# THE PREVALENCE, ASSOCIATED FACTORS AND COMPLICATIONS OF PERI-IMPLANT FEMUR FRACTURE FOLLOWING RETROGRADE INTRAMEDULLARY NAILING AT MUHIMBILI ORTHOPAEDIC INSTITUTE

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# THE PREVALENCE, ASSOCIATED FACTORS AND COMPLICATIONS OF PERI-IMPLANT FEMUR FRACTURE FOLLOWING RETROGRADE INTRAMEDULLARY NAILING AT MUHIMBILI ORTHOPAEDIC INSTITUTE"

**By**

**Benny Tettei Adjei**

**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine (Orthopaedic and Traumatology) of**

**Muhimbili University of Health and Allied Sciences**
**October, 2024**

## CERTIFICATION

The undersigned certifies that they have read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **"The prevalence, associated factors and complications of peri-implant femur fracture following retrograde intramedullary nailing at Muhimbili Orthopaedic Institute"** in partial fulfillment of the requirements for the award of the degree of Master of Medicine (Orthopaedic and Traumatology) of Muhimbili University of Health and Allied Sciences.

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(Supervisor)

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**Date**

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**Dr. Msami Evarist Ngowi**

(Co-supervisor)

_____

**Date**

## DECLARATION AND COPYRIGHT

I, **Benny Tettei Adjei,** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

**Signature**…… **Date**……

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## DEDICATION

I dedicate this work to my family, whose love and support have been my greatest source of strength throughout this journey. To my parents, for instilling in me the values of perseverance and dedication, and to my siblings, for always being there to encourage and uplift me. Your belief in me has been a constant source of motivation.

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Finally, I dedicate this research to all healthcare professionals, especially those at Muhimbili Orthopaedic Institute, who work tirelessly to improve the lives of others. Your commitment to excellence and patient care is truly inspiring, and it is my hope that this work contributes to your ongoing efforts. Thank you for the dedication and compassion you bring to your work every day.

## ABSTRACT

**Introduction:** Peri-implant femur fracture is a likely increasing entity in orthopaedic traumatology. However, the prevalence, associated factors and anticipated complications for peri-implant femoral fractures following retrograde intramedullary nail at Muhimbili Orthopaedic Institute are not evident. The main goal of this study was to determine the prevalence, associated factors and complications among patients who developed peri-implant femur fracture following retrograde intramedullary nailing at MOI - January, 2008 to December, 2022.

**Method:** The study design was a retrospective descriptive cross-sectional study and employed the use of secondary data from the SIGN database. The MUHAS Institutional Ethical Review Board committee (IRB) was consulted for approval and ethical clearance. Patients were identified from the SIGN database (those with femur fractures, those receiving antegrade IM nailing and those receiving retrograde IM nailing). Medical records and radiological reports of patients receiving retrograde IM nailing were reviewed and appropriate data were collected using structured questionnaire. Independent variables included demography, nail size, nail tip location and complications of PIFF whilst dependent variable was peri-implant femur fracture. Data was analysed as prevalence, percentages, mean and Chi-square test.

**Results:** Out of 3076 patients treated with retrograde IMN, 29 (0.94%) experienced PIFF. Notably, 69% of these patients were aged 18-39 years, and 79% were male. The predominant nail sizes were 9mm and 10mm, each constituting 34.5% of the cases with the 360mm nail length being the most frequent (31%). 69% of PIFF cases had their nail tip positioned below the lesser trochanter, with mean a distance of 28.4mm, though this was not statistically significant ($p=0.232$). Remarkably, no complications were reported following PIFF treatment.

**Conclusion:** The study concludes that the incidence of PIFF following retrograde IMN at MOI is relatively low. The findings highlight the need for a surgical plan tailored to each patient's unique characteristics as well as prioritizing meticulous pre-operative planning and intra-operative techniques which can in the long run reduce the risk of PIFF. Nonetheless, further study to investigate whether these factors are independent risk factors is highly recommended.

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**ABBREVIATIONS**

| | | |
|---|---|---|
| PIFF | - | Peri implant femur fracture |
| BMD | - | Bone mass density |
| BMI | - | Body mass index |
| CMN | - | Cephalomedullary nail |
| IM | - | Intramedullary |
| MOI | - | Muhimbili Orthopaedic Institute |
| USA | - | United States of America |
| WHO | - | World Health Organization |
| SPSS | - | Statistical Package for the Social Sciences |

## DEFINITIONS

**Peri-implant fracture: -** A fracture which occurs in association with an implant e.g. nails, plates or screws etc, used to treat a previous injury that is still attached to the bone.

**Orthopaedic Implant: -** A medical device placed either inside or outside a bone to provide fixation for the bone.

**Intramedullary nail: -** It is an orthopaedic implant used for long bone fracture fixation.

**Osteoporosis: -** A condition in which bones becomes weak and brittle.

**Retrograde intramedullary nailing: -** A femoral nailing technique with a distal entry from the condyles or through an inter-condylar notch as starting point.

**Load to failure: –** It is the load value at the failure point that is where a sharp drop in the load occurs after the main part deformation and energy absorption.

**Osteosynthesis: –** A surgical procedure that stabilizes and joins the ends of fractured (broken) bones by mechanical devices such as metal plates, pins, rods, wires or screws.

## OPERATIONAL TERMS

**Prevalence: -** Proportion or percentage of the population who have a specific characteristic (PIFF) during the period under study.

**Implant characteristics**: - It is the intramedullary nail's size (diameter) and length which are intrinsic material properties.

**Technique characteristic: -** It is the location of the intramedullary nail's tip upon operative insertion into the femur bone.

# CHAPTER ONE

## INTRODUCTION

### 1.1 Background

The femur is the longest and strongest bone in the human body, anatomically there are three parts; proximal, shaft and distal.[1] The femoral isthmus and the subtrochanteric region are subjected to large amount of force which predispose to fractures especially in the elderly. [2, 3] Road traffic crash, a high energy mechanism of injury, is the most common cause of femur fractures amongst young patients where as the cause in older patients is mostly osteoporosis combined with low energy mechanisms for example a fall from standing height. [4, 5] Femur shaft fractures for which intramedullary nailing implant are preferentially prescribed are in ascendency in recent times.[6,7]

Retrograde intramedullary nailing has proven to be effective in the treatment of fractures of the femoral shaft and very advantageous for distal one-third and supracondylar fractures. [8] Indications currently based on which this surgical technique is employed includes multisystem injuries, multiple fractures (including ipsilateral lower limb combination injuries), ipsilateral vascular injuries, peri-prosthetic fractures, and morbid obesity. [9, 10] In retrograde intramedullary nailing, the nail is inserted into the canal at the knee (intercondylar notch is employed as the entry point) and pushed up the medullary canal. The retrograde nail usually should terminate above or at the level of the lesser trochanter. [11]

Advances in medicine and orthopaedic implant technology have dramatically increased the number of patients undergoing operative treatment of femur fractures and hence possible increase in PIFF. [12] Peri-implant fractures occur in association with an implant used to treat a previous fracture or condition. Peri-implant femoral fractures (PIFF) happen in a femur containing implants used for fracture fixation. [13]

The mere presence of an implant modifies the elasticity of specific bone segments, generating transition zones (stress risers) which are at increased risk of peri-implant fractures. A bone stress riser develops in areas of weakness that concentrate stress. These

include previous fracture sites, site of bone tumour, bone infection, current or previous implant site and they undergo deformity leading to fracture. [14, 15, 16, 17]



**Figure 1: X-ray showing PIFF in the subtrochanteric area**



**Figure 2: X-ray showing peri-implant femur fracture in the subtrochanteric area**

Biomechanically, the femur is subject to remodelling and turnover with variability based on use and trauma. Multi-directional forces acting on the femur makes it prone to stress-related injures including peri-implant fractures. Stress riser fractures are stress fractures that occur due to the presence of cortical defect (holes), changes in stiffness, sharp corners and cracks (fracture lines). Stress fractures occur in bones because of low-bone strength and high chronic mechanical stress placed on the bone. [15, 18]

Risk factors for peri-implant femur fracture is distinguished as patient factors, technical problems during implant placement (intra-operative factors), trauma and implant removal (postoperative factors). Patient factors includes age, sex, educational status, social habits (smoking and alcoholism) and co-morbidities like diabetes mellitus, obesity, malignancy, metabolic bone disease and osteoporosis. [19]

Intra-operatively, technical problems encountered during implant placement includes (1) press-fit implant, where there is larger nail compared to the medullary canal (2) nail tip ending in the stress area [3] bone stock compromised during revision procedure (4) limited incision technique leading to poor visualization of anatomy (5) cracks occurring between screw holes during internal fixation (6) multiple drilling attempts at locking sites. Post-operatively, sustaining new injury either trivial or substantial force, direct or indirect mechanisms will lead to peri-implant femur fracture. [19, 20]

Classifications: Peri-implant femur fracture is classified based on the type of implant (nail, plate or screw), the location of the fracture (type 1- at the tip, type 2 – distal to implant), and healing status of the original fracture (A- healed, B- not healed, C- failing) (Chan et al). [21]

Peri-implant femur fracture poses substantial morbidity and but less likely to leads to disability if diagnosed early and managed appropriately. Local complications include non-union, mal-union, knee stiffness, mechanical failure, deep vein thrombosis and surgical site infection, whereas systemic complications reported includes haemorrhage, pulmonary embolism and pneumonia. Bidolegui et al., in a retrospective study reported DVT (8.33%) as the complication recorded among retrograde nailed patient who received operative management for PIFF. [22]

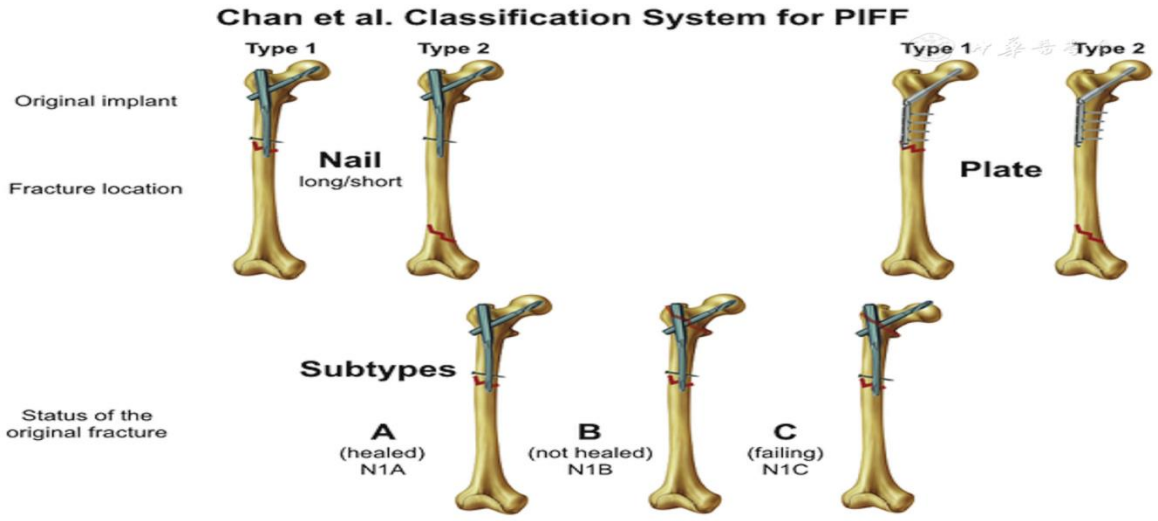



**Figure 3: Chan et al. classification system for PIFF**

## 1.2 Problem Statement

World-wide, there is an increase in femur fractures due to high-speed travel and mechanization. Intra-medullary nailing as treatment option for these femur fractures is also increasing. There is a likelihood of more cases of retrograde nailing as a preferred technique. As such peri-implant fracture is a likely increasing entity in orthopaedic traumatology. However, the Prevalence, associated factors and anticipated complications for peri-implant femoral fractures following retrograde intramedullary nail at Muhimbili Orthopaedic Institute are not evident.

### 1.3 Conceptual Framework

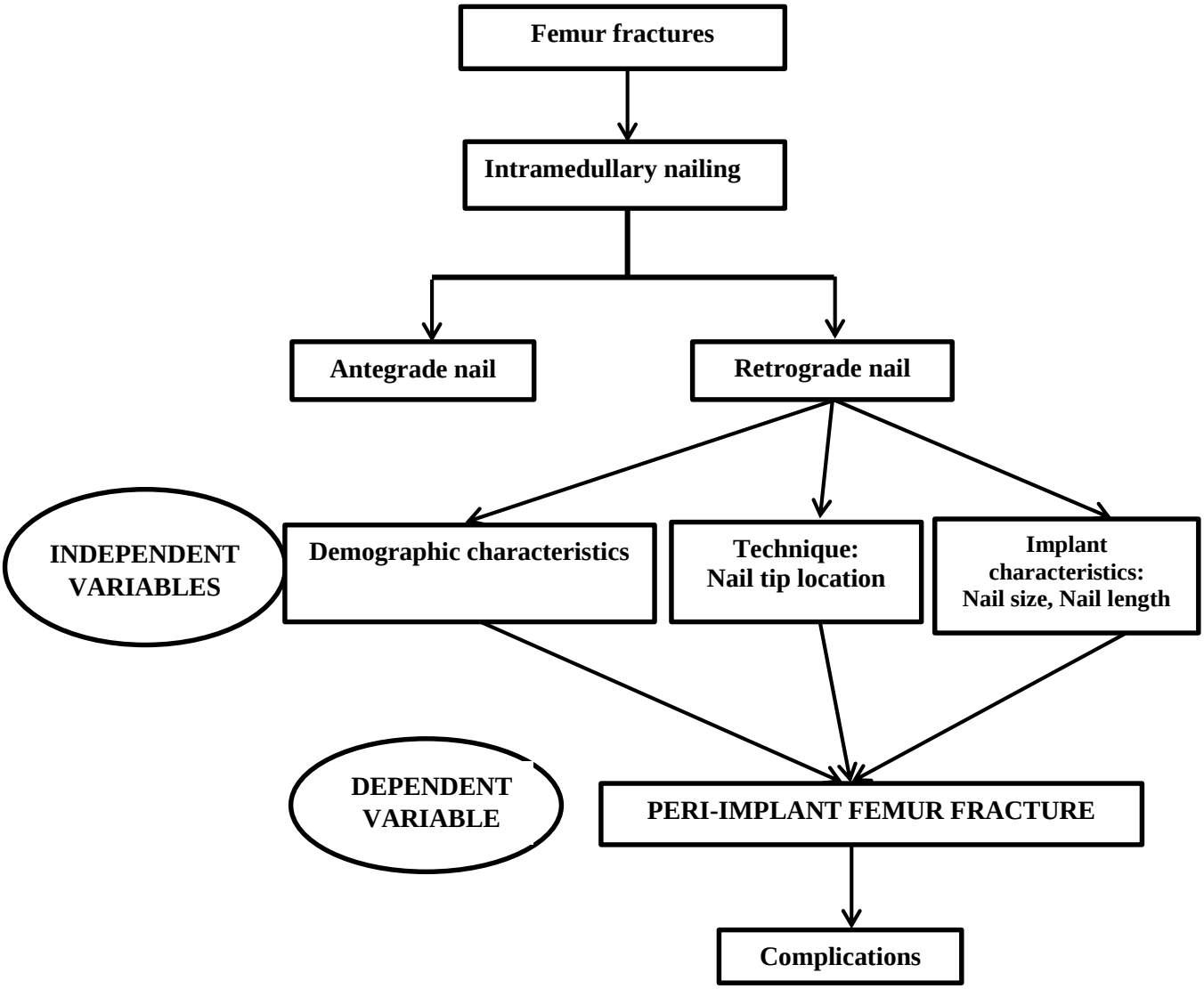



**Figure 4: Diagrammatic scheme of conceptual framework of the study.**

**Description of conceptual framework:**

Patients reporting with femur (shaft) fractures at MOI, are managed intra-operatively using intramedullary nailing as one of the options. The intramedullary nailing can either be antegrade or retrograde approach. Among the patients that are managed with retrograde intramedullary nailing, some are at risk of developing peri-implant femur fracture. The development of PIFF can be associated with the patients' demographic characteristics (age and sex), technique characteristics (nail tip location) and implant characteristics (nail size and nail length). Upon sustaining PIFF, some may develop fracture related complications.

## 1.4 Rationale

This study will provide an assessment of the Prevalence, associated factors and complications of peri-implant femur fractures following retrograde intramedullary nailing.

The results from this study will provide orthopaedic surgeons with insight of the potential associated factors and accompanying complications of peri-implant femur fractures following retrograde intramedullary nailing and allow them to take the necessary interventions.

Lastly, data from this study may serve as the basis for further research studies on peri-implant femur fractures retrograde intramedullary nailing.

## 1.5 Research Questions

### 1.5.1 Broad Research Question

What is the prevalence, contributing factors, and consequences of peri-implant femur fracture in patients who received retrograde femur nailing at MOI?

### 1.5.2 Specific Research Questions

1. What is the prevalence of peri-implant fractures in retrograde intra-medullary nailing?
2. What factors are associated with peri-implant fractures in retro-grade intra-medullary nailing?
3. What complications arise from peri-implant femur fracture following retrograde intra-medullary nailing?

## 1.6 Research Objectives

### 1.6.1 Broad Objectives

To determine the prevalence, associated factors and complications among patients who developed peri-implant femur fracture following retrograde intramedullary nailing at MOI - January, 2008 to December, 2022.

### 1.6.2 Specific Objectives

1. To determine the prevalence of peri-implant femur fracture following retrograde intra-medullary nailing at MOI - January, 2008 to December, 2022.
2. To determine the associated factors for peri-implant femur fracture following retrograde intra-medullary nailing at MOI - January, 2008 to December, 2022.
3. To determine complications among patients who developed peri-implant femur fracture following retrograde intra-medullary nailing at MOI - January, 2008 to December, 2022.

## 1.7 Literature Review

### Prevalence of PIFF:

Retrograde intramedullary nailing is a proven method for fixing distal femur fractures in recent times. [23] Globally, the rapidly growing and aging population has led to an increase in fracture-related procedures, increasing the number of patients who will possibly suffer from peri-implant fracture. [20] According to Yogi et al. (2020), the prevalence of peri-implant femur fractures following intramedullary nailing was 2.7% in a study involving 37 adult patients treated at a tertiary healthcare center in Aurangabad, India, from November 2017 to December 2018.[30]

### Associated factors for PIFF:

Generally, the risk of fracture is higher in women than in men due to the difference in BMD, bone size and bone strength between men and women. [21] The trend is same in terms of PIFF. Bidolegui et al., in their study recorded 81.8% to be women who sustained PIFF. This was a retrospective case series of 33 PIFF patients aged 18 years and above in two level I trauma centers between January 2008 and December 2017. [22]

Mean age of the patient that had PIFF was 79.72 (+/- 6.94) years with a range between 70 – 96 years according to Bidolegui et al. [22] Muller et al., 2016, found a mean age for PIFF to be 84.8 years (range 57 – 95 years) in a retrospective study of PIFF patients between 2006 and 2015. [24] On the other hand, age-associated reductions, such as in sense of balance, coordination, and proprioception combined with reduced vision resulting in an uncoordinated limb loading and increased risk of falling found in the elderly which happens to be the age bracket of PIFF is worth noting. It is also worth noting however, that there is a smaller subgroup of young patients involved in high-velocity motor vehicle accidents resulting in PIFF.

The retrograde nail usually should terminate at the level of the lesser trochanter according to Gebhard et al. [14] Avoidance of the retrograde intramedullary nail ending below the level of the lesser trochanter to avert proximal femoral stress risers and possible fractures was emphasized by Hak et al. [25] Toni et al evaluated the optimum location from a biomechanical standpoint and were of the view that proximal locking in the subtrochanteric region poses potential risks such as pertrochanteric fracture because the

nail end or locking screws acts as stress-risers. Nine (9) synthetic femora with the 42-cm nails inserted (group I) showed a mean load to failure of 2335 Newtons. The mean load to failure in the nine (9) synthetic femora with the 38-cm nails inserted (group II) was 2006 N. The difference between these two means was significant (P = 0.0080). The entire synthetic femora of group I and of group II failed at the proximal end of the nail or at the proximal interlocking screw interface. All synthetic femora of group III failed in the subtrochanteric region with a mean load to failure of 2904 N. The cadaveric femora of groups I, II and III failed at the femoral neck with a mean load to failure of 3478 N across all three groups. They indicated in their discussions that, there is biomechanical proof that hardware in the subtrochanteric region does act as a stress-riser. The results supported longer nail usage as the mean load to failure was higher in the 42cm nail group. Nonetheless, the researchers observed that the synthetic femora did not precisely simulate the mechanical properties of the cadaveric specimens, these results emphasized the constrains in using synthetic bone model, but may demonstrate that these particular bone models were engineered to be more representative of young human femora which have not lost their mechanical stiffness in the femoral neck region. Despite the short falls, the biomechanical data achieved from the role of synthetic femora is useful and may support positioning of the proximal end of the nail and proximal locking screws at or above the level of the lesser trochanter in the younger patient. [17]

