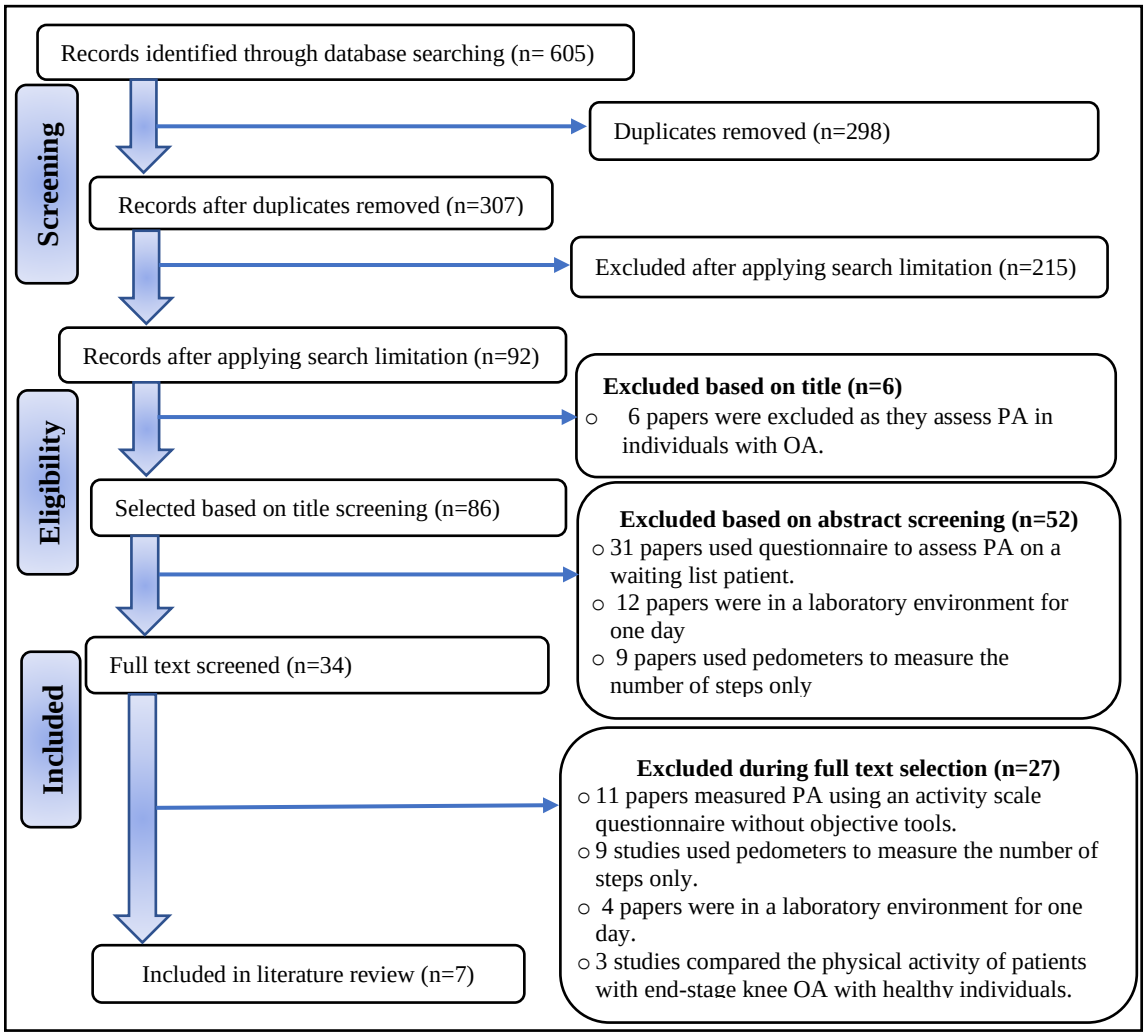

Figure 2-9. PRISMA Flow Diagram for Physical Activity

The studies by Harding et al. (2014) and Kahn et al. (2015) show no objective changes at 6 months and 1-year post-TKA, based on an ActiGraph1 GT1M accelerometer. Outcomes are based on sedentary and active time and average daily activity count (Harding, Holland, Delany, & Hinman, 2014; Kahn & Schwarzkopf, 2015). However, these studies used a hip worn ActiGraph that records minimal acceleration in a standing position and offers a sitting

position with similar output. ActiGraph is an energy classification accelerometer that may inaccurately infer body posture, and vice versa for posture-classification accelerometers (Granat, 2012).

In similar findings by Vissers et al. (2013), Activity Monitor (AM) accelerometer measurements 4 years post-TKA and showed no change in PA records (Vissers, Bussmann, de Groot, Verhaar, & Reijman, 2013). The study used a non-feasible accelerometer with 3 sensors and 500-gram weights resulting in limiting the assessment time to 48 hours, which may not capture real free-living physical activity.

The results of two studies by Robertson (2016) & Wimmer (2015) are limited to PA assessment post-TKA, without preoperative measurement, that may lead to an inability to compare PA changes (Robertson, Battenberg, Kertzner, & Schmalzried, 2016; Wimmer, Nechtow, Schwenke, & Moisio, 2015). The last two studies, using activPAL, are by Meiring et al. (2016), for which the results are not yet published, and by Lutzner et al. (2014), which shows an improvement in the number of steps over pre-surgery levels but less than that of an age-matched control (Lutzner, Kirschner, & Lutzner, 2014; Meiring et al., 2016).

The current conflict in accelerometer outcomes post-TKA may be due to many confounding factors, such as accelerometer measurements not being in a standardized timeline with regard to the timing of TKA and mixed subjects' post-knee and -hip arthroplasty. In addition, each accelerometer has different outcomes depending on the study objectives and accelerometer placement, such as time spent on PA, rest time, intensity of PA or energy expenditure, which affect the results and conclusion.

The hardware accelerometer introduced by Morlock et al., the AM accelerometer, and the activPAL accelerometer assess, in addition to the steps per day, the time spent lying, standing and sitting. This accelerometer category – postural classification devices – has the ability to determine the inclination of one or more body segments and drive the body position. The AM and Morlock et al. accelerometers are heavy, which is a disadvantage, at 500 grams and 100 grams respectively. They consist of three sensors applied to the sternum and one on each thigh. Their heavy weight and multiple sensors require professional application and the patient needs to take it off for sleeping or showering, which may decrease the time it is worn and its feasibility. On the other hand, the activPAL had the advantage of being light in weight at only 20 grams, with one small sensor easily applied to the mid-thigh and also waterproof. The patients can wear it day and night, which improves the accuracy of measurements (see Table 2-21).

A new updated version of ActiGraph1, the GT3X, assesses body position in addition to a step count. It is worn as an elastic nylon belt around the waist, and the patient is requested to take it off for a shower or bath (Meiring et al., 2016). ActiGraph is one of a number of energy expenditure classification devices that record acceleration in a set time and assign values to estimate acceleration magnitude within a set time period to reflect body movements. It has the ability to estimate energy expenditure but may overestimate low-level activities and underestimate vigorous ones. Its ability to detect body posture is limited due to minimal acceleration records when standing, and similarly in a sitting position because it worn at hip level (Granat, 2012).

In contrast, activPAL has the ability to measure volume free-living PA, by considering external environmental confounding factors in addition to patterns of PA and sedentary behaviour. It assesses low-energy positions (sitting and lying) to estimate sedentary behaviour. It also accurately assesses the start time for each position and the duration spent in it. In a similar manner, it estimates upright events (standing, stepping) time in addition to the number of steps and average cadence (Granat, 2012). ActivPAL showed good inter-device reliability, ranging from 0.79 to 0.99. The mean percentage differences between activPAL and direct observation for the total time spent sitting and standing were 0.19% (limit of agreement from −0.68% to 1.06%) and 1.4% (limit of agreement from −6.2% to 9.1%) (Grant, Ryan, Tigbe, & Granat, 2006).

In summary, activPAL is small, lightweight, waterproof, reliable and valid and offers simple application to patients. Therefore, the current study will use an activPAL accelerometer to measure PA before and after TKA to capture changes in the time spent in a sedentary/ active position and the number of steps per day for seven days with the best available accelerometer. The following section will assess the quality of two previous studies that used activPAL to evaluate PA post-TKA according to the measurement criteria summarized in Table 2-22.

The study protocol by Meiring et al. (2016) shows good methodology with combined accelerometers and PROMs to assess the effect of TKA on habitual physical activity and sedentary behaviour in adults with osteoarthritis, although the results have not yet been published. The study by Lutzner et al. (2014) had the advantages of a standardized surgical procedure and prosthesis type, with clear sample procedures and inclusion criteria. However, there are some limitations that may make their results questionable. The activPAL was attached over the anterolateral of the tibia instead of the midline anterior aspect of the upper thigh and measurements length was limited to four days, all this against the

manufacturer's recommendations, which may affect the data accuracy (Edwardsona et al., 2016). A technical failure during data collection led to a loss of around 20.6% of data (62 data set) for a TKA group and 9.3% (43 data set) for a control, which may affect the results and conclusion drawn. Generalisation is limited to a small age range, 67–70.6 years. To the best of our knowledge, no study has explored physical activity outcomes post-TKA using activPAL as an objective reliable method to explore whether PA changes in detail in terms of volume and patterns post-TKA according to the manufacturer's use recommendations in terms of application location, duration of measurements and other essential technical factors to enhance the accuracy of outcomes.

Table 2-20. Characteristics and results for physical activity levels using an accelerometers post- Total Knee Arthroplasty Studies (1/3).

Research title	Author	Subjects	Methodology	Results	Conclusion	Limitations
Knee flexion and daily activities in patients following total knee replacement	Wimmer 2015	32 patients assessed post-TKA Does not clarify the time of measurement post-TKA.	Hardware introduced by Morlock et al. and a portable data logger collecting data from three sensors at 30Hz, weighs less than 100 g	Test duration 11.3 ± 1.2. 9.3 ± 1.2 stationary activity. 0.9 ± 0.5 dynamic, 1.1 ± 0.4 unrecognized. Walking 3102 cp12 H	Subjects spent most of the time sitting, followed by standing and walking.	It has to be manually set for each subject & calibration. Heavy. Measures walking and stair stepping, lying down, sitting and standing. 12 hours' wearing time. No preoperational data available.
Management factorials in primary arthroplasty defining high activity in arthroplasty patients	Robertson 2016	13 patients with active lifestyle undergoing lower-limb arthroplasty	Accelerometer worn on the ankle (StepWatch Activity Monitor (SAM)). Measures the gait cycle /minute (cpm) and percentage intensity of activity Worn for 9 days	Mean cpd 8,273 Mean cpy 3,019,737 Mean gait speed 19 4.3% high activity (58 per min.) 9.4% moderate activity (135 per min.) No patient required revision surgery	Highly active patients Perform > 3 million cpy (8,200 cpd/ 16,400 steps pd). Or complete 1 hour of high activity daily. Or perform >40% cpd with high activity	Patients instructed to wear it each morning. Doesn't measure standing or rest time. Assessment taken 1.8 to 15.8 years post-arthroplasty. Mixed hip and knee arthroplasty.
Physical functioning four years after total hip and knee arthroplasty	Vissers 2013	21 patients 4 years post-TKA	AM accelerometer measure walking, cycling, climbing stairs and general movement. Compares pre, 6 months and 4 years post-TKA	Daily activity did not Increase after 4 years compared to 6 months. Patients spent significantly more time lying & less time sitting.	4-year post-TKA patients continued to improve in perceived physical functioning, capacity.	Weight 500 g 3 sensors on the sternum and one sensor on each thigh 48h record

Table 2-20. Characteristics and results of physical activity level using accelerometers post-total knee arthroplasty studies (2/3)

Research title	Au.	Subjects	Methodology	Results	Conclusion	Limitations
Do activity levels increase after total hip and knee Arthroplasty?	Harding 2014	44 patients TKA & THA pre/ 6 months post	ActiGraph1 GT1M activity monitor worn around waist for minimum of 10 hours on 7 consecutive days. Remove it for sleeping and bathing.	No change in objectively measured physical activity over time. No change in activity intensity after arthroplasty. Sedentary time before 82% and 83% 6 months post.	Most people in the study at 6 months post-arthroplasty did not meet the American Physical Activity Guidelines.	Impractical for patients to remove it and wear it daily. Doesn't measure standing or rest time. Mixed hip and knee arthroplasty. Unstandardized measurements over 4–7 days.
Does total knee arthroplasty affect physical activity levels? Data from an osteoarthritis initiative	Kahn 2015	63 patients included in a pre-TKA group and 60 patients in a post-TKA group after I year	ActiGraph1 GT1M activity monitor for 4–7 days	No significant difference (P = 0.57) in average daily activity count between pre-TKA patients (186,878.7 counts/day) and post-TKA patients (197,376.8 counts/day).	Patients' self-reported symptoms of knee pain, knee functions were better post TKA. No significant difference in objective measures of physical activity between pre-TKA and post-TKA	Observed different patients at the same time point rather than the same patients before and after (No accelerometer data from the same patients before and after TKA). Did not measure accelerometer in a standardized timeline with regard to the timing of TKA.

Table 2-20. Characteristics and results of physical activities level using accelerometers post-total knee arthroplasty studies (3/3)

Research title	Au.	Subjects	Methodology	Results	Conclusion	Limitations
Patient activity after TKA depends on patient-specific parameters	Lutzner et al. 2014	97 assessed before and 1-year post-TKA in comparison with 39 age-matched control	ActivPAL measures total steps, moderate to vigorous activity, time spent lying, sitting, standing, walking Attached over the anterolateral tibia for 4 days awake and asleep.	Improvements in: Steps 5,278 to 6,473 (1,195 steps/day). Moderate PA 1,150 to 1,935. Time spent lying, sitting or standing or walking did not change	All activity measurements after TKA were less than that of the age-matched control, 13,375 steps per day 6,562 moderate PA 2.9 hours per day walking. Only 16 patients met PA guidelines post-TKA.	Four consecutive days may not capture activity behaviour (recommended to include weekends and weekdays). The device was applied to the anterolateral aspect of the tibia a position not in compliance to recommendation and a position not previously validated. This may measure the number of steps but cannot distinguish between sitting and standing. 20.6% loss of data for TKA group and 9.3% for control due to a technical failure. Selection bias as many eligible patients were not included for different reasons.
Rationale, design and protocol of a longitudinal study assessing the effect of total knee arthroplasty on habitual physical activity and sedentary behaviour in adults with osteoarthritis	Meiring 2016	107 participants	Pt assessed one week before and 6 weeks, 6 months post-TKA using ActiGraph GTX3+ and activPAL monitors Both worn by participants for 24 h/day for seven days	N/A	N/A	N/A

Table 2-21. Measurements Criteria for commonly used Accelerometers to assess Physical Activities.

Commercial technology name	Accelerometer type	Results	Commonly used	Battery life	accuracy	weight
RT3 tri-axial research tracker kit	Three-dimensional accelerometer	Displays performance graphs and activity unit kilocalories or metabolic activity	Gold standard for energy expenditure.	30 days	97%	67 g
ActivPAL Professional	A uni-axial piezoresistive accelerometer.	Accurately measure the physical behaviour results in 3 categories: sitting/lying, standing and stepping. It also measures cadence and number of steps of the user over a day or week.	Validated for the amount of time spent sitting, lying etc. Shown to be highly accurate for step number and cadence. The monitor also provides data for energy expenditure.	> 8 days	98%-99%	20 g
ActiGraph GT1M	Single-axis piezoelectric accelerometer can be programmed to turn itself on at a specific time.	The device can measure activity count, steps count, calorie and estimate activity levels across a range of ages and clinical groups.	Energy expenditure classification devices that record acceleration in a set time and assign values to estimate acceleration magnitude within a set time period to reflect body movements. Mainly used with children and adolescents and sleep pattern studies due to its good reproducibility, validity and feasibility within these groups.	14 days	99%	27 g
Cyma StepWatch3	StepWatch is a microprocessor-controlled step counter.	Shows higher estimates of steps per day (>18%) than actual steps taken at slow walking speeds when compared to observational records.	Validated activity monitor for use on healthy, obese, amputees, stroke, spinal injury, young and old	60 days	91–99%	38 g
Dynastream AMP331	Two accelerometers (one uni-axial, one bi-axial)	Its multi-dimensional motion-tracking ability offers a continuous method of measuring distance and velocity travelled	Customised for the recreational running market, runners and walkers.	7–10 days	97–99%	50 g
PAM:Prosthetic Activity Monitor	Incorporates one bi-axial and one uni-axial accelerometer.	Monitors the level of daily activity: walking patterns and steps	Lower-limb amputee patients	7 days	96%	50 g
IDEEA: intelligent device for energy expenditure and activity	Physical activity assessment, portable gait analysis, energy expenditure analysis and functional capacity evaluation monitor	Provides information on the onset, duration and frequency of each activity and computes the amount and intensity of these activities.	Comprises multiple sensors located at numerous points on upper and lower leg, wrist, sternum and foot via cables. This hinders its use for long-term ambulatory monitoring. Reduced accuracy for up/downstairs).	3 days	98%	59 g

Table 2-22. Critical Appraisal Skills Program (CASP) for activPAL studies post Total Knee Arthroplasty.

CASP section	Criterion	Meiring 2016	Lützner Dipl-Päd et al. 2014
Validity of result	Population defined	YES	YES
	Intervention described	YES	YES
	Study design	YES	YES
	Outcome defined	YES	YES
	Patient randomization (recruitment)	YES	YES
	Researchers/assessors blinded	NO	NO
	Similar group baseline	NA	YES
	Equal intervention	YES	YES
	All subjects accounted for in conclusion	NA	NO
The results	Clearly defined outcomes	NA	YES
	Non-selective reporting of outcomes	NA	NO
	Appropriate statistical methods	NA	YES
	Statistical significance reported	NA	YES
Results value	Inferential statistics employed	NA	YES
	Generalizability	NA	NO
	Confidence intervals presented	NA	NA
	Clinical relevance defined	NA	YES
	Benefits worth the cost	NA	YES
	Relevant to present evidence base	NA	YES
	Total score	6 /19, 32%	15/19, 79%

2.2.5 Patients experience studies

More than half of patients' early concerns post-TKA are not considered in commonly used patients report outcome measures (PROMs). Individual interviews with 30 patients 6 weeks post-TKA concluded that 32 patient concerns were not covered sufficiently in KOOS, WOMAC and OKS, as shown in Table 2-23 (Rastogi, Davis, & Chesworth, 2007). In agreement with that, five patients post-TKA with an age range of 51–78 years (2 females, 3 males) reported some improvement in their physical activity 6 months post-operation. However, only 33% of them showed a mild (1.3–2.7%) reduction in sedentary activity based on accelerometer measurements. The patients explained that activity limitations pre-operation were due to pain and post-TKA due to other new limitations, such as age and comorbidities. Their personal belief about physical activity that it is enough to know you can (Harding, Holland, Hinman, & Delany, 2015).

This confirms that current medical outcomes evaluation for intervention implications differ from the patients' perspective. This may be explained by the dissatisfaction of some of patients post-TKA. So, more sensitive to patients experience assessment methods is required rather than profession-driven tools.

Table 2- 23. Individual interview findings of Early Patient concerns following total knee arthroplasty and patient reported outcome measures (n = 30) (Rastogi, Davis, & Chesworth, 2007).

	Concern	WOMAC	KOOS	OKS
Body function	Decreasing pain in surgical knee	YES	YES	YES
	Reducing swelling in surgical leg	×	YES	×
	Avoiding infection in surgical knee	×	×	×
	Sleeping better at night	×	×	×
	Increasing bend in surgical knee	×	YES	×
	Increasing straightening in surgical knee	×	YES	×
	Increasing strength in both legs	×	×	×
Activities	Getting out of bed on your own	YES	YES	×
	Getting in/out of a bath	YES	YES	×
	Putting on your own shoes and socks	YES	YES	×
	Dressing yourself	×	×	×
	Walking on a flat surface	YES	YES	YES
	Walking on uneven ground	×	×	×
	Descending stairs	YES	YES	YES
	Ascending stairs	YES	YES	×
	Cooking your own meals	×	×	×
	Doing your own housework	×	×	×
	Heavy domestic duties	YES	YES	×
	Light domestic duties	YES	YES	×
	Getting in/out of a car	YES	YES	YES
	Sitting comfortably in a car	×	×	×
	Doing exercises as prescribed by physiotherapist	×	×	×
Participation	Driving a vehicle	×	×	×
	Going shopping	YES	YES	YES
	Returning to hobbies (e.g. dancing, gardening)	×	×	×
	Going back to regular exercise classes or sport	×	×	×
Environmental factors	Being less of a burden on spouse or caregiver	×	×	×
	Having the support of family members	×	×	×
	Having the support of neighbors	×	×	×
	Receiving competent help from healthcare workers in a timely manner	×	×	×
Total		11/32	14/32	5/32

To assess the patient's insider's view of their social life and sense of illness, further modification and changes to their personal, emotional and social life post-TKA using qualitative methods is essential. To assess the complexity of living with musculoskeletal conditions at the individual level or group and population levels, multiple methods are recommended to explore data in depth, taking advantage of both methodologies and minimising their limitations (Ong & Richardson, 2006).

Therefore, in order to assess these patients' concerns and other quality of life aspects post-TKA requires further assessment tools, more than controlled experiments testing define isolated variables. Qualitative research offers useful methods to explicate the complexity and deeper meaning of patient experiences and outcomes post-TKA. Qualitative methods provide richness of understanding of patients' views, which may cover quantitative methods' gaps and limitations to improve healthcare services and patients' satisfaction rate (Beaton & Clark, 2009).

In the previous quantitative sections, we sought to explore outcomes post-TKA to accept or reject the deductive hypothesis. In contrast, patients' experience and their perceptions of current outcome measurements post-TKA are poorly understood. In order to explore this area a qualitative method is appropriate as it facilitates the collection of in-depth experiences and perceptions of individuals about a specific phenomenon which, in this case is outcomes post TKA. Specifically, a phenomenological approach allows for the collection of diverse and unique patient experiences and outcomes post-TKA (Beaton & Clark, 2009).

Focus-group discussions (FGD) have an advantage over other qualitative methods such as individual interviews, documents, observation and field notes. It provides an extra dimension to gather data and a wider degree of spontaneity in the patients' views expressed, in contrast to one-to-one interviews where the interaction is limited between patients and researcher and depends on patient responses (Westby & Backman, 2010). In accordance with PRISMA, a systematic review of the focus-group discussion literature was conducted electronically according to the search strategy explained in section one.

Inclusion criteria: Any study assessing patient experience or outcomes at any point in time post-primary TKA using focus-group discussions or interviews as qualitative methods.

Exclusion criteria: Any qualitative study using data-collection methods other than focus-group discussions (FGD), such as individual interviews, documents, observation and field notes. Any study exploring preoperational patients' decision-making for knee arthroplasty or preoperational experience of knee osteoarthritis while they are on a waiting list for TKA.

Search results

A PRISMA search strategy was used to devise a transparent article-selection process, which is summarised in Flow Diagram 2-10. After electronic filtration of the first stage search to restrict the results to articles in English, about humans and produced between 2004 and 2017, around 1,726 articles were identified. After duplication exclusion and applying search limitations, 43 studies satisfied the inclusion criteria. Abstract screening for 15 papers satisfied the eligibility criteria, only 3 of them are included. Nine studies were excluded because they explored preoperational patients' decision-making for knee arthroplasty or preoperational experiences of knee osteoarthritis while they were on a waiting list for TKA. The remaining three excluded papers use individual interviews as data-collection methods. The quality of the included studies according to the Critical Appraisal Skills Program (CASP) is clarified in Table 2-24.

The three included studies explore patients' experiences and outcomes post-primary TKA using recent focus-group discussions, in 2010, 2015 and 2016, which is consistent with the

recent growth in the use of qualitative methodologies within the field of orthopaedics (Table 2-25). A qualitative methodology is an additional tool to overcome the limitations of quantitative research in being able to explicate patients' experiences and views to improve the quality of health service based on patients' perceptions. To date, its potential has been underrecognized (Beaton & Clark, 2009).

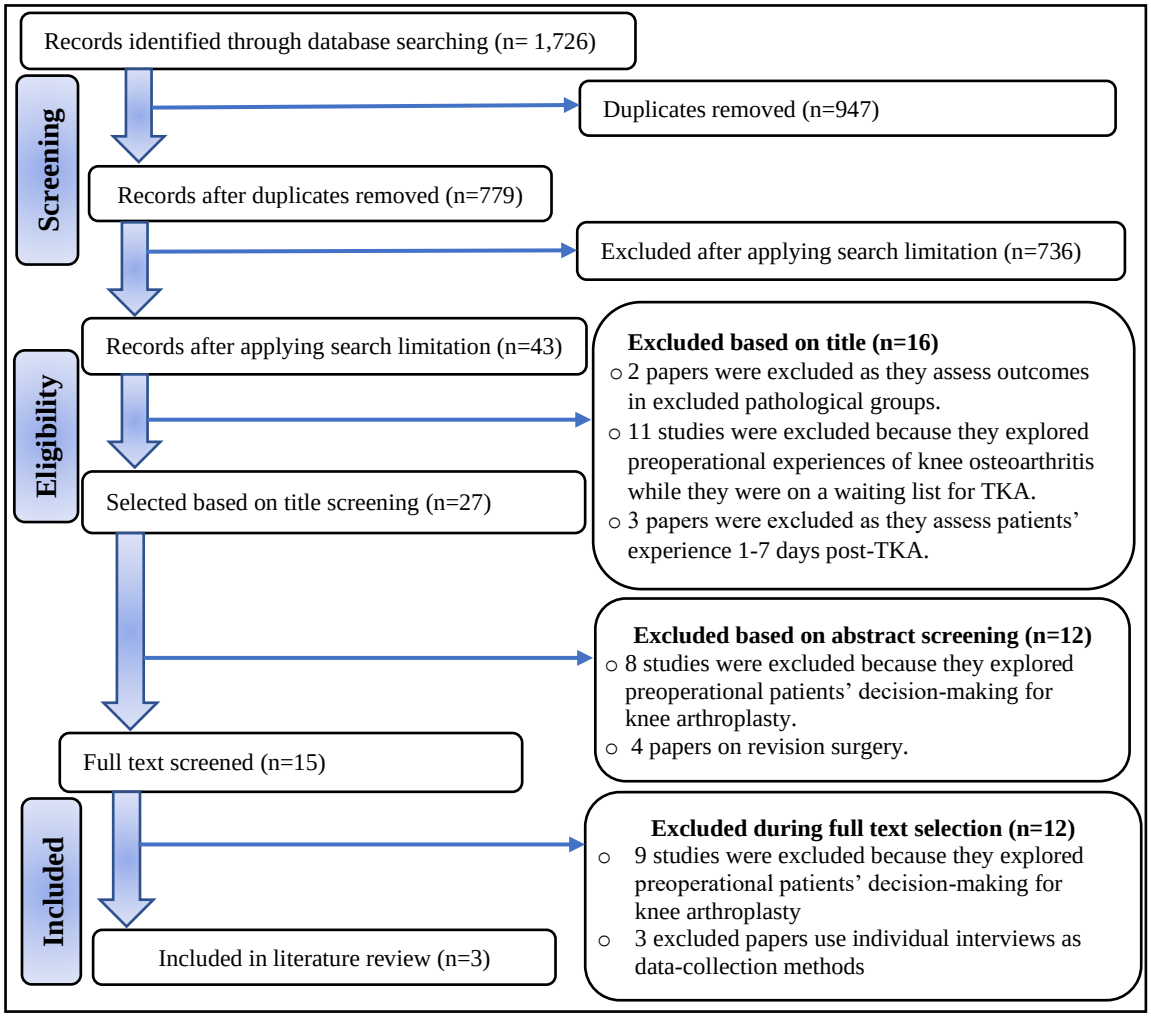

Figure 2- 10. PRISMA Flow Diagram for Focus Group Discussion studies

A recent study by Zacharia et al., (2016) explores patient satisfaction, expectations and other subjective quality of life domains, such as emotional and social functioning, post-TKA in an Indian population with focus-group discussions (FGDs). FGDs showed loss of function was the main concern, followed by pain and deformity, pre-operation. Preoperative social disability, such as being restricted to home, dependency and stopping working or reduced work efficiency may lead to depression and mental stress. Preoperative expectations strongly affect satisfaction levels post-operation; these depend on many factors, such as educational level, socioeconomic and other factors. Inadequate post-rehabilitation care and insufficient instruction were reported by most patients. Interestingly, based on FGDs, patient

with good knee society scores (KSS) post-surgery had low satisfaction levels while another group with low KSS had reasonable satisfaction levels (Zacharia et al., 2016).

Other FGDs and separate individual interviews conducted by Westby & Backman, (2010) in a different age group with different education levels explored 32 patients' views on rehabilitation and outcomes post-operation. From the results emerged six themes from patients after both TKA and total-hip arthroplasty (THA). Communication between patients and health teams was poor which can negatively influence patients' satisfaction and outcomes. Poor communication leads to unclear or unrealistic expectations, which are a second theme. Clear communication and education pre-operation may modify patient expectations in terms of acute pain level, sleep disturbance, help from family and functional recovery. Effective and timely education can improve patients' attitudes as a third theme. A positive attitude acknowledging the mind-body connection can influence post-TKA recovery. The fourth theme concerns the importance of family support in the early stages and rehabilitation, which improves patients' overall satisfaction. The fifth theme is recovery barriers at the system level, for providers and patients. Patient factors like coping with pain, psychology, attitude and motivation play an essential role. At the system level are factors such as waiting for surgery, the cost of treatment and limited rehabilitation services. The final theme concerns getting back to normal after surgery, which differs according to expectations, age, lifestyle and other factors. These results are based on mixed participants who underwent both TKA and THA, so it is hard to isolate knee findings and whether they encounter different problems (Westby & Backman, 2010).

These two study populations differ in age range, education level and FGD timing post-TKA but show similar findings. The first study by Zacharia et al. (2016) had an age range of 60–65 years, participants were manual labourers of low and medium socioeconomic status who were assessed three years post-TKA, while the second study by Westby & Backman (2010) included younger subjects, age range 46–78 years, most of them highly educated and involved in FGDs one-year post-TKA. Both found poor preoperative education or insufficient instruction led to low levels of satisfaction post-operation due to unexpected or unrealistic expectations. Both groups' main concern post-operation was functional recovery, which varied according to many factors such as age, socioeconomic level, education and expectations. Rehabilitation service barriers were another concern for both groups.

FGDs conducted by van Egmond et al. (2015) explored nine patients' experience 6 weeks post-TKA – their average age was 68.2 years, six of them were females – and found pain was the main issue, even with prescribes medication, especially in the first week. All of them

received standardized physiotherapy with different strategies. None had any sleep disturbance. Most of them reported no problems with their wounds. Most of the patients requiring home-care service were living alone. Most patients preferred to use a rollator for transportation indoors, rather than crutches. All patients highly appreciated the opportunity to call the orthopaedics consultant if they needed to. Only two patients contact him, one regarding pain and other for a wound-irritation issue. Overall, they were satisfied, but this was not checked with objective measurements or specific tools. A small number of patients were included without quantitative analysis and the presence of one of the orthopaedic surgeons in an FGD session may interfere with the conclusion. There are insufficient details of their demographic characteristics and answers are not linked to patients, which may limit in-depth correlation or analysis (van Egmond, Verburg, Vehmeijer, & Mathijssen, 2015).

All three studies are summarized in Table 2-25 and 2-26, the total number for all patients in all three studies was 70 patients post-primary TKA (52 females, 18 males). Their age range was 46–78 years with different socioeconomic and educational levels, home situations and work statuses. The study by van Egmond et al. (2015) was mainly concerned with patients in an acute stage post-surgery as FGDs were held 6 weeks post-TKA. In the remaining two studies (one year or more than 3 years), the conclusions were similar although the patient samples were different. The main concern for all participants was their return to valued daily activities but no one explored exactly what functions and activities were their main concerns. While educational levels were different, both groups' findings stress the importance of preoperative education about outcomes, pain, swelling and length of recovery. Communication with health providers was valued by patients, but they need more information from the surgeon before surgery and to have access to the surgeon post-operation if required to improve their comfort and confidence levels. In a low to medium socioeconomic population, poor education greatly affects the realism of expectations and the severity of osteoarthritis pre-operation may lead to maximum gains post-TKA. In a highly educated population, the need for family support or home service, a limited or costly rehabilitation service and difficult transportation were the main concerns.

In term of analysis, all the analyses examined content and only the study by Westby et al. (2010) used thematic analysis for content. The study by Zacharia et al. (2016) was the only one to state findings post-TKA, in the other two studies the findings are mixed together for both TKA and total hip arthroplasty, which does not support accuracy as they encounter different problems. A methodology of appropriate quality is required to explore patients' experiences and outcomes post-TKA to overcome the limitations clarified in Tables 2-24 &

2-26. To the best of our knowledge, no study has explored patient experiences and outcomes post-TKA using focus-group discussions one year after surgery to explore whether there are factors that might help us to understand why some patient medical outcome measurements were good but they were not satisfied, or vice versa. Exploration of potential barriers to functional recovery may support future modifications that might improve outcomes post-TKA.

Table 2- 24. Qualitative Critical Appraisal Skills Program (CASP) for Focus Groups post Total Knee Arthroplasty studies.

	Criterion	Zacharia et al. 2016	Westby et al. 2010	Van Egmond 2015
Screening	Clear statement of research aim	Yes	Yes	Yes
	Is the goal important and relevant?	Yes	Yes	Yes
	Are qualitative methods appropriate for the goal?	Yes	Yes	Yes
	Interpret/ illuminate subjective experience?	Yes	Yes	Yes
Recruitment & data collection	Are qualitative methods justified for the aim?	Yes	Yes	Yes
	Participant selection explained	No	Yes	Yes
	Selected participants appropriate to access the required knowledge	Yes	Yes	Yes
	Clear data-collection method (interview ….)	Yes	Yes	Yes
	Clear methods conduction (topic guide ...)	Yes	Yes	Yes
	Justify modifications to study if present	Yes	Na	Na
	Clarify data-recording methods (notes, video)	Yes	Yes	Yes
	Discusses data saturation	Yes	Yes	No
Researcher effect, ethics and data analysis	Considers the relationship between researcher and participants and potential bias during data collection, formulates questions.	No	Yes	Yes
	Considers the influence of any changes to the research design.	Yes	N/A	N/A
	Sufficient explanation of participants to confirm ethical standards	Yes	Yes	Yes
	Discusses informed consent, confidentiality and any possible effects of study	No	No	No
	Approval of ethical committee	Yes	Yes	No
	Sufficient analysis process description	Yes	Yes	Yes
	Clear categories/themes derived from data if used	Na	Yes	Na
	Sufficient data presented to support findings	Yes	Yes	No
	Considers contradictory data	No	No	No
	Critically examines potential bias, influence in analysis and data selection	No	Yes	Yes
Findings	Clear statement of findings	Yes	Yes	No
	Adequate discussion of evidence, both for and against study argumentation	No	No	No
	Credibility of findings (triangulation, respondent validation, more than one analyst)	Yes	Yes	No
	Findings are discussed in relation to the original research question	Yes	Yes	Yes
	Considers the findings in relation to current practice, policy and research-based literature.	Yes	Yes	Yes
	Identifies new areas where research is necessary	Yes	Yes	Yes
	Discusses whether/how findings can be transferred to other populations or considers other ways in which research may be used	Yes	Yes	No
Total score		23/29 79%	26/29 89%	20/29 69%

Table 2- 25. Characteristics and results of Qualitative Focus Group Discussion Studies post Total Knee Arthroplasty Population.

Research Title	Author	Subjects/methods	Results	Conclusion
Patients' and health professionals' views on rehabilitation practices and outcomes following total hip and knee arthroplasty for osteoarthritis: a focus-group study	Westby 2010	Patients: 32 post-TKA & THA 19 males/ 11 females Ages 46–78 years 15 highly educated 44 health professionals 11 focus groups & 8 interviews	Six key themes emerged: 1) Let's talk (issues related to patient-health professional and inter-professional communication) 2) Expecting the unexpected (observations about unanticipated recovery experiences) 3) It's attitude that counts (the importance of the patient's positive attitude and participation in recovery) 4) It takes all kinds of support (along the continuum of care) 5) Barriers to recovery (at patient, provider and system levels) 6) Back to normal (reflecting the diversity of expected outcomes).	Patients offered different, but overlapping views compared to health professionals regarding rehabilitation practices and outcomes following THA and TKA.
Patient-based outcome analysis is important to determine the success of total-knee arthroplasty: results of a focus-group discussion	Zacharia 2016	42 patients post-TKA Ages 60–65 years 3 years post-TKA 24 females, 18 males 4 focus-group discussions Knee-society score X-rays	There is a discrepancy between the satisfaction levels of patients and surgeons. There is a difference in satisfaction level achieved depending on socioeconomic, geographic, and cultural characteristics. Satisfaction affected by preoperative expectations. Social disabilities: restriction to home, dependency & stopping working caused depression & mental stress. Improper rehabilitation and advice post-rehabilitation were reported by most patients. Patients with good knee-society scores (KSS) post-surgery have low satisfaction levels and another group with reasonable satisfaction levels have low KSS.	Newer assessment tool combining radiological, surgeon-based assessment and patient satisfaction based on their socioeconomic status and cultural characteristics, which are required for different populations.
Early follow-up after primary total-knee and total-hip arthroplasty with rapid recovery: focus groups.	Van Egmond et al. 2015	9 patients 6 weeks post-TKA Av. age 68.2 years 6 females	One focus -group discussion 6 weeks post-TKA, semi-structured, 90 minutes: Pain was the main issue even with medication. All received standardized physiotherapy. Did not have any sleep disturbance. Most of them reported no problems with their wounds. Living alone maximized the need for home-care services. They preferred using a rollator for indoor transportation indoors rather than crutches. All patients highly appreciated the opportunity to call the orthopaedics consultant if they needed to. Overall, they were satisfied.	

Table 2- 26. Summary of focus-group studies post-total knee replacement.

Item	Zacharia et al. 2016	van Egmond et al. 2015	Westby et al. 2010
Number of participants	42 patients (85% female)	9 patients (6 females, 3 males)	19 patients & 4 spouses (11 females, 8 males)
Patient ages	60–65 years	68.2 years (av.)	46–78 years
Socioeconomic status	Low to medium (India)	Not clarified (Netherlands)	Not clarified Canada & US
Education level	Low	Not clarified	15/19 college education
Home situation	Not clarified	5 have partner, 4 do not	Not clarified
Work status	5 manual labourers, 5 farmers, 8 housewives, 7 sedentary work	Not clarified	10/19 retired
Sampling methods	Not clarified	Selective to ensure sufficient diversity	Ethnically diverse sample (most Caucasian, one African American, one Aboriginal)
Time post-TKA	At least 3 years post-TKA	6 weeks post-TKA	One-year post-TKA
Length of FGD	Not clarified	90 minutes	120 minutes
Moderator	1	2	2
Analysis	Content analysis without correlation	Content analysis without correlation	Thematic content analysis
Limitations	Sampling not clarified, ditto FGD details	Mixed results of FGD for TKA and THA. Surgeon attended a FGD.	Mixed results of FGD for TKA and THA.
Findings	Education level highly affects realism of expectations. Severe preoperational disease may lead to more functional gain post-TKA. Preoperational education is essential. Importance of surgeon and patient relations. Satisfaction based on ability to: Walk Negotiate stairs Go to work Use squat toilet Pray	Pain was the main complaint, even with medication. All received standardized physiotherapy. No sleeping disturbance. Only one patient experienced a wound problem. Most patients living alone required home services. Rollator preferred for indoor mobility rather than crutches. All satisfied with attainability of hospital.	<u>Communication:</u> Need more time from surgeon to improve their comfort level. Call and see what's going on really important to patients. <u>Expecting the unexpected</u> Unexpected pain and swelling. Sleep disturbance, even with medication. Length of recovery. <u>It's attitude that counts</u> Positive and adhere to exercise plan, using leg post-TKA. <u>Support</u> Need family support post-TKA or home services. Having access to surgeon is essential. <u>Barriers to recovery</u> Limited, costly and long wait for rehabilitation post-TKA in addition to transportation difficulty. <u>Back to normal</u> All wanted to return to normal and the questioner did not measure that.

2.2.6 Patients' satisfaction

Patients' satisfaction within healthcare as a concept was defined in 1873 (Ware, Snyder, Wright, & Davies, 1983). It is recommended to consider patients' perception of outcomes after surgery as part of quality control for healthcare providers (Donabedian, 1988). Satisfaction post-TKA is usually linked to functional improvements and pain reduction. Many research attempts to improve the understanding of patients' satisfaction post-TKA, as the degree of satisfaction post-TKA is significantly less than for post-total hip arthroplasty, with up to 20% of patients post-TKA not being satisfied (Hamilton et al., 2012; Klit, Jacobsen, Rosenlund, Sonne-Holm, & Troelsen, 2014; Neuprez et al., 2016; Noble et al., 2006; Scott et al., 2010).

Patients' satisfaction post-TKA is usually measured using a five-point Likert scale (very satisfied, satisfied, neutral, dissatisfied, very dissatisfied) (Lizaur-Utrilla, Martinez-Mendez, Miralles-Munoz, Marco-Gomez, & Lopez-Prats, 2016; Ozdemir et al., 2017; Van Onsem et al., 2016), a 4-point Likert scale (very satisfied, satisfied, unsure, dissatisfied) (Clement, MacDonald, Patton, & Burnett, 2015; Clement et al., 2018; Goudie, Deakin, Ahmad, Maheshwari, & Picard, 2011; Kim, Kwon, Kang, Chang, & Seong, 2010), a visual analogue scale (VAS) for satisfaction (Collados-Maestre, Lizaur-Utrilla, Martinez-Mendez, Marco-Gomez, & Lopez-Prats, 2016; Sauder et al., 2019) or by asking patients if they are satisfied with their TKA (and given the options of answering "Yes", "No" or "I'm not sure") (Halawi et al., 2019; Jacobs & Christensen, 2014; Jacobs, Christensen, & Karthikeyan, 2014). To understand patients' satisfaction and the factors that may affect it, a systematic review of the patient satisfaction post-primary TKA literature was conducted electronically according to the search strategy in section one.

Inclusion criteria: Any study measuring patients' satisfaction post-primary TKA.

Exclusion criteria: To maintain the focus on the study objective to assess the effect of patient factors on satisfaction post-TKA, any other surgical or medical intervention factors were excluded. Any study assessing satisfaction following arthroplasty revision, unicompartmental knee arthroplasty or studies comparing different surgical approaches or medication on patients' satisfaction; studies assessing the differences in patients' satisfaction between different rehabilitation protocols or home-care service or nursing-staff care or pain-management approaches; studies analysing satisfaction post-TKA with specific pathologies, such as cerebrovascular disease, fibromyalgia, bleeding disorder and rheumatoid arthritis; studies estimating patients' satisfaction based on patient reported outcome measure scores (PROMs) were excluded.

Search results

A PRISMA search strategy was used to devise a transparent article-selection process, which is summarised in Flow Diagram 2-11; after electronic filtration of a first-stage search to restrict the results to articles in English, about humans and in peer-reviewed journals produced between 2004 to the present, 163 articles were identified. After duplication exclusion, 97 studies satisfied the inclusion criteria; after title and abstract-screening, 70 studies were excluded; 35 papers measured the effects of different surgical approaches or medication used post-TKA to enhance satisfaction on recovery. Seventeen studies assessed satisfaction level variation between different rehabilitation programmes, early discharge, patients' home service and pain medication management post-TKA. Nine papers estimated patients' satisfaction based on PROM scores, such as WOMAC, KOOS and OKS. Five studies compared satisfaction following primary and revision/ unicompartmental arthroplasty. Four studies assessed satisfaction post-TKA in patients with a history of cerebrovascular disease, fibromyalgia, bleeding disorder or rheumatoid arthritis. Full-text screening found that 27 papers satisfied the eligibility criteria, these are included and summarised in Table 2-27.

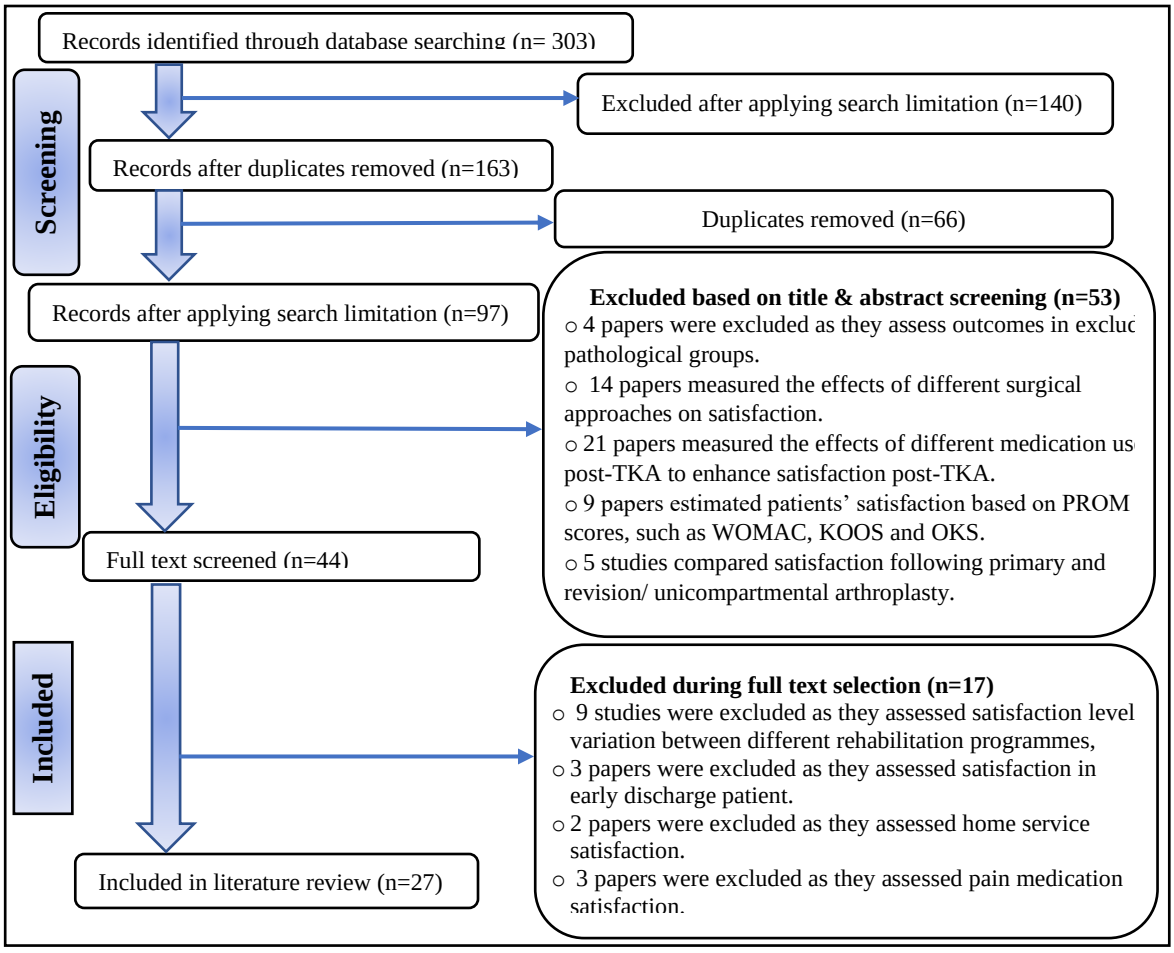

Figure 2- 11. PRISMA Flow diagram for patients' satisfaction post-Total Knee Arthroplasty.

Twelve papers assessed the factors that might affect satisfaction one-year post-TKA, 6 studies assessed the effect 2–5 years post-TKA, one study assessed satisfaction 24 hours after surgery, four studies developed predictions for 3 months and one year post-TKA, two studies assessed the satisfaction rate at one year post-TKA in Korean and Saudi patients, one recent study assessed satisfaction with single question correlation with other PROMs, and one study assessed satisfaction changes 9 years post-TKA. The main limitations of previous studies were in sampling methods, assessor blindness, follow-up being limited to the short and medium term, using non-validated methods to assess satisfaction, and conclusions based on low levels of evidence which may increase the risk of conclusion bias (Table 2-28).

A recent study by Halawi et al., (2019) investigated the top five factors that reduce patients' satisfaction one-year post-TKA based on a standardized scripted telephone call. The patients' responses were summarised as percentages: pain (41%), functional limitations (26%), presence of complications post-surgery (17%), unrealistic expectations (4%), quality of care and staff (11%) (Lizaur-Utrilla et al., 2016). The rest of the studies assessed one or more factors of patients' satisfaction at one-year post-TKA and it was found that the factors negatively influencing post-operative satisfaction were: a waiting time longer than six months; patients having a fixed flexion contracture, weak quadriceps strength, lower back pain, depression and poor mental health; patients being morbidly obese; a failure to achieve patient expectations; functional disabilities in high flexion activities; poor PROM scores post-TKA; and poor general health (Clement & Burnett, 2013; Clement et al., 2015; Clement et al., 2018; Collados-Maestre et al., 2016; Culliton, Bryant, Overend, MacDonald, & Chesworth, 2012; Deakin, Iyayi-Igbinovia, & Love, 2018; Furu et al., 2016; Goudie et al., 2011; Kim et al., 2010; Lizaur-Utrilla et al., 2016; Thambiah, Nathan, Seow, Liang, & Lingaraj, 2015). In contrast, the time of surgery, the duration of surgery and affective temperament did not affect patients' satisfaction one year post-TKA(Benditz et al., 2017; Ozdemir et al., 2017).

Six studies showed that the medium term (2–5 years) factors that negatively affected patients' satisfaction were: African American race, less severe degenerative changes before arthroplasty, pain post-TKA, passive knee flexion range of motion and fixed flexion contracture (Goudie et al., 2011; Jacobs & Christensen, 2014; Jacobs et al., 2014). Patients' satisfaction in the medium term was positively affected by improvements in knee flexion range of motion and improvements in functional activity, such as climbing stairs and squatting (Ha, Park, Song, Kim, & Park, 2016; Nakahara et al., 2015).

There was a conflict regarding the effect of age and BMI on patients' satisfaction in the short and medium term post-TKA. This may be due to differences in methodology, in the tools used

to assess and report satisfaction, the assessment time frame, and differences in categorising age and BMI in their analyses (Clement et al., 2018; Goh et al., 2017; Jacobs et al., 2014).

Four studies predict patients' satisfactions at 3 and 12 months post-TKA based on PROM scores (OKS, KOOS, KSS), pain catastrophizing scale, knee flexion range of motion, meeting preoperative expectations, satisfaction with pain relief and satisfaction with the hospital experience (Hamilton et al., 2013; Kunze et al., 2019; Van Onsem et al., 2016; Williams et al., 2013).

The study by Shannak et al, (2017, assessed changes in patients who were dissatisfied or unsure at one-year post-TKA for 9 years. The results showed that 46.7% of such dissatisfied patients remained so. Of the patients were unsure about their satisfaction at one-year post-TKA, 20.8% remained so, 21.9% and 57.3% became dissatisfied and satisfied, respectively. However, satisfied patients' long-term changes were not assessed in this study (Shannak, Palan, & Esler, 2017).

Although patients' overall satisfaction post-TKA is commonly measured using one question with different options to answer (binary, 4- or 5-point Likert scale, VAS), this may not accurately assess the reasons behind dissatisfaction. A patient's overall satisfaction may be affected by the hospital experience, surgical complications, pain reduction, functional improvements and expectation achievements. Therefore, it is recommended to use satisfaction tools that cover each issue in isolation and elicit responses in more depth to understand the impact of each factor on satisfaction (Harland, Dawkin, & Martin, 2015; Loth, Giesinger, Giesinger, Howie, & Hamilton, 2019).

In conclusion, there was a conflict regarding the effect of patient's age and BMI in the short and medium term post-TKA, and the long-term effect was not clear. The effects of all the factors in the short and medium term are not completely understood in the long term post-TKA. The available evidence fails to conclusively support any preoperative predictors of medium- and long-term satisfaction post-TKA. Long-term changes in patients' satisfaction post-TKA are not assessed. Understanding long-term changes and factors that might improve patients' satisfaction post-TKA could improve the overall experience and outcomes. Although satisfaction assessments using multiple questions showed a deeper understanding than those using a single question, the current study used a single question as data were collected previously. The prospective study used the same methods to maintain homogeneity in comparisons between the two groups.

Table 2- 27. Characteristics and Results of Patients' satisfaction studies Post-Total Knee Arthroplasty Studies (1/6).

Research title	Author	Subjects	Methodology	Conclusion
Patient Dissatisfaction After Primary Total Joint Arthroplasty: The Patient Perspective	Halawi et al., 2019	276 patients assessed 1-year post-TKA	Patients were then contacted via telephone to enquire about their satisfaction with their surgery	The most common reasons for dissatisfaction after TKA were persistent pain (N = 19/46, 41%), functional limitations (N = 12/46, 26%), surgical complications and reoperation (N = 8/46, 17%), staff or quality of care issues (N = 5/46, 11%), unmet expectations (N =2/46, 4%).
Negative impact of waiting time for primary total knee arthroplasty on satisfaction and PROMs	Lizaur-Utrilla et al., 2016	192 patients followed for one-year post-TKA	Prospective observational study of patient satisfaction that was assessed on a five-point Likert scale at one post-operative year	Dissatisfaction rate was also higher in patients waiting longer than six months Waiting time longer than six months negatively influenced post-operative satisfaction and patient-related outcome at one-year post-TKA.
Postoperative pain and patient satisfaction are not influenced By time of day and duration of knee and hip arthroplasty: a prospective cohort	Benditz et al., 2017	623 patients were analyzed 24 hours after primary total knee for patient satisfaction	Assess the effect of time of day and duration of TKA and THA on postoperative pain perception and patient satisfaction	Neither the time of day nor the duration of surgery has any influence on patient satisfaction and postoperative pain 24 hours after total knee or hip arthroplasty.
Patient and Intraoperative Factors Influencing Satisfaction Two to Five Years After Primary Total Knee Arthroplasty	Jacobs et al., 2014	989 primary TKAs (755 patients; 248 male, 507 females; age = 65.0 ±9.0 years, BMI = 34.3 ± 6.9	Patient satisfaction was determined by asking patients if they were satisfied with their TKA and were given the options of answering “Yes”, “No” or “I'm not sure”.	The two factors that appeared to be associated with the greatest risk of dissatisfaction were African American race and less severe degenerative changes at the time of surgery. African American patients were three times more likely to be dissatisfied with their TKA. Intraoperatively, those with less severe degenerative changes were 2.1 times more likely to be dissatisfied.

Table 2- 27. Characteristics and Results of Patients' satisfaction studies Post-Total Knee Arthroplasty Studies (2/6).

Research title	Author	Subjects	Methodology	Conclusion
Factors Influencing Patient Satisfaction Two to Five Years After Primary Total Knee Arthroplasty	Jacobs et al., 2014	768 TKAs (799 patients; 276 male, 523 female; age = 64.8 ± 9.3 years, BMI = 34.2 ± 6.9 kg/m^2)	With 2 to 5-year follow-up of 768/959 (80%), evaluated the prevalence of dissatisfied patients and determined which factors were most related to patient satisfaction.	Of the 768 TKAs, 80 were dissatisfied with their procedure (10.4%). Postoperative Knee Society Pain Scores and passive knee flexion were mostly related to a lack of satisfaction. Age, gender and BMI did not appear to be related to patient satisfaction.
Flexion Contracture Following Primary Total Knee Arthroplasty: Risk Factors and Outcomes	Goudie et al., 2011	The study cohort was 811 knees (806 patients, 5 bilateral TKAs). The follow up was 24.3±1.2 months	To quantify the effect of fixed flexion contracture on patient satisfaction) at 2 years with a 4-point Likert scale (very satisfied, satisfied, unsure, dissatisfied)	Patients with fixed flexion contracture had lower patient satisfaction (P=.036).
Quadriceps strength affects patient satisfaction after total knee arthroplasty	Furu et al., 2015	28 patients who underwent 30 primary TKAs	Assess the correlation between satisfaction and muscle strength using the 2011 Knee Society Scoring System	Postoperative patient satisfaction significantly correlated with knee symptoms, functional activity, knee extensor strength and walking status.
Concomitant lower back pain impairs outcomes after primary total knee arthroplasty in patients over 65 years: a prospective, matched cohort study	Collados-Maestre et al., 2016	Prospective cohort of 48 patients with LBP and 96 without followed for 3.5 years post-TKA	Assess the difference between two groups' satisfaction post-TKA using visual analogue scale (VAS) for satisfaction.	The mean VAS score for satisfaction was significantly higher in patients with non-LBP than those with LBP (76.7 vs 64.5, P = 0.001).

Table 2- 27. Characteristics and Results of Patients' satisfaction studies Post-Total Knee Arthroplasty Studies (3/6).

Research title	Author	Subjects	Methodology	Conclusion
Patient age of less than 55 years is not an independent predictor of functional improvement or satisfaction after total knee arthroplasty.	Clement et al., 2018	2,589 patients undergoing a primary TKA	A retrospective cohort assessed whether an age of less than 55 years was an independent predictor of functional outcome and satisfaction, using a four-point Likert scale	An age of less than 55 years is not an independent predictor of functional outcome or rate of patient satisfaction after TKA. However, depression and poor mental health are significantly more prevalent in patients less than 55 years old and were independently associated with a lower satisfaction rate.
Affective temperament does not influence satisfaction after total knee arthroplasty.	Özdemir et al., 2017	143 patients who underwent total knee arthroplasty for arthrosis 5	To ascertain whether a negative affective temperament affects patient satisfaction and outcome measures (pre-/1 year)	No relationship was determined between temperament and satisfaction (P=.734). Overall, the satisfaction rate of the procedure in our patients was 93%.
A comparison of outcomes in morbidly obese, obese and non-obese patients undergoing primary TKA and THA.	Deakin et al., 2018	1,014 TKA operations were included	To determine and compare the outcomes of non-obese, obese and morbidly obese patients undergoing arthroplasty	In the morbidly obese group, fewer patients were very satisfied, although this was only approaching significance (72% vs 84% and 84%, Chi-squared p =0.054) but there was no significant difference in the numbers of unsure or dissatisfied (3% vs 6% and 6%, p = 0.635).
Post-operative Oxford knee score can be used to indicate whether patient expectations have been achieved after primary TKA	Clement et al., 2015	322 TKA performed during the study period	Patient satisfaction was assessed using a four-point Likert scale: very satisfied, satisfied, neutral, dissatisfied	Failure to fulfil patient expectations, for 15 of the 17 assessed, significantly increased the risk of dissatisfaction at 1 year ($p<0.05$).
The Relationship Between Expectations and Satisfaction in Patients Undergoing Primary TKA	Culliton et al., 2012	Literature review to examine the relationship between expectations and satisfaction in 5 studies. Multivariate analysis of the relation between expectations and satisfaction reported separately for TKA recipients.		Preoperative expectations did not correlate with postoperative satisfaction. However, postoperative satisfaction was predicted by how well postoperative expectations were met after surgery.

Table 2- 27. Characteristics and Results of Patients' satisfaction studies Post-Total Knee Arthroplasty Studies (4/6).

Research title	Author	Subjects	Methodology	Conclusion
Regional differences between the US, Scandinavia and South Korea in patient demographics and patient-reported outcomes for TKA	Sauder et al., 2019	A total of 398 TKA patients from three regions were assessed: 169 in Scandinavia, 129 in the US, 100 in South Korea	Regional variation in satisfaction scores from preoperative, 1-, 3- and 5-year	Scandinavian patients were significantly less satisfied at a 1-year visit than US and South Korean patients ($p < 0.001$; mean difference = 1.5). From 1-year to 5-year visits, the Scandinavian cohort was independently associated with lower levels of satisfaction.
Internal Validation of a Predictive Model for Satisfaction After Primary TKA	Kunze et al., 2019	484 consecutives primary TKA patients	Assess satisfaction using a continuous scale (1-10) to predict satisfaction 1-year post-TKA	11-question knee survey conferred a 97.5% sensitivity value and a 95.7% negative predictive value on identifying at-risk patients for postoperative patient dissatisfaction.
A New Prediction Model for Patient Satisfaction After Total Knee Arthroplasty	Onsem et al., 2016	107 patients pre- and 3 months post-TKA including RA and traumatic	To predict satisfaction 3 months post-TKA using a 5-point Likert scale	Based upon preoperative parameters, we were able to partially predict satisfaction and dissatisfaction 3 months after TKA.
Functional Disabilities and Satisfaction After Total Knee Arthroplasty in Female Asian Patients	Kim et al., 2010	Consequently, 387 (372 female and 15 male) patients (622 knees	Questionnaire were posted to assess patient satisfaction in Korean patients 1-year post-TKA using a 4-point Likert scale	Dissatisfied patients had more severe functional disabilities than satisfied ones. Dissatisfied patients tended to perceive functional disabilities in high flexion activities as more important than satisfied ones.
The Quality of Life (QOL) after Total Knee Arthroplasties among Saudi Arabians: A Pilot Study	Al-Omran, 2014	52 patients mean age of 64.75 years	Assessed pain, walking and asked whether they were satisfied	Overall satisfaction of 93% (8.37 ± 1.32).

Table 2- 27. Characteristics and Results of Patients' satisfaction studies Post-Total Knee Arthroplasty Studies (5/6).

Research title	Author	Subjects	Methodology	Conclusion
Patient satisfaction after total knee arthroplasty: an Asian perspective	Thambiah et al., 2015	Data of 103 Asian patients who underwent 110 TKAs	Patient satisfaction was assessed one year postoperatively using a 5-point Likert scale.	Patient satisfaction correlated with postoperative WOMAC function scores ($p = 0.028$), postoperative WOMAC final scores ($p = 0.040$) and expectations being met ($p = 0.033$). Neither age nor BMI was significant in predicting lower patient satisfaction.
Correlations between patient satisfaction and ability to perform daily activities after TKA, why patients aren't satisfied	Nakahara et al., 2015	387 patients completing the questionnaire (62 men and 325 women) for OA & RA	The 2011 Knee Society Knee Scoring System Questionnaire was mailed to patients, follow-up at 5 years	"Climbing up or down a flight of stairs," "getting into and out of a car" and "squatting" are very important and distressing activities that significantly correlate with patient satisfaction after TKA.
A regional registry study of 216 patients investigating if patient satisfaction after total knee arthroplasty changes over a time period of 5 to 20 years	Shannak et al., 2017	93 (43%) males and 123 (57%) females with a mean age of 67.1 years (SD 8.6) for OA, RA and traumatic	Patients were asked whether they were satisfied with their TKA (Dissatisfied/Satisfied/Unsure). Follow-up time period was 9.1 years	Of 120 patients who were initially dissatisfied, 46.7% remained so. Of 96 patients who were initially unsure, 20.8% remained so, 21.9% and 57.3% became dissatisfied and satisfied, respectively. The primary reason for continued dissatisfaction was persistent pain
Patient satisfaction after total knee arthroplasty is affected by their general physical well-being	Clement et al., 2013	Prospectively compiled data for 2,330 primary TKAs were used.	Patient satisfaction was assessed 1 year post-operatively using a four-point Likert scale	Patients with poor post-operative SF-12 PCS and those with subclinical improvement in their general physical well-being are significantly less likely to be satisfied at 1 year.

Table 2- 27. Characteristics and Results of Patients' satisfaction studies Post-Total Knee Arthroplasty Studies (6/6).

Research title	Author	Subjects	Methodology	Conclusion
What determines patient satisfaction with surgery? A prospective cohort study of 4,709 patients following total joint replacement	Hamilton et al., 2013	4,709 individuals undergoing primary lower limb joint replacement	Overall satisfaction on a four-point scale in addition to satisfaction with five facets (pain, mobility, expectation, sport & experience at one year).	Overall patient satisfaction was predicted by: (1) meeting preoperative expectations (OR 2.62 (95% CI 2.24 to 3.07)), (2) satisfaction with pain relief (2.40 (2.00 to 2.87)), (3) satisfaction with the hospital experience (1.7 (1.45 to 1.91)), (4) 12 months (1.08 (1.05 to 1.10)) and (5) preoperative (0.95 (0.93 to 0.97)) Oxford scores.
PROMs, Quality of Life and Satisfaction Rates in Young Patients Aged 50 Years or Younger After TKA	Goh et al., 2017	114 patients aged 50 years or younger (age, 47.0 years) for OA & RA	Satisfaction scores were recorded using a 6-level Likert scale pre- and 2 years post-TKA.	Patients aged 50 years or younger undergoing TKA can experience significant improvements, have their expectations met, and be satisfied with their surgeries, at rates similar to those of non-age-restricted populations.
Early postoperative predictors of satisfaction following TKA	William et al., 2013	A cohort of 486 TKA patients.	Predict 12-month satisfaction using a 4-point scale	Both 3-month OKS (OR=1.15, p b 0.001), and knee flexion (OR=1.03, p = 0.009) were significant predictors of subsequent12-month satisfaction.
Increased range of motion is important for functional outcome and satisfaction after TKA in Asian patients	Ha et al., 2016	630 patients post-TKA with a minimum 2-year follow-up	Satisfaction on a 4-point scale for 4 questions (pain, mobility, recreation & overall satisfaction).	Changes in ROM positively and weakly associated with patient satisfaction after TKA.
Single-item satisfaction scores mask large variations in pain, function and joint awareness in patients following total joint arthroplasty	Loth et al., 2019	434 TKA patients (mean age 70.4 ± 9.2 years; 54.8% female)	Postoperative 12 months satisfaction was assessed using a 5-point Likert scale, single-item question	Although higher patient satisfaction with outcome is associated with better function, very satisfied patients showed substantial variation in absolute scores and improvement scores as assessed by these PROMs. Difficulty in interpreting the meaning of a single satisfaction question, as this provides limited information on outcome and may be biased by factors unrelated to the intervention.

Table 2- 28. Critical Appraisal Skills Programme (CASP) for Patients' Satisfaction Post-Primary Total Knee Arthroplasty (1/2)

CASP	Criteria	Lizaur-Utrilla et at., 2016	Sauder et al., 2019	Jacobs et al., 2014	Clement et al., 2018	Jacobs et al., 2014	Benditz et al., 2017	Özdemir et al., 2017	Deakin et al., 2018	Collados-Maestre et al., 2016	Goudie et al., 2011	Furu et al., 2015	Clement et al., 2015
Validity of results	Study design	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO	YES
	Population defined	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Risk factors exposed/described	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
	Outcomes defined	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Clear detection of beneficial/harmful effects	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Represents a defined population	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES
	Includes all prospective population without bias	YES	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO	NO
	Uses subjective/objective measurements	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Uses valid measurements	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	All subjects use same exposure procedure	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES
	Establishes reliable system for detecting all cases	YES	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	YES
	Subjects/assessors blinded	NO	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO
	Identifies important confounding factors	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Considers confounding factors in the analysis	NO	YES	YES	YES	YES	YES	NO	NO	NO	YES	NO	YES
	Sufficient follow-up length	NO	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES
	Follow-up sufficient	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Results	Bottom line of results	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Reports rates/proportions	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Strength of association RR	YES	NO	NO	YES	NO	YES	YES	YES	YES	YES	YES	YES
	Absolute risk reduction ARR	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	Confidence-interval range	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	The effects of bias, chance and confounding factors have been minimised in the results.	NO	YES	YES	YES	YES	YES	NO	NO	NO	NO	NO	YES
	Reliable methods/ study design	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Results value	Results applicable to local population	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Cohort design is appropriate	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES
	Relevant to present evidence base	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Supported by evidence, more than recommendations	YES	NO	YES	NO	YES	NO	YES	NO	NO	NO	NO	NO
	Total score	22/28 79%	23/28 82%	23/28 82%	22/28 79%	23/28 82%	21/28 75%	21/28 75%	20/28 71%	21/28 75%	21/28 75%	19/28 68%	24/28 85%

Table 2- 28. Critical Appraisal Skills Programme (CASP) for Patients' Satisfaction Post-Primary Total Knee Arthroplasty (2/2)

CASP	Criteria	Halawi et al., 2019	Al-Omran, 2014	Kunze et al., 2019	Kim et al., 2010	Onsem et al., 2016	Thambiah et al., 2015	Nakahara et al., 2015	Shannak et al., 2017	Clement et al., 2013	Hamilton et al., 2013	Goh et al., 2017	Williams et al., 2013	Ha et al., 2016	Loth et al., 2019
Validity of results	Study design	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Population defined	YES	NO	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES
	Risk factors exposed/described	YES	NO	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
	Outcomes defined	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Clear detection of beneficial/harmful effects	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Represents a defined population	NO	NO	YES	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO
	Includes all prospective population without bias	NO	NO	NO	YES	NO	NO	YES	YES	YES	YES	YES	NO	YES	YES
	Uses subjective/objective measurements	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Uses valid measurements	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	All subjects use same exposure procedure	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Establishes reliable system for detecting all cases	NO	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	NO	YES	YES
	Subjects/assessors blinded	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO	YES	NO	NO	NO
	Identifies important confounding factors	YES	NO	YES	YES	YES	YES	NO	NO	NO	NO	NO	NO	YES	NO
	Considers confounding factors in the analysis	YES	NO	YES	NO	YES	YES	NO	NO	NO	NO	NO	NO	YES	YES
	Sufficient follow-up length	YES	YES	YES	NO	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Follow-up sufficient	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Results	Bottom line of results	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Reports rates/proportions	YES	YES	YES	NO	YES	NO	NO	YES	YES	YES	YES	YES	YES	YES
	Strength of association RR	YES	NO	YES	NO	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES
	Absolute risk reduction ARR	NO	NO	YES	NO	YES	NO	NO	YES	YES	YES	NO	NO	NO	NO
	Confidence-interval range	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	The effects of bias, chance and confounding factors have been minimised in the results.	YES	NO	YES	NO	YES	YES	YES	NO	NO	YES	YES	NO	YES	YES
	Reliable methods/ study design	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Results value	Results applicable to local population	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Cohort design is appropriate	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Are the benefits worth the cost?	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Relevant to present evidence base	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
	Supported by evidence, more than recommendations	NO	NO	YES	NO	YES	NO	NO	YES	YES	YES	NO	YES	NO	NO
	Total score	20/28 71%	16/28 57%	25/28 89%	17/28 61%	23/28 82%	20/28 71%	22/28 79%	25/28 89%	23/28 82%	25/28 89%	22/28 79%	20/28 71%	24/28 85%	23/28 82%

2.2.7 Factors that may predict outcomes post-TKA

A plethora of studies have explored the factors associated with poor outcomes in order to improve their management and improve patient satisfaction post-TKA. The literature shows consistent agreement of several factors that affect short- and medium-term outcomes (1–2 years) post-TKA. Poor outcomes post-TKA are associated with high expectations, depression, anxiety and mental status pre-operation; poor preoperational general health and OKS score; and other joint pain (Bonnin, Basiglini, & Archbold, 2011; Ethgen et al., 2004; Hamilton et al., 2012; Hepinstall, Rutledge, Bornstein, Mazumdar, & Westrich, 2011; Kim, Fraser, Kahn, Lyman, & Figgie, 2012; Maxwell et al., 2013; Scott, Howie, MacDonald, & Biant, 2010; Scott et al., 2016; W-Dahl, Sundberg, Lidgren, Ranstam, & Robertsson, 2014). There is conflicting evidence regarding the effects of age, gender, implant type and operational technique. Ethgen et al. (2004) concluded that age is not an obstacle to effective surgery, while the study by Bonnin et al. (2011) found that patients less than 60 years old are associated with chronic knee pain (Bonnin et al., 2011; Ethgen et al., 2004). So, younger patients may need further care to minimise the chronic pain risk post-TKA than patients older than 60 years of age.

In terms of implant type, the study by Hamilton et al. (2012) found that triathlon implants had better outcomes than a kinemax group when using OKS, though this cannot exclude a subjective effect. However, objective method studies using 3D motion analysis have found no differences between or functional advantages of different types of implants (Abdel et al., 2014; Liebensteiner et al., 2015; Sosio, Gatti, Corti, Locatelli, & Fraschini, 2008; Tibesku et al., 2011).

Most patient factors have been identified as poor outcome factors post-TKA remained uncertain as regards their importance and degree of effect, so accurate prediction of short- and long-term outcomes post-TKA is crucial. A valid clinical prediction tool will allow patients to make surgery decisions with realistic outcome expectations based on personalised outcome predictions, which may improve their satisfaction post-surgery.

In term of clinical practice, exploring accurate predictions for future prognoses post-TKA may improve case selection for TKA and patients' pre-operation preparation, and enhance post-operation management, which may improve the satisfaction percentage. This is supported by a study by Riddle et al. (2011), which found significantly greater reductions in pain severity and greater functional improvements post-TKA in 18 patients with high levels of pain catastrophizing pre-TKA after they had pre-operation preparation compared with a

control group. The pre-operation preparation comprised of 8 sessions of psychologist-directed pain coping skills training (Riddle et al., 2011).

The available studies tend to explore predictors using PROMs in the short to medium term, 6–37 months; these cannot assess factors in the long term, 5–10 years (Bade, Kittelson, Kohrt, & Stevens-Lapsley, 2014; Bade, Wolfe, Zeni, Stevens-Lapsley, & Snyder-Mackler, 2012; Brown et al., 2009; Ethgen et al., 2004; Hamilton et al., 2012; Ko et al., 2013; Lingard, Katz, Wright, & Sledge, 2004; Lungu, Desmeules, Dionne, Belzile, & Vendittoli, 2014; Scott et al., 2010; Tambascia et al., 2016).

Of two recent prospective studies with a ten-year follow-up, one predicts OKS outcomes and the other predicts patients' satisfaction (Jiang, Sanchez-Santos, Judge, Murray, & Arden, 2017; Shannak, Palan, & Esler, 2017). The generalizations in their conclusions are limited because the prediction tools are not validated. Both prospective samples had limitations, such as: the dissatisfaction response rate was higher than the satisfaction response rate in a satisfaction study; and the patients included in OKS study were younger and in better health as regards both pre-operative OKS and mental health than the excluded group. To date, no study has developed and validated a prediction tool for patient factors that explains the long-term variability in OKS score and satisfaction post-TKA.

2.2.8 Overall Summary of the Literature Review

The aim of the literature review was to ascertain the methods which would help to assess functional outcomes and patients' experiences post-TKA, in addition to possible factors that may affect outcomes or predicted outcomes. The following is a summary concluded from the previous extended review, followed by the literature gaps that formulate the thesis' rationale and objectives.

KOOS, OKS and WOMAC are the PROMs most commonly used and recommended for assessment post-TKA, despite their limitations in terms of comprehensive assessment of patients post-TKA, such as expectations, satisfaction, function and quality of life. Both KOOS and OKS show good reliability, validity and responsiveness with a post-TKA population. Both had similar values for ceiling effect in a 12-month follow-up. The OKS has the advantage that it is simple and short, has better reliability scores with TKA patients, clear MIDC values and clear outcome categories. In contrast, KOOS has the advantage of being more suitable for young patients to assess, in sufficient depth, function, sport, recreation and knee-related quality of life. There is no available gold standard that covers all the gaps and is suitable for broad age requirements post-TKA, with a suitable balance between complexity and simplicity.

Patients' Performance Based Outcome Measures are simple and feasible functional tests able to capture different aspects of patient function, they differ from PROMs and do not require any cultural adaptation. They show excellent to good psychometric properties with a post-TKA population. Timed up-and-go test, a valid quick functional assessment tool, 30 s chair-stand test, timed up and Go and walking test showed good correlation with knee extensor and flexor muscle strength. The Stair climb test correlated with knee flexion range of motion. The Star Excursion Balance Test assesses dynamic balance in multiple directions, which may better mimic daily life activity requirements, and it has excellent inter-rater reliability for healthy participants.

ActivPAL is small, lightweight, waterproof, reliable and valid and offers simple application to patients. It can measure volume free-living PA, by considering external environmental confounding factors in addition to patterns of PA and sedentary behaviour. It assesses low-energy positions (sitting and lying) to estimate sedentary behaviour. It also accurately assesses the start time for each position and the duration spent in it. In a similar manner, it estimates upright events (standing, stepping) time in addition to the number of steps and average cadence.

In order to explore patients' experience post TKA, a qualitative method is appropriate as it facilitates the collection of in-depth experiences and perceptions of individuals about a specific phenomenon which, in this case is outcomes post TKA. Focus-group discussions (FGD) had an advantage over other qualitative methods, it provides an extra dimension to gather data and a wider degree of spontaneity in the patients' views expressed, in contrast to one-to-one interviews where the interaction is limited between patients and researcher and depends on patient responses.

The available evidence fails to conclusively support any preoperative predictors of medium- and long-term satisfaction post-TKA. Long-term changes in patients' satisfaction post-TKA are not assessed. Understanding long-term changes and factors that might improve patients' satisfaction post-TKA could improve the overall experience and outcomes.

Literature conflicts regarding the factors that affect the outcome post TKA may be due to unstandardized outcome measurements, different methodologies and measurement time post-TKA. No study develops a valid prediction tool for patients' factors that explain the long-term variability of outcome and satisfaction post-TKA.

2.2.9 Risk of methodology bias

The overall critical appraisal results varied for each outcome measurement. The PROMs studies' scores range from 89% – 57%, PBOMs from 95% – 74%, physical activity from 85% – 50%, the focus group discussion (FGD) studies' score range from 89%-69% and patients' satisfaction score range from 89%-57%. The PROMs studies' main risks of bias were methods used to select the included patients, randomisation, blindness, not including all subjects in the results without enough clarification, ignoring confounding factors in the outcome measurements and analyses, and the sample mixing different pathologies or interventions. PBOMs studies had less risk of bias and the main limitation concerned randomisation, assessor blindness and similarity of the group baseline. PA studies' main risk of bias were due to the failure to report the psychometric properties of the accelerometer that was used, insufficient details regarding reported outcomes and how they were measured, not considering confounding factors in the results and analysis, limited follow-up post-TKA, no randomisation, the sample selection not representing the population, no blindness, and not all participants completing the follow-up. Most of the studies for all outcomes post-TKA did not consider confounding factors in their results and analyses, which may affect the generalisation of findings. For example, the presence of a previous chronic condition, physical activity limitation before surgery, a patient's age and psychology may affect the outcome post-TKA and should be considered to improve the generalisation of outcomes and improve the understanding of affecting factors. FGD studies' main risk of bias were due to insufficient clarification about informed consent, confidentiality and any possible effects of study; insufficient discussion of evidence, both for and against study argumentation; and not considers contradictory data. Patients' satisfaction main limitations were in sampling methods, assessor blindness, follow-up being limited to the short and medium term, using non-validated methods to assess satisfaction, and conclusions based on low levels of evidence which may increase the risk of conclusion bias. The overall risk of bias across the studies ranges from low to high, and high-risk findings should be interpreted with caution. The main limitation of the current review is its inability to perform a meta-analysis due to the heterogeneity of outcomes across studies. This limited the ability to derive pooled estimations for effect sizes and, overall, clearer findings for each outcome method. However, the minimal detectable changes concluded for the PROMs and PROMs clarify expected outcome changes post-TKA.

2.3 A gap in the literature

According to Oxford University Innovation, only two studies have assessed an Arabic version of OKS. One was limited to male patients with a low mean age and the other study's sample was mixture of knee pathologies, and both lacked a responsiveness assessment post-TKA. The current study assessed psychometric properties in both male and female patients and validity correlation will hinge on Arabic KOOS and VAS, in addition to responsiveness after 6–12 months. This is covered in the reliability section of the methodology in Chapter 3. The Star Excursion Balance Test (SEBT) reliability was explored as no previous study has assessed the reliability of SEBT in end-stage knee OA patients, see the reliability section of the methodology in Chapter 3. Responsiveness results 6 and 12 months post-TKA are covered in the prospective study in Chapter 6.

In reviewing the literature on the factors that may predict short- and long-term (1–10 years) patient outcomes and satisfaction post-TKA, no previous study has developed and validated a prediction equation. Therefore, the current study assesses the association between pre-surgery factors with outcome and satisfaction one, five- and ten-years post-surgery. Predicting valid factors may improve case selection for TKA and patients' pre-operation preparation, which may improve their satisfaction post-surgery. The prediction tools for both outcomes and satisfaction post-TKA were developed and validated in Study One (Chapter 4).

To assess the aforementioned patients concerns and expectations post-TKA requires further assessment tools, more than controlled experiments testing define isolated variables. Qualitative research offers useful methods to explicate the complexity and deeper meaning of patient experiences, functional recovery and outcomes expectations post-TKA. Qualitative methods provide a richness of understanding of patients' views, which may include quantitative methods' gaps and limitations to improve healthcare services and patient satisfaction rates (Beaton & Clark, 2009). No study has explored patient experiences and outcomes post-TKA using focus-group discussions one year after surgery to explore whether there are factors that might help us to understand why some patients' medical outcome measurements are good, but they are not satisfied, and vice versa. The exploration of functional recovery and expectations may be able to support future modifications and thus improve outcome satisfaction post-TKA, this is covered in detail in Study Two in Chapter 5.

In the preceding review of the literature on outcome measurements post-TKA, it is apparent that most previous literature has assessed outcomes with different methods, such as PROMs, PBOMs, balance and physical activity. None of them have assessed outcomes using a combination of OKS, PBOMs, balance and physical activity in order to capture the

comprehensive scope of outcomes and assess their correlation with PA as objective measurements. No previous study has assessed outcomes using PBOM tests as per OARSI recommendations post-TKA: 30 sec. chair-stand test (30sCT), stair-climb test (SCT), timed up-and-go test (TUG) and 6 min. walking test (6MWT) .In the Saudi Arabian population, no studies have explored outcomes post-TKA in terms of OKS, balance or physical activity. These prospective assessments are covered in Study Three in Chapter 6.

The current thesis used OKS as a PROM, as it simple for patients, has good measurement properties, clear MIDC values and straightforward outcome categories, has been well validated for this group of patients and is used by the U.K. Department of Health in the National Joint Registry.

The Star Excursion Balance Test (SEBT) used with patients post-TKA, rather than other dynamic balance tests, as it is feasible, does not require specific or costly instruments, measures balance in multiple directions, which is closer to daily activity requirements.

Regarding physical activity assessment, activPAL has been shown to be superior to other accelerometers, given its ability to measure volume free-living PA by considering external environmental confounding factors, in addition to patterns of PA and sedentary behaviour. It assesses low-energy positions (sitting and lying) to estimate sedentary behaviour. It also accurately assesses the start time for each position and the duration spent in it. In a similar manner, it estimates upright event (standing, stepping) times, in addition to the number of steps and cadence (Granat, 2012). No study has explored physical activity outcomes post-TKA using activPAL as an objective reliable method to explore whether PA improves in terms of both volume (the time spent in sedentary/ active positions and the number of steps per day) and pattern post-TKA to enhance the accuracy of outcomes. Therefore, the current study used an activPAL to measure PA before and after TKA in order to capture the volume and event-based patterns of PA for seven days, see Study Three in Chapter 6.

No previous study has made a comparison of knee arthroplasty approaches in two different countries/ regions on the outcome, or whether OKS scores post-TKA change differently in United Kingdom (UK) and Middle East patients. This is assessed at the end of Chapter 6.

2.4 Rationale for the project's Research Question and Objectives

The body of work planned for the thesis comprises three studies assessing the outcomes of total knee arthroplasty, in addition to two reliability studies (Figure 2-12). The novelty of this research depends on it being the first study to develop and validate a prediction equation for long-term outcome and satisfaction post-TKA. It is the first study to explore functional

recovery and expectations one-year post-TKA using a focus group to collect more individual details. A unique aspect of this work is that it is the first study to explore physical activity volumes and event-based patterns post-TKA. Moreover, it is the first assessment of outcomes in a Saudi Arabian population and the first assessment of outcomes compared knee arthroplasty approaches in two different countries/ regions, such as the UK and the Middle East. Further details of each study are given below:

Study One

To date, no published research has developed and validates outcomes and satisfaction predictions one, five and ten years post-TKA. Accurate preoperative prediction is crucial to minimize the potential for unrealistic expectations about outcomes and may help to understand why some outcomes are not successful.

The focus of this retrospective study is exploring outcomes post-primary total knee arthroplasty (TKA) using pre/post-operative scores involving : Oxford Knee Score (OKS), University of California Los Angeles activity score (UCLA), EQ-5D general health questionnaire, visual analogue scales (VAS) for pain, function, expectations and satisfaction, knee range of motion, and medical history data to correlate these data with outcome and patient satisfaction post-TKA at Stepping Hill Hospital, noted as one of the best hospitals in the country for knee surgery, it provides high-quality and safe care and has one of the largest ranges of orthopaedic services in the UK.

Study One Objectives:

- To assess changes in OKS, UCLA, pain, function and satisfaction at different time points post-TKA (pre-TKA, six months, one year, five and ten years post-TKA).
- To develop and validate short, medium and long-term prediction equations for outcomes post-TKA.
- To develop and validate short, medium and long-term prediction equations for satisfactions post-TKA.

Study One Hypotheses

- There are significant changes in OKS, UCLA, pain, function and satisfaction at different time points post-TKA (pre-TKA, six months, one year, five and ten years post-TKA).
- There is a correlation between Oxford Knee Score (OKS) and all included predictors in the short, medium and long term post-TKA.
- There is a correlation between satisfaction and all included predictors in the short, medium and long term post-TKA.

Study Two

All previous studies have utilised questionnaires and objective-based examinations of individuals post-TKA. To the best of our knowledge, no study has explored patient experiences and outcomes post-TKA using focus-group discussions one year after surgery to determine whether there are factors that might help us to understand why some patient medical outcome measurements are good, but they were not satisfied, and vice versa. The exploration of patients' expectation, functional recovery and limitations may support future modifications and thus improve outcomes post-TKA. Qualitative assessment methods, such as focus-group discussions with patients, can explore, in depth, both their perceptions and other factors that may affect outcomes.

Study Two Objectives

- To gain an in-depth understanding of the experiences and perceptions of patients about outcomes post-TKA and to explore whether there are factors that might help us to understand why some patients' medical outcome measurements are good, but they are not satisfied, and vice versa.
- To gain insights into functional recovery and limitations post-TKA.
- To gain insights into outcome expectations.
- To make recommendations for future patients based on patients' views.

Reliability Studies

1-Arabic version of Oxford Knee Score (OKS-Ar)

No study has assessed the reliability, validity, responsiveness, ceiling and floor effect of the Arabic version of OKS on both male and female patients with end-stage knee osteoarthritis.

Study Objective

- Examine the internal consistency, reliability, validity and responsiveness of the Arabic version of Oxford Knee Score before and one-year post-total knee arthroplasty in both male and female Saudi patients;

Null Hypotheses

- The reliability, validity and responsiveness of the Arabic version of Oxford Knee Score post-total knee arthroplasty in both male and female Saudi patients will be insufficient.

2- The Star Excursion Balance Test

No studies have assessed dynamic balance responsiveness post Total Knee Arthroplasty using SEBT or a reliability with end-stage osteoarthritis patients.

Study Objective

Examine the test-retest reliability of the Star Excursion Balance Test before and after total knee arthroplasty in both male and female Saudi patients.

Null Hypotheses

The repeatability of the Star Excursion Balance Test before total knee arthroplasty in both male and female Saudi patients will be insufficient.

Study Three

To the best of our knowledge, no study has explored outcomes post-TKA using PROMs, PBOMs, physical activity and functional balance measurement tools. No study has compared knee arthroplasty approaches outcomes in two different countries/ regions, such as the UK and the Middle East.

Study three Objective:

To gain a better understanding of recovery post- total knee arthroplasty (TKA) in a Saudi population, explore whether there are factors which can help us to understand why some patient outcomes are not successful and identify prediction factors for progression. This is a prospective study, measuring outcomes six and twelve months' post-TKA, with the following objectives:

- Measure patient outcomes changes post-TKA using Arabic versions of Oxford Knee Score (OKS), Knee Injury and Osteoarthritis Outcome Score (KOOS), visual analogue scale for pain and satisfaction as patient self-reporting outcome measurements;
- Assess functional recovery post-TKA according to Osteoarthritis Research Society International recommendations using performance-based measurements: 30 sec. chair-stand test, stair-climb test, timed up-and-go test and a 6-min. walk test.
- Evaluate dynamic balance improvements post-TKA using a Star Excursion Balance as a valid objective method;
- Evaluate physical behaviour changes post-TKA using activPAL as an objective method;

- To assess physical activity correlation with all other outcome (OKS, KOOS, SEBT, and PBM) and determine the best significant predictors for physical activity before and one year after TKA.
- To assess the effect of patient factors and medical history on physical activity one-year post-TKA to determine the value of their effect.
- To assess patient satisfaction one-year post-TKA correlation with all other outcomes (OKS, KOOS, SEBT, PBM, pain and physical activity) and determine the best significant predictors for satisfaction one-year post-TKA.
- To compare patients' outcomes from two knee arthroplasty approaches used in the UK and the Middle East (using 12-month OKS data from Study One).

Study Three Hypotheses

- There are significant changes post-TKA in Oxford Knee Score, Knee Injury and Osteoarthritis Outcome Score and visual analogue scale for pain.
- There are significant changes post-TKA in performance-based measurements: 30 sec. chair-stand test, stair-climb test, timed up-and-go test and a 6-minute walk test.
- There are significant changes post-TKA in dynamic balance using a Star Excursion Balance test.
- There are significant changes in physical behaviour post-TKA using an activPAL accelerometer.
- There is a correlation between physical activity and all other outcomes (OKS, KOOS, SEBT, and PBM) and no significant predictors for physical activity one-year post-TKA.
- There is a significant effect of patient factors and medical history on physical activity post-TKA.
- There is a correlation between satisfaction and all other outcomes (OKS, KOOS, SEBT, PBM, pain and physical activity) and no significant predictors for patient satisfaction one-year post-TKA.
- There is a significant difference in Oxford Knee Score between the two knee arthroplasty approaches applied in the UK and the Middle East at all time points post-TKA (6 and 12 months).

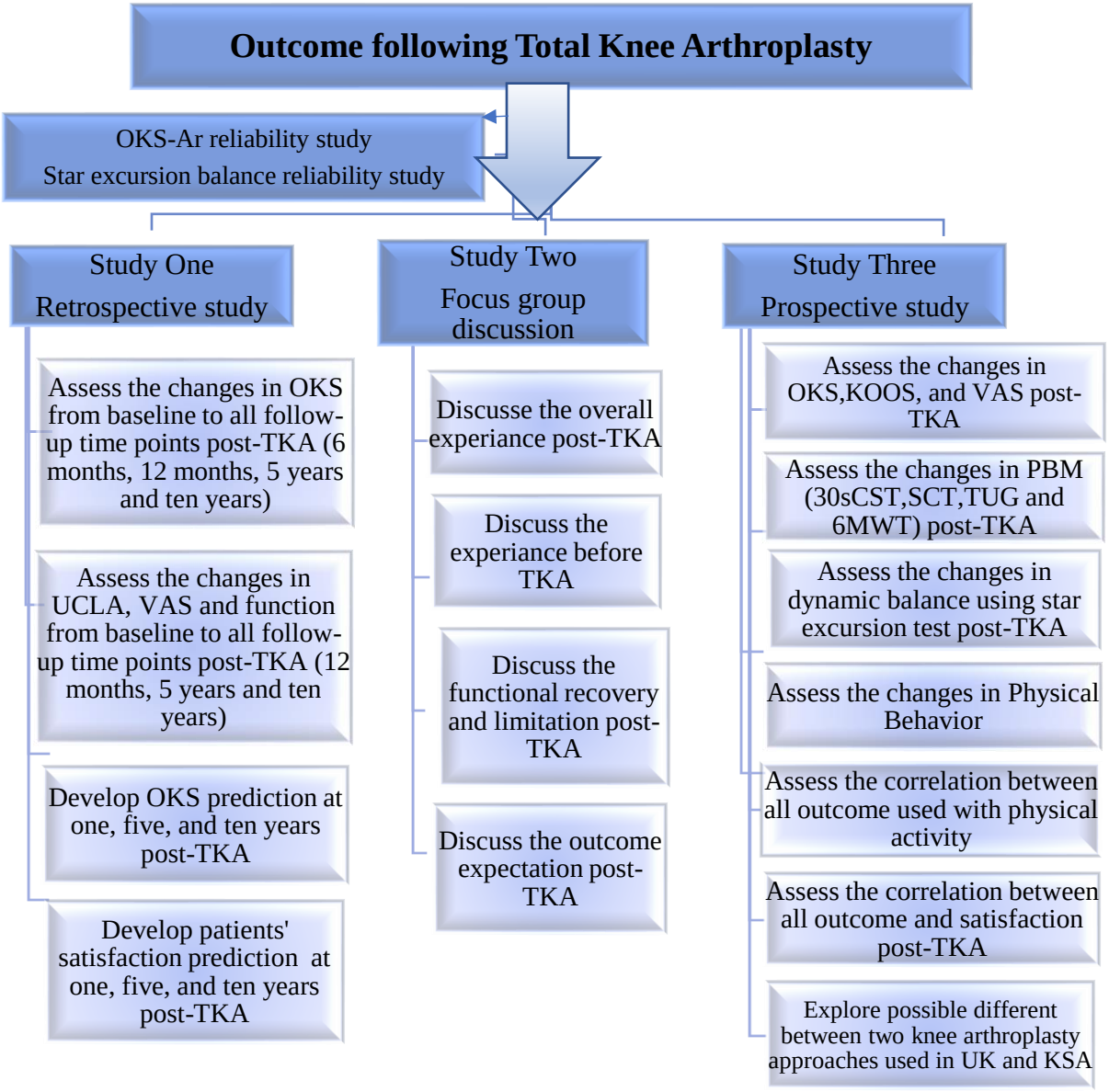

Figure 2- 12. Overall thesis structure.

Chapter 3 – Methodology

3.1 Introduction

This methodology chapter contains two main sections and is based around a multiple methods design that utilised. A multiple methods design improves the integrity with deeper illustration of the findings (Beaton & Clark, 2009). The focus on patient's views helps to understand how to improve healthcare services and patient satisfaction rates. The first section of this chapter clarifies the research methodology used to pursue the research objectives and assess the research hypothesis in addition to research ethical considerations, data protection and risk assessment. The second section assesses the reliability of the Arabic version of Oxford Knee Score (OKS-Ar) and the Star Excursion Balance test which have previously not been performed.

No gold standard method can assess patients' functional recovery post-total knee arthroplasty (TKA), different measures have been used prospectively. Both subjective and objective measurements tools as well as patients' concerns and experiences are assessed. The subjective measurements tools used have been based on previous literature recommendations such as the Oxford Knee Score (OKS) and Knee Injury and Osteoarthritis Outcome Score (KOOS). The objective measurements tools used are performance-based measurements (PBM), Star Excursion Balance test (SEBT), and physical activity volume and pattern. Both subjective and objective measurements were analysed statistically in a quantitative study. Conversely, patients' concerns and experiences were explored using qualitative methods, a focus-group discussion (FGD). Therefore, a multiple-method design was used to test the study hypotheses and to attain the research objectives. A multiple - method approach provides richness in understanding patients' views, which may fill in the gaps and limitations of quantitative methods and is an addition to quantitative analyses of outcomes.

In Section Two, the reliability of both the Arabic version of Oxford Knee Score and the Star Excursion Balance test was assessed. Two studies have assessed an Arabic version, one was limited to male patients with a low mean age and the other study's sample was mixture of knee pathologies, and both lacked a responsiveness assessment post-TKA. The reliability, validity and responsiveness post-TKA in both male and female patients were assessed in this section. Responsiveness is the questionnaire ability and sensitivity to detect the changes before and post the intervention. Effect size calculated based on the ratio of the mean change in pre- and postoperative scores; and then divided by the pre-intervention standard deviation. Commonly it used to compare different clinical measures, the effect size is considered large, moderate and small if the value 0.8, 0.5 and 0.2 respectively (Dunbar, Robertsson, Ryd, &

Lidgren, 2000). Low tool sensitivity may maximise ceiling effects and produce type-2 errors during hypothesis testing (Giesinger et al., 2014).

Regarding the Star Balance test, only one study has assessed its reliability in patients with early to moderate knee OA (Kanko et al., 2019). Its reliability with end stage knee OA and responsiveness post-TKA are unclear. Therefore, its reliability and responsiveness are assessed in patients diagnosed with end-stage knee osteoarthritis.

3.2 Multiple-methods approach:

The multiple-methods approach is used as an alternative when both qualitative and quantitative research are assessed together to answer the research questions. It is a recognised and credible approach championed by many writers (Creswell & Creswell, 2018; Creswell & Plano Clark, 2018; Gorard & Taylor, 2004; Greene, Caracelli, & Graham, 1989; Johnson & Onwuegbuzie, 2004; Tashakkori & Teddlie, 1998).

The multiple-methods approach focuses on the link between qualitative and quantitative methods and the use of each method's advantages to answer research questions with minimal limitations (Hammond, 2005). Further, the findings from more than one method confirm the outcome is due to the phenomena itself, rather than the methods used (Tashakkori & Teddlie, 1998). It is a problem rather than a theory driven approach, answering research questions from different philosophical traditions (paradigms) to improve the accuracy of findings and gain a complete picture of the outcome, in addition to compensating for the strengths and weaknesses of each method. It provides the opportunity to check the outcome of one method against another, assess the impact of each method, and improve confidence in the accuracy of the outcome (Creswell, 2007; Creswell & Creswell, 2018; Denscombe, 2014; Denzin & Lincoln, 2011).

3.2.1 Multiple-methods approach pragmatism:

A paradigm is defined as 'a comprehensive belief system, world view, or framework that guides research and practice in the field' (Willis, 2007). Five essential factors can be defined by a suitable research paradigm: ontology, epistemology, methodology, technique and data analysis (Denzin & Lincoln, 2011) (Table 3-1). The philosophical basis of the quantitative paradigm is positivism and the qualitative paradigm is based on interpretivism. However, the multiple-method approach does not have its roots in either interpretivism or positivism but covers the large area in the middle. The multiple-method approach is based on pragmatism; it mixes the approaches effectively to provide the best opportunity to answer the research question. The multiple-method approach pragmatic ontology, the truth is what is useful, and epistemology are the best methods to answer research questions. It uses a

philosophy that attempts to fit together the insights provided by both quantitative and qualitative methods into a practical solution to conduct effective research. The aim of the multiple-method approach is not to replace the quantitative or qualitative but draw from the strengths of both types of pure research while minimising the weaknesses (Creswell & Creswell, 2018; Denscombe, 2014; Greene et al., 1989; Hammond, 2005; Johnson & Onwuegbuzie, 2004; Willis, 2007).

Table 3- 1. Research paradigm, ontology, epistemology and method.

Assumptions of Approach	Qualitative Research	Quantitative Research	Multiple-method Research
Ontological Perceptions of Reality	Multiple subjectively derived realities co-exist	Single objective world	Truth is what is useful. Reality is constantly renegotiated, debated, and interpreted in light of its usefulness in new and unpredictable situations.
Epistemological Theory of Knowledge	Researchers interact with phenomenon (personal investment). Derived mainly from critical theory and constructivism.	Researchers are independent from the variables under study (detached). Derived mainly from positivism.	The best method is the one that solves the problem.
Axiological Study of Underlying Values	Researchers act in a value-laden and biased fashion.	Researchers act in a value-free and unbiased manner.	Incorporates subjective and objective views into the study.
Rhetorical Use of Language	Use of personalised, informal and context-based language	Use of impersonal, formal and rule-based text	Uses both formal and informal language to explore the phenomena.
Research hypothesis / question	Researchers use induction, multi-process interventions, and context-specific methods.	Researchers use deduction, cause and effect relationships, and context-free methods.	A combination of induction and deduction is used to understand the situation.

3.2.2 The rationale for using a multiple-methods approach and timeline

Alternative perspectives using both qualitative and quantitative methods may enable a complete overview of a patient's outcome and answering research questions from different philosophical paradigms. A combination of methods and data sources exploit the strengths from both and may minimise the bias and weakness of a single method. In terms of analysis, each method addresses a research issue arising from the results not produced by other methods. A multiple-methods design improves the integrity with deeper illustration of the findings. As the current study's aim is to evaluate outcomes post TKA and is timeframe limited, both qualitative and quantitative served alongside each other at the same time post TKA (concurrent, independent, triangulation multiple-method design) (QUAN+ qual). The

qualitative method aims to understand the patient's experience, views and expectations post TKA without any plan for generalisation. At the same time, the quantitative functional outcomes were assessed using the recommended methods to gain a complete picture of functional improvements. Combining both outcomes from quantitative and qualitative methods may improve understanding of the functional and patient outcomes post TKA, and the possible correlations or predictions that may exist (Schoonenboom & Johnson, 2017). This may be helpful in improving patient satisfaction or further modifications to the patient care process such as the patient's selection, education, preparation or expectations modification before surgery. The current parallel multiple-method approach explored the patient's experience post TKA without any firm hypothesis at the beginning, in addition to testing the hypothesis of functional improvements post TKA. Exploring the patient's experience post TKA was not possible with any available purely quantitative methods, and the functional improvements post TKA cannot be accurately measured with purely qualitative methods. Therefore, the parallel multiple-method approach benefits this research in several ways and is an appropriate design to answer the research questions regarding patients' functional outcomes post TKA.

3.2.2.1 Qualitative study methodology:

The aim of the current study is to portray patients' lives post TKA, to map their experiences and see things through their eyes. To explore the patients' point of view, feelings and perspective during the year post TKA, a phenomenological approach was used to understand what satisfied them and what other factors may affect their satisfaction post TKA.

The phenomenological approach is an alternative social research approach to positivism, as it is not based on measurements or statistics. It emphasises subjectivity, description, interpretation and agency. It is a proven approach in health research to understand the patient's perception, attitude, beliefs, feelings and experiences of an intervention (Mackey, 2005). The objective of the phenomenological approach is to gain a clear picture of an experience not yet understood, directly from the people who are experiencing it, without any process of quantifying, categorising or theorising the findings.

The research centres around the patient's life post TKA, rather than health measurements or other investigations. Phenomenology explores the ways patients interpret the TKA intervention and makes sense of their personal experiences. A phenomenological approach was used in the current study as each patient sees the experience in a different way, and the approach rejects the belief in one universal reality or theory that fits all patients. There were similarities and differences among the patients' experiences post TKA and multiple realities

evolved. The main advantage of the phenomenological approach is providing adequate, complex and in-depth descriptions of the experience as faithful to the original as possible. The phenomenological researcher does not edit the patient's experience or modify it in order to present a coherent life experience (Creswell & Creswell, 2018; Denscombe, 2014; Mackey, 2005).

A researcher with a background as a physiotherapist is used to listening to patients' experiences and feedback after treatments. So, it was not possible to view FGD experience data in an objective and neutral way and FGD interpretation of patients' experiences post-TKA may influenced by the researcher's personal experiences and beliefs. Therefore, to maintain a balance between researcher reflexivity being 'relativist' and naturalism being 'realist', full, transparent detailed descriptions of the FGD are presented as they naturally exist. In addition, the analysis and themes formulation were performed by two independent researchers to enhance the naturalism and credibility of the findings. The evolved themes were described and shaped as the two independent researchers agreed on them. Despite the researcher aiming to temporarily suspend her own beliefs and assumptions in order to gain a clear understanding of how the patients saw things, it was an advantage to have some previous experience in this area in order to again full understanding and enhance the hermeneutic perspective where there is a 'fusion of horizons'.

The detailed descriptions of the patients' experiences after TKA was followed by critical analysis of the findings and was linked to the previous literature. The semi-structured approach to the FGD embraced a phenomenological philosophy which allowed the patients to raise any issue was important to them that the experience was seen with sufficient depth from their point of view. The strength of the phenomenological approach is the emphasis on subjectivity, but it may become a weakness when used by alternative stance research. The current study's aim is to explore the patients' experiences post TKA without theorising or generalising, which is what the phenomenological approach provides (Creswell & Creswell, 2018; Denzin & Lincoln, 2011; Taylor & Francis, 2013).

3.2.2.2 Quantitative study methodology:

Two studies, one retrospective and the other prospective, with clear deductive hypotheses were tested. Both were based on positivism (objective data), acting in a value-free and unbiased manner and using reliable and valid assessment tools to explore functional outcome changes post TKA (Creswell & Creswell, 2018; Greene et al., 1989; Johnson & Onwuegbuzie, 2004; Tashakkori & Teddlie, 1998).

Due to the time limitation for the project, retrospective data analysis is the best available option to assess outcome changes one, five- and ten-years post- TKA. A retrospective study randomly analysed pre- and post-TKA changes using Oxford Knee Score, University of California, Los Angeles (UCLA) activity scale, pain, function, expectations, satisfaction, a general health questionnaire and range of motion before and after surgery to explore possible correlations or predictions with outcomes and satisfaction. Further details of the outcome measurement tools used, and protocols, may be found in Chapter Four.

The prospective study assessed the functional outcome before and after TKA using the Oxford Knee Score and Knee Injury and Osteoarthritis Outcome Score as the patients' reported outcome scores. Functional assessments used a 30-second chair test, a stair-climb test, a six-minute walk test and a timed up-and-go test. Dynamic balance was assessed using a Star Excursion test. Free living physical behaviour was assessed using activPAL accelerometers. Further details of the outcome measurement tools used, and protocols, may be found in Chapter Six.

3.3 Ethical Considerations

Ethical Principles for Medical Research Involving Human Subjects – World Medical Association (WMA), Declaration of Helsinki. All studies subjects were adult patients. Ethical approval was obtained before recruitment began. As participation in the study was voluntary, participants had the right to withdraw at any time without giving any reason. They also had the right to have a printed copy of the study information sheet at least 24 hours for prospective studies and two weeks for focus group discussion before data-collection sessions. Before beginning, subjects needed to sign a consent form and were advised they had the right to clarify any concerns regarding the study with the researcher.

A patient's participation or otherwise did not affect the quality of service, all patients received conventional orthopaedic care and a standard level of physiotherapy according to hospital protocols. In retrospective study, the included records were anonymised, and all patients included already have previously provided written consent for the use of their data for scientific research purposes; therefore, no further patient consent required during the study.

3.3.1 Data Protection

To complying with the Data Protection Act (1998), all study data remained anonymous and were stored in a secure computer with a password. All participant data were accessed by the researcher only and remained anonymous and confidential. All data transported on computer discs, CDs and USB memory sticks were anonymous, identified only by codes and

encrypted to protect against loss. All data and informed consent forms were safely stored in a locked cabinet in the Allerton Building (Investigator's Office) at the School of Health and Society in accordance with University regulations and destroyed within 3 years of the graduate award.

3.3.2 Risk Assessment

No physical or psychological harm from the study tests was expected to come to the participants or the researcher. According to a Research Ethics risk assessment, no risk or adverse action was likely to occur from the study measurements as these are part of regular medical assessments in orthopaedic and physiotherapy practice.

All study participants must understand the language of the study, other patients will be excluded to avoid any language barriers.

The study's inclusion criteria included only healthy participants post-total knee arthroplasty and excluded any complicated cases, such as infections or fractures, and other special needs patients, such as blind or deaf, to exclude minority groups.

The study did not address any sensitive issues/ feelings/ experiences.

The researcher carried out the data-collection procedure as she had 8 years of experience with orthopaedics patients.

The researcher worked in a safe, indoor, non-isolated setting with enough preparations made in case of emergency, e.g. fire.

If first aid was required, a hospital qualified first aider could be called.

3.4 Inclusion and exclusion criteria:

Potential research participants/records were excluded from the study if they:

Were scheduled for bilateral knee or unilateral knee revision surgery;

Could not read and understand English for the United Kingdom population or Arabic for the Saudi Arabia population;

Had limited function due to musculoskeletal conditions other than unilateral knee osteoarthritis;

Had been diagnosed with uncontrolled diabetes mellitus or blood pressure;

Had been diagnosed with any neurologic disorders, such as stroke, Parkinson's disease, multiple sclerosis, haemophilia or psychological pathologies.

Had advanced osteoporosis or some other unstable chronic disease;

Had been diagnosed with a peripheral vascular or uncontrolled cardiac disease.

Participants were further excluded post-surgery if they developed any surgical complications, such as deep-vein thrombosis, uncontrolled infection or fracture.

3.5 Reliability, validity and responsiveness

The psychometric analysis of measures is important to estimate accuracy, consistency, and minimise the measurement error (random and systematic). Therefore, the reliability of measures such as OKS-Ar and SEBT needs to be undertaken.

3.5.1 Psychometric analysis of the Arabic version of Oxford Knee Score for end-stage knee osteoarthritis.

The Oxford knee questionnaire (OKS) is a reliable, valid and responsive assessment tool for individuals with knee osteoarthritis. However, there are only two studies assessing the Arabic version of the OKS (OKS-Ar). The study by Alghadir et al. (2017) was limited to male patients only, even though there is a greater risk in females for prevalent and incident knee osteoarthritis than males, with females tending to have more severe knee OA than males. The other paper by Ahmed et al. (2019) was a mixture of knee pathology (30 subjects for anterior cruciate ligament reconstruction, 20 subjects for partial meniscectomy, 20 subjects for high tibial osteotomy, and only 30 subjects for total knee arthroplasty), so it is difficult to isolate the knee arthroplasty findings as they encounter different problems. Neither Arabic study assessed responsiveness following TKA, or ceiling and floor effects. The purpose of the study was to explore the reliability and validity of the OKS-Ar in both male and female patients with end-stage knee osteoarthritis, including an assessment of responsiveness following TKA.

3.5.1.1 Methods

After ethical approval was obtained from both Salford University (HSR1617-39) and King Khaled University Hospital ethical committees (E-17-2395), each patient signed a consent form, they were first given an Arabic language form during a preadmission session. Preadmission sessions are usually 7–10 days before the admission date for recent laboratory tests and X-ray requirements. Patients were instructed to complete Arabic versions of Oxford Knee Score (OKS), Knee injury and Osteoarthritis Outcome Score (KOOS) and visual analogue scale (VAS) before arthroplasty as baseline data in order to assess the correlation with the Arabic version of KOOS and VAS and determine the construct validity (for Arabic versions of Oxford Knee Score, Knee injury and Osteoarthritis Outcome Score and visual analogue scale see Appendix 4 of study 3).

A second measurement was taken at least one week after the first to assess the test-retest reliability on admission day for the Arabic version of Oxford Knee Score.

A third measurement was taken six months post-surgery during a follow-up visit to evaluate the responsiveness at that point (Hyong & Kim, 2014; Impellizzeri, Mannion, Leunig, Bizzini, & Naal, 2011; Jenny & Diesinger, 2011; Naal et al., 2009).

Participants

Between March 2017 and October 2017, the metric properties of the Arabic version of OKS were assessed in 100 patients waiting for knee replacement. Eighty females and twenty male patients had a mean age of 62 ± 7.8 years. The body-mass-index means were 36.05 ± 5.13 for females and 30.02 ± 4.56 for males.

Data processing:

OKS data entry was performed according to OKS guidelines 2015, with scores for each question (item) from 0 to 4, with 0 being the worst outcome and 4 being the best. The scores were then summed to produce an overall score between 0 (worst possible) to 48 (best possible). The pain component was the sum of scores for items 1, 4, 5, 6, 8, 9 and 10 and the function component was the sum of scores for items 2, 3, 7, 11 and 12. All data were entered manually into an excel sheet.

All KOOS items were scored from 0 (no problem) to 4 (extreme problems), and each of the five scores was calculated as the sum of the items included; scores were then transformed into a 0–100 scale, with zero representing extreme knee problems and 100 representing no knee problems. KOOS data were entered manually into a KOOS-formulated excel sheet that calculated transformed scores for each subscale separately according to KOOS guidelines using the formula: (100 – (Actual raw × 100)/possible raw score range).

The assessor measured VAS data according to the position of the patient's mark with a ruler, from the no pain end of a 100 mm-long horizontal line, in millimetres, and converted it into points (0 points = no pain to 100 points = intolerable pain). The points were entered manually into an excel sheet.

Statistics analysis:

Construct validity was assessed via correlation with the Arabic version of KOOS and VAS using Spearman and linear correlation. Reliability was explored using three statistical analysis methods: Spearman's correlation between two measurements, test and re-test mean difference and a Bland-Altman plot. Internal consistency was assessed based on Cronbach's alpha values. The ceiling effect determined the percentage of responses between the maximum score reduced by one standard deviation, while the floor effect determined the minimum score increased by one standard deviation.

Responsiveness is the questionnaires ability and sensitivity to detect the changes before and after the intervention. Effect size was calculated based on the ratio of the mean change in pre- and postoperative scores; and then divided by the pre-intervention standard deviation. Commonly it used to compare different clinical measures, the effect sizes are considered large, moderate and small if the value 0.8, 0.5 and 0.2 respectively (Dunbar, Robertsson, Ryd, & Lidgren, 2000).

The assumption of a normal distribution of the OKS differences before and 6 months after TKA, was violated as assessed by a Kolmogorov-Smirnov test and a P value < .05 (Table 3-2). Therefore, non-parametric analysis was used to explore questionnaire-score differences post-TKA using a Wilcoxon signed-rank test.

Table 3- 2. Kolmogorov-Smirnov normality test.

Questionnaire	Statistic	df	Significance
OKS pre total knee arthroplasty	.178	100	.001
OKS post total knee arthroplasty	.150	100	.001
OKS difference	.098	100	.018

OKS= Oxford Knee Score

3.5.1.2. Results

Feasibility: All participants completed the questionnaire without difficulty at all three-time points.

Oxford Knee Score Validity results:

Spearman correlation with other scales:

The OKS pain component was significantly related to KOOS pain component (*rs* = .74, p < 0.01), and VAS score (*rs* = −.46, p < 0.01) (Table 3-3). The OKS functional component was significantly correlated with KOOS symptom (*r* = .37), KOOS Activities of Daily Living (*rs* = .72), and KOOS quality of life (*rs* = .66) (all P < .01). In contrast, the KOOS sport and recreation scores were not correlated with the OKS functional components (p = .57 [>0.01]) (Table 3-4).

Table 3- 3. Pain Components Spearman correlations.

	KOOS pain	VAS
Correlation Coefficient	.744	−.46
Sig. (2-tailed)	.001	.001

Correlation significant at the 0.01 level (2-tailed).

Table 3- 4. Functional Component Spearman correlations

	KOOS Symptoms	KOOS Activities of Daily Living	KOOS Sport & Recreation	KOOS Quality of Life
Correlation Coefficient	.37	.72	.05	.66
Sig. (2-tailed)	.001	.001	.57	.001

Correlation significant at the 0.01 level (2-tailed).

Linear Correlation

1-OKS Pain component correlation

The OKS Pain component showed a strong positive correlation with the KOOS pain subscale, as the variables increased concurrently. Both scales show a good condition with a high score and sever pain with a low score (Figure 3-1). In contrast, the OKS pain component showed a weak negative correlation with visual the analogue scale (VAS); as the VAS score increased, the OKS pain component decreased (Figure 3-2).

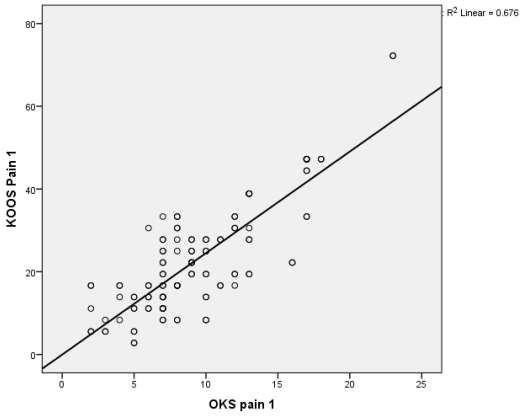

Figure 3- 1. Scatter diagram showing the correlation between Oxford Knee Score (OKS) and Knee Injury and Osteoarthritis Outcome Score (KOOS) pain component.

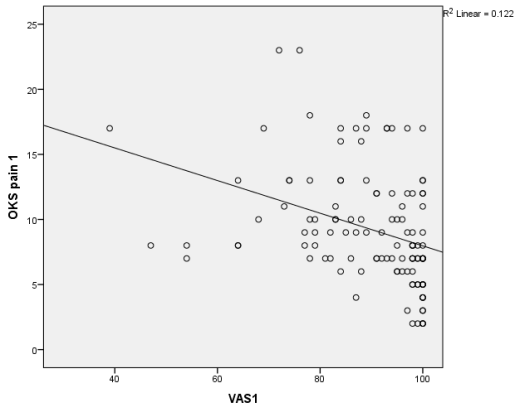

Figure 3- 2. Scatter diagram showing the correlation between Oxford Knee Score (OKS) pain component and Visual Analogue Scale (VAS).

2-OKS Functional component correlation

The OKS functional component showed a strong positive correlation with the KOOS Activities of Daily Living subscale (Figure 3-3), a weak positive correlation with the KOOS Symptom subscale (Figure 3-4), a moderate positive correlation with the Quality of Life subscale (Figure 3-5) and no correlation with the Sport and Recreation subscale (Figure 3-6).

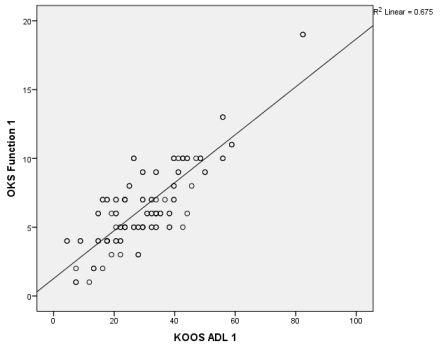

Figure 3- 3. Scatter diagram showing the correlation between Oxford Knee Score (OKS) functional component and Knee Injury and Osteoarthritis Outcome Score (KOOS) activities of Daily Living subscale.

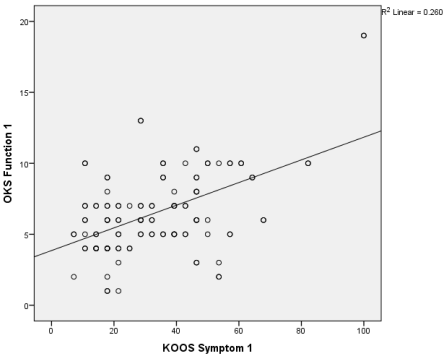

Figure 3- 4. Scatter diagram showing the correlation between Oxford Knee Score (OKS) functional component and Knee Injury and Osteoarthritis Outcome Score (KOOS) Symptom subscale.

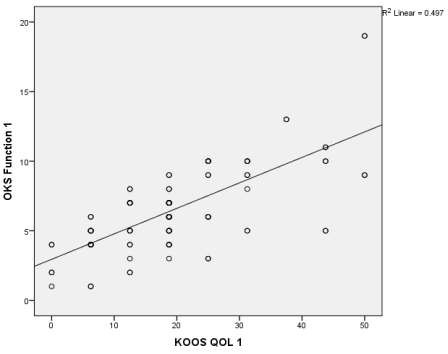

Figure 3- 5. Scatter diagram showing the correlation between Oxford Knee Score (OKS) Functional component and Knee Injury and Osteoarthritis Outcome Score (KOOS) Quality of Life subscale.

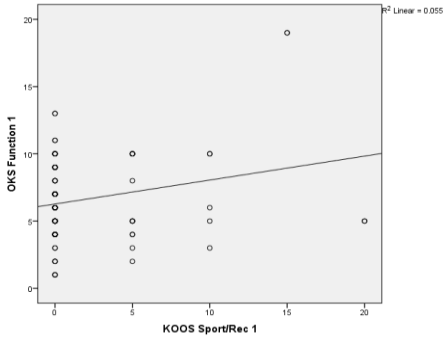

Figure 3- 6. Scatter diagram showing the correlation between Oxford Knee Score (OKS) functional component and Knee Injury and Osteoarthritis Outcome Score (KOOS) Sport and Recreation subscale.

Oxford Knee Score Reliability results

The Kolmogorov-Smirnov test results were significant (non-normal) for all OKS question scores ($p < .05$). Spearman's correlation coefficient was used as the parametric assumption violated. The total value for the first and second OKS measurements was significantly correlated ($rs = .94$, $p < .001$). All questions showed excellent to large correlation with *rs* ranging between .92 and .70 ($rs = .68$) (Table 3-5). There were no significant differences between the test and re-test mean scores ($p = .804$; mean .0431, Std Deviation= 1.87 and low standard error of mean =.173).

Table 3- 5. Spearman's rho correlations between the two Oxford Knee Score (OKS) measurements.

Item	Correlation Coefficient	Sig. (2- tailed)
Question 1	.731	.000
Question 2	.890	.000
Question 3	.806	.000
Question 4	.758	.000
Question 5	.760	.000
Question 6	.814	.000
Question 7	.887	.000
Question 8	.914	.000
Question 9	.803	.000
Question 10	.921	.000
Question 11	.705	.000
Question 12	.760	.000
Pain component	.935	.000
Function component	.896	.000
Total score	.945	.000

Correlation significant at the 0.01 level (2-tailed).

In addition, the Bland-Altman plot showed almost all scores were within the limits of agreement (95% CI: –0.366 to .326), which confirmed the high reliability of the Arabic version of OKS (Figure 3-7).

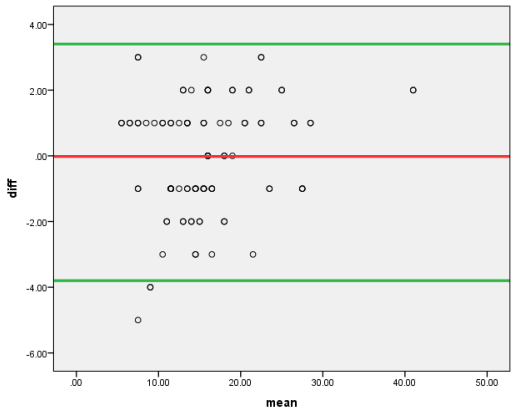

Figure 3- 7. Bland-Altman plot showing reliability of Arabic version of Oxford Knee Score.

Internal consistency

The Arabic version of OKS showed a high internal consistency, with all Cronbach's α at .84 and all the corrected item total corrections at above 0.3. The alpha values did not improve beyond than .84 if one item was deleted (Table 3-6).

The Arabic version of KOOS showed a high internal consistency, all Cronbach's α at .85 and all the corrected item total corrections at above 0.3. However, the alpha values improved to .88 if the sport and recreation questions were deleted.

Table 3- 6. Internal Consistency of the Arabic version of Oxford Knee Score (OKS).

	Total OKS	Function score	Pain score
Cronbach's Alpha	.849	.754	.744

Ceiling and floor effect

The presence of a ceiling effect was tested by determining the percentage of responses between the maximum score reduced by one standard deviation (48 – 1SD). Before operation, there was no ceiling effect found (with no score above 42). Six months after TKA, a 2% ceiling effect found (only 2 scores above 42). The floor effect was studied by determining the percentage of responses between the minimum score increased by one standard deviation (0 + 1SD). There was no floor effect before and after the operation (no score below 6) (Tables 3-7, 3-8 and Figure 3-8).

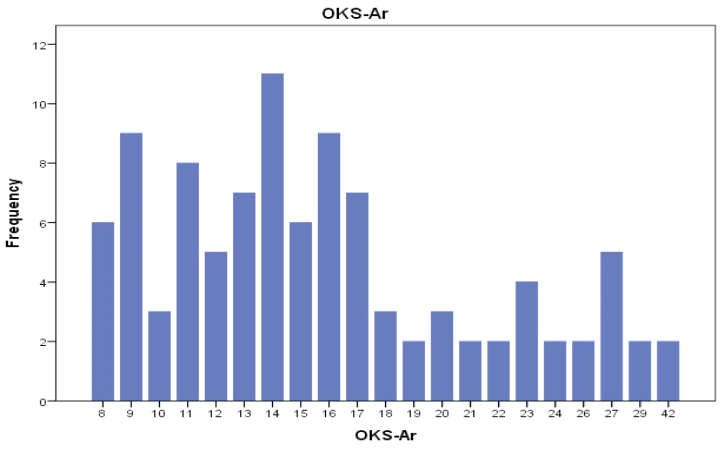

Figure 3- 8. Global Oxford Knee (OKS) Score.

Table 3- 7. Global Oxford Knee Score.

Pre-operation		Post-operation	
Total Score	**Frequency**	**Total Score**	**Frequency**
8	6	23	2
9	9	27	2
10	3	29	4
11	8	30	6
12	5	31	5
13	7	32	14
14	11	33	15
15	6	34	4
16	9	35	1
17	7	36	18
18	3	37	12
19	2	38	4
20	3	39	9
21	2	40	1
22	2	41	1
23	4	43	2
24	2		
26	2		
27	5		
29	2		
42	2		
Total	100		100

Table 3- 8. Descriptive statistic of Arabic version of Oxford Knee Score.

Item	Mean	Std. Deviation	Std. Error	Minimum	Maximum
TOTAL OKS	16.12	6.6	.663	8	42

Oxford Knee Score Responsiveness

A Wilcoxon signed-rank test determined that there was a significant median increase in score post TKA (20 points improvements) -high scores associated with better performance- as Ps<.0005, z= 9.35. Both pain and function subscale showed a statistically significant median increase in score post TKA (Table 3-9). The effect size of OKS-Ar 6 months post TKA was large 3.09.

Table 3- 9. A Wilcoxon signed-rank test for Oxford Knee Score (OKS) before and after total knee arthroplasty.

	Median before TKA	Median post-TKA	Median difference	Test Statistic	Standard error	Standardized test statistic (Z)	Asymptotic sig. (2- sided test)
OKS total score	14	34	20	5.050	290.71	8.686	.000
OKS pain subscale	9	21	12	5.050	290.54	8.691	.000
OKS function subscale	5	12	7	4.656	272.79	8.534	.000

3.5.1.3 Discussion:

This is the first study to explore the reliability, validity and responsiveness of the OKS-Ar for both male and female patients. The study demonstrates that the OKS-Ar is a feasible, reliable, valid and responsive assessment tool for pain and function for individuals with end-stage osteoarthritis of the knee and whose main language is Arabic.

Most studies assess construct validity using the 36-Item Short Form Survey (SF-36), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or the Knee Society Score. No study has explored the correlation with the Knee injury and Osteoarthritis Outcome Score (KOOS) even though it is one of the common specific knee-joint PROMs. The current study shows a good correlation between the OKS-Ar functional component, KOOS-Ar activity of daily living and quality of life subscales. The pain component shows significant agreement with the KOOS-Ar pain subscale. This agrees with: the WOMAC correlation found in German (Naal et al., 2009), Arabic (Alghadir et al., 2017) and Turkish (Tugay et al., 2016) studies; and pain score in SF-36 correlation in the original English version (Dawson et al.,1998), a Chinese version (Xie et al., 2007) and a Thai version (Charoencholvanich et al., 2005).

In terms of test re-test values and correlation coefficients, the reproducibility of OKS-Ar shows excellent agreement between the two measures, with no significant difference. This aligns with the original English version (Dawson et al.,1998) and other translated studies that assess repeatability, such as in German (Naal et al., 2009), Arabic (Alghadir et al., 2017) and Turkish (Tugay et al., 2016) cohorts.

Absolute reliability was assessed by a Bland Altman plot and confirms no significant bias. This agrees with the original English version (Dawson et al.,1998) and two translated studies in German (Naal et al., 2009) and Arabic (Alghadir et al., 2017) cohorts.

The internal consistency of OKS-Ar shows a good Cronbach's α value, similar to both the original English OKS (Dawson et al., 1998) and other official translated versions, such as into French (Jenny et al., 2010), German (Naal et al., 2009), Chinese (Xie et al., 2007), Arabic (Alghadir et al., 2017; Ahmed et al. 2019), and Turkish (Tugay et al., 2016).

The floor and ceiling effects of OKS-Ar are like those of the original version (Dawson et al., 1998) and other official translations (Naal et al., 2009; Jenny et al., 2011; Xie et al., 2007; Charoencholvanich et al., 2005; Alghadir et al., 2017; Tugay et al., 2016). The average scores pre-surgery agrees with the Turkish study (Tugay et al., 2016), which is the only study to use the updated 2015 scoring system and so is easy to compare with (overall score between 0 (worst possible) and 48 (best possible)). The remaining studies use the original

scoring system; overall scores range from 12 to 60 (12 being the best outcome). Although the studies use different scoring systems, this does not affect the psychometric scale properties, and all show similar values.

The current study is the only one to explore the responsiveness/ sensitivity of translated OKS after TKA. The study shows a large effect size, which agrees with the original English version (Dawson et al.,1998). In conclusion, the OKS-Ar is a reliable, valid and responsive instrument for Arabic-speaking patients with knee osteoarthritis.

3.5.2 Repeatability of the Star Excursion Balance Test for end – stage Knee Osteoarthritis

Peripheral joint arthritis affects balance and consequently decreases physical activity (Hinman et al., 2002; Noren et al., 2001). Instability in end-stage knee OA is one of the main factors that correlate with disability and a high risk of falling (Kauppila et al., 2009; Zasadzka et al., 2015). Assessing balance improvement post-TKA is essential to capture functional improvements. A dynamic balance assessment has advantages over a static one, in that it closely mimics physical activity demand and the history of falling in the OA population accrues during activity rather than in a static position.

The Star Excursion Balance Test (SEBT) assesses dynamic balance in multiple directions, which may better mimic daily life activity requirements. It showed good reliability for healthy participants and early to moderate stage knee OA; and it is feasible as it does not require specific or costly instruments (Kanko et al., 2019). Two studies found significant improvements in balance using a Star Excursion Balance Test after 6 or 12 weeks of training for mild to moderate individuals with knee OA following an exercise programme (Al-Khlaifat et al., 2016; Kanko et al., 2019). Interestingly, no studies have assessed dynamic balance post-TKA using SEBT or undertaken a reliability study with end stage of OA patients. The purpose of this study was to assess the SEBT reliability as no previous study has assessed the reliability of SEBT in end-stage knee OA patients and responsiveness post-TKA. The responsiveness results are described in Chapter 6 with prospective study findings to avoid repetition.

3.5.2.1 Methods

Study procedure:

After ethical approval was obtained from both Salford University (HSR1617-39) and King Khaled University hospital ethical committees (E-17-2395), patients were instructed to perform the first functional balance test during a preadmission session. Preadmission

sessions are usually 7–10 days before the admission date for recent laboratory tests and X-ray requirements.

A second measurement was taken at least one week after the first to assess the test-retest reliability on admission day (Hyong & Kim, 2014; Impellizzeri et al., 2011; Jenny & Diesinger, 2011; Naal et al., 2009).

In the Star Excursion Balance Test, three tape measures were fixed to the clinic floor, one oriented anteriorly to the apex and two aligned at 135° to the anterior tape in the posterolateral and posteromedial directions (Fullam et al., 2014) (Figure 3-9).

After explaining the procedure, the researcher demonstrated the test to the patient to clarify its requirements. The patient stood in the centre of the grid and was instructed to stand on the affected or operated leg while reaching out as far as possible in one of three directions with the other lower extremity, and then return that leg to the centre. The participant was asked to perform the test barefoot, keeping the heel of the stance leg on the floor at all times and to bend the knee of the stance leg. If the participant did not carry out any of these instructions, the trial was repeated.

Each participant first performed four training trials in all directions to minimise the learning effect, followed by rest. Participants were asked to complete three consecutive trials in each reach direction.

The assessor measured the reach distance in each direction in centimetres and then normalised the average of the three trials to leg length. Limb length was measured while lying in a supine position, from the anterior superior iliac spine to the centre of the ipsilateral medial malleolus. Reach distances were normalised to limb length by calculating the maximum reach distance (%MAXD) using the formula: (excursion distance/limb length) ×100 (Coughlan et al., 2012; Fullam et al., 2014; Robinson & Gribble, 2008).

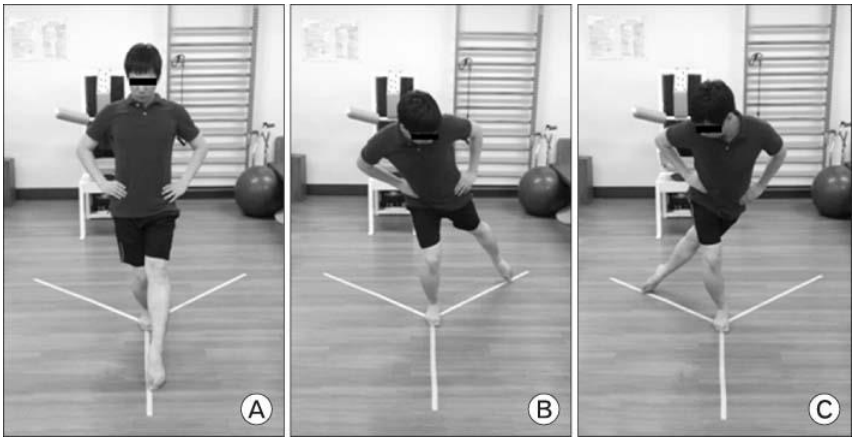

Figure 3- 9. The three-direction balance test

Participants

Between March 2017 and October 2017, the reliability of the SEBT was assessed in 35 consecutive patients waiting for knee replacement. Twenty-four females and eleven male patients had a mean age of 62 ± 9 years. The leg length mean was 74.8 ± 5.7.

Sample Size Estimation

For a general sample size estimation, a sample of 35 patients was deemed enough to determine whether an ICC of .88 is significantly higher than 0.70 with two measurements session per subjects, the alpha level at 0.05 and power at 90% (Hyong & Kim, 2014; Walter et al., 1998).

Statistical analysis

According to the Kolmogorov-Smirnov test, the Star Excursion Balance test measurements, D (35) =0.1, and *P* values for all directions < .05, were all non-significant and normally distributed (Table 3-10).

Reliability was explored using three statistical analysis methods: Pearson's correlation between two measurements, test and re-test mean difference and a Bland-Altman plot (Field, 2009). The standard error of measurement (SEM) = (standard deviation $\times \sqrt{(1 - \text{ICC}))}$ (Thomas, Nelson, & Silverman, 2015) and minimum detectable change (MDC) ($1.96 \times \sqrt{2}$ ×SEM) were employed to assess absolute reliability (Kropmans, Dijkstra, Stegenga, Stewart, & de Bont, 1999).

Table 3- 10. Kolmogorov-Smirnov normality for Star Excursion Balance test.

Measurement direction	Statistic	df	Significant
First measurement of SEBT anterior direction	.126	35	.178
First measurement of SEBT posteromedial direction	.118	35	.200
First measurement of SEBT posterolateral direction	.108	35	.200
Second measurement of SEBT anterior direction	.134	35	.118
Second measurement of SEBT posteromedial direction	.114	35	.200
Second measurement of SEBT posterolateral direction	.124	35	.192

SEBT= Star excursion balance test, df = degrees of freedom.

3.5.2.2 Results

As the data were normally distributed, correlation was analysed using a Pearson's correlation test. The two measurements of normalised SBET correlated significantly in all three directions, all *P*s <.001. Anterior direction correlation r= .99, posteromedial direction r= .99 and posterolateral direction r= .98 (Table 3-11).

Table 3- 11. Star Excursion Balance test correlation matrix.

	Second measurement of SEBT anterior direction	Second measurement of SEBT Postero-medial direction	Second measurement of SEBT Postero-lateral direction
First measurement of SEBT anterior direction	.999	.789	.855
First measurement of SEBT posteromedial direction	.797	.997	.836
First measurement of SEBT Posterolateral direction	.857	.853	.987

SEBT= Star excursion balance test.

The SEBT shows excellent ICC in all directions .99, the standard error of measurements (SEM) ranges from 0.92 to 0.74 cm for all directions and the MDC ranges from 2.57 to 2.05cm (Table 3-12). There were no significant differences between the test and re-test mean scores in all three directions, as all *P* values were larger than 0.05 (Table 3-13).

Figures 3-10, 3-11 and 3-12, Bland-Altman plots, confirm that almost all scores in all test directions were within limits of agreement, and this indicates good absolute reliability.

Table 3- 12. Intraclass Correlation Coefficient

Star Excursion Balance Test Direction	Intraclass Correlation	95% Confidence interval		Standard error of measurements	Minimal detectable changes
		Lower Bound	Upper bound		
Anterior direction	.99	.999	1.00	0.91 – 0.92	2.54 – 2.57
Posteromedial direction	.99	.997	.999	0.74 – 0.75	2.05 – 2.08
Posterolateral direction	.99	.986	.997	0.79 – 0.77	2.21 – 2.13

Table 3- 13. One Sample T-Test for Star Excursion Balance Test

Star Excursion Balance test direction	Mean	Standard deviation	Standard error of mean	Significant
Anterior direction	0.059	0.44	0.074	.431
Posteromedial direction	0.189	0.65	0.111	.099
Posterolateral direction	0.164	1.34	0.227	.474

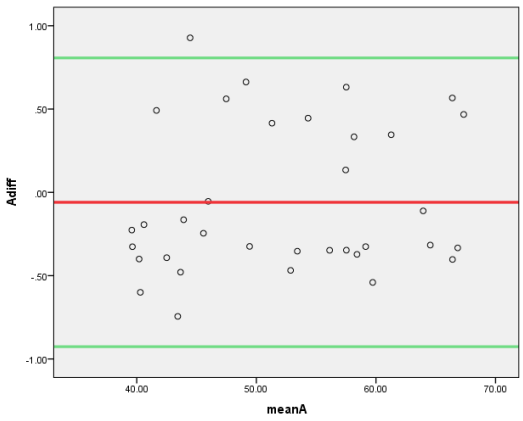

Figure 3- 10. Bland-Altman plot showing reliability of anterior direction in a Star Excursion Balance Test.

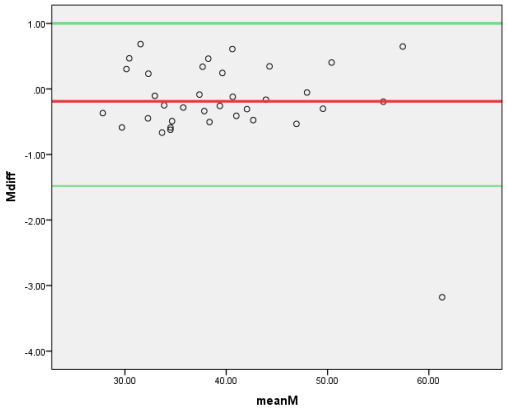

Figure 3- 11. Bland-Altman plot showing reliability of posteromedial direction in a Star Excursion Balance Test.

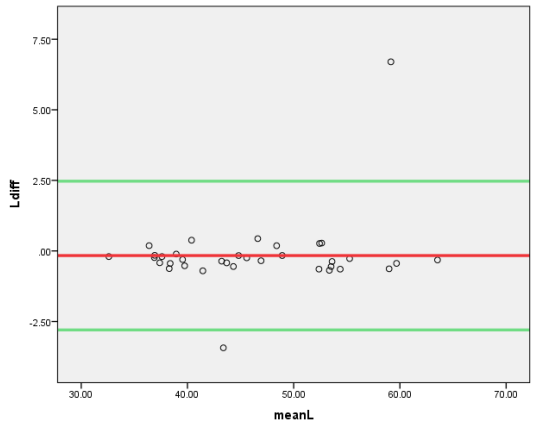

Figure 3- 12. Bland-Altman plot showing reliability of posterolateral direction in a Star Excursion Balance Test.

3.5.2.3 Discussion:

The normalised Star Excursion Balance Test showed excellent reliability in end-stage knee OA patients in all three directions. This result adds to the body of knowledge that exists regarding its usefulness as a feasible dynamic balance assessment tool in both the clinical and research fields.

The current intra-reliability results agree with previous studies' correlation coefficients for healthy athletes, early to moderate knee OA, and post-anterior cruciate ligament (ACL) injury with an ICC range of .96-.88. The test re-test showed no significant difference between the two measurements' means and this in accordance with previous reliability

studies (Gribble et al., 2012; Hertel et al., 2000; Hyong & Kim, 2014; Kanko et al., 2019; Linek et al., 2017; Munro & Herrington, 2010).

There was excellent agreement between the two measures using B&A plots, and 97% of the current study's scores in three directions were within limits of agreement. Despite the SEBT being widely used in lower-limb injuries, no previous study has assessed it absolute reliability using B&A plots. B&A quantifies the possible bias between mean differences in addition to agreement intervals.

The current study's normalised SEM range of 0.92–0.74% falls below the healthy and early knee OA reliability range of 2.21–5.5, this may be due to limited balance ability in patients with end stage knee OA and thus subsequently limit the SEM range (Hertel et.al., 2000; Hyong & Kim, 2014; Kanko et al., 2019; Linek et.al, 2017). Low SEM indicate high reliability, accuracy and sensitivity for SEBT to detect dynamic balance changes in end stage knee OA patients (Liaw et al., 2008). In addition to estimating absolute reliability, MDC provides a reference for clinicians regarding expected true values for SEBT for end- stage knee OA. The MDC for end stage knee OA ranges from 2.57–2.05%, which is lower than healthy, athletic and early knee OA participants for whom the range is 6.68–13% (Hyong & Kim, 2014; Kanko et al., 2019; Linek et.al., 2017).

The limitations of the study are the small sample size and only assessing intra-rater reliability. Hence a future study is recommended to assess inter-rater reliability with a larger sample size. In conclusion, the normalised SEBT showed excellent reliability in end-stage knee OA patients in all three directions, it was highly accurate and sensitive to detect dynamic balance changes post-TKA.

Chapter 4 - Retrospective study

4.0 Introduction

Poor patient outcomes and factors associated with dissatisfaction are crucial questions post-TKA. Many previous studies have focused on intervention factors, such as surgical protocol and type of prosthesis type, and drawn insufficient conclusions to explain the variability in outcomes post-TKA. Understanding patient factors may clarify other factors that affect prognoses post-TKA to allow enhancing patient preparation sufficiently before surgery to maximise outcomes and satisfaction (Moons, Royston, Vergouwe, Grobbee, & Altman, 2009; Santaguida et al., 2008). The prediction tool is an equation devised from multiple stages of statistical analysis of hundreds or thousands of patients' data to estimate post-TKA outcomes based on pre-surgery patient factors. A valid clinical prediction tool will allow patients to make surgery decisions with realistic outcome expectations based on personalised outcome predictions, which may improve their satisfaction post-surgery. To date, there has been no valid prediction tool for patient factors that explain the long-term (10 years) variability in outcomes and satisfaction post-TKA. Only one recent study, by Sanchez-Santos et.al. (2018), developed and validated predictions for OKS scores over the short-term (one-year) post-TKA (Sanchez-Santos et al., 2018). Therefore, the main aim was to assess the association between pre-surgical patient factors and patients' satisfaction and short-, medium- and long-term (one, five- and ten-years) outcomes post-surgery. A secondary aim of the study was to assess OKS score, UCLA, pain, function and satisfaction at different time points post-TKA (6 months, one, five and ten years).

4.1 Materials and methods

4.1.1 Study design:

This was a retrospective analysis of outcomes at one, five and ten years post-TKA for all patients underwent a primary TKA by one of five consultant surgeons at Stepping Hill Hospital. Ethical approval was obtained from Salford University (HSR1617-137, Appendix 1), the NHS Health Research Authority (18/HRA/0168, Appendix 2) and Stepping Hill Hospital (Appendix 3). All patients' records at Stepping Hill Hospital, with data spanning more than one year, were reviewed if they were scheduled for primary unilateral TKA for end-stage knee osteoarthritis and were in a stable and controlled medical condition.

4.1.2 Inclusion and exclusion criteria

Records were considered eligible if the following criteria were met; at least one preoperative record no more than 6 months prior to surgery, and one, five- or ten-years' postoperative records available. Regarding OKS, a maximum of two missing questions per questionnaire.

In a case of 1 or 2 missing scores, the mean value representing all other responses fills this gap**.** Potential research records were excluded from the study if a patient did not consent to the use of their records for research purposes.

4.1.3 Sampling frame

The inclusion of a minimum of 400 patient records -comprising both males and females- was planned, to achieve 80% power to detect associations between preoperative factors and post-TKA outcomes at a 5% level and a correlation coefficient of 0.2. This explores the prediction factors that account for more than 4% of outcome variations, which is less than the Oxford Knee Score clinically detectable changes (4- 5 points) (Cohen, 1988).

The number of predictors included in the regression model is crucial to maintain regression validity, a rule of thumb indicates a minimum of 10–15 cases' data for each predictor. If a small effect size needs to be detected (any small confounding factors) a larger sample size is required (Fig. 4-1). In random data, expected R=k/(N-1), where k= number of predictors and N is the sample size. Therefore, a small sample size will be limited to strong effect predictors while a larger sample size may show medium to small effects (Field, 2009).

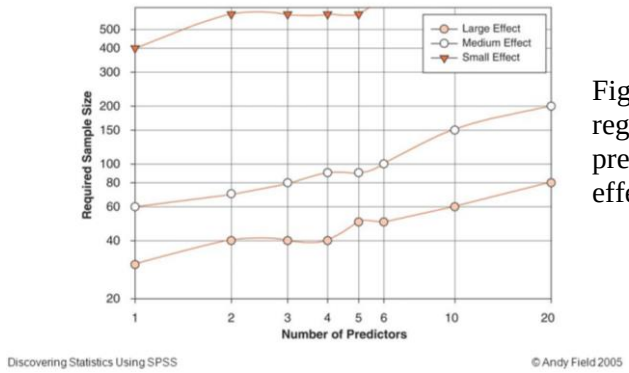

Figure 4- 1. Sample size required in regression depending on the number of predictors and the size of the expected effect.

4.1.4 Data collection procedures

From November 2017 to the end of January 2019, retrospective data collection was analysed in four consecutive stages to achieve the research objectives. In the first stage, all available questionnaire data were manually entered into an Excel spreadsheet as the type of knee surgery was not clarified on the form to confirm eligibility with regard to the inclusion criteria. Questionnaire data included were as follows: patient's name, hospital identification number, Oxford Knee Score (OKS), University of California Los Angeles activity score (UCLA), pain score using a horizontal 10 cm visual analogue scale (VAS) before, 1, 5 or 10 years post-TKA in addition to current function, expectation achievements from surgery and satisfaction on a visual analogue scale at all assessments time points post-TKA (Appendix 4). Function assessed on a horizontal 10 cm visual analogue scale ranges from "could not be

worse" (0) up to "normal function" (100); the expectation scale ranges from "nowhere near my expectations" (0) to "far exceeded my expectations"(100); and the satisfaction visual analogue scale ranges from not at all(0) to completely satisfied (100). The second stage of retrospective data collection was linking (data-merging) the questionnaire data to the hospital admissions database to gain further information to confirm the suitability of records, such as: NHS number, medical history, date of surgery, previous contralateral knee replacement, Charlson Comorbidity Index (CCI), readmission for revision and other details that might affect a patient's outcome and satisfaction post-TKA. The CCI provide a standardised reliable method to assess comorbidity. The commonly used version identifies 17 comorbidity conditions that correlate with mortality and assigns weights to each of them, ranging from 6 points to 1 point. The summation of points from the 17 conditions ranges from a maximal disease burden (29) to a no disease burden (0) (Voskuijl, Hageman, & Ring, 2014). The third stage was linking the study's Excel spreadsheet with the hospital surgery database to confirm the type of surgery, the presence of complications, range of motion (ROM) before surgery, body mass index (BMI) and other surgical details. The last stage of data collection was to link the study's Excel spreadsheet with NHS-PROM sheets to obtain OKS scores at six months post-TKA using NHS numbers as a reference, this sheet had just 1,221 complete records (Figure 4-2).

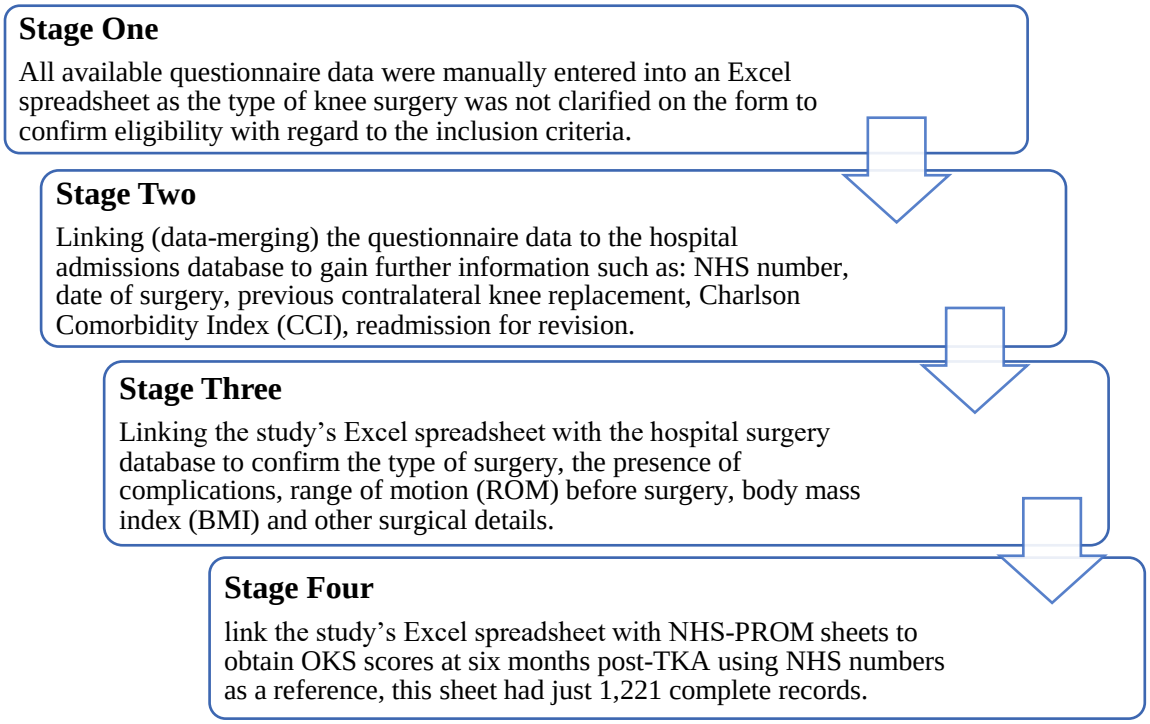

Figure 4-2. Retrospective data collection stages for outcomes post-Total knee Arthroplasty.

4.2 Data analysis

To achieve the research objectives, data analysis was conducted in two phases: the first phase was to explore the changes in OKS, satisfaction, UCLA, pain, and function at different time points post-TKA (6 months, one, five and ten years). The second phase was to correlate outcomes with the available data to draw conclusions about possible outcomes and satisfaction post-TKA in a prediction equation.

4.2.1 Phase One data analysis: To explore the changes from baseline to all follow-up time points post-TKA (6 months, 12 months, 5 years and ten years) with different sample sizes, the data were analysed along two groups to maintain the transparency of data selection and thus minimise the impact of bias (Rotelli, 2015) (Figure 4-3). The first group analysed all complete Oxford Knee Score (OKS) data at all time points, including 6 months follow-up. As the 6-month follow-up points exclude more than 2,000 patient records, a second group excluded 6 months follow-up to assess the changes at all time points without the 6-month limitation. The second group was subdivided into three groups: OKS score changes without 6-month data; satisfaction score changes; and UCLA, VAS and function data, as the PROMs database did not include UCLA or pain scores (Figure 4-3). The detailed exclusions at each time point in both groups are clarified in the following section.

4.2.2 Phase Two data analysis: To predict OKS and patients' satisfaction post-TKA, a multiple linear regression was run with the available data to conclude the best prediction equation that might explain patients' variability in outcomes and satisfaction at one, five and ten years post-TKA. Then, the developed model was validated using a simple bootstrap approach.

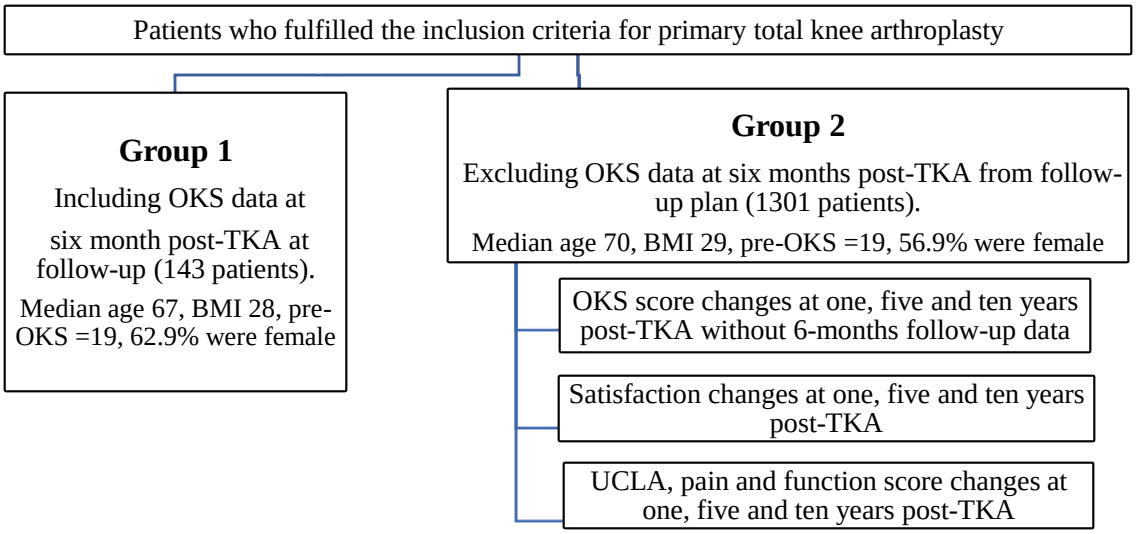

Figure 4-3. Phase one data analysis grouping.

4.3 Phase one analysis

Assumption analysis

The current independent variable (factors) were measured at two, three or four time points (before TKA, 6, 12 months, 5 and 10 years post-TKA) and both dependent and independent variables were measured on a continuous level. Hence, a parametric test for related samples is determined to be the best option if data are normally distributed (paired-sample t-test or one-way repeated measures ANOVA) based on the number of factors (number of measurement time points). If the normality assumption is violated, non-parametric analysis was used, either Wilcoxon signed-rank tests or Friedman tests based on the number of factors. In the case of three or more factors, a post hoc comparison test was then applied to explore where significance lay, if present, using a Bonferroni correction test. Pairwise comparisons were calculated using the data set to decrease the chance of Type I errors that might result from multiple comparisons with t-tests or Wilcoxon signed-rank tests (Girden, 1992; Weinfurt, 2000). The effect size was calculated based on the following formula: $\omega^2 = (k-1)(F-1)/(k-1)(F-1)+ nk$, where k = number of levels of within-subject factors, F = value of the F-statistic and n = sample size (Keppel & Wickens, 2004). Commonly used to compare different clinical measures, the effect size is considered large, moderate or small if the value is 0.8, 0.5 or 0.2, respectively (Dunbar et al., 2000). The final study Excel spreadsheet was exported to SPSS statistical software (IBM SPSS v.20) to proceed with statistical analysis.

Phase One Results

The current section presents an analysis of retrospective data for two groups: including with OKS data at 6 months and without OKS data at 6 months (Fig.4-3). OKS changes at each follow-up time point with different sample sizes are presented in the following section, descriptive data at all time-points are summarised in Table 4-1.

Patient Features

A Mann-Whitney U test was run to determine if there were any significant differences in patient's age, BMI, pre-surgery OKS and CCI between the group with six months of data (143 patients) and without (1301 patients) to ensure the representativeness of patient subsets, as the assumption of normality was violated when assessed by a Kolmogorov-Smirnov test, P value < .05. The median age was significantly different, patients' median age at six months follow-up group was 2 years more than the without 6 months of data follow-up group. BMI, pre-surgery OKS and CCI medians were not significantly different between the two groups (Table 4-2). A chi-square test showed no significant difference in gender proportions,

P=076. Females were more numerous in the group with 6 months of data than the group without (92.9 % vs 56.9%).

Table 4-1. Oxford Knee Score (OKS), descriptive statistics at different time points post- total knee arthroplasty (TKA).

Analysis pathway	Sample size	Length of follow-up	Time point	Mean	Standard Deviatio	Standard Error of the Mean	95% Confidence Interval	
							Lower Bound	Upper Bound
Including 6 months post-TKA data in analysis	N= 143	Pre, 6, and 12 months post-TKA	Pre-Total Knee Arthroplasty	19.5	6.8	.57	18.4	20.6
			6 months Post-Total Knee Arthroplasty	29.0	4.9	.41	28.2	29.8
			12 months Post-Total Knee Arthroplasty	38.5	3.6	.30	37.8	39.1
	N= 36	Pre,6 months, 12 months, and 5 years post-TKA	Pre-Total Knee Arthroplasty	19.03	4.3	.71	17.6	20.5
			6 months Post-Total Knee Arthroplasty	38.47	4.4	.74	36.9	39.9
			12 months Post-Total Knee Arthroplasty	43.28	2.5	.43	42.4	44.1
			5 years post-Total Knee Arthroplasty	43.50	2.5	.37	42.7	44.3
Excluding 6 months post-TKA data from analysis	N= 1301	Pre- and 12 months post-TKA	Pre-Total Knee Arthroplasty	19.4	6.0	.14	7.0	36.0
			12 months Post-Total Knee Arthroplasty	36.2	5.0	.17	24.0	48.0
	N= 783	Pre, 12months , and 5 years post-TKA	Pre-Total Knee Arthroplasty	19.38	6.6	.24	18.9	19.8
			12 months Post-Total Knee Arthroplasty	38.12	6.5	.23	37.7	38.6
			5 years Post-Total Knee Arthroplasty	38.37	6.8	.24	37.9	38.9
	N= 149	Pre, 12 months, 5 and 10 years post-TKA	Pre-Total Knee Arthroplasty	20.36	6.8	.56	19.3	21.5
			12months Post-Total Knee Arthroplasty	38.32	6.1	.49	37.3	39.3
			5 years Post-Total Knee Arthroplasty	38.17	6.2	.51	37.2	39.2
			10 years Post-Total Knee Arthroplasty	35.64	6.4	.52	34.6	36.7

Table 4- 2. Demographic data for patients in two follow-up groups post-TKA, group one (with six months of follow-up data) and group two (without six months of data).

		Completed records at pre/one-year post-total knee arthroplasty							
		Age		Body mass index (BMI)		Charlson Comorbidity Index (CCI)		Pre-surgery Oxford Knee Score	
		with 6 months follow-up group	without 6 months follow-up group	with 6 months follow-up group	without 6 months follow-up group	with 6 months follow-up group	without 6 months follow-up group	with 6 months follow-up group	without 6 months follow-up group
Patient characteristics	N=	143	1301	143	1301	143	1301	143	1301
	Median	67	70	28	29	0	0	19	19
	Interquartile range	11	13	7	6	1	1	11	9
	Minimum	47	47	18	22	0	0	7	7
	Maximum	88	92	44	47	4	4	35	36
	No. (%) of female patients	62.9% (90) in analysis group with 6 months of data / 56.9% (753) in analysis group without 6 months of data. P=.076							
Mann-Whitney U test	Standardized test statistic	-2.28		-.726		-.025		-.150	
	Significant P	.022		.468		.681		.381	

4.3.1 Group one: Data analysis including 6 months

A total of 143 patient records were identified with a complete Oxford Knee Score (OKS) before TKA and at 6- and 12-months follow-up. Excluded records containing incomplete information at all follow-up time points are clarified in Fig. 4-4.

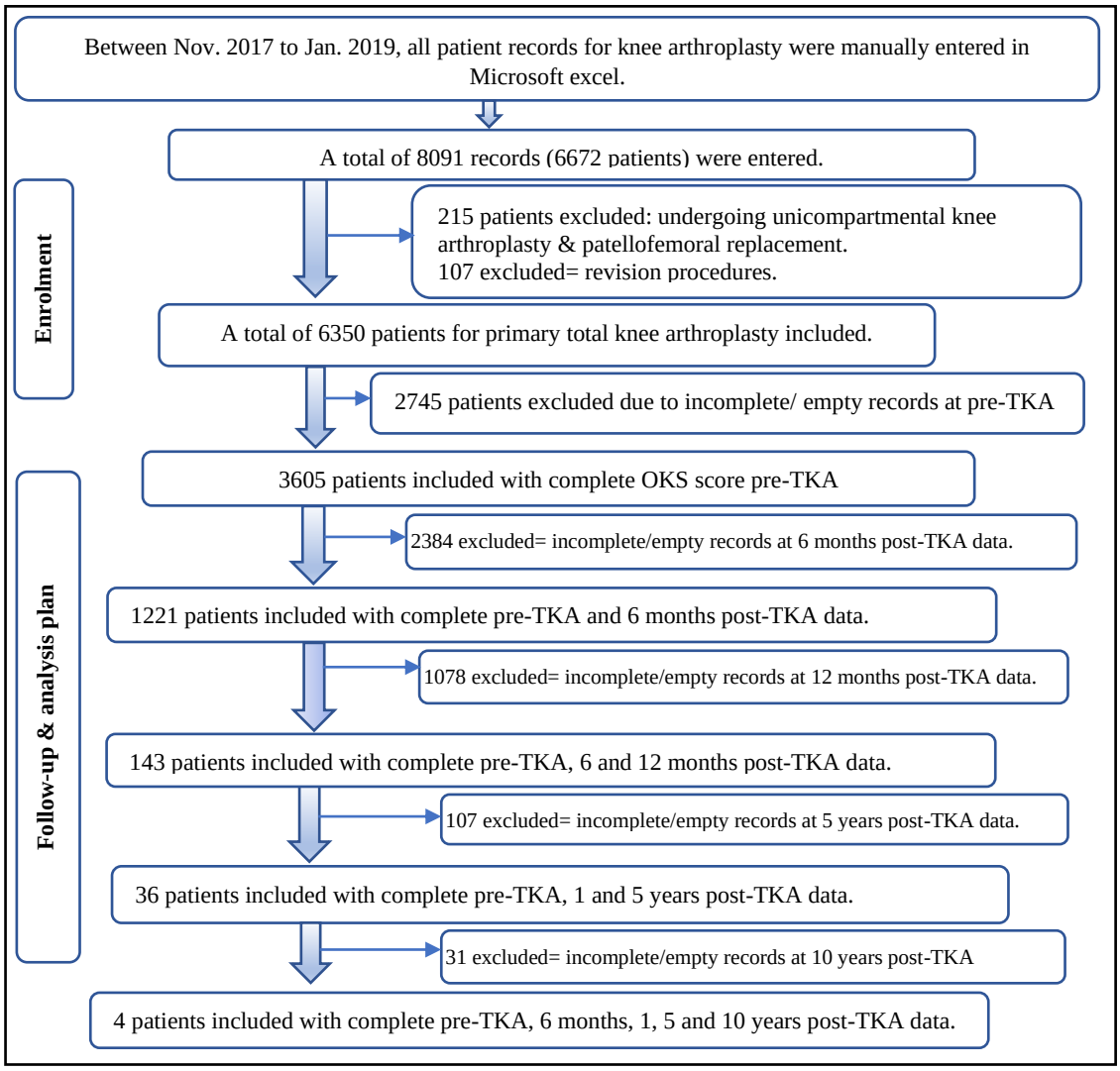

Figure 4-4. Patient selection flowchart for Oxford Knee Score (OKS) data including 6 months of data in a follow-up plan

Assumption analysis: OKS was normally distributed at each time point, as assessed by a Kolmogorov-Smirnov test (*P*s >.05) and by the inspection of a boxplot as there were no outliers (4-5). A Mauchly's test of sphericity indicates that the assumption of sphericity was violated for both follow-up lengths, i.e. one and five years post-TKA. Approximate chi-squared for the data set follow up for one and five years is χ^2 (2) = 135.1, χ^2 (2) = 35.5, respectively, and both *Ps* =.0005. Therefore, one-way repeated measures ANOVA results were corrected according to the Greenhous & Geisser calculation (Keppel & Wickens, 2004).

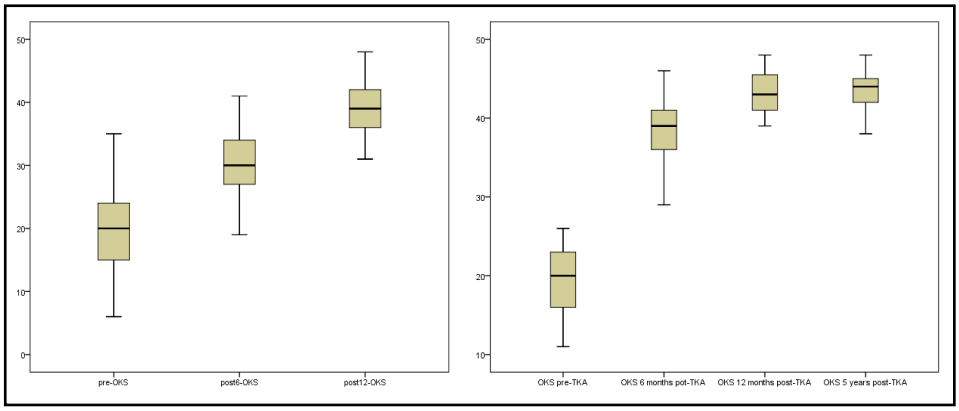

Figure 4- 4. Oxford Knee Score boxplot at all time points post total knee arthroplasty (TKA) (pre-TKA, 6 months post-TKA and 12 months post-TKA)

4.3.1.1 Oxford Knee Score changes six and twelve months post-TKA

OKS changes were assessed for 143 patients (Fig. 4-4); 90 females and 53 males who had a mean age of 67 ± 8 years (range, 47–88); and the body mass index mean was 28.28 ±5.7. OKS was significantly different at the three different time points, F (1.24,175.7) =811.67, p =.0005, with a large effect size (partial eta squared) = .85 (Table 4-3). There was a significant improvement in OKS from 19 (95% CI, 18 to 20) pre-TKA to 29 (95% CI, 28 to 29) at 6 months post-TKA and to 38 (95% CI, 37 to 39) at 12 months post-TKA. A post hoc analysis with a Bonferroni adjustment revealed that OKS was significantly improved from pre-TKA to 6 months post-TKA by 9 points (95% CI, 8 to 10 score); from 6 months post-TKA to 12 months by 9 points (95% CI,8 to 9); and from pre-TKA to 12 months post-TKA by 18 points (95% CI, 17 to 20) (Table 4-4 & Figure 4-6).

4.3.1.2 Oxford Knee Score changes at six months, twelve months and five years post-TKA

OKS changes were assessed in 36 patients (Figure 4-4); 19 females and 17 males who had a mean age of 65 ± 7 years (range, 47-81); and the body mass index mean was 31±6.3. OKS was significantly different at the four different time points, F (2.1,73) =654.3, p =.0005, with a large effect size (partial eta squared) = .95 (Table 4-3). There was a significant improvement in OKS from 19 (95% CI, 17 to 20) pre-TKA to 38 (95% CI, 36 to 39) at 6 months post-TKA; to 43 (95% CI, 42 to 44) at 12 months post-TKA; and to 43 (95% CI, 42 to 44) at 5 years post-TKA. A post hoc analysis with a Bonferroni adjustment revealed that OKS was significantly improved from pre-TKA to 6 months post-TKA by 19 points; (95% CI, 17 to 21 score); from 6 months post-TKA to 12 months by 4 points (95% CI,3 to 6); from pre-TKA to 12 months post-TKA by 24 points (95% CI, 22 to 26); and from pre-TKA post-TKA to 5 years by 24 points (95% CI,22 to 26); but there were no significant changes between one and five years post-TKA (.23 scores 95% CI,-.58 to 1) (Table 4-4& Figure 4-6).

4.3.1.3 Oxford Knee Score changes six months, twelve months, five and ten years post-TKA

OKS changes were assessed in 4 patients (Figure 4-4); 2 females and 2 males who had a mean age of 63 ± 7 years (range, 53-70); and the body mass index mean was 29.5± 3.1. As the sample size was extremely small and the normal distribution criteria were violated, a Friedman test was used as a nonparametric alternative test for a one-way repeated ANOVA to analyse OKS changes at five points (pre, one, five, and ten years post-TKA). OKS improved post-TKA from pre-TKA (median=16) to six months post-TKA (median=40), from 12 months post-TKA (median=40) to five years post-TKA (median=42). There were no changes between six and twelve months post-TKA as the median remained at 40. However, OKS showed a reduction from five years (median=42) to ten years post-TKA (median=41). No differences were significant, χ^2 (2) = 8.4, *P*= 0.78.

Table 4- 3. Tests of Within-Subjects Effects for Oxford Knee Score (OKS) post total knee arthroplasty

Analysis pathway	Sample size	Length of follow-up	Source		Type III Sum of Squares	df	Mean Square	F/t	Significant	Partial Eta Squared
Including 6 months post-TKA data in analysis	N= 143	Pre, 6, and 12 months post-TKA	Time	Sphericity Assumed	25735	2	12867.7	811.67	.000	.851
				Greenhouse-Geisser	25735	1.24	20798.7	811.67	.000	.851
			Error (Time)	Sphericity Assumed	4502	284	15.85			
				Greenhouse-Geisser	4502	175.7	25.63			
	N= 36	Pre,6 months, 12 months, and 5 years post-TKA)	Time	Sphericity Assumed	14521	3	4840	654.3	.000	.949
				Greenhouse-Geisser	14521	2.09	6962	654.3	.000	.949
			Error (Time)	Sphericity Assumed	776.8	105	7.39			
				Greenhouse-Geisser	776.8	73	10.64			
Excluding 6 months post-TKA data from analysis	N=1301	Pre-TKA - 12 months post-TKA				1300		82.7	.000	
	N= 783	Pre,12 months, and 5 years post-TKA)	Time	Sphericity Assumed	185903	2	92951.9	2478.2	.000	.760
				Greenhouse-Geisser	185903	1.95	95292.2	2478.2	.000	.760
			Error (Time)	Sphericity Assumed	58662.3	1564	37.5			
				Greenhouse-Geisser	58662.3	1525	38.5			
	N= 149	Pre,12 months, 5 and 10 years post-TKA)	Time	Sphericity Assumed	33023.9	3	11007.9	296.43	.000	.667
				Greenhouse-Geisser	33023.9	2.9	11328.4	296.43	.000	.667
			Error (Time)	Sphericity Assumed	16487.9	444	37.14			
				Greenhouse-Geisser	16487.9	431.4	38.21			

Table 4-4. Oxford Knee Score post total knee arthroplasty score changes, pairwise comparisons.

Analysis pathway	Number of patients	Length of follow-up	Time (I)	Time (J)	Mean Difference (I-J)	Standard Error	Significant	95% Confidence Interval for Difference	
								Lower Bound	Upper Bound
Including 6 months post-TKA data in analysis	N=143	Pre, 6, and 12 months post-TKA	1	2	-9.5	.562	.000	-10.87	-8.14
				3	-18.9	.549	.000	-20.30	-17.64
			2	1	9.5	.562	.000	8.14	10.87
				3	-9.5	.219	.000	-9.99	-8.94
			3	1	18.9	.549	.000	17.64	20.30
				2	9.5	.219	.000	8.94	9.99
	N=36	Pre,6 months, 12 months, and 5 years post-TKA)	1	2	-19.5	.811	.000	-21.71	-17.18
				3	-24.3	.744	.000	-26.33	-22.17
				4	-24.5	.721	.000	-26.48	-22.46
			2	1	-19.5	.811	.000	17.18	21.71
				3	-4.8	.553	.000	-6.35	-3.26
				4	-5.0	.589	.000	-6.68	-3.38
			3	1	24.3	.744	.000	22.17	26.33
				2	4.8	.553	.000	3.26	6.35
				4	-.22	.288	1.000	-1.03	.58
			4	1	24.5	.721	.000	22.46	26.49
				2	5.0	.589	.000	3.38	6.68
				3	.22	.288	1.000	-.58	1.03
Excluding 6 months post-TKA data from analysis	N=783	Pre, 12 months, and 5 years post-TKA)	1	2	-18.7	.285	.000	-19.43	-18.06
				3	-18.9	.328	.000	-19.78	-18.21
			2	1	18.7	.285	.000	18.06	19.43
				3	-.249	.314	1.000	-1.01	.504
			3	1	18.9	.328	.000	18.21	19.78
				2	.249	.314	1.000	-.504	1.01
	N=149	Pre, 12 months, 5 and 10 years post-TKA)	1	2	-17.9	.662	.000	-19.73	-16.19
				3	-17.8	.732	.000	-19.76	-15.85
				4	-15.3	.762	.000	-17.31	-13.23
			2	1	17.9	.662	.000	16.19	19.73
				3	.154	.640	1.000	-1.56	1.87
				4	2.7	.708	.001	.792	4.58
			3	1	17.8	.732	.000	15.85	19.76
				2	-.154	.640	1.000	-1.87	1.56
				4	2.5	.724	.004	.594	4.47
			4	1	15.3	.762	.000	13.24	17.31
				2	-2.6	.708	.001	-4.58	-.79
				3	-2.5	.724	.004	-4.47	-.59

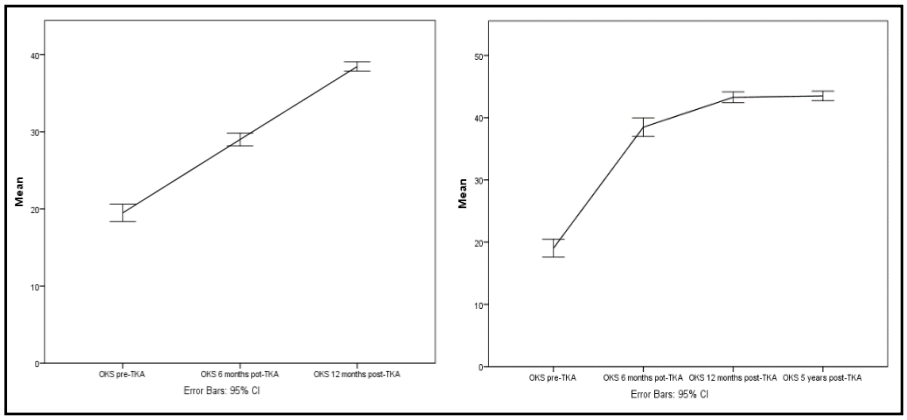

Figure 4-5. Oxford Knee Score changes post-total knee arthroplasty.

4.3.2 Group two: excluding 6 months in the data analysis

The second group analysis excluded 6 months follow-up to assess the changes at all time points without the 6-month limitation. Group two was subdivided into three groups: OKS score changes without 6 months of data; satisfaction score changes; and UCLA, VAS and function data without 6 months of data as the PROMs 6-month database did not include UCLA, pain, function and satisfaction assessments. Detailed exclusions for each subdivision at each time points in group two are clarified in the following section.

4.3.2.1 Assumption analysis for OKS score changes

A total of 1,301 patient records were identified with complete Oxford Knee Score (OKS) before TKA at and 12 months follow-up. Excluded records containing incomplete information at all follow-up time points are clarified in Fig. 4-7. OKS was normally distributed at all points post-TKA point, as assessed by a Kolmogorov–Smirnov test (Ps >.05). There were no outliers in the data, as assessed by the inspection of a boxplot (4-8). Therefore, a paired-sample t-test was used to compare the mean difference before and 12 months post-TKA; and a one-way repeated measures ANOVA was used to assess the changes for more than two points, descriptive data are summarised in Table 4-1. A Mauchly's test of sphericity indicates that the assumption of sphericity was violated for both follow-up lengths, five and ten years post-TKA. Approximate chi-squared for the data set follow up for five and ten years is χ^2 (2) = 19.9, χ^2 (2) = 37.3, respectively, and both *Ps* =.0005. Therefore, the one-way repeated measures ANOVA results were corrected according to a Greenhous & Geisser calculation.

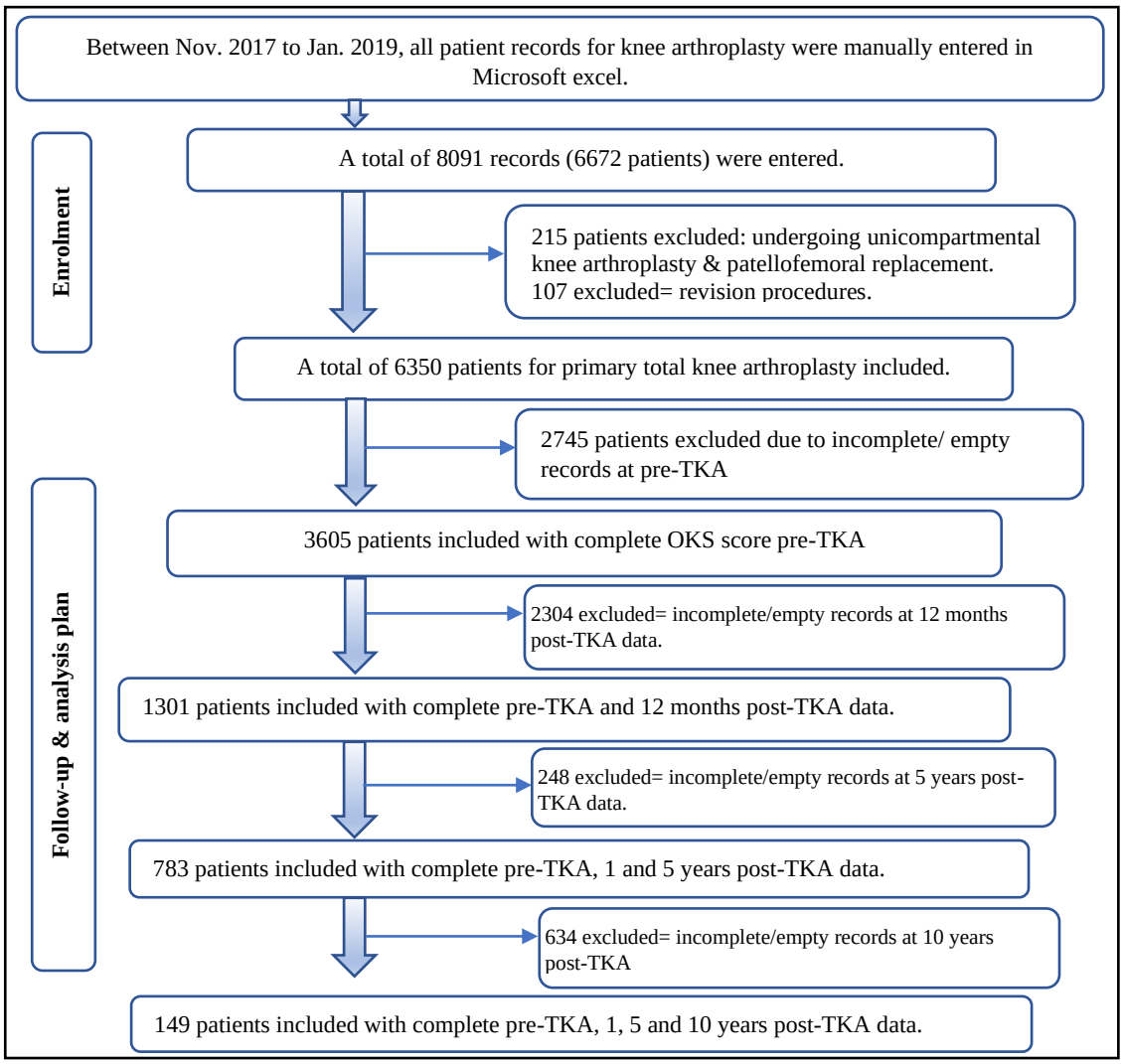

Figure 4- 6. patient selection flowchart for Oxford Knee Score (OKS) data excluding 6 months from the follow-up plan

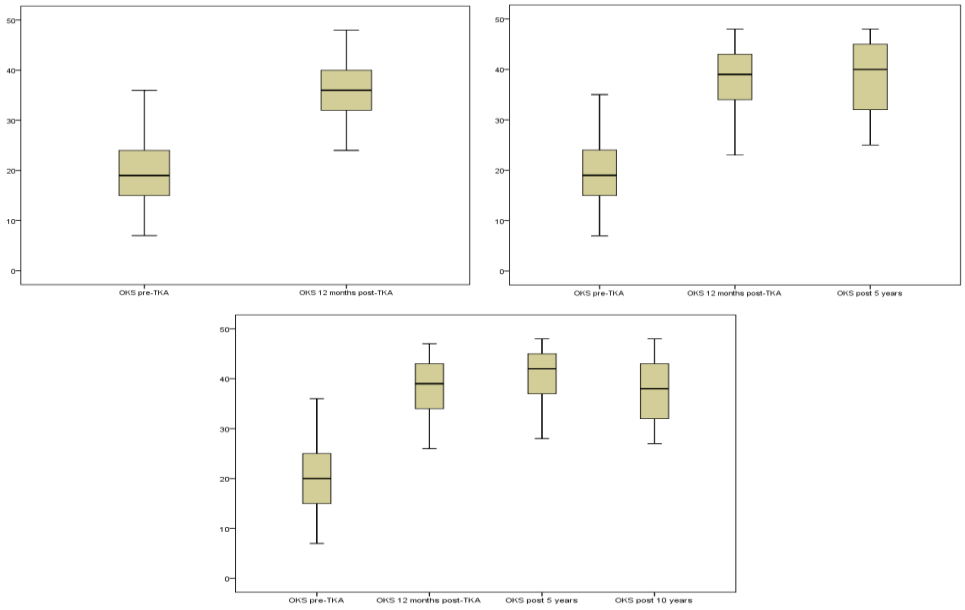

Figure 4-7. Oxford Knee Score boxplot at all time points post-total knee arthroplasty (TKA) (pre-TKA, 12 months and 5 years post-TKA).

4.3.2.1.1 Oxford Knee Score changes before and twelve months post-TKA

OKS changes were assessed in 1,301 patients (Figure 4-7); 753 females and 548 males had a mean age of 69 ± 8 years (range, 47–92); and the body mass index mean was 29.29 ±4.5. The OKS mean score was significantly different at 12 months post-TKA, *t* (1,300) =82.70, p =.0005 (Table 4-3). There was a significant improvement in OKS from 19 (95% CI, 7 to 36) pre-TKA to 36 (95% CI, 24 to 48) at twelve months post-TKA.

4.3.2.1.2 Oxford Knee Score changes twelve months and five years post-TKA

OKS changes were assessed in 783 patients (Figure 4-7); 443 females and 340 males had a mean age of 68 ± 8 years (range, 47-91); and the body mass index mean was 29.5 ± 3.6. OKS score was significantly different at the three different time points, *F* (1.95,1525.6) =2478.2, *p* =.0005, with a large effect size (partial eta squared) = .8 (Table 4-3). There was an improvement in OKS from 19 (95% CI, 18 to 20) pre-TKA to 38 (95% CI, 37 to 38) at 12 months post-TKA; and to 38 (95% CI, 37 to 38) at 5 years post-TKA. A post hoc analysis with a Bonferroni adjustment revealed that OKS score significantly improved from pre-TKA to 12 months post-TKA by 18 points (95% CI, 18 to 19 score); and from pre-TKA to 5 years by 18 points (95% CI, 18 to 19); but there were no significant changes between one and five years post-TKA (.25 scores 95% CI,-.5 to 1.0) (Figure 4-9 & Table 4-4).

4.3.2.1.3 Oxford Knee Score changes at twelve months, five and ten years post-TKA

OKS changes were assessed in 149 patients (Figure 4-7); 75 females and 74 males who had a mean age of 66 ± 7 years (range, 47-81); and the body mass index mean was 29.4 ± 4.2. OKS score was significantly different at four different time points, *F* (2.9,431) =296.4, *p* =.0005, with a medium effect size (partial eta squared) =0.7 (Table 4-3). There was an improvement in OKS from 20 (95% CI, 19 to 21) pre-TKA to 38.3 (95% CI, 37 to 39) at 12 months post-TKA; to 38.2 (95% CI, 37 to 39) at 5 years post-TKA; and a reduction to 35.6 (95% CI, 34 to 36) at 10 years post-TKA. A post hoc analysis with a Bonferroni adjustment revealed that OKS significantly improved from pre-TKA to 12 months post-TKA by 18 points (95% CI, 16 to 19 score); from pre-TKA to 5 years by 18 points (95% CI, 15 to 19); from pre-TKA to 10 years by 15 points (95% CI, 13 to 17); but there were no significant changes between one and five years post-TKA (.15 scores 95% CI,-1.6 to 1.9) (Figure 4-9 & Table 4-4).

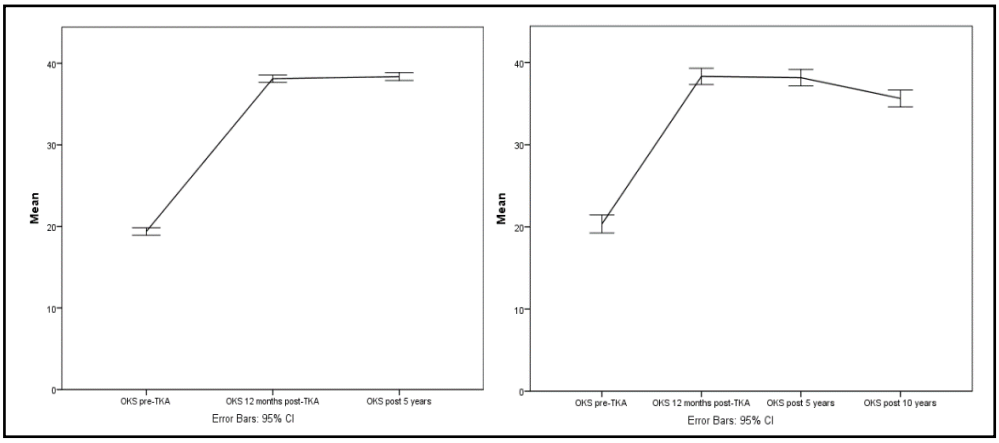

Figure 4- 8. Oxford Knee Score changes post-total knee arthroplasty.

4.3.2.2 Satisfaction changes post-TKA

Satisfaction changes were assessed in 783 patients (Figure 4-10); 443 females and 340 males had a mean age of 68 ± 8 years (range, 47-91); and the body mass index mean was 29.5 ± 3.6. The normality assumption for satisfaction score was violated, as assessed by a Kolmogorov-Smirnov test (*P*s <.05), at all follow-up time points. Therefore, a Wilcoxon signed-rank test was used as a nonparametric alternative test for a paired-sample t-test to analyse scores one and five years post-TKA and a Friedman test to analyse scores one, five and ten years post-TKA.

The satisfaction scores of 783 patients were analysed using a Wilcoxon signed-rank test to assess patients' satisfaction changes from one to five years post-TKA. The satisfaction scores elicited nonsignificant improvements between one and five years post-TKA, with a median increase from 90 at one year to 92 at five years, (z=1.86, *P*=.062) (Table 4-5).

The satisfaction scores of 149 patients were analysed using a Friedman test to assess patients' satisfaction changes ten years post-TKA. The satisfaction scores elicited nonsignificant improvements between one, five and ten years post-TKA, with a median increase from 90 at one year to 92 at five years, then a decrease to 91 at 10 years post-TKA (χ^2=3.13, *P*=.210) (Table 4-5).

Table 4- 5. Patients' satisfaction descriptive statistics and changes at three time points, at one, five and ten years, following total knee arthroplasty (TKA)

Satisfaction	Sample size	Median	Interquartile range	Minimum	Maximum	Standardized test statistic	Significant	test statistic	Significant
first year post-TKA	1301	90	12	71	100	1.86	.062	3.13	.210
5 years post-TKA	783	92	18	51	100				
10 years post-TKA	149	91	8	61	98				

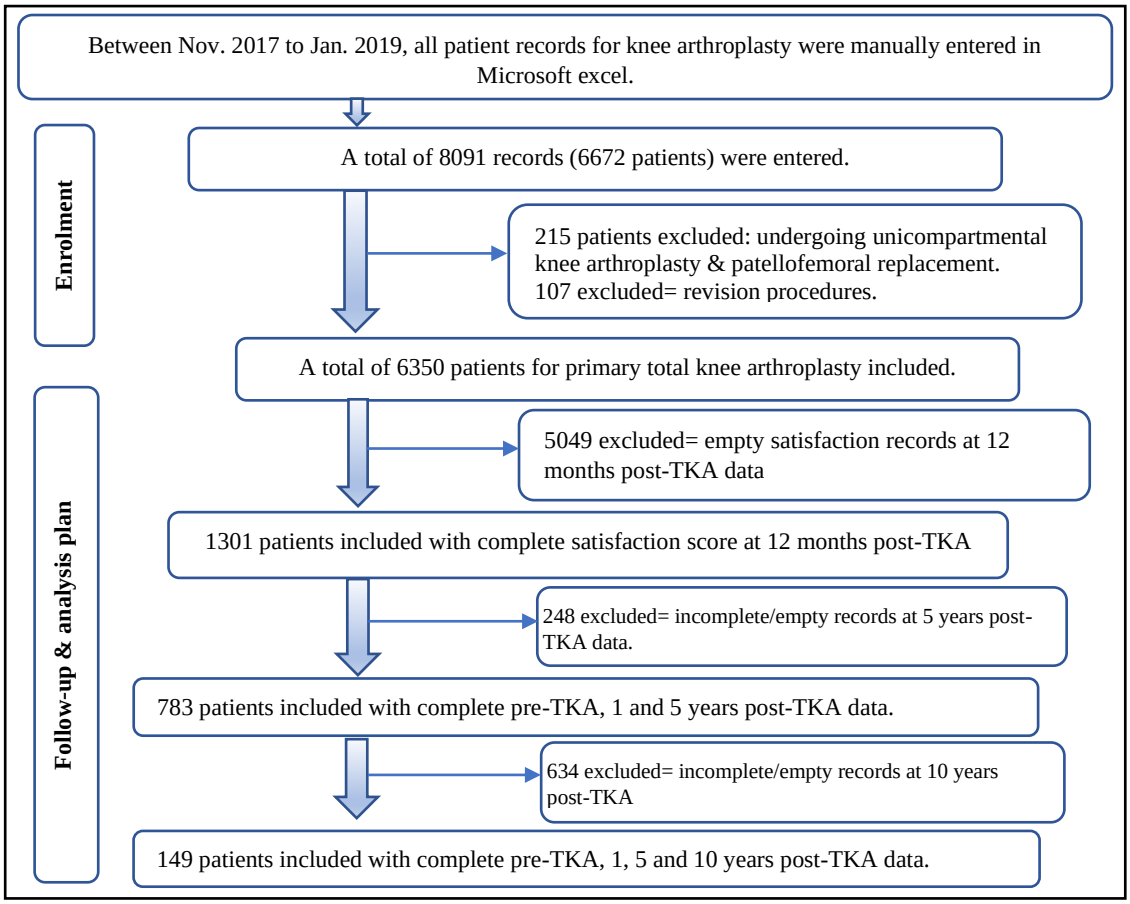

Figure 4- 9. Patient selection flowchart for patients' satisfaction post-Total Knee Arthroplasty (TKA).

4.3.2.3 University of California Los Angeles (UCLA) activity score, pain score using a visual analogue scale (VAS) and visual analogue scale for function.

Assumption analysis: The normality assumptions for UCLA, pain and function score were violated, as assessed by a Kolmogorov–Smirnov test (*P*s <.05), at all follow-up time points. Therefore, a Wilcoxon signed-rank test was used as a nonparametric alternative test for a paired-sample t-test to analyse the score before and twelve months post-TKA; and a Friedman test was used as a nonparametric alternative test for a one-way repeated ANOVA to analyse score changes at three time points (pre, one and five years post-TKA); and four time points (pre, one, five and ten years post-TKA).

4.3.2.3.1 UCLA, VAS and function scale changes from pre-TKA to 12months post-TKA: UCLA, VAS and function scores were assessed in 1,301 patients (Figure 4-11); a Wilcoxon signed-rank test determined that there was a significant median increase in UCLA score and function score; and a significant median reduction in pain score (z=30.38, z= 31.26 and z= -31.25), respectively, with all Ps values =.0005 (Table 4-6).

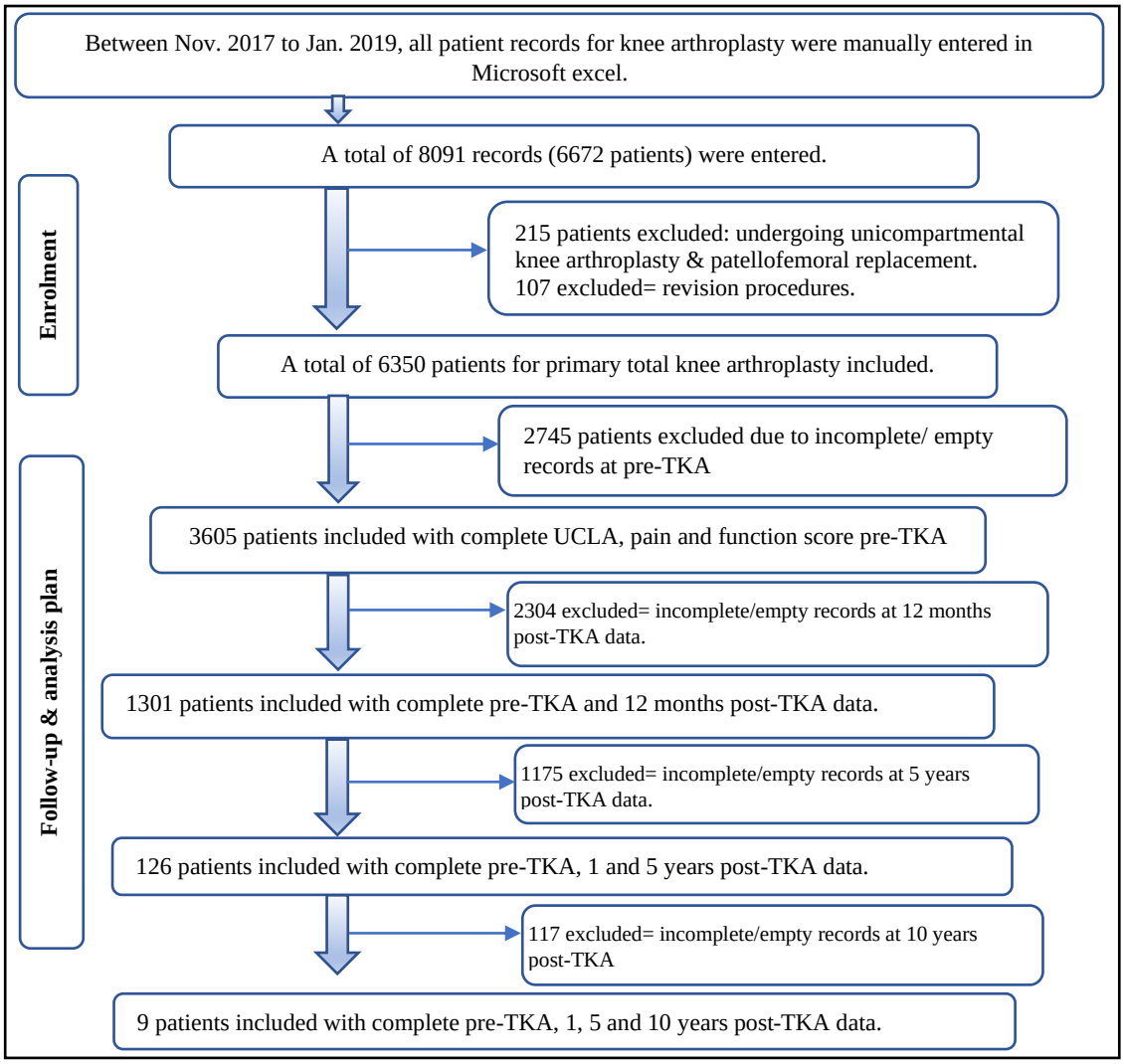

Figure 4- 10. Patient selection flowchart for University of California Los Angeles (UCLA) activity score, pain score using a visual analogue scale (VAS) and visual analogue scale for function post-Total Knee Arthroplasty (TKA).

4.3.2.3.2 UCLA, VAS, and function scale changes from pre-TKA to 5 years post-TKA

UCLA, VAS and function scores were assessed in 126 patients (Figure 4-11); a Friedman test was run to determine if there were differences in UCLA, pain and function scores 5 years post-TKA. UCLA, pain and function scores were significantly different at the different time points post-TKA χ^2 (2) = 182.8, P=.0005, χ^2 (2) =192.6, P=.0005 and χ^2 (2) = 192.6, P=.0005 respectively. UCLA, pain and function median changes are shown in Table 4-6. Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons, the UCLA, pain and function scales revealed significant differences between pre-TKA and twelve months post-TKA; and between pre-TKA and five years post-TKA. However, there were no significant differences between one and five years post-TKA (Table 4-7).

4.3.3 Summary of the Phase One analysis

Different sample sizes in all the analysis groups showed statistically significant improvements in OKS from pre-surgery to six months, one and five years post-TKA, but no significant changes between one and five years post-TKA. This was followed by a significant reduction at ten years post-TKA. Satisfaction scores showed nonsignificant improvements between one, five and ten years post-TKA. UCLA, pain and function scores revealed statistically significant improvements at one and five years post-TKA. Similar to OKS, there were no significant differences in these scores between one and five years post-TKA.

Table 4-6. A nonparametric test for University of California Los Angeles (UCLA) activity score, pain score using a visual analogue scale (VAS) and function visual analogue scale before and after total knee arthroplasty.

Number of patients	Follow-up	scale	Median before TKA	Median At 12 months	Median At 5 years	Test Statistic	Standard error	Standardized test statistic (Z)	Asymptotic sig. (2- sided test)
N= 1301	Pre-TKA and 12 months post-TKA	UCLA	4	6		751,076	12,323	30.38	.000
		VAS	84	9		.000	13,553	-31.25	.000
		Function	16	92		846,951	13,552	31.26	.000
N= 126	Pre-TKA, 12 months and 5 years post-TKA	UCLA	4	6	7	182.8			.000
		VAS	81	8	10	192.7			.000
		Function	19	85	87	192.6			.000

Table 4- 7. University of California Los Angeles (UCLA) activity score, pain score using a visual analogue scale (VAS) and function visual analogue scale changes post- total knee arthroplasty, pairwise comparisons.

Follow-up	Sample 1/Sample2	Test Statistic	Standard Error	Std. Test Statistic	Significance	Adjusted Significance
UCLA changes 5 years post-TKA	pre-TKA/ 12 months post-TKA	-1.35	.126	10.74	.000	.000
	pre-TKA/ 5 years post-TKA	-1.41	.126	11.18	.000	.000
	12 months post-TKA/ 5 years post-TKA	-.06	.126	.44	.659	1.000
Pain changes in visual analogue scale 5 years post-TKA	pre-TKA/ 12 months post-TKA	1.58	.126	12.57	.000	.000
	pre-TKA/ 5 years post-TKA	1.42	.126	11.24	.000	.000
	12 months post-TKA/ 5 years post-TKA	.167	.126	1.32	.186	.558
Function analogue scale changes 5 years post-TKA	pre-TKA/ 12 months post-TKA	1.47	.126	11.69	.000	.000
	pre-TKA/ 5 years post-TKA	1.53	.126	12.13	.000	.000
	12 months post-TKA/ 5 years post-TKA	.056	.126	.44	.659	1.000

4.4 Phase Two analysis

To explain the variability in patient outcomes and satisfaction one, five and ten years post-TKA, multiple regressions were run to estimate predictor equations. OKS and satisfaction at each follow-up time point post-TKA (one, five and ten years) were explored based on the available independent variables. The developed prediction equation was validated at each timepoint post-TKA using simple bootstrap methods. The bootstrap is a precise and powerful statistical tool that estimates the standard error of the regression coefficient and its

95% confidence interval based on automatically randomly sampling 1000 data to estimate bias corrected accelerated (BCa). It is called residual resampling because it is a computer process algorithm to: perform a regression on original data; randomly resample residuals; construct a new Y* and regress the new Y* to x original variables and repeat that several times; finally estimate the regression model R^2 and standard error (Field, 2009; Oredein, Olatayo, & Loyinmi, 2011; Sillabutra et al., 2016). To understand how well the regression model fits, adjusted R^2 was considered more than R^2. Adjusted R^2 corrects sample positive bias in order to provide a value that would be expected in the population at large. In addition, R^2 estimates the effect size according to Cohen's (1988) classification (small, 0.10 – < 0.30; medium, 0.30 – < 0.50; large, ≥ 0.50).

4.4.1. Patient Features

A Friedman test with pairwise comparisons was run to determine if there were any significant differences in patient's age, BMI, CCI and pre-surgery OKS between the three groups to ensure the representativeness of patient subsets: follow-up at one year (1,301patients), at five years (783 patients) and at 10 years (143 patients), as the assumption of normality was violated when assessed by a Kolmogorov-Smirnov test, P value < .05. The median age was significantly different between follow up at one and 10 years, there were no significant differences between other follow-up time points. Patients' age in the first-year group was 3 years greater than in the 10-year follow-up group. BMI, pre-surgery OKS and CCI medians were not significantly different between the three groups. A chi-square test showed no significant difference in gender proportions *P*=.110, females were mote numerous in the one-year follow-up group than the others (Table 4-8).

Table 4- 8 Demographic data for the patient groups at different follow-up time-points post-Total Knee Arthroplasty (one year, five years and ten years).

		Age			Body mass index (BMI)			Charlson Comorbidity Index (CCI)			Pre-surgery Oxford Knee Score		
		One year	Five years	Ten years	One year	Five years	Ten years	One year	Five years	Ten years	One year	Five years	Ten years
Patient characteristics	N=	1301	783	143	1301	783	143	1301	783	143	1301	783	143
	Median	70	68	67	29	29	28	1	1	1	19	19	20
	Interquartile range	12	13	10	3.5	3.5	3.5	1	2	1	9	11	11
	Minimum	47	47	50	22	22	23	0	0	0	8	9	9
	Maximum	91	87	81	44	43	44	4	4	4	34	34	36
	No. (%) of female patients	57.9% (753) in the one-year group, 56.6% (443) in the five- year group, 50.3% in the 10-year group, P=.110											
Friedman test	Standardized test statistic	3.3			1.24			1.01			1.67		
	Significant P	.002			.078			.183			.432		

4.4.2 OKS and satisfaction predictions one-year post-TKA

Assumption analysis

A multiple regression was run to predict OKS and satisfaction one year post-TKA from 19 variables: gender, age, BMI, history of previous contralateral TKA, Charlson Comorbidity Index (CCI) score, presence of arthritis in other joints, OKS score before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, self-reporting of anxiety, depression and general health, expectation achievements and satisfaction score at one-year, pre-TKA knee joint extension and flexion range of motion (ROM), and knee ROM after arthroplasty. All 19 variables were entered in the regression model using stepwise entry as there were no previous hypotheses for predictors. This method has the advantage of adding all predictors in the model and then calculating their contribution one by one by assessing the significance value of a t-test. Then, the significance value is compared against criterion removal. This may minimise type Ⅱ error due to missing a fact predictor that predicts the outcome. There was linearity as assessed by partial regression plots and a plot of studentised residuals against predicted values. A Durbin-Watson statistic for OKS and satisfaction, respectively, of 1.26,1.5 indicates the independence of residuals. There was homoscedasticity, as assessed by a visual inspection of a plot of studentised residuals against unstandardized predicted values. Multicollinearity was assessed by tolerance, variance inflation factor (VIF) and correlation values. No tolerance value was larger than 0.1, no VIF value was larger than 10 and no independent variable correlation was larger than 07; therefore, the presence of multicollinearity was minimised. The regression standardised normality assumption was met, assessed by a Q-Q plot. No unusual points were present as no studentised deleted residual was larger than ± 3 standard deviation, no Cook's distance value was larger than 1, no leverage value was larger than 0.2 (Weisberg, 2014).

Findings: The multiple regression model for 1,301 patients demonstrated significant predictions for OKS and satisfaction one-year post-TKA, F (7,1293) = 1226.7, F (8,1292) = 276, respectively, and *Ps*=.0001. Regression coefficients and 95% confidence intervals (CI) are shown in Table 4-9. For OKS predictions, seven variables were identified as significant predictors of OKS one-year post-TKA. Two positive predictors were found: pre-TKA UCLA score and a history of previous contralateral TKA. The remaining predictors had a negative effect (self-reported general health status, self-reported depression, self-reported anxiety, CCI score, and history of arthritis in other joints) (Table 4-10). The regression model excluded 12 variables that non-significantly affect OKS scores one-year post-TKA (gender, age, BMI, OKS score before surgery, pain score pre-TKA, function score pre-TKA,

expectation achievements and satisfaction score, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty).

For satisfaction prediction, eight variables were identified as significant predictors of satisfaction one-year post-TKA. Four positive predictors were found: older in age, a high BMI, a history of previous contralateral TKA and expectation achievement score at 12 months post-TKA. The remaining four predictors had a negative effect (self-reported anxiety and depression, self-reported general health status, a history of arthritis in other joints). The regression model excluded 11 variables that non-significantly affect satisfaction scores one-year post-TKA (gender, OKS score before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, Charlson Comorbidity Index (CCI) score, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty).

Validation: The developed OKS and satisfaction one-year post-TKA prediction equation was validated using a bootstrap approach. There was a minor bias in the bootstrap coefficient (less than .009), all factors included in the model showed a significant effect, and the standard error was less than the original model. The developed regression model's constant coefficient value is 95% confident between 47.72 and 49.36 for OKS and between 29.5 to 47 for satisfaction (Table 4-11).

4.4.3 OKS and satisfaction predictions five years post-TKA

Assumption analysis

A multiple regression was run on 783 patients to predict OKS satisfaction five years post-TKA from 23 variables (17 pre-surgery variables and six variables at one year post-TKA): gender, age, BMI, history of previous contralateral TKA, CCI score, presence of arthritis in other joints, OKS before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, self-reporting of anxiety, depression and general health, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty, OKS one year post-TKA, UCLA one year post-TKA, pain score one year post-TKA, function score and expectation achievement and satisfaction at one year post-TKA. All multiple regression assumptions were met for the model and the data entry was stepwise method.

Findings: The regression model significantly predicts OKS and satisfaction five years post-TKA, $F(4,778) = 1921$, $F(4,778) = 280$, respectively, and Ps=.0005. Regression coefficients and 95% confidence intervals (CI) are shown in Table 4-9. For OKS predictions, four variables were identified as significant predictors of OKS five years post-TKA. One positive predictor was found: OKS score at one-year post-TKA; three negative predictors were self-

reported depression, self-reported general health, the presence of arthritis in other joints. The regression model excluded 19 variables that non-significantly affect OKS scores five years post-TKA (gender, age, BMI, OKS before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, a history of previous contralateral TKA, CCI score, self-reporting of anxiety, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty, UCLA one year post-TKA, pain score one year post-TKA, function score, expectation achievement and satisfaction at one year post-TKA).

For satisfaction prediction, four variables were identified as significant predictors of patients' satisfaction five years post-TKA. The expectation achievement score at one-year post-TKA was the only positive predictor, the remaining three predictors were negative: pain score one-year post-TKA, self-reporting of depression and general health (Table 4-10). The regression model excluded 19 variables that non-significantly affect OKS scores five years post-TKA (gender, age, BMI, OKS before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, history of previous contralateral TKA, CCI score, presence of arthritis in other joints, self-reporting of anxiety, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty, OKS one year post-TKA, UCLA one year post-TKA, function score and satisfaction at one year post-TKA).

Validation: The developed OKS and satisfaction five years post-TKA prediction equation was validated using a bootstrap approach. There was a minor bias in the bootstrap coefficient (less than .008) and all factors included in the model showed a significant effect. The developed regression model's constant coefficient value is 95% confident between 10 to 13.5 for OKS and between 60.5 to 74.8 for satisfaction (Table 4-11).

4.4.4 OKS and satisfaction predictions ten years post-TKA

Assumption analysis

A multiple regression was run on 149 patients to predict OKS and satisfaction ten years post-TKA from 29 variables (17 pre-surgery variables, six variables at one year and six variables at 5 years post-TKA): gender, age, BMI, OKS before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, history of previous contralateral TKA, CCI score, presence of arthritis in other joints, self-reporting of anxiety, depression and general health, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty, OKS one and five years post-TKA, UCLA one and five years post-TKA, pain score one and five years post-TKA, function score one and five years post-TKA, expectation achievement and satisfaction at one and five years post-TKA. All multiple regression assumptions were met for the model and the data entry was stepwise entry method.

Findings: The regression model significantly predicted OKS and satisfaction ten years post-TKA, F (3,145) = 376, F (3,145) = 80.2, respectively, and *Ps*=.0005. The regression coefficients and 95% confidence intervals (CI) are shown in Table 4-9.

For OKS prediction, three variables were identified as significant predictors of OKS ten years post-TKA. One positive predictor was found: OKS score at one-year post-TKA; and two negative predictors were found: pain score at one-year post-TKA, and self-reported general health status. The regression model excluded 26 variables that non-significantly affect OKS scores ten years post-TKA (gender, age, BMI, OKS before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, history of previous contralateral TKA, CCI score, presence of arthritis in other joints, self-reporting of anxiety and depression, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty, OKS five years post-TKA, UCLA one and five years post-TKA, pain score five years post-TKA, function score one and five years post-TKA, expectation achievement and satisfaction at one and five years post-TKA).

For satisfaction prediction, three variables were identified as significant predictors of patients' satisfaction ten years post-TKA. Two negative predictors were found: self-reported general health status and pain score at one-year post-TKA; the positive predictor was outcome achievement score at one-year post-TKA (Table 4-10). The regression model excluded 26 variables that non-significantly affect OKS scores ten years post-TKA (gender, age, BMI, OKS before surgery, UCLA before TKA, pain score pre-TKA, function score pre-TKA, history of previous contralateral TKA, CCI score, presence of arthritis in other joints, self-reporting of anxiety and depression, pre-TKA knee joint extension and flexion range of motion (ROM), knee ROM after arthroplasty, OKS at one and five years post-TKA, UCLA one and five years post-TKA, pain score five years post-TKA, function score at one and five years post-TKA, satisfaction at one and five years post-TKA, and expectation achievement at five years post-TKA).

Validation: The developed OKS and satisfaction ten years post-TKA prediction equation was validated using a bootstrap approach. There was a minor bias in the bootstrap coefficient (less than .008) and all factors included in the model showed a significant effect. The developed regression model's constant coefficient value is 95% confident between 9.7 to 17 for OKS and between 74 to 92.5 for satisfaction (Table 4-11).

Table 4-8. Regression coefficients of Oxford Knee score (OKS) and patients' satisfaction post-total knee arthroplasty (TKA) for current data

Dependent variable	Model	Unstandardised coefficients		Standardised coefficients	t	Significance	95% Confidence Interval for B	
		B	Std. Error	Beta			Lower bound	Upper bound
OKS one-year post-TKA	constant	48.56	.368		132.12	.000	47.84	49.28
	Self-reported general health status	-3.79	.107	-.538	-35.35	.000	-3.99	-3.58
	History of previous contralateral TKA	2.50	.125	.250	19.95	.000	2.26	2.75
	Self-reported anxiety	-1.31	.114	-.161	-11.52	.000	-1.54	-1.09
	Pre-TKA UCLA score	.312	.041	.085	7.71	.000	.233	.392
	Self-reported depression	-.675	.147	-.059	-4.59	.000	-.964	-.387
	History of arthritis in other joints	-.585	.137	-.052	-4.27	.000	-.854	-.316
	Charlson Comorbidity Index score	-.133	.049	-.033	-2.69	.001	-.229	-.036
Satisfaction one-year post-TKA	(Constant)	38.36	4.26		9.01	.000	30.01	46.72
	age	.210	.042	.087	5.03	.000	.128	.292
	BMI	.242	.088	.051	2.75	.006	.070	.414
	History of previous contralateral TKA	4.45	.836	.103	5.33	.000	2.82	6.09
	Self-reported depression	-6.03	.878	-.146	-6.87	.000	-7.75	-4.31
	History of arthritis in other joints	-2.09	.734	-.053	-2.85	.004	-3.54	-.654
	Self-reported general health status	-1.72	.605	-.061	-2.84	.005	-2.91	-.531
	Self-reported anxiety	-2.82	.650	-.079	-4.34	.000	-4.09	-1.55
	Expectation achievements	.531	.016	.611	32.47	.000	.499	.563
OKS Five-years post-TKA	(Constant)	11.76	.762		15.430	.000	10.27	13.26
	OKS 12 months post-TKA	.696	.014	.834	50.45	.000	.669	.723
	Self-reported depression	-.773	.119	-.080	-6.49	.000	-1.01	-.54
	History of arthritis in other joints	-.612	.143	-.055	-4.27	.000	-.893	-.330
	Self-reported general health status	-.448	.092	-.071	-4.87	.000	-.629	-.268
Satisfaction Five-years post-TKA	(Constant)	66.60	3.93		16.96	.000	58.89	74.31
	Pain (VAS) score 12 months post-TKA	-.748	.063	-.320	-11.94	.000	-.871	-.625
	Expectation achievements one-year post-TKA	.515	.031	.484	16.74	.000	.455	.576
	Self-reported depression	-2.33	.823	-.075	-2.83	.005	-3.95	-.717
	Self-reported general health status	-1.79	.642	-.070	-2.78	.006	-3.05	-.524
OKS Five-years post-TKA	(Constant)	13.66	2.05		6.66	.000	9.61	17.71
	Pain (VAS) score 12 months post-TKA	-.043	.013	-.134	-3.23	.002	-.070	-.017
	OKS 12 months post-TKA	.583	.041	.748	14.26	.000	.502	.664
	Self-reported general health status	-.467	.205	-.109	-2.28	.024	-.872	-.062
Satisfaction Ten-years post-TKA	(Constant)	83.52	4.54		18.39	.000	74.54	92.49
	Self-reported general health status	-3.26	.679	-.284	-4.79	.000	-4.60	-1.92
	pain (VAS) one-year post-TKA	-.431	.070	-.416	-6.18	.000	-.569	-.294
	Expectation achievements one-year post-TKA	.221	.050	.273	4.44	.000	.123	.318

Table 4-9. Regression model summary for Oxford Knee Score (OKS) and patients' satisfaction post-total knee arthroplasty (TKA).

Dependent variable	Adjusted R square	Multiple Regression equation
OKS one-year post-TKA	86.8%	= 48.56 + (2.50 × previous contralateral TKA) + (.312 × pre-UCLA score) – (3.79 × self-reported score of general health status) – (1.31 × self-reported score of anxiety) – (.675 × self-reported score of depression)– (.585 × Hx. Of arthritis) – (.133 ×CCI score)
Satisfaction one-year post-TKA	62.1%	=38.36 + (.21 × age) + (.24 × BMI) + (4.45 × previous contralateral TKA) + (.53 × expectation achievements score) – (6.03 × self-reported score of depression) – (2.1 × Hx. Of arthritis) – (1.72 × self-reported score of general health status) - (2.82× self-reported score of anxiety)
OKS Five-years post-TKA	90.8%	=11.76 + (.69 × OKS one-year post-TKA) – (.77 × self-reported score of depression) – (.61 × Hx. Of arthritis) - (.45 × self-reported score of general health status)
Satisfaction Five-years post-TKA	59.3%	=66.6 + (.515 × expectation achievements score at one year) – (.748 × VAS pain score at one-year post-TKA) – (2.33 × self-reported score of depression) – (1.78 × self-reported score of general health)
OKS Ten -years post-TKA	88.4%	= 13.66 + (.58 × OKS one-year post-TKA) - (.04 × VAS pain score at one-year post-TKA) - (.45 × self-reported score of general health)
Satisfaction ten -years post-TKA	61.6%	= 83.52 – (3.26 × self-reported score of general health) – (.43 × VAS pain score one-years post-TKA) + (.22 × expectation achievements score at one year)

*The data codes for all histories: 0=No, 1= Yes; gender 1= female, 2= male; CCI score =Charlson Comorbidity Index score, self-reported score of general health status 1=excellent, 2=very good, 3=good, 4-fair, 5=poor; self-reported score of anxiety 1= I'm not anxiety, 2= I'm moderate anxious , 3= I'm extremely anxious; self-reported score of depression1= I'm not depressed, 2= I'm moderately depressed, 3= I'm extremely depressed.

4.4.5 Summary of Phase Two analysis

Patients' satisfaction and OKS scores are multifactorial, the prediction equations at each timepoint post-TKA are summarised in table 4-10. The factors associated with low OKS scores post-TKA are pre-TKA low score in self-reported general health, depression and anxiety, presence of arthritis in other joints and prevalence of co-morbidities. Additionally, OKS score at ten years post-TKA is negatively affected by pain score one-year post-TKA. A high pre-TKA UCLA score and a history of contralateral knee arthroplasty indicate a high OKS score post-TKA. OKS scores at 5 and 10 years post-TKA are positively affected by OKS scores at one-year post-TKA.

A high satisfaction score is associated with older age, a history of previous contralateral knee arthroplasty, a high BMI, and expectation achievements score at one-year post-TKA. A low satisfaction score is associated with low scores in self-reported general health, depression and anxiety, the presence of arthritis in other joints and pain score at one-year post-TKA.

Table 4-10. Regression coefficients internal validation using a bootstrap approach for Oxford Knee Score (OKS) and patients' satisfaction post-total knee arthroplasty (TKA) (B=1,000)

Dependent variable	Model	Bootstrap				BCa 95% Confidence Interval	
		B	Bias	Std. Error	Significant	Lower	Upper
OKS one-year post-TKA	constant	48.56	-.009	.432	.001	47.72	49.36
	Self-reported general health status	-3.79	.007	.137	.001	-4.06	-3.51
	History of previous contralateral TKA	2.50	.009	.149	.001	2.21	2.82
	Self-reported anxiety	-1.31	.002	.111	.001	-1.52	-1.09
	Pre-TKA UCLA score	.312	.000	.040	.001	.237	.386
	Self-reported depression	-.675	-.003	.127	.001	-.926	-.417
	History of arthritis in other joints	-.585	.005	.146	.001	-.866	-.296
	Charlson Comorbidity Index score	-.133	-.002	.047	.002	-.218	-.047
Satisfaction one-year post-TKA	(Constant)	38.36	-.193	4.62	.001	29.47	47.00
	age	.210	.002	.042	.001	.130	.305
	Expectation achievement score	.531	.000	.020	.001	.491	.573
	BMI	.242	.001	.089	.007	.060	.418
	History of previous contralateral TKA	4.46	-.020	.819	.001	2.89	6.10
	Self-reported depression	-6.03	-.052	1.12	.001	-8.22	-3.99
	History of arthritis in other joints	-2.09	-.126	.853	.006	-4.28	-.76
	Self-reported general health status	-1.72	.044	.650	.012	-2.97	-.30
	Self-reported anxiety	-2.82	.005	.655	.001	-4.16	-1.55
OKS Five-years post-TKA	(Constant)	11.76	-.005	.879	.001	10.00	13.47
	OKS 12 months post-TKA	.696	.000	.016	.001	.662	.729
	Self-reported depression	-.773	.003	.128	.001	-1.04	-.517
	History of arthritis in other joints	-.612	.007	.157	.001	-.919	-.282
	Self-reported general health status	-.448	.000	.095	.001	-.643	-.256
Satisfaction Five-years post-TKA	(Constant)	66.60	-.004	3.952	.001	59.03	74.10
	Expectation achievement score	.515	.001	.030	.001	.460	.575
	Pain (VAS) score 12 months post-TKA	-.748	.000	.070	.001	-.879	-.613
	Self-reported depression	-2.33	.008	.878	.009	-4.16	-.462
	Self-reported general health status	-1.79	-.002	.737	.017	-3.19	-.393
OKS Five-years post-TKA	(Constant)	13.66	-.004	1.91	.001	9.79	17.01
	OKS 12 months post-TKA	.583	.001	.038	.001	.516	.662
	Pain (VAS) score 12 months post-TKA	-.043	-.001	.014	.002	-.069	-.016
	Self-reported general health status	-.467	.001	.197	.018	-.838	-.077
Satisfaction Ten-years post-TKA	(Constant)	83.52	-.008	4.83	.001	74.22	92.50
	Self-reported general health status	-3.26	-.007	.714	.001	-4.75	-1.99
	pain (VAS) one-year post-TKA	-.431	.004	.070	.001	-.556	-.280
	Expectation achievements one-year post-TKA	.221	.002	.052	.001	.116	.328

4.5 Discussion

This is the first study to attempt to develop and validate a prediction model for long-term outcomes and patients' satisfaction post-TKA, in addition to tracking their changes over several years. The current study found five predictors for low OKS scores at one-year post-TKA: low scores in self-reported general health, depression and anxiety, presence of arthritis in other joints and prevalence of co-morbidities. The association between low mental and physical health before surgery with a poor outcome post-TKA is in line with previous studies but was not validated for long-term predictions (Jiang et al., 2017; Lingard et al., 2004;

Lungu, Vendittoli, & Desmeules, 2016; Sanchez-Santos et al., 2018; Wood et al., 2016). A strong association between osteoarthritis in the contralateral knee and a poor outcome was previously concluded in the short term post-TKA (Lungu et al., 2016; Maxwell et al., 2013), but no previous study has assessed the long-term association or made predictions to compare with.

Two indicators were found for a high OKS score post-TKA in the current study: a high pre-TKA UCLA score and a history of contralateral knee arthroplasty. High self-reporting of a function such as UCLA before surgery is associated with a high score post-TKA, this is in accordance with the results obtained previously that assessed function using the physical function domain of SF-36 (Lingard et al., 2004). Therefore, it is recommended to concentrate on improving activity level as much as possible before arthroplasty to improve the outcome post-TKA. Future studies are recommended to assess this form of patient preparation using different methods, such as swimming or unload classes to motivate patients. In addition, this can be used to modify the individual patient's expectation based on his/her UCLA score before surgery regarding the outcome post-TKA. No previous study has assessed the effect of previous contralateral knee arthroplasty on outcomes to compare our findings with.

Regarding long-term OKS predictions, the current study found that OKS at five and ten years was strongly affected by the OKS score after one year, and this partially agrees with the prospective study by Jiang et al. (2017). Their study results showed that worse preoperative OKS was associated with worse OKS in both the short and long term, whereas the current study found no significant effect of pre-OKS on short- or long-term outcomes post-TKA. Response bias cannot be excluded in this prospective study as those included for analysis tended to be younger and healthier than non-respondents. In addition to mixing their study sample with both osteoarthritis and rheumatoid arthritis, not validating their predictors limits their findings to the sample (Oredein et al., 2011).

Age and gender did not significantly predict short- or long-term outcomes post-TKA, which contradicts previous studies (Jiang et al., 2017; Sanchez-Santos et al., 2018; Lingard et al., 2004). The medium- and long-term effect factors studied were prospective, and sample bias cannot be excluded; in addition, without validation, the results are limited to their sample (Sillabutra et al., 2016). A short-term study was developed, and validated predictions based on a mixed sample of osteoarthritis and rheumatoid arthritis and it is well known that sex hormones emerge as independent risk factors in rheumatoid disease (Da Silva & Hall, 1992). A recent study showed the gender difference in osteoarthritis patients post-TKA, the

symptoms were worse in females pre-operation and in the acute stage but by 6 weeks postoperatively sex differences were no longer evident (Nandi et al., 2019). This agrees with the current study and study by Lingard et al. (2004), as there was no significant effect of gender in either the short or medium term post-TKA (Lingard et al., 2004).

As physical and mental health significantly affects both short- and long-term OKS post-TKA, it affects patients' satisfaction, too. The current study concludes that a low satisfaction score is associated with low mental and general health, the presence of arthritis in other joints and the pain score at one-year post-TKA. Previous studies obtained comparable results in terms of the negative effect of low physical and mental health and the effect of the presence of pain on short- and medium-term patient satisfaction, although there were differences in their sample age and BMI (Bryan et al., 2018; Dhurve et al.,2017; Halawi et al., 2019; Hamilton et al., 2013; Jacobs et al., 2014). The negative effect of arthritis in other joints on long-term patient satisfaction is in accordance with the results obtained by Shannak et al. (2017), where patients with arthritis in other joints were two to three times more likely to be dissatisfied post-TKA (Shannak et al., 2017). Similarly, patients' satisfaction was significantly lower in patients with a history of low back pain in comparison without (Collados-Maestre et al., 2016).

The developed prediction equations', for both OKS and satisfaction post-TKA, main limitations were not assessed, nor the effect of socioeconomic deprivation, because these data were not available to the researcher. There is a conflict regarding the effect of socioeconomic deprivation on patients' outcome and satisfaction post-TKA, some studies conclude that socioeconomic deprivation is significantly associated with worse short-term outcomes (Neuburger, Hutchings, Black, & van der Meulen, 2013; Sanchez-Santos et al., 2018). In contrast, other studies elucidate the effect of sociodemographic factors that explain <1% of total variability in short-term outcomes post-TKA based on data from three different sources: the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man; National Health Service (NHS) England Patient Reported Outcome Measures; and Hospital Episode Statistics (Edwards et al., 2018; Murray, Birdsall, Sher, & Deehan, 2006). A comparable finding was obtained for the medium-term effect of socioeconomic deprivation post-TKA in 13 centres in 4 countries, the socioeconomic factor did not significantly affect outcomes. Patients with a lower socioeconomic background showed a good ability to compensate for their worse pre-surgical scores and achieve similar outcomes to patients with a high socioeconomic background at 2 years post-TKA (Davis, Lingard, Schemitsch, & Waddell, 2008). This conflict may be due to many factors, such as different

measurements methods being used to assess outcomes and socioeconomic deprivation; measurements at different times post-TKA, although the majority are between 6-24 months post-TKA. To understand the effect of socioeconomic deprivation on long-term outcomes post-TKA requires a population-based large cohort study.

In term of OKS changing in the years post-TKA, the current study showed statistically significant improvements in OKS from pre-surgery to six months, one and five years post-TKA, but no significant changes between one and five years post-TKA. This was followed by a significant reduction at ten years post-TKA. The current study findings agree with previous studies assessing long-term trends in terms of mean values pre-TKA and pattern of changing. The OKS means in the short and long term in the current study (38, 35) were higher than in a previous study (34, 30) (Williams et al., 2013). In the previous study, patients' mean age at surgery was 71± 9 years, i.e. older than in the current one, which may explain the minor differences in OKS as ageing may affect the overall performance. The OKS reduction at 10 years post-TKA may be due to the normal ageing effect. A significant difference was found in physical activity and function between young elderly (60-69 years) and old elderly (70-80 years), which may due to reductions in muscle strength, flexibility, agility and endurance (Milanovic et al., 2013; Mozolic, Hugenschmidt, Peiffer, & Laurienti, 2012).

All post-TKA outcomes (OKS, UCLA, pain and function scores) were significantly better than pre-TKA at all time points, with scores peaking at one-year post-TKA. They then remained at the same level and at 10 years showed a significant reduction. As all four tools are self-reporting measures for pain and function, they obtained similar findings and responses post-TKA.

Satisfaction scores changed post-TKA and showed non-significant improvements between one, five and ten years post-TKA, which is similar to those of Shannak et al. (2017), who found that 87% of dissatisfied patients remained dissatisfied over 9 years in follow-ups post-TKA (Shannak, Palan, & Esler, 2017). So, patient satisfaction at one-year post-TKA is the key to medium- and long-term satisfaction. Satisfaction at one-year post-TKA was higher in older age and for a high BMI, this may be due to their low expectations from surgery and their main target being just to be pain-free, and so they were not interested in being more active. This is supported by the double un-standardised regression coefficient value (B) for expectation achievements in the prediction equation. The strongest factor was a history of previous contralateral arthroplasty, which may have a real effect on surgery outcome expectations based on previous experience. Failure to fulfil expectations correlated with

dissatisfaction in the short-term post-TKA in previous studies, but there are no studies that have assessed medium- and long-term effects to compare findings with (Clement et al., 2015, Thambiah et al., 2015). A deeper understanding of patients' satisfaction and expectations post-TKA is described in the following chapter.

The current study has several strengths, such as: a large sample size was collected and transparently analysed to minimise bias; it included a wide range of predictors to minimise confounding factors; it validated predicted short- and long-term outcomes and a satisfaction model post-TKA using a bootstrapping technique for internal validation; and there was a long-term follow-up over 10 years post-TKA.

The limitations of current study are: limited data from one trust rather than using a population- based-cohort; not measuring the effect of other predictor variables such as socioeconomic and surgery details (surgical approach, tourniquet, anaesthetic, skin closure and surgeon volume); the predicted equation was not externally validated to another sample. A future study is recommended to externally validate the predicted model to improve generalisation.

Despite OKS being widely used to measure patient outcomes post-TKA, it does not correlate with patient satisfaction nor predict it. Long-term satisfaction mainly depends on patients' expectation achievements, the presence of pain and general health. Expectation correlate with short-term patients' satisfaction post-TKA is in accordance with previous studies (Clement et al., 2015; Mahomed et al., 2002; Scott et al., 2016). No objective measurements tools were available to estimate or predict patients' expectations and satisfaction without possible under/ overestimation. Therefore, in the next chapter, the focus group discussion is explored in more depth regarding patients' expectations, the factors that modify it, satisfaction and the overall experience one-year post-TKA to assess recovery from the patients' prospective. In Chapter 6, the prospective study assesses the prediction model for outcome and satisfaction based on objective measurement to improve the understanding of function and patients' recovery post-TKA without under/ overestimation or recall bias. In addition, it objectively assesses physical activity changes post-TKA.

Chapter 5- Focus group discussion

5.0 Introduction

The previous chapter concluded that patient satisfaction at one-year post-TKA is the key to medium- and long-term satisfaction. A high satisfaction score is associated with older age, a history of previous contralateral knee arthroplasty, a high BMI, and expectation achievements score at one-year post-TKA. However, it is not clear how these factors affect patients' satisfaction or what patient concerns, expectations and experiences are one-year post-TKA. To assess the patient's experiences and aspects of their quality of life post-TKA requires further investigation beyond the quantitative assessments and the controlled experiments designed to test defined variables are needed. Qualitative research offers useful methods to explicate the complexity and deeper meaning of patient experiences and outcomes post-TKA. Qualitative methods provide an opportunity to gain a deeper understanding of patients' experiences and views, which may cover the gaps and limitations of quantitative methods with the aim of improving healthcare services and hence, patient satisfaction rates (Beaton & Clark, 2009). No study has previously explored patient experiences, expectations, satisfaction and functional outcomes post-TKA using focus-group discussions one year after surgery to identify whether there are factors that might help us to understand why some patients' outcome measurements are good, but they are not satisfied, and vice versa.

5.1 Patients and methods

5.1.1 Study design

A qualitative approach utilising a focus group is useful for exploring poorly understood areas such as outcomes and experiences post-TKA to generate possible findings or hypotheses. It has advantages over one-to-one interviews as the interaction among group members provides an extra dimension to gather data and a wider degree of spontaneity in the patients' views expressed, in contrast to one-to-one interviews where the interaction is limited between patients and researcher and depends on patient responses. The interaction in a group allows patients to refine their views considering others' views and facilitates further spontaneous expression (Denscombe, 2014; Sim & Snell, 1996). Support for feelings by group members with similar experience encourages less verbal individuals to contribute more than in one-to-one interviews (Westby & Backman, 2010).

Although data from a focus-group sample could be considered limited, compared to data from questionnaires, they provide a flexible structure that allows patients to express their own views and feelings in their own words, while questionnaires limit that ability. Indeed,

the subject response depends on the types of questions asked in questionnaires, they can be considered a way of collecting quantitative data. For example, questions may ask respondents for a yes/no response or to pick the most appropriate answer from a list provided by the researcher. The main limitation of a focus-group discussion is the small sample size while purposive sampling that may threaten the external validity and generalisation of results; however, generalization is not a primary concern in this exploratory stage. Focus-group findings or hypotheses can be tested using structural questionnaires and quantitative methods in a further stage of research (Beaton & Clark, 2009). Having obtained ethical approval from Salford University (HSR1617-46, Appendix 1), the NHS Health Research Authority (17/LO/0838, Appendix 2) and Stepping Hill Hospital (Appendix 3).

5.1.2 Recruitment and Sampling frame

The medium of focus groups (with 8–10 patients) is preferred to allow a group of patients to share their perceptions and experiences post-surgery, with sufficient quantity and diversity of views while balancing the facilitator's ability to manage all patients' participation for 90–120 minutes (Bloor, 2006; Kitzinger, 1995; Sandelowski, 1995).

Purposive sampling was used to recruit the most relevant patients to answer the research questions, such as mixed genders to explore gender-experience differences, wide BMI range, mixed education levels, and mixed work and retired to explore return to work barriers (Schwandt, 2001).

The participants were recruited at Stepping Hill Hospital. Sample criteria require was clarified for all five orthopaedic surgeons at the hospital. Any patients attending for a one-year follow-up visit who are willing to participate in a focus-group study were included in a research-patients list. A participant information sheet and an informed consent form and an agreement for electronic recording were sent via Royal Mail or email to each participant four weeks before the study to allow participants to consider their involvement in the study and have the time to decide whether to contribute. They were able to change their minds on the day should they wish to do so with no impact on their future or current health care.

5.1.3 Inclusion and Exclusion Criteria:

The study included the patients who have undergone primary unilateral total knee arthroplasty within the last year and can read and understand English. No age, gender or educational level limitations were used. The exclusion criteria are in accordance with the exclusion criteria in the methodology chapter.

5.1.4 Specific ethical considerations for FGD

In addition to the general ethics and data protection procedures explained in the methodology chapter, the focus-group electronic recording and transcript were stored on an encrypted file server at the University of Salford and protected by a password according to the University's data management policy. Patients identified themselves by their first name only and their length of experience post-TKA, then in the transcript stage their names were replaced by pseudonyms.

5.1.5 Risk Assessment:

No physical or psychological harm from the study's focus group was expected to come to the patients or the researcher. According to a Research Ethics risk assessment, no risk or adverse action was likely to arise from the study as all topics and questions covered are suitable for discussion in a semi-public setting.

A skilled expert facilitator was utilised who:

1. Instructed all group members to be respectful to each other and to respect each other's confidentiality.
2. Facilitated in-depth interviewing and support and appreciate all patient contributions, in addition to controlling as much as possible any patients with dominant personalities, if present, and allow others to participate.
3. Provided immediate support to any participant in case he/she was upset by the session.
4. Seeked to maintain calm conversation and avoid any aggression, although all topics and questions covered are suitable for discussion in a semi-public setting and not sensitive issues.

In the case of an aggressive uncontrolled participant, the researcher was to take the participant out of the group and proper initial support was be given to the participant while the facilitator continued with the other group members and gave enough support to them.

If a participant required further organizational support from an orthopaedics consultant or psychological advice, a referral was to be sought.

If participants became distressed by revealing their experiences, then they were to be able to cease their contribution to the group. They were to be supported by the clinical service staff and/or directed to PALS, depending on the issue(s) raised

The focus-group discussion was carried out in a private comfortable room at the Stepping Hill Hospital site where access would be easier for patients as they would be familiar with it from their recent experience. The hospital room was in a safe, indoor, non-isolated setting with enough preparations made in case of an emergency, e.g. fire.

5.1.6 Focus group data collection:

The FGD was held on 31 January 2018. An ice-breaking activity was used to begin, followed by refreshments; then, the facilitator gave a general introduction to the group-discussion topic, followed by patients identifying themselves, giving their names and length of experience post-TKA. The focus group was facilitated by a focus-group expert and the researcher using open-ended questions in order to prompt free discussion (Table 5-1 and Appendix 4). All proposed question and probes were based on previous FGD post-arthroplasty and the researcher's previous experience with TKA patients. All topics and questions covered were suitable for discussion in a semi-public setting. A facilitator controlled as much as possible any participants with dominant personalities, if necessary, and encouraged others to participate. The whole discussion was recorded by electronic means, in addition to field notes being taken by both facilitator and researcher. The researcher's email details were given to the participants so that they could email their thoughts if they felt uncomfortable discussing any issues in the group situation (Lehoux, Poland, & Daudelin, 2006; Palomba & Banta, 1999; Sim & Snell, 1996).

5.2 Data Analysis Process

The focus group discussion (FGD) was transcribed and analysed manually by two independent researchers according to thematic analysis, as recommended by Braun and Clarke (2006). Thematic analysis is defined as a qualitative descriptive method to identify and analyse narrative material to report patterns, or themes (Braun & Clarke, 2006). It has the advantage of flexibility; other analysis methods are tied to or based on a particular theoretical or epistemological position. Its flexibility provides rich and detailed data about current phenomena after total knee arthroplasty (TKA).

The identification of themes was largely based on the current narrative data and patient responses in the FGD transcription rather than the questions used in the FGD. In the current narrative data, the researcher captures anything important, essential, or repeated from patients following TKA as a theme or sub-theme. The identification of themes is an inductive, or bottom-up, method that does not require engagement with the literature at this stage. The analysis is a recursive (nonlinear) process, moving from one phase to another as needed. The recommended six phases used in the current data analysis are as follows and are summarised in Figure 5-1.

Table 5-1. Focus group post total knee arthroplasty discussion guide.

Main question/area	Probes
How was your experience of Total Knee Arthroplasty (TKA)?	
Functional improvements after TKA	Have you experienced any improvement in your function? What types of activity have improved? To what extent?
Loss of function after TKA	Have you experienced any loss of function? For how long? What modifications have you made to compensate for that? What are your barriers?
Satisfaction and expectations	How do you feel about your surgery now? Does it satisfy all your expectations? What were your expectations? Are you planning surgery for your other knee if it has the same complaint? Would you recommend surgery to your friends or relatives?
Health team communication	Did you receive sufficient information and explanation about surgery and expectations in advance from the health team? Was that sufficient for what you needed to know before surgery? Do you think that has affected your satisfaction after surgery? What is the most important information you think all patients should know before surgery?
Rehabilitation services	Have you received or are your receiving physiotherapy post-surgery? For how long? How many sessions? Were or are you satisfied with it? What do you recommend in terms of physiotherapy services?
What are your recommendations to future TKA patients	
Do you have additional concerns not covered during this meeting regarding the period after hospital discharge up to a one-year follow-up?	

5.2.1 Phase One: Familiarising the Researcher with Current Narrative Data

This phase starts with FGD transcription and then followed by repeated active reading of the text to identify patterns, meanings, or specific patients' concerns. Then, notes are made of ideas that will be of use in the following phase of analysis.

5.2.2 Phase Two: Initial Code Generation

Subsequent to the repeated active reading of the text and note-making, an initial code is generated. Coding, the first part of analysis, organises patient responses into meaningful categories. Coding is based on patient feedback more than the FGD questions. Through this entire phase, coding is systematically applied to the current text data, with equal attention spent on all sections. This process is executed manually by note-writing or using a highlighter pen to identify potential patterns. As the researcher cannot anticipate what information will be of interest in the following stages, all potential themes/patterns are coded. All data, including the patients' responses from the dominant experience, are coded without smoothing out or ignoring inconsistencies in the data.

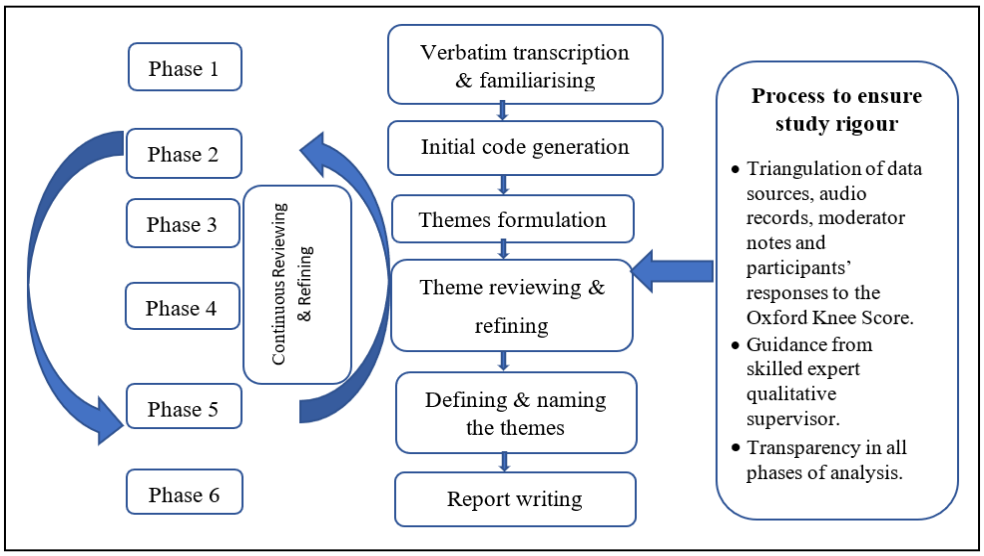

Figure 5-1. Data analysis flow chart

5.2.3 Phase Three: Theme Formulation

The codes developed in the previous phase are arranged in a list, then sorted into to potential themes. Tables and mind maps suggesting different codes and possible combinations, or overarching themes are helpful at this stage. Some codes represent main themes and others form sub-themes (Braun & Clarke, 2006).

5.2.4 Phase Four: Theme Reviewing and Refining

Themes developed in the previous section are reviewed to ensure there are sufficient data to support them without too much diversity. At this stage, some themes merge, while others are broken down in to two separate themes. Balance between internal homogeneity and external heterogeneity is considered at this stage to formulate themes that cohere meaningfully with clear and identifiable distinctions (Patton, 1990). The review is made in two stages to maintain the required balance. The first review at the coded level ensures that the themes are coherent. If the themes are not coherent with codes extracted, new themes are created. The second stage of review assesses the validity of each theme in relation to the original data and ensures the themes accurately reflect the meaning of the original. If the thematic map works after these two stages of review, we progress to Phase Five; otherwise, recoding and new themes are generated to improve the map (Patton, 1990).

5.2.5 Phase Five: Defining the Themes and Naming

In this stage, the themes determined in the previous phase are defined: what the theme tells us about the patient's experience post-TKA, when it happened, and so on. Sub-theme details are also defined at this point. The main aim of this stage is to define each theme in sufficient detail, ensuring coherence and internal consistency of data without duplication or too much diversity. The researcher then names the themes in concise, evocative language.

5.2.6 Phase Six: Report Writing

The primary output of this stage is a transparent description of the narrative data analysis process to prove the validity of the analysis used. The report includes some interpretation of the findings, not only a collection of similar and different experiences post-TKA. To explicate the data, illustration and support from previous studies are used to link the findings with related results (Braun & Clarke, 2006; Vaismoradi, Turunen, & Bondas, 2013).

5.3 Trustworthiness

Qualitative study trustworthiness criteria and techniques are defined by Lincoln and Guba (1985) and summarised in Figure 5-2. Credibility is a trustworthiness technique defined as the level of confidence that the research study's findings are based on the participants' narratives and words rather than potential researcher bias, this may be assessed using different techniques such as: participant checks, prolonged engagement, persistent observation, triangulation (data sources, methods, investigators), peer debriefing, analysis of negative cases and referential adequacy (Nowell, Norris, White, & Moules, 2017; Tobin & Begley, 2004). Therefore, to improve the credibility of the findings in the current study, two techniques were used: the researcher's persistent observation and during the FGD without interfering whilst an experienced facilitator chaired the discussion; using triangulation in assessments and analyses. Patients' functional changes post-TKA were assessed using FGD questions and OKS scores taken at the beginning of session. In terms of analysis, this was done by two independent researchers (researcher and researcher co-supervisor). Therefore, the differences between the two assessments methods for functional changes post-TKA (OKS and FGD) and two independent researchers' analyses are clarified in the following findings sections. Member-checking or participant verification was not performed due to the practical difficulties of returning FGD transcripts to patients with no evidence showing its efficiency in enhancing confirmability (Long & Johnson, 2000).

Transformability clarifies if the research findings are transferable to other patient groups (Braun and Clarke, 2013). To enhance the research findings' transformability, there are extensive and deep descriptions of current patients who are participating, the interventions they underwent, and all the details that may improve the reader's view of the study circumstances so as to estimate the possibility of applying the findings to their own patients. Thick description in the analysis is supported by quotations from all participants for each theme to improve trustworthiness.

Dependability in qualitative research is similar to reliability in quantitative research, this can be improved with a clear and detailed description of the study methodology, analyses and decisions made in the following audit trail. Confirmability in qualitative research is similar to objectivity in quantitative research, it is the value of the researcher's influence on the study findings. The findings in a qualitative study mainly result from a process of interpretation by the researcher. So, to maintain confirmability in a qualitative study, the researcher must keep an open mind and consider alternative explanations of findings. Therefore, the current study analysis was conducted by two independent researchers, followed by an open discussion to draw a conclusion from the findings, from two independent perspectives, to improve confirmability (Collingridge & Gantt, 2019; Denscombe, 2014; Tobin & Begley, 2004).

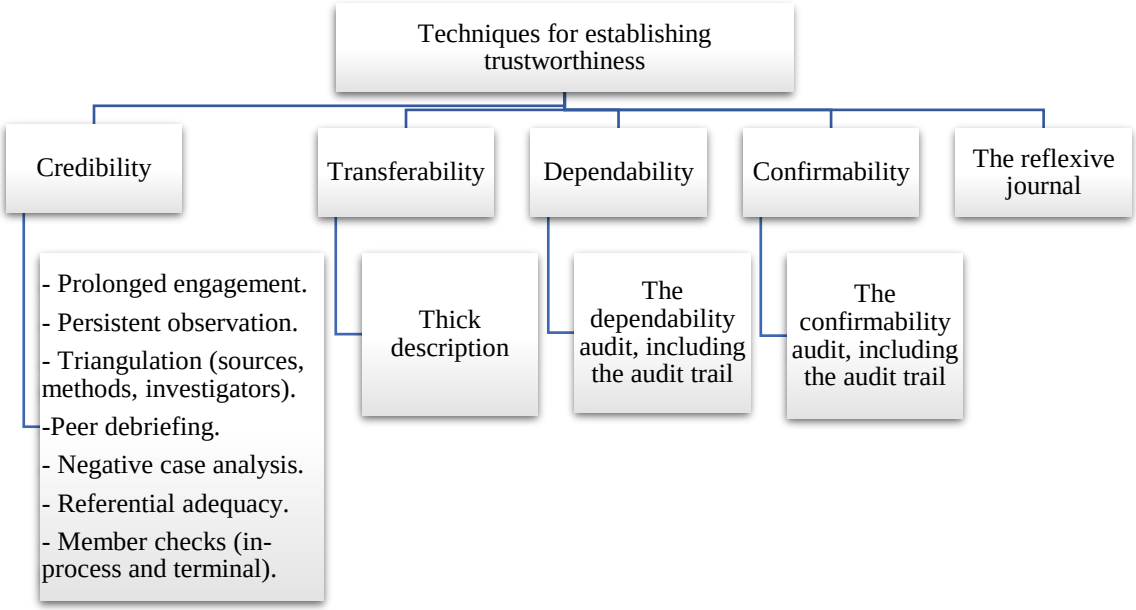

Figure 5- 2. Summary of techniques for establishing trustworthiness (Lincoln and Guba 1985).

5.3.1 Research audit trail

In line with Seale's (1999) guidelines, a research audit trail was developed to demonstrate to the reader the authenticity of the study findings and improve trustworthiness, in addition to all the details clarified in the previous methodology chapter and the methods section in the current chapter. There are two kinds of qualitative research audit trails, intellectual and physical. The intellectual one determines the transparency of the researcher's influence throughout the research process. The physical one clarifies the developments stages of the

research, starting with the research question(s) and methodology decisions. Both intellectual and physical audit trails are presented in the following sections.

5.3.1.1 Intellectual research audit trail

An intellectual audit trail shows the researcher reflexivity throughout a qualitative research study, the following presents the intellectual audit trail.

5.3.1.1.1 Initial philosophical position:

The researcher's philosophy is predominantly positivist due to previous experience as a physiotherapist and completing quantitative research for a master's science degree that was mainly based on testing a research hypothesis via statistical analysis.

5.3.1.1.2 Positivist position questioning:

During the process of the current thesis making methodology decisions to choose suitable methods to answer the thesis' questions, the researcher became aware of the limitations of positivist research. Exploring patients' experiences post TKA was not possible with any available purely quantitative methods. In-depth understanding of complex social issues, such as experience, expectations and satisfaction post-TKA, would not be effectively captured through administering questionnaires and analysing the findings statistically.

5.3.1.1.3 Search for a philosophical stance:

After attending research methods courses at the University of Salford, and extensive research methodology reading, the researcher concludes that an interpretivist position was a more convenient foundation to answer the research question. Capturing the contextual depth of patients' experiences post-TKA not possible with research using value-free quantitative objective methods.

5.3.1.1.4 Considering alternatives for evidence collection:

A phenomenological approach was used in the current study, as each patient sees their experience in a different way, and this approach rejects a belief in one universal reality or theory that fits all patients. There were similarities and differences among the patients' experiences post-TKA and multiple realities evolved. The main advantage of a phenomenological approach is in providing adequate, complex and in-depth descriptions of experience that are as faithful to the original as possible. A phenomenological researcher does not edit the patient's experience or modify it in order to present a coherent life experience (Creswell & Creswell, 2018; Denscombe, 2014; Mackey, 2005).

5.3.1.1.5 Interpreting the evidence:

Thematic analysis was chosen as it has the advantage of flexibility; other analysis methods such as content analysis are tied to or based on a particular theoretical or epistemological

position aiming to quantify or categorise the findings to formulate a theory, which is not the objective of the current study. Therefore, flexible thematic analysis was used as it provides rich and detailed data about current phenomena after total knee arthroplasty to improve our understanding and make the picture clear for practitioners and possibly modify certain factors to improve future patients' experience (Braun & Clarke, 2006).

5.3.1.1.6 Distillation of themes from the data:

The identification of themes was largely based on current narrative data and patient responses in the FGD transcript rather than the questions used in the FGD. In the current narrative data, the researchers capture anything important, essential or repeated from patients following TKA as a theme or sub-theme. The identification of themes is an inductive, or bottom-up, method that does not require engagement with the literature at this stage. The analysis is a recursive (nonlinear) process, moving from one phase to another as needed (Braun & Clarke, 2006).

5.3.1.2 Physical research audit trail

A physical audit trail shows the researcher's methodology decisions as follows:

5.3.1.2.1 Identification of the research problem:

There is no previous evidence that deeply clarifies the factors that may affect patients' experience, satisfaction, expectations and functional outcome at one-year post-TKA. The exploration of patients' expectations, satisfaction, functional recovery and limitations may support future modifications and thus improve outcomes post-TKA.

5.3.1.2.2 Reviewing the literature:

An in-depth review of patients' experiences, expectations and satisfaction post-TKA using the FGD methods literature was undertaken. Three studies were identified, one assesses experience at the acute stage (6 weeks post-TKA), three years post-TKA and one-year post-TKA. The previous FGD at one-year had some limitations such as: the sample mixed both TKA and total hip arthroplasty, which does not support accuracy, as these patients encounter different problems and barriers; the study objective was mainly to explore the experience of rehabilitation practice, not the overall experience; themes were formulated based on patients', their spouses' and health professionals' views, and this means their conclusions are not isolated from the people who are experiencing surgery.

5.3.1.2.3 Research proposal:

A research proposal was written and submitted to the University of Salford's ethical committee for approval. The proposal clarified the study objectives and the research questions. Then, the proposal was submitted to the NHS health research authority for

approval. Finally, the proposal was discussed with the Research and Innovation Department at Stockport Hospital for research implementation and organisation. The study methodology is registered at ClinicalTrials.gov (NCT03064334).

5.3.1.2.4 Data Collection methods

An FGD was used as it has advantages over other qualitative methods, such as individual interviews, documents, observation and field notes. It provides an extra dimension to gather data and a wider degree of spontaneity in the patients' views expressed, in contrast to one-to-one interviews, where the interaction is limited between patients and researcher and depends on patient responses.

5.3.1.2.5 Designing a research timing framework:

The next step involved designing a research framework to enhance the understanding of patients' experiences post-TKA. The retrospective study in the previous chapter concluded that satisfaction at one-year post-TKA is the key to medium- and long-term satisfaction. However, it was not clear how the conclusion drawn affects patients' satisfaction or what patient concerns, expectations and experiences are one-year post-TKA. Therefore, an FGD was run to improve the understanding of patients' experiences at one-year post-TKA.

5.3.1.2.6 Number of Participants

Commonly, an FGD group includes between 6 and 8 participants, to allow a group of patients to share their perceptions and experiences post-surgery, with sufficient quantity and diversity of views, while balancing the facilitator's ability to manage all patients' participation (Bloor, 2006; Kitzinger, 1995; Sandelowski, 1995; Wilkinson, 1998).

5.3.1.2.7 Number of Focus Group Discussions

The aim of FGDs in the current thesis was to explore patients' experiences post TKA and improve the understanding of the findings from the retrospective study without any intention to theorise or generalise. Therefore, organising one FGD was a pragmatic decision to answer the research question due to the time limitation on data collection. Although the study achieved sufficient numbers to meet the requirements of a purposive sampling framework, an additional focus group, particularly in another hospital, may have provided different opinions and experiences.

Another focus group of Saudi patients would have enhanced the results, but a pragmatic decision was made due to the practical difficulties of arranging a mixed gender FGD in Saudi Arabia for sociocultural and religious reasons. The older Saudi patients generation commonly exhibit conservative behaviour and with attendance of another gender – if they accepted that – their responses might not be detailed and beneficial for the study objectives.

Two separate FGDs, one for each gender, could improve the understanding of Saudi patients' experiences post-TKA, but it would be hard to compare this with a mixed UK group, given the limitations of group gender variation and language difference. Therefore, due to the time limitation of the thesis, one FGD in the UK was arranged to illuminate patients' experiences and satisfaction post-TKA, rather than reaching a saturation level in the findings and comparing findings to see differences in different populations.

5.3.1.2.8 Selection of FGD participants: In order to elicit patients' in-depth experience post-TKA, the included participants comprised both genders and had a history of single and bilateral TKA experiences, which facilitated the exploration of differences between first experience and second. There were mixed education levels (high school and bachelor's degree), different surgeons, and wide BMI range (26-41).

5.3.1.2.9 Data collection: The FGD was facilitated by a focus-group expert with attendance by the researcher and an orthopaedic surgeon as a researcher co-supervisor (not the surgeon who conducted TKA on patients). The presence of the researcher co-supervisor sought to achieve a balanced analysis, as both researcher and co-supervisor attended the FGD and wrote notes and comments in addition to recording the interchange of views for transcription.

5.3.1.2.10 Data analysis:

The analysis was done by two independent researchers (researcher and co-supervisor) according to the data analysis process in the previous section (Lincoln and Guba 1985). Both researchers arranged transcript data in a table and listed evolving codes in a righthand column. Table 5-2 is an example to clarify the data coding process. Each researcher formulated conclusion codes in themes and sub-themes as an independent mind map (Fig. 5-3). Then, a meeting was held to discuss the codes, themes and subthemes to improve the credibility of the findings and interpretation of the transcript. There was good agreement between the two assessors for the codes that evolved, the a difference was in themes and subthemes formulation as shown in their mind maps (Fig. 5-3). After a discussion, four main themes were agreed, the 'recovery experience' theme in assessor 2's mind map was broken down into two themes: 'recovery experience theme' and 'ADL changes theme'. The 'First TKA experience theme' in assessor 1's mind map was combined with the 'recovery experience theme' to form larger overarching themes to cover the recovery experience via four sub-themes. The final themes were reviewed, refined, defined and named and included in a final mind map (Fig. 5-4) and in the FGD findings in the following section.

Table 5- 2. Example of initial codes generation for the focus group discussion transcript (1/2).

Commentary	codes
"With the second one I put up with it longer than I probably should have done, and umm if I didn't have – the operation that I had in hospital but a few years ago it would have been so much better, but you can't change that can you"	2ed TKA Timing
"I waited 27months for my second knee replacement because I had a problem with my spine I had to have spinal surgery in between but I have noticed the difference in them''	2edTKA Timing
"I think obviously the operation is the main focus and the surgeons they do a really good job but I think the physio are a lot to be thanked for certainly in my case, umm because umm she gave me a lot of advice in terms of what to do and I am still doing it even now every day, and I have had no trouble whatsoever with my leg, well either of them now and I am just so grateful to them and what has happened and how life has changed so much"	Surgeon, PT Feedback, Life change
"I think too, it starts out with the attitude that you have before you have the operation, you go into it determined that you are going to do X,Y and Z and that is it"	Outcome belief Pt. attitude
"I think when you go into an operation, well any kind of operation – you have got to have that positive determination. When I had my left one done I was absolutely past the suicidal stage because the pain was that bad.	Outcome belief Sever pain post TKA
"Anyway the man I saw there, I forgot his name and he said he will refer me to his colleague so that is the only way I got to Stepping Hill because waiting for the GP's you wait forever"	Referral process
"Mine did as much as they could, or He could prevent me from having to have the operation. I was told I shouldn't really be having a knee replacement until I was 70 because of the length of life of a new replacement, and so he was very good he gave me steroid injections for at least 3 years to just keep me going until like you I got to a point where I wasn't able to walk every far and I dreaded going shopping, I dreaded going out with my grandchildren if they said let's go for a walk and I would say oh yes and within about 5minutes I was in a lot of pain. It seemed like it was until you reached 70 or around that age they won't refer you and you have become so much in pain that you say anything is brilliant after that."	Referral process Alternative treatment Before TKA experience
"And I think in a way it is a force economy pushing you and pushing you to the limit because by the time you get to that point, what other damage has it done to other bones, nerves, tissue and whatever – so you know as women we are used to oh we just get on with it, but even we reach a point where we can't take anymore and we need some treatment of some sort, replace or whatever.	Before TKA experience
"Well I had arthritis in both my knees about 10 years ago, had arthritis in my left knee for about 12 years but that was made worse because I had a ruptured cruciate ligament in my posterior which made my arthritis worse but I had orthoscopy didn't really do much for me I must admit but I went on a website and sent for these heel sole inserts which are brilliant and I still wear them today in my other shoe, in both shoes actually because they are brilliant. Wear two at a time and without them before the operation I couldn't walk half a mile but with them I could walk a lot further"	Alternative treatment
''before I had my operation I couldn't walk –funny thing I could play golf 3 times a week, walk for miles with a sore knee it was bad but it was bearable but I couldn't walk from the supermarket with a bag of shopping to the car 50 yards without putting the bags down I was in agony, walking on something soft it was entirely different"	Activity limitation before TKA
"My GP said try Ibuprofen and paracetamol regularly 3 times a day the Ibuprofen and I was a little bit worried about taking it for such a long time so every now and again I had a bit of a break and I don't think it actually helped. Then they put me on quite a high powered painkiller which made me ill and really sick, dizzy so I came off those and went back on the ibuprofen and the paracetamol and then he started doing steroid injections into the knee ever 6months and I think I had them for 3 years"	Alternative treatment
"I found that helpful because with the first one we were told nothing, whereas this one at Stepping Hill they explained it is not magic, you have got to work yourself as well"	Education expectation
"I think that was the thing that was imprinted, you have got to exercise ASAP because if you don't…" Well you lose your muscles but it's going to be a hell of a lot more painful if you don't"	Outcome belief
"It wasn't sort of extreme expectations, it was simply and solely mobility, able to do things that you normally do but haven't been able to do because you haven't been able to stand the pain and stiffness and everything else. It is just that focus of getting sort of normality and that better quality of life. I think that was my main expectation."	expectation

Table 5- 2. Example of initial codes generation for the focus group discussion transcript (2/2).

Commentary	codes
"I do gardening or I used to do a lot of gardening, I can't kneel after surgery"	Post ADL limitation
"I can get down on the floor and my husband will say I'll give you a hand and it's like no and I roll over – bring everything together. You learn to live with the limitations shall we say you adapt to them"	Post ADL limitation
"Yeah I can climb up ladders and I can do anything but it is the kneeling I think"	Recovery experience
"I think Mr ------- is very realistic when I saw him because my knee – I forget what he call it when you can bend the knee, it wasn't great and he said it is not going to be really flexible when you have a new knee but it will be far less painful and you will be able to do a lot more without pain. I think you forget that kind of pain, it is a bit like childbirth you forget it otherwise you wouldn't go on and have another child would you but you know it then makes you realise that it is going to be swollen and it is going to be really badly bruised. Then with my second knee because I knew it was going to be ok in the end I did things quicker, I was more confident."	Expectation modification Recovery experience 2nd experience
"It gives you part of your life back doesn't it, and I think that is worth the pain and discomfort for a few weeks. As long as you do your bit and continue the surgeons work then you know"	Recovery experience
"It gives you confidence back doesn't it (Yes) to do things you were quite anxious about doing before a knee replacement. I can remember going around Sainsbury which has got quite hard floors, but I really dreaded going shopping or my daughter would say shall we go to Stockport and have a look around the shops and I would say I am not sure about that, but now I don't have to worry"	Recovery experience
"The thing with arthritis you have got to keep moving, I can walk before the operation I could walk but I was in pain. Even if I went to the library for half hour just standing there looking at books I was in agony just standing and not moving. At the airport standing in the queue for an hour just checking in I was in agony just waiting for your baggage just agony"	ADL limitation before TKA
"I think with the activities it is the same thing but I felt I had to sit down much more just to rest my knees because they were hurting a lot but now I can just carry on"	ADL changes post TKA
"I would say exercise before you go in not for day or weeks but for months once you have got arthritis exercise helped me recover"	recommendation
"My doctor from the first time he gave me a list of exercises to do, I was offered that before hand – from the GP – my GP gave me 3 or 4 sheets of exercises to do to help strengthen the knee and that is when I started to do it probably 5- 6 years before I had the operation I was given that to make it stronger"	GP/ referral experiance
"Yeah I think the bicycles help my knee definitely, do it as low as you can so it is really bending which is what you wouldn't normally do on a bike would you"	post TKA recommendation
"Having them both done has improved the quality of my life 100% it is just unbelievable I can't thank the hospital enough"	Post TKA experience
"Probably about 6-7weeks I started to walk a few weeks with crutches and then one crutch, probably about 2 months it was April had operation in December, and 2 months after in February I said I can't walk my right knee is terrible, between February and April it gradually went. After that they gave me a brace on my right knee in case it got worse, I had already planned to have a brace and the brace I can't tell the difference if I don't wear the brace on short differences but I wear it all the time now in case it is sore, but the open brace is very good. It got worse but then it got better without a doubt."	Recovery length
"I mean I came for reviews and that, and they said to me after about 3 visits if you are happy and you are carrying on with the exercise we don't need to see you again and I have kept on with the exercises. I have been doing exercises for that knee, and this knee and for my back before I can get going in the morning about 1hr – 1hr 30"	PT post TKA
"Well I have got a grandson who well he will be 10 this year but he has always been interested in fossils and rocks and geology and minerals - he got that from me unfortunately, but he said to me last year he said 'oh nanny I will be glad when your leg is better' and I said why he said 'then we can go fossiling' and I had said to him sometime before when I have had my knee done then maybe we will be able to go fossiling so we ended up in Whitby last July and I was climbing cliffs, climbing rocks. So you know that to me speaks volumes because 12 months before I was in so much pain, if I hadn't of had my knee done I don't think I would be here now it was that bad".	go back to that you wouldn't normally

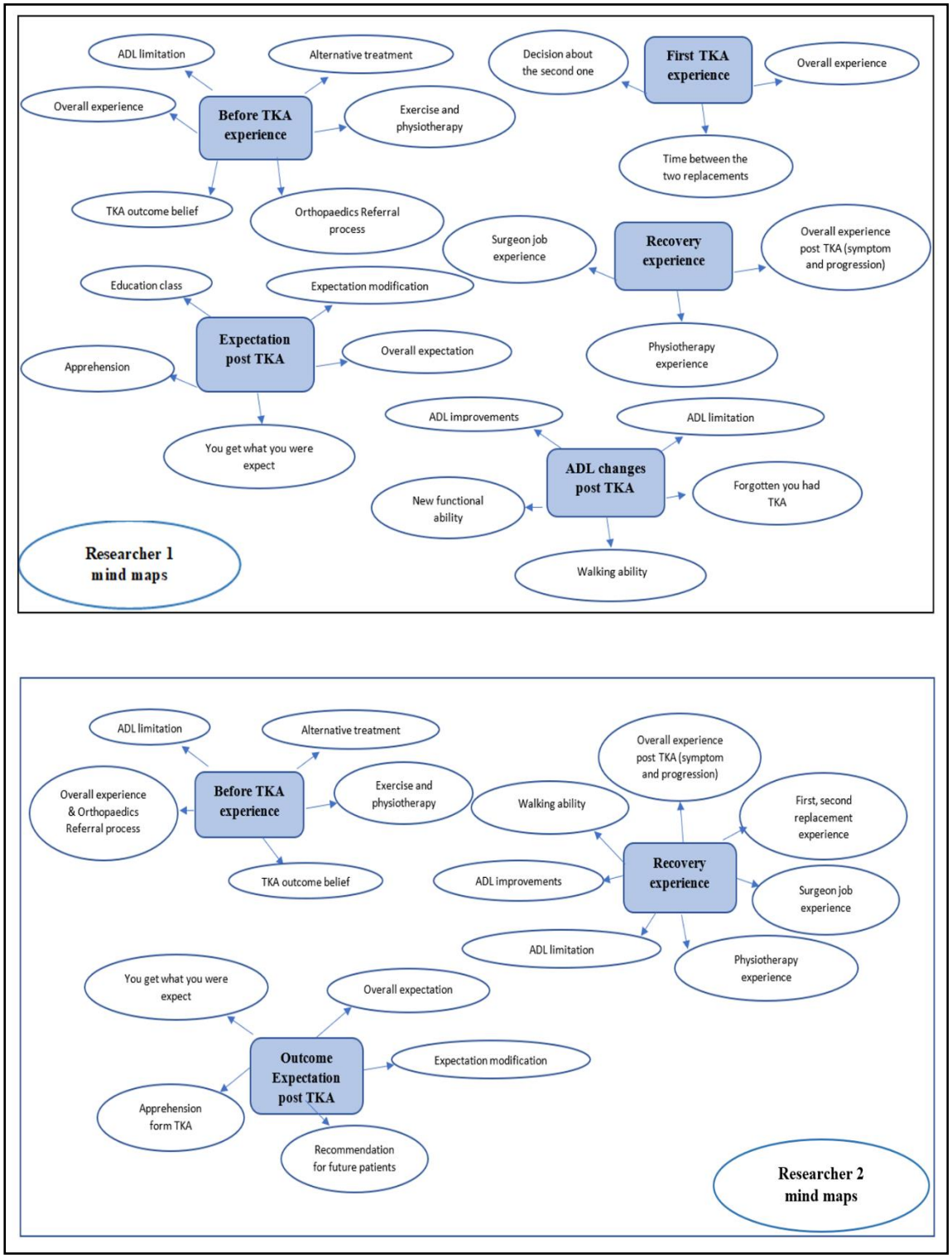

Figure 5- 3. Themes and sub-themes mind maps for both independent researchers

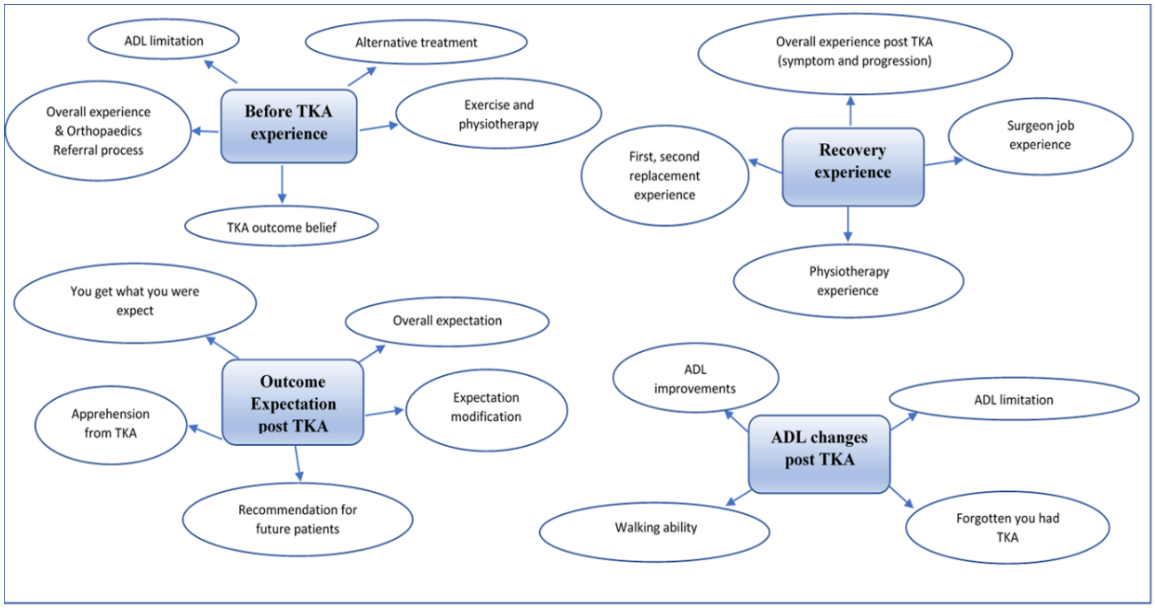

Figure 5- 4. Agreed themes and sub-themes mind maps.

5.4 FGD Findings

5.4.1 Participants

A total of 10 patients were invited for the FGD. Two of them declined with regret, as the time and day were not convenient for them, one patient gave no response, and the remaining seven patients attended the FGD. Patients' characteristics and Oxford Knee Scores are summarised in Table 5-3.

The included participants' ages range from 70–82 years. They were all retired, so we could not explore the barriers for work return. They have a mixed history of single and bilateral TKA experiences, which facilitates exploration of the differences between the first experience and the second. All participants have a high school education level and two had a bachelor's degree in education. Three of them have partners, while the remaining did not, which may help us understand the role of family assistance post-TKA. All Oxford Knee Scores showed satisfactory knee joint function (44–48), except in the case of one patient, who showed mild to moderate knee function (33). All of them lost kneeling ability post-TKA.

5.4.2 Key themes

The focus group discussion analysis by two independent researchers, as clarified in the previous section, resulted in four themes, with four or five subthemes under each theme (Fig. 5-4). The themes cover patient experience before and after knee replacement, improvements and limitations of activity of daily living (ADL) after surgery, expectations from surgery

and advice for future replacement patient' summary in figure 5-5. The quotes below are attributed to patients by initial, plus age and gender (e.g. 70.F is a 70-year-old female).

Table 5- 3. Focus Group Discussion Patient Characteristics and Oxford Knee Scores

Participant Code	Age	Gender	BMI	TKA Date	Education Level	Marital Status	Oxford Knee Score
P.	70	Female	35	First 2012 Second 2016	High School	Married	41
M.	80	Female	31	2016	High School	Widowed	42
Ji.	72	Female	28	First 2015 Second 2016	Bachelor's Degree	Married	33
K.	80	Female	26	2016	High School	Widowed	48
Br.	82	Female	41	First 2007 Second 2016	High School	Divorced	45
Ba.	76	Male	34	First 2014 Second 2016	Bachelor's Degree	Married	43
Jo.	77	Male	42	First 2009 Second 2016	High School	Divorced	44

5.4.3 Theme one: Recovery experience

A substantial amount of the focus group discussion time was spent discussing functional recovery after TKA, revealing four subthemes to cover the diversity of post-TKA experiences: the overall experience post-TKA in term of symptoms and progression issues, the experience with the orthopaedic surgeon, their experience of physiotherapy and differences between first and second knee replacements.

Sub- theme 1 - The overall post-TKA experience

All patients agreed on the severity of post-TKA symptoms for a few weeks or months, followed by a gradual reduction in pain accompanied by functional improvements that helped them regain their confidence.

> *"I think you forget that kind of pain, it is a bit like childbirth you forget it otherwise you wouldn't go on and have another child, would you? I remember with my first one I was really quite depressed and cried quite a lot the first fortnight because of how painful, how bruised and how swollen it was and kept doing these exercises and thinking it is not getting better, it is not getting better and then suddenly you start to be able to walk on your two crutches, then your one crutch"* (M. 80.F).

Also, one participant revealed her opinions on the longer-term physical benefits,

> "*… it might never feel as pain free as my left now, I can walk, and I can move. It gives you part of your life back doesn't it, and I think that is worth the pain and discomfort for a few weeks''* (P.70.F) and another talked about

the psychological impact, *"It gives you confidence back doesn't it? to do things you were quite anxious about doing before a knee replacement"* (J. 72.F).

"I think you do things naturally now without thinking about it, you just get up and get on with it" (Br.82.F).

"6-7weeks I started to walk a few weeks with crutches and then one crutch, probably about 2 months. It's changed my life now" (Ba.76.M)

"Having them both done has improved the quality of my life 100% it is just unbelievable I can't thank the hospital enough" (J.77.M).

The overall experience post-TKA began with severe pain and swelling – which was ultimately forgotten – for a few weeks or months, followed by gradual improvements in physical activity and confidence. The overall quality of life improved post-TKA.

Sub- theme 2 - Their experience with the orthopaedic surgeon

All patients reported having a satisfactory experience with their surgeon, who tried all possible conservative options before surgery. Only two patients said their details experience with surgeon, and the others agreed with that.

"He checked that I had tried everything, and he said I think you need a knee replacement" (M.80.F).

"the surgeons they do a really good job in my case" (J.77.M).

In addition, all the surgeons advised patients to attend the pre-TKA educational class to learn more before the surgery and played a crucial role in modifying their pre-surgery expectations.

"The surgeon didn't say it would be perfect, but it will be better than it is now" (Ba.76. F).

"The doctor is very realistic when I saw him, he said it is not going to be really flexible when you have a new knee, but it will be far less painful, and you will be able to do a lot more without pain" (M.80.F).

All patients had good experiences with their orthopaedic surgeons, who tried every possible conservative treatment before moving on to surgical intervention. Outcome expectations post-TKA were modified to be more realistic by both the surgeon and the educational class.

Sub- theme 3 - Their experience of Physiotherapy

Patients' experience with physiotherapy post-TKA varied; it was excellent for two patients in terms of quality of exercise and advice.

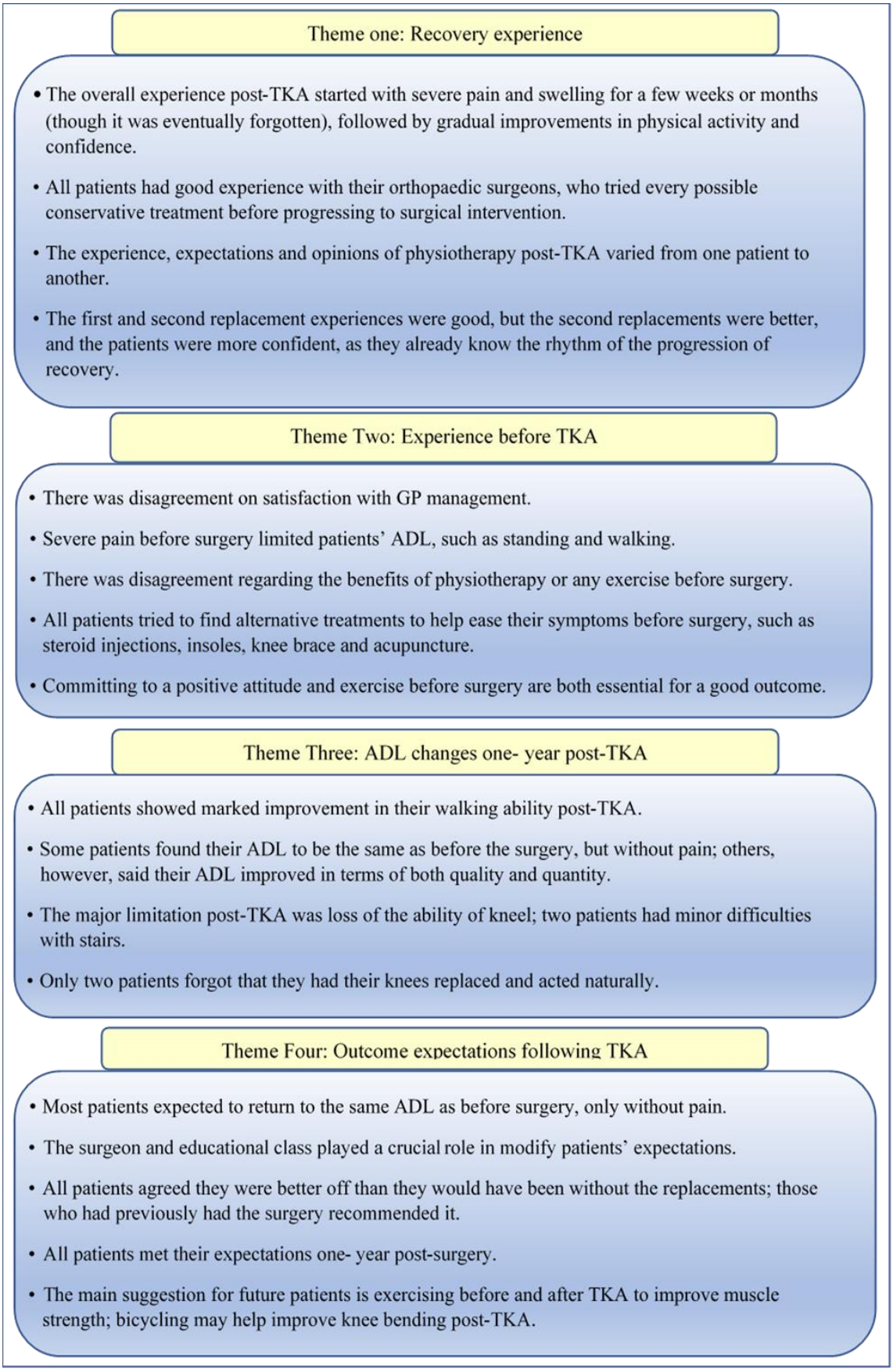

Figure 5-5. Focus group discussion themes summary

"*Mine was excellent yeah, I couldn't have wished for better" (Br. 82.F).*

"the physio was absolutely excellent. I think the physio are a lot to be thanked for certainly in my case, because she gave me a lot of advice in terms of what to do and I am still doing it even now every day, and I have had no trouble whatsoever with my leg" (J.77.M).

However, three patients were not satisfied with their physiotherapy experience, due to the content and number of the treatment sessions. They expected more than exercise and advice; they wanted manipulation or other manual treatments for more than three to six post-TKA sessions.

"Just giving you the exercises, I came 6 times, they just put you through the exercises for about an hour and checked your bend, but the exercises that they gave and the exercises that we did and the physio I was already doing it anyway" (Ba.76.M).

"I mean I came for reviews and that, and they said to me after about 3 visits if you are happy and you are carrying on with the exercise we don't need to see you again and I have kept on with the exercises" (P.70.F).

"they didn't do any manipulation at physio; it was just telling you what to do" (J.72.F).

One patient was dissatisfied because physiotherapy service was not offered to her in the hospital, and she paid for it herself.

"I wasn't offered any for either knee from Stepping Hill, so I paid privately for it" (M.80.F).

The last patient did not attend any physiotherapy sessions or do any of the exercises, because she believed that walking was the most suitable exercise for her.

"I don't do exercises; I walk so that is my best exercise – I don't do none of this" (K.80.F).

The experience, expectations and opinions of physiotherapy post-TKA varied from one patient to another. Two patients were satisfied with the exercise and advice. However, three patients were not satisfied, as they expected more than advice and exercise. One patient believed that simply walking is the best exercise post-TKA, while another patient was dissatisfied with physiotherapy because she had to pay for it privately.

Sub- theme 4 - Differences between experiences of first and second knee replacements and the time between them.

Although patients with more than one primary joint replacement experience were not considered in the semi-structured questions in the FGD, the patients raised many issues and concerns regarding the difference between the first and second replacements, how they decided to have a second replacement and the time between the two surgeries. Five FGD participants had both knees replaced, the recent knee in the previous twelve to thirteen months and the first between one and eight years previously.

All patients agreed that their knees had different recovery progressions, but the second experience was better, as they felt more confident and knew what was going on.

"with my second knee because I knew it was going to be ok in the end I did things quicker, I was more confident" (M.80.F).

"I struggled for years, I then had that one done, and I learnt from that so the second" (Ba.76.M).

"Different for each one" (P.70.F).

Two patients' timing between the surgeries was between five and eight years; they wished it had been shorter.

"I would rather have it done sooner but I had other pathology" (P.70.F).

"Hope short time, I would rather have it done for the other knee as soon as possible" (J.77.M).

Only one patient's first experience was horrible, and she was very upset about it because nobody told her what was going on.

"eventually, I said I would never have a second one done, I would never ever after this first one but eventually you have to, but I would try anything rather than have it done. We weren't told anything, and you were like lamb to the slaughter really and it's not right" (J.72.F).

Overall, both the first and second replacement experiences were good, but the second replacements were better; the patients had more confidence because they knew the rhythm of the progression of recovery. One patient's first experience was horrible. Two of five patients wished that the time between their replacements had been shorter.

5.4.4 Theme Two: Experience before TKA

Although patients' experience before TKA was not considered in the semi-structured questions in the FGDs, the patients raised many issues that they believed strongly

affected the TKA outcome and their satisfaction with it. The following five sub-themes were identified: the overall experience before TKA and the referral process to the orthopaedic surgeon, ADL limitations before TKA, exercise and physiotherapy before TKA, any alternative treatments that may have helped them improve their conditions before surgery and, finally, their beliefs about the post-TKA outcome.

Sub- theme 1 - Pre-TKA experience with the general practitioner (GP) and orthopaedics referral process

Four patients were completely satisfied with their experience with the general practitioner before the orthopaedics referral in terms of referral timing and the conservative treatments provided to them before the referral.

"Mine *did as much as they could, or He could prevent me from having to have the operation. I was told I shouldn't really be having a knee replacement until I was 70 because of the length of life of a new replacement, and so he was very good he gave me steroid injections for at least 3 years to just keep me going until like you I got to a point where I wasn't able to walk every far and I dreaded going shopping, I dreaded going out" (M.80.F).*

"I struggled for 10 years, my GP gave me 3 or 4 sheets of exercises to do to help strengthen the knee and that is when I started to do it probably 5- 6 years before I had the operation I was given that to make it stronger" (Ba.76.M).

"my GP has been superb" (J.77.M)

"they are under such pressure, but they did their best" (Br.82.F).

Three patients were not satisfied due to the severity of their symptoms and long waits before referral, which may have risked further joint damage.

"When I had my left one done, I was absolutely past the suicidal stage because the pain was that bad. we can't take anymore, and we need some treatment of some sort, replace or whatever. Instead of pushing us right to the limits and risking further damage, then surely it is better to sort it when it is necessarily – we don't all go to the doctors and say oh I want a new this, and a new that for the hell of it – we go because it is something that is absolutely necessary to the change of quality of our lives so why not attend to it."(P.70.F).

"they won't refer you and you have become so much in pain that you say anything is brilliant after that. My knee got damaged because it was a very bad knee and should have got it done ages ago" (J.72.F).

"waiting for the GP's you wait forever. I will never forget, and I couldn't walk, and that went on for a couple of months and I come round to the A&E", "I waited 12 months in agony and then I am sure he told me the bones were rubbing together, no wonder I was in agony" (K.80.F).

There was disagreement in terms of satisfaction with GP management; four patients were satisfied in terms of the conservative treatments provided, advice from the GP and the recommended exercises. In contrast, three patients were not satisfied, as their GPs pushed them to the limit and would not refer them until they could not walk due to severe pain.

Sub- theme 2 - ADL limitation before TKA

Severe pain before surgery limited patients' walking ability to five minutes or fifty yards.

"but I couldn't walk from the supermarket with a bag of shopping to the car 50 yards" (J.77.M).

"where I wasn't able to walk every far and I dreaded going shopping, I dreaded going out with my grandchildren if they said let's go for a walk and I would say oh yes and within about 5minutes I was in a lot of pain" (M.80.F).

Severe pain before surgery limited two patients from doing anything, including walking.

"I couldn't walk, I couldn't do any things, it was in severe pain" (K.80.F).

"I agree the pain was severe I couldn't do any things" (P.70.F), (J.72.F) & (Br.82.F).

On the other hand, one patient said his ability to walk was good before surgery, but he was in severe pain during any activities that required standing.

"*I can walk before the operation I could walk but I was in pain. Even if I went to the library for half hour just standing there looking at books I was in agony just standing and not moving. At the airport standing in the queue for an hour just checking in I was in agony just waiting for your baggage just agony" (Ba.76.M).*

All patients agreed that severe pain before surgery limited their daily activities, their ability to stand and their walking ability; some even suffered during a brief walk for shopping.

Sub- theme 3 - Exercise and physiotherapy experience before TKA

The pre-TKA exercise and physiotherapy experience varied from one patient to another. Two patients recommended physiotherapy before TKA as it helped alleviate their symptoms and improve the muscle strength.

"The physio did a lot of manipulation, gave me exercises to do to try and strengthen the muscles around the knees because they know they are not still particularly strong" (K.80.F).

"the physio was absolutely excellent, gave me exercises to strengthen the leg muscles" (J.77.M).

However, three patients did not recommend pre-TKA physiotherapy, because it would not improve their case or because the recommended exercise was available on a website.

"it didn't help very much. I may have given up with them" (J.72.F).

"I may have given up with them leisurely yes because I was still working as a teacher at the time, so it was trying to fit in doing exercises as well as working" (M.80.F).

"I went to physio, but I don't recommend much to it" "I don't think physio would have helped, the only way I think physio would help is if they gave you exercises to do, which you can get online anyway, the same exercises anyway (Ba.76.M).

Three patients tried to keep themselves fit with regular swimming, yoga and golf.

"I kept my right knee under control by doing the twice a week the yoga and the keep fit" (Br.82.F).

"I did swimming with difficult" (M.80.F).

"I couldn't walk –funny thing I could play golf 3 times a week" (Ba.76.M).

Two patients had no physiotherapy visits before surgery.

"Never had it before" (P.70.F).

"Never even occurred that I could have it to be honest (Br.82.F).

There was disagreement among patients regarding the benefits of physiotherapy or other exercise before surgery. Two patients recommended physiotherapy to improve muscle strength before surgery, while three patients did not because they found it

difficult to stick with the sessions and all the exercises were already available online. Two patients did not attend any physiotherapy sessions before their TKAs. Interestingly, three patients maintained their overall fitness – despite the severity of their pain – through regular yoga, swimming and golf.

Sub- theme 4 - Alternative treatment before TKA

All patients used pain medication before surgery; its controlled pain for all except one patient, who had a steroid injection in the knee every six months for three years before the TKA.

> *"I try Ibuprofen and paracetamol regularly 3 times a day the Ibuprofen and I was a little bit worried about taking it for such a long time so every now and again I had a bit of a break and I don't think it actually helped. Then the GP started doing steroid injections into the knee every 6months and I think I had them for 3 years" (M.80.F).*

Two patients found their walking ability improved with insoles, but another patient who tried insoles found that they made no difference for her.

> *"I went on a website and sent for these heel sole inserts which are brilliant, and I still wear them today in my other shoe, in both shoes actually because they are brilliant. Wear two at a time and without them before the operation I couldn't walk half a mile but with them I could walk a lot further (Ba.76.M).*
>
> *"Yes, I have to wear heeled inserts and for me they worked, If I hadn't had those it would have been unbearable" (K.80.F).*
>
> *"Shoes insole! they didn't do anything for me" (P.70.F).*

One patient preferred to walk while wearing a knee brace.

> *"I wear the brace on my right knee just in case it is sore. I don't like to walk without it" (Ba.76.M).*

Two patients found acupuncture useful in controlling their symptoms.

> "the exercise didn't help very much I had acupuncture which did, I found the acupuncture very good the guy I went to" (M.80.F).
>
> "acupuncture very good" (J.72.F).

All but two patients tried to find alternative treatments that might help ease their symptoms before surgery. One patient tried steroid injections, two others used insoles, one preferred a knee brace and two found acupuncture useful.

Sub- theme 5 - Patients' beliefs about post-TKA outcome

All the patients agreed on the importance of a determined, positive attitude before surgery.

"I think when you go into an operation, well any kind of operation – you have got to have that positive determination" (P.70.F).

"I think too, it starts out with the attitude that you have before you have the operation, you go into it determined that you are going to do X, Y and Z and that is it" (J.77.M).

"it is an attitude of mind a lot because with the things my yoga and my keep fit my one aim was to get back doing that as quickly as I could, and I got back to it gently but very quickly" (Br.76.F).

In addition, all patients agreed on the importance of starting exercise as soon as possible post-TKA to improve muscle strength and facilitate the recovery process.

"you have got to exercise ASAP because if you don't Well you lose your muscles but it's going to be a hell of a lot more painful if you don't" (J.72.F).

"start trying to move and start doing some little bit of exercise which is the way I approached it with my first one" (Br.76.F).

"if you don't exercise You lose your muscles, don't you" (P.70.F).

"I think exercising that you need before the operation I think is you should definitely do it" (Ba.76.M).

Interestingly, one patient believed that male patients had better outcomes than female patients.

"I read somewhere or heard that women don't have a good result as men for some reason" (M.80.F).

Another patient believed that the overuse of the knees in sport led to severe osteoarthritis and that a having a TKA on one knee would make the other knee deteriorate more rapidly.

"I've always been a football player and watcher and what I think caused my major problem was playing too long. I played until I was early 60s. I find there are lots of footballers that have a lot of knee replacements. I think once you have the one knee put right the other one is going to deteriorate" (J.77.M).

All patients agreed on two important issues before surgery: being determined to have a positive attitude and starting exercise as soon as possible. Other individuals offered

opinions such as males enjoying better outcomes than females and knee overuse leading to early joint deterioration.

5.4.5 Theme Three: ADL changes one-year post-TKA

One of the main objectives of the FGD was to explore post-TKA functional improvements from the patient point of view. The patients' feedback on this theme was classified into four sub-themes to cover the diversity of functional improvements: walking ability improvements, other ADL improvements and limitations, new functional ability following TKA and exploring whether they ever forgot that they had undergone a TKA.

Sub- theme 1 - Walking ability one year following TKA

As previously mentioned, all patients had notable limitations in their walking ability before TKA; many could not walk for more than five minutes due to severe pain. At one-year post-TKA, they all reported marked improvements in their walking ability. When we asked if they could walk to a specific shop that required 45 minutes of walking from the hospital, they all answered that they could.

"*Yeah brilliant" (M.80.F), (Ba.76.M) & (J.77.M).*

"Yeah, no pain" (P.70.F), (K.80.F) & (Br.82.F).

"Yeah, yeah" (J.72.F).

Sub- theme 2 - ADL improvements post-TKA

Three patients agreed that their ADL quality and quantity post-TKA were the same as before the surgery but were now free of pain.

"Now, I can do the same amount of activity time before TKA but pain free" (J.72.F).

"It's definitely improved everyone's quality of life now. Now, I can do the Same amount of activity time before TKA but pain free" (Ba.76.M).

"yeah, the same amount of activity time before TKA but without pain" (J.77.M).

However, one patient showed quality improvements in her activity, as she no longer needed to take rests or short breaks during activities, as she did before the surgery.

"I think with the activities it is the same thing, but I felt I had to sit down much more just to rest my knees because they were hurting a lot but now I can just carry on" (M.80.F).

Two patients indicated improvements in both quality and quantity of ADL; they did everything naturally without thinking or worrying, as they did before the surgery.

"I think you do things naturally now without thinking about it, you just get up and get on with it, I can climb up ladders and I can do anything" (Br.82.F).

"I can take the dog for a walk now, I couldn't before, and he is a big dog – he takes me. Same here I couldn't go to the soft play area with my grandchildren if I haven't had my knees done" (P.70.F).

One undertook many new activities that she could not perform before her TKA.

"we ended up in Whitby last July and I was climbing cliffs, climbing rocks" (P.70.F).

The overall ADL comparison before and after TKA varied from one patient to another. Some felt it was the same but pain free, while others felt their ADL improved in term of both quality and quantity.

Sub- theme 3 - ADL limitations and difficulties post-TKA

All patients could not kneel after TKA, although some of them could do that before surgery.

"I do gardening, or I used to do a lot of gardening, I can't kneel. Before TKA, I was kneeling and gardening on those things you have, and it hurt but there is no way I could do it now" (Br.82.F).

"No, I can't kneel it hurts" (J.72F).

"Never tried kneeling" (J.77.M).

"No, I can't kneel" (P.70.F).

"Never tried kneel" (Ba.76.M).

"Never tried kneel" (M.80.F).

Two patients mentioned difficulties due to pain when walking up or down stairs.

"Pain during walk up the stairs Up mainly – I put pressure on my replacement knee to lift myself up. I feel as though it is pushing out from my knee and it is tight as if someone is pushing" (Ba.76.M).

"Pain when going down the stairs with the one knee I feel I am having to turn it sideways I have go down" (M.80.F).

The major limitation post-TKA was an inability to kneel. Two patients found minor difficulties in going up or down stairs; no other limitations were mentioned.

Sub- theme 4 - Forgetting they had a TKA

Only two patients said that they act neutrally without any apprehension and forget that they had knee replacement surgery. The other patients said that they did not forget, as

they have minor pain and discomfort with some activities such as walking up or down stairs.

"My left one from 8 years ago you know I never even think about it. I think you do things naturally now without thinking about it, you just get up and get on with it" (Br.82.F).

"I'm the same, I never even think about it" (P.70.F).

5.4.6 Theme Four: Outcome expectations following TKA

This theme explores what the patients expected to gain from surgery and the factors that modified those expectations, any apprehension they faced before surgery, whether their expectations were met and what they recommend for future patients to improve their experience and outcome.

Sub- theme 1 - Overall expectation following TKA

All agreed that they would feel better, but the meaning of "better" varied from patient to patient. Three patients said their main goal from the surgery was to be better and return to normal ADL before surgery without pain or limping.

"We all expected success, and we all expected to come out swinging. No more limping". doing the same things that you were doing but with no pain" (Ba.76M).

"It wasn't sort of extreme expectations, it was simply and solely mobility, able to do things that you normally do but haven't been able to do because you haven't been able to stand the pain and stiffness and everything else. It is just that focus of getting sort of normality and that better quality of life" (P.70.F).

"doing the same things that you were doing but with no pain" (M.80.F).

"we were going to be back to normal that is how I felt about it". No more limping" (Br.82.F).

Two patients expected to return to playing their favourite sports, football and yoga.

"I wanted to get back to my keep fit and yoga" (Br.82.F).

"I am looking at the possibility of walking football and having a go at that" (J.77.M).

Two patients said they expected everything to be better but did not specify any symptom or ADL.

"will be better" (J.72.F) & "K.80.F).

Most patients' primary expectation was a return to the same ADL as before surgery, but without pain or limping. Two patients had specific expectations of being able to return to playing a specific sport, while two other patients had no specific expectations post-TKA.

Sub- theme 2 - Expectation modification

Two patients' expectations were modified by surgeons, who clarified that TKA was not a magic treatment, but that they would be able to do more with less or even no pain.

"*The doctor is very realistic when I saw him, he said it is not going to be really flexible when you have a new knee, but it will be far less painful, and you will be able to do a lot more without pain" (M.80.F).*

"The surgeon didn't say it would be perfect, but it will be better than it is now" (Ba.76.M).

The other five patients' expectations were modified after they attended the educational class, which advised them to be more realistic about the outcome.

"I came to both knees. I found that helpful they explained it is not magic, you have got to work yourself as well" (J.72.F).

"Yes, I did. they explained How sore you were going to be. To expect it to be sore first 4 or 5 weeks" (Ba.76.M).

"I came to a talk with a physio, I found that helpful" (K.80.F).

"Oh yes I came. It was helpful, I recommend making the educational class compulsory before surgery" (Br.82.F).

The expectations were modified to be more realistic by the surgeon and through attending an educational class pre-TKA. The class provided complete information about what to expect immediately after surgery, such as soreness and swelling for several weeks and what patients should do after their TKAs.

Sub- theme 3 - Apprehension before TKA

Four patients knew others who previously had the surgery and recommended it; no patients talked with anyone who regretted having the surgery.

"I only knew one and she said oh my god you must have it done, she said it is absolutely brilliant" (P.70.F).

"No, people they recommended it" (Br.82.F) & (J.77.M).

One patient believed that recovery varies from one patient to another.

"I haven't spoken to anyone who have regretted it, some have taken longer to recover, and I know someone who it took him 2 years before it started to feel normal and natural – he wasn't in pain it just felt different" (Ba.76.M).

One patient believed that the condition after surgery would be better than not having the surgery.

"so much in pain that you say anything is brilliant after that" (M.80.F).

All patients agreed they were better than they would be without knee replacements, and those who had previously had the surgery recommended it.

Sub- theme 4 - Meeting expectations

All patients said their expectations were met one-year post-surgery, without any other comments. One patient found more of her expectations met after her second replacement than after her first.

"Definitely both have been brilliant" (P.70.F) & (Ba.76.M).

"Yeah brilliant" (M.80.F), (K.80.F) & (Br.82.F).

"More, definitely both have been brilliant" (J.77.M).

"yes, more than the first one" (J.72.F).

Sub- theme 5 - Recommendation and advice for future patients

All participants agreed on the importance of exercise before and after surgery, even if it hurt to do so, so they advised all patients to strengthen their muscles before surgery and warned them to expect pain and discomfort for several months after surgery.

"you get a better quality of life and if you want some normality in your movement then get it done, but you have got to do your bit as well. You have discomfort for about 3 or 4 months and then I think I think it is alright that was me anyway. I did the exercises I was told to but that was all of it" (P.70.F).

"It is going to hurt, Definitely worth it" (J.77.M).

"Exercises even if it hurts" (M.80.F).

"Yeah exercise is the most important thing even before and even afterwards you just keep going" (J.72.F).

"You have got to build up your muscles because we are not using them all the time, they go weak, so if you prepare for the operation by exercising" (Br.82.F).

"I would say exercise before you go in not for day or weeks but for months once you have got arthritis exercise helped me recover" (Ba.76.M).

Two patients recommended bicycle exercise to improve muscle strength and increase knee flexibility.

"Using Bike: Yeah, I think the bicycles help my knee definitely, do it as low as you can so it is really bending which is what you wouldn't normally do on a bike would you" (M.80.F).

"I can cycle - It helped my knee bend in those 3 weeks going I have been about 8 times and I can feel the difference" (Ba.76.M).

All future patients were also advised to ask their surgeon and medical team about suitable painkiller options and any concerns before the surgery.

"More information about Painkillers which work" (K.80.F).

"*More information about Painkillers which work. Some people after the operation said they couldn't sleep for months and months, tossing and turning that is what concerned me, but I slept like a tot but that was because of the morphine. That is the only thing that worked for me" (Ba.76.M).*

"When you go in and you meet all the people and the nurse's staff that leave you under no illusion, anything you want to know they will tell you. So really it is your own fault if you don't know what is going to happen" (Br.82.F).

The summary of advice for future patients is as follows: a) exercise is important before and after surgery to improve muscle strength; b) bicycling post-TKA improves knee bending, according to two patients; c) clarifying all concerns before surgery such as suitable painkillers.

5.5 Discussion

This is the first focus group discussion (FGD) to explore patients' experiences one year after total knee arthroplasty (TKA). The study identified four main themes: the recovery experience post-TKA, the experience before-TKA, activity of daily living (ADL) changes post-TKA, and post-TKA outcome expectations. The recovery experience has four sub-themes: the overall experience, experience with orthopaedic surgeons, experience with physiotherapy, and the differences between first and second knee replacements. Patients' main post-TKA concern was the severity of pain and swelling post-surgery that lasted for weeks, even with pain medication. This finding accords with concerns expressed by patients in previous studies by van Egmond et al. (2015) and Westby et al. (2010), despite differences in FGD timing, patients' ethnicity, and patient age ranges. All patients agreed that they did

not anticipate the severity of post-TKA pain, even with pain medication, and that nobody had told them how much pain and swelling would occur after the TKA.

All participants in the present study were satisfied with their orthopaedic surgeon experience both before and after surgery. This result diverges from the patient feedback reported by Westby et al. (2010) and Zacharia et al. (2016); those subjects complained about poor communication with surgeons. Those patients also recommended that surgeons devote more time to listening to patients to improve their comfort and confidence levels. The high satisfaction reported in the present study may be due to three reasons. First, the patients' concerns and questions about surgery were covered in an optional educational class before surgery and no previous study has explored the effect of an educational intervention before surgery on patients' satisfaction with surgeon communication to compare our findings with. A second possible explanation for the high satisfaction in the current FGD may be due to the participants' ages, all the current participants were quite old (70–82 years), in comparison with the previous FGD study age range of 46–78 years; older patients are commonly not as demanding as the young. A third possible explanation for surgeon satisfaction in the current FGD is that five out of seven patients had a previous contralateral knee arthroplasty and so the surgical experience was familiar them. Therefore, a future study is recommended with a wide age range and limited one arthroplasty experience to explore the effect of pre-TKA education classes on patients' satisfaction with their surgical experience to overcome the current sample limitations.

The patients reported varying experience and satisfaction with post-TKA physiotherapy. Differences in satisfaction may result from different expectations, as some patients expected more than exercise and advice: manual therapy, manipulation, and more than three to six sessions. By contrast, patients in Westby et al.'s (2010) study were unsatisfied due to long waiting lists for physiotherapy service and the high cost of private service. Similar results were reported by van Egmond et al. (2015), as most patients did not receive proper post-TKA rehabilitation or advice. Accordingly, clarifying the post-TKA physiotherapy objective for patients before surgery may enhance their taking an active role in exercise and improve their satisfaction.

This is the first FGD to explore the difference between first and second knee replacements experience. Five patients had two experiences; they all agreed that the second experience was better because they felt more confident and knew what was going on. This may clarify the impact of pre-TKA education, as patients progress well and have greater levels of confidence if they know in detail what is likely to occur.

Although patients' experience before-TKA was not directly addressed in the semi-structured questions in the FGD reported here, the patients talked about it extensively, particularly how it could affect outcomes and overall post-surgical experience. This theme covers five areas: their experience with general practitioners (GP), ADL limitations before surgery, exercise and physiotherapy pre-TKA, and alternative treatments that helped them to control their symptoms before TKA. The present study obtained results comparable to those found in Westby et al. (2010) in terms of satisfaction with GP service and the timing of referral to the orthopaedic surgeon. The patients were satisfied with GPs for the conservative treatments they provided and their exercise recommendations. The main dissatisfaction was due to waiting a long time before the orthopaedic surgeon referral; some patients had to wait so long that they could not walk due to severe pain.

Severe pain before surgery led to ADL limitations like walking, standing, and shopping. This accords with the results of Zacharia et al. (2016), where pre-TKA pain was reported to limit patients' ADL, cause earning losses due to their inability to work, and lead to their dependence on others for help with stairs and long walks. Thus, patients' mental health was affected before surgery and may affect post-TKA outcomes.

Despite the severity of pre-TKA pain, most patients agreed on the importance of strengthening muscles through physiotherapy sessions, following an online exercise programme at home or keeping fit with swimming or yoga. In addition, the patients recommended foot insoles, knee braces, and acupuncture to control the severity of pain before the TKA. Interestingly, this agreement was not found in any previous FGDs comprised of patients who underwent TKA.

All FGD participants agreed on the importance of a positive attitude and starting exercise as soon as possible after surgery. These results are similar to those found by Westby et al. (2010), who also reported on the importance of a positive attitude before surgery. Emotional well-being in the form of hope, self-worth, and confidence has been recognised as a crucial factor in coping with post-surgical outcomes (Street, Makoul, Arora, & Epstein, 2009).

The third theme involved exploring ADL changes one year after the TKA. The FGD revealed that all patients' walking ability and ADL improved in both quality and quantity, largely because those activities were now pain-free. This reinforces the results found by Westby et al. (2010) and Zacharia et al. (2016). Those patients were all satisfied with their ADL improvements: activities such as walking, climbing stairs, and returning to work were pain-free. On the other hand, none of the FGD participants could kneel post-TKA, a limitation also reported in the study by Zacharia et al. (2016), where all participants were

unable to use the squat toilets that they had used before surgery. ADL limitations may affect the level of post-TKA satisfaction. For instance, patients who were told about this limitation before surgery showed higher satisfaction levels than those who did not know in advance that they would be obliged to use western toilets post-TKA (Zacharia et al., 2016). Thus, clarifying possible post-TKA limitations in educational classes or during surgical consultations is highly recommended.

The last sub-theme explored the return to normality or acting naturally without apprehension post-TKA. The FGD in the present study reported similar results to those found in Westby et al. (2010), and both are based almost entirely on individuals' definitions of normality. Some patients defined it as being able to do everything they could before surgery without any kind of pain or limping. Based on this definition, a few patients had minor pain or discomfort with some ADL like stairs, but the majority felt normal after one year. Others defined normality as being able to once again play the sports they enjoyed before the end stage of degeneration without pain or limitations, thus ignoring the aging factor. This illustrates the powerful impact of patient expectations from surgery that is explored below.

The last theme deals with patient expectations, expectation modifications, and the degree to which patients expected what they ultimately experienced. The results reported here agree with those found in Westby et al. (2010); all patients expect to feel better, but- as the previous paragraph makes clear- the meaning of "better" or "normal" differs from one patient to another. Patients' expectations ranged from performing the same ADL as before surgery without pain or limping to returning to play their favourite sport without limitations. Unclear or unrealistic expectations about post-TKA outcomes and recovery periods may lead to disappointment, great pain, and even depression.

All patients initially expected that the surgery would work "like magic" and that they would be perfect immediately afterwards. Their expectations were modified to be more realistic by their surgeons and by attending a pre-TKA educational class. After those interventions, patients learned to expect soreness and swelling for four to five weeks, that they would have to work on their own recovery through exercise, and that, while the new knee would not be really flexible, it would be far less painful. The participants in the present study agreed with those in Westby et al. (2010) on the importance of modifying expectations before surgery either though consulting with the surgeon or by taking a compulsory educational class. This may explain the high level of satisfaction post-TKA reported in the present study, as patients reported that surgery met their expectations.

In the FGD reported here, it was found that participants who were satisfied with their post-TKA experience had satisfactory knee joint function (44–48) based on the Oxford Knee Score (OKS). This contradicts the results found in the FGDs reported by Zacharia et al. (2016); they found no association between satisfaction among FGDs and participants' Knee Society Scores (KSS). The participants with high KSS showed low satisfaction in their FGDs, while patients with low KSS reported higher satisfaction. This could be due to the focus of the KSS on pain, knee range of motion, and alignments; it has only three questions for function (walking ability, using stairs, and using a walking aid). By contrast, the OKS is largely based on functions of daily living like bathing, using public transportation, walking ability, moving from sitting to standing positions, limping, kneeling, stability, housework, shopping, and stairs (Mont et al., 2015).

On the other hand, only the patient with mild to moderate knee function (33) showed moderate satisfaction in the FGD due to a poor experience with her first knee surgery. Her satisfaction as expressed in the FGD was good with her second knee replacement, which may illustrate the effect of overall experience on the score of patient-reported outcome measurements (PROMs), at least for some patients. Further study is recommended to explore the discrepancy between satisfaction expressed in FGDs and different types of PROMs.

In summary, patient attitude, sufficient pre-operative education, expectation modification, communication with the surgeon, and patients' taking an active role in rehabilitation may all affect post-TKA outcomes and satisfaction. Hence, the recommendation is to address all these issues before TKA to maximise outcomes and patient satisfaction.

5.4.1 Strengths of the study

This is the first FGD to explore patient experience one year after TKA and the differences in experience between first and second knee replacements. It boasts many methodological strengths, including the methods of data collection and analysis. An FGD gathers data with a greater degree of spontaneity in the patients' views than one-to-one interviews, where the interaction is only between a patient and researcher and there is a heavy reliance on patient responses. The present study finds that honesty, as promoted by a transparent description of the narrative data analysis process by two independent researchers, improved the credibility of the findings. Moreover, the flexible thematic analysis provides rich and detailed data about post-TKA experiences that enhance the findings' credibility. Including both males and females, a mixture of unilateral and bilateral experiences, wide range of BMI, and patients from different surgeons all improve the richness of the findings.

5.4.2 Limitations and future recommendations

There are some limitations in the FGD reported here. The findings are based on one FGD, but the recommended level of data saturation is reached after four to six FGD sessions. Therefore, the findings cannot be generalised to a broader population due to the small sample size, limited age range and small number of discussion groups. We thus recommend testing these findings against other FGDs using structural questionnaires and quantitative methods. As to limitations within the sample, all the present study participants were retired, so we could not explore return-to-work barriers or a younger age group's experiences and needs; in addition, all participants were highly educated. Access to health care and associated programs is not universal and differs from country to country, so other patient experiences and barriers may differ from the findings reported here. Exploring post-TKA experience in different cultures and countries might help capture important differences. Finally, although one surgeon was present at the FGD, all patients spoke freely as he was not their surgeon.

5.4.3 Clinical recommendations

Sufficient communication between surgeon and patients before surgery may improve patient confidence and self-efficacy to lead to the most positive attitude possible.

Modify any unrealistic or unclear expectations regarding recovery rates and outcomes is crucial to minimising post-TKA disappointment, as is clarifying possible ADL limitations after surgery.

The intensity and duration of post-TKA pain were both generally unexpected among the patients in this FGD. Clear and realistic guidance should be provided about pain issues, along with an appropriate plan to control acute post-TKA pain.

Patients should be advised to strengthen the relevant muscles before TKA and as soon after surgery as is feasible.

Clear post-TKA physiotherapy objectives may enhance the patient's role in rehabilitation. Elucidating what to expect from physiotherapy services post-TKA in term of treatment options based on an evidence-based protocol and the number of sessions authorised by hospital policy may reinforce patient satisfaction.

Although the picture of the patients' short-long outcomes, experiences and satisfaction became clearer based on previous retrospective analysis and FGD, it is still not clear if free-living physical activity improves post-TKA or if it affects their satisfaction. Therefore, the next chapter prospectively assesses objective outcomes changes post-TKA and their correlation with patients' satisfaction.

Chapter 6- Prospective study to assess functional outcomes post-Total Knee Arthroplasty

6.0 Introduction

In reviewing the literature in Chapter Two on outcome measurements post- total knee arthroplasty (TKA), it is apparent that most of the previous literature has assessed outcomes with different methods, such as PROMs, PBOMs, and physical activity. None of them have assessed outcomes using a combination of OKS, PBOMs, balance and physical behaviour in order to capture the comprehensive scope of outcomes. In the Saudi Arabian population, no studies have explored outcomes post-TKA in terms of OKS, balance or free- living physical behaviour.

A unique aspect of this work is that it is the first study to explore physical activity volumes and event-based patterns post-TKA. Assessment in the current study was not limited to physical activity (PA) in term of steps and stepping time per day, but also assesses physical behaviour (PB), which objectively measures sedentary time, breaks in sedentary time, moderate-to-vigorous physical activity (MVPA), slow-to-moderate physical activity (SMPA) and total physical activity volume (steps number, time spent on stepping, sedentary, standing and upright) (Henson et al., 2013).

Moreover, it is the first study to correlate objective outcomes with free-living PA and satisfaction to devise an objective prediction equation that may improve the understanding of individual patients' outcomes and satisfaction post-TKA. Understanding individual recovery post-TKA and exploring the factors that affect it may help to prepare patients before surgery or modify their expectations to maximise their outcomes and satisfaction as much as possible.

A secondary aim of the study was to assess the differences in outcome between two knee arthroplasty approaches in two different countries (the United Kingdom (UK) and the Kingdom of Saudi Arabia (KSA)) using 12-month OKS data from Study One and the current study's TKA to determine the strengths and weaknesses of each approach and environmental limitations, if present, in order to improve health service provision and patients' outcomes and satisfaction.

6.1 Patients and methods

6.1.1 Study design and participants

The study was a prospective six- and twelve-month follow-up trial to explore outcomes post-TKA. Salford University Ethical Panel approval (HSR1617-39, Appendix 1) and King Khalid University Hospital Approval (E-17-2395, Appendix 2) were obtained. The study methodology is registered at ClinicalTrials.gov (NCT02998125). All patients scheduled for elective primary unilateral TKA for end-stage knee osteoarthritis, who were in a stable and

controlled medical condition according to exclusion criteria in the previous methodology chapter, were invited to participate during preadmission orthopaedics clinic visits to King Khaled University Hospital, Riyadh between March and May 2017 (Figure 6-1).

An information sheet was given to all participants who matched the inclusion criteria and agreed to participate in surgery-booked confirmation appointments to clarify the objectives of the study. Surgery-booked confirmation appointments are usually arranged 2–3 weeks before the admission date. Before participating, patients completed a consent form and were advised of their right to clarify any concerns about the study with the researcher. A patient's participation or otherwise did not affect the quality of service they received, all patients received conventional orthopaedic care and a standard level of physiotherapy according to hospital protocols.

6.1.2 Sample-size estimation for outcome measures

6.1.2.1 Oxford Knee Score (OKS)

The required sample-size estimation for Oxford Knee Score was based on the previous study's one-year follow-up post-TKA standard deviation for difference and effect size (Beard et al., 2015). The standard deviation of difference (σ) =10.02, effect size = 4 points with a significance level of α 0.05 and a power of (1-β) 0.95 indicated a minimum of 82 patients was required. In consideration of a possible 20 per cent drop-out due to a long follow-up, the corrected sample size required was 103 patients (Naing, 2003) .

6.1.2.2 Performance-based measurements (PBMs)

Sample-size estimation for performance-based measurements post-TKA was based on the standard deviation of difference (σ) and effect size from the previous study, with a significance level of α=0.05 and a power of (1-β) 0.95. The estimation indicated that we needed 41 participants to determine an anticipated group difference with effect size .79 on a timed up-and-go test (Mizner et al., 2011). A minimum of eight patients was required to detect minimal important changes in a 6-minute walking test which was 26 metres post-TKA (Naylor et al., 2016). To detect minimal detectable changes of 5.49 seconds in a stair-climb test, a minimum of seven patients was required (Kennedy et al., 2005). In consideration of a possible 20 per cent dropout due to long-term follow-up, the corrected sample size estimated for all performance-based measurements was 50 patients (Naing et al., 2003).

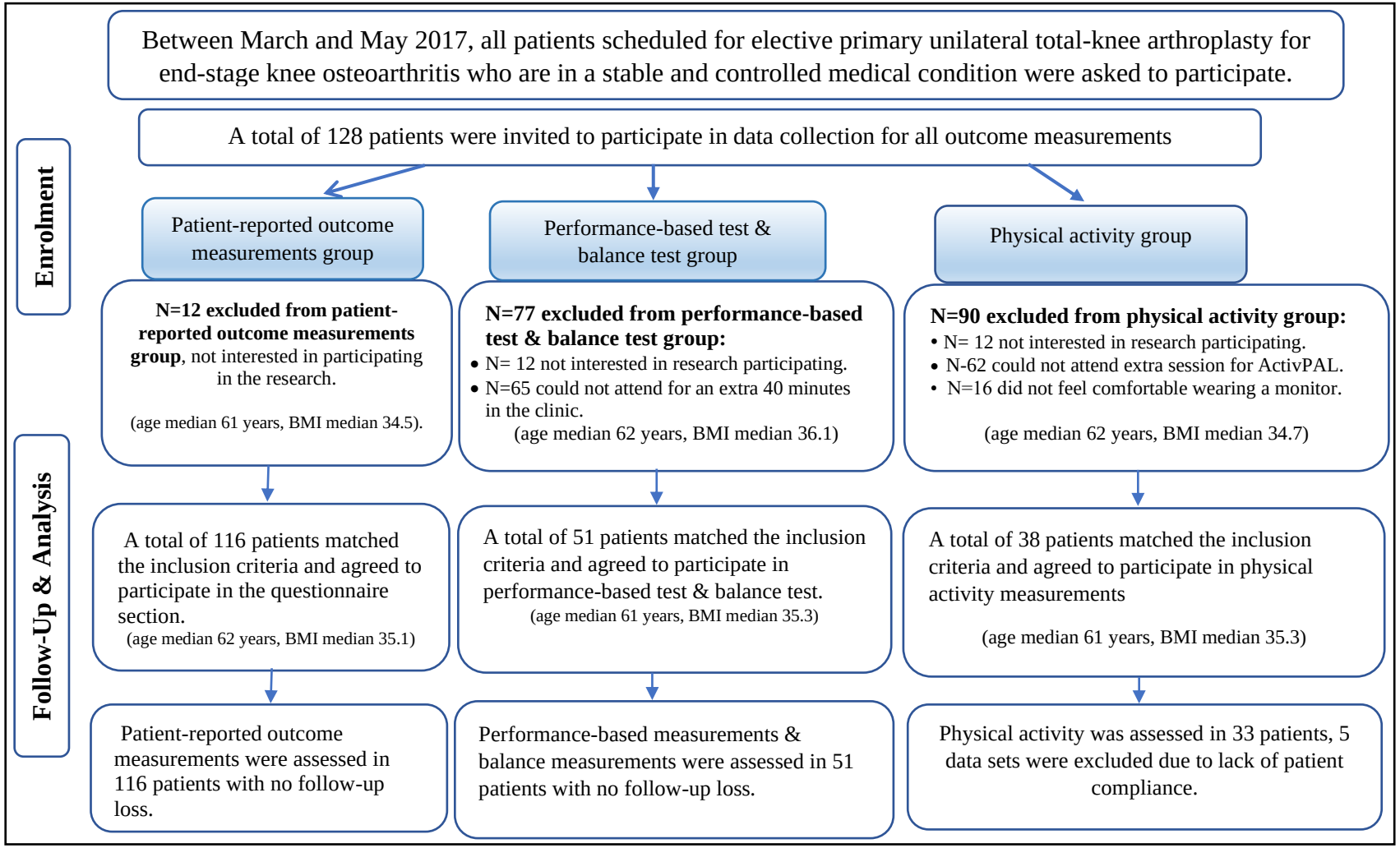

Figure 6- 1. Patient flowchart showing exclusions

6.1.2.3 Star-excursion balance test (SEBT)

No previous study has used a Star-excursion balance test post-TKA, therefore the required sample size was estimated based on the assumption that a difference of 1 standard deviation in the sample mean would be a clinically meaningful difference with a significance level of p=0.05 and a power of 90%. So, a minimum sample size of 40 patients was required. In consideration of a possible 20 per cent drop-out due to a long follow-up, the corrected sample size required was a minimum of 48 patients (Betsy & Carmen, 2007; Cohen, 1988).

6.1.2.4 Physical Behaviour (PB)

Power-calculation methods based on the level of confidence and degree of variability obtained from the available literature are not applicable to the current study as the only available study that explored physical behaviour using an activPAL monitor post-TKA showed no significant changes in the time spent sitting, lying and stepping between pre- and post-operation. However, the study did show improvements in the number of steps and the current study targets overall improvements in activity in terms of cadence rather than isolating the number of steps (Lutzner et al., 2014). The required sample size estimated was based on the assumption that a difference of 1 standard deviation in the sample mean would be a clinically meaningful difference, with a significance level of p=0.05 and a power of 80%. Therefore, a minimum sample of 30 patients was required (Betsy & Carmen, 2007; Cohen, 1988). In consideration of a possible 20 per cent drop-out due to a long follow-up, the corrected sample size required was 36 patients (Naing, 2003).

6.1.2.5 Compare the OKS score between the UK and KSA patients

Sample-size estimation for OKS score comparisons between two independent groups post-TKA was based on the standard deviation of difference (σ) and effect size from the previous study, with a significance level of α=0.05 and a power of (1-β) 0.95. The estimation indicated that we needed 104 participants to confirm an anticipated group difference with an effect size of 4 points on OKS score (Beard et al., 2015; Naing et al., 2003).

6.1.3 Surgical Intervention and Rehabilitation

All patients underwent a midline incision with a medial parapatellar approach to surgery by one of five consultant surgeons. No intra-operative complications were reported. Three different prosthesis designs were used; NexGen® LPS Flex cemented knee replacement or Persona knee replacement system manufactured by Zimmer, Inc. and Attune® knee replacement system manufactured by DePuy Synthes. High-flexion knee prostheses are preferred in the KSA, rather more than traditional standard posterior-stabilized total knee arthroplasty designs because of their superiority in supporting more fulfilling flexion

activities, such as squatting, kneeling and cross-legged sitting, as these are essential for religious and cultural participation (Jain et al., 2013).

The aim of in-patient physiotherapy is to mobilize patients on the first day after surgery, employing either weight-bearing or partial weight-bearing as tolerated. In-patient exercises include bed exercise, lower limb strengthening, range of motion exercises, gait training and stair training, all designed to get patients back to an acceptable level of functional independence. Out-patient physiotherapy continues for not less than one month, with an average of three physiotherapy sessions per week. The exercise programme includes progressive lower-limb range-of-motion exercises, strengthening exercises and gait-and-balance training.

Arthroplasty approaches in the UK differ slightly as standard posterior-stabilized total knee arthroplasty designs are more common and out-patient physiotherapy commonly ranges between 3-6 sessions based on patient preference. The sessions aim to educate patients and develop their confidence to perform suitable range-of-motion knee exercises and lower limb strengthening exercises at home. In-patient physiotherapy is similar in terms of content and objectives.

6.1.4. Outcome-measurement protocols

6.1.4.1. Oxford Knee Score, Knee-injury and Osteoarthritis Outcome Score and pain visual analogue scale. Patients were asked to fill out the forms independently, without any interpretation. Visual analogue pain scale was used to assess pain before and after surgery and to evaluate the construct validity of the Arabic version of Oxford Knee Score. The scale consists of a 100 mm-long horizontal line ranging from no pain to intolerable pain. Patients were instructed to make a mark on the line at a point that matched their pain. An assessor measured the position of the mark with a ruler, in millimetres, and converted it into points (0 points = no pain to 100 points = intolerable pain) (Bullens et al., 2001).

6.1.4.2. Assessment of performance-based measurements was made by four physical functional clinical tests according to Osteoarthritis Research Society International recommendations post-arthroplasty surgery (30 s chair-stand test, stair-climb test, timed up-and-go test and a 6 m walk test). The order of tests was in randomised and included 10 minutes of rest between tests to minimize the fatigue effect (Kennedy et al., 2005).

6.1.4.2.1 Thirty second chair-stand test;

Based on a published protocol, a chair of 17 inches (45cm) height was used as the starting position for patients sitting with their arms across their chest. Patients were instructed to stand and then sit with good buttock placement and back support, their hands-on armrests

and feet correctly placed, then stand again as fast and safely as they could. The assessor counted the number of complete chair stands within 30 s. The mean of two trials was used for analysis (Gill & McBurney, 2008; Unver et al., 2015).

6.1.4.2.2. Stair-climb test

Using a stopwatch accurate to 1/100 s, an assessor measured the time required for a patient, using a handrail if required, to ascend and descend a flight of twelve steps, each 18 cm high and 28 cm deep. Patients were instructed to ascend and descend the stairs as quickly, safely and comfortably as they could. The mean of two trials was used for analysis (Mizner et al., 2011).

6.1.4.2.3 Timed up-and-go test

According to a published protocol, the test procedure used a stopwatch accurate to 1/100 s; a chair of standard 45 cm height, with armrests, was placed on an outdoor level footpath and a line 3 metres from the chair was drawn. Patients were instructed to stand up from the chair, using the arms if required, walk 3 metres to the line, then turn around, walk and sit back down on the chair as quickly, safely and comfortably as they could. An assessor started timing as the patient leant forward to stand up and stopped when the patient's hips made contact with the seat to sit down. An average of two repetitions was analysed (Ko et al., 2013; Mizner et al., 2011; Podsiadlo & Richardson, 1991).

6.1.4.2.4 Six-minute walk test

Based on published guidelines, this test measured how far patients could walk in 6 minutes along a level 25-metre footpath. Patients could use an assistive device if required, take a rest if necessary and have standardized encouragement after each minute. The assessor asked the patient to stop after 6 minutes. Only one test was performed to avoid fatigue (Ko et al., 2013; Mizner et al., 2011).

6.1.4.3. Balance was assessed using the simple Star Excursion Balance Test, which is considered to be a reliable, valid dynamic test to identify dynamic balance deficits in patients with lower-extremity conditions (Gribble et al., 2012; Hertel et al., 2006). In the Star Excursion Balance Test, three tape measures were fixed to the clinic floor, one oriented anteriorly to the apex and two aligned at 135° to the anterior tape in the posterolateral and posteromedial directions (Fig. 6-2) (Fullam et al., 2014).

After explaining the procedure, the researcher demonstrated the test to the patient to clarify its requirements. The patient stood in the centre of the grid and was instructed to stand on the affected or operated leg while reaching out as far as possible in one of three directions with the other lower extremity, and then return that leg to the centre. The participant was

asked to perform the test barefoot, keeping the heel of the stance leg on the floor at all times and to bend the knee of the stance leg. If the participant did not carry out any of these instructions, the trial was repeated. Each participant first performed two training trials in two directions to minimize the learning effect, followed by rest. Participants were asked to complete three consecutive trials in each reach direction.

The assessor measured the reach distance in each direction in centimetres and then normalised the average of the three trials to leg length. Limb length was measured while lying in a supine position, from the anterior superior iliac spine to the centre of the ipsilateral medial malleolus. Reach distances were normalised to limb length by calculating the maximum reach distance (%MAXD) using the formula: (excursion distance/limb length) ×100 (Coughlan et al., 2012; Fullam et al., 2014; Robinson & Gribble, 2008).

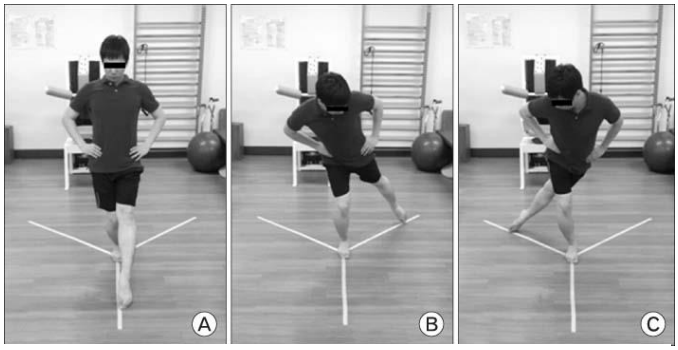

Figure 6- 2. Setup for the Star Excursion Balance Test.

6.1.4.4.Physical activity measurements were taken using an activPAL activity monitor (PAL Technologies, Glasgow, UK) as this proven accelerometer provides objective quantification of free-living physical activity without any modification (Dahlgren et al., 2010; Schmalzried et al., 1998). It was suitable as it is light in weight (20g), includes an inclinometer and is small in size (53 x 35 x 7 mm, Fig. 6-3). The device was worn by patient's mid-thigh, secured by non-allergic waterproof adhesive tape under their clothes, for 7–8 days before surgery and for 6 and 12 months afterwards. Clear written and verbal instructions were given to patients as they had to wear it all day and all night, except when bathing or swimming (they could take a shower with it on). After the test period, the monitor was removed, and data downloaded for analysis using ActivPAL software. The accelerometer estimated the time spent in different body positions, such as lying, sitting and standing, plus the numbers of steps taken. This allowed a clear objective estimation of the rest and active time of participants before and after surgery, averaged over 7–10 days (Lutzner et al., 2014; Meiring et al., 2016).

Figure 6- 3. The ActivPAL monitor.

6.1.4.5 Comorbidity assessments

To assess the effect of comorbidity on PA changes post-TKA, the Charlson Comorbidity Index (CCI) was used. It was published in 1987 as a valid method to classify comorbid conditions that affect mortality. The CCI provide a standardised reliable method to assess comorbidity. The commonly used version identifies 17 comorbidity conditions that correlate with mortality and assigns weights to each of them, ranging from 6 points to 1 point. The summation of points from the 17 conditions ranges from a maximal disease burden (29) to a no disease burden (0) (Voskuijl, Hageman, & Ring, 2014).

6.1.5 Testing Procedures

Patients were first given Arabic language forms during a preadmission session. Preadmission sessions are usually 7–10 days before the admission date for recent laboratory tests and X-ray requirements. Patients were instructed to complete Arabic versions of OKS, KOOS and visual analogue scale (VAS) before arthroplasty as baseline data (Appendix 3 for Arabic version and Appendix 4 for English versions). In addition to completing the questionnaire, an assessment using PBMs and SEBT measurements was performed (30 s chair-stand test, stair-climb test, timed up-and-go test and a 6 m walk test) while adhering to Osteoarthritis Research Society International recommendations for post-arthroplasty patients (Dobson et al., 2013). The activPAL monitor was applied to patients to measure their physical activity 7–8 days before surgery, with clear instructions for use at home.

In admission sessions in an orthopaedics inpatients ward, an activPAL was collected from each patient. Second and third measurement sessions at 6 and 12 months post-TKA were conducted in an orthopaedics outpatient's clinic exactly like the first measurement procedures. The last measurement at 12 months post-TKA had extra outcomes, patients were instructed to complete a satisfaction scale in addition to the original questionnaire including (OKS, KOOS AND VAS), full details are clarified in Figure 6-4(Hyong & Kim, 2014; Impellizzeri et al., 2011; Jenny & Diesinger, 2011; Naal et al., 2009).

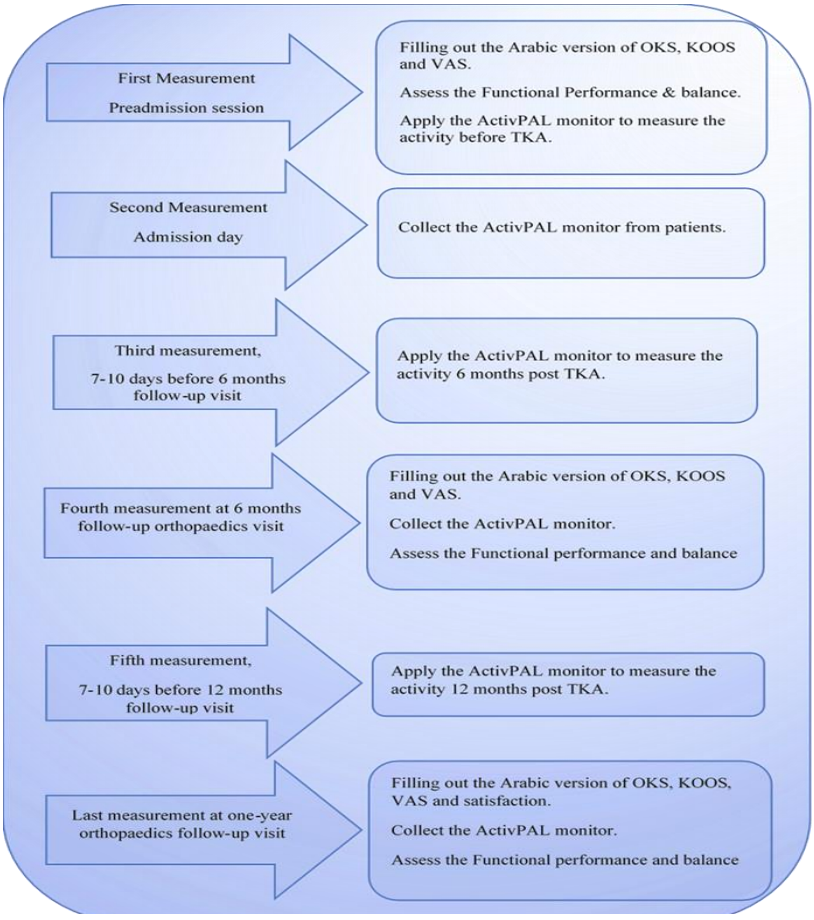

Figure 6-4. Testing procedure for outcomes post-total knee arthroplasty

6.1.6 Data processing

6.1.6.1 Patient-reported outcomes:

OKS data entry was undertaken according to OKS guidelines 2015, with scores for each question (item) from 0 to 4, with 0 being the worst outcome and 4 the best. The scores were then summed to produce an overall score between 0 (worst possible) to 48 (best possible).

6.1.6.2 Physical-behaviour (PB) measurements

PB data were extracted from the activPAL monitor using the manufacturer's software (V7.2.32), then the CSV format file was imported into an Excel sheet for further analysis using Excel and SPSS (SPSS Inc., Chicago, IL, USA, release 21 for Windows). An event file for each patient contained more precise information in a chronological list for all periods of sitting/ lying, stepping and standing and each step, with the time each period began and period duration, and this was used to analyse cadence improvements (Granat, 2012). The amount of data was rounded to 24-hour data sets and the incomplete data sets of the first and last days were removed. Full 24-hour data sets at all three time points were analysed.

To explore overall changes in the cadence bands post-TKA, the total time spent in cadence bands of less than 60 steps/minute (purposeful steps), slow to medium steps (between 60

and 100 steps/minute) and moderate to vigorous MVPA (>100 steps/minute) each week prior to TKA, 6 and 12 months post-TKA was explored in all bout lengths for each participant. In addition, MVPA time was explored for bouts ≥10 continuous minutes, bouts 5 continuous minutes and bouts ≥ one continuous minute [12,19] (Granat, 2012; Schmalzried et al., 1998; Tudor-Locke et al., 2018).

6.2 Results

The current results cover four main sections; the first section contains outcome changes 12 months post- TKA. So, all the questionnaire data, PBMs and SEBT results are analysed in the first part. The second section covers physical behaviour analysis in terms of both volume and pattern changes 12 months post-TKA. Table 6-1 shows the demographic characteristics of the patients for each outcome measurement group. The Kruskal-Wallis H test was used as the normality assumption was violated, as assessed by a Kolmogorov-Smirnov test ($p < 0.05$), for both age and BMI. The test showed that the patients who participated were not significantly different from those who could not volunteer due to their age, gender or BMI in all three groups ($P>.05$) (Table 6-1).

The third section explores the correlation between all outcome measurements with PA and satisfaction, concluding with prediction equations. The last section compares OKS score outcomes before, six and twelve months post-TKA between two different approaches in the UK and the KSA.

6.2.1 Section one: outcome changes 12 months post-TKA

Assumption Analysis

To explore the changes in OKS, KOOS, VAS, SEBT and PBM tests post-TKA, a Friedman test was used as a non-parametric test alternative to one-way repeated measures ANOVA, because the assumption of normality distribution is violated, as assessed by a Kolmogorov-Smirnov test ($p < 0.05$) for all questionnaire data. A Friedman test is used to determine whether any statistically significant differences exist between three or more related groups, in this case pre-TKA, 6 months post-TKA, and 12 months post-TKA. Then, pairwise comparisons were performed with a Bonferroni correction for multiple comparisons (Altman, 1991). The effect size calculated based on the following formula $w=\chi^2\omega/N(K-1)$, where $\chi^2\omega$: the Friedman test statistic value, N: sample size and K: the number of measurements per subject (Tomczak & Tomczak, 2014). Commonly it used to compare different clinical measures, the effect size is considered large, moderate and small if the value 0.8, 0.5 and 0.2 respectively (Dunbar et al., 2000).

Table 6 - 1. Demographic Characteristics of Patient Cohorts

		Questionnaire patients				Performance-based measurement & balance patients				Physical activity patients			
		Age		Body Mass index (BMI)		Age		Body Mass index (BMI)		Age		Body Mass index (BMI)	
		Included patients	Excluded patients	Included patients	Excluded patients	Included patients	Excluded patients	Included patients	Excluded patients	Included patients	Excluded patients	Included patients	Excluded patients
Patient characteristics	N=	116	12	116	12	51	65	51	65	33	83	33	83
	Median	62	61	35.1	34.5	61	62	35.3	36.1	61	62	35.3	34.7
	Interquartile range	10	15	6.5	8	13	11	6.7	9	9.5	12	7.29	11
	Minimum	43	46	20.6	20.5	43	45	23.79	23.1	46	43	28.54	20.6
	Maximum	85	81	48.5	48.1	85	78	48.5	48.3	85	82	44.90	48.5
	No. (%) of female patients	96 (82.8%)				42 (82.4%)				27 (81.8%)			
Kruskal-Wallis H test	Standardized test statistic	.331		.679		.393		.082		.597		.844	
	Significant P	.740		.497		.694		.735		.550		.399	

6.2.1.1 Questionnaire data

A total of 128 patients were invited to participate in the study, of which 116 patients agreed to participate in the questionnaire section, the remaining 12 patients were not interested in participating in the research. Between March 2017 and October 2018, patients' reported outcome measurments were assessed in 116 patients awaiting knee replacement, six and twelve months post-surgery (Figure 6-1). Ninety-six female and 20 male patients had median ages of 61 years (range 43–81 years) and 69 years (range 54–85 years), respectively. The body-mass-index medians were 36.05 for females and 30.02 for males.

6.2.1.1.1 Oxford Knee Score (OKS) analysis

Total OKS, functional and pain components were significantly different at the different time points post-TKA: (χ^2 (2) = 232), (χ^2 (2) = 209.6) and (χ^2 (2) = 221.49), with $p < 0.0005$, respectively. The median changes for all time points in Table 6-2. Post hoc analysis revealed significant differences in total OKS, functional and pain components at all time points post-TKA, with $p = 0.0005$, the effect size was large 4.5 (Table 6-3).

6.2.1.1.2 Knee injury and Osteoarthritis Outcome Score (KOOS) analysis

KOOS pain, symptom, ADL, sport and QoL subscales were significantly different at the different time points post-TKA: (χ^2(2) = 216.23), (χ^2 (2) = 201.974), (χ^2 (2) = 184.92), (χ^2 (2) = 93) and (χ^2 (2) = 182.74), with $p < 0.0005$, respectively. The median changes for all time points in Table 6-2. Post hoc analysis revealed significant differences in KOOS pain, symptom and ADL subscales at all time points (between pre-and 12 months post-TKA, pre-TKA and 6 months post-TKA, 6 months post-TKA and 12 months post-TKA, $p = 0.0005$), whereas the sport and QoL subscales were statistically significant different between pre-TKA and 6 months post-TKA and between pre-TKA and 12 months post-TKA, but with no significant changes between 6 and 12 months post-TKA. The effect size for KOOS pain, symptom, ADL, sport and QoL subscales were large 3.7, 3.1, 3.6, 0.7 and 3.5 respectively (Table 6-3).

6.2.1.1.3 Visual Analogue Scale (VAS) analysis

Pain scores using VAS were also significantly different at the different time points post-TKA, (χ^2 (2) = 217.03, $p < 0.0005$). The median changes for all time points in Table 6-2. Post hoc analysis showed significant differences in VAS at all time points post-TKA p = 0.0005, the effect size was large 3.7 (Table 6-3).

Table 6 -2. Questionnaire median changes post-total knee arthroplasty

Questionnaire		Pre-TKA		6 months post-TKA		12 months post-TKA	
		Median	Interquartile Range	Median	Interquartile Range	Median	Interquartile Range
KOOS	Pain subscale	19	16	64	11	78	6
	Symptom	32	28	79	11	93	6
	ADL	29	19	78	8	84	6
	sport	0	0	5	5	5	5
	QoL	19	12	69	6	69	6
OKS	Total score	14	6	34	5	40	2
	Function	5	1	12	3	15	1
	pain	9	5	21	4	25	1
VAS		94	16	18	166	2	6

Table 6 -3. Questionnaire data Pairwise Comparisons

Questionnaire	Sample 1/Sample2	Test Statistic	Standard Error	Std. Test Statistic	Significance	Adjusted Significance
Overall OKS score	pre-TKA/6 months post-TKA	-1.00	.131	-7.616	.000	.000
	pre-TKA/12 months post-TKA	-2.00	.131	-15.232	.000	.000
	6 months post-TKA/12 months post-TKA	-1.00	.131	-7.616	.000	.000
OKS functional component	pre-TKA/6 months post-TKA	-1.095	.131	-8.338	.000	.000
	pre-TKA/12 months post-TKA	-1.853	.131	-14.115	.000	.000
	6 months post-TKA/12 months post-TKA	-.759	.131	-5.777	.000	.000
OKS pain component	pre-TKA/6 months post-TKA	-1.073	.131	-8.174	.000	.000
	pre-TKA/12 months post-TKA	-1.927	.131	-14.673	.000	.000
	6 months post-TKA/12 months post-TKA	-.853	.131	-6.500	.000	.000
KOOS pain subscale	pre-TKA/6 months post-TKA	-.974	.131	-7.419	.000	.000
	pre-TKA/12 months post-TKA	-1.922	.131	-14.641	.000	.000
	6 months post-TKA/12 months post-TKA	-.948	.131	-7.222	.000	.000
KOOS symptom subscale	pre-TKA/6 months post-TKA	-.931	.131	-7.091	.000	.000
	pre-TKA/12 months post-TKA	-1.862	.131	-14.181	.000	.000
	6 months post-TKA/12 months post-TKA	-.931	.131	-7.091	.000	.000
KOOS ADL subscale	pre-TKA/6 months post-TKA	-1.181	.131	-8.994	.000	.000
	pre-TKA/12 months post-TKA	-1.741	.131	-13.262	.000	.000
	6 months post-TKA/12 months post-TKA	-.560	.131	-4.267	.000	.000
KOOS sport subscale	pre-TKA/6 months post-TKA	-.841	.131	-6.401	.000	.000
	pre-TKA/12 months post-TKA	-1.034	.131	-7.878	.000	.000
	6 months post-TKA/12 months post-TKA	-.194	.131	-1.477	.140	.419
KOOS QoL subscale	pre-TKA/6 months post-TKA	-1.483	.131	-11.292	.000	.000
	pre-TKA/12 months post-TKA	-1.517	.131	-11.555	.000	.000
	6 months post-TKA/12 months post-TKA	-.034	.131	-.263	.793	1.000
VAS	pre-TKA/6 months post-TKA	.767	.131	5.843	.000	.000
	pre-TKA/12 months post-TKA	1.884	.131	14.345	.000	.000
	6 months post-TKA/12 months post-TKA	1.116	.131	8.502	.000	.000

6.2.1.2 Performance-based Measurements (PBM) and balance analysis

A total of 128 patients were invited to participate in the study, of which 51 patients agreed to participate in a functional performance and balance test, the remaining 65 patients could not volunteer for this part due to time factors, as the measurement sessions required an extra 40 minutes in the clinic (Figure 6-1). The 51 patients who participated were not significantly different from those who could not volunteer in their age, gender or BMI (P>.05) (Table 6-1). Forty-two female and nine male patients had median ages of 60 (range, 43–81) and 70 years (range, 54–85), respectively. Body-mass-index medians were 36.14 for females and 30.40 for males. The 30-s chair-stand test (30s CST), the stair-climb test (SCT), the timed up-and-go test (TUG) and the six-minute walk test (6MWT) were significantly different at the different time points post-TKA, (χ^2 (2) = 102), (χ^2 (2) = 102and (χ^2 (2) = 99) and (χ^2 (2) = 102) with $p < 0.0005$, respectively. The median changes for all time points in Table 6-4. Post hoc analysis showed significant differences in at all time points post-TKA, $p = 0.0005$. The effect size for 30s CST, SCT, TUG and 6 MWT were large 2.5, 1.3, 1.2 and 1.5 respectively. (Table 6-5).

Table 6 -4. Performance-based measurement test median changes post-total knee arthroplasty

Performance-based measurement test	Pre-TKA		6 months post-TKA		12 months post-TKA	
	Median	Interquartile Range	Median	Interquartile Range	Median	Interquartile Range
30-s chair-stand test (repetitions)	8	4	13	3	15	3
Stair-climb test (seconds)	54	49	36	19	30	16
Timed up-and-go test (seconds)	16	14	11	8	8	4
Six-minute walk test (metres)	261	104	276	110	298	102

Table 6 -5. Performance-based measurement test: Pairwise Comparisons

Performance-based measurement test	Sample 1/Sample2	Test Statistic	Standard Error	Std. Test Statistic	Significant	Adjusted Significance
30-s chair-stand test (repetitions)	pre-TKA/6 months post-TKA	-1.00	.198	-5.05	.000	.000
	pre-TKA/12 months post-TKA	-2.00	.198	-10.10	.000	.000
	6 months post-TKA/12 months post-TKA	-1.00	.198	-5.05	.000	.000
Stair-climb test (seconds)	pre-TKA/6 months post-TKA	1.00	.198	5.05	.000	.000
	pre-TKA/12 months post-TKA	2.00	.198	10.100	.000	.000
	6 months post-TKA/12 months post-TKA	1.00	.198	5.05	.000	.000
Timed up-and-go test (seconds)	pre-TKA/6 months post-TKA	.941	.198	4.75	.000	.000
	pre-TKA/12 months post-TKA	1.941	.198	9.80	.000	.000
	6 months post-TKA/12 months post-TKA	1.00	.198	5.05	.000	.000
Six-minute walk test (metres)	pre-TKA/6 months post-TKA	-1.00	.198	-5.05	.000	.000
	pre-TKA/12 months post-TKA	-2.00	.198	-10.10	.000	.000
	6 months post-TKA/12 months post-TKA	-1.00	.198	-5.05	.000	.000

6.2.1.3 Star Excursion Balance test (SEBT)

The SEBT anterior, posteromedial and posterolateral directions were significantly different at the different time points post-TKA, (χ^2 (2) = 96.12), (χ^2 (2) = 100.04) and (χ^2 (2) = 100.04), with $p < 0.0005$, respectively. The median changes for all time points in Table 6-6. Post hoc analysis showed significant differences in anterior, posteromedial and posterolateral at all time points post-TKA, $p = 0.0005$. The effect size for SEBT anterior, posteromedial and posterolateral directions were large 1.6, 2.8 and 2.4 respectively (Table 6-7).

Table 6-6. Star Excursion Balance test median changes post-total knee arthroplasty

Star Excursion Balance direction	Pre-TKA		6 months post-TKA		12 months post-TKA	
	Median	Interquartile Range	Median	Interquartile Range	Median	Interquartile Range
Anterior direction	51.5	16.4	60.3	14.7	63.70	15
Posteromedial direction	37.8	9	41.9	9.8	54.4	8.3
Posterolateral direction	43.0	13.7	51.2	11.1	53.4	11.7

Table 6-7. Star Excursion Balance Test Pairwise Comparisons

Star Excursion Balance direction	Sample 1/Sample2	Test Statistic	Standard Error	Std. Test Statistic	Significant	Adjusted Significant
Anterior direction	pre-TKA/6 months post-TKA	-.941	.198	-4.753	.000	.000
	pre-TKA/12 months post-TKA	-1.941	.198	-9.802	.000	.000
	6 months post-TKA/12 months post-TKA	-1.00	.198	-5.056	.000	.000
Posteromedial direction	pre-TKA/6 months post-TKA	-.961	.198	-4.852	.000	.000
	pre-TKA/12 months post-TKA	-1.980	.198	-10.00	.000	.000
	6 months post-TKA/12 months post-TKA	-1.02	.198	-5.149	.000	.000
Posterolateral direction	pre-TKA/6 months post-TKA	-.961	.198	-4.852	.000	.000
	pre-TKA/12 months post-TKA	-1.980	.198	-10.00	.000	.000
	6 months post-TKA/12 months post-TKA	-1.02	.198	-5.149	.000	.000

In summary, all outcome measurements were statistically different at all time points post-TKA except for the sport and QoL KOOS subscales that were statistically different between pre- and 12 months post-TKA. Therefore, the null hypothesis is rejected for KOOS, OKS, VAS, SEBT and PBM post-TKA.

6.2.2 Section two: Physical behaviour analysis

Changes in free-living physical behaviour (PB) before, 6 months and 12 months following total knee arthroplasty (TKA) were explored in both volume and pattern. The first part of this analysis assesses the volume changes in sedentary, standing, upright, and stepping time, in addition to changes in patient steps numbers. The second section assesses the pattern of free-living changes in terms of time spent in different cadence bands and correlating the findings with physical activity guideline recommendations.

A total of 128 patients were invited to participate in study, of which 38 patients agreed to volunteer and wore an activity monitor for PB assessment. The remaining 78 patients were either outside Riyadh, could not attend extra sessions or did not feel comfortable wearing a monitor for 7–8 days before and after surgery. Between March 2017 and October 2018, PB was assessed in 38 patients waiting for knee replacement, and then six months after their surgery. However, only 33 included a full 24 hours for 7–8 days before and after TKA. Five data sets were excluded due to lack of patient compliance and the records being for less than 7 days (Figure 6-1). The 33 patients who participated were not significantly different from those who could not volunteer in their age, gender or BMI (P>.05) (Table 6-1).

Twenty-seven female and six male patients had median ages of 59 years (range, 46–76) and 76 years (range, 63–85) years, respectively. The body-mass-index medians were 37.21 for females and 32.38 for males. All patients wore an activPAL accelerometer for 7–8 consecutive days preoperatively, at a six- and twelve-months follow-up without difficulty.

6.2.2.1 Volume of physical Behaviour Analysis

To explore the PB changes prior to TKA, 6 months post-TKA, and 12 months post-TKA, a one-way repeated measure analysis of variance (ANOVA) was used as the PB is independent variable measured at a continuous level with 1 within-subject factor (dependent) consisting of 3 categorical level/time points (before TKA, 6 months post-TKA, and 12 months post-TKA). The three essential assumptions for repeated ANOVA tests were examined in the following section, no significant outlier at any level/time point of the within-subject factor, normal disruption of the dependent variable for each time point, and sphericity assumption using Mauchly's Test, in which the variances of the differences between all-time points of the within-subject factor must be equal. A *post hoc* comparison test was then applied to explore where the significance lies, if present, using the Bonferroni correction test. The pairwise comparisons were calculated using the data as a whole to decrease the risk of Type I errors that may result in multiple comparisons with t-tests or Wilcoxon signed-rank tests (Girden, 1992; Weinfurt, 2000). The effect size calculated based

on the following formula $\omega^2 = (k-1)(F-1)/(k-1)(F-1)+nk$, where k= number of levels of the within-subjects factors, F= value of the F-statistic and n= sample size (Keppel & Wickens, 2004).

Assumption Analysis

When assessed using box plots, there were no outliers in stepping and upright times. However, two outliers in sedentary time, two outliers in standing time, and one outlier in steps number were detected. Their values did not reveal them to be extreme, and so they were included in the analysis, as illustrated in Figure 6-5 (Ghosh & Vogt, 2012).

The scores for all PB at each time point before and after TKA were normally distributed, as assessed by a Kolmogorov-Smirnov test, p-value > 0.05 (Table 6-8). Mauchly's Test of Sphericity indicates that the assumption of sphericity was not violated for sedentary, standing, stepping, and upright times, as the p-value (p > 0.05) was not statistically significant (Table 6-9).

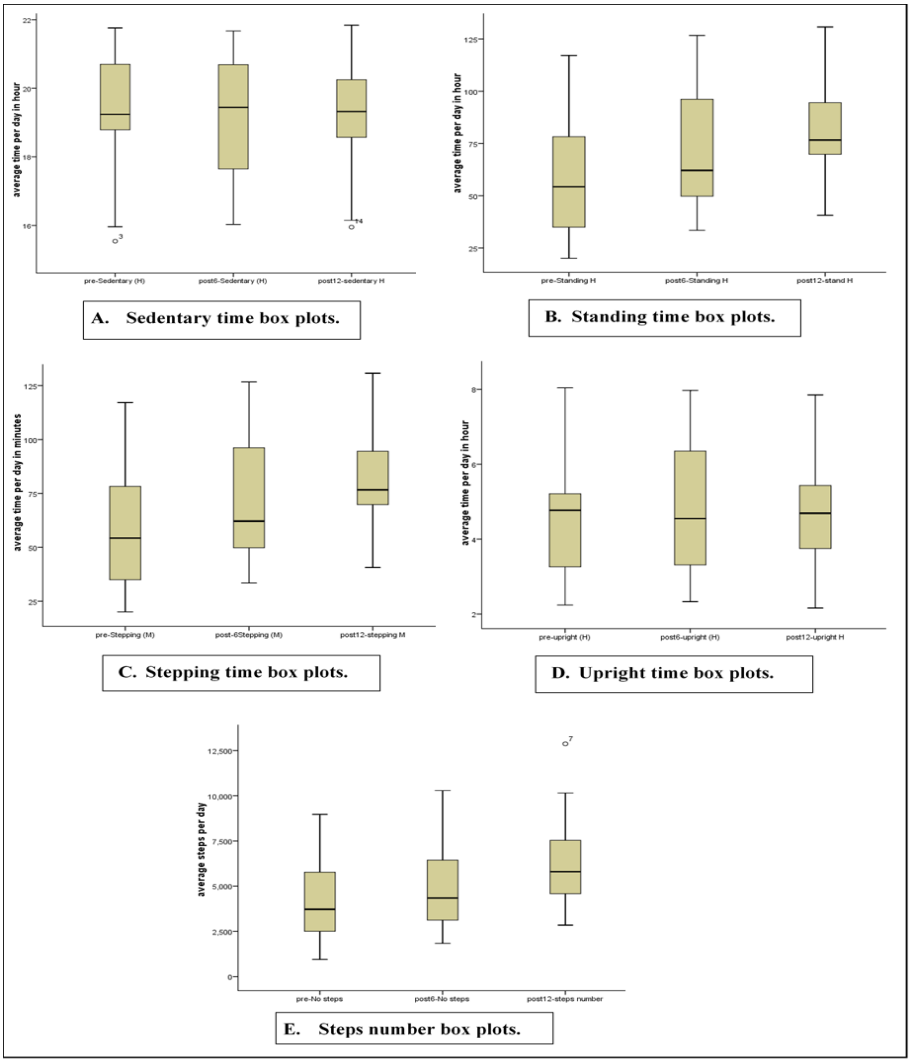

Figure 6-5. Physical Behaviour Boxplots

Table 6 - 8. Kolmogorov-Smirnov Normality Test for Physical Behaviour

Activity	Time Points	Statistic	df	Significance
Sedentary	Pre-Total Knee Arthroplasty	0.134	33	0.141
	6 Months Post-Total Knee Arthroplasty	0.124	33	0.200
	12 Months Post-Total Knee Arthroplasty	0.129	33	0.176
Standing	Pre-Total Knee Arthroplasty	0.089	33	0.200
	6 Months Post-Total Knee Arthroplasty	0.117	33	0.200
	12 Months Post-Total Knee Arthroplasty	0.135	33	0.132
Stepping	Pre-Total Knee Arthroplasty	0.114	33	0.200
	6 Months Post-Total Knee Arthroplasty	0.138	33	0.111
	12 Months Post-Total Knee Arthroplasty	0.106	33	0.200
Upright	Pre-Total Knee Arthroplasty	0.116	33	0.200
	6 Months Post-Total Knee Arthroplasty	0.124	33	0.200
	12 Months Post-Total Knee Arthroplasty	0.113	33	0.200
Steps	Pre-Total Knee Arthroplasty	0.112	33	0.200
	6 Months Post-Total Knee Arthroplasty	0.113	33	0.200
	12 Months Post-Total Knee Arthroplasty	0.112	33	0.200

Table 6 -9. Physical Behaviour, Mauchly's Test of Sphericity

Within Subject Effect	Mauchly's W	Approx. Chi-square	df	Significant	Epsilon		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Sedentary	0.894	3.490	2	0.175	0.904	0.955	0.500
Standing	0.955	1.436	2	0.488	0.957	1.00	0.500
Stepping	0.983	0.525	2	0.769	0.983	1.00	0.500
Upright	0.905	3.095	2	0.213	0.913	0.966	0.500
Steps	0.641	13.807	2	0.001	0.736	0.762	0.500

Accepting the sphericity assumption indicates that the one-way repeated measures ANOVA will not be biased, and no further adjustments, such as Greenhouse-Geisser, Huynh-Feldt, or the Lower-bound, are needed. However, as indicated in Table 6-9, the Mauchly's Test of Sphericity indicates that the assumption of sphericity had been violated for steps ($\chi 2(2) = 13.807$, $p = 0.001$). Therefore, the one-way repeated measures ANOVA results were interpreted based on Greenhouse-Geisser adjustments.

Physical Behaviour Volume One-way Repeated Measure ANOVA Result

As shown in Table 6-10, 6-11 and Figure 6-6, the stepping time and numbers of steps were significantly different at 6 months post-TKA (F (2,64) = 57.78, $p < 0.0001$) and 12 months post-TKA (F (1.47,47.08) = 260.63, $p < 0.0001$). The partial eta squared values for stepping time and steps (partial η2 or ηp2) equalled 0.644 and 0.891, respectively, and the partial omega squared values (partial ω2 or ωp2or population effect size) equalled .54 and .84, respectively. The values are smaller than the partial eta squared values due to bias compensation (Keppel & Wickens, 2004). As no prior hypothesis existed regarding which post-TKA time might affect the stepping time and steps numbers, *post hoc* testing was used

to explore potential significances. This testing proved that the (p-value) was statistically significant for each pairwise comparison and gave the confidence interval for mean difference for each comparison (Maxwell, 1980). There was a statistically significant increase in stepping time and steps at both 6 and 12 months post-TKA ($p < 0.0001$).

Table 6 -10. Physical Behaviour Descriptive Statistics

Activity	Time Points	Mean	Standard Deviation	Standard Error of Mean	95% Confidence Interval	
					Lower Bound	Upper Bound
Sedentary Time (Hour)	Pre-Total Knee Arthroplasty	19.48	1.51	0.26	18.94	20.01
	6 months Post-Total Knee Arthroplasty	19.27	1.66	0.29	18.68	19.86
	12 months Post-Total Knee Arthroplasty	19.08	1.54	0.27	18.53	19.62
Standing Time (Hour)	Pre-Total Knee Arthroplasty	3.47	1.27	0.22	3.02	3.92
	6 months Post-Total Knee Arthroplasty	3.64	1.44	0.25	3.13	4.15
	12 months Post-Total Knee Arthroplasty	3.54	0.97	0.17	3.20	3.89
Stepping Time (Minute)	Pre-Total Knee Arthroplasty	58.64	25.74	4.48	49.52	67.77
	6 months Post-Total Knee Arthroplasty	70.12	25.39	4.42	61.11	79.12
	12 months Post-Total Knee Arthroplasty	81.30	22.95	3.99	73.16	89.44
Upright Time (Hour)	Pre-Total Knee Arthroplasty	4.48	1.45	0.25	3.96	4.99
	6 months Post-Total Knee Arthroplasty	4.73	1.67	0.29	4.14	5.32
	12 months Post-Total Knee Arthroplasty	4.88	1.47	0.26	4.36	5.41
Steps Number	Pre-Total Knee Arthroplasty	4240	2268	394	3435	5044
	6 months Post-Total Knee Arthroplasty	4853	2108	367	4105	5601
	12 months Post-Total Knee Arthroplasty	6174	2287	398	5363	6985

Table 6 -11. Physical Behaviour Tests on Within-Subject Effects

Source			Type III Sum of Squares	df	Mean Square	F	Significance	Partial Eta Squared
Sedentary	Time	Sphericity Assumed	2.63	2	1.32	0.94	0.396	0.029
	Error (Time)	Sphericity Assumed	89.63	64	1.40			
Standing	Time	Sphericity Assumed	0.46	2	0.23	0.22	0.807	0.007
	Error (Time)	Sphericity Assumed	67.98	64	1.06			
Stepping	Time	Sphericity Assumed	8469.9	2	4234.93	57.78	**0.000**	0.644
	Error (Time)	Sphericity Assumed	4690.8	64	73.29			
Upright	Time	Sphericity Assumed	2.76	2	1.38	1.09	0.343	0.033
	Error (Time)	Sphericity Assumed	81.09	64	1.27			
Steps	Time	Sphericity Assumed	64494631	2	32247315	260.63	0.000	0.891
		Greenhouse -Geisser	64494631	1.47	43837682	260.63	**0.000**	0.891
	Error (Time)	Sphericity Assumed	7918775	64	123730			
		Greenhouse -Geisser	7918775	47.08	168202			

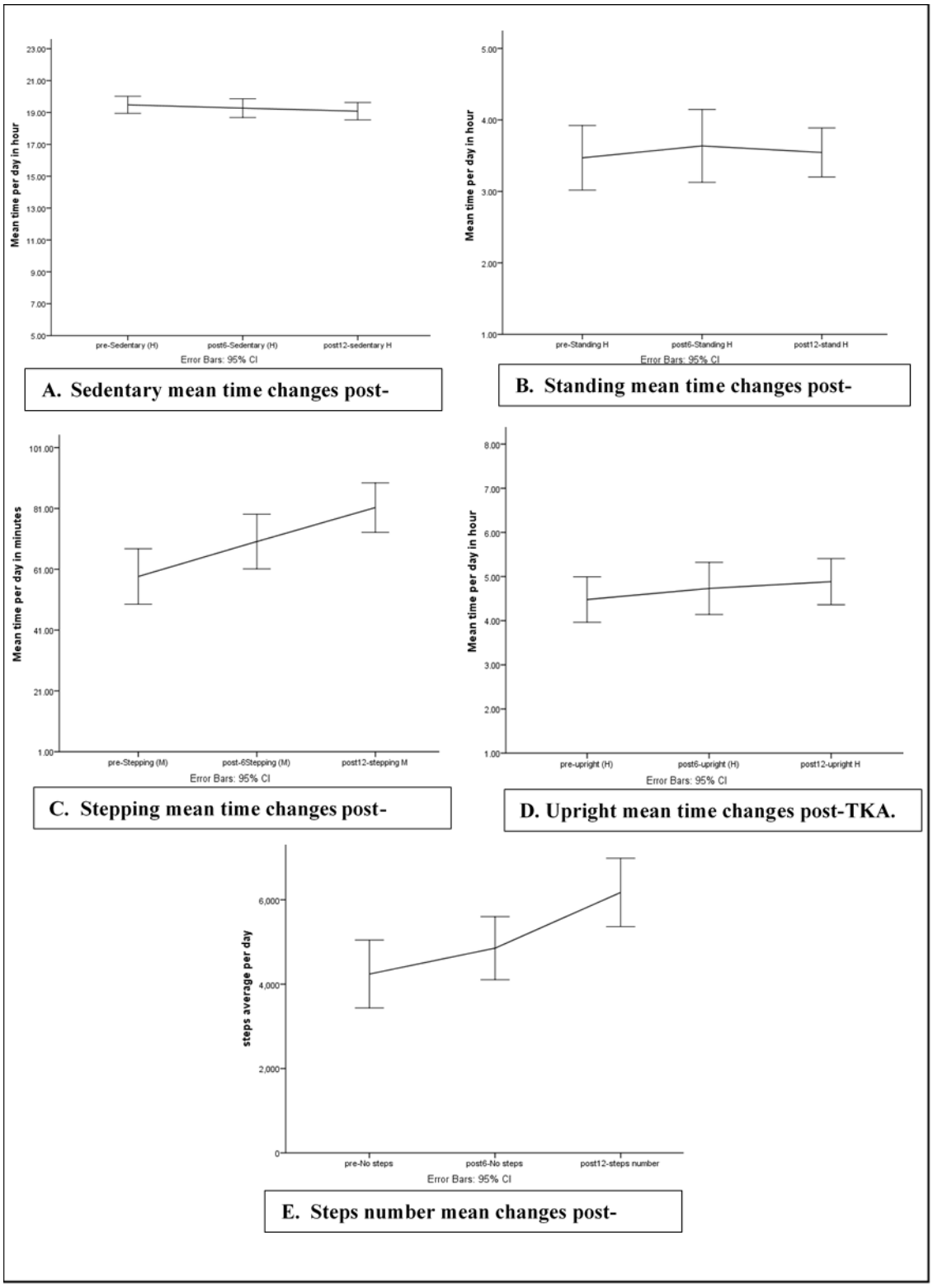

Figure 6-6. Physical Behaviour Means Changes Post-TKA.

As shown in Table 6-12, the stepping time increased from pre-TKA by 11.48 ±2.05 minutes (95% CI, 16-64 to 6.310) at 6 months post-TKA, by 22.66 ±2.24 minutes (95% CI, 28.31 to 16.99) at 12 months post-TKA, and by 11.2 ±2.03 minutes (95% CI, 16.3 to 6.05) from 6 months post-TKA to 12 months post-TKA. The steps number demonstrated significant increases at 6 months post-TKA at 613 ± 89 steps (95% CI, 839 to 386), 12 months post-TKA at 1934 ± 105 steps (95% CI, 2200 to 1668), and between 6 months post-TKA and 12 months post-TKA at 1321 ± 58 steps (95% CI, 1467 to 1174) (Table 6-12).

Table 6 -12. Stepping Time and steps Pairwise Comparisons

Physical activity	Time (I)	Time (J)	Mean Difference (I-J)	Standard Error	Significant	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
Stepping time	1	2	-11.48	2.04	.000	-16.64	-6.31
		3	-22.66	2.24	.000	-28.32	-16.99
	2	1	11.48	2.04	.000	6.31	16.64
		3	-11.18	2.03	.000	-16.32	-6.05
	3	1	22.66	2.24	.000	16.99	28.32
		2	11.18	2.03	.000	6.05	16.32
Steps Number	1	2	-613.35	89.63	.000	-839.79	-386.91
		3	-1934.38	105.35	.000	-2200.53	-1668.24
	2	1	613.35	89.63	.000	386.91	839.79
		3	-1321.03	58.02	.000	-1467.61	-1174.46
	3	1	1934.38	105.35	.000	1668.24	2200.53
		2	1321.03	58.02	.000	1174.5	1467.61

As shown in Table 6-10, the sedentary mean time reduced post-TKA, and improvements in both standing and upright times were observed. However, as illustrated in Table 6-11 and Figure 6-6, TKA did not lead to any significant differences between the mean times pre-TKA, 6 months post-TKA, and 12 months post-TKA for sedentary (F (2,64) = 0.940, p = 0.396), standing (F (2,64) = 0.216, p = 0.807), and upright times (F (2,64) = 1.088, p = 0.343).

The partial eta squared (partial η2 or ηp2) represents the sample effect size based on within-subjects factor variability, with values equalling 0.029 for sedentary, 0.007 for standing, and 0.033 for upright. The partial omega squared (partial ω2 or ωp2) that estimates the population effect size was calculated based on the following equation: ω2 = *(k-1)(F-1)/(k-1)(F-1)+n k,* where k = the number of levels of the within-subjects factor, F = the value of the F-statistic, and n = the number of participants. The partial ω2 = 0.00122, 0.0160, and 0.0018 for sedentary, standing, and upright times, respectively.

6.2.2.2 Patterns of Free-living Physical Behaviour

To explore overall changes in the cadence bands post-TKA, the total time spent in cadence bands of purposeful steps per day (less than 60 steps/minute), slow to medium steps per day (more than 60 and less than or equal 100 steps/minute) and moderate to vigorous MVPA (>100 steps/minute) each week prior to TKA, 6 and 12 months post-TKA was explored in all bout lengths for each participant (Tudor-Locke et al., 2018). In addition, MVPA time was explored for bouts ≥10 continuous minutes, bouts ≥ 5 continuous minutes and bouts ≥ one continuous minute to correlate the findings with PA guideline recommendations (Granat, 2012; White, Gabriel, Kim, Lewis, & Sternfeld, 2015).

6.2.2.2.1 The purposeful and slow to medium steps Assumption Analysis:

The accumulated mean time spent in all cadence bands improved post-TKA, as shown in Figure 6-7. To explore whether this improvement was significant post-TKA, the cadence band changes in purposeful and slow to medium were assessed using a one-way repeated measures ANOVA. There were no outliers in cadence bands of slow to medium steps, as assessed by a box plot, and two outliers in cadence bands of purposeful steps. Their values did not indicate they were extreme, and so they were included in the analysis (Ghosh & Vogt, 2012). The data were normally distributed, as assessed by a Kolmogorov-Smirnov test, p-value > 0.05 (Table 6-13). The sphericity assumption was not violated for either cadence, as assessed by a Mauchly's Test, χ^2 (2) =.485, $p = 0.785$, χ^2 (2) = 4.380, $p = 0.112$, respectively.

The purposeful and slow to medium steps results:

The cadences elicited a significantly increase over time for both slow to medium and purposeful steps (F (2,64) = 117.8, $p < 0.0005$), (F (2,64) = 65.6, $p < 0.0005$), respectively (Figure 6-8 & 6-9). The purposeful steps mean time increased from 369 ± 189 minutes prior to TKA to 458 ± 161 minutes at 6 months post-TKA and to 593 ± 188 minutes at 12 months post-TKA. The slow to medium steps mean time increased from 232 ± 148 minutes prior to TKA to 326 ± 147 minutes at 6 months post-TKA and to 457 ± 179 minutes at 12 months post-TKA. Post-hoc analysis with Bonferroni adjustments revealed a significant difference between the mean at the different time points post-TKA ($p<.05$) for both purposeful and slow to medium steps. To assess pattern changes in more depth, the following section assess the changes in time spent on moderate to vigorous physical activity (MVPA).

Table 6 -13. Kolmogorov-Smirnov Normality Test for Physical Activity pattern.

Cadence band	Time Points	Statistic	df	Significance
Time spent in cadence less than 60 steps per minute /day	Pre-Total Knee Arthroplasty	.144	33	.080
	6 Months Post-Total Knee Arthroplasty	.124	33	.951
	12 Months Post-Total Knee Arthroplasty	.120	33	.958
Time spent in cadence more than 60 steps per minute /day	Pre-Total Knee Arthroplasty	.149	33	.060
	6 Months Post-Total Knee Arthroplasty	.124	33	.200
	12 Months Post-Total Knee Arthroplasty	.147	33	.067

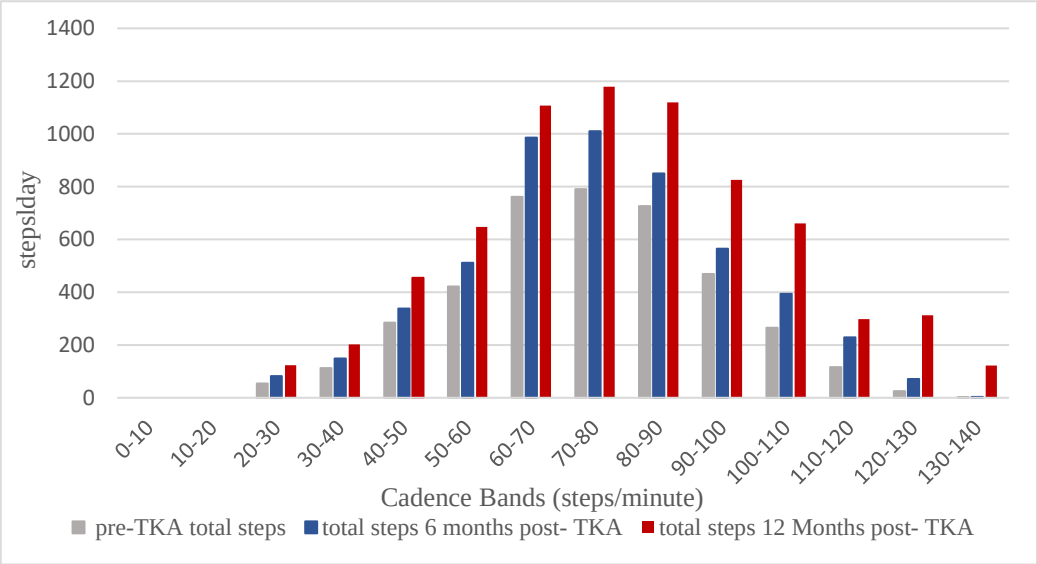

Figure 6- 7. Cadence Band changes Post-Total knee arthroplasty.

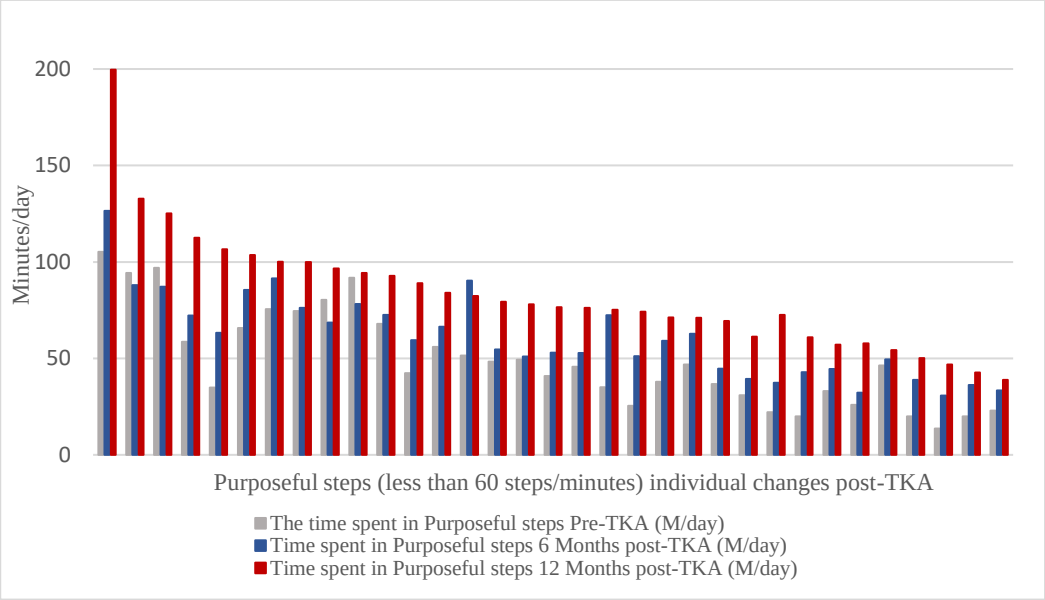

Figure 6-8. Purposeful steps (less than 60 steps/ minute) changes post-Total knee arthroplasty.

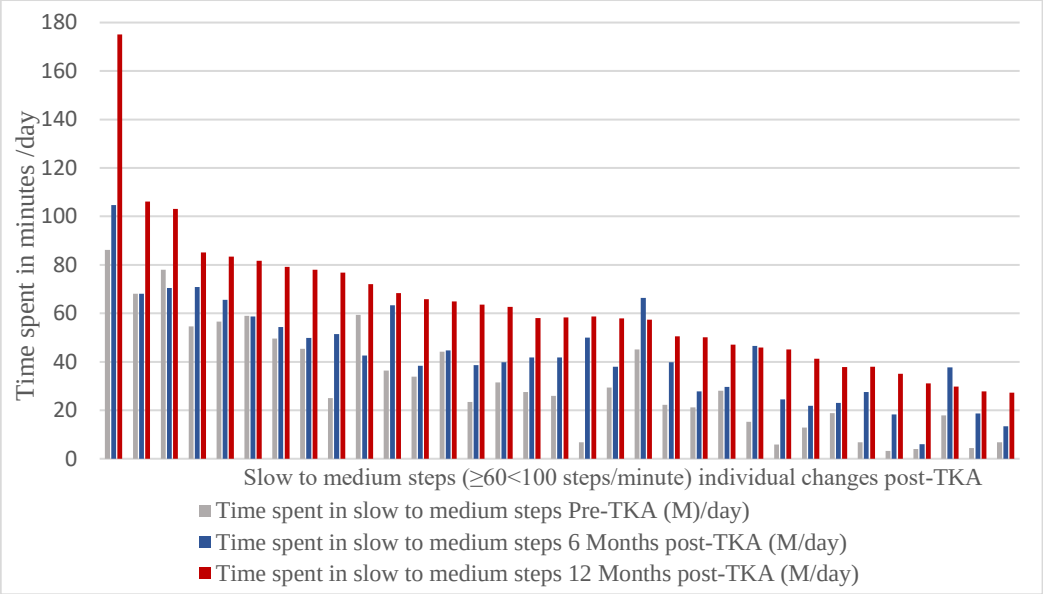

Figure 6-9. Slow to medium steps (≥60 <100 steps/ minute) changes post-Total knee arthroplasty.

6.2.2.2.2 Moderate to Vigorous Physical Activity (MVPA) Changes post-TKA Assumption Analysis:

The individual accumulated time spent in MVPA (>100 steps/min) per week and the number of MVPA steps prior to TKA, 6 and 12 months post-TKA was explored in all bout's length. To explore the changes in time and steps per week spent in MVPA post-TKA, the Friedman test was used as a non-parametric test alternative to the one-way repeated measure ANOVA, because the assumption of normality distribution is violated as assessed by the Kolmogorov-Smirnov test ($p < 0.05$), as shown in Table 6-14. The Friedman test is used to determine whether there any significant differences exist between three or more related groups, in this case pre-TKA, 6 months post-TKA, and 12 months post-TKA (Altman, 1991).

Table 6 -14. Kolmogorov-Smirnov Normality Test for Moderate to Vigorous Physical Activity

MVPA	Time Points	Statistic	df	Significance
Time Spent in MVPA/Week	Pre-Total Knee Arthroplasty	0.24	33	0.000
	6 Months Post-Total Knee Arthroplasty	0.24	33	0.000
	12 Months Post-Total Knee Arthroplasty	0.20	33	0.001
MVPA Steps Number/Week	Pre-Total Knee Arthroplasty	0.35	33	0.000
	6 Months Post-Total Knee Arthroplasty	0.33	33	0.000
	12 Months Post-Total Knee Arthroplasty	0.20	33	0.001

MVPA changes post-TKA:

The time spent in MVPA per week was significantly different at 6 months post-TKA, and 12 months post-TKA (χ^2 (2) = 18.727. p < .0001). The median changes were from 6.6 minutes (pre-TKA) to 10.5 minutes (6 months post-TKA) to 41.7 minutes (12 months post-TKA). Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons to minimize the risk of a Type I error. The MVPA values were significantly different between pre-TKA and 12 months post-TKA (p = 0.0001) and between 6 months and 12 months post-TKA (p = 0.003). No statistically significant differences were detected between pre-TKA and 6 months post-TKA (Table 6-15).

Table 6 -15. Moderate to Vigorous Physical Activity (MVPA) Time and Steps Pairwise Comparisons

MVPA	Sample 1/Sample2	Test Statistic	Standard Error	Std. Test Statistic	Significance	Adjusted Significance
MVPA Time	Pre-TKA/6 Months Post-TKA	-0.18	0.25	-0.74	0.460	1.000
	Pre-TKA/12 Months Post-TKA	-1.00	0.25	-4.06	0.000	**0.000**
	6 Months Post-TKA/12 Months Post-TKA	-0.82	0.25	-3.32	0.001	**0.003**
MVPA Steps	Pre-TKA/6 Months Post-TKA	-0.21	0.25	-0.86	0.389	1.000
	Pre-TKA/12 Months Post-TKA	-0.97	0.25	-3.94	0.000	**0.000**
	6 Months Post-TKA/12 Months Post-TKA	-0.76	0.25	-3.08	0.002	**0.006**

The MVPA steps values were significantly different at both post-TKA time points (χ2 (2) = 17.152, p < 0.0005). The median changes were from 704 steps (pre-TKA) to 1128 steps (6 months post-TKA) to 4586 steps (12 months post-TKA). The MVPA steps values were significantly different between pre-TKA and 12 months post-TKA (p = 0.0005) and 6 months post-TKA and 12 months post-TKA (p = 0.002). No statistically significant differences were detected between the pre-TKA value and the 6 months post-TKA value (Table 6-15).

6.2.2.2.3 Physical activity guideline. The MVPA performance was compared to the health-enhancing PA guideline recommendation. As illustrated in Figure 6-10, most patients did not meet the recommendation 12 months post-TKA. Only 24% of the participants (8 patients) met the recommendation of 150 minutes of moderate-to-vigorous activity per week for all bout lengths (Figures 6-11); 6% of the participants (2 patients) met the recommendation of 150 minutes of moderate-to-vigorous activity per week in bouts ≥10 continuous minutes (Figures 6-10).

The Purposeful walking post-TKA results were compared to the U.S adult patterns reported in the National Health and Nutrition Examination Survey (NHANES) (Tudor-Locke et al., 2011). US adults spent around 8.7 hours (522 minutes/ day) at a cadence of less than 60 steps/ minute, which is more than current study participants. In summary, the free-living physical activity volume and pattern changes post-TKA summarised in figure (6-12).

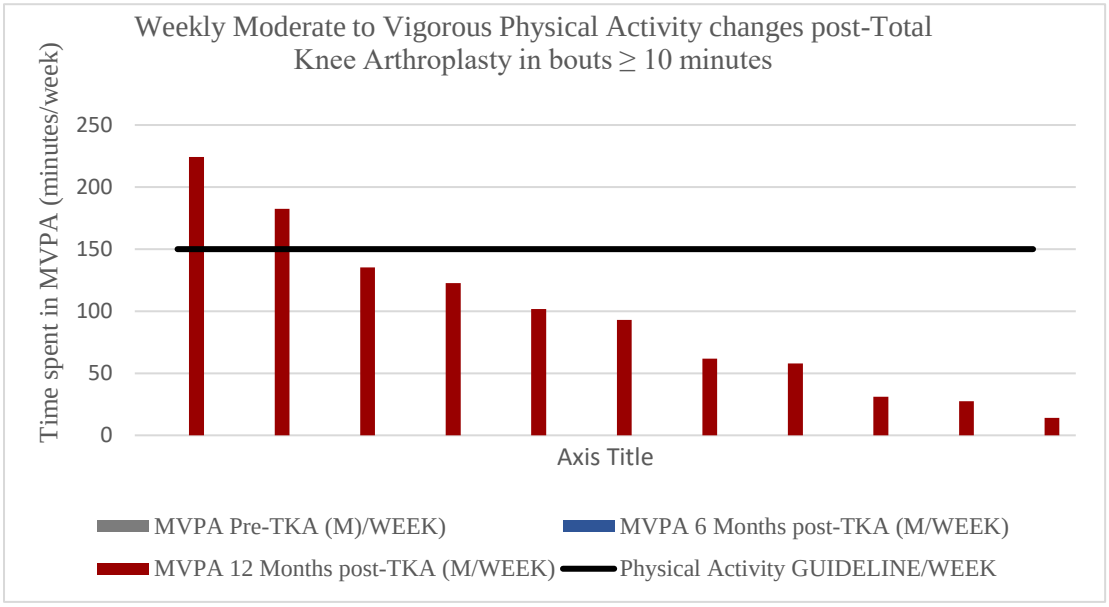

Figure 6-10 Moderate to Vigorous Physical Activity Improvements Post-TKA in bouts ≥10 minutes

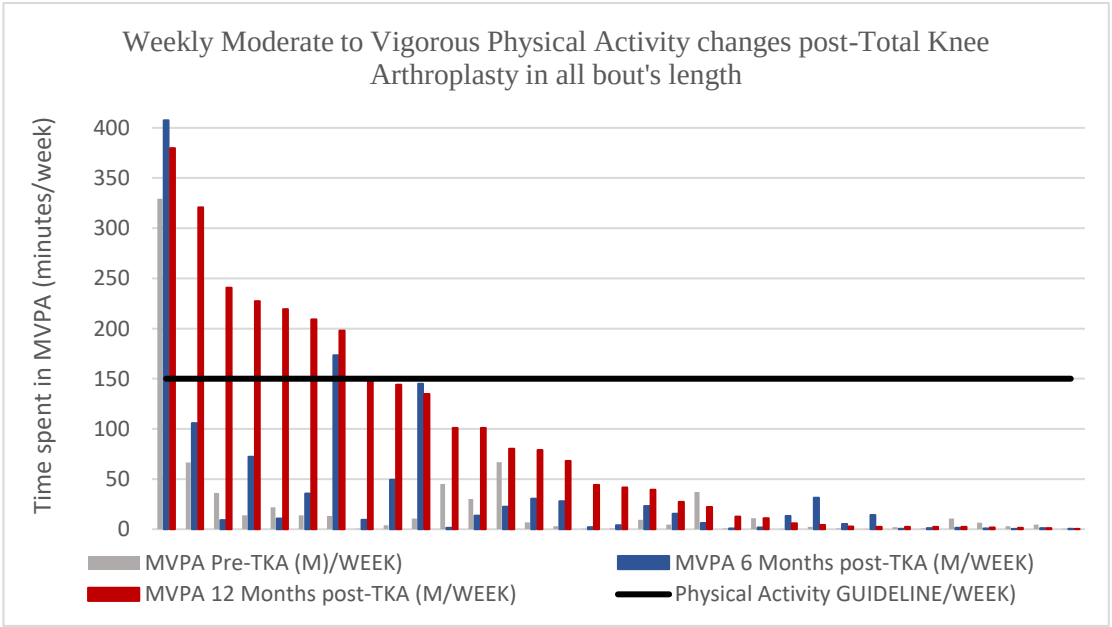

Figure 6-11. Moderate to Vigorous Physical Activity Improvements Post-TKA in all bout lengths.

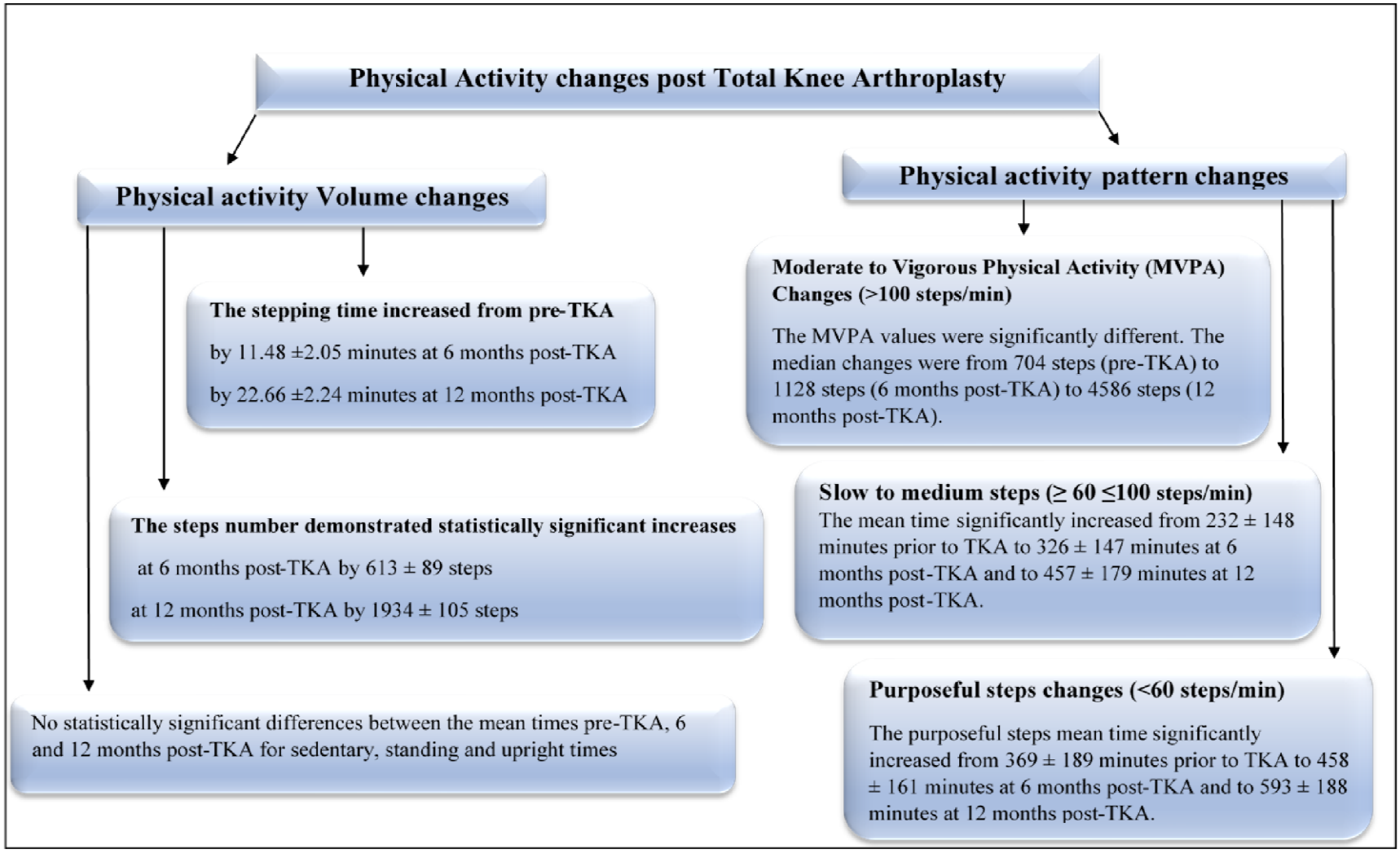

Figure 6-12. Free- living physical Behaviour changes post-Total knee arthroplasty summary.

6.2.3 Section three: Physical activity and Satisfaction regression analysis

The current analysis section assesses PA and satisfaction correlations with other outcome measurements and patients' characteristics such as: age, MBI, gender and Charlson Comorbidity Index (CCI). The correlations were examined with all outcome measurements' absolute score and changes in outcomes. To understand PA changes and patients' satisfaction post-TKA, a multiple linear regression model using a stepwise technique was used with predictive variables selected if their significance was p=0.1 to accommodate the possibility of variation in achieving significance once the confounding effect of another variable was controlled.

Correlation Assumption Analysis

Seven assumptions need to be considered to produce a valid regression model result. The first and second assumptions, confirmed as a dependent variable (PA & satisfaction) and independent variables (OKS, KOOS, SEBT, PBM), were measured at the continuous level. The other five assumptions were assessed for each correlation pair separately; the presence of a linear relation between the dependent and independent variables was assessed by the visual inspection of a scatterplot, the independence of observation was confirmed using a Durbin-Watson statistic, with no significant outliers; the homoscedasticity of data was checked by the inspection of a plot of unstandardized or standardized residual values against unstandardized or standardized predicted values, with a normal distribution of residuals found based on a histogram (with a superimposed normal curve) and probability plot of standardized residuals (Weisberg, 2014).

In a multiple regression analysis, four additional assumptions need to be considered to maintain regression validity. The assumption of no studentized deleted residuals greater than ±3 standard deviation, no leverage values greater than 0.2, no values for Cook's distance above 1 were met and the possibility of multicollinearity is excluded as no independent variables have a correlation greater than 0.7, all tolerance values are above 0.1 and VIF is less than 10 (Hair, Black, Babin, & Anderson, 2014). To understand how well the regression model fits, adjusted R^2 was considered more than R^2. Adjusted R^2 corrects sample positive bias in order to provide a value that would be expected from the population at large. In addition, R^2 estimates the effect size according to Cohen's (1988) classification (small, 0.10 – < 0.30; medium, 0.30 – < 0.50; large, ≥ 0.50).

2.6.3.1 Physical activity post-TKA prediction

The previous PA analysis section showed that stepping time and step numbers significantly improved post-TKA, therefore the correlations with other outcomes were limited to those. A multiple linear regression was run to explore possible predictions of stepping time and step numbers based on absolute pre-TKA measurement scores and changes in outcomes (OKS, KOOS, VAS, SEBT, PBOMs and all PA components). The model significantly predicts post-stepping time based on pre-stepping time and patients' history of contralateral knee arthroplasty (F (2,30) = 56.7, p=.001), adjusted R^2=.777. High pre-TKA stepping ability and a history of contralateral knee arthroplasty significantly increased post-TKA stepping time. The regression equation for post-stepping is as follows: 25.41 + (.605 × pre-stepping time in minutes) + (12.69 × history of contralateral knee arthroplasty); contralateral previous TKA value labels were 1 for no and 2 for yes (Table 6-16). The model excludes all variables that do not significantly predict stepping time, as clarified in Table 6-17.

The model significantly predicts the number of steps post-TKA based on pre-steps and a history of contralateral knee arthroplasty (F (2,30) = 142.9, p=.001), adjusted R^2=.899. High pre-TKA steps and a history of contralateral knee arthroplasty significantly increased post-TKA steps. The regression equation for post-steps is as follows: 1245 + (.665 × pre-steps) + (1083.8 × history of contralateral knee arthroplasty); contralateral previous TKA value labels were 1 for no and 2 for yes (Table 6-16). The model excludes all variables that do not significantly predict the number of steps, as clarified in Table 6-18.

Table 6 - 16. Regression model for patients' stepping time and number of steps post-total knee arthroplasty (TKA).

Dependent variable	Model	Unstandardised coefficients		Standardised coefficients	t	Significance	95% Confidence Interval for B	
		B	Std. Error	Beta			Lower bound	Upper bound
Stepping time post-TKA	constant	25.41	6.48		3.92	.001	12.17	38.64
	Stepping time pre-TKA	.605	.102	.679	5.95	.001	.398	.813
	History of contralateral knee arthroplasty*	12.69	5.28	.274	2.41	.001	1.92	23.47
Steps post-TKA	constant	1245	407.3		3.06	.001	413-2	2076
	Steps pre-TKA	.665	.080	.735	8.31	.001	.502	.829
	History of contralateral knee arthroplasty*	1083.8	366.0	.262	2.96	.002	336.3	1831

* Contralateral previous TKA value labels were 1 for no and 2 for yes

Table 6 - 17. Variables excluded for stepping time post-Total knee arthroplasty regression model

Model	Beta In	t	Sig.	Partial Correlation	Collinearity Statistics		
					Tolerance	VIF	Minimum Tolerance
Age	.008	.089	.929	.017	.954	1.04	.525
BMI	.042	.443	.661	.082	.792	1.26	.464
Gender	.125	1.526	.138	.273	.996	1.00	.533
Charlson Comorbidity Index (CCI)	.264	3.406	.512	.528	.999	1.18	.999
Pre-sedentary	-.084	-.787	.438	-.145	.616	1.62	.396
Pre-standing	.061	.677	.504	.125	.859	1.16	.490
Pre-upright	.102	.952	.349	.174	.612	1.63	.398
Pre-Visual analogue scale	-.017	-.195	.846	-.036	.919	1.88	.523
Pre-KOOS-pain	-.054	-.636	.530	-.117	.990	1.01	.533
Pre-KOOS-symptom	-.132	-1.610	.118	-.286	.990	1.01	.530
Pre-KOOS-ADL	-.034	-.389	.700	-.072	.929	1.07	.513
Pre-KOOS-sport	-.107	-1.177	.249	-.214	.837	1.19	.486
Pre-KOOS-QoL	.032	.372	.713	.069	.981	1.01	.527
Pre-OKS	-.031	-.347	.731	-.064	.913	1.09	.515
Pre-SEBT-ANTERIOR	.039	.415	.681	.077	.794	1.26	.483
Pre-SEBT- POSTEROMEDIAL	-.047	-.524	.604	-.097	.882	1.13	.475
Pre-SEBT-POSTEROLATERAL	.017	.189	.851	.035	.866	1.15	.510
Pre-30 SEC CST-PRE	.031	.349	.729	.065	.907	1.10	.522
Pre-SCT	.001	.008	.993	.002	.744	1.34	.448
Pre-TUG	-.044	-.500	.621	-.092	.909	1.10	.519
Pre-6 MWT	-.030	-.322	.750	-.060	.808	1.23	.513
VAS change	.024	.284	.779	.053	.995	1.00	.533
KOOS pain change	.064	.761	.453	.140	.987	1.01	.529
KOOS symptom change	.143	1.762	.089	.311	.984	1.01	.528
KOOS ADL change	.051	.576	.569	.106	.914	1.09	.500
KOOS sport change	.118	1.245	.223	.225	.755	1.32	.438
KOOS QoL change	-.022	-.258	.798	-.048	.973	1.02	.521
OKS change	.041	.466	.645	.086	.936	1.06	.519
SEB ANTERIOR change	-.159	-1.967	.059	-.343	.972	1.02	.520
SEB POSTEROMEDIAL change	-.180	-2.246	.032	-.385	.952	1.05	.510
SEB POSTEROLATERAL change	-.060	-.685	.499	-.126	.917	1.09	.492
CST change	-.007	-.077	.939	-.014	.994	1.00	.532
SCT change	-.010	-.119	.906	-.022	.929	1.07	.502
TUG change	-.050	-.579	.567	-.107	.947	1.05	.523
6 MWT change	.079	.933	.359	.171	.971	1.03	.521

Table 6 - 18. Variables excluded for steps number post-Total knee arthroplasty regression model

Model	Beta In	t	Sig.	Partial Correlation	Collinearity Statistics		
					Tolerance	VIF	Minimum Tolerance
Age	.005	.080	.936	.015	.962	1.04	.398
BMI	-.030	-.462	.648	-.085	.775	1.29	.390
Gender	.049	.862	.396	.158	.990	1.02	.402
Charlson Comorbidity Index (CCI)	.252	3.406	.342	.528	.977	1.001	.977
Pre-sedentary	-.040	-.557	.582	-.103	.632	1.58	.335
Pre-standing	.031	.500	.621	.092	.867	1.15	.384
Pre-upright	.046	.635	.530	.117	.628	1.59	.336
Pre-Visual analogue scale	-.054	-.924	.363	-.169	.946	1.05	.401
Pre-KOOS-pain	.011	.184	.856	.034	.932	1.07	.378
Pre-KOOS-symptom	-.005	-.080	.937	-.015	.955	1.04	.389
Pre-KOOS-ADL	.037	.634	.531	.117	.946	1.05	.389
Pre-KOOS-sport	-.064	-1.057	.299	-.193	.867	1.15	.381
Pre-KOOS-QoL	-.007	-.114	.910	-.021	.972	1.02	.397
Pre-OKS	.019	.326	.747	.060	.925	1.08	.394
Pre-SEBT-anterior	.047	.744	.463	.137	.817	1.22	.374
Pre-SEBT- posteromedial	.036	.613	.545	.113	.927	1.07	.385
Pre-SEBT-posterolateral	.043	.712	.482	.131	.870	1.14	.376
Pre-30 SEC CST	.037	.616	.542	.114	.915	1.09	.394
Pre-SCT	-.107	-1.823	.079	-.321	.858	1.16	.388
Pre-TUG	-.006	-.106	.916	-.020	.921	1.08	.393
Pre-6 MWT	.025	.413	.683	.076	.882	1.13	.392
VAS change	-.013	-.227	.822	-.042	.990	1.01	.404
KOOS pain change	.005	.078	.938	.015	.978	1.02	.397
KOOS Symptom change	.009	.158	.875	.029	.994	1.00	.404
KOOS ADL change	-.047	-.830	.414	-.152	.996	1.00	.404
KOOS sport change	-.034	-.585	.563	-.108	.944	1.05	.384
KOOS QoL change	.008	.128	.899	.024	.938	1.06	.381
OKS change	-.034	-.573	.571	-.106	.912	1.09	.373
SEB anterior change	.148	2.492	.069	.420	.766	1.30	.347
SEB posteromedial change	.031	.540	.593	.100	.967	1.03	.392
SEB posterolateral change	-.034	-.582	.565	-.108	.948	1.05	.398
CST change	.064	1.094	.283	.199	.906	1.10	.367
SCT change	-.032	-.547	.589	-.101	.926	1.08	.376
TUG change	.011	.186	.854	.035	.976	1.02	.396
6 MWT change	-.035	-.590	.560	-.109	.939	1.06	.383

6.2.3.2. Satisfaction post-TKA prediction

To understand patients' satisfaction post-TKA, a multiple regression model was run to explore possible predictions based on both absolute and changes in outcomes (OKS, KOOS, VAS, SEBT, PBOMs and all PA components). The developed satisfaction model significantly predicted satisfaction post-TKA, F (4,30) = 23.08, P=.0001, based on stepping time and pain score at one-year post-TKA. Stepping time and pain post-TKA explain 58% of satisfaction variability one-year post-TKA (adjusted R^2=.580 and R^2.606). Patients' satisfaction one-year post-TKA may be predicted based on stepping time and the presence of pain, whereas it cannot be predicted before surgery. High stepping ability and a low pain score at 12 months post-TKA significantly increase patients' satisfaction. The regression equation for patients' satisfaction is in the following form: = 49.29 + (.438 × stepping time at 12 months post-TKA in minute) - (1.04 × pain score on visual analogue scale at 12 months post-TKA) (Table 6-19). The correlations with absolute scores (before and after TKA) and improvement scores are summarised in Table 6-20. The regression model excludes all variables that do not significantly predict satisfaction (Table 6-21).

Table 6 -19. Regression model summary for patients' satisfaction post-total knee arthroplasty (TKA).

Model	Unstandardised coefficients		Standardised coefficients	t	Significance	95% Confidence Interval for B	
	B	Std. Error	Beta			Lower bound	Upper bound
constant	49.29	12.39		3.98	.000	23.98	74.59
Stepping time in minutes 12 months post-TKA	.438	.121	.532	3.61	.001	.190	.685
Pain score on a VAS 12 months post-TKA	-1.04	.472	-.325	-2.21	.002	-2.00	-.078

Summary of section three

To conclude the correlation section, PA (stepping time, steps) variations after knee arthroplasty were significantly explained based on a patient's stepping ability before arthroplasty and a history of contralateral knee arthroplasty, with a large effect size according to Cohen (1988). However, no significant correlation or explanation for PA variation were found based on OKS, KOOS scores, PBOMs and SEBT. Patients' satisfaction one-year post-TKA may be predicted based on stepping time and the presence of pain post-TKA with a large effect size, whereas it cannot be predicted before surgery.

Table 6 - 20. Satisfaction correlation with absolute score before and after total knee arthroplasty (TKA), and post-TKA changes in outcome measurements

Correlation pairs		Pearson Correlation	significant
Satisfaction score correlation with **absolute** score pre-TKA	Age	.283	.085
	BMI	.186	.150
	Gender	.004	.491
	Charlson Comorbidity Index (CCI)	.267	.097
	Satisfaction & pre-sedentary time	-.306	.068
	Satisfaction & pre-standing time	.140	.219
	Satisfaction & pre-stepping time	.329	.074
	Satisfaction & pre-upright time	.302	.084
	Satisfaction & pre-steps number	.382	.096
	Satisfaction & pre-OKS score	.219	.110
	Satisfaction & pre-KOOS pain subscale	.142	.215
	Satisfaction & pre-KOOS symptom subscale	.003	.494
	Satisfaction & pre-KOOS ADL subscale	.254	.077
	Satisfaction & pre-KOOS sport and recreation subscale	.293	.069
	Satisfaction & pre-KOOS pain quality of life subscale	.018	.461
	Satisfaction & pre-pain score	.179	.160
	Satisfaction & pre-30s CST	.303	.073
	Satisfaction & pre- TUG	-.276	.060
	Satisfaction & pre- SCT	-.454	.064
	Satisfaction & pre- 6MWT	.396	.071
	Satisfaction & pre- SEBT anterior	.353	.082
	Satisfaction & pre- SEBT posterolateral	.287	.092
	Satisfaction & pre- SEBT posteromedial	.219	.110
Satisfaction score correlation with **absolute** score post-TKA	Satisfaction & post-sedentary time	-.412	.179
	Satisfaction & post -standing time	.291	.092
	Satisfaction & post- stepping time	.736	.000
	Satisfaction & post -upright time	.451	.064
	Satisfaction & post- steps number	.692	.061
	Satisfaction & post-OKS score	.096	.297
	Satisfaction & post-KOOS pain subscale	.022	.452
	Satisfaction & post-KOOS symptom subscale	.155	.195
	Satisfaction & post-KOOS ADL subscale	.036	.420
	Satisfaction & post-KOOS sport and recreation subscale	.269	.065
	Satisfaction & post-KOOS pain quality of life subscale	.199	.133
	Satisfaction & post-pain score	-.660	.000
	Satisfaction & post-30s CST	.405	.160
	Satisfaction & post- TUG	-.427	.167
	Satisfaction & post- SCT	-.514	.091
	Satisfaction & post- 6MWT	.427	.127
	Satisfaction & post- SEBT anterior	.336	.068
	Satisfaction & post- SEBT posterolateral	.342	.066
	Satisfaction & post- SEBT posteromedial	.129	.237
Satisfaction score correlation with **changes** post-TKA	Satisfaction & post-sedentary time change	-.097	.295
	Satisfaction & post -standing time change	.080	.330
	Satisfaction & post- stepping time change	.054	.383
	Satisfaction & post -upright time change	.142	.215
	Satisfaction & post- steps number change	.060	.369
	Satisfaction & post-OKS score change	.199	.134
	Satisfaction & post-KOOS pain subscale change	.138	.222
	Satisfaction & post-KOOS symptom subscale change	.030	.433
	Satisfaction & post-KOOS ADL subscale change	.244	.086
	Satisfaction & post-KOOS sport and recreation subscale change	.336	.068
	Satisfaction & post-KOOS pain quality of life subscale change	.070	.349
	Satisfaction & post-pain score change	.061	.368
	Satisfaction & post-30s CST change	.063	.364
	Satisfaction & post- TUG change	.218	.112
	Satisfaction & post- SCT change	.238	.091
	Satisfaction & post- 6MWT change	.026	.444
	Satisfaction & post- SEBT anterior change	.059	.373
	Satisfaction & post- SEBT posterolateral change	.090	.309
	Satisfaction & post- SEBT posteromedial change	.147	.207

Table 6 - 21. Variables excluded for patients' satisfaction at one-year post-total knee arthroplasty regression model.

Model	Beta In	t	Sig.	Partial Correlation	Collinearity Statistics		
					Tolerance	VIF	Minimum Tolerance
Age	-.156	-1.171	.251	-.209	.962	1.039	.962
BMI	.145	.989	.331	.178	.804	1.244	.804
Gender	-.125	-.937	.356	-.169	.966	1.035	.966
Charlson Comorbidity Index (CCI)	.182	1.399	.172	.247	.984	1.017	.984
Pre-sedentary	.168	1.192	.243	.216	.654	1.530	.440
Pre-standing	-.148	-1.204	.238	-.218	.856	1.168	.540
Pre-stepping	.035	.149	.882	.028	.245	4.087	.195
Pre-upright	-.189	-1.329	.194	-.240	.632	1.581	.425
Pre- steps number	.170	.616	.542	.114	.175	5.702	.146
Post-sedentary	.199	1.298	.204	.234	.547	1.829	.458
Post-stand	-.223	-1.634	.113	-.290	.671	1.491	.495
Post-upright	-.208	-1.276	.212	-.230	.482	2.075	.424
Post-steps number	.160	.469	.643	.087	.116	8.605	.099
Pre-VAS	.024	.202	.842	.037	.932	1.073	.587
Pre-KOOS-pain	.155	1.357	.185	.244	.977	1.023	.592
Pre-KOOS-symptom	.058	.501	.620	.093	.992	1.008	.600
Pre-KOOS-ADL	.126	1.087	.286	.198	.971	1.030	.599
Pre-KOOS-sport	.121	1.020	.316	.186	.929	1.076	.571
Pre-KOOS-QoL	-.036	-.298	.768	-.055	.937	1.067	.570
Post-KOOS-pain	-.025	-.213	.833	-.039	.999	1.001	.604
Post-KOOS-symptom	-.058	-.485	.631	-.090	.956	1.046	.581
Post-KOOS-ADL	-.049	-.422	.676	-.078	.982	1.018	.596
Post-KOOS-sport	-.132	-1.085	.287	-.197	.886	1.129	.536
Post-KOOS-QoL	.052	.433	.668	.080	.947	1.056	.578
Pre-OKS	.109	.899	.376	.165	.907	1.103	.548
Post-OKS	-.080	-.674	.506	-.124	.951	1.052	.596
Pre-SEBT-anterior	.068	.542	.592	.100	.846	1.182	.551
Post-SEB-anterior	.104	.858	.398	.157	.900	1.112	.589
Pre-SEB-posteromedial	.011	.092	.927	.017	.926	1.079	.594
Post-SEB-posteromedial	.055	.458	.650	.085	.931	1.074	.563
Pre-SEB-posterolateral	.070	.575	.570	.106	.897	1.115	.558
Post-SEB-posterolateral	.066	.528	.601	.098	.864	1.157	.570
Pre 30 sec CST	.072	.592	.558	.109	.906	1.103	.588
Post 30 sec CST	-.036	-.257	.799	-.048	.692	1.445	.556
Pre-SCT	-.191	-1.584	.124	-.282	.860	1.163	.569
Post-SCT	-.14	-1.100	.280	-.200	.723	1.382	.562
Pre- TUG	-.054	-.447	.658	-.083	.913	1.095	.580
Post-TUG	-.074	-.559	.581	-.103	.774	1.293	.562
Pre- 6MWT	.112	.902	.374	.165	.850	1.176	.582
Post-6MWT	.147	1.193	.243	.216	.849	1.177	.572
Sedentary change	.001	.007	.994	.001	.962	1.039	.585
Standing change	.013	.110	.913	.020	.985	1.015	.598
Stepping change	-.018	-.149	.882	-.028	.979	1.021	.594
Upright change	.017	.140	.889	.026	.946	1.057	.578
Steps change	-.043	-.364	.718	-.067	.977	1.023	.594
VAS change	.024	.202	.842	.037	.943	1.060	.571
KOOS-pain change	-.150	-1.315	.199	-.237	.983	1.017	.595
KOOS-symptom change	-.070	-.598	.555	-.110	.990	1.010	.599
KOOS-ADL change	-.128	-1.107	.278	-.201	.976	1.025	.601
KOOS-sport change	-.156	-1.291	.207	-.233	.876	1.141	.534
KOOS QoL change	.053	.450	.656	.083	.972	1.028	.589
OKS change	-.127	-1.069	.294	-.195	.919	1.088	.557
SEB anterior change	.055	.453	.654	.084	.916	1.092	.554
SEB-posteromedial change	.055	.445	.660	.082	.880	1.137	.536
SEB-posterolateral change	-.023	-.190	.851	-.035	.918	1.090	.557
CST change	-.092	-.800	.430	-.147	.997	1.003	.603
SCT change	-.143	-1.245	.223	-.225	.976	1.025	.592
TUG change	-.047	-.397	.694	-.074	.947	1.056	.586
6-MWT change	.072	.618	.541	.114	.980	1.021	.593

6.2.4 Section Four: Comparing the outcomes from two different knee arthroplasty approaches

6.2.4.1. Statistical analysis

A preoperative demographic data comparison between patients from the UK and the KSA was conducted using a Mann-Whitney U test and chi-square analyses where appropriate. To compare OKS mean differences between two independent groups (UK and KSA) over three timepoints post-TKA, a two-way mixed ANOVA was used. A two-way mixed ANOVA is used to determine whether there is a difference between independent groups over time, so it has one between subjects' factor (UK and KSA group), one within subjects' factor (repeated measure over time: pre, 6 and 12 months post-TKA) and three covariates (age, gender and BMI) to understand their effect on OKS changes.

6.2.4.2 Assumption analysis

The normality assumption for residuals was violated and there was no non-parametric test alternative for a two-way ANOVA. Therefore, the analysis was done in two ways: a first track was via a two-way ANOVA, although the normality assumption was violated, the current sample size was not too small and the ANOVA was considered fairly robust in its deviation from normal (Fox, 2016). The second option was transforming the data: positively skewed data were transformed to log10 of the score, negatively skewed data were transformed using the reflect and logarithmic equation (log10(1+ highest score in original data - the original data)), then proceeding to analysis using a two-way ANOVA (Fox, 2016). The transformed and non-transformed methods produced similar findings, so the following interpretation is based on the non-transformed analysis.

6.2.4.3. Patient Features

A Mann-Whitney U test was run to determine if there were any significant differences in the patients' age and BMI between the UK & KSA samples as the assumption of normality was violated when assessed by a Kolmogorov-Smirnov test and a P value < .05. The distribution of age and BMI were almost similar as assessed by visual inspection (Figure 6-13). Age and BMI medians were significantly different, patients' age in the UK sample was 5 years older than the KSA, and the BMI median in the UK sample was 7 points smaller than in the KSA (Table 6-22). A chi-square test showed a significant difference in gender proportions, P=001. Males were higher in the UK sample than the KSA one (37% vs 17%) (Table 6-23).

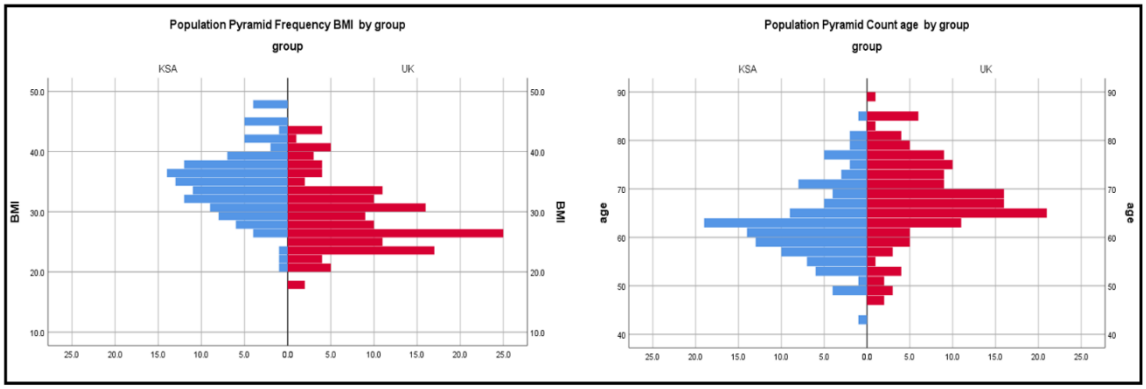

Figure 6- 13.Patients' age and Body Mass Index (BMI) differences between the United Kingdom (UK) and the Kingdom of Saudi Arabia (KSA) groups.

Table 6 - 22. Demographic data for patients in the United Kingdom (UK) and Kingdom of Saudi Arabia (KSA) samples.

		Age		Body mass index (BMI)	
		UK patients	KSA Patients	UK patients	KSA Patients
Patient characteristics	Median	67	62	28	35.1
	Interquartile range	11	10	7	6.5
	Minimum	47	43	18	20.6
	Maximum	88	85	44	48.5
Mann-Whitney U test	Standardized test statistic Z	5.39		7.56	
	Significant P	.001		.001	

Table 6 - 23. Crosstabulation and gender proportions in the United Kingdom (UK) and the Kingdom of Saudi Arabia (KSA) samples.

		Gender		Total	Chi-square test significant
		Female	Male		
UK	Count	90	53	143	.001
	Expected count	102.7	40.3	143	
	% within group	62.9%	37.1%	100%	
KSA	Count	96	20	116	
	Expected count	83.3	32.7	116	
	% within group	82.8%	17.2%	100%	
Total	Count	186	73	259	
	Expected count	186.0	73.0	259	
	% within group	71.8%	28.2%	100%	

6.2.4.4. OKS score difference findings

OKS score descriptive data in each group at different time points are summarised in Table 6-24. To assess the two groups' differences, the sphericity assumption was assessed using a Mauchly's test, the assumption was violated for two-way interaction, χ^2 (2) = 97.2, *P*= .0005. Therefore, the ANOVA results were corrected based on Greenhouse-Geisser.

Table 6 - 24. Oxford Knee Score descriptive data for United Kingdom (UK) and Kingdom of Saudi Arabia (KSA) patients post-Total Knee Arthroplasty.

Group	Time	Mean	Std. Deviation	95% Confidence Interval	
				Lower Bound	Upper Bound
UK	Pre-TKA	19.4	6.8	18.16	20.65
	6 months post-TKA	28.9	4.9	28.03	29.92
	12 months post-TKA	38.4	3.6	37.68	39.07
KSA	Pre-TKA	15.2	4.6	14.33	16.03
	6 months post-TKA	34.7	3.5	33.92	35.21
	12 months post-TKA	40.2	1.6	39.94	40.52

The time post-TKA and different groups (UK & KSA) showed significant effects in OKS changes, F (1.3,328) = 12.23, F (1.3,328) = 72.39 respectively, both P=. 001 and a small effect size (Table 6-25). Patients' age, gender and BMI did not show any significant effects on OKS changes at all three time-points post-TKA $P \geq .05$ (Table 6-25).

Table 6 - 25. Two-way mixed ANOVA within subjects' effects of group, time post-TKA, age, gender and Body Mass Index (BMI) on Oxford Knee Score (OKS) changes post-TKA.

OKS score within subjects' effect		df	Mean Square	F	Sig.	Partial Eta Squared
time	Sphericity assumed	2	159.983	12.230	.000	.046
	Greenhouse-Geisser	1.29	246.342	12.230	.000	.046
time * age	Sphericity assumed	2	8.684	.664	.515	.003
	Greenhouse-Geisser	1.29	13.372	.664	.453	.003
time * BMI	Sphericity assumed	2	21.853	1.671	.189	.007
	Greenhouse-Geisser	1.29	33.649	1.671	.197	.007
time * group	Sphericity assumed	2	947.029	72.395	.000	.222
	Greenhouse-Geisser	1.29	1458.232	72.395	.000	.222
time * Gender	Sphericity assumed	2	20.426	1.561	.211	.006
	Greenhouse-Geisser	1.29	31.452	1.561	.215	.006
time * group * Gender	Sphericity assumed	2	7.454	.570	.566	.002
	Greenhouse-Geisser	1.29	11.478	.570	.494	.002
Error(time)	Sphericity assumed	506	13.081			
	Greenhouse-Geisser	328.62	20.143			

A multiple comparisons analysis was run to understand where significance lay in the time post-TKA (pre, 6 and 12 months post-TKA) and between two groups (UK, KSA). At the baseline before TKA, OKS was significantly different for the UK group (19 ± 6) compared to the KSA group (15 ± 4), a difference of 4 points. At 6 months post-TKA, OKS was statistically significant different in the UK group (29 ± 5) compared to the KSA group (34

± 3), a difference of 5 points. At 12 months post-TKA, the OKS was not statistically significant different in the UK group (38 ± 3) compared to the KSA group (40 ± 1), a difference of 1.8 points (Table 6-26) (Figure 6-14).

In summary, although patients' demographic data and OKS before surgery were significantly different between the two groups, OKS scores at 12 months post-TKA was not significantly different.

Table 6 - 26. Bonferroni multiple comparisons between two groups at different times post-Total Knee Arthroplasty.

Time point	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
Pre-TKA	UK	KSA	4.233	.772	.001	2.703	5.763
	KSA	UK	-4.233	.772	.001	-5.763	-2.703
6 months post-TKA	UK	KSA	-5.595	.574	.001	-6.733	-4.457
	KSA	UK	5.595	.574	.001	4.457	6.733
12 months post-TKA	UK	KSA	-1.853	.356	.063	-2.558	-1.149
	KSA	UK	1.853	.356	.063	1.149	2.558

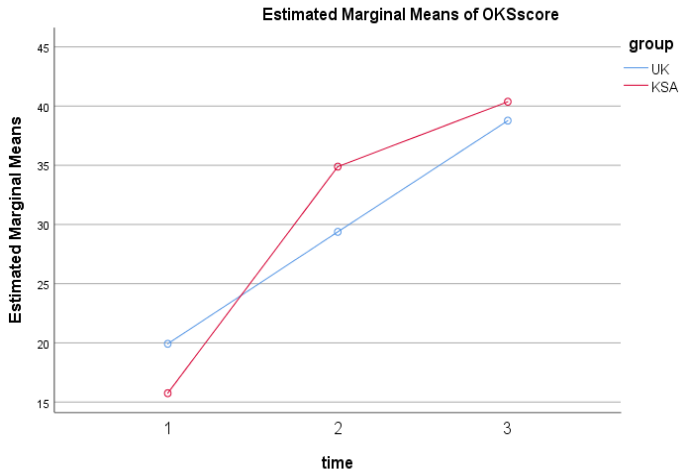

Figure 6- 14. OKS mean difference between two knee arthroplasty approaches used in the UK and the KSA.

6.2.5. Overall Summary of results post- Total knee arthroplasty

All outcome measurements (KOOS, OKS, VAS, SEBT and PBM) were statistically improved at all time points post-TKA. However, the sport and QoL KOOS subscales that were only different between pre- and 12 months post-TKA.

Stepping time and step numbers improved significantly at all time points post-TKA. Sedentary time reduced post-TKA, and improvements in both standing and upright times were observed. However, this did not lead to any significant differences between mean times pre-TKA, 6 months post-TKA and 12 months post-TKA.

The time spent in different cadence bands significantly improved at 12 months post-TKA (purposeful steps, slow to medium steps, moderate to vigorous steps). Only 24% of the participants (8 patients) met the recommendation of 150 minutes of moderate-to-vigorous activity per week for all bout lengths, with only 6% of the participants (2 patients) meeting the recommendation of 150 minutes of moderate-to-vigorous activity per week in bouts ≥10 continuous minutes.

The correlation section showed, PA (stepping time, steps) variations after knee arthroplasty were significantly explained based on a patient's stepping ability before arthroplasty and a history of contralateral knee arthroplasty, with a large effect size. However, no significant correlation or explanation for PA variation were found based on OKS, KOOS scores, PBOMs and SEBT. Patients' satisfaction one-year post-TKA may be predicted based on stepping time and the presence of pain post-TKA with a large effect size, whereas it cannot be predicted before surgery.

Although patients' demographic data and OKS before surgery were significantly different between the two groups (UK AND KSA), OKS scores at 12 months post-TKA was not significantly different.

6.3 Discussion

The study has demonstrated that significant increases in OKS, KOOS, VAS, SEBT and PBM scores at six and twelve months post-TKA. Moreover, PB significantly improved 12 months post-TKA in terms of volume (stepping time & steps number) and pattern (purposeful, slow to moderate and moderate to vigorous and slow physical activity). However, other PA volume components such as sedentary, standing and upright times were improved, but did not meet the statistical significance level.

OKS increased significantly by 20–26 points at 6 and 12 months post-TKA respectively, where high scores are associated with better performance. The current improvement values agree with the improvements in scores found by Marx et al. (2005), where 266 patients post-

primary knee arthroplasty showed a 21–25-point improvement at 6 and 12 months respectively post-TKA. The remaining three studies assessing outcomes 6 and 12 months post-TKA show less improvement in OKS scores, ranging from 13–16 points at 6 months and 15–18 point at 12 months (Hamilton et al., 2012; Hamilton et al., 2012; Judge et al., 2011). This may be due to higher OKS scores before operations in these studies; the minimum OKS score was 19 for all studies, while the current study shows that the worst OKS median score in the literature before TKA was 14 points. In terms of the age factor, all previous studies had a mean age 70 years or more, while the current study's mean age was 65 years. This may explain the large improvement in OKS scores post-TKA as the current patients were younger. In the same way, KOOS and VAS improved in line with improvements on the OKS scale at all time points post-TKA and in accordance with the results obtained by Rose et al. (2003).

The SEBT showed a significant median increase in all three directions at all time points post-TKA, and the effect size was large, ranging from 1.6–2.8. This is the first study to assess the responsiveness of SEBT post-TKA. In two studies that have used an SEBT with a knee OA population, the effect sizes after 6 and 12 weeks of an exercise programme were 0.7-0.8 (Al-Khlaifat et al., 2016; Kanko et al., 2019). Those improvements are smaller than the current findings due to differences in the nature of the subjects' pathology and the marked improvements expected in joints stability post-TKA. Although their age range and BMI were similar, they were grade 2 and 3 knee osteoarthritis according to the Kellgren and Lawrence system. Joint-stability improvements post-TKA differed from mid-stage osteoarthritis improvements after 6-12 weeks of exercise. However, in conclusion, the current findings are similar for effect size in younger participants with anterior cruciate ligament (ACL) deficiency at around 3.51(Herrington, Hatcher, Hatcher, & McNicholas, 2009). A better understanding of joint stability improvement post-TKA requires further research, as it is different in nature from end-stage knee osteoarthritis and ACL injuries. No previous study has assessed responsiveness and effect size post-TKA to compare the current findings with.

All PBMs show significant median increases at different time points post-TKA with a large effect size. The median difference for a 30s CST at 12 months post-TKA was a 7-repetition improvement with a large effect size. The previous MDC concluded by Gill et al. (2008) was a 1.6 repetition post-exercise programme in patients on a waiting list for knee and hip arthroplasty subsequent to end-stage osteoarthritis and rheumatoid arthritis. Therefore, the

current improvements post-TKA are larger than previous ones due to the different nature of the pathology, which is specific to knee joint post-arthroplasty.

The SCT median difference at 12 months post-TKA was 24 seconds with a large effect size. Two previous studies used SCT to assess outcomes post-TKA and found differences that were smaller than in the current study. The study findings of Kennedy et al. (2005) are different from the current results as there were differences in their participants and measurements in the acute stage. The participants were a mixture of both hip and knee arthroplasty and the measurement time was in acute stage, 5 weeks post-TKA, which differs from the current study concerning long-term outcome assessments. The second study by Mizner et al. (2011) obtained comparable results in term of a large effect size of .84, though the mean difference at 12 months post-TKA was only 7 seconds. Although both studies' participants were similar in terms of age and exclusion criteria, the baseline measurements pre-TKA were better than in the current study. The pre-TKA SCT median time for the current study was 54 seconds, whereas in the study by Mizner et al. (2011) it was 19 seconds; this may explain the large differences in the current study's SCT performance post-TKA. In other words, the current patients' SCT performance was low pre-TKA, which may lead to large improvements post-TKA as their pain reduced, and vice versa in the study by Mizner et al. as their performance was good pre-TKA and they showed minor improvements afterwards.

TUG was significant different at different time points post-TKA with a large effect size of 1.2. The time required to perform TUG reduced by 8 seconds at 12 months post-TKA, whereas the only study that assessed TUG 12 months post-TKA was by Mizner et al. (2011) and showed a medium effect size of .79 and a 2-second reduction. The pre-TKA values for the study by Mizner et al. were better than for the current participants, at 10 and 16 seconds respectively. This may confirm the similar results in 30 CST and SCT, the low functional performance pre-TKA showed larger improvements 12 months post-TKA.

6MWT was significantly different at different time points post-TKA, with a median improvement of 37 metres at 12 months post-TKA. One previous study by Mizner et al. (2011) assessed 6MWT 12 months post-TKA and showed a medium effect size and 81 metres improvements at 12 months post-TKA. Although 6MWT pre-TKA scores were low in current study, they did not show marked improvements in other tests, such as 30s CST, SCT and TUG. This may be due to differences in the inclusion criteria, the study by Mizner et al. excluded any patients with a BMI of more than 40 while the current study had no limitation regarding BMI. The BMI of 21% of the current study participants was more than

40 and the other study's BMI mean was 30± 4. A BMI above 40 is one of the predictors that disrupts 6MWT performance and may be due to a reduction in cardio-pulmonary capacity and effort tolerance (Donini et al., 2013).

The present study is the first to explore physical behaviour (PB) changes post-TKA. PB 12 months post-TKA improved significantly in terms of volume (stepping time increased by 23 minutes per day & steps number increased by 1934 steps per day) and pattern (purposeful, slow to medium steps and moderate to vigorous physical activity).

Only two studies are available that assess PA post-TKA, the first by Meiring et al. with no results yet published (Meiring et al., 2016). The second by Lutzner et al. had many methodology limitations, making their conclusion questionable Lutzner et al., (2014). In their study the device was applied to the anterolateral aspect of the tibia a position not in compliance to recommendation and a position not previously validated. This may measure the number of steps but cannot distinguish between sitting and standing. In addition, they only recorded for 4–6 days, which may not be enough to capture actual PB performance, including weekend and working days. The current study steps performance improved by 1,934 steps per day at 12 months post-TKA; this improvements by 45.6%, which is higher than the previous study by Lutzner et al. who reported a 22.6% improvement (Lutzner et al., 2014). These daily step improvements resulted in approximately 2.3 million steps annually (SD 834,755 steps), this may help to improve their overall health. A few studies have measured the numbers of steps post-TKA, but their methods did not meet the recommendations, such as measurements on one day, using a pedometer which has been considered inaccurate for detecting the number of steps or not measuring steps before surgery to detect improvements (Tsonga et al., 2011; Walker, Heslop, Chandler, & Pinder, 2002). Lutzner et al., showed no significant change in stepping time, which is surprising considering their demonstrated increase in steps.

Many previous studies concluded that PA post-TKA remained at or below pre-surgery level, which may be due to many confounding factors that affect the accuracy of their conclusions. Those studies' conclusions were based on PB patients' reported outcome measures (questionnaire) or using energy expenditure as a measure of PB. A few studies rely on questionnaires so the risk of subjective under/ overestimation and recall bias cannot be excluded (Chang, Kim, Kang, Chang, & Kim, 2014; Kersten, Stevens, van Raay, Bulstra, & van den Akker-Scheek, 2012; Smith et al., 2018). Other studies that assessed PB post-TKA concluded that it remained at or below pre-surgery level used postural multiple-sensor design accelerometers. This postural accelerometer's heavy weight and multiple-sensor

design (one sensor along the lateral aspect of the thigh, a second one on the lateral aspect of the calf with connecting cables to a processor monitor at hip level) render it unsuitable for wearing round the clock and their records cover fewer than the recommended number of days, which makes their results questionable(Arnold, Walters, & Ferrar, 2016; Hammett et al., 2018; Harding, Holland, Delany, & Hinman, 2014; Paxton et al., 2015; Vissers et al., 2013). Differences in methodology in terms of monitors' sensitivity and accuracy, the numbers of days worn and the times of day when they were worn have crucial effects on the results and may explain the reasons behind these variations.

The major change detected by the present study was a 583% increase in the time spent on MVPA 12 months post-TKA, it was 6 minutes per week at the baseline and this increased to 41 minutes per week at 12 months post-TKA. The MVPA at 6 months post-TKA showed a 75% improvement, it improved from 6 minutes to 10.5 minutes. In fact, 41 minutes of MVPA per week is less than for symptomatic knee OA (1–24 minutes/day) and the general US population of a similar age (1–22 minutes/day) (Thoma et al., 2018). This may be due to a different measurement methodology being used, and their conclusion being based on an ActiGraph uniaxial accelerometer. ActiGraph is an energy expenditure accelerometer that inaccurately assesses energy expenditure based on cut-off points and thresholds to classify the intensity of activity based on many regression equations. So, overestimation of low-level activity and underestimation of vigorous activity cannot be excluded (Granat, 2012).

One novel feature of this study was the ability to look at how MVPA steps accumulated, considering both MVPA stepping time and sedentary time interruption according to new public health recommendations (Healy et al., 2008). ActivPAL accurately and precisely estimated the time spent in each stepping intensity (start and end time in seconds), therefore stepping event lengths were assessed accurately. The current study found that 6% of the participants met the recommendation of 150 minutes of MVPA per week in events ≥10 continuous minutes. Furthermore, 24% of participants accumulated 150 minutes per week of MVPA for all event lengths, this indicates more interruption of sedentary time. According to an Australian cohort study, regular interruption of sedentary time has positive health benefits such as: improving the profile of triglyceride and plasma glucose, in addition to reducing body mass index and waist circumference (Healy et al., 2008). Prolonged sedentary time is associated with reduced blood flow, pulmonary oxygen uptake and fat metabolism, which increases the risk of chronic diseases such as diabetes mellitus and cardiovascular disease (Vasankari et al., 2017). Therefore, to understand the full picture of PB changes post-TKA, it is essential to measure the time spent in MVPA, sedentary time and sedentary

time interruption. Further motivation activity classes and behavioural interventions post-TKA are recommended to improve PA and reduce the sedentary time interval to meet PA guideline recommendations and enhance the health benefits as pain reduces.

High stepping ability before surgery and a history of contralateral knee arthroplasty significantly increased stepping at 12 months post-TKA. No previous study assessed PA before and after surgery using objective methods with which to compare our findings. The strong correlation between stepping ability before and after arthroplasty may explained by a person's lifestyle. If a patient is generally active and pain limits that, it is logical that if the pain decreases then stepping will increase subsequently. However, patients with end stage knee OA suffer for years from persistent pain that limits activity, which may boost sedentary behaviour before surgery and require a long time to change it post-TKA. Therefore, modifying a sedentary lifestyle and enhancing activity before surgery using any unload methods to minimise the pain may improve stepping and satisfaction post-TKA.

A positive effect of contralateral knee arthroplasty on stepping ability post-TKA is expected, as if both knees are without pain following arthroplasty then functional ability becomes better. In the case of one knee being replaced and the other commonly having some degree of degenerative change, this will limit patient function even after TKA.

Patients' age, gender and BMI did not significantly correlate with stepping time post-TKA in the current study, and this partially agrees with Lutzner Dipl-Pad et al. (Lutzner et al., 2014). The study by Lutzner Dipl-Pad et al. concluded that there was an association with both gender and BMI but not patient's age in 97 patients, without clarifying the effect size and strength of correlation (adjusted R squared). This disagreement over the effect of gender and BMI on stepping time may be due to differences in sample sizes in the regression models. The current study's sample size was small in comparison to the number of predictors analysed, and this limits the regression model's ability to strong effect predictors. while a larger sample size may show more confounding factors with medium to small effects (Field, 2009). To assess the patient factors that may influence PA accurately, a future study with a larger sample size is recommended.

Satisfaction at 12 months post-TKA increased with stepping ability and decreased with pain score at 12 months post-TKA. The negative effect of pain score using VAS at 12 months post-TKA on patients' satisfaction accords with many previous studies (Halawi et al., 2019; Hamilton et al., 2013; Jacobs & Christensen, 2014; Shannak, Palan, & Esler, 2017). Stepping ability's positive effect on patient satisfaction was not assessed before using objective methods to facilitate comparing our findings. However, the current findings show that

satisfaction was strongly affected by functional improvements post-TKA. This agrees with previous studies, although they used different tools, they measured functional changes based on either functional components of PROMs or on specific function task improvements, such as climbing up or down stairs, getting into and out of a car and squatting (Furu et al., 2016; Halawi et al., 2019; Kim, Kwon, Kang, Chang, & Seong, 2010; Loth, Giesinger, Giesinger, Howie, & Hamilton, 2019; Nakahara et al., 2015). Although the functional improvement assessment tools differed, they drew similar conclusions, and this confirms the strong effect of functional improvements on patients' satisfaction post-TKA. Therefore, any interventions to improve PA post-TKA may strongly improve patient satisfaction.

The current study found no significant correlation between OKS, KOOS and PB. This agrees with other studies assessing the correlation between questionnaire and activPAL outcomes for sedentary time (Busschaert et al., 2015; Chastin, Culhane, & Dall, 2014). Therefore, it is recommended wherever possible to use objective methods to assess PB (Healy et al., 2011).

The OKS differences between two knee arthroplasty approaches showed that OKS before surgery was significantly different between the two groups but not significantly different at 12 months post-TKA. For the significantly lower pre-TKA OKS in KSA patients may be due to their significantly higher BMI compared to the UK cohort, and this is comparable to Baker et al.'s (2012) conclusion. Their study showed significant differences in OKS pre-TKA between different BMI groups and the improvements in OKS post-TKA were similar for all BMI groups (Baker et al., 2012). Another possible explanation for the significantly low OKS before surgery in the KSA patients is the long waiting list for surgery, patients were waiting up to 12 months for an orthopaedics consultation and a further 12–24 months for surgery. This waiting time is considerably longer than in the United Kingdom (Lingard et al., 2004). The marked improvement in OKS scores at 12 months post-TKA in comparison with the scores before surgery may be due to many factors. First, the KSA patients were significantly younger than the UK patients, and intensive rehabilitation post-TKA for a minimum of 12 sessions may motivate patients to exercise and enhance their recovery. In addition, a high-flexion knee prosthesis enhances more flexion activities, and this may improve kneeling question responses and other activities requiring flexion, such as stairs, getting in and out of a car or using public transportation. A future study is recommended to assess outcomes using more homogeneous samples and other objective tools to capture objective outcome differences between the two approaches with minimal confounding factors, such as free-living activity changes post-TKA to determine the strengths and

weaknesses of each approach, if present, to improve health service provision and patient outcomes and satisfaction.

Our findings have many implication for clinical practice. Arthroplasty significantly decrease the pain, although it may not be adequate to improve the patients PA and further intervention required. Effective stratigies is essencial to modify the the sedentry life style and increase the PA performance pre/post-TKA. The developed individual stepping prediction equation may be used before surgery as a clinical stratification tool to identify patients who should attend further intervention sessions before surgery, such as walking or load classes or behavioral treatment, to enhance their satisfaction post-TKA. Activity motivation classes and behavioral treatments pre-TKA may improve patients' stepping before and subsequently maximise stepping post-TKA and their satisfaction. The indivedual prediction tool may help to formulate personalised PA performance targets before proceeding to surgery. In addition, the PA prediction equations can be use as individual PA estimation tools to predict PA post-TKA and modify unrealistic expectations before surgery.

The study has many strong points regarding sampling, e.g. although the PB sample size was small it may reflect the general population, as it include both genders and a wide age group and does not have significant differences with large PROM samples in terms of age, gender and BMI. In addition, the recruitment was from a large teaching hospital with wide eligibility for the whole population. The sample size collected in all outcome measurements in the study was within the estimated sample sized required to avoid over/under estimation of the results and statistical/clinical significance conflicts. In term of the measurement approch strengths, the PB etimated based on the average of minimum of 7 days to include the variation in weekdays and weekend. The PB measurements timline were standarised for all time points pre/postTKA to eliminate the constant error.

The study has several limitations: sleeping time was included in sedentary time, which may affect the accuracy of sedentary time changes, as sleeping may improve as pain reduces. Although OKS scores did not change significantly after the first year, it not clear if PB will be similar or it improved. Therefore, a 12-month follow up may not reflect maximum functional recovery post-TKA, so a longer follow-up is recommended. The study indicates no significant effect of patient factors, that may be due to the small sample size and so a future study is recommended with a larger sample size. The formulated prediction equation requires further validation with a larger sample size.

A limitation of the comparison between two arthroplasty approaches is that the sample sizes were not equal, and the follow-up was short, which may affect the accuracy of the

conclusion. A future study is recommended to assess functional outcome differences between the two approaches but with a larger sample size, a longer follow-up and using objective methods such as activPAL, as we cannot exclude recall or under/overestimation bias from the conclusion.

6.4. Conclusion

Patients-reported outcome measures (PROMs) such as OKS, KOOS, VAS did not reflect the magnitude of the functional improvements post-TKA, and there is a clear discordance between subjective and objective methods. Objective free-living PA methods capture actual improvements post-TKA. Unfortunately, they are not correlated with PROMs, which emphasises the need to use objective methods in addition to PROMs, which merely track subjective improvements and may be influenced by recall bias. Although PA improved in terms of stepping and step numbers and patterns, it did not meet PA guideline recommendations. This affirms that arthroplasty alone is unlikely to improve PA and thus educational or behavioural treatments are crucial. Behavioural and motivational classes pre- and post-TKA may change sedentary behaviours to meet PA recommendations and improve overall health. Using the developed individual stepping prediction equation before surgery as a clinical stratification tool to identify patients who need further preparation and to modify their expectations may maximise outcomes and satsfaction post-TKA.

Chapter 7- Discussion and conclusion

This thesis set out to examine functional outcomes, experiences and satisfaction post-TKA, whereby a multiple-method approach was utilised to help further our knowledge in these areas. One of the main advantages of a multiple-method approach is to be able to conduct a wider scope of research projects with more flexibility and deeper illustration of the findings to attain the research objectives. In the present study, it allowed exploration of a wider scope of patients' outcomes post-TKA; tracked short- and long-term changes to outcomes and satisfaction post-TKA; provided deeper insights into patients' experiences, expectations and satisfaction; correlated data to predict short- and long-term outcomes and satisfaction post-TKA; and measured free-living physical activity post-TKA to meet the research objectives. The findings from each study of the research have been discussed in their respective chapters and are not repeated here. This current section focuses on the overall study's main findings and their contribution to the general field of outcomes following TKA (Figure 7-1).

The retrospective study (chapter 4) concluded that outcomes and patients' satisfaction one-year post-TKA is the key to long-term outcomes and satisfaction. OKS scores at one-year post-TKA positively affect OKS scores at five and ten years post-TKA. Satisfaction at one-year post-TKA did not changes at five and ten years post-TKA. Therefore, the factors that affect outcomes and satisfaction after one year should be paid more attention.

One of the prediction factors for good OKS and patient satisfaction one-year post-TKA is previous contralateral knee arthroplasty. This agrees with the FGD findings, as all patients agreed that the second experience was better, they were more confident and knew what to expect. Technically, the procedure is the same for both knees but with a second experience they felt better, more confident and have better OKS scores and satisfaction; this may be due to clear expectations. Therefore, educational classes before surgery are strongly recommended to clarify the process, the progression timeline in detail, the severity of symptoms post-TKA, expected outcomes and limitations, which may improve outcomes and satisfaction. In addition, any possible intervention before surgery that makes the knee arthroplasty journey clearer is recommended, such as discussions with individuals with a history of arthroplasty or real patient testimonials to clarify their experience with daily life details pre/post-TKA.

Interestingly, the history of contralateral knee arthroplasty effects is not limited to better satisfaction post-TKA, the prospective study showed a significant positive effect on stepping time post-TKA. This may be due to other factors rather than just realistic expectations pre-TKA, as if both knees are without pain following arthroplasty functional ability becomes better. In the case of one knee being replaced and the other commonly having some degree

of degenerative changes, this will limit patient function even after TKA. This was confirmed in the retrospective study as the presence of other joints with arthritis had a significant negative effect on short- and medium-term outcomes post-TKA. This point needs consideration, educational and expectation modifications due to the difference in recovery between first and contralateral knee arthroplasty. In addition, further conservative intervention and education may be required to decrease the risk of contralateral knee arthroplasty, although this was not assessed in the thesis.

Expectation achievements were one of three main factors still affecting patients' satisfaction in the short, medium and long term post-TKA in the retrospective study. Outcome expectations post-TKA varied from person to another and the meaning of being better differed from one person to another based on the FGD findings. All patients in the FGD agreed on the crucial role of the surgeon and educational classes before replacement to modify their expectations and make them more realistic and clearer. One example of expectations pre-TKA that needs modification pre-TKA is kneeling ability. All patients in the FGD lost their ability to kneel post-TKA and this was similar to the prospective study findings as the majority lost their kneeling ability. This means they cannot use a squat toilet or pray on the floor as before in end stage of knee arthritis. So, norms and expectations differ from one person to another and this emphasises the value of education and expectation modification pre-TKA, which has a strong effect on patients' satisfaction post-TKA.

The second and third factors still affecting patients' satisfaction in the short, medium and long term post-TKA in the retrospective study were general health and pain. We cannot do much to improve general health before surgery as function is limited due to pain; however, as TKA improves physical behaviour (PB) this may improve general health. A plethora of studies agree with the positive effect of improving PA on general health. Improving PA is associated with a decreased risk for a variety of chronic diseases, such as cardiovascular disease, hypertension, diabetes mellitus, certain cancers, depression, obesity and premature death (Berlin, Storti, & Brach, 2006; Lengfelder, 2001; van Dijk et al., 2016). In addition, increasing PA is strongly associated with longer life expectancy, even in individuals with multimorbidity (Chudasama et al., 2019). A future study is recommended to assess the efficiency of patient education classes, support groups to motivate walking and improving PA, and behavioural treatments to improve overall PB post-TKA to enhance general health and subsequent satisfaction.

Regarding pain, it is well known that residual pain is one of the major causes of dissatisfaction post-TKA (Burns et al., 2015). A further study is required to assess the value of pain psychology and physiology, such as pain catastrophizing and sensitisation, for outcomes post-TKA and possible interventions for that. Catastrophizing is defined as a tendency to magnify or exaggerate the threat value or seriousness of pain sensation, and sensitisation increases sensitivity to nociceptive input and reduces pain thresholds in patients with anxiety and depression (Arendt-Nielsen et al., 2010; Bonnin et al., 2011; Quartana, Campbell, & Edwards, 2009; Skou et al., 2013; Wylde, Palmer, Learmonth, & Dieppe, 2013). So, a patient psychology featuring depression and anxiety negatively affects the outcome, satisfaction and residual chronic pain post-TKA. There was a similar finding in the prospective study as satisfaction was strongly affected by the presence of pain. The FGD came to a comparable conclusion as all patients agreed on the importance of a determined and positive attitude before surgery and that this positively affects their functional recovery post-TKA. Hence, psychological preparation for patients pre-TKA is crucial to modify behaviour, and this may improve the outcome and satisfaction accordingly.

An additional predicting factor for satisfaction post-TKA, concluded from the prospective study, is stepping ability. This is in accordance with the findings of the FGD, as all patients showed a marked improvement in their walking ability in terms of quality and quantity as they expected. Although significant improvements in OKS, KOOS, PBMs, SEBT and stepping post-TKA, only 6% of the patients met the PA guideline recommendations to maintain good health. This clarifies the importance of the difference between statistical and clinical effects in research findings. So, a future study is recommended to assess the efficiency of activPAL monitors if they are used as biofeedback to motivate patients to meet the PA recommendations and maximise the benefits from surgery.

There were no significant differences between the two arthroplasty approaches and OKS scores at one-year post-TKA, although the pre-TKA scores were significantly different. Each approach used different implant prosthesis and rehabilitation protocols; the nonsignificant difference in OKS scores cannot expect/predict the PB difference. A future study is recommended to assess the difference in PB between the two approaches using objective methods. Using an objective, valid and reliable tool such as activPAL, in addition to standardising the method procedure to eliminate constant errors is recommended. This may reveal other factors that affect PB, such as the environment, culture, or health practices which may need further consideration.

There is an agreement regarding no effect of gender, age or BMI on outcomes post-TKA in terms of OKS score and PA concluded from both retrospective and prospective studies. This is similar to the conclusion drawn from the comparison between UK and KSA patients, although the age and BMI differences between the two groups of patients and their OKS score at 12 months were not significantly different. This agrees with previous studies that concluded there was no age or gender effect on OKS scores post-TKA (Ethgen et al., 2004; Lingard et al., 2004). A recent study found a gender difference in osteoarthritis patients post-TKA, the symptoms were worse in females pre-operation and in the acute stage, but by 6 weeks postoperatively sex differences were no longer evident (Nandi et al., 2019). Similarly, the OKS improvements in different BMI groups post-TKA were similar (Baker et al., 2012). However, this contradicts previous studies by Jiang et al. (2017) and Sanchez-Santos et al. (2018) due to sample differences, their samples were a mix of osteoarthritis and rheumatoid arthritis, and it is well known that sex hormones emerge as independent risk factors in rheumatoid disease (Da Silva & Hall, 1992). This conflict over the effect of age, gender and BMI on outcomes post-TKA may be due to the nature of pathology before arthroplasty, rather than the procedure itself.

The retrospective study showed that OKS did not correlate with or predict satisfaction, and the prospective study concluded that OKS did not correlate with or predict satisfaction or PB. So, the OKS may be used as a feasible tool to measure outcomes post-TKA but not to correlate with or measure satisfaction or PB. The satisfaction expressed in the FGD differed from overall satisfaction scale in the PROMs. Patients' satisfaction answers in the FGD started with pre-TKA (symptoms, GP, surgeon, physiotherapy, surgery timing) and extended to post-TKS (symptoms, medical care received, pain control, physiotherapy service, recovery, walking ability, ADL improvements and limitations, meeting expectations). This clarifies the variation in each outcome measurement method and the importance of using both subjective and objective tools to capture the bigger picture of functional changes post-TKA. The patient's satisfaction post-TKA is multifactorial and mainly effected by stepping ability and meeting expectations. So, pre-TKA intervention to improve stepping ability is a crucial aspect to improve satisfaction, in addition to clear and realistic expectations before surgery. The individual patient's preparation in terms of physical ability (stepping ability) and behavioural modification (realistic expectation) is the key to post-TKA satisfaction.

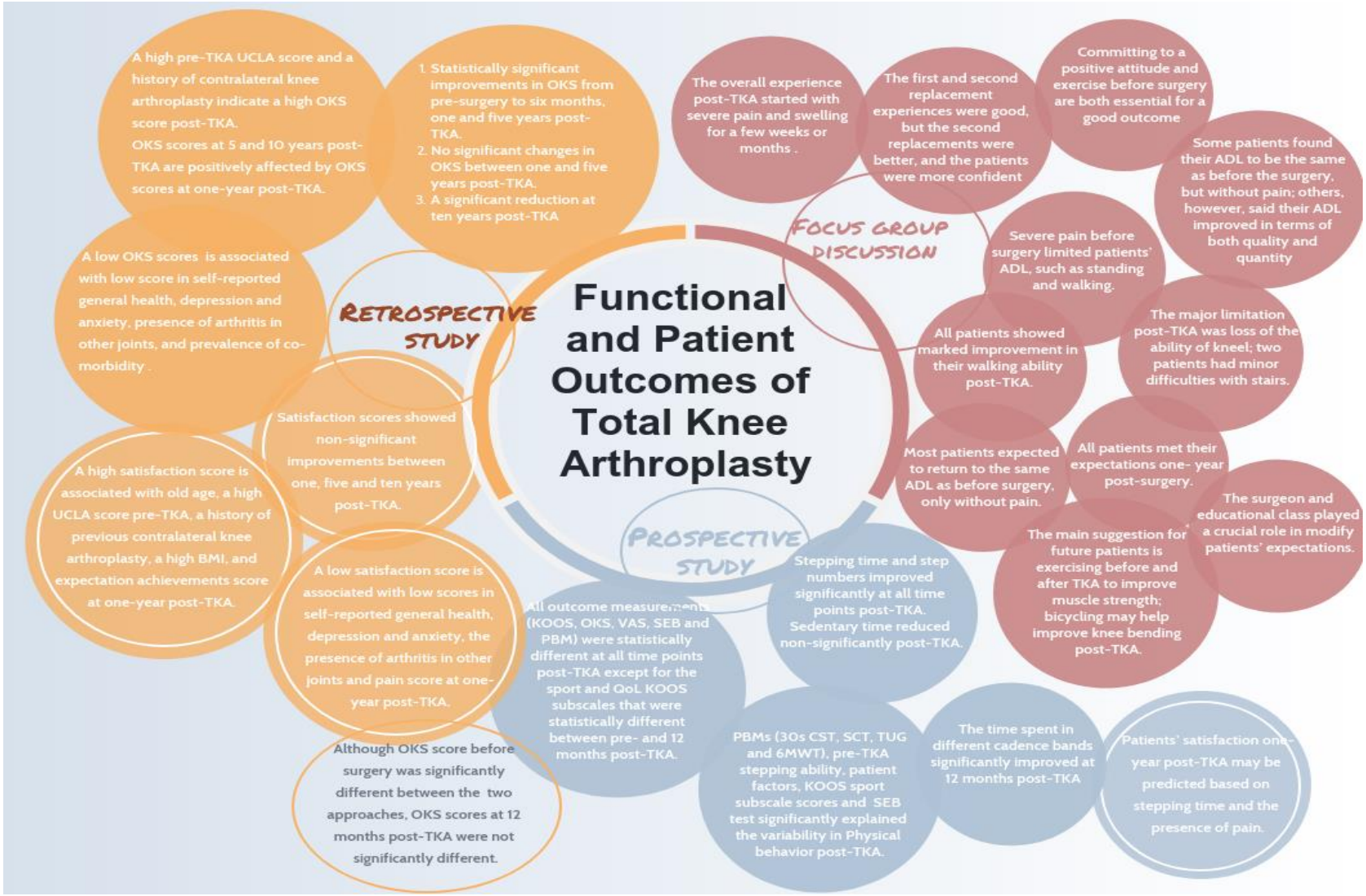

Figure 7-1. Summary of overall thesis' main findings

Contributions and implications for practice:

This thesis makes several contributions to the literature in addition to providing an overview of short- and long-term outcomes and satisfaction post-TKA. It provides validated predictions for short- and long-term outcomes and satisfaction post-TKA. It has identified significant factors and has the power to predict good and poor outcomes and satisfaction post-TKA and can enhance proper patient selection and preparation for knee arthroplasty.

Short-term OKS predictions post-TKA may be used to modify patient expectations before surgery as expectations are one of the significant predictors for short- and long-term satisfaction post-TKA. The study highlights the effect of patients' psychology pre-TKA on outcomes, satisfaction and the presence of residual pain post-TKA. Therefore, it is recommended to provide enough individual education, activity motivation groups, physical activity classes and behavioural preparations to improve physical performance before surgery, modify unrealistic expectations and thus improve outcomes and satisfaction post-TKA.

The long-term pattern of change in OKS post-TKA showed a peak improvement at one year, followed by a plateau for several years, then a significant reduction at ten years post-TKA. This long-term change pattern allows health practitioners to plan any further behavioural and motivation interventions such as classes or activity groups to improve functional outcomes after the first year or to maintain outcomes for more than ten years post-TKA. Improving PB post-TKA can enhance overall health and may decrease the effect of comorbidities or the need for contralateral arthroplasty.

The FGD paints an in-depth picture of patients' experiences post-TKA and the important issues that affect their satisfaction, such as: severity of symptoms; surgeon communication; what to expect from physiotherapy services; pain control options; recovery time frame; the patient's role in rehabilitation; ADL improvements, limitations and expectations; recommendations from previous patients who have undergone arthroplasty. Hence, proper standardised educational and behavioural interventions are required to clarify all the above issues, as it crucial to improve their experience, expectations and satisfaction post-TKA.

A significant reduction in pain post-TKA leads to significant improvements in stepping time, steps and pattern. One novel feature of this study was the ability to look at how MVPA steps accumulated, considering both MVPA stepping time and sedentary time interruption. The current study found that 6% of the participants met the recommendation of 150 minutes of MVPA per week in events ≥10 continuous minutes. Furthermore, 24% of participants accumulated 150 minutes per week of MVPA for all event lengths, this indicates more

interruption of sedentary time. This has positive health benefits and reduced the sedentary time risk of chronic diseases. This can be enhanced to meet physical activity recommendations with further motivation interventions, such as behavioural or exercise programmes. For example, activPAL or reliable smart watches can be used as biofeedback to motivate patients to improve their PB post-TKA. Setting personal targets may be based on the number of steps per day or reminders to interrupt the sedentary interval. This has been used to motivate stroke patients and has shown significant effect in comparison to control groups without any tools (Dong et al., 2018; Lawrie et al., 2018).

The developed individual stepping prediction equation may be used before surgery as a clinical stratification tool to identify patients who should attend further interventions before surgery, such as walking or unload classes or behavioral treatment to enhance PA before-TKA and subsequently imoprove satisfaction post-TKA. In addition, the stepping prediction equations can be use as individual PA estimation tools to predict PA post-TKA and modify unrealistic expecations before surgery.

Patient reported outcome measures (PROMs), such as OKS and KOOS, did not reflect the magnitude of functional improvements post-TKA and there is a clear discordance between outcomes and objective methods. The variations in each outcome measurement method and poor correlation emphasise the importance of using both subjective and objective tools to capture a holistic view of functional changes post-TKA.

The Arabic version of OKS is a feasible, valid, reliable and sensitive measure that can be used to assess pain and function in individuals whose main language is Arabic and who have end-stage knee OA.

The SEBT is a highly reliable tool to measure dynamic balance in all three directions with end-stage knee OA patients. SEBT is a sensitive and accurate way to detect balance changes post-TKA at six- and twelve-months post-arthroplasty.

Limitations of the research and future research recommendations

In addition to the limitations previously outlined in each section, a possible criticism of this study relates to the small sample size in the FGD and the prospective study. In addition, the FGD and retrospective studies were conducted in one of the best hospitals in the country. This may explain the high satisfaction rate in both studies, and this may not represent all trust outcomes. So, a future study is recommended using population-based cohort sampling to improve the generalisability of the findings.

The knee arthroplasty approaches comparison was based on subjective methods, so under/overestimation and recall bias cannot be excluded. A future study is recommended to

assess the differences in PB between the two approaches using objective methods. A comparison is recommended using an objective, valid and reliable tool such as activPAL, in addition to standardising the method procedure to eliminate constant errors. This may reveal other factors that affect PB, such as the environment, culture, or health practices which may need further consideration.

The study assessed pain based on visual analogue scales without pain sensitisation or catastrophising assessments to exclude their effects on outcomes post-TKA. So, a future study is recommended using valid and reliable methods to assess pain sensitisation and catastrophising effects on short- and long-term outcomes post-TKA, such as a handheld pressure algometer and a pain catastrophising scale.

The FGD was limited to one group, a future study recommended to continue until saturation is reached in different health centres. In addition, most of the patients in FGD agreed on the importance of exercise before surgery and its value for good outcomes post-TKA. To ease the severity of pain pre-TKA without weight-bearing activity, they found swimming and cycling useful. This finding was not assessed prospectively in the current study to explore its effect on outcomes, so a future study is recommended to explore the effect of pre-TKA strengthening exercises on outcomes post-TKA.

The physical behaviour (PB) follow-up in current study was limited to one year, so the long-term pattern of change post-TKA remains unclear and requires a future study with a longer follow-up.

The effects of other confounding factors were not assessed in either the retrospective or the prospective studies, such as socioeconomic and surgical details. Thus, a future study is recommended to assess the effects on short and long-term outcomes post-TKA.

A future study is recommended to explore the differences in PB and change after a first and a contralateral knee arthroplasty. This may clarify the appropriate timing between the two, and the effect on overall functional recovery.

Finally, the relevance and generalisability of the study findings need consideration due to many factors. The retrospective study's conclusion requires external validation with a different sample, the FGD was limited to one group without reaching saturation level, and the PB prospective study's small sample size may not be representative of general patients post-TKA.

Conclusion

Total knee arthroplasty is the gold standard treatment for end-stage knee osteoarthritis, it significantly decreases pain and improves functionality. Patient-reported outcome measures (PROMs) peaked post-TKA at one year and remained steady for several years, before a significant reduction at 10 years. Patients' functional outcomes and satisfaction post-TKA are multifactorial, and the first year is key to long-term outcomes and satisfaction. The prediction equation developed may help to estimate outcomes, design individual pre-TKA behavioural treatments and modify unrealistic expectations to improve outcomes and satisfaction post-TKA. In addition, general education classes can clarify the overall experience, such as: the severity of symptoms post-TKA, pain control options, expected care post-surgery from surgeons and physiotherapy, possible functional limitations and improvements.

Physical behaviour (PB) improved post-TKA in both volume and pattern six and twelve months post-TKA. No correlation was found between PB and OKS and KOOS. There is a clear discordance between PB outcomes and PROMs, this emphasises the need to use objective methods in addition to PROMs, which merely track subjective improvements and may be influenced by recall bias. The developed stepping prediction equation may improve individual patient preparation and modify unrealistic expectations according to their performance before surgery and thus improve their satisfaction post-TKA.

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Appendixes

Study One Appendixes

Appendix 1 -Salford University Ethical Panel approval

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

7 June 2017

Dear Bodor,

RE: ETHICS APPLICATION HSR1617-137 – 'Retrospective analysis of patient outcome questionnaire following primary knee replacement.'

Based on the information you provided I am pleased to inform you that your application HSR1617-137 has been approved to go forward to NRES.

Once you have received it, please submit a copy of the NRES approval letter to Health-ResearchEthics@salford.ac.uk so that it can be placed on your application file.

If there are any changes to the project and/or its methodology, please inform the Health Research Ethics Support team as soon as possible.

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

Appendix 2 -Health Research Authority approval

NHS
Health Research Authority

Ms Bodor Bin Sheeha
P03 Brian Blatchford Building
University of Salford
Frederick Road Campus
M6 6PU

Email: hra.approval@nhs.net

22 September 2017

Dear Ms Bin Sheeha,

Letter of HRA Approval

Study title:	**Retrospective analysis of patient outcome questionnaire following primary knee replacement.**
IRAS project ID:	**232226**
REC reference:	**18/HRA/0168**
Sponsor	**UNIVERSITY OF SALFORD**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

Appendix 3 - Stockport NHS Foundation Trust letter of access

Stockport NHS
NHS Foundation Trust

Bodor Bin Sheeha
Flat 94
94 City Lofts
Salford Quays
M50 3TS

Research & Innovation Office
F08, Pinewood House
Stepping Hill Hospital
Poplar Grove
Stockport
SK2 7JE

Tel: 0161 419 5801 / 5814
E: Research.Development@stockport.nhs.uk

20th November 2017

Dear Bodor,

Letter of access for research
Study: **Patients' views on outcomes following total knee arthroplasty / Exploring outcomes post-primary total knee arthroplasty (TKA) using the available pre/post-operative Patients Reported outcome scale / Measure the patient's outcome before and after total knee arthroplasty.**

This letter confirms your right of access to conduct research through Stockport NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **13 November 2017** and ends on **30 November 2018** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in the confirmation of capacity and capability for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received this as well as the 'greenlight' from the sponsor to commence recruitment to the project.

The information supplied about your role in research at Stockport NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Stockport NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Stockport NHS Foundation Trust you will remain accountable to your employer **University of Salford** but you are required to follow the reasonable instructions of **Professor David Johnson** in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Stockport NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

Your Health. Our Priority.

You are required to co-operate with Stockport NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Stockport NHS Foundation Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (https://digital.nhs.uk/article/1200/Confidentiality) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

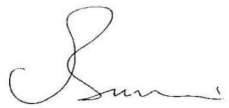
You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Stockport NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely



Dr Gillian Burrows
Deputy Medical Director and R&I Chair

cc: Prof. Richard Jones, Academic Supervisor University of Salford r.k.jones@salford.ac.uk
Joanne O'Gara, HR for Stockport NHS Foundation Trust
Prof. David Johnson, Consultant Orthopaedic Surgeon, Stockport NHS FT

Study Two Appendixes

Appendix 1- Salford University Ethical Panel approval

Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

13 February 2017

Dear Bodor,

RE: ETHICS APPLICATION HSR1617-46 – 'Patients' views on outcomes following total knee arthroplasty: a focus-group study.'

Based on the information you provided I am pleased to inform you that your application HSR1617-46 has been approved to go forward to NRES.

Once you have received it, please submit a copy of the NRES approval letter to Health-ResearchEthics@salford.ac.uk so that it can be placed on your application file.

If there are any changes to the project and/or its methodology, please inform the Health Research Ethics Support team as soon as possible.

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

Appendix 2 - Health Research Authority approval

NHS
Health Research Authority

Ms Bodor Bin sheeha
P03 Brian Blatchford Building
Salford University
Salford University
M6 6PU

Email: hra.approval@nhs.net

31 August 2017 (re-issued 31.08.2017)

Dear Ms Bin sheeha

Letter of HRA Approval

Study title:	**Patients' views on outcomes following total knee arthroplasty: a focus-group study**
IRAS project ID:	**224594**
REC reference:	**17/LO/0838**
Sponsor	**University of Salford**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

Appendix 3- Stockport NHS Foundation Trust letter of access

Stockport NHS
NHS Foundation Trust

Bodor Bin Sheeha
Flat 94
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Research & Innovation Office
F08, Pinewood House
Stepping Hill Hospital
Poplar Grove
Stockport
SK2 7JE

Tel: 0161 419 5801 / 5814
E: Research.Development@stockport.nhs.uk

20th November 2017

Dear Bodor,

Letter of access for research
Study: **Patients' views on outcomes following total knee arthroplasty / Exploring outcomes post-primary total knee arthroplasty (TKA) using the available pre/post-operative Patients Reported outcome scale / Measure the patient's outcome before and after total knee arthroplasty.**

This letter confirms your right of access to conduct research through Stockport NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **13 November 2017** and ends on **30 November 2018** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in the confirmation of capacity and capability for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received this as well as the 'greenlight' from the sponsor to commence recruitment to the project.

The information supplied about your role in research at Stockport NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Stockport NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Stockport NHS Foundation Trust you will remain accountable to your employer **University of Salford** but you are required to follow the reasonable instructions of **Professor David Johnson** in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Stockport NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

Your Health. Our Priority.

Appendix 4- Focus Group Agenda and Discussion Guide

Agenda

Refreshments and thank participants for attending.
Explain the aims of the study to the participants and ensure all participants have signed a consent form and a recording agreement.
Reiterate to participants that they are able to leave the focus group and study at any time.
Remind participants that they will remain anonymous, be audio-recorded and might be anonymously quoted verbatim.
Respecting other group members.
Conduct the focus group, summarise and distribute the researcher's contact details if participants wish to discuss any issues after the group session.

Discussion guide

How was your experience of Total Knee Arthroplasty (TKA)?

Functional improvements after TKA
Probes: Have you experienced any improvement in your function? What types of activity have improved? To what extent?

Loss of function after TKA
Probes: Have you experienced any loss of function? For how long? What modifications have you made to compensate for that? What are your barriers?

Socioeconomic aspects
Probes: In the course of your routine activities do you need help. Do you need family support? (for how long? for what tasks?) Do you need social-health services? (for how long? for what?) Were you able return to work after TKA? (if not, why? what are the barriers?)

Satisfaction and expectations
Probes: How do you feel about your surgery now? Does it satisfy all your expectations? What were your expectations? Are you planning surgery for your other knee if it has the same complaint? Would you recommend surgery to your friends or relatives?

Health team communication
Probes: Did you receive sufficient information and explanation about surgery and expectations in advance from the health team? Was that sufficient for what you needed to know before surgery? Do you think that has affected your satisfaction after surgery? What is the most important information you think all patients should know before surgery?

Rehabilitation services
Have you received or are your receiving physiotherapy post-surgery? For how long? How many sessions? Were or are you satisfied with it? What do you recommend in terms of physiotherapy services?

What are your recommendations to future TKA patients?
Do you have additional concerns not covered during this meeting regarding the period after hospital discharge up to a one-year follow-up?

Techniques to consider: Probing questions, reflecting back, Repeating, Active listening, Summarising

Study Three Appendixes
Appendix 1- Salford University Ethical Panel approval

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
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T +44(0)161 295 2280

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13 February 2017

Dear Bodor,

RE: ETHICS APPLICATION–HSR1617-39–'A Psychometric Analysis of the Arabic Version of Oxford Knee Score before and after Total Knee Arthroplasty in a Middle East population and an exploration of outcomes post-total knee arthroplasty in the Middle East.'

Based on the information you provided I am pleased to inform you that application HSR1617-39 has been approved.

If there are any changes to the project and/or its methodology, then please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

Appendix 2- King Khalid University Hospital Approval

Kingdom of Saudi Arabia
King Saud University(034)
P.O.Box 7805 Riyadh 11472
Tel: +966 11 4670011
Fax: +966 11 4671992
http://medicalcity.ksu.edu.sa

المملكة العربية السعودية
جامعة الملك سعود (034)
ص.ب ٧٨٠٥ الرياض ١١٤٧٢
هاتف : ٠١١ ٤٦٧٠٠١١ ٩٦٦+
فاكس : ٠١١ ٤٦٧١٩٩٢ ٩٦٦+

جامعة الملك سعود
King Saud University

المدينة الطبية الجامعية

06.04.2017 (09.07.1438)
Ref. No. 17/011/IRB

To: **Dr. Ahmad Bin Nasser**
Consultant Surgeon
Chairman of the Orthopedic Surgery Department
King Saud University Medical City
Email: ahmadbn@mac.com
Principal Investigator

Cc: Bodor Bin Sheeha – PhD Student
Co-Investigator

Subject: **Approval of Research Project No. E-17-2395**

Study Title: "A Psychometric Analysis of the Arabic Version of Oxford Knee Score before and after Total Knee Arthroplasty in a Middle East population and an exploration of outcomes post-total knee arthroplasty in the Middle East"

Type of Review: Expedite
Date of Approval: 05 April 2017
Date of Expiry: 06 April 2018

Dear Dr. Ahmad Bin Nasser,

I am pleased to inform you that your above-mentioned research project submitted to the IRB was reviewed and approved on 05 April 2017 (08 Rajab 1438). You are now granted permission to conduct this study given that your study does not disclose participant's identity and poses no risk to the patients.

As principal investigator, you are required to abide by the rules and regulations of the Kingdom of Saudi Arabia and the research policies and procedures of the KSU IRB. If you make any changes to the protocol during the period of this approval, you must submit a revised protocol to the IRB for approval prior to implementing the changes. Please quote the project number shown above in any future correspondence or follow-ups related to this study.

We wish you success in your research and request you to keep the IRB informed about the progress and final outcome of the study in a regular basis. If you have any question, please feel free to contact me.

Thank you!

Sincerely yours,

Dr. Ayman A. Al-Eyadhy
Chairman of IRB
Health Sciences Colleges Research on Human Subjects
King Saud University College of Medicine
P. O. B ox 7805 Riyadh 11472 K.S.A.
Email: aleyadhy@ksu.edu.sa

كلية الطب
لجنة أخلاقيات البحوث الطبية
College Medicine
Institutional Review Board (IRB)

/rubie

Appendix 3 - Arabic Questionnaire

استبيان لتقييم الحالة الصحية للركبة

تاريخ اليوم: ..../...../1438. تاريخ الميلاد: ...../...../..... العمر: .....سنة

الاسم: ..... الجنس: □ ذكر □ أنثى

هل انت مدخن □ نعم □لا الركبة الأشد ألم: □ يمين □ يسار □ كلتاهما

الحالة الاجتماعية: □ عازب □ متزوج □ مطلق □ أرمل

الوظيفة: □ موظف مكتبي □ موظف ميداني □ معلم □ متقاعد □ ربة منزل

المؤهل العلمي:□ ابتدائي □متوسط □ثانوي □دبلوم □بكالوريوس □ماجستير □دكتوراه

ضع إشارة × في المكان الذي يعبر عن ألم ركبتك الان حيث يمثل اقصى اليمين اشد/ أسوء ألم ممكن تحمله بينما أقصى اليسار لا تشعر بألم اطلاقا

I----------I

أشعر بألم شديد جدا **لا أشعر مطلقا باي ألم**

فضلا اجب عن هذا السؤال في حال انك خضعت لعملية مفصل الركبة.

ضع إشارة × في المكان الذي يعبر عن مدى رضائك عن نتائج العملية الان حيث يمثل اقصى اليمين عدم الرضا بينما أقصى اليسار الرضا التام.

I----------I

غير راض **راض تماما**

هذه المعلومات سوف تساعدنا لمعرفة كيف تشعر بركبتك وقدرتك على إنجاز نشاطاتك اليومية

أجب كل سؤال بوضع علامة (√) واحدة على الإجابة المناسبة أمام كل سؤال، وإذا كنت غير متأكد من الإجابة الرجاء اختيار أقرب إجابة ممكنة.

أعراض المرض

ينبغي الإجابة على هذه الأسئلة المتعلقة بالأعراض المصاحبة لركبتك خلال الأسبوع الماضي.

S1 ماهي شدة صعوبة فرد الركبة عند استيقاظك في الصباح؟

□ لا صعوبة □ خفيفة □ متوسطة □ شديدة □ شديدة جدا

S2 ما هي شدة صعوبة فرد الركبة بعد وضع الجلوس، التمدد أو الاسترخاء في وقت لاحق من نفس اليوم؟

□ لا صعوبة □ خفيفة □ متوسطة □ شديدة □ شديدة جدا

S3 هل يوجد تورم في ركبتك؟

□ لا يوجد □ نادرا □ أحيانا □ غالبا □ دائما متورمه

S4 هل تشعر بأي خشخشة أو تسمع طقطقة أو أي نوع آخر من الأصوات عندما تحرك ركبتك؟

□ لا أبدا □ نادرا □ أحيانا □ غالبا □ دائما

S5 هل ركبتك تعلق/ تقفل عندما تقوم بالحركة ؟

□ لا أبدا □ نادرا □ أحيانا □ غالبا □ دائما

التيبس

الأسئلة التالية تتعلق بدرجة تيبس (تصلب) مفصل الركبة الذي أحسست به خلال الأسبوع الماضي. التيبس هو الشعور بالتقييد أو البطيء في سهولة حركة مفصل الركبة.

S6 هل يمكنك فرد ركبتك بالكامل (علي الآخر)؟

□ دائما □ غالبا □ أحيانا □ نادرا □ لا ابدا

S7 هل يمكنك ثني ركبتك بشكل كامل (علي الأخر) ؟

□ دائما □ غالبا □ أحيانا □ نادرا □ لا ابدا

الألم

P1 كم مرة تحس بألم في ركبتك عادة؟

□ لا أبدا □ كل شهر □ كل اسبوع □ كل يوم □ دائما

ماهي شدة الألم التي قد تكون شعرت بها الأسبوع الماضي خلال أدائك للنشاطات الآتية...؟

P2 اللف و الاستناد (الارتكاز) علي الركبة المصابة

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P3 فرد الركبة بالكامل

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P4 ثني الركبة بالكامل مثل وضع الجلوس للتشهد في الصلاة

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P5 المشي على الأرض المستوية

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P6 طلوع أو نزول السلالم

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P7 في الليل، أثناء وجودك في السرير للنوم

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P8 وضع الجلوس أو الاستلقاء

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

P9 عندما تقف لبضع دقائق (اقل من 10 دقائق)

□ غير مؤلم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

أنشطة الحياة اليومية

ما هو مستوى الصعوبات التي واجهتها في الركبة الأسبوع الماضي...؟

A1 في نزول الدرج

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A2 في صعود (طلوع) الدرج

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A3 القيام من وضع الجلوس

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A4 الوقوف لأكثر من 10 دقائق

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A5 انحناء الجسم عند النزول لالتقاط الأشياء من علي الأرض او الركوع

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A6 المشي على أرض مستوية

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A7 الصعود و النزول من السيارة

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A8 الذهاب للتسوق

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A9 لبس الشرابات القصيرة أو الطويلة

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A10 القيام /النهوض من السرير

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A11 خلع الشرابات القصيرة أو الطويلة

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A12 النوم في السرير (التقلب علي أحد الجانبين أو الحفاظ علي وضع ثابت للركبة)

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A13 عند قيامك بالاستحمام

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A14 وضع الجلوس

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A15 عند قيامك بقضاء الحاجة (قياما و قعودا من علي كرسي الحمام)

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A16 الأعمال المنزلية المجهدة كتحريك و نقل الصناديق الثقيلة، شطف البلاط ...الخ

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

A17 الأعمال المنزلية الخفيفة كالطبخ، و مسح الغبار، ...الخ

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة شديدة □ صعوبة شديدة جدا

النشاط الرياضي والمهارات اللازمة لممارسة الهوايات

ما الصعوبات التي قابلتها في الركبة الأسبوع الماضي؟

SP1 ثني الركبتين من وضع الوقوف

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة شديدة □ صعوبة شديدة جدا □ لا أستطيع

SP2 الجري

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة شديدة □ صعوبة شديدة جدا □ لا أستطيع

SP3 القفز / النط

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة شديدة □ صعوبة شديدة جدا □ لا أستطيع

SP4 اللف و الاستناد (الارتكاز) علي الركبة المؤلمة

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة شديدة □ صعوبة شديدة جدا □ لا أستطيع

SP5 النزول و الارتكاز علي الركبتين كالنزول للسجود في الصلاة او الفرفصاء

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة شديدة □ صعوبة شديدة جدا □ لا أستطيع

الركبة المصابة وعلاقتها بنمط الحياة

Q1 إلى أي مدي تشملك مشاكل ركبتك أو تمثل مساحة من ذهنك أو تفكيرك؟

□ لا أفكر بها مطلقا □ شهريا □ أسبوعيا □ يوميا □ دائما

Q2 هل قمت بتعديل أسلوب حياتك لتجنب الأنشطة التي قد تسبب تلف او ألم في ركبتك؟

□ لا مطلقا □ تعديلات بسيطة □ تعديلات متوسطة □ تعديلات كبيرة □ تعديلات جذرية

Q3 ما مدي قلقك من عدم تمتك بكفاءة أداء ركبتك ؟

□ لست قلق □ قلق لا يذكر □ قلق متوسط □ قلق شديد □ قلق شديد جدا

Q4 بشكل عام، ما مدى الصعوبات التي تقابلها عند ممارسة حياتك الطبيعية بسبب مشاكل ركبتك ؟

□ بدون أي صعوبة □ صعوبة بسيطة □ صعوبة شديدة □ صعوبة شديدة جدا □ لا أستطيع

شكرا جزيلا لإجابتك على كل الجزء الأول في هذا الاستبيان الخاص بتقييم الألم خلال <u>الأسبوع الماضي</u>

ضع علامة صح في مربع واحد عن كل سؤال لوصف اعراض ركبتك خلال الأربع الأسابيع الماضية:

س1. خلال الأربعة أسابيع الماضية، كيف تصف الألم الذي عادة ما كان ينتابك في ركبتك؟

□ لا يوجد ألم □ ألم خفيف □ ألم متوسط □ ألم شديد □ ألم شديد جدا

س2. خلال الأربعة أسابيع الماضية، هل واجهت أي صعوبات في غسل وتجفيف جميع أجزاء جسمك بسبب مشكلة ركبتك؟

□ لم أواجه صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة بالغة □ مستحيل أن افعل ذلك

س3.خلال الأربعة أسابيع الماضية، هل واجهت أي صعوبات في صعود أو النزول من السيارة، أو عند استخدام وسائل النقل العام بسبب ركبتك؟

□ لم أواجه صعوبة □ صعوبة بسيطة □ صعوبة متوسطة □ صعوبة بالغة □ مستحيل أن افعل ذلك

س4.خلال الأربعة أسابيع الماضية، كم من الوقت كنت قادرا على المشي قبل أن يصبح الألم بركبتك شديداً؟

(سواء باستخدام عصا أو بدونها)

□ بدون ألم أكثر من 30 دقيقة □ 16-30 دقيقة □ 5-15 دقيقة □ في المنزل فقط □ لا على الاطلاق الم شديد عند المشي

س5.خلال الأربعة أسابيع الماضية، بعد تناول وجبة بالجلوس على كرسي ، ما هو مقدار الألم الذي كنت تشعر به عند الوقوف من على الكرسي بسبب ركبتك؟

□ ليس مؤلما على الإطلاق □ مؤلم قليلا □ مؤلم بشكل متوسط □ مؤلم جدا □ لا يطاق

س6. خلال الأربعة أسابيع الماضية، هل كنت تعرج أثناء المشي، بسبب ركبتك؟

□ نادرا / أبدا □ في بعض الأحيان، أو فقط في البداية

□ في كثير من الأحيان، وليس فقط في البداية □ في معظم الأوقات □ كل الوقت

س7. خلال الأربعة أسابيع الماضية، هل كنت تستطيع أن تركع على ركبتك وأن تنهض من الركوع؟

□ نعم بسهولة □ بصعوبة قليلة □ بصعوبة متوسطة □ بصعوبة بالغة □ لا، مستحيل

س8. خلال الأربعة أسابيع الماضية، هل كان ألم الركبة يسبب لك مشاكل أثناء النوم ليلاً؟

□ لم يحدث في أي ليلة □ فقط ليلة أو ليلتين □ بعض الليالي □ معظم الليالي □ كل ليلة

س9.خلال الأربعة أسابيع الماضية، الى أي مدى منعك الألم في ركبتك من القيام بعملك المعتاد بما في ذلك الأعمال المنزلية؟

□ لم يحدث على الإطلاق □ بشكل قليل □ بشكل متوسط □ بشكل كثير □ بشكل تام

س10.خلال الأربعة أسابيع الماضية، هل شعرت بأن ركبتك قد' تنهار 'أو تخذلك فجأة؟

□ نادرا /أبدا □ في بعض الأحيان، أو فقط في البداية

□ في كثير من الأحيان، وليس فقط في البداية □ في معظم الأوقات □ كل الوقت

س11.خلال الأربعة أسابيع الماضية، هل تمكنت من أن تتسوق لشراء مستلزمات المنزل بنفسك؟

□ نعم، بسهوله □ بصعوبة قليلة □ بصعوبة متوسطة □ بصعوبة بالغة □ لا، مستحيل

س12. خلال الأربعة أسابيع الماضية، هل كنت قادرا على نزول الدرج لطابق واحد؟

□ نعم، بسهوله □ بصعوبة قليلة □ بصعوبة متوسطة □ بصعوبة بالغة □ لا، مستحيل

في النهاية، الرجاء التأكد من أنك أجبت على جميع الأسئلة.

شكرا جزيلا لك.

Appendix 4- Oxford Knee Score (OKS)

Appendix 4- Oxford Knee Score (OKS)

Check (□) 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 □Moderate □Severe

2. During the past 4 weeks, have you had any trouble with washing and drying yourself (All over) because of your knee?

□No trouble at all □Very little trouble □Moderate trouble

□Extreme difficulty □Impossible to do

3. During the past 4 weeks, have you had any trouble getting in and out of a car or using public transportation because of your knee? (Whichever you would tend to use)

□No trouble at all □Very little trouble □Moderate trouble

□Extreme difficulty □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 cane)

□ No pain/more than 30 minutes □16 to 30 minutes □5 to 15 minutes

□Around the house only □Not at all/severe pain when walking

5. During the past 4 weeks, after a meal (sitting 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?

□ Rarely/ never □Sometimes, or just at first □Often, not just at first

□Most of the time □All of the time

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

□Yes, easily □With little difficulty □With moderate difficulty

□With extreme difficulty □No, impossible

8. During the past 4 weeks, have you been troubled by pain from your knee in bed at night?

□No nights □Only 1 or 2 nights □Some nights

□Most nights □Every night

9. During the past 4 weeks, how much has pain from your knee interfered with your usual work (including housework)?

□Not at all □A little bit □Moderately □Greatly □Totally

10. During the past 4 weeks, have you felt that your knee might suddenly "give out" or let you down?

□ Rarely/ never □Sometimes, or just at first □Often, not just at first

□ Most of the time □ All of the time

11. During the past 4 weeks, could you do the grocery 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 □No, impossible