EARLY OUTCOMES OF PRIMARY TOTAL KNEE REPLACEMENT:

A MULTICENTER STUDY

A Research Dissertation Submitted in Partial Fulfilment for the Award of Master of Medicine in Orthopedics Surgery, University of Nairobi.

by

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DECLARATION

This research dissertation is my original work and has not been presented in this university or any other higher learning institution for the awarding of a degree. All works used from other authors have been accordingly referenced.

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DEDICATION

Dedicated to my loving parents, my beautiful wife and my two children. Thank you for believing in me. Thank you for your prayers and for holding my hand throughout this journey of life. Because of you, I am.

My mother Faith Wangeci Nyagah; my motivator.

My father Stephen Nyagah Ngari; the future is bright.

My children; Darrell Nyagah and Eliana Wangeci; the sky will never be the limit.

My wife; Jackline Mbatha; my pillar of strength.

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LIST OF ACRONYMS AND ABBREVIATIONS

BMI	Body Mass Index
CDC	Center for Disease Control
DVT	Deep Venous Thrombosis
KNH	Kenyatta National Hospital
NRS	Numeric Rating Scale
OKS	Oxford Knee Score
ROM	Range of Motion
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
TKR	Total Knee Replacement

DEFINITION OF TERMS

Clinical characteristics: Defined in this study as age, gender, BMI and physiotherapy.

Early outcomes: Occurrence of range of motion, pain, temperature difference and numbness of the knee after 90 days after total knee replacement surgery.

Range of motion: The degree to which a knee can be flexed from a maximal extended point. Active range of motion in flexion to be measured.

Total knee replacement: Defined in this study as the replacement of the articular surfaces (femoral condyles and tibial plateau) of the knee joint.

ABSTRACT

Background: The number of TKR surgeries performed daily in Kenyan hospitals is increasing significantly. Existing research shows that the procedure is associated with significant morbidity and complication risks. The incidence of early post-operative outcomes is unknown in Kenya.

Objectives: To describe the early outcomes of Total Knee Replacement among patients undergoing the procedure in three hospitals in Kenya.

Study design: Prospective cross-sectional study.

Study site: Orthopedic units of Kenyatta National Hospital, Kiirua Hospital and Kikuyu Hospital.

Methodology: Sixty-one patients had undergone the TKR procedure were recruited through consecutive sampling technique. Baseline characteristics included variables such as age, sex, and BMI. Patients were followed up prospectively and outcome variables included post-operative range of motion, pain score, the temperature difference between operated and non-operated knee, and altered sensation. Patient satisfaction was assessed using the Oxford Knee Score tool.

Results: The mean age of study participants was 70.5 an SD 7.9, median of 70 years and a range of 52 – 85 years. Females were 45 (74%) and 16 (26%) were male patients. The mean BMI was 29.1, with a median of 28.3, an SD of 3.8, and a range of 19.3 to 37. The patients who received hospital-based physiotherapy were 45.9%, home-based were 36.1% of the patients while 18.0% of the patients received both home and hospital physiotherapy. The mean range of motion was 83.7 degrees (°), SD 12.6, a median of 83.7° and a range of 60° to 113°. The majority of the patients, 18 (29.5%), had a pain score of 3. The mean temperature difference was 0.18 with an SD of 0.131, the median was 0.179 with a range of 0 to 0.6. Forty-two patients (68.9%) had altered sensation

while in 19 (31.1%), the sensation was not altered. According to Oxford Knee Score (OKS), the moderate score was 10 (16.4%), the good score was 42 (68.9%) and the excellent score was 9 (14.8%). Increasing age was associated with a decline in range of motion (p =0.001). Patients with higher BMI had a greater pain score while the greater the pain score the more the dissatisfaction according to the Oxford Knee Score.

Conclusion: ROM was less than optimum after TKR and increasing age was associated with reduction in ROM. Majority of the patients reported moderate pain scores after TKR which lies in line with other similar studies. Patients reporting altered sensation were comparable to other studies. Patient satisfaction after TKR is comparable to other settings. This study provides valuable information that can be used to improve the quality of care and the outcomes of TKR in Kenya.

CHAPTER ONE

1.0 INTRODUCTION

The knee is the largest joint in the human body and is required in locomotion and proprioception. It is composed of two joints: the tibiofemoral component and the patellofemoral component. The role of the patellofemoral component is to act as a lever for the extensor mechanism where the patella act as a transmitter of the tensile force originating from the quadriceps tendon to the patellar tendon. At 45 degrees of flexion of the knee, the highest force of contact between the femoral trochlea and patella happens, with the forces at the joint achieving seven times the weight of the body at a deep squatting position. The articulation at the tibiofemoral joint allows transmission of the weight of the body from the femur to the tibia generating joint forces amounting to three to four times the total weight of the body, while walking and climbing (1).

Total Knee Replacement also referred to as Total Knee Arthroplasty (TKA), involves replacing a destructed knee joint with a prosthesis (2). Degenerative OA is progressive and commonly affects the knee joint. It is characterized by insidious degeneration and diminished articular cartilage. Primary OA is the most prevalent indication for TKR. However, other potential indications for TKR include inflammatory arthritis, malignancy, dysplasia, and fractures with knee joint deformity (3).

Just like every other surgical procedure, knee replacement surgery has its risks and outcomes, following the procedure. Some of the commonest outcomes following knee replacement include, but are not limited to, joint stiffness, haemorrhage, damage to the adjacent structures during surgery (i.e., ligaments, nerves and blood vessels), complications related to prolonged immobilization such as DVT, chronic knee pain, wound infection, and infection of the prosthetic joint that could subsequently lead to sepsis. Other outcomes of TKR include paresthesia, reduced

ROM, especially in patients with poor ROM pre-operatively, chronic knee pain and hotness of the knee. Mobility and lifestyle limitations secondary to chronic pain make the patients unable to perform normal activities such as driving, working, sleeping, and carrying out domestic duties (4). Achievement of a functional range of motion is one of the most important goals of TKR. Early ROM predicts functional ROM 1 year after TKR (5). Early outcomes can be assessed using the Oxford Knee score tool which assesses patient satisfaction as it measures pain degree and level of function.

The incidence of early outcomes following the TKR surgery has remained largely unknown as well as their associated contributors. The main aim of this research was to investigate the incidence of early onset post-operative outcomes after TKR and associated clinical patient level characteristics.

1.2 Gaps in literature in sub-Saharan Africa

Despite TKR being one of the most prevalent joint replacement procedures, a paucity of information on the early results of total knee replacement surgery exists, especially in Sub-Saharan Africa and Kenya.

TKR is an expensive surgery thus there are significantly a smaller number of patients who would otherwise need the surgery who truly undergo the procedure. This limits the availability of data. The early outcomes are tell-tale signs of satisfaction of the patient following TKR and inform on immediate care till full recovery.

1.3 Justification.

It is important to develop sufficient data to enhance the audit of the successes and failures of TKR. A significant number of TKR surgeries are performed every day in Kenyan Hospitals. Existing research shows that complications are relatively common after TKR.

Understanding the early outcomes of TKR would improve follow-up and management of patients to optimise patient satisfaction. The findings of this study aim to inform on local practice guidelines as well as policies geared towards improving the care of patients undergoing TKR. Previous studies that have been done on outcomes after primary TKR involved a small population of study subjects.

1.5 Research Question

1. What are the early outcomes after total knee replacement?

1.6 Study Objectives

Broad objective

To describe the early outcomes of Total Knee Replacement surgery in patients undergoing the procedure in varied hospitals in Kenya.

Specific objectives

1. To determine the range of motion, pain magnitude, temperature difference and paresthesia after TKR.
2. To establish the association between the clinical characteristics and early outcomes among patients after total knee replacement surgery.
3. To assess patient satisfaction after TKR at 3 months.

1.7 Conceptual framework

Early outcomes after TKR with clinical characteristics that ultimately influence patient satisfaction with the procedure (Figure 1).

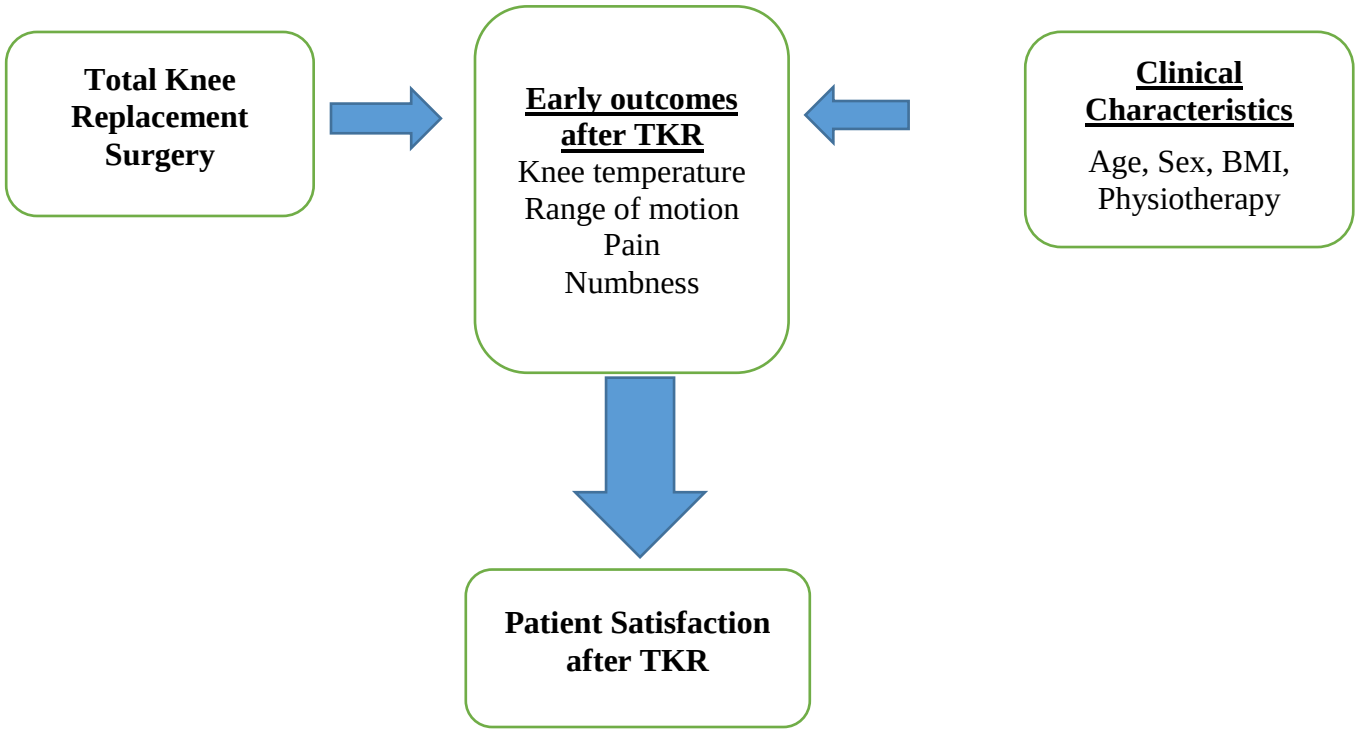

Figure 1: Conceptual framework showing early outcomes of TKR, and clinical characteristics.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Background and outcomes of total knee replacement.

Total knee replacement contributes significantly to the treatment of knee osteoarthritis with its incidence growing rapidly. Knee replacement has been in existence since the 1860s when the first implantation of an iron hinge joint was performed by a German surgeon, Themistocles Gluck. In the 1970s, there was further popularization of the procedure with the initial total condylar knee prosthesis placed in 1974. The current TKR procedures utilize principles developed in this era (6).

The outcomes of TKR are of great concern to the patient. Systematic reviews show that outcomes of TKR influence patient satisfaction after surgery. Key concerns among patients influencing treatment satisfaction are the functional results and pain relief after surgery (7). The use of surgeon-based rating scales assumes that patients and surgeons agree to one degree of knee arthroplasty success. However, there is a great difference between the patient's and surgeon's evaluation of the outcome (8).

2.2 Early outcomes of primary TKR

2.2.1 Range of motion

A key measure of early outcomes following TKR surgery is the range of motion (ROM). It has been shown to improve to a maximum at six months after surgery and also contributes to general patient satisfaction (9). In a study by Hirotaka et al, 2017, there was a gradual improvement of extension with a plateau at 6 months and a flexion improvement with a plateau at 3 months (9).

An optimal range of motion has been found to result in better engagement in day to day including sitting down, locomotion and going upstairs, kneeling, bathtub use, as well as gardening (10).

Factors associated with a better range of motion postoperatively have been noted to be, patients aged less than 60 years, those with a satisfactory ROM preoperatively, as well as those with no comorbidities. Similar studies have also alluded that patients with a poor pre-knee range of motion did not record substantial improvement in their range of motion post-operatively. Bagheri et al. in concurrence with this reported better postoperative ROM in patients with good flexion arc before surgery (11). Quadriceps elasticity has also been seen to be reduced, affecting the extensor mechanism of the knee thus reducing the ROM. Other studies also note that not only the extensor mechanism is affected, but also flexion. This is secondary to atrophy and shortening associated with restricted ROM pre-TKR(12). It has also been in question whether the type of prosthesis used in the replacement affects the overall ROM. Sancheti and colleagues' research did not report any significant relationship between ROM and high flexion prosthesis. Contrary to other studies, the age and gender of the patients did not affect the overall ROM outcome, same as using different tourniquet protocols (13).

According to Nabin KS et al, 2019, factors that were found for better ROM after TKR were age (younger than 60 years), better ROM before surgery, and lower fixed flexion deformity before surgery (14). Akihiro K and colleagues, 2005 described the ROM prior to surgery, aetiology, BMI, and age of the patient as the key factors affecting the final result (15).

Other factors that have been indicated to influence postoperative ROM include the thickness of the patella, joint line height postoperatively, successive rehabilitation and pain (16).

2.2.2 Pain after TKR

Post-TKR pain is a common outcome. As many as 30% of patients reported chronic knee pain after the procedure in a systematic review (17). A study by Alberto M et al., 2017 found that the prevalence of knee pain was 21% at one month, 13% at 3 months and 12.7% at six months (18).

Pain after knee replacement can be related or non-related to the joint, and some of them are also due to unexplained causes. Joint related causes of pain after knee replacement include instability and loosening of the implants causing excessive stress to the joint, causing peri-prosthetic fractures, dysfunction of the popliteal tendon (19), patella irritation on the lateral facet, and infections (20). The anterior knee has been reported to be more commonly affected, at a prevalence of 5-10%, and this has been presumed to be due to resurfacing of the patella, raising queries on whether patella replacement is warranted during TKR. Overhanging of femoral and tibial constituents also leads to collateral ligaments impingement, causing chronic pain.

Non-joint-related causes of chronic pain after TKR include irritation of the soft tissues, neuropathic pain, and vascular, hip, and neurological disease. Risk factors associated with chronic pain post-operatively include the female gender, high pain intensity in the pre-operative period, and the younger age group (21).

Most patients with chronic pain post TKR do not present to the healthcare facilities for management. This gives a false prevalence and institution of management, which is heavily expensive and leads to addiction in patients chronically using opioids. Patients with chronic pain are functionally limited, are at risk of opioid abuse and addiction, and are also at risk of acquiring mental health problems like anxiety and depression (17).

The optimum pain management methods after TKR is a controversial subject. Strong opioids have been found to achieve better pain control (22).

Patient reported pain outcomes are key to optimal pain management according to a study by Emilija et al, 2021. Authors further explain that scheduled pain management in contrast to patient reported pain control protocol achieves better pain control (23).

Following TKR, patients report maximum pain within the first two weeks at home. The pain was most frequent during Daily Living Activities (ADL) resulting in interference with sleep. It was not relieved by an opioid. Thus optimal pain management immediately after surgery is recommended to mitigate the persistence of pain (24).

2.2.3 Temperature of the knee

Differential skin temperature post-TKR is between the operated knee and the non-operated knee is a common occurrence. A study by Haidar SG et al found that immediately in the post-operative period the differential knee skin temperature was 2.9 degrees Celsius at one week and progressively declined to 0 degrees at 24 months (25).

An elevated skin temperature on the operated knee can also be a measure of patient satisfaction following the procedure. Higher knee temperature has been associated with poor satisfaction scores (26).

Causes of elevated knee temperature have been documented as surgical trauma and irritation response due to the insertion of an implant. However, infection though a rare occurrence at an incidence of 2% can also contribute. Positive correlations with operated knee temperature elevations include the American Society of Anesthesiologists (ASA) scores and the Body Mass Index (BMI) (26).

Inflammation is significant up to 6 months post-op, thus increased temperature, but this had been noted to decrease gradually (27). The most common inflammatory mediators that have been implicated in high temperatures are CRP, ESR and interleukin 6(28). Compression and cryotherapy have been successfully used to help mitigate increased local heat caused by inflammation. When cold is applied on the joint, it reduces intraarticular temperatures. Several

studies indicate a peak in temperature on day 5 after surgery, with some patients still having high temperatures even one year post TKR (26).

2.2.4 Paraesthesia

During knee replacement surgery, nerve damage is a relatively common complication. The saphenous nerve is commonly involved. A study by Dinshaw et al. involving 31 patients undergoing TKR demonstrated that as many as 70% of participants experienced disturbances in sensations at the region of its nervous supply (29). However, 27% of the patients recognized an improvement in the deficit over time, although the resolution was never complete (30). It was concluded that creating awareness of tingling as a side effect postoperatively contributed to early recognition by the patients, with less anxiety and timely control. Blackburn et al. also reported an incidence of numbness in 68% of their patients, around the surgical scar, and concluded that, although tingling is a common outcome, it is not associated with the surgical outcome, and does not contribute to the overall prognosis (30,31).

Jariwala et al. reported a high prevalence (53%) of paresthesia after TKR, in their study to identify the effect of numbness on the functional outcome. The females were more commonly affected at 75%, and 8.7% of the patients reported discomfort. The size of the incision was also directly proportional to the numbness. The study concluded that the functional outcome after TKR was not affected by numbness (32).

When paresthesia (numbness) is compared to the Patient Reported Outcome Measures (PROMs), a positive correlation has been reported, with a higher prevalence seen in the midline incision in comparison to the anteromedial incision, giving a better flexion angle after surgery and numbness score, thus positively affecting kneeling (33). However, a study by Brett McDonald documents that despite a frequent occurrence of sensory disturbance in the operated knee of 64.3%, the

disturbance did not affect patient satisfaction or kneeling ability. However, the authors advocate for counselling of patients preoperatively regarding the same (34).

Comorbid conditions like diabetes have been seen to directly affect the occurrence of numbness following TKR. Chanpoo et al. reported a longer time period in the recovery of numbness after TKR in diabetic patients compared to non-diabetic patients (35).

2.2.5 Patient satisfaction after TKR

Oxford Knee score has been commonly utilized to measure patient satisfaction after TKR. Other tools like Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) have also been used to measure the same. However, Oxford Knee Score has been adopted more globally because it is easier to fill and is specifically designed to measure patient satisfaction after knee replacement surgery (36,37). Oxford knee score measures pain outcome and knee function (range of motion). It is a 12-point tool with a total score of 48. Each question is set up as a Likert scale with 4 being the best score and 0 being the worst score. 0 – 19 is poor score, 20 – 29 is moderate, 30 – 39 is a good score and 40 – 48 is an excellent score (38).

2.3 Complications of TKR.

Just like any other surgical procedure, TKR carries its own complications, from the point of care intraoperatively to post-operative care. Complications are very important in assessing outcomes of operative procedures in medical practice, as it guides in creating better systems to improve the quality of healthcare in a given population. In the assessment of outcome measures and quality of surgical procedures, surgical literature has used complications to compare the safety, quality and efficacy of surgical treatments and surgical implants.

Healey *et al.* emphasized the need to differentiate between an adverse event from a complication, stating that not all adverse events are complications. CDC defines a surgical site infection as that

which presents within 1 year of the first operation. After one year, the infection is considered an adverse event, and most of these are directly associated with medical and surgical treatments (39).

Complications associated with TKR can be classified as perioperative (intraoperative and post-operative) or as immediate and late complications. Intraoperative complications include injury to the adjacent structures such as blood vessels, which can cause profuse bleeding, therefore, increasing the need for blood transfusion and surgical repair, nerve injury causing neural deficits, and ligament injury requiring surgical repair.

Post-operative complications are the most common, with the two most common being, deep periprosthetic joint infections, where a sinus tract may be communicating with the prosthesis (39), and wound infections that would require surgical revisions. Some of the post-operative complications are associated with prolonged immobilization before the patient can bear weight. These include deep venous thrombosis (40) and subsequent pulmonary embolism, stiffness due to limited range of motion, hypostatic pneumonia, and psychological and mental anxiety.

Other post-operative complications include instability and malalignment, periprosthetic and implant fracture, loosening of the implant (41) and implant failure, tibiofemoral and patellofemoral dislocation (42), reoperation, readmission, revision, and increased mortality rate.

Risk factors for early complications after TKR

Several risk factors predisposing patients to infections after TKR have been identified. These risk factors have been classified into patient related factors and surgical factors. Regardless of whether one undergoes revision knee arthroplasty or primary knee replacement, the risk of infection ranges between 0 to 10% but current literature does not report a significant difference in the risk stratification.

Surgical factors that influence the occurrence of infection after TKR include sterile glove changing, preparation of skin before surgery, extended surgical time, single stage TKR, bleeding and post-op hematoma, prophylaxis against microbials and utilization of topical anti-microbial agents, and care of the wound (43). Long duration of wound exposure in prolonged duration of surgery was directly linked to a higher incidence of infection.

Wound healing and the general outcome after TKR have been associated with the patient's general status prior to surgery. An elevated SSI risk in underweight and overweight patients is described in the United Kingdoms' TKR national surveillance database. Obese patients, (BMI > 30 kg/$m^{2)}$, have double the rate of infection compared to that of patients with normal weight, which is a BMI between 18.5–24.9 kg/m^2. Data from England and Wales demonstrates a rising average BMI of patients undergoing primary TKR. In England, the BMI was 28.6 while in Wales it was 30.6 in 2011. This has led to an increased risk of infection (44).

Other patient related factors predisposing to infection include age, smoking, chronic alcohol use, male gender, other comorbid diseases such as rheumatoid arthritis, hypertension, peripheral vascular diseases, diabetes mellitus and other autoimmune diseases, previous fracture adjacent to the knee, and wound-related complications (45). Kurtz *et al.* reported a lower risk of infection in women as compared to men, as well as elevated odds of infection among those with comorbid conditions (46). The immunosuppressive drugs administered for Rheumatoid Arthritis inhibit proper wound healing, making the patients prone to infections (47).

Increasing age escalates the risk of infection after TKR due to the ageing of the immune system and unfavourable status of nutrition. On the contrary, Muilwijk and colleagues. and Baier and colleagues did not demonstrate a significant relationship between chronological age and surgical site infection following primary TKR (48,49).

Females are considered to have a higher risk of occurrence of chronic pain after TKR(48). However, patients with highly graded pain pre-operatively, and patients of the younger age group, have been noted to sustain chronic pain post-TKR.

Risk factors associated with reduced ROM post-operatively include poor pre-knee ROM, patients of the older age group (more than 60 years), and those with co-morbid conditions(35). Generally, patients with poor physiological functions are at risk of poor outcomes post-TKR. Some studies have reported significant hotness of the knee, in patients with low haemoglobin count (50).

Most studies have shown that patients that developed paresthesia post-operatively reported a reduction in the tingling over time, although the resolution was not complete (33). Patients with chronic knee pain, although managed by regular pain relievers and cold compressors, report knee pain almost throughout the course of their lives (17).

In patients with good ROM pre-TKR, the range of motion is sustained post-operatively. This applies to patients with poor ROM pre-knee, as they sustain a non- satisfactory ROM post-op (16). Patients with elevated local temperatures also report gradual decrease in time.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

A prospective cross-sectional study. Patients who have recently undergone TKR were recruited and assessed on the clinical and demographic exposures as well as the early outcomes of the procedure at the stipulated time of the study.

3.2 Study Setting

This research was conducted at the Kenyatta National Hospital (KNH), Kikuyu Mission Hospital and Kiirua Mission Hospital Orthopaedics departments.

KNH is a training and national referral institution, with a significant number of knee replacement surgeries taking place at the institution. Similarly, Kikuyu and Kiirua Hospitals, located in Kiambu and Meru counties respectively, are dedicated orthopaedics training centres.

3.3 Study population

The study population was comprised of patients who had undergone primary total knee replacement during the study period. They were required to have been operated on within the preceding 3 months at the start of the data collection of the research.

3.4 Inclusion and Exclusion Criteria

3.4.1. Inclusion criteria

- Patients who had primary total knee replacement surgery at the selected hospitals after three months.

3.4.2 Exclusion Criteria.

- Patients who underwent revision TKR.
- Patients who underwent bilateral TKR.

- Patients who decline to give consent.
- Patients with co-morbidities such as RA, gout, SLE and traumatic knee

3.5 Sample Size Determination

The Fisher formula was used to calculate the sample size as follows:

$N = Z^2p\ (1 - p) / d^2$

N = size of the study sample,

Z = Standard error from the mean corresponding to 95% confidence level = 1.96

P = The prevalence of knee pain after TKR is 30% from the study by Wylde et al.,2018 (17).

D = desired level of precision = 0.05

$N = 1.96^2 * 0.13\ (1 – 0.13) / 0.05^2$

N = 323

An estimated 75 patients are operated in the selected facilities in 3 months.

Thus, adjusting for a small population,

N*n / N+n

Hence 323 * 75 / 323 + 75

Thus, the sample size = 61 study participants.

3.6 Sampling Procedure

A total number of 61 patients were recruited through consecutive sampling technique. If the selected patient was not eligible or declined to be a participant in this research, the next most

eligible patient was approached for possible enrollment. This was repeated until the sample size of 61 is attained.

3.7 Variables

3.7.1 Dependent variables

- Occurrence of early outcomes (ROM, pain, temperature difference, and paraesthesia) after knee replacement surgery

3.7.2 Independent variables

- Age
- Sex
- BMI
- Physiotherapy

3.8 Data Collection

The structured data collection sheet was used.

Patients who underwent total knee replacement surgery were recruited 90 days after undergoing the procedure and clinical characteristics and outcome variables were measured as defined in the study.

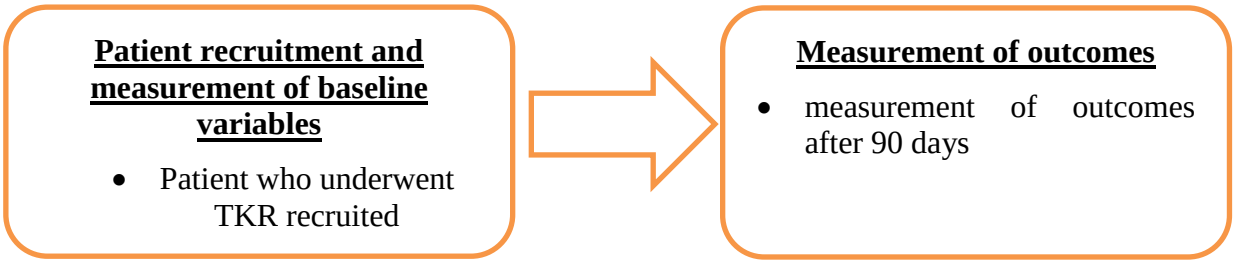

Figure 2: Study flowchart

3.8.1 Measurement of outcomes

Recruitment of Participants

The patients were informed about the study protocol, and the minimum requirements to be a participant. Those who met the inclusion criteria were recruited.

Range of motion

The knee ROM was measured in degrees of flexion. A fully extended knee measured 0º of flexion. Meanwhile, a fully bent knee measured 140º of flexion.

A goniometer was utilized in measuring the ROM in degrees. With the patient in supine, knee in extension, the lateral epicondyle of the femur was identified where the goniometer fulcrum was placed. The stationary goniometer arm was aligned to the femur and the greater trochanter with the mobile arm aligned to the fibula and the lateral malleolar. The knee was brought to the maximum flexion point and the reading on the goniometer was taken.

Pain

Numeric Rating Scale (NRS) was used to collect data for the pain score.

0 indicated no pain with 10 indicating the worst pain ever.

Participants were requested to pick a number between 0 and 10 that best indicated their current level of pain after 90 days following TKR.

NRS was chosen since its utility has been validated in clinical practice and was widely adopted.

Temperature difference between operated and non-operated knee

The participant was placed in a supine or sitting posture at the edge of the examination couch. Knees were placed at 90 degrees of flexion. A portable infrared thermometer was utilized for measuring knee skin temperature on both knees and a temperature reading in the operated and the non-operated knee was taken. The temperature was taken from the superomedial region to the patella approximately 1cm from the skin.

The difference in temperature was calculated as follows:

Temperature of the operated knee – temperature of the non-operated knee

Paraesthesia

Self-reporting method was used to assess the level of sensation around the knee.

Patients sat on the examination couch with their lower limbs in extension and mapped out the region of reduced skin sensation using their index fingers.

3.9 Quality assurance measures

A pilot study was conducted to pretest the data collection tool by interviewing 5% of the participants out of the total sample size. This helped in calculating the total time it would take to fill one form to completion and the efficacy of the tool in capturing adequate data. All questions were filled on the tool.

3.9.1Recruitment and Training procedures

Research assistants (one medical officer and two physiotherapists) were trained for one day on what the study protocols were and what was required of them from the principal investigator. They received training on how to capture data from patients into the data collection tool to ensure that collected data was standard and uniform.

3.10 Ethical Considerations

Departmental authorization for the study dissertation was obtained from the department of orthopaedics surgery.

Subsequently, ethical review and approval of the study protocol was sought from the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee.

All the research participants were required to give written informed consent which was preceded by an explanation of the purpose of the study.

Participation in this research was voluntary with no incentives, monetary refunds or gifts offered to participate. The confidentiality of the participants was assured by assigning numbers to identify study participants. Personal identifying information was coded.

This study had no identifiable risks as no drugs were given, no procedures and no specimens were taken.

Declining to participate in this research did not interfere with the routine care a participant should receive.

3.11 Data Management

Data was entered into a password protected Microsoft Excel spreadsheet. Only the principal investigator and authorized personnel were allowed to access the data.

All hard copy data collection tools were placed under lock and key to avoid unauthorized access.

3.12 Data Analysis

The data was cleaned and entered into SPSS version 24.0 for data analysis.

To outline the quantitative features of participants for continuous variables, averages, standard deviation, and median were utilized while frequencies and percentages were applied for categorical variables.

The incidence of defined outcomes after TKR was derived as a proportion of patients who had specific outcomes after TKR out of the total sample size.

To assess the associations for the specified outcomes, the Chi-square test of independence was utilized for differences in proportions and Student T-test was used for differences in means.

For multivariate analysis, independent risk factors for specified outcomes after TKR were assessed using the logistic regression technique. Odds ratios and 95% confidence intervals for Odds ratios were utilized to report the results of the regression model.

Statistical significance was set at <0.05.

Data presentation was done using tables of counts, pie and bar charts.

3.13 Data dissemination

Once data is analyzed and the manuscript developed, study findings will be disseminated to relevant stakeholders such as orthopaedics units of the varied hospitals. The manuscript will also be published in a peer-reviewed medical journal.

3.14 Study Limitations

Loss to follow-up. Potential patients in the prospective study may be lost to follow-up. However, they were traced using their contacts in the hospital database to enhance accrual.

CHAPTER FOUR

4.0 RESULTS

This study investigated 61 patients who had undergone total knee replacement in 3 facilities including, Kenyatta National Hospital (1 patient), Kiirua (20 patients) and Kikuyu (40 patients) Mission Hospitals. After 90 days post-surgery, patients were interviewed, and clinical exam was conducted.

The results are presented in the following order, i) demographic, and ii) clinical characteristics as per the study objectives.

4.1 Demographic and clinical characteristics

4.1.1 Sex

There were 45 (73.8) female patients and 16 (26.2%) male patients (Figure 3).

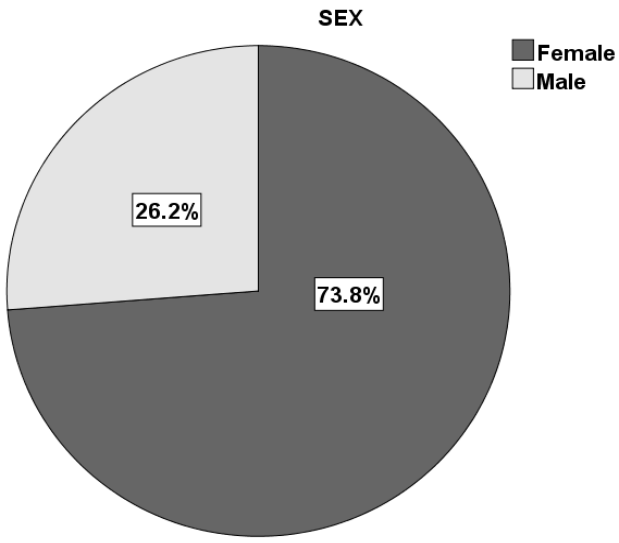

Figure 3: Sex distribution

4.1.2 Age

The mean age of the participants was 70.5 with a standard deviation of 7.9, a median of 70 and a range of 52 to 85 (Figure 4).

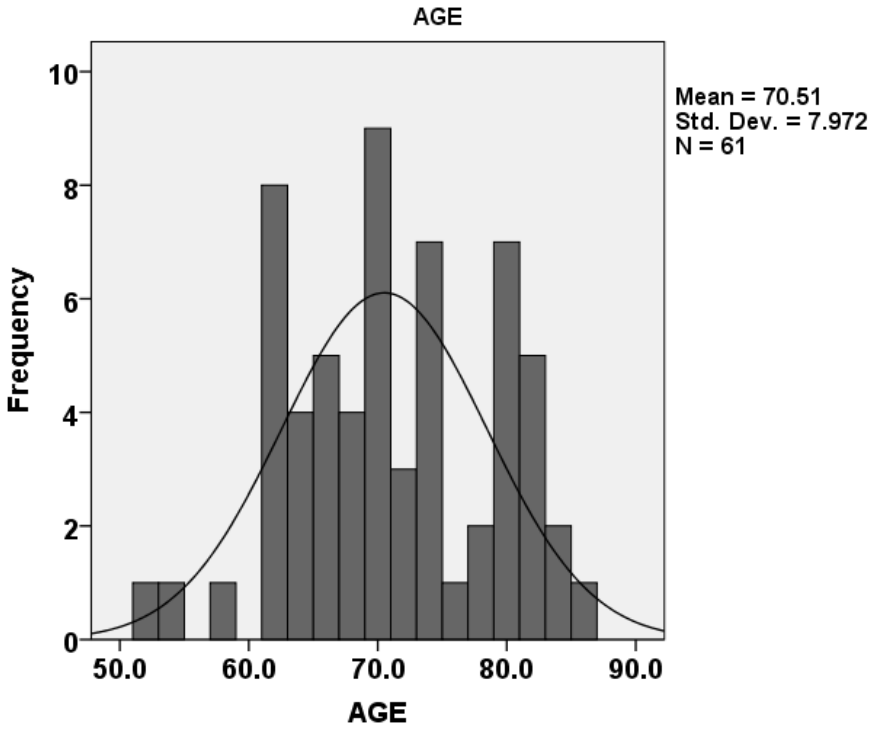

Figure 4: Histogram of age distribution

4.1.3 Body Mass Index (BMI)

The mean BMI was 29.1, with a median of 28.3 and a standard deviation of 3.8 and a range of 19.3 to 37 (Figure 5)

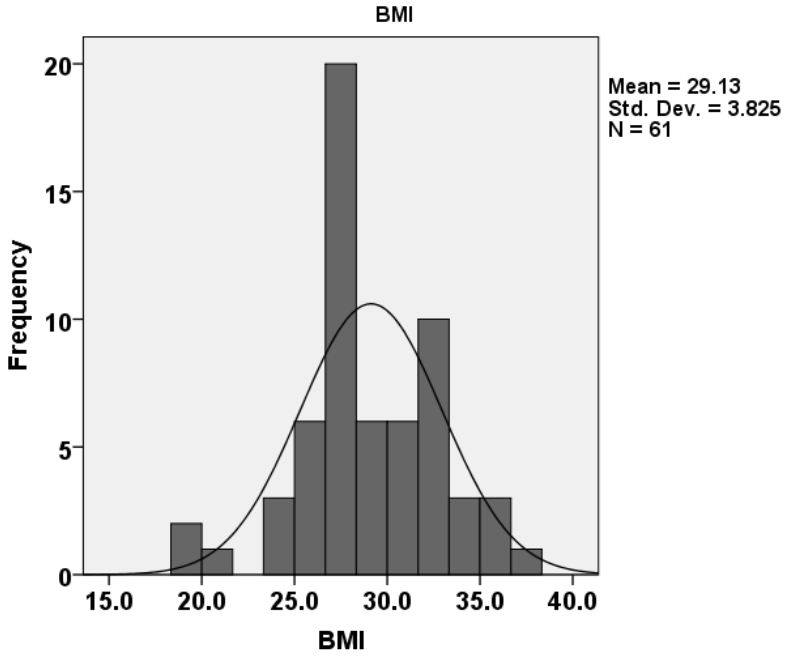

Figure 5: Histogram of BMI

4.1.4 Physiotherapy

The patients who received hospital-based physiotherapy were 45.9%, those who received home based were 36.1% of the patients while 18.0% of the patients received both home-based and hospital-based physiotherapy (Figure 6).

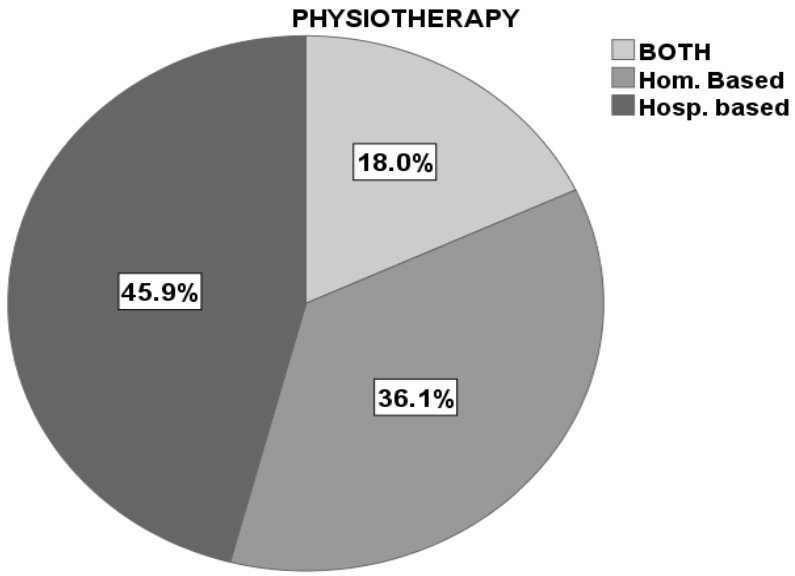

Figure 6: Pie chart of physiotherapy attendance

4.2 Clinical characteristics

4.2.1 Range of motion

The mean range of motion was 83.7, the standard deviation of 12.6, a median of 83.7 and a range of 60 to 113 (Figure 7).

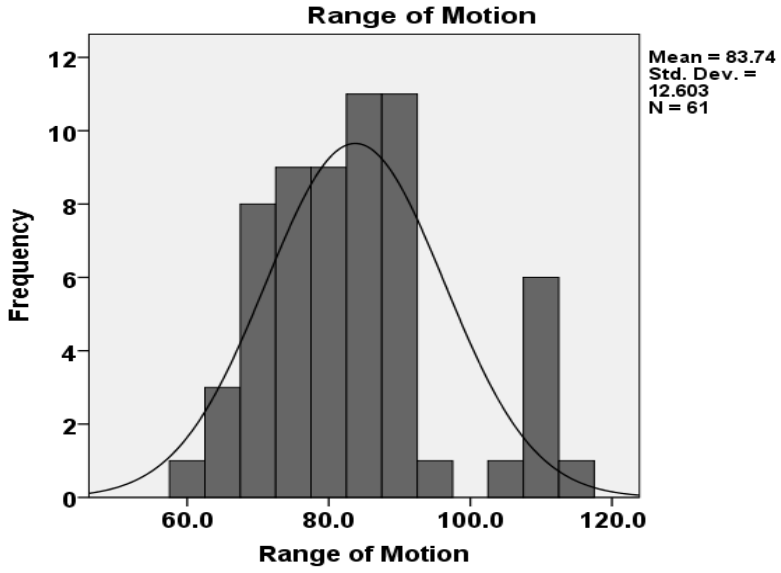

Figure 7: Histogram of range of motion

4.2.2 Pain Score

Most of the patients, 18 (29.5%), had a pain score of 3 (Figure 8).

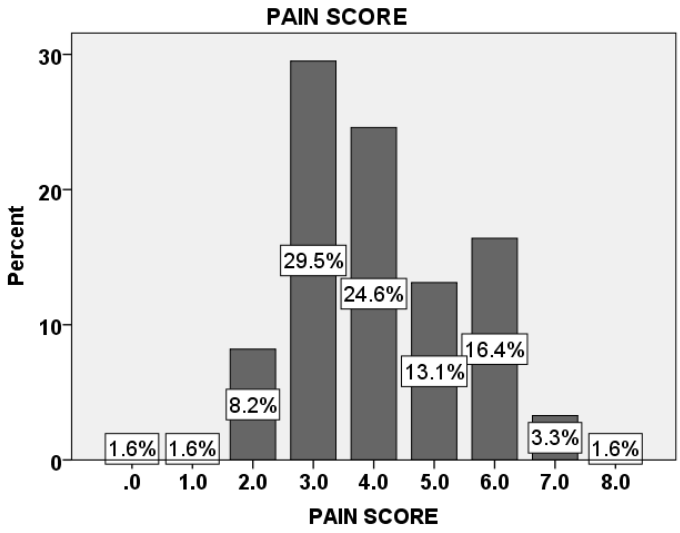

Figure 8: Bar chart of Pain score

When the pain was graded into no pain, mild moderate and severe, the majority of patients, 54.1% had moderate pain (Figure 9).

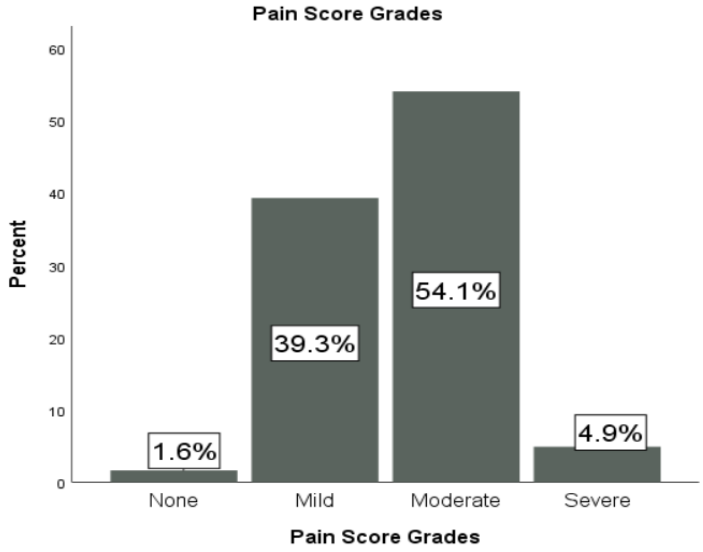

Figure 9: Bar chart of pain grades

4.2.3 Temperature Difference

The mean temperature difference was 0.18 with a standard deviation of 0.131, the median was 0.179 with a range of 0 to 0.6 (figure 10).

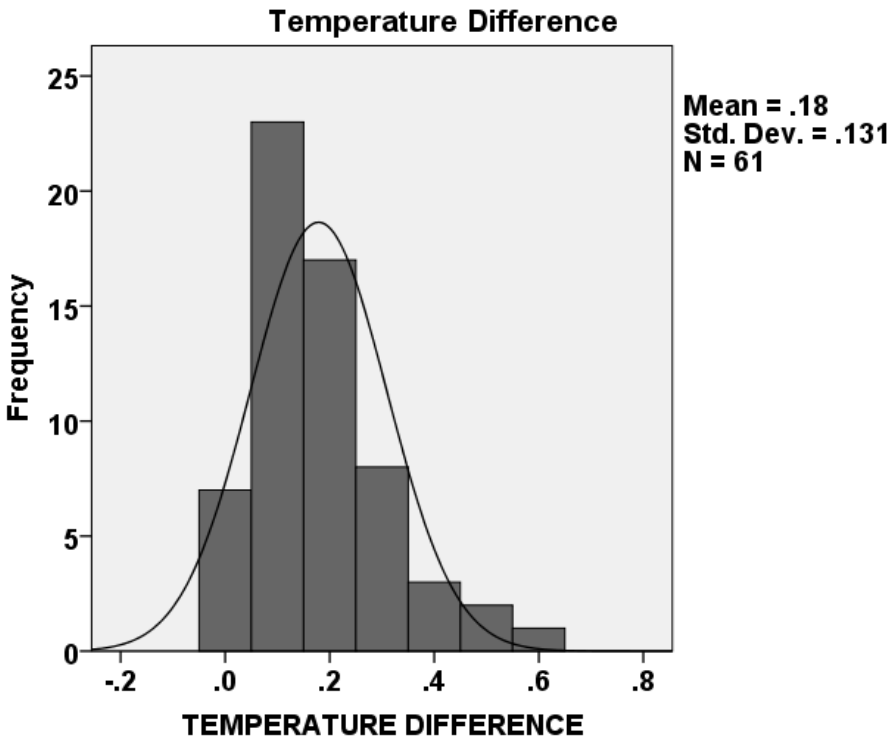

Figure 10: Histogram of temperature difference

4.2.4 Sensation

Forty-two patients (68.9%) had altered sensation while 19 (31.1%) the sensation was not altered (Figure 11).

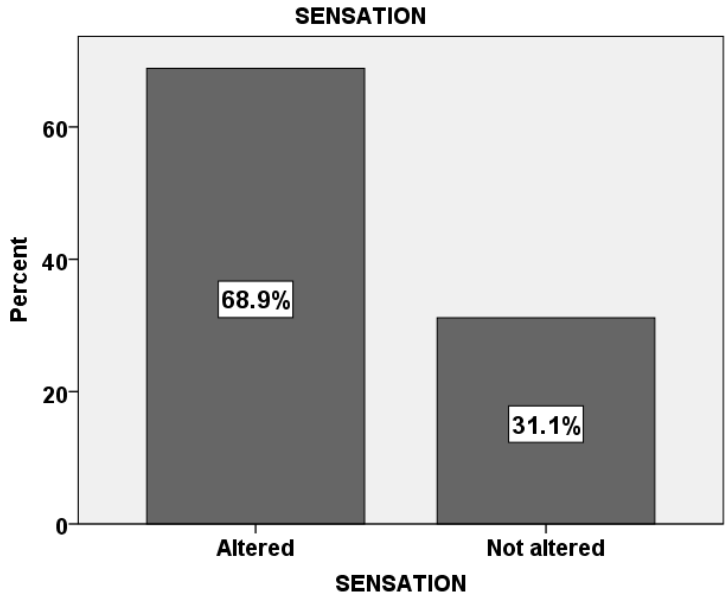

Figure 11: Sensation levels

4.2.5 Oxford Knee Score (OKS)

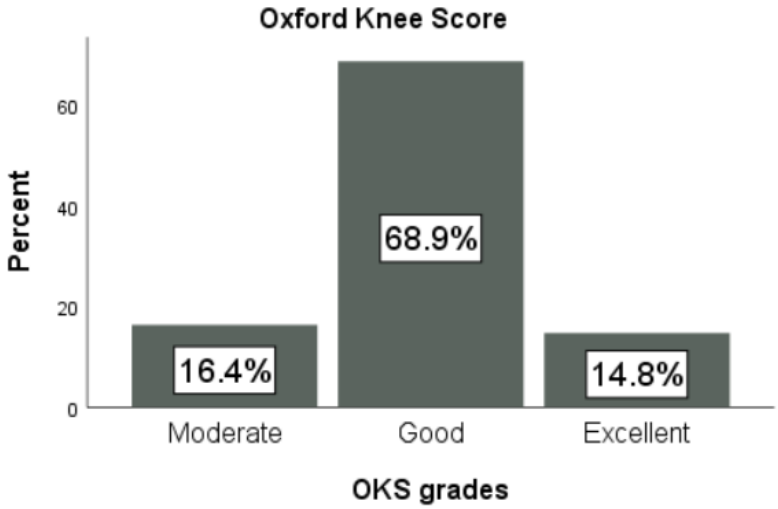

Figure 12: The Oxford Knee Score

Table 1: The Oxford Knee Score grades

Oxford Knee Score	**Count**	**Percentage**
Excellent	9	14.8
Good	42	68.9
Moderate	10	16.4

4.3 Associations of early outcomes after Total Knee Replacement

An assessment of determinants of early outcomes following TKR was done. This would help identify patients at risk of specific early outcomes.

4.3.1 Associations of range of motion and clinical and demographic characteristics

Table 2: Association of range of motion

i) Comparisons of ROM with continuous variables

Variables	**P-Value**	**Coefficient**	**95% Confidence Interval**	
Age	**0.001**	-0.712	-1.02	-0.29
Temperature Difference	**0.038**	30.3	1.40	46.9
BMI	**0.231**	-0.527	-1.22	0.300

Increasing age was associated with a reduction in ROM.

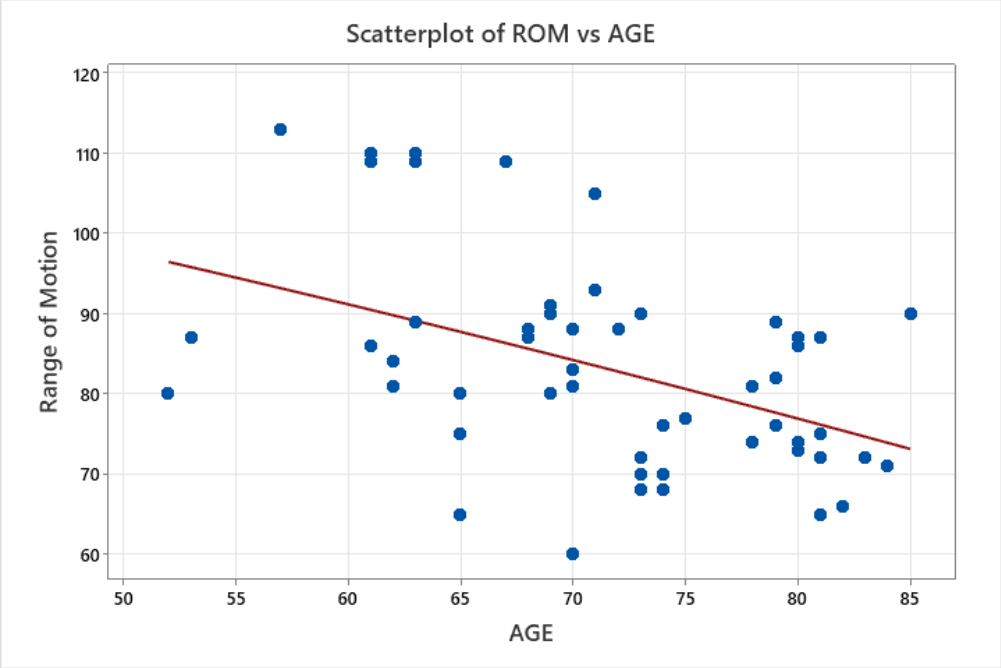

Figure 13: Scatter plot of range of motion and age

ii) Comparison of ROM with categorical variables

Variable	**Counts**	Mean	SD	P value
Sex				
Male	**16**	85.1	13.7	0.628
Female	**45**	83.3	12.3	
Physiotherapy				
Home-based	22	84.1	14.0	0.971
Hospital-Based	28	83.7	12.3	
Both	11	83.0	11.4	

Sex and physiotherapy were not associated with ROM.

4.3.2 Associations of pain score

Table 3: Associations of pain

Variables	**P-Value**	**95% Confidence Interval**	
Age	0.235	-0.09	0.035
Sex(M)	0.75	-0.326	0.451
Physiotherapy			
Home-based	0.060	-0.02	0.96
Hospital-based	0.057	-0.014	0.94
Temperature Difference	0.826	-1.21	1.50
BMI	**0.001**	0.037	0.127

Increasing BMI was associated with severity of pain.

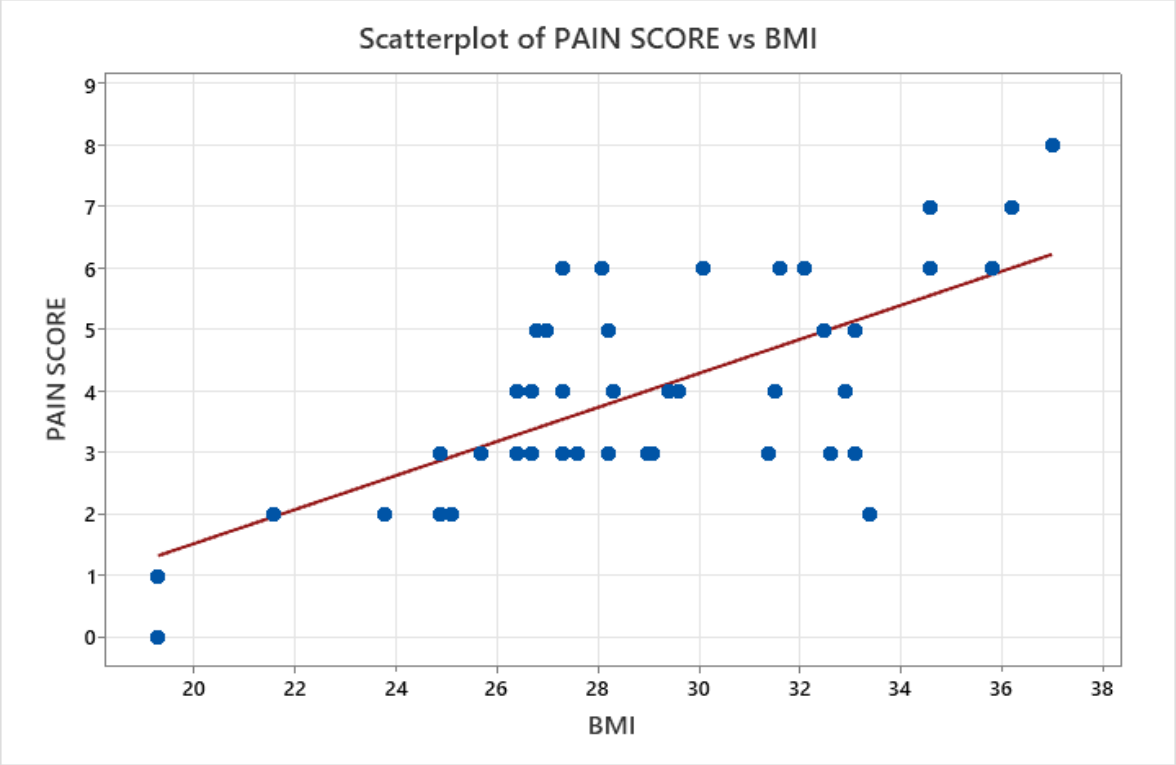

Figure 14: Scatter plot of pain score and BMI

4.3.3 Associations of sensation

Associations of sensation are demonstrated in Table 4. None of the factors were significant (Table 4).

Table 4: Associations of sensation

Variables	**P-Value**	**95% Confidence Interval**	
Age	0.39	-0.02	0.01
Sex(M)	0.61	-0.36	0.21
Physiotherapy			
Home-based	0.846	-0.322	0.392
Hospital-Based	0.679	-0.275	-0.419
Temperature Difference	0.361	-0.532	1.44
BMI	0.983	-0.032	0.033

4.3.4 Oxford Knee Score

Associations of Oxford knee scores are demonstrated in Table 5.

Table 5: Associations of Oxford Knee Score

Variables	**P-Value**	**Coefficient**	**95% Confidence Interval**	
Age	0.238	-0.109	-0.289	0.07
Sex(M)	0.39	na	-0.46	0.18
Physiotherapy		na		
Home-based	0.83		-0.36	0.44
Hospital-based	0789		-0.34	0.44
Temperature Difference	0.876	1.192	-13.73	16.12
BMI	0.536	0.155	-0.336	-0.646
Pain score	**0.001**	-2.38	-3.81	-0.95

Only the pain score was associated with OKS; as the pain score increased the OKS score decreased.

CHAPTER FIVE

5.0 Discussion

5.1 Background

This study aimed at assessing early outcomes of TKR (ROM, pain, temperature difference between operated and non-operated knee, and paresthesia). It also assessed the associations of early outcomes with various clinical characteristics (age, gender, BMI, and physiotherapy).

5.2 Clinical Characteristics

Most patients who underwent knee arthroplasty were above the age of 65, with only 24.5% of patients being under the age of 65. The mean age was found to be 70.5 years, which is consistent with other studies that have reported the mean age of patients undergoing knee arthroplasty to be in the range of 65 to 75 years (51, 52). However, the age range in this study was quite wide, with patients ranging from 52 to 85 years. The findings confirm that knee arthroplasty is a common procedure for older patients (over 65 years).

In this study, there were significantly more female patients (73.8%) than male patients (26.2%) who underwent total knee arthroplasty. This is in line with previous research that has consistently found that women are more likely to undergo knee arthroplasty than men (52, 53). This may be due to differences in bone density, joint structure, and hormonal factors between men and women that can affect the development of knee osteoarthritis (54).

Healthcare providers need to be aware of these sex differences when planning and providing care for patients who undergo total knee arthroplasty. The study's findings on BMI reveal that the mean BMI of patients who underwent knee arthroplasty was 29.1, which is in the range of overweight. This is consistent with previous studies that have found a higher BMI to be associated with an increased risk of knee osteoarthritis (55).

The study demonstrated a significant proportion of patients (45.9%) received hospital-based physiotherapy, while 36.1% received home-based physiotherapy. This is important as physiotherapy is a crucial part of postoperative care for patients who undergo knee arthroplasty (56). In this study, neither hospital-based nor home-based physiotherapy had a significant association with ROM, pain score, sensation, or OKS after TKR. Previous research has found that home-based physiotherapy can be just as effective as hospital-based physiotherapy in improving patient outcomes after knee arthroplasty (57). This suggests that healthcare providers should consider both home-based and hospital-based physiotherapy options when planning postoperative care for patients.

5.3 Early Outcomes

The mean range of motion (ROM) of patients who underwent total knee arthroplasty was 83.7, with a range of 60 to 113. This is in line with previous studies that have found a significant improvement in the range of motion after knee arthroplasty. In a study by Hirotaka et al, 2017, there was a gradual improvement of extension with a plateau at 6 months and a flexion improvement with a plateau at 3 months (9).

The findings of the study revealed that most patients (29.5%) had a pain score of 3, with moderate pain being the most common category (54.1%). These findings tie well with previous studies that have reported moderate pain as the most common pain category in patients after TKR (58).

In addition, 68.9% of patients had altered sensation, which is a higher percentage compared to a study by Black et al, 2013, which reported sensory changes in 27% of patients after knee arthroplasty (30) while comparable to others such as Dinshaw et al, Blackburn et al, and Sivaraman et al, 2009 who demonstrated sensory changes in 70%, 68% and 73% respectively (29,31,59).

When evaluating patient satisfaction, most patients had a favourable OKS score, demonstrating adequate patient satisfaction. Approximately sixty-nine percent (68.9%) had a good score with 14.8% having an excellent score. These findings are similar to those reported by Mohammad et al (60), where most patients had a good Oxford Knee Score.

5.4 Associations of Early Outcomes

The regression models demonstrated that age was significantly associated with a decline in range of motion (ROM) (p=0.001), less so with pain score (p=0.26). A higher age was associated with decreased ROM and increased pain scores. This finding is consistent with previous studies, which have reported that older age is a significant predictor of poor outcomes in patients with total knee arthroplasty (61).

The temperature difference between the affected and unaffected limbs had a significant association with ROM (p=0.04), with higher temperature differences being associated with decreased ROM. This study confirmed prior reports that state that following surgery, the skin temperatures of the operated knee, as well as the adjacent knee, and especially the disparity in these temperatures rise significantly (62). In individuals who have undergone TKR and seen an elevation in knee skin temperature, it's critical to distinguish between an infectious and non-infectious response (63). BMI had a significant association with ROM (p=0.225) and pain score (p=0.001), with high BMI being associated with decreased ROM and increased pain scores. In terms of reported outcome measures after TKR, higher BMI and obesity have been generally associated with inferior outcomes (64). However, BMI did not have a significant association with sensation or OKS.

The multivariate analysis showed that ROM and pain score were significant predictors of early outcomes in patients with total knee replacement (p=0.01 and p=0.004, respectively). This finding is consistent with previous studies that have reported a significant association between ROM, and

pain scores outcomes in patients with total knee replacement (67). The study did not find any significant association between OKS or sensation and early outcomes.

5.5 Limitations

The study's limitations include selection bias as the study relied on consecutive sampling, which could have led to the exclusion of suitable patients who declined to participate. There is also limited generalizability of the study because it was conducted in only three hospitals, which may not be representative of the entire population of patients who have undergone primary TKR in Kenya. The short-term follow-up, of 90 days after TKR surgery, although standard for measuring early outcomes, may not provide a comprehensive assessment of the long-term outcomes of TKR. The study's outcomes were also limited to knee range of motion, pain, the temperature difference between operated and non-operated knee, and paraesthesia.

5.6 Conclusion

The study found that ROM was less than optimum after TKR and increasing age was associated with a reduction in ROM. Majority of the patients reported moderate pain scores after TKR which lies in line with other similar studies. Patients reporting altered sensations were comparable to other studies. Patient satisfaction after TKR is comparable to other settings. It was mainly tied to pain score. This study provides valuable information that can be used to improve the quality of care and the outcomes of TKR in Kenya.

5.7 Recommendations and Future Research

Based on the findings of this study, several recommendations can be made for improving the outcomes of total knee replacement in Kenya. Firstly, it is recommended that older patients who are to undergo TKR should be counselled to manage their expectations after the procedure as advanced age was associated with reduced ROM and increased pain scores.

Secondly, patients who are to undergo TKR are to be advised on weight management measures as elevated BMI can negatively influence post-total knee replacement outcomes leading to decreased ROM and increased pain scores. This suggests the importance of maintaining a healthy weight before the surgery.

Lastly, there is a need for further research to identify the risk factors associated with poor early outcomes of total knee replacement in Kenya. The study could explore the factors that contribute to pain, reduced range of motion, and low satisfaction levels among patients after surgery. This will enable healthcare providers to develop more targeted interventions aimed at reducing these negative outcomes.

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LIST OF APPENDICES

Appendix 1: Informed consent – English Version

PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY: ADULT PATIENT CONSENT FORM

Title of Study: EARLY OUTCOMES OF PRIMARY TOTAL KNEE REPLACEMENT: A MULTICENTER STUDY

Principal Investigator: Dr Caleb Karuga

Institution: University of Nairobi**,** Department of Orthopaedics Surgery.

Introduction:

I am Dr Caleb Karuga. I am currently pursuing my postgraduate studies at the University of Nairobi. As part of my studies, I am required to undertake research. I am researching early outcomes after Total Knee Replacement Surgery at Kenyatta National Hospital, Kikuyu and Kiirua Hospitals. The purpose of this consent form is to provide you with adequate information to help you decide whether or not to be a participant in the study. You are free to ask any questions about the research, its purpose, implications of participating in the study, risks and benefits, volunteer rights, and any added information not included in this form that needs clarification. After your questions are satisfactorily answered, you can decide whether to take part in the study or not. This process is known as 'informed consent'. After you agree to take part in this study, I will request you to sign your name on this form.

You should understand the general principles which apply to all participants in medical research:

i) Participation in the study is voluntary.

ii) You have a right to withdraw from the study at any time without necessarily giving a reason for your withdrawal.

iii) If you refuse to take part in the study, this does not in any way affect services provided to you in the facility or any other health facility.

A copy of this form will be provided to you for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Protocol No. _____

What Is This Study About?

The above researchers are interviewing individuals who are undergoing fetal anomaly scans. The reason for the interview is to find out your progress after TKR. All those who take part in this research study will also have imaging and blood tests reviewed. There are no further investigations or tests required. There will be approximately 61 participants in this study who are randomly chosen. We request your consent to consider taking part in this study.

What Will Happen If You Decide to Be in This Research Study?

If you agree to take part in this research, the following will happen:

You will be interviewed in an area where your privacy is guaranteed, and you are comfortable answering questions. The interview will take a few minutes. After the interview has finished, I will request to go through your ultrasound report. If necessary, we will ask for your phone number to

contact you. Any contact information you provide will be used only by people conducting this study and will never be shared with others.

Are There Any Risks, Harms Discomforts Associated with This Study? Generally, medical research has the potential to introduce psychological, social, emotional and physical risks. One of the risks of being in the study is loss of privacy. Any information you give us is confidential and we will keep it private. We will identify you with a code number in a password-protected computer database and all our paper records will be kept in a secure cabinet. You have the right to decline the interview, or any questions asked in the process. Also, all our staff conducting this study are professionals with training in these examinations/interviews.

Are There Any Benefits Being in This Study?

The study will help us understand better the rates of infection after Total knee replacement surgery and contributing factors at Kenyatta National Hospital and other selected hospitals. This will further enable us to create feasible local guidelines guiding the same.

Will Being in This Study Cost You Anything?

No additional costs will be incurred.

Can I Withdraw from The Study Anytime?

Participation in the study is voluntary and you have a right to withdraw from the study at any time without necessarily giving a reason for your withdrawal. This does not in any way affect services provided to you in the facility or any other health facility.

For more information about your rights as a research participant, you may contact the following persons:

Principal investigator:

Dr Caleb Karuga

Department of Orthopedics and Trauma Surgery

University of Nairobi.

Telephone no: 0721645192

Lead Supervisor:

Dr Edward Gakuya

Department of Orthopedics and Trauma Surgery,

University of Nairobi.

Telephone no: 0721932799

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix 2- Consent Form (Statement of Consent)-ADULTS

Participant's statement

1. I have read this consent form or had the content read to me and I understood.
2. I have been given the chance to ask questions about this research study.
3. I have had my questions answered adequately in a language I understand.
4. The potential risks and benefits have been explained to me in a clear and precise manner.
5. I understand that I take part in this study voluntarily and that I can withdraw anytime.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes/ No

I agree to provide contact information for follow-up: Yes /No

Participant printed name: _____

Contact (mobile number): _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: **Dr Caleb Karuga**

Date: _____ Signature _____

Role in the study: Principal investigator.

For more information, contact:

Principal investigator:

Dr Caleb Karuga

Department of Orthopedics and Trauma Surgery

University of Nairobi

Telephone no: 0721645192

Lead Supervisor:

Dr. Edward Gakuya

Department of Orthopedics and Trauma Surgery,

University of Nairobi.

Telephone no: 0721932799

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix 3 - Fomu ya Idhini Ili Kushiriki Katika Utafiti- (Watu Wazima)

Kichwa Cha Utafiti: EARLY OUTCOMES OF PRIMARY TOTAL KNEE REPLACEMENT: A MULTICENTER STUDY

Mpelelezi Mkuu Na Ushirika Wa Kitaasisi: Dr. Caleb Karuga, Mwanafunzi wa Shahada ya Uzamili Katika Chuo Kikuu Cha Nairobi, Idara ya Magonjwa ya mifupa.

Hivi sasa ninaendelea na masomo yangu ya uzamili katika Chuo Kikuu cha Nairobi. Katika masomo yangu, ninahitajika kufanya utafiti.

Ningependa kukuambia juu ya utafiti unaofanywa na mtafiti aliyeorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa habari za kutosha ili kukusaidia kuamua iwapo utakuwa mshiriki wa utafiti au la. Uko huru kuuliza maswali yoyote juu ya utafiti, madhumuni yake, ni nini maana ya wewe kushiriki katika utafiti, ikiwa kuna hatari yoyote inayohusika na faida yoyote, haki za kujitolea, na habari yoyote iliyoongezwa isiyojumuishwa katika fomu hii na inahitaji ufafanuzi. Baada ya kujibu kwa kuridhisha maswali yako yote, unaweza kuamua kushiriki katika utafiti au la. Utaratibu huu unajulikana kama 'idhini ya habari'. Baada ya kukubali kushiriki katika utafiti huu, nitakuomba utie sahihi jina lako kwenye fomu hii.

Unapaswa kuelewa kanuni za jumla ambazo zinatumika kwa washiriki wote katika utafiti wa matibabu:

i. Kushiriki katika utafiti ni kwa hiari.

ii. Wakati wowote unaweza kuamua kujiondoa kwenye utafiti.

iii. Ukikataa kushiriki katika utafiti, hii haiathiri huduma unayopewa katika kituo hicho au kituo kingine chochote cha afya.

Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO AULA

Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi Nambari_____

Utafiti Huu Unahusu Nini?

Watafiti hapo juu wanawahoji watu ambao wanapitia picha ya ujauzito kuchunguza ukuaji mzuri wa kijusi. Sababu ya mahojiano ni kujua umri wako, idadi ya watoto na umri wa ujauzito. Picha za ULTRASOUND za ujauzito za wote watakaoshiriki katika utafiti huu zitakaguliwa na watafiti. Hakuna uchunguzi zaidi au vipimo vinahitajika. Kutakuwa na takriban washiriki _____ katika utafiti huu ambao wamechaguliwa bila mpangilio. Tunaomba idhini yako kufikiria kushiriki katika utafiti huu.

Je, Nini Kitatokea Ukiamua Kuwa Kwenye Utafiti Huu?

Ikiwa unakubali kushiriki katika utafiti huu, yafuatayo yatatokea:

Utahojiwa katika eneo ambalo faragha yako imehakikishiwa na unahisi vizuri kujibu maswali. Mahojiano yatachukua dakika chache. Baada ya mahojiano kumalizika, nitaomba kupitia …….. Ikibidi, tutauliza nambari yako ya simu kuwasiliana nawe. Maelezo yoyote ya mawasiliano utakayotoa yatatumika tu na watu wanaofanya utafiti huu na hawatashirikiwa na wengine kamwe.

Je, Kuna Athari Zozote, Madhara, Usumbufu Zinazohusiana Na Utafiti Huu?

Kwa ujumla, utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemko na kiafya. Moja ya hatari ya kuwa katika utafiti huu ni kupoteza faragha. Habari yoyote unayotupatia ni ya siri na itachukuliwa kama siri.

Tutatumia nambari ya kukutambulisha kwenye hifadhidata ya kompyuta inayolindwa na nywila na rekodi zetu zote za karatasi zitahifadhiwa kwenye baraza la mawaziri iliyofungwa. Una haki ya kukataa mahojiano au maswali yoyote yanayoulizwa katika mahojiano. Pia, wafanyikazi wetu wote wanaofanya utafiti huu ni wataalamu wenye mafunzo katika mitihani / mahojiano haya.

Je, Kuna Faida Zozote Ziko Katika Utafiti Huu?

Utafiti huo utatusaidia kuelewa vizuri jinsi …….. za kuchunguza ukuaji mzuri wa kijusi. Hii itapanua zaidi ufahamu wetu……..

Je, Kuna Gharama Kuwa Katika Utafiti Huu?

Hakuna gharama za ziada zitakazopatikana.

Je, Ninaweza Kuondoka Kwenye Utafiti Wakati Wowote?

Kushiriki katika utafiti ni kwa hiari na una haki ya kujiondoa kutoka kwa utafiti na kwamba wakati wowote unaweza kuamua kujiondoa kwenye utafiti bila lazima kutoa sababu ya kujitoa kwako. Hii haiathiri kwa vyovyote huduma unazopewa katika kituo hicho au katika kituo kingine chochote cha afya.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na watu wafuatao:

Mchunguzi Mkuu:

Dr Caleb Karuga

Department of Orthopedics and Trauma surgery

University of Nairobi

Nambari ya Simu: 0721645192

Msimamizi Mkuu:

Dr Edward Gakuya

Department of Orthopedics and Trauma Surgery

University of Nairobi.

Nambari ya Simu: 0721932799

Ama,

Katibu,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Nambari ya simu :. 2726300 Ext. 44102

Email:uonknh_erc@uonbi.ac.ke.

Appendix 4 – Fomu Ya Idhini (Watu Wazima).

Kichwa Cha utafiti: EARLY OUTCOMES OF PRIMARY TOTAL KNEE REPLACEMENT: A MULTICENTER STUDY

Jina la Mtafitu: Dr. Caleb Karuga, mwanafunzi wa Shahada ya Uzamili Katika Radiology Chuo Kikuu cha Nairobi, Idara ya ……

1. Nimesoma fomu hii ya idhini au nimesomewa yaliyomo na nilielewa.

2. Nimepewa nafasi ya kuuliza maswali juu ya utafiti huu.

3. Nimejibiwa maswali yangu vya kutosha katika lugha ninayoelewa.

4. Hatari na faida zinazowezekana nimeelezewa kwa njia wazi.

5. Ninaelewa kuwa mimi hushiriki katika utafiti huu kwa hiari na kwamba ninaweza kujiondoa wakati wowote.

Kwa kusaini fomu hii ya idhini, sijatoa haki yoyote ya kisheria ambayo ninayo kama mshiriki wa utafiti.

Ninakubali kushiriki katika utafiti huu: Ndio / Hapana

Ninakubali kutoa habari ya mawasiliano kwa ufuatiliaji: Ndio / Hapana

Jina la mshiriki aliyechapishwa: _____

Mawasiliano (nambari ya rununu): _____

Saini ya mshiriki / Stempu ya kidole gumba _____ Tarehe _____

Kauli ya mtafiti

Mimi, aliyesainiwa chini, nimeelezea kabisa maelezo yanayofaa ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kwamba mshiriki ameelewa na kwa hiari ametoa idhini yake.

Jina la mtafiti: DR. Caleb Karuga: _____

Saini _____

Wajibu katika utafiti: Mchunguzi mkuu.

Kwa habari zaidi, wasiliana na:

Mchunguzi Mkuu:

Dr. Caleb Karuga,

Department of Orthopedics and Trauma surgery

University of Nairobi

Nambari ya Simu: 0721645192

Msimamizi Mkuu:

Dr Edward Gakuya

Department of Orthopedics and Trauma Surgery

University of Nairobi

Nambari ya Simu: 0721932799

Ama,

Katibu,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Nambari ya simu:. 2726300 Ext. 44102

Email:uonknh_erc@uonbi.ac.ke.

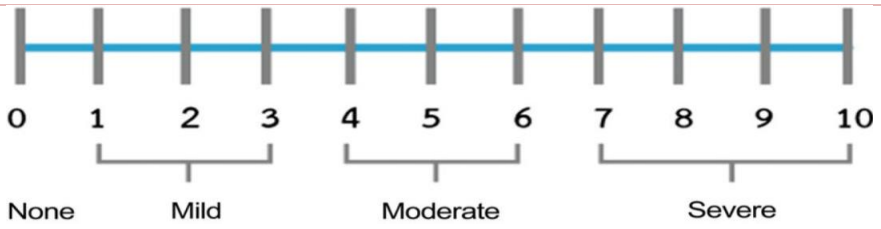
Appendix 5: Data collection tool

Title: **EARLY OUTCOMES OF PRIMARY TOTAL KNEE REPLACEMENT: A MULTICENTER STUDY**

Investigator: Dr Caleb Karuga, Resident Department of Orthopedics and Trauma Surgery, University of Nairobi

Form no: …….

1. Age……. years
2. Sex: Male / Female
3. Weight ….kg
4. Height …. Cm
5. BMI …… kg/m2
6. Physiotherapy: Hospital based…. Home based….
7. Clinical Assessment after 90 days after total knee replacement

Outcome	**After 90 days**
Range of Motion in degrees	Grading of Suboptimal Active ROM in Flexion SEVERE 0 TO 30 DEGREES ☐ MODERATE 31 TO 60 DEGREES ☐ MILD 61 TO 90 DEGREES ☐ OPTIMUM 90 TO 140 DEGREES ☐
Pain score	
Temperature difference in degrees Celsius	

between the operated knee and contralateral knee	
Sensation	Altered… Not altered…

8. Patient satisfaction after total knee replacement

NEW OXFORD KNEE SCORE QUESTIONNAIRE

Please answer the following 12 questions. Choose only one answer per question. The value for each answer is indicated to the right of the answer. Total up all of your answers to obtain a total score out of 48 points. ***Please only consider how you have been getting on during the past four weeks***

1. How would you describe the pain you have usually from your knee? **Score**

None – **4**
Very mild – **3**
Mild – **2**
Mild moderate – **1**
Severe – **0**

2. Have you had any trouble with washing and drying yourself all over because of your knee?

No trouble at all – **4**
Very little trouble – **3**
Moderate trouble – **2**
Extreme difficulty – **1**
Impossible to do – **0**

3. Have you had any trouble getting in and out of a car or using public transport because of your knee?

No trouble at all – **4**
Very little trouble – **3**
Moderate trouble – **2**
Extreme difficulty – **1**
Impossible to do – **0**

4. If you were to kneel down could you stand up afterwards?

Yes, easily – **4**
With little difficulty – **3**
With moderate difficulty – **2**
With extreme difficulty – **1**
No, impossible – **0**

7. Have you been able to do your own household shopping on your own? **Score**

Yes, easily – **4**
With little difficulty – **3**
With moderate difficulty – **2**
With extreme difficulty – **1**
No, impossible – **0**

8. For how long have you been able to walk before the pain from your knee became severe (with or without a stick)?

No pain, even after more than 30 minutes – **4**
16-30 minutes – **3**
5-15 minutes – **2**
Around the house only – **1**
Unable to walk at all – **0**

9. Have you been able to walk down a flight of stairs

Yes, easily – **4**
With little difficulty – **3**
With moderate difficulty – **2**
With extreme difficulty – **1**
No, impossible – **0**

10. After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your knee?

Not at all painful – **4**
Slightly painful – **3**
Moderately painful – **2**
Very painful – **1**
Unbearable – **0**

5. Have you been limping when walking because of your knee?

Rarely/never – **4**
Sometimes or just at first – **3**
Often, not just at first – **2**
Most of the time – **1**
All of the time – **0**

6. Have you felt that your knee might suddenly give way or let you down?

Rarely/never – **4**
Sometimes or just at first – **3**
Often, not just at first – **2**
Most of the time – **1**
All of the time – **0**

11. How much pain from your knee interfered with your usual work (including housework)?

Not at all – **4**
A little bit – **3**
Moderately – **2**
Greatly – **1**
Totally – **0**

12. Have you been troubled by pain from your knee in bed at night?

No nights – **4**
Only 1 or 2 nights – **3**
Some nights – **2**
Most nights – **1**
Every night – **0**

Total Score: /48

Grading of OKS	
Score 0 to 19	poor
Score 20 to 29	moderate
Score 30 to 39	good
Score 40 to 48	excellent