Inserting a large nail is usually advisable because full contact between the medullary canal and nail, which provides stability and offers maximum torsional, bending and axial load resistance. Advancement in metallurgy and nail designs has led to the use of smaller nails as an alternative that does not compromise the stability. Smaller IM nails will reduce the rigidity of the fixation system and offer large enough transmission of load to the fracture site to stimulate micro-movement hence induce callus formation. [26] Nonetheless, smaller diameter nail may on the other hand increase inter-fragmentary motion, thereby increasing the load transmitted through the nail, leading to delayed union time, non-union, implant failure and peri-implant fracture. [27]

Sinclair et al., documented that smaller IM nail needs limited reaming which has some benefits including: 1) minimizes alteration of bony architecture, 2) provides ideal bone microenvironment for osteoinduction, 3) reduce thermal necrosis in the cortical bone to preserve blood flow. [28] Larger nail insertion has the disadvantage of reduction in bone strength, iatrogenic fracture propagation, and iatrogenic femoral canal bursting. [29]

**Complications of PIFF:**

Bidolegui et al., 2022, in their study, reported seven (7) 21.2% complications which were evenly distributed among patients treated either with nail or plate: Three (3) 9.1% had surgical site infections, Two (2) 6.1% had deep venous thrombosis, One (1) 3.3% had pulmonary embolism and one (1) 3.3% had community-acquired pneumonia. There were no cases of non-union or mechanical failure of the original implant. [22] The one-year mortality following PIFF was reported to be 34% in a retrospective cohort study of 1965 patients aged 50 years or older operated between 2003 and 2015 (Kruse et al, 2022). [29] Chan et al., 2018, in their multi-centered retrospective case series study noted a relative high incidence of PIF complications (20%, 11/53). This comprised surgical complications such as re-fracture (8%) and non-union (4%). [23]

# CHAPTER TWO

## METHODOLOGY

### 2.1 Study Design

This study was a cross-sectional descriptive retrospective study of patients who had peri-implant femur fractures following retrograde intramedullary nailing at Muhimbili Orthopaedic Institute.

### 2.2 Study setting

The research was conducted at the MOI which provides tertiary orthopaedic, trauma, and neurosurgical services. The facility receives patients with femur shaft fractures from all around Dar-es-Salaam as well as referrals from all Tanzania regions and neighbouring countries.

Patients with femur shaft fractures are initially assessed in the emergency department, where they undergo a thorough clinical evaluation and diagnostic imaging to determine the severity and type of fracture. Upon diagnosis, patients are channeled into various treatment pathways based on the nature of their fracture and clinical status.

Operative management (emergency or elective) is the mainstay treatment pathway of femur shaft fracture at MOI. Polytraumatized patients with unstable, complex and or open (OA/ OTA type III) femur shaft fractures are managed with external fixation, otherwise they are managed with intramedullary nailing as early total care management, except when there is intra-articular extension where plate fixation are employed. Stable patients with medical co-morbidity and or elderly patients are admitted on skin traction for elective fixation upon medical stabilization.

The facility is endowed with advanced diagnostic imaging modalities like x-ray, CT scan and MRI, well equipped functional operating theatres with modern instrumentation as well as skilled orthopaedic surgeons, anesthesiologists and nursing staffs trained in trauma management and orthopaedic care. Surgeries are conducted with by orthopaedic specialist or by orthopaedic residents.

Patients are managed post-operatively in the wards and then discharged. They are then followed up on scheduled clinic visits for review ie. at 6th, 12th, 24th and 52nd week..

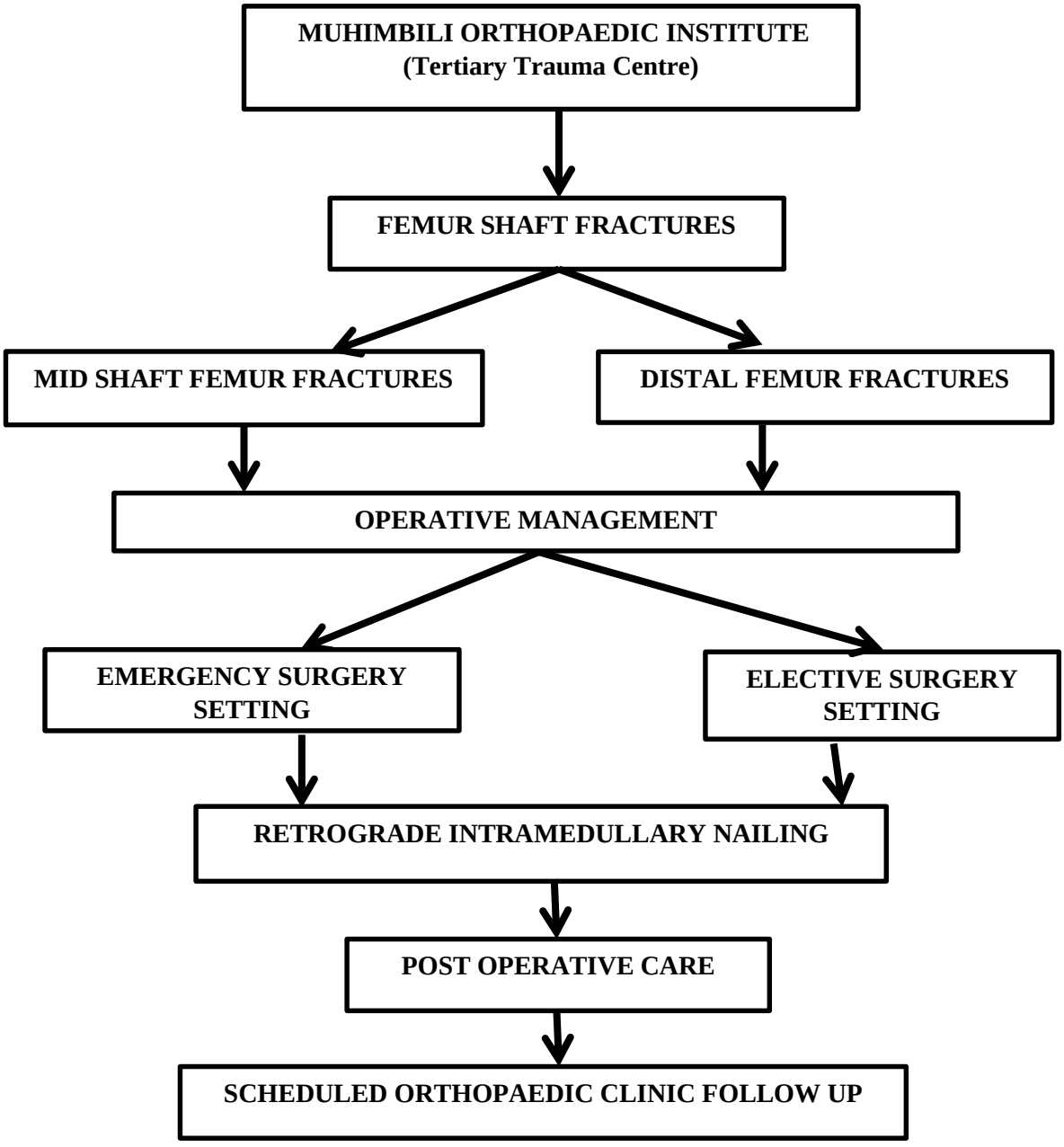



**Figure 5: Schematic diagram of protocol of management of femur fractures at MOI:**

### 2.3 Study period

The study was undertaken between May and December 2023.

### 2.4 Study population

The study included all patients aged 18 years and above who had undergone retrograde intramedullary nailing at MOI between January 2008 and December 2022 and developed peri-implant fractures.

### 2.5 Sample size

The sample size estimated for this study was 41 and calculated by using the formula below:

$$n = Z^2 P(1-P)/ d^2$$

where;

***n***= Sample size

***Z***= Z statistic - level of confidence (95%)

***P***= Expected prevalence, 2.7% quoted from a published article on PIFF (Yogi et al., 2020)[30]

***d***= Precision (5%)

**Hence;** $n = 1.96^2 \times 0.027(1-0.027)/ 0.05^2$, **n= 41**

### 2.6 Sampling technique / strategy.

All patients with peri-implant femur fracture following retrograde intramedullary nailing at MOI within the inclusion criterion were included in this study.

### 2.7 Study variables

**Independent variables:**

1. Demographic characteristics (Sex, Age)
2. Implant characteristics (Nail size, Nail length)
3. Technique characteristics (Location of nail tip)
4. Complications of peri-implant femur fracture (PIFF)

**Dependent variable:**

1. Peri-implant femur fracture (PIFF).

### 2.8 Inclusion and exclusion criteria

#### 2.8.1 Inclusion criteria.

All patients aged 18 years and above who had peri-implant femur fracture following retrograde intramedullary nailing at MOI (January 2008 – December 2022).

#### 2.8.2 Exclusion criteria

Four (4) patients were excluded from the study; two (2) patients' pre-operative radiographical data were not available, two (2) had incomplete clinical records on initial surgery.

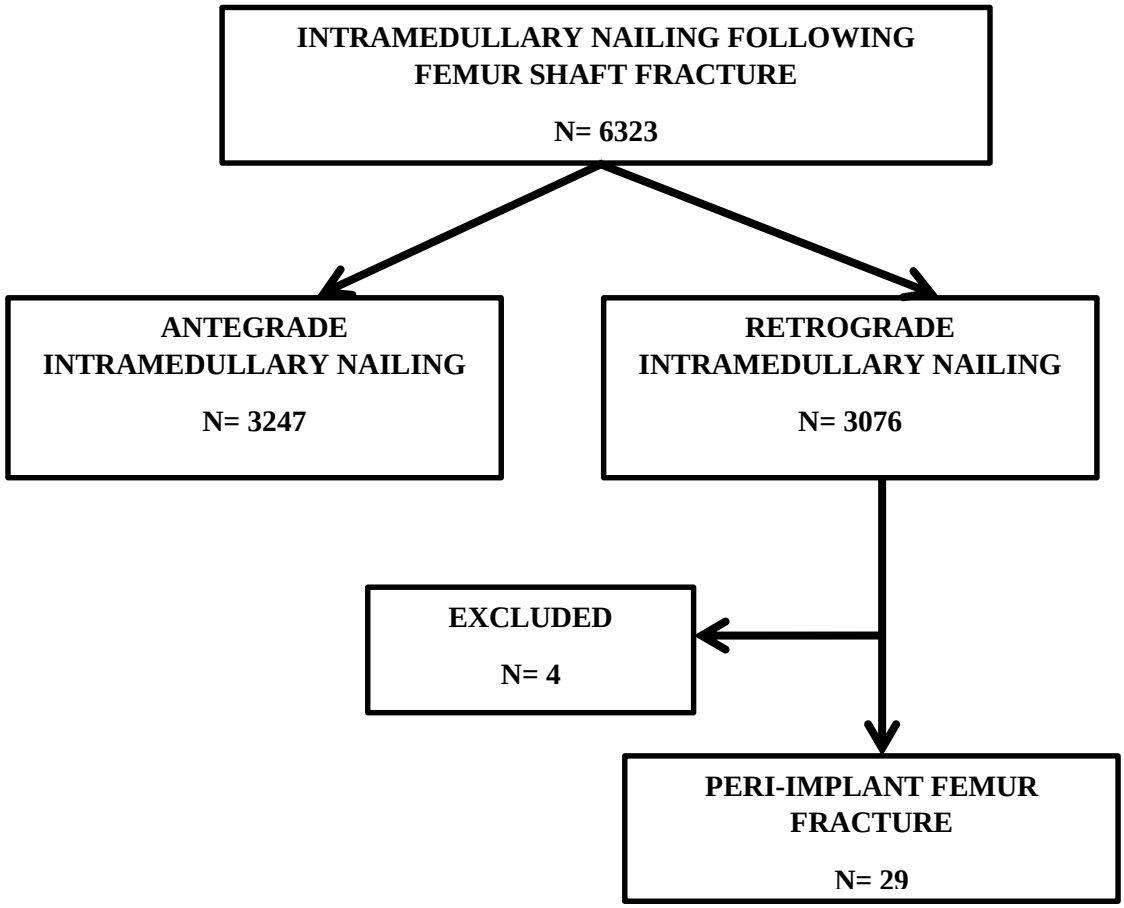



**Figure 6: Schematic diagram of patient flow chart:**

## 2.9 Data collection process

### Questionnaire and data collection tools

Data collection was carried out with the help of structured questionnaire. The questionnaire was made up of five parts:

1. The first part consisted of a count of the total number of patients with retrograde nail for the study period generated from the SIGN data base.
2. The second part consists of participants' demographic data, obtained from the SIGN nail data base and also from the patients' files.
3. The third part consist implant characteristics which were derived from the SIGN database. Both standard SIGN nail and FIN nail were included. The following were noted; 1) Date surgery was done 2) Type of nail 3) Nail size 4) Nail length 5) Date of PIFF 6) Mechanism of injury 7) PIFF involving screw hole 8) Which screw hole involved.
4. The fourth part consists of nail tip location were assessed from the post-surgery radiological report.

   Post-operative radiographic images (digital) were analysed and the mid-line aspect of the lesser trochanter was used as the reference point. Using the digital ruler, the reference horizontal line was drawn. The distance of the nail tip from the reference line was measured using the digital ruler and documented as well as noting if it was either above or below the reference line appropriately.

5. The fifth part consists of the complications encountered by patient after sustaining PIFF. Documented evident complications were ticked among selected options.

Steps to obtain required data from SIGN database:

- With internet connectivity either on laptop or desktop, a browser search for www.signsurgery.org was entered.
- Username and password were entered to gain access to the database (Username and password were obtained from SIGN program facilitator for MOI).
- On the menu bar, "Research" was selected.
- Two (2) queries were utilized using the opened dialogue box to obtain the list of patients:

- The first query: to select “Retrograde Femur”: select search category: Fracture, then enter search parameter - Surgical Approach in the first drop box and then select Retrograde Femur in the second drop box.
- The second query: to select the data period, selected “All” for the search category and then “Admission data” for the first search parameter drop box. The subsequent drop box selection were as follows: “between” -> ”January” -> ”1” -> ”2008” and “December”-> ”31”->”2022”
- The search button at the bottom left of the “Research” page was then selected for the list of patients. Each patient’s details were reviewed and those who have peri-implant fracture were included in the study.

**2.10 Pre-test or pilot testing**

The structured questionnaire was sent to colleagues or experts for the validity of the questions, how feasible are they in our culture, and the phrasing and timing especially for the research tools.

The questionnaire was subjected to a feasibility review using 8 patients (20%) of the study sample to find out unclear statements or words that might need to be revised.

Appropriate revisions of the questionnaire were done due unclear information and lapses identified.

**2.11 Data management**

Investigator had an oversight in the collection of the data throughout all steps of data collection through review of documentation in the patients’ files and radiological results as posted by the radiology department as well as data of Muhimbili Orthopaedic Institute in the Surgical Implant Generation Network (SIGN) database.

SIGN database, a world-wide recognized online internet based data collections system of patients with fracture from lower and middle income countries. Upon treating a patient’s fracture, surgeons upload and keys in radiographs and patients details respectively into the database.

The researcher assigned specific number to each patient’s questionnaire and data collected methodologically and according to outlined steps by the researcher. The data collected

were entered into Microsoft access form, exported as excel worksheet and shared with the Supervisor as per post-graduate guidelines.

### 2.12 Data analysis

Statistical software (SPSS version 20) was used to manage and analyze the data. Categorical variables were summarized by counts and percentages, while continuous variables were summarized by means and standard deviation.

| **Specific Objective** | | **Data Analysis Plan** |
|---|---|---|
| 1. | To determine the prevalence of peri-implant femur fracture following retrograde intra-medullary nailing at MOI - January, 2008 to December, 2022. | Count of cases will be noted:<br>Total number of retrograde IM nailed patients was our denominator. Total number of patients with peri-implant fracture was numerator. The prevalence of PIFF among patients retrograde nailed was calculated and described. |
| 2. | To determine the associated factors for peri-implant femur fracture following retrograde intra-medullary nailing at MOI - January, 2008 to December, 2022. | The age, sex, nail size, nail length and nail tip location data obtained and documented in the questionnaire were analysed descriptively as counts, prevalence and percentage as well as described the mean and standard deviations. Statistical test of association was analysed by use of Chi-square test to determine the association between categorical variables and peri-implant femur fractures as well as logistic regression analysis. |
| 3. | To determine complications among patients who had peri-implant femur fracture following retrograde intra-medullary nailing at MOI - January, 2008 to December, 2022. | Lists of the complications obtained from patients' medical records as documented on the questionnaire. The data was descriptively analysed as counts. |

### 2.13 Ethical considerations

The MUHAS Institutional Ethical Review Board committee (IRB) was accessed for approval and ethical clearance.

This study was a retrospective study involving the use of secondary data and did not involve direct interactions with patients. Hence, I requested for waiver of informed consent from MUHAS IRB.

# CHAPTER THREE

## RESULTS

In this study, a total of three thousand and seventy-six (3076) patients underwent treatment utilizing retrograde intramedullary nailing at MOI between January 2008 and December 2022, constituting a portion (48.6%) of 6323 patients treated by intramedullary nailing. Out of this number twenty-nine (29) patients had peri-implant fractures following retrograde intramedullary nailing at MOI during the study period. The proportion of peri-implant femur fracture among patients treated with retrograde intramedullary at MOI between January 2008 and December 2022 was found to be 0.94% (Figure 5). Sixty-nine percent (69.0%) were aged 18 – 39 years and 79% were males as illustrated in Table 1. With respect to the type of nail that was used, 79.3% of the patients had been managed with the standard SIGN nail and the remaining with FIN nail (Figure 6).

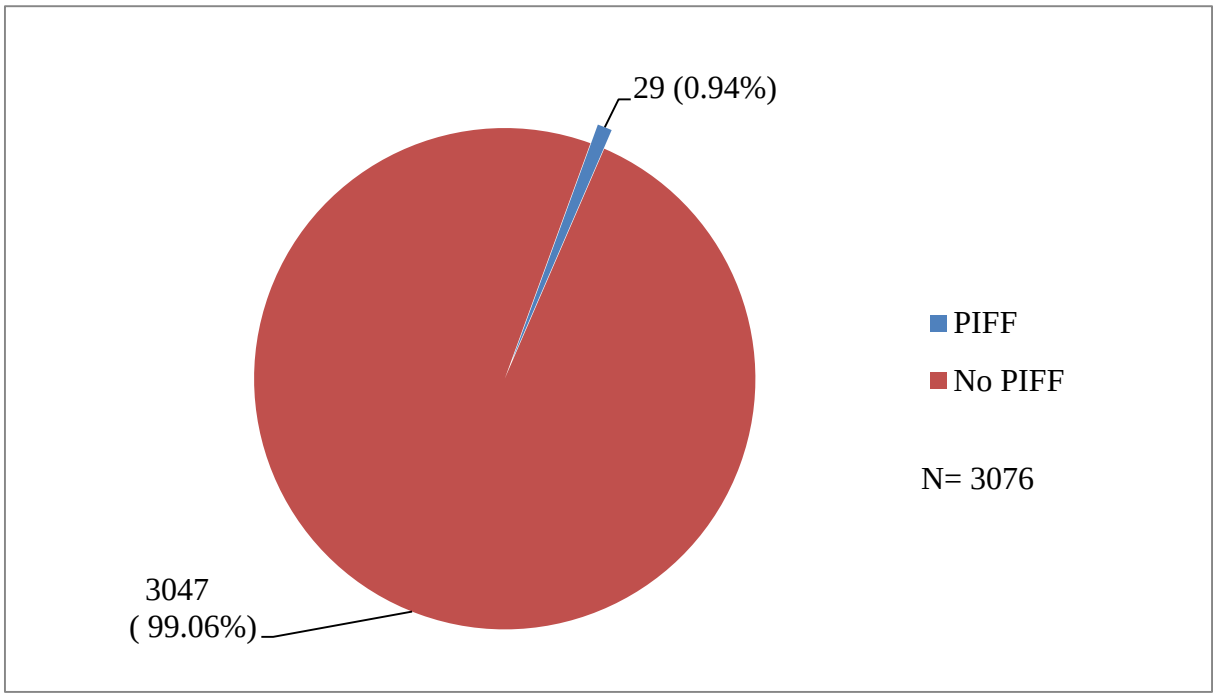



**Figure 7: Proportion of PIFF among patients treated with retrograde intramedullary nailing at MOI, January 2008 - December 2022**

**Table 1: Age and sex distribution of patients with PIFF following retrograde intramedullary nailing at MOI, January 2008 - December 2022. (N=29)**

| Variable | Frequency (n) | Percent (%) |
|---|---|---|
| Age group (years) | | |
| 18 – 39 | 20 | 69.0 |
| 40 – 59 | 5 | 17.2 |
| 60 – 79 | 4 | 13.8 |
| Sex | | |
| Male | 23 | 79.3 |
| Female | 6 | 20.7 |

Table 1 shows that among patients with PIFF following retrograde intramedullary nailing with majority of patients (69%) were aged 18-39 years, with 17.2% aged 40-59 years, and 13.8% aged 60-79 years. Males predominated significantly, representing 79.3% of the patients, while females accounted for 20.7%.

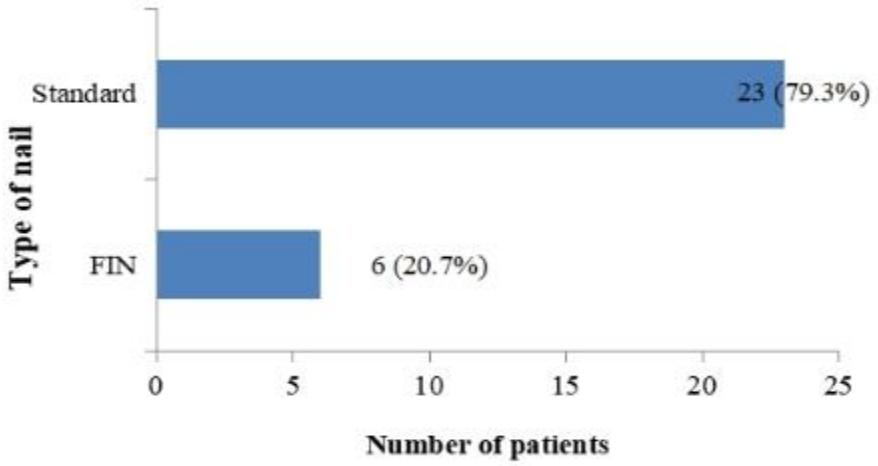



**Figure 8: Type of nail used among patients with PIFF following retrograde intramedullary nailing at MOI, January 2008 - December 2022. (N=29)**

Figure 6 shows that among the 29 patients with PIFF following retrograde intramedullary nailing at MOI, 79.3% received standard nails, while 20.7% received FIN. The choice of nail type depends on fracture characteristics, bone quality, surgeon preference and surgeon experience.

The range of nail sizes observed in our patients encompassed diameters from 8mm to 12mm and lengths varying between 280mm and 400mm. The most prevalent nail sizes were 9mm and 10mm in diameter, each representing 34.5% of the total nails used (Figure 7). In terms of length, the 360mm nail length was most frequently employed, constituting 31% of cases (Figure 8). Examining the location of nail tips in relation to peri-implant femur fractures, we found that sixty-nine percent (69%) of patients exhibited the nail tip positioned below the lesser trochanter, with a mean distance of 28.4mm (Table 2), although this observation did not achieve statistical significance (p=0.232) (Figure 9).

None of the twenty-nine (29) patients with peri-implant femur fracture had complication after treatment of PIFF.




**Figure 9: Nail size (diameter) among patients with PIFF following retrograde intramedullary nailing at MOI, January 2008 - December 2022.**

The nail size among patients studied ranged from 8mm to 12mm. The most common nail sizes used were 9mm and 10mm, each accounting for 34.5% of the total nails as shown in Figure 7 above.

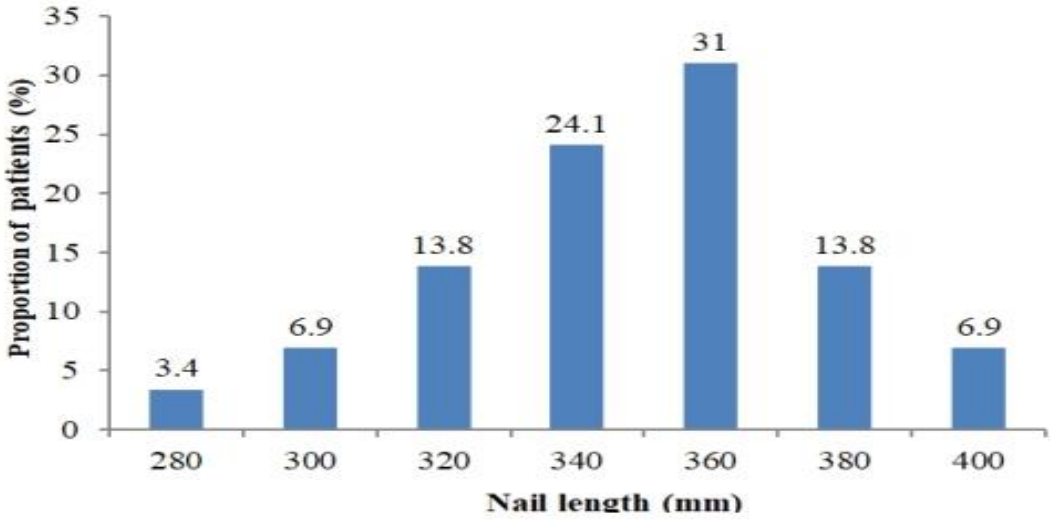



**Figure 10: Nail length among patients with PIFF following retrograde intramedullary nailing at MOI, January 2008 - December 2022.**

Figure 8 depicts the predominant length nails was 340 mm and 360 mm, accounting for 55.1% of the total. Shorter and longer nails are used much less frequently.

**Table 2: Nail tip location of patients with PIFF following retrograde intramedullary nailing at MOI, January 2008 - December 2022. (N=29)**

| Nail tip locations ( _lesser trochanter) | Frequency (n) | Percent (%) | Mean distance (mm) |
|---|---|---|---|
| Above | 9 | 31.0 | 22.3 |
| Below | 20 | 69.0 | 28.4 |
| **Total** | **29** | **100** | |

Table 2, shows that most of the patients (69%) with peri-implant femur fractures had their nail tips positioned below the lesser trochanter with a mean distance of 28.4mm.

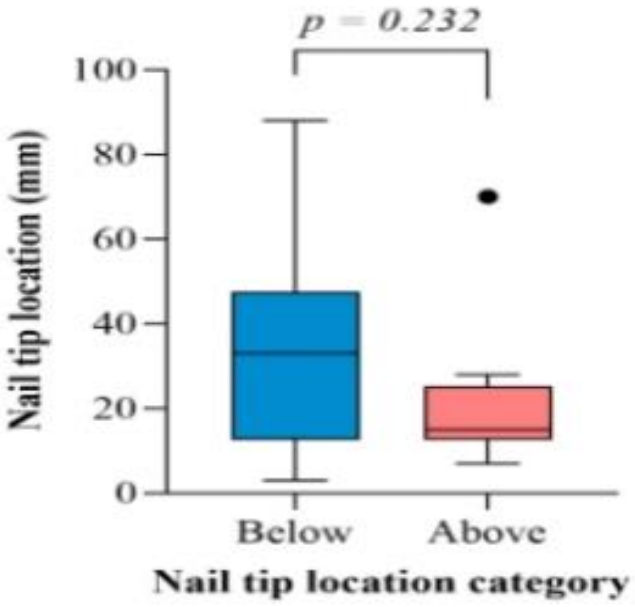



**Figure 11: Box plot of nail tip location length versus either above or below lesser trochanter among patients with PIFF following retrograde intramedullary nailing at MOI, January 2008 - December 2022.**

Figure 11, shows that most of the patients with peri-implant femur fractures had their nail tips positioned below the lesser trochanter with a calculated p-value of 0.232.

# CHAPTER FOUR

## DISCUSSION

The observed proportion of PIFF in this study population, at 0.94%, is notably lower compared to previously reported rates. For instance, Yogi et al. (2020) reported a prevalence of 2.7% following IMN, suggesting potential variations in patient populations, surgical techniques, and implant characteristics across different cohorts. Such differences underscore the multifactorial nature of PIFF etiology, necessitating a comprehensive understanding of contributing factors to guide clinical decision-making.

Notably, the demographic profile of PIFF cases in this study presents a departure from the typical pattern observed in orthopaedic literature. While PIFF predominantly affects elderly individuals, as evidenced by studies such as Bidolegui et al. (2022) and Muller et al. (2017), this study identified a majority of cases in younger patients aged 18 to 39 years. This demographic shift raises intriguing questions regarding the influence of age-related factors versus high-velocity trauma or underlying bone pathology in predisposing younger patients to implant-related complications.

Furthermore, the predominance of male patients among PIFF cases in this study does not align with established trends in orthopaedic literature, where women typically exhibit higher fracture risk due to differences in bone density and strength compared to men. This gender disparity has been extensively documented in studies such as Bidolegui et al. (2022) and Sinclair et al. (2018), highlighting the need for gender-specific risk stratification and tailored intervention strategies in orthopaedic practice.

Regarding nail characteristics, studies by Gebhard et al. (2014) and Toni et al. (2001) have explored the biomechanical implications of nail size and positioning, emphasizing the importance of achieving optimal fixation stability while mitigating stress risers and potential fracture risk. The observed distribution of nail sizes and lengths in this study underscores the importance of individualized treatment planning and implant selection based on anatomical considerations and fracture characteristics. While the frequent use of 9mm and 10mm nail diameters, along with the 360mm nail length, reflects prevailing

surgical preferences, it is essential to recognize the need for tailored approaches to accommodate anatomical variations and optimize implant biomechanics.

A notable observation pertains to nail tip positioning relative to anatomical landmarks. The majority (69%) of peri-implant fractures occurred with the nail tip positioned below the lesser trochanter, averaging 28.4mm in distance. Although statistical significance was not attained ($p=0.232$), this trend highlights the importance of precise nail placement to minimize biomechanical stress concentrations and subsequent fracture risk. Further biomechanical modelling and prospective studies are warranted to validate these observations and inform optimal nail positioning strategies.

Remarkably, none of the patients in this study experienced complications following treatment for PIFF, suggesting favourable outcomes in terms of postoperative management and functional recovery. However, the limited sample size and short-term follow-up period preclude definitive conclusions regarding long-term treatment efficacy and implant survivorship. Longitudinal studies with extended follow-up durations, such as those conducted by Kruse et al. (2022) and Chan et al. (2018), are warranted to assess the durability of treatment outcomes and identify potential late complications associated with PIFF management.

The findings of this study contribute significantly to the understanding of peri-implant femur fractures (PIFF) following retrograde intramedullary nailing (IMN) at the Medical Orthopaedic Institute (MOI) between January 2008 and December 2022. Here, we discuss the findings in the context of existing literature, highlighting key insights and potential implications for clinical practice.

### 4.1 Limitation of the study

This study had some limitations which included:

1. Incomplete data, inaccurate data and poor radiographic quality, hence some sampled patients could not be included.
2. There were variable follow-up (long/ short term) periods of patients.
3. This is a retrospective study, therefore cannot control variables
4. Missing data/ information
5. Poor generalizability

# CHAPTER FIVE

# CONCLUSION AND RECOMMENDATION

## 5.1 Conclusion

In summary, this study has provided a comprehensive descriptive analysis of peri-implant femur fractures (PIFF) following retrograde intramedullary nailing (IMN) at the Medical Orthopaedic Institute (MOI) spanning from 2008 to 2022.

The observed proportion of 0.94% sheds light on the relatively low incidence of this complication within the study population.

Notably, the demographic distribution of PIFF cases deviated from the typical pattern, with a significant proportion occurring in younger patients aged 18 to 39 years. Furthermore, the predominance of male patients among PIFF cases does not align with established gender disparities in fracture risk, emphasizing the importance of gender-specific considerations in treatment planning and prognostication. The distribution of nail sizes and lengths reflects prevailing surgical preferences and implant selection strategies. However, it is imperative for surgeons to consider the biomechanical implications of nail characteristics, including size and positioning, to optimize fixation stability while mitigating stress risers and potential fracture risk.

The absence of complications following treatment for PIFF is encouraging, albeit with the caveat of a limited sample size and study design.

## 5.2 Recommendations

Building upon the findings of this study, several recommendations are proposed to refine clinical practice and enhance patient care:

1. Although the prevalence of PIFF in our study was relatively low, we recommend conducting a larger, multi-center study to gain a more comprehensive understanding of PIFF cases

2. Based on the identified associated risk factors of PIFF from this study, we recommend the adoption of a surgical plan tailored to each patient's unique characteristics as well as prioritizing meticulous pre-operative planning and intra-operative techniques which can in the long run reduce the risk of PIFF. Nonetheless, a further study to investigate whether these factors are independent risk factors is highly recommended.

3. While this study did not observe any complications, we recommend conducting a prospective, randomized, multi-center study to further investigate this area.

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# APPENDICES

## Appendix I: Research questionnaire

**MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**SCHOOL OF MEDICINE**

**DEPARTMENT OF ORTHOPAEDICS, TRAUMATOLOGY AND NEUROSURGERY**

"PREVALENCE, ASSOCIATED FACTORS AND COMPLICATIONS OF PERI-IMPLANT FEMUR FRACTURE FOLLOWING RETROGRADE INTRAMEDULLARY NAILING AT MOI"

**RESEARCH QUESTIONNAIRE**

| | | | |
|---|---|---|---|
| Serial Number: | ..... | ….. | …. |
| Date of data collection | ….. | …. | …. |

**Total patients with retrograde nail for the study period:** ____

**A. DEMOGRAPHY:**

1. Age (years):

| 18 – 39 | | 40 – 59 | | 60 - 79 | | 80 & above | |
|---|---|---|---|---|---|---|---|

2.Sex:

| Male | | Female | |
|---|---|---|---|

**B. IMPLANT CHARACTERISTICS:**

1. Date of Surgery:……..…

2. Type of nail:

| | | | |
|---|---|---|---|
| Standard SIGN | | FIN | |

3. Nail size: …….mm

4. Nail length: …….mm

5. Date of PIFF: …….

6. Mechanism of injury:

| | |
|---|---|
| Motor traffic crash | |
| Fall from height | |
| Trivial injury | |
| Other(s) | |

Specify……..

7. PIFF involving screw hole:

| | | | |
|---|---|---|---|
| Yes | | No | |

8. If Q7. is Yes, which screw hole is involved:

| | |
|---|---|
| Proximal | |
| Distal | |

**C. TECHNIQUE CHARACTERISTICS:**

1. Nail tip location: …….mm

| above | | below | | lesser trochanter |
|---|---|---|---|---|

**D. PERI-IMPLANT FEMORAL FRACTURE (PIFF) COMPLICATION:**

1. PIFF Complication:

| | |
|---|---|
| Infection | |
| DVT/ PE | |
| Vascular injury | |
| Nerve injury | |
| None | |
| Other(s) | |

Specify:……..

**Appendix II: Informed consent waiver request letter**

**BENNY TETTEI ADJEI**

**HD/MUH/G148/2021**

**15th JUNE, 2023**

**INSTITUTIONAL REVIEW BOARD**

**MUHAS**

**P.O. BOX 65001**

Dear Sir/ Madam,

**REQUEST FOR WAIVER OF INFORMED CONSENