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SCHOOL OF MEDICINE & PHARMACY

Patient reported outcomes after femur shaft fracture surgery at Kigali University Teaching Hospital

Thesis Submitted in Partial Fulfillment of the requirements for the award of a Master of Medicine in Orthopedic Surgery at the University of Rwanda

By Dr. NSHIMIYIMANA Protogene

Supervisors: Prof. BUTERA M. Alex

Dr. BYIRINGIRO Jean Claude

Kigali, May 2019

Declaration

The Researcher:

I hereby declare that this research study is my original work and has not been presented to any other Institution. No part of this research should be reproduced without the authors' consent.

Sign: _____ Date 31/05/2019

Dr. NSHIMIYIMANA Protogène

The supervisor(s):

We hereby declare that this research has been submitted by Dr. NSHIMIYIMANA Protogène with our approval at University of Rwanda, College of Medicine and Health sciences

Signature : _____ Date : 31.05.2019

Prof Alex M. BUTERA

Signature : _____ Date : 31.05.2019

Dr. Jean Claude BYIRINGIRO

Dedication

"*To my wife Claudine UMUBYEYI and my Daughter Thalia Lana KAYIJAMAHE, to my father and my beloved mother gone too soon and to my Family for their unconditional support during this residency program; this work is Dedicated"*

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To you all, a big thank you

Dr. NSHIMIYIMANA Protogène

ABSTRACT

Background: Femur shaft fractures are common injuries in orthopedic trauma. Their treatment is generally by surgical means, but their outcome may differ between the surgeon's and the patient's perspective. Numerous studies have shown that even properly managed femur shaft fractures result in decreased physical function and quality of life, and only patients are the most accurate in describing their own symptoms, pain, function, and quality of life.

Methods: This study used mixed quantitative and qualitative methods to understand perceptions about the outcomes for adult patients (18years and above) operated at CHUK for femur shaft fracture with at least 6 months period of post-surgery. We used PROMIS tool a 10-items 5 points Likert Scale which is used to have a feedback from patients on how health services delivery and intervention have affected their quality of life, daily function and symptoms of severity. Demographic data such as age and gender were collected. Internal reliability was measured using Cronbach's alpha and validity tested using principal components analysis. The association between patient satisfaction and other categorical variables was analyzed and tested using Kruskal Wallis test. A comparison using T-test was performed for locked-nail and other methods.

Results: A total of 83 patients operated for femur shaft fractures were included in the study. The mean age of patients was 30.8 (std dev 7.8) years, Male to female ratio was 3.6:1, All the 10 items of PROMIS had positive inter-items correlation ranging from 0.3 to 0.9 (mean 0.53) with high internal consistency reliability (Cronbach alpha 0.933); two principal components had eigenvalues greater than 1 and explained 75% and more of the variation in the data. The overall patient's satisfaction was very good with mean total scores of 43.7/50, with male slightly more satisfied than female (mean total scores of >45, 44 out of 50 respectively) but this was not statistically significant. Preoperative immobilization with traction; reduced preoperative waiting time; surgery with closed method locked intramedullary nail were factors associated with better patient reported outcome.

Conclusion: The patient reported outcome after femur shaft fracture surgery is very good with overall satisfaction 43.7/50 and PROMIS is a valid and reliable tool for patient reported outcome in our settings and our findings are consistent with most of published studies. Implementation or routine use of this tool will improve the patient-centered care based on perception of outcome.

Key words: PROMIS, Femur shaft fracture, patient satisfaction.

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List of Acronyms and Abbreviations

ANOVA: Analysis of Variances

CHUK: University Teaching Hospital of Kigali

CI: Confident Interval

CMHS: College of Medicine and Health Sciences

DASH: Disabilities of the Arm, Shoulder, and Hand
DVT: Deep Vein Thrombosis

E.g.: exempli gratia ("for example")

EC: Ethic committee

et al.: and others

etc.: et cetera (= and other similar things)

ETC: Early Total Care

FAAM_ADL: foot and ankle ability measure activities of daily living

FFI: foot function index
GH: Global Health

HIV: Human Immunodeficiency Virus

HRQOL: Health Related Quality Of Life

ICHOM: International Consortium for Outcome Measurement

IM: Intramedullary Nailing

IRB: Institutional Review Board

LEFS: Lower Extremity Functional Scale
LMICs: Low- and Middle-Income Countries

MAX: Maximum

MIN: Minimum

MTSS: Medial Tibial Stress Syndrome Score
Obs: Observation

PASS: Patient Acceptable Symptom State

PF: Physical function

POP: Plaster of Paris

PROMIS: Patient Reported Outcome Measures Information System

PROMs: Patient Reported Outcome Measures

PROs: Patient Reported Outcomes
PTSD: Post Traumatic Stress Disorders

P-value: probability value

SF: short form

SF-36: Short Form 36-item

spFAAM: sport module of Foot and Ankle Ability Measure
SPSS: Statistical Package for the Social Sciences

STATA: STAtistics and daTA

Std: Standard deviation

TESS: Toronto Extremity Salvage Score
USA: United State of America

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

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CHAPTER I: INTRODUCTION

I.1 Background

Femur shaft fractures are among common injuries in orthopedic trauma. They are diagnosed across all age groups and are attributable to a variety of mechanisms. There is an age and gender-related bimodal distribution tendency of fractures with high-energy trauma injuries occurring most frequently in young males and simple falls from standing in elderly females (1).

The incidence of diaphyseal femur fractures ranges from 9.9 to 21 for every 100,000 persons/year with 60-62% occurring in men and 38-40% in women. The average age is 25 years, with a maximum incidence peak among 15 and 24 years of age. The cause in the majority of cases is high-energy trauma, mainly from road traffic accidents (80-90%), and fractures caused by minor trauma occur in patients above 60 years (2,3).

In our region, femur fractures also constitute a significant burden. A. Hollis et al. in Tanzania found a prevalence of 39% of femur shaft fractures with males commonly affected at 65% of patients especially those aged between 21-30years of age(4). The Same study also found that motor traffic accidents (71%) were the most common mechanisms of injury in young patients while fall caused fractures in the older population. E. Twagirayezu et al in Rwanda found road traffic trauma (71.5%) as the commonest causes of lower limb open fractures with 17.6% being femur fractures(5). Femur fracture is very common at University Teaching Hospital of Kigali (CHUK), as evidenced by the Rwanda Ministry of Health report of 2013 which state that femur shaft fractures are fourth leading cause of overall hospital emergency admission, and among ten first causes of consultation to outpatient clinic(6).

Femur shaft fractures result in significant morbidity if not well managed. One study by M. Braten et al found numerous complications after femur shaft fracture management including: superficial and/or deep infection, thromboembolic disease, adult respiratory distress syndrome, delayed union, malunion or non-union, failed implant, hip pain, pain (Hip and/or knee) and limb length discrepancy (7). Mechanism of injuries, mainly road traffic accidents, which caused femur fractures, may also cause psychological and emotional problems like post-traumatic stress disorder (PTSD) and severe depression which play a negative role in patient's quality of life. One study from Australia showed that Road traffic accident trauma victims report significant sequelae that influence functional status, psychological well-being, quality of life and return to work following severe injury(8). Depressed patients have a tendency to develop pain medication dependency, social isolation and may delay patients' recovery or decreased functional outcome(9–11).

The other consequences of injuries that can affected patients perceived overall quality of life include social and financial problems. Medical costs, lost productivity, hospital length of stay does not capture the psychosocial losses associated with road traffic crashes, either to those

injured or to their families. A qualitative study done in Malawi found that patients who sustained a lower extremity injury experienced substantial physical morbidity, work disruption, changes in social activities, and feelings of dependency, which led to social isolation, personal and household economic loss, and psychological distress(12). The same study also showed that immobility led to limitations in performing activities of daily living and reduced productivity or discontinuation with vocational goals.

The management of femur shaft fractures is generally by surgical means. Surgery is preferred because it allows early return to activity, reduces hospital length of stay, reduces morbidity related to long staying in bed. Surgery is contraindicated in patients with severe co-morbidities for whom nonoperative management is used(13–15). Many surgical options are available but the locked intramedullary nail is the gold standard in femur shaft fracture management(4,13,16,17).

Surgery, even though largely accepted and known as the best treatment option for the femoral shaft fracture, doesn't guarantee a total cure without any disability (18). Functional limitation and impairment persist despite a good union rate of 97-100% following a femur shaft intramedullary nailing (19). Senders et al. in their study on outcome after isolated femur fracture managed with locking intramedullary nail in conditions optimized to the maximum (including surgery performed by experienced orthopedic or trauma surgeon with femoral nailing technique, patient on traction table, under image intensifier and with no delay in fixation) found that disability after a fracture of the femoral shaft fixation still exist and is mainly due to persistence of knee pain(20). Other reported persisting symptoms which may lead to disability are hip pain and Trendelenburg gait due to weak hip abductor muscles due to the injury itself or trauma caused by surgery(19).

Poverty-related factors including shortage of personnel and theatre spaces, lack of proper orthopedic implants, the burden of road traffic crashes, socio-economically poor patients, and delayed definitive surgery have a negative impact on the outcome of the management of femur shaft fractures in the Low-and Middle-Income Countries (LMICs) (4,15). Studies done in Uganda found that femur fractures needed surgery but limited local resources to fund the surgical treatment as an options for orthopaedic trauma patients leads to dependence of patients on their friends, family, and charitable organization (21,22). Although in Rwanda we have improved in pre-hospital care and referral systems, delays in definitive operative treatment are noticed at the referral hospitals, and delays in getting definitive treatment at referral hospitals is due to the surgical care need exceeding available resources capacity including lack of surgeons and theatre time(23,24).

Data about the patients 'perceived outcomes following the surgical treatment are very scarce or non-existent in the LMIC. We still lack information about whether the treatment given to patient in our setting and particularly at CHUK have changed their quality of lives and about how they are satisfied. The idea of measuring the outcomes of treatment in health care was promoted by Ernest Amory Codman in the early 1900s, but, until recently, his concepts were generally ignored. Although presently no ideal method exists to measure outcomes, the information collected depends on the reason the outcome information is required. Measuring surgical outcome may be difficult or challenging as intervention efficacy is not always apparent

immediately, complications often comes late, and follow-up of patients is limited. However, with use of validated tools in research we are able to measure how our interventions improve the patient health care, and the health services delivery systems(25,26).

The Patient Reported Outcome Measures Information System (PROMIS) is a tool used to have a feedback from patients on how health care delivery systems and intervention have improved their quality of life, daily function and symptoms severity, and it helps health care givers to fill a vital gap in knowledge about outcome and whether healthcare intervention makes differences in people's lives.(27) It is a 10 items global health tool that allows measurement of 3 main outcome component of a disease: Physical health, Mental health and social health. The PROMIS validity, reliability, and feasibility have been tested for a number of diseases, and it was found that it is a short and flexible tool that is feasible, provide reliable evidence and precise measurements of commonly studied Patient Reported Outcomes (PROs)(28–30). In trauma, it has been used and validated for upper extremity, ankle injuries and Anterior Cruciate Ligament injuries(31–33).

Global Health PROMIS (10) SF(34)

Please respond to each item by marking one box per row

		Poor	**Fair**	**Good**	**Very good**	**Excellent**
Global 01 PF	In general, would you say your health is…	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 02 SH	In general, would say your quality of life is…	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 03 PH	In general, how would you rate your physical health?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 04 MH	In general, how would you rate your mental health, including your mood and ability to think?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 05 SH	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 09 SH	In general, please rate how well you carry out your usual social activities and roles. (this include activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Function	**Not at all**	**A little**	**Moderately**	**Mostly**	**Completely**
Global 06 PH	To what extent are you able to carry out your everyday physical activities such as walking,	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	climbing stairs, carrying groceries, or moving a chair?					
	In Past 7 days	**Always**	**Often**	**Sometimes**	**Rarely**	**Never**
Global 10 MH	How often have you been bothered by emotional problem such as feeling anxious, depressed or irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
		Very severe	Severe	Moderate	Mild	None
Global 08 PH	How would you rate your fatigue on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 07 PH	How would you rate pain on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

I.2 Problem statement and Justification of the study

Surgically managed femur shaft fractures, in general, have satisfactory results in terms of clinical and radiological evaluation, but this is provider or health care professionals' outcome evaluations on behalf of patients(35). Numerous studies have shown that even properly managed femur shaft fractures result in decreased physical function and quality of life(13,15), and only patients are most accurate in describing their own symptoms, pain, function, and quality of life.

This study helped us understand how patients with femur shaft fracture surgically managed at University Teaching Hospital of Kigali perceive their outcome. The feedback from patient is important, as we are promoting patient-centered care, because it helps evaluate how effective and safe health care providers address patient's needs. The knowledge from the results of this study will help hospital managers and health care providers to improve the quality and safety of health care delivery and strengthening of health care system. We chose to use PROMIS as a useful tool for assessing orthopaedic outcomes and reflect not only the affected part but the hole patients' health perception.

I.3 Research question

How do Patients perceive their outcome following femur shaft fracture fixation at CHUK?

I.4 Objectives

I.4.1 General objective:

To describe the patient reported outcome after femur shaft fracture surgery.

I.4.2 Specific objectives:

- To assess the validity of PROMIS for assessing the level of satisfaction of patients after femur shaft fracture surgery.
- To describe the level of satisfaction of patients after femur shaft fracture surgery at CHUK using the PROMIS.
- To describe the relationship between the patients' satisfaction and the three components of the Global Health PROMIS.
- To describe the relationship between the patients' satisfaction and their demographic and treatment factors.

CHAPTER II: LITERATURE REVIEW

II.1 Outcome of surgical management of fractures

The general objective of fracture management in orthopedic surgery is to allow patients return to the pre-injury functional status. Surgery is one of the treatment options used to achieve this objective and is mostly preferred because it helps to achieve anatomical reduction and strong stabilization and allows early mobilization to prevent bedridden related complications like Deep vein thrombosis (DVT), pulmonary embolism, and chest infection. The surgical management of fractures usually results in good outcomes although patient's expectations may vary from those of the surgeon who might have observed similar injuries and might have a more accurate expectation of likely outcomes.

The patient reported outcome may be influenced by presurgical patient expectation. Suk et al. (36) report that orthopedic surgeons have difficulties in providing presurgical patient expectations regarding long-term outcomes for ankle fracture surgery. Other patient's characteristics like smoking, education levels, and personal income were among factors that have impact on expected outcome. Ghosh, et al. reported that younger age and higher education levels were associated with higher Return To Work rates and factors associated with delayed or no return to work were pain, range of movement, muscle strength, major complication, infection, implant failure, preinjury job type, Socio-demographic status, insurance status, institutional problems like surgery delayed due to unavailability of implant or unavailability of theater(36).

II.2 Outcome of the surgical management of femur shaft fractures

Femoral fractures are often associated with multiple injured patients, and discussions of treatment scheme has been raised in the 1970ies. In that decade, several studies highlighted the role of early definitive treatment or Early Total Care (ETC) of femoral shaft fractures as this reduces respiratory related complications, mortality and hospital length of stay(16). However, in recent years, H. Pape et al. described the changes in the treatment of femoral shaft fractures in multiple injured patients where there was a shift from early total care in the 1980s to damage control orthopedics from 1993-2000 with a significant reduction in the incidence of systemic complications in general and this independently on the type of femur fixation used(37).

Modern clinical practice guidelines commonly recommend surgery for the femoral shaft fractures in adults, except in some special cases, since protracted immobility can cause severe complications(38). Intramedullary nailing is presently considered the "gold standard" for fixation of femoral shaft fractures(39). The advantages of intramedullary nailing for femoral shaft fractures in adults include short hospital-stay, rapid union of the fracture and early functional use of the limb(40). Surgical fixation with plates is another alternative method to restore anatomical

axis and length of femur. But it has it's own complications like: scaring of quadriceps muscle (20-30%), restricted knee range of motion and reoperation risk increased(41).

S. Ogunlade et al. in his experience of femur plating, found 77.2% of patients to have excellent to good outcome of treatment, however he also found complications that are related to fractures occurred in 9 fractures (5.7%) which included surgical infections in four fractures (2.5%) and implant broken in five fractures (3.2%). He concluded that femoral shaft plating is good treatment option if the principles of fixation are carefully followed and in countries where initial cost of procurement of equipments for closed nailing may not be imminent, and thus provides a safe, efficient and low-cost method of fixation of femoral shaft fracture(42). In their study comparing femoral nailing and plating, S. Thapa et al. found that there was no statistical difference in the outcome of intramedullary interlocking nailing and that of dynamic compression plating in case of fracture of the shaft of the adult femur(43).

The outcome of femur fracture is generally good when surgically treated early, compared to patient managed non-operatively. Delay in femur shaft fracture fixation over two weeks may result in poor outcome when compared to those treated with early stabilization(44). Early surgical management of femur shaft fractures results in excellent result regarding union and less complication. Sikka et al. report four cases of professional athletes who sustained isolated femur fractures fixed with either an anterograde or retrograde intramedullary nail and were able to return to play after 1 year(36).

II.3 Factors that influence the outcome of fractures

The outcome of fractures surgically managed is generally influenced by many factors. E. Santolini et al. found 10 risk factors associated with long bone non-union including; open fracture, an open method of fracture reduction, smoking, presence of post-surgical fracture gap, infection, wedge or comminuted types of fracture, high degree of initial fracture displacement, inadequate mechanical stability, poor local vascular supply, and the presence of the fracture in the tibia as compare to femur(45). Obesity is another factor that predisposes to poor fracture outcome because the obese physiology is associated with a higher risk for complications, including infection, failure of fixation, and nonunion(46).

The timing of fracture fixation has a crucial value because many studies have shown that early fracture stabilization is associated with better functional outcome and minimum or nil complications compared to late fixation which is associated with increased complications and poor outcomes (47,48). J. Byrne et al in their study comparing early femoral shaft fixation and delayed fixation found that delayed fixation was associated with high risk of development of pulmonary embolism and increased hospital length of stay(49). D. Shim et al report that delayes in femur shaft fixation and use of skeletal traction as temporally stabilization of femur fracture more than 7 days was associated with disuse muscle atrophy especially the quadriceps femoris, lower post-surgical recovery and decreased clinical outcome(50).

Physiotherapy is another factor that influences the fracture surgery outcome. The role of physiotherapy is to reduce postoperative complications and duration of hospitalization as well as to promote rapid and safe return to function in hope to minimize disability. M. Paterno et al. reported a case managed by intensive early rehabilitation following surgical fixation of a femoral shaft fracture and the result was early resolution of impairments and functional limitations and decreased disability(51). Other studies have demonstrated that early physiotherapy reduced inpatient stay, increased day case surgery rates with significant cost savings; and delay in physiotherapy was related to increased risk for in-hospital mortality especially for elderly peoples(21,52).

Some factors are believed to be associated with lower outcomes following the femur shaft fractures. Those are smoking, decreased knee range of motion, persistent pain, complication requiring reoperation and compromised fracture healing, time to operation, type of operative fixation, wound infection and development of pressure sores(53,54). In one study they demonstrated that smoking was a higher risk of developing long bone diaphyseal (humerus, femur or tibia) nonunion, whether open or closed(55). Complications that causes reoperations included infection, malunion angulation and implant failure. The plate fixation has a higher rate of failure compared to intramedullary nailing for femur shaft fractures(56). Persisting pain is observed in knee, thigh, groin, and buttock, with knee pain being the most common and most severe source of patient discomfort(20,57)

II.4 Outcome evaluation

As by world health organization outcome measure is defined as a "change in the health of an individual, group of people, or population that is attributable to an intervention or series of interventions." The International Consortium for health outcomes measurement (ICHOM) defines health outcomes as "the results that matter mostly to patients" rather than those that matter to health care givers and healthcare organizations. The aim or goal of measuring outcomes is to improve the patient experience of care, improve the health of the population and reduce the per capital cost of healthcare(25). Measuring outcome involve the use of clinical indicators across a number of domains, and those indicators are grouped into outcome measures, instruments or tools which are used to assess the effectiveness of clinical intervention and standardized measures on which best practices is determined and must be appropriate to the clinical perspective chosen (reliable and valid)(58).

The outcomes are generally classified into- clinical (e.g. cure, survival), humanistic (e.g. role performance, emotional status) and economical (e.g. expenses, saving). In clinical, the outcomes can be clinician reported (e.g. performance of the patient), caregiver reported (e.g. functional status), physiologic (e.g. radiographic consolidation), an observer reported outcomes or patient-reported (e.g. symptoms)(59).

The patient reported outcome measures has gained influence in current practice as patients have an central role to play in communicating the impact of disease and the effectiveness of

healthcare. The patient reported outcomes are a unique indicator of the impact of diseases on patients, helpful in creating a rapport between patients and healthcare provider, useful in the interpretation of clinical outcome and treatment decision making(60,61).

Patient-reported outcomes seem to be of more importance in future than another clinical outcome (like: Clinician reported outcome, observer reported outcome and performance outcome) which emphasize on the efficacy of treatment or intervention regardless of the patient point of view(59). Clinicians are known to underestimate the patient's symptoms, and poorly detect and document symptoms that significantly cause the impact on patient function(62). Clinicians tend to be very optimistic that their patients will respond to treatment and could succumb to expectation bias. S. B. Cohen et al. in their study found that patient-reported outcome measures may be more sensitive to treatment effect than are physician-reported outcome measures and they recommended that in evaluating treatment outcome, clinicians and researchers should consider assigning greater importance to patient-reported outcome measures(62).

II.5 PROMIS

The Patient-Reported Outcome Measurement Information System or PROMIS role is to provide clinicians and researchers access to efficient, precise, and valid PRO measures. PROMIS uses rigorous qualitative and quantitative methods, including construct definitions, literature reviews, input from experts and focus groups, literacy and translation reviews, and cognitive interviews.

The way a patient judges the effectiveness of a given treatment is by perceiving changes in presenting complains and PROMIS provides that. It provides the means to determine the effectiveness of health care intervention and provide means to assess the value of a given health intervention to patients. The PROMIS item banks offers the potential for efficient (minimizes item number without compromising reliability), flexible (enables the optional use of interchangeable items), and precise (has a minimal error in estimate) measurement of commonly studied PROs(29).

The patient reported outcome has gained attention in recent days as patients and surgeon evaluate outcome on distinct perspective. Orthopedic surgeons overestimate the evolution of the injury and the level of recovery compared to patients' own ratings(63). Surgeons' ratings were directed by objective, treatment-related factors, whereas patients' ratings were not. The outcome measures commonly used by orthopaedic surgeons, such as fracture union, do not predict patient satisfaction(63), I. Harris et al. surveyed on admission, and at six months later patients with long bone fractures ((humerus, radius, ulna, femur or tibia) after motor vehicle trauma and found that Surgeons were highly satisfied with patient progress than the patients, with satisfaction rates of 88.0% for surgeons, and 74.6% for patients; Similarly, 66.7% of surgeons rated patient recovery as good, compared to 44.4% of patients(63).

PROMIS has been compared with other validated PROMs commonly used in orthopedic patients and has been found to provide the advantage of having fewer questions and can be administered rapidly and applied to a broader patient population while remaining highly reliable. For lower

limb, PROMIS has been compared with FAAM-ADL (foot and ankle ability measure activities of daily living); FFI (foot function index); LEFS (Lower Extremity Functional Scale); MTSS (Medial Tibial Stress Syndrome Score); SF-36 (Short Form 36-item Health Survey: RAND Corporation); spFAAM (sport module of Foot and Ankle Ability Measure); TESS (Toronto Extremity Salvage Score); WOMAC (Western Ontario and McMascter University Osteoarthritis Index) and found that PROMIS was completed in significantly less time, provides much freedom and flexibility, reliable and demonstrated greater or equivalent unidimensionality (36,64,65). For upper limb, PROMIS has been compared with DASH (Disabilities of the Arm, Shoulder, and Hand) and Quick-DASH in patients with hand and upper extremity orthopedic conditions and showed good to excellent correlation(64). Morgan et al. evaluated the construct validity of PROMIS instruments by examining correlations with well-validated measures commonly used to assess patients with knee osteoarthritis and their results support the construct validity of PROMIS Anxiety and Depression in measuring these domains among patients with symptomatic knee osteoarthritis (64).

II.5.1 Why PROMIS?

PROMIS as validated and reliable tool used in orthopedic patients assess general health and the function including overall physical health, mental health, social health, pain, fatigue, and overall perceived quality of life. When it comes to Global Health Patient-Reported Outcome Measures, the PROMIS Global-10 is the newest of the validated tools available and PROMIS has been created to minimize or respond to the burden of use of multiple patient reported outcome instruments and allow comparable results(66). For our study PROMIS will help us assess the general outcome of patients operated for femur shaft fractures, their physical function, persistent symptoms and their quality of life, in other word the PROMIS capture the whole picture of our patients and results obtained will help us improve the quality of healthcare to patients with femur shaft fractures.

Chapter III: RESEARCH METHODOLOGY

III.1 Study design

This was a Retrospective and cross-section study; we used mixed quantitative and qualitative methods to understand perceptions about the outcomes for patients operated at CHUK for femur shaft fracture with at least 6 months period of post-surgery. we used PROMIS tool which is a 10-item 5 points Likert Scale to describe perceptions of patients, and quantitative methods to assess factors underlying perceptions.

III.2 Study site

The study was conducted at University Teaching Hospital of Kigali (CHUK), orthopedic surgery department where almost all femur shaft fractures are managed by operative measures and we use different options including locked intramedullary nail, non-locked nail, plates and screws and external fixation for some complex fractures. CHUK is the largest hospital located in District of Nyarugenge at KN 4 Ave, Kigali City. It is also the biggest referral hospital of the country with a capacity of 519 beds. CHUK provides quality healthcare to the population, training, clinical research and technical support to district hospitals.

III.3 Study population

III.3.1 Inclusion criteria

All adult patient, 18 years and above, with femur shaft fracture at least 6months post-surgical fixation at CHUK

Simple fracture and Isolated femur shaft fracture

III.3.2 Exclusion criteria

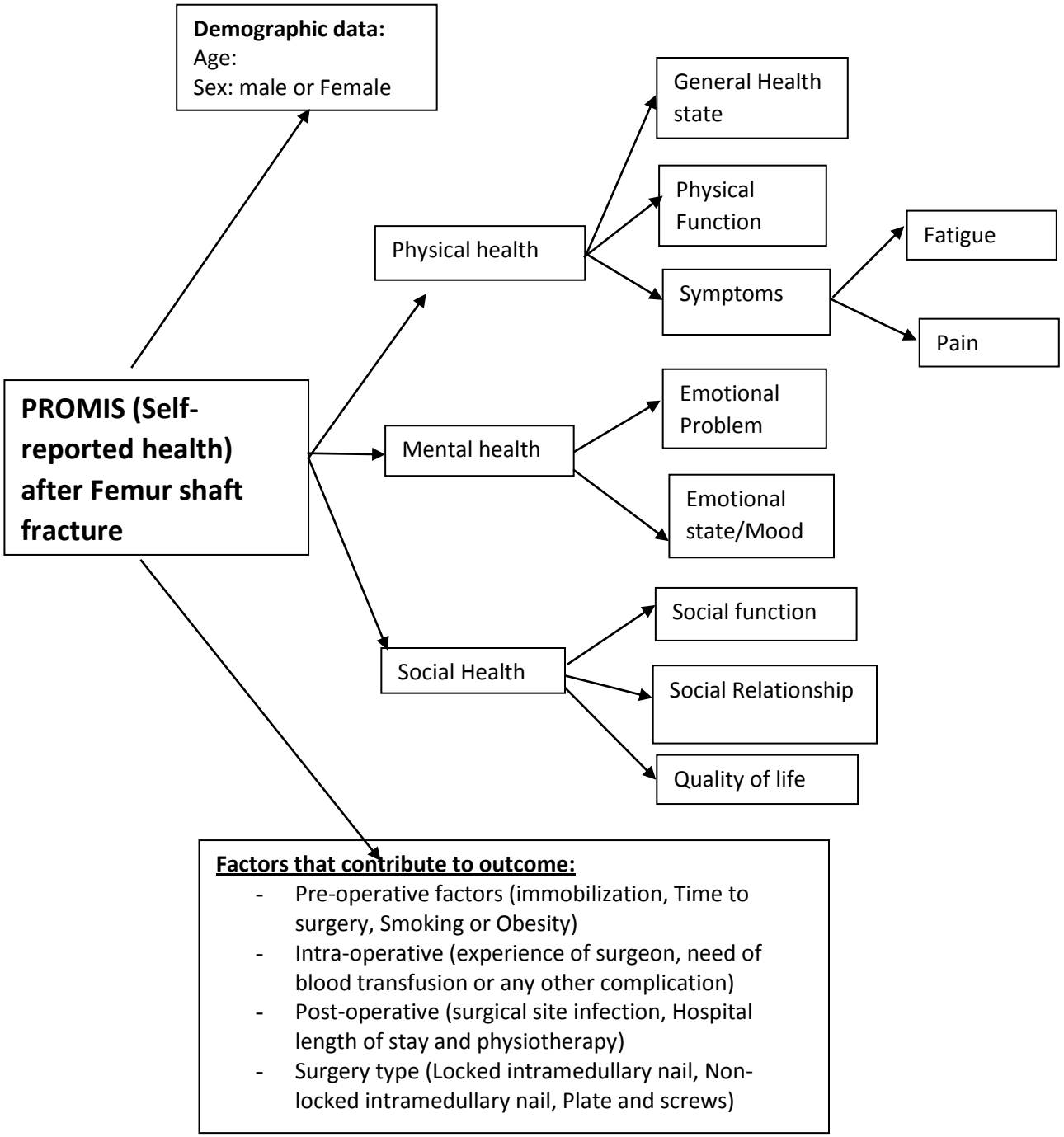
Affection or diseases that prohibiting oriented response to the questionnaire

Refusal to sign a consent form for the study

Femur shaft fracture managed non-operatively

Complex femur fracture

III.4 Conceptual framework



III.5 Sampling

III.5.1 Samples sizes

Sample size calculation used prevalence of diaphyseal femur fracture of 5.6% as reported by P. Chigblo et al. in a study of Epidemiology of Fractures in a Tropical Country (Benin) as there was no published data from our country. We have used the formula to calculate sample size in descriptive and cross-section study when estimating single proportion.

$$\mathbf{n = Z^2\ P(1 - P)/D^2}$$

With Z=1.96; P=0.056; D=0.05, we will use sample size of 81 patients.

Z=Confidence level at 95% (standard value of 1.96)

P= Prevalence

D= Range of confident interval (CI)

III.6 Data collection and analysis

We enrolled patients with operated femur shaft fractures. Theatre registry of CHUK was used to identify patients operated for femur shaft fracture and we used patients records to get phone numbers. The patients were called and requested to participate in the study, and an appointment for review in the outpatient department was scheduled. At outpatient clinic, explanation was provided, and informed consent was obtained before inclusion in the study. The data on patient satisfaction was collected using 10-items 5 points Likert Scale tool-based questionnaire, the administration of the questionnaire was done by the researcher. The internal reliability of this tool was measured by Cronbach's Alpha which measures the coefficient of reliability of the tool.

We used mean, standard deviation, minimum and maximum to provide quantitative insight into the data. Graphs such histogram and boxplot were also used to describe patient satisfaction.
Frequencies including percentages for each category were also used for data description.
The correlation between patient satisfaction and other continuous data was measured by Pearson linear correlation coefficient.

The association between patient satisfaction and other categorical variables was analyzed using Analysis of Variance (ANOVA) after checking the underlying assumptions of normality and constant variance. Where assumptions found to be violated; data transformations (square, log, square root, etc.) was envisaged; if in vain a nonparametric analysis of Variance (Kruskal Wallis test) was used. Furthermore, a comparison using T-test was performed for locked-nail and other methods.

All data entry and analysis activities were carried out respectively using SPSS 23 and Stata 13. All statistical tests were performed at 95 % confidence level.

III.7 Ethical consideration

III.7.1 Confidentiality

Patient identity was protected by code number different from hospital record. Data sheets and other related research records were stored in a locked cabinet and on a secured laptop and access limited was only to the research team.

III.7.2 Risks and benefits

Participants did not receive direct benefit from this study and the risks to participant in our study was minimal because they were asked to come back to CHUK. Participants were asked questions, the participants were assessed and managed according to normal medical management; there were no extra care charges. Participation was voluntary, and the participant did not get any compensation.

However, participation in this research allowed a better understanding of patients reported outcome after femur shaft surgery and brought a crucial basis for evaluating changes in the management of femur shaft fractures and improve quality of care and safety of patients.

III.7.3 Informed consent

After a full explanation to participant about the purpose, risks, and benefits of the study, an informed consent was signed by the participant. We have written forms in KINYARWANDA and ENGLISH. Participation in the study was voluntary and participants had the right to withdraw from our study at any time and without any pursuit.

III.7.4 Ethical approval

This research was approved by College of Medicine and Health Sciences/ Institutional Review Board (CMHS/IRB) with approval notice: No 363/CHHS IRB/2018 and Ethic committee from CHUK with ref: EC/CHUK/722/2018.

Chapter IV: RESULTS

IV.1 General characteristics of the population

Gender of patients					
Variable	Frequency	%			
Gender					
Male	65	78.31			
Female	18	21.69			
Age of patients					
Variable	N	Mean	Std. Deviation	Minimum	Maximum
Age of patient	83	30.8	7.802	18	60

Table 1: General characteristics of patients

There is male predominance compare to female with 78.31% and 21.69% respectively with a male to female ratio of 3.6:1.

The mean age of patients was 30.8 year with a standard deviation of 7.8; minimum and maximum age of 18 and 60 years respectively.

IV.2. Validity testing

Cronbach's Alpha statistic					
Cronbach's Alpha	N of Items				
0.933	10				
Summary statistics of items					
Statistic	N of Items	Mean	STD	Minimum	Maximum
Item Means	10	4.37	0.29	3.89	4.72
Item Variances	10	0.33	0.09	0.13	0.45
Inter-Item Correlations	10	0.57	0.14	0.31	0.96
Items principal component analysis					
Component	Eigenvalue	Difference	Proportion	Cumulative	
Comp1	6.35	5.2	0.63	0.63	
Comp2	1.15	0.39	0.11	0.75	
Comp3	0.76	0.28	0.08	0.83	
Comp4	0.48	0.06	0.05	0.87	
Comp5	0.42	0.07	0.04	0.91	
Comp6	0.35	0.04	0.03	0.95	
Comp7	0.3	0.13	0.03	0.98	
Comp8	0.17	0.14	0.02	1	
Comp9	0.03	0.03	0	1	
Comp10	0	.	0	1	
Physical, social and mental health component analysis					
Component	Eigenvalue	Difference	Proportion	Cumulative	
Comp1	2.55543	2.24033	0.8518	0.8518	
Comp2	0.315106	0.185645	0.105	0.9568	
Comp3	0.129461	.	0.0432	1	

Table 2: Validity and Reliability testing

The alpha coefficient for the ten items is 0.933, suggesting that the items have relatively high internal consistency.

The mean score of items were 4.37/5 (std 0.29) with minimum and maximum scores of 3.89 and 4.72 respectively; for 10 items the means is 43.7/50 which is the overall patient satisfaction. the mean of item variance was 0.33 and inter-item correlations was 0.57.

The first two principal components have eigenvalues greater than 1 in items principal components analysis. Eigenvalues represent the total amount of variance that can be explained by a given principal component and this means that two components explain 75% of the

variation in the data. If 75% is an adequate amount of variation explained in the data, then the two first principal components should be used

Only the first principle component has eigenvalue greater than 1in sub-group principal components analysis which explain 85.18% of variations in the data.

IV. 3 Patient satisfaction

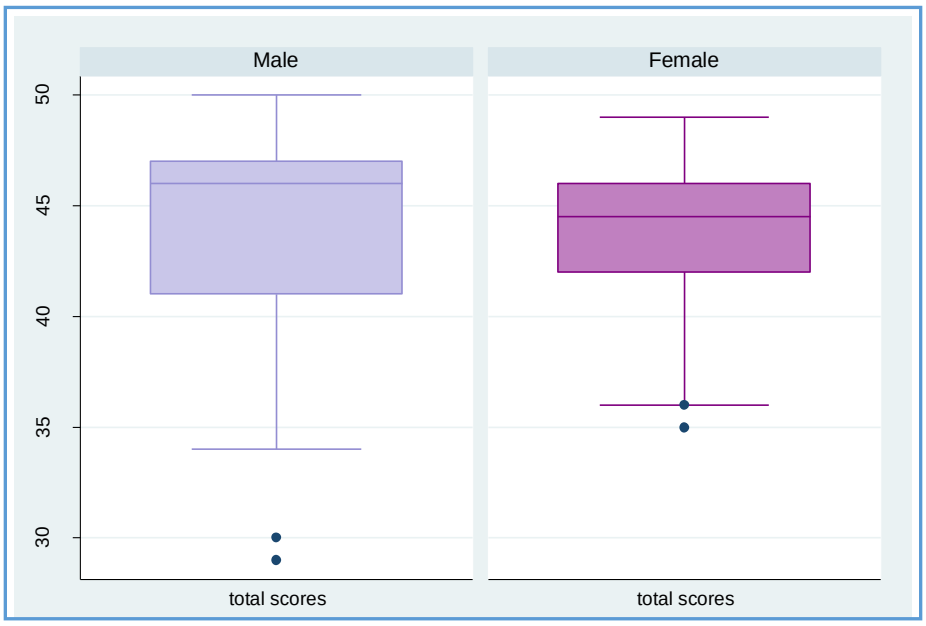


Figure 1. Total Scores by gender

This Boxplot shows that patient reported outcome was very good with mean total score around 45/50 with male slightly more satisfied than female.

Descriptive Statistics of physical, social and mental health components					
Variable	N	Mean	Std. Deviation	Minimum	Maximum
Physical Health	83	21.02	2.16	14	25
Social Health	83	13.23	1.66	7	16
Mental Health	83	9.4	1.02	6	10
Satisfaction scores by other clinical variables					
Variable	N (%)	Mean	STD	Min	Max
Locked intramedullary nail					
Open Method	32(38.6)	41.9	5.2	29	49
Closed Method	14(16.9)	46.5	1.7	44	49
Non-locked intramedullary nail	37(44.6)	44.2	4	34	50
Plate and screws	1(1.2)	40		40	40
Surgical site infection					
No	81(97.6)	43.7	4.5	29	50
Yes	2(2.4)	40.5	7.8	35	46

Table 3: Patient satisfaction

Table 3 shows that the three component of PROMIS, physical health had mean scores of 21.02/25 (std dev 2.16) with minimum scores of 14 and maximum score of 25; Social health had mean scores of 13.23 out of 15 (std dev 1.66) with minimum scores of 7 and maximum of 15; and the mental health mean score of 9.40 (std dev 1.02) with minimum and maximum scores of 6 and 10 respectively

Analysis of surgical stabilization technique: patients who were managed with Closed method locking intramedullary nail reported excellent result with mean total scores of 46.6/50, followed by Non-locked intramedullary nail, open method locked intramedullary nail and plate and screws fixation with mean total scores of 44.2/50, 41.9/50 and 40.0/50 respectively.

Analysis of surgical site infections: patients who developed surgical site infection had a decrease of satisfaction compared to those who didn't develop infection with mean total scores of 43.7/50 and 40.5 respectively.

IV.4 Associations of patient's satisfaction analysis

Association between patient satisfaction (Total scores) and other variables			
Variable	Numbers	Rank sum	P-value
Gender			0.669
Male	65	2768.5	
Female	18	717.5	
Surgeon			0.003
Senior resident	40	2003	
Consultant	43	1483	
Preoperative immobilization			0.049
POP	13	390	
Traction	70	3096	

Table 4: Association between patient's satisfactions and other clinical variables

The results of association tested using Kruskal Wallis test (Non-parametric ANOVA) shows the surgeon profile was associated with satisfaction (P-value=**0.003**), meaning that there is a difference in satisfaction across surgical profile. This association might favor senior residents because the rank sum of total scores was higher for senior resident than consultant. The reason behind is that majority of femur shaft fractures managed by senior residents were acute from accident and emergencies. Similarly, preoperative immobilization was also associated with better patient satisfaction (P-value=0.049) for those with traction than those with POP.

IV.5 Patients satisfaction association testing

Open and closed methods comparison						
Variable	Numbers	Mean	STD	95 % CI		P-value
Closed method	14	46.5	1.7	45.5	47.5	0.001
Open method	32	41.9	5.2	40	43.8	
Correlation of satisfaction with Preoperative time and hospitalization time						
	Total Scores(P)	Preoperative waiting time(P)	Hospitalization time(P)			
Total Scores	1	-0.13(0.237)	-0.22(0.050)			
Preoperative waiting time		1	0.27(0.013)			
Hospitalization time			1			

Table 5: Testing of patient's satisfaction association

Open method of interlocking nail has less satisfaction compared to other remaining methods; however closed method of interlocking nail shows better satisfaction than other remaining methods.

There is a relation between pre-operative waiting time and hospital length of stay as there is increase in pre-operative time consequently there is increased hospital length of stay.

Chapter V: DISCUSSION

V.1: General characteristics of the Population

There was a male gender predominance in our study with male to female ratio= 3.61:1 and these findings were similar to findings from a previous study done in same center by E. Twagirayezu et al. in which they found a male to female ratio of 3.3:1 and it is also similar to what A. Hollis at al. found in the epidemiology and treatment of femur fractures at a northern Tanzanian referral center(4,5). Only a study done in India reported a very high male to female ratio where they were comparing2 groups of femur shaft fractures and in group A all 30 recruited patients were male and in group B out of 25 patients recruited only 1 was female. No study found with female predominance.

Femoral shaft fractures are more common in young adults with mean age of 30.8 years (std 7.8), with minimum and maximum of 18 and 60 years respectively. and this is consistent with vast majority of other published studies where the mean age is found in 30s like Study by E. Twagirayezu et al. at CHUK where the mean age was 31years, a study by E. Eliezer et al. at Muhimbili orthopedic institute, Tanzania where they found that Mean age was 31.6years, and study by J. Byrne et al. in USA where the median age was 36 years(5,49,56). S. Salminen Tet al. on Population Based Epidemiologic and Morphologic Study of Femoral Shaft Fractures found that femur shaft fractures had bimodal distributions first in 2nd and 3rd decades (15 to 24 years) of life and the second in elderly following minor trauma (75 years of age or older), the young patients populations were more commonly involved than older ones (67). Unlike the findings, however, other studies report a mean age around 50s like study by E. Köseoğlu et al. in Turkey where they found mean age of 48.8 years and study by E. Rodriguez-Merchan et al in Spain where they found mean age of 51.95 years(2,68).

V.2: Tool validity and reliability testing

The result of this study showed that using Cronbach's alpha test items have relatively high internal consistency with alpha coefficient for the ten items of 0.933 indicating good reliability. similar results were obtained; two studies by Hung et al. found high item reliability (Cronbach alpha = 0.98) in one on Computerized Adaptive Testing Using the PROMIS Physical Function Item in Orthopaedic Trauma Patients and alpha coefficient of 0.96 in the other study on Validation of PROMIS Physical Function Computerized Adaptive Tests for Orthopaedic Foot and Ankle Outcome Research(69,70). a study by I. Katzan et al. found a coefficient of 0.875 and 0.823 for MCS (Mental component scale) and PCS (Physical component scale) respectively(71). A scoping metanalysis study revealed that PROMIS performed efficiently, accurately, and reliably in assessing patient reported Health Related Quality of Life (HRQOL) in

multidisciplinary surgical publications, with orthopedic surgeon the ones leading the use of PROMIS(72).

The inter-item correlations between all 10 items range from 0.31 to 0.96, this is similar of finding by R. Hays et al. in study on Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items where item-scale correlations for the 10 global health items ranged from 0.53 to 0.80. The eigenvalues from a principal components' analysis of the 10 global items were 6.35, 1.15, 0.76, 0.48, 0.42, 0.35, 0.30, 0.17, 0.03, 0.00(73). Similar to findings in same study cited above where the eigenvalues from a principal components' analysis of the 10 global items were 6.25, 1.20, 0.75, 0.44, 0.39, 0.30, 0.22, 0.20, 0.18, and 0.05. and all of this above provide some support for the construct validity of the global items(73). Same study also supported the concepts of two components like our findings where we had two components with eigenvalues greater than 1 with 75% of variations in the data; Hays et al. study found two components with eigenvalue greater than 1; and this means that two principal components should be used from 10 items. Although study by B. Schalet et al.: Linking the VR-12 to the PROMIS Global Health Scale support the two components, they found some items on social health mixed with items on mental health scale(74).

V.3: Patient's satisfaction analysis

The overall patient reported outcome was excellent, with male slightly more satisfied than female with mean total score of 46/50 and 44/50 respectively. This is in contrary with what J. Baumhauer et al. found in their study on Can Women Live with More Symptoms than Men? where they found that Females are more likely to judge their physical abilities as acceptable at a lower PROMIS PF threshold value compared to males(75). Kristensen et al. found that men were less likely to have a successful rehabilitation, reduced ability to return to their home or mobilize independently 4 months after hip fractures and also had high in-hospital stay and one year mortality compare to women(76).

V.3: Patient satisfaction and association analysis

Closed method of interlocking nail was the best method with excellent patient reported outcome score compared to non-locking nail or open method of locking intramedullary nail. D. Mukherjee in his comparative study of management of fracture shaft of femur by open versus closed intramedullary interlocking nailing, although focusing on clinical outcome rather than patient perceptions, found that both closed and open methods of nailing do not differ much with respect to the post-operative complication, time of fracture union and the functional outcome(77). I. Arris et al. in their study of outcome after intramedullary nailing of femoral shaft fractures

investigated patient reported outcome using a Short Form-36 questionnaire (SF-36) scores and found that in patients with isolated injuries, the scores were not significantly lower than the norms(79). S. Sadic et al. concluded that interlocking intramedullary nailing is the treatment of choice for femoral shaft fractures with closed method having more advantages (like reduced risk of infection and reduced problems with severely comminuted fractures, less scars formation) than open method(80).

In our study we found that reduced preoperative waiting time, reduces the hospital length of stay thus more satisfying patient reported outcome. In our study the mean preoperative waiting time (From injury to the surgery time) was 6 days and the mean hospital length of stay was 15 days. This delay is thought to be due delayed in transfer system in Rwanda as CHUK is a tertial hospital receiving patients from the District hospitals, T. Nkurunziza et al. investigate the Referral patterns and predictors of referral delays for patients with traumatic injuries in rural Rwanda and found that >50% were transferred in a period of 2days and the remaining delayed more than 2days and the reasons of delaying were awaiting appointment , lack of space at referral hospitals, and financial barriers(27). This delay is Similar to what is reported by a study by Afsar SS et al. where the average hospital stay of the patients and average delay in operation were 14.2 days and 6.68 days respectively(81). S. Sadic et al. in their study report an average length of hospital stay was l5,5 ± 7,6 days(80). However, the recommended treatment time for femur shaft fractures is within 24hr following injury. J. Byrne et al found that patients treated at centers in which delayed fixation was most common were at significantly greater risk of Pulmonary Embolism and required longer hospital stay(49).

Surgeon profile was associated with satisfaction (P-value=0.003), and this association might favor senior residents because the rank sum of total scores was higher for senior residents than consultant. Comparable results were obtained by I. Harris et al. in their study Orthopaedic trauma surgery performed by unsupervised and supervised trainees: complication rates compared, found that of 6361 orthopaedic trauma operations performed, 3754 (59%) were by unsupervised trainees of varying experience, whereas 2494 (39%) were by supervised trainees or consultants. The overall complication rate was 4.0%; the number was significantly higher in the supervised than unsupervised group and, treatment error (fixation failure and mal reduction of fractures) was significantly more frequent in the supervised than unsupervised group(82). A. Khoury et al. in their study where at Level I Trauma Center 47% of the procedures were performed by residents without an attending surgeon's supervision, while at the Regional Trauma Center 21% were performed without senior orthopedic surgeon present there was no significant differences in fracture healing or postoperative complications(78). In a systematic review of the effects of residency training on patient outcomes concluded that patient care appears safe and of equal quality when delivered by residents. However, M. Bukur reported different findings in his study on Influence of Resident Involvement on Trauma Care Outcomes that resident involvement in trauma care may be associated with worse patient outcomes(83).

The infections rate was 2.4% and affected negatively the patient reported outcome with mean total scores of 40.5/50 compared to mean total scores of 43.7/50 for those who didn't develop infection. In study by S. Young et al. on Complications after intramedullary nailing of femoral fractures in a low-income country A prospective study of follow-up, HIV infection, and

microbial infection rates after IM nailing of 141 femoral fractures at a central hospital in Malawi found the infection rate at 5% and was associated with serious complications and often leads to reduced range of knee motion and overall patient outcome(84).

V.4: Limitation of the study

We faced some limitation in our study mainly due to that it was a retrospective study.

We did not know the drivers of choice of implant used for femur shaft fractures fixation nor the decision to perform open versus closed reduction method as this have been contributed to the overall patient satisfaction. Also due to the fact that we have to call patients some did not manage to come for follow up. Further prospective study design will enable better patient follow up and enrollment.

CHAPTER VI: CONCLUSIONS AND RECOMMENDATIONS

VI.1 Conclusion

We conclude that the overall patient reported outcome after femur shaft fracture surgery was very Good with mean total scores of 43.7/50. Reduced preoperative waiting, and surgery with closed method locked intramedullary nail were associated with better patient reported outcome.

We conclude also that PROMIS is a valid and reliable tool for patient reported outcome and our findings are similar to most of published studies.

VI.2 Recommendations

- We recommend the use of PROMIS 10 items 5 points liker's scale in clinical practice for patient follow up
- We recommend use of locked intramedullary nail as treatment of choice in femur shaft fractures
- We recommend also early femur shaft fixation.
- Further studies should investigate more on the two components of the PROMIS tool.

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APPENDICES

Data collection form

Patient code: …

Demographic data:

Age: … years

Sex: male ☐ female ☐

Surgery type:

Locked intramedullary nail:

- Open method ☐
- Closed method ☐

Non-locked intramedullary nail ☐

Plate and screws ☐

External fixation ☐

Information related to surgery and factors that contribute to outcome:

pre-operative:

- Immobilization type POP ☐ Traction ☐
- Time to surgery: …….. Days
- Smoking: Yes ☐ No ☐
- Obesity: Yes ☐ No ☐

Perioperative complication

- Experience of surgeon: consultant ☐ senior resident ☐ junior resident ☐
- The need for blood transfusion: Yes ☐ No ☐

- Iatrogenic fracture (neck of femur, intertrochanteric, sub trochanteric): Yes ☐ No ☐

Post-operative:

- Surgical site infection: Yes ☐ No ☐
- Physiotherapy and rehabilitation therapy: Done yes ☐ No ☐

if yes at District hospital ☐r Referral hospital ☐

- Hospital length of stay: …… days
- Global Health PROMIS Global Health (10) SF(34)

	QUALITY OF HEALTH	Poor Nabi (Nta kigenda)	Fair Neza ariko buke	Good Neza	Very Neza cyane	Excellent Neza bihebuje
Global 01	In general, would you say your health is… Muri rusange wavuga ko ubuzima bwawe buhagaze bute?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 02	In general, would say your quality of life is… Muri rusange wavuga ko imibereho yawe ihagaze ite?	☐ 1	☐ **2**	☐ 3	☐ 4	☐ 5
Global 03	In general, how would you rate your physical health? Muri rusange wavuga ko ubuzima bwawe bw'umubiri buhagaze bute?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Global 04	In general, how would you rate your mental health, including your mood and ability to think? Muri rusange wavuga ko ubuzima bwawe bwo mu mutwe buhagaze bute, ushyizemo n'uburyo wiyumva (mood)n'uko	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	ubasha gutekereza (thinking ability)?					
Global 05	In general, how would you rate your satisfaction with your social activities and relationships? Muri rusange wavuga ko kunyurwa kwawe ku bijyanye n'ibikorwa ndetse n'imibanire bihagaze bite?	1	2	3	4	5
Global 09	In general, please rate how well you carry out your usual social activities and roles. (this include activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.) Muri rusange, garagaza uko ukora ibikorwa byawe bya buri munsi n'uruhare ubigiramio (ibi birimo ibikorerwa mu rugo, ku kazi, aho utuye, n'inshingano nk'umubyeyi, umwana, umugabo/umugore, umukozi, inshuti,etc)	1	2	3	4	5
Physical function						
		Not at all Sinabigeraga eza	A little Birangora cyane	Moderately Birangora buke	Mostly Akenshi ndabishobora	Completely Nta kibazo mbigirahoo
Global 06	To what extent are you able to carry out your everyday physical activities such as	1	2	3	4	5

	walking, climbing stairs, carrying groceries, or moving a chair? Ni ku ruhe rugero ushobora gukora ibikorwa byawe bya buri munsi bisaba intege, nko kugenda n'amaguru, kuzamuka amaj ingazi(escaliers), gutwara ibyo wahashye, kwimura intebe?					
Symptoms						
	In Past 7 days Mu minsi 7 ishize	Always Ndabihoran a	Often Kenshi cyane	Sometim es Rimwe na rimwe	Rarely Gake	Never Nta na rimwe
Global 10	How often have you been bothered by emotional problem such as feeling anxious, depressed or irritable? Ni inshuro zingahe wagize ibibazo bishingiye ku marangamutima,nko kumva ufite umutima uhagaze, ufite agahinda gakabije cg ufite uburakari?	1	2	3	4	5
		Very severe Birakabije cyane	Severe Birakabije	Moderate Kiri mu rugero	Mild Kiroroh eje	None Ntawo/Nt abwo
Global 08	How would you rate your fatigue on average? Ni gute wapima ikigereranyo cy'umunaniro wagize?	1	2	3	4	5
Global 07	How would you rate pain on average? Ni gute wapima ikigereranyo cy'ububabare wagize?	1	2	3	4	5

Consent form in English

PART I: INFORMATION SHEET

RESEARCH: "Patient reported outcomes after femur shaft fracture surgery at Kigali University Teaching Hospital"

Principal investigator: Dr. NSHIMIYIMANA Protogene, Senior resident in orthopedic surgery

I am carrying out the above-mentioned research at university teaching hospital of Kigali

I warmly welcome in my research, further explanation is going to be given and feel free to ask any question.

- The purpose of this study is to evaluate how patients perceive their outcome after femur shaft surgery
- Participation in this study is voluntary. Medical care will not be denied to you in case you decline to participate in the study. You may terminate participation at any time with no consequences whatsoever.
- You will be recruited at arrival to your out-patients follow up and you will be asked a series of question using a questionnaire form
- Patients in this study will not be subject to any harmful intervention.
- In this study, no reimbursements of any kind will be provided, participation is voluntary.
- The information that we collect from this research project will be kept confidential. Your identification code will be kept locked and only available to the principal investigator.
- The patient is free to refuse to participate in this study and refusal to participate will not affect his/her treatment.
- The results of this study will be published, and policy makers informed for possible use of information to improve the quality of services delivery

PART II: CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I (or witness) have had the opportunity to ask questions about it and any questions that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant/Witness……....

Signature of Participant/Witness ……

Date ……/…. /….. (Day/month/year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that Filling a Questionnaire will be done

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent…….

Signature of Researcher /person taking the consent……

Date……/……/…..... (Day/month/year)

Researcher contact:

Dr. NSHIMIYIMANA Protogene

Tel: + 250 788458384

E-mail : protos20@gmail.com

If you have questions about your rights in the study, contact

CMHS / UR Directorate of Research, Technology Transfer and Consultancy

Tel: + (250) 788563312

Chairperson – IRB CMHS / University of Rwanda

Prof Kato J. NJUNWA, Tel 0788490522

Consent form in Kinyarwanda “Amasezerano yo kwemera kujya mu bushakashatsi”

UBUSHAKASHATSI: **“Patient reported outcomes after femur shaft fracture surgery at Kigali University Teaching Hospital”.**

UMUSHAKASHATSI: Dr NSHIMIYIMANA Protogene, umuganga w’umunyeshuli w’inzobere mu kubaga amagufa.

Ndabashimira cyane kandi mbahaye ikaze kubwo kwinjira muri ubu bushakashatsi.Uraza guhabwa ibisobanuro kuburyo burambuye kandi nawe ushobora kubaza ikibazo kubyo udasobanukiwe.

 Ubu bushakashatsi bugamije kureba uko abarwayi babazwe igufa ryo mu itako/ikibero mu bitaro bya kaminuza bya kigalibakiriye ubuvuzi bahawe n’uburyo babayeho nyuma yo kubagwa.

 Kwinjira mubushakashatsi ni ubushake bwawe.Mu gihe utifuza kubwinjiramo ntacyo bihungabanya mukuvurwa kwawe

 Mukimara kugera munzu y’indembe n’inkomere muzakirwa n’umuganga uzabakira akabasaba gutanga amwe mumakuru azifashisha muri ubu bushakashatsi maze ahite agusuzuma akoresheje Ottawa ankle rules hanyuma agusabire guca mucyuma kugirango turebe ko udafite imvune.Ibisubizo byo mucyuma nabyo bizakenerwa mubushakashatsi bwacu.

 Ubu bushakahatsi nta bibazo bihari byagutera

 Muri ubu bushakashatsi nta gihembo icyo aricyo cyose uzahabwa

 Amakuru uzatanga cyangwa ayerekeranye n’uburwayi bwawe azagirwa ibanga

 Mugihe udashaka kwinjira muri ubu bushakashatsi ni uburenganzira bwawe kubyanga

 Ibizava muri ubu bushakashatsi bizamenyeshwa abashinzwe gufata ibyemezo kugirango bongere ireme ry’ubuvuzi buhabwa abanda barwayi bagize ikibazo nk’icyawe

KURUHANDE RW’UMURWAYI

Nyuma yo gusoma cg gusomerwa ibyerekeranye nubu bushakashatsi.Nabonye(cg umpagarariye) umwanya wo kubaza ibibazo kandi nasobanuriwe bihagije.Nkaba nemeye kwinjira muri ubu bushakashatsi.

Amazina y'umurwayi/umuhagarariye……..

Umukono w'umurwayi/umuhagarariye…… Italiki ……. /…. /……

/……

KURUHANDE RWA MUGANGA

Maze gusobanurira umurwayi ibyerekeranye nubu bushakashatsi,ndemezako yasobanukiwe nibigiye gukorwa birimo Kuzuza igipapuro cyabugenehe cy'ikusanyamakuru y'ubushakashakatsi

Ndemeza ko umurwayi namusobanuriye bihagije kandi yagize umwanya wo kubaza ibibazo ndetse ahabwa n'ibisubizo k'uburyo burambuye. Ndahamya ko nta gahato yashyizweho kuko kwinjira muri ubu bushakashatsi ari ubushake.

Amazina Ya muganga……..

Umukono wa muganga…… Italiki ……. /…. /……

Ukeneye ibindi bisobanuro wahamagara:

Dr. NSHIMIYIMANA Protogene

E-mail : protos20@gmail.com

Phone number: + 250 788458384

Ufite ikibazo ku burenganzira bwawe muri ubu bushakashatsi, wabaza:

esearchcenter@ur.ac.rw, CMHS / University of Rwanda

Directorate of Research, Technology Transfer and Consultancy

PO Box 3286 Kigali

Tel: + (250) 788563312

Chairperson - IRB, CMHS / University of Rwanda

Prof Kato J. NJUNWA Tel 0788490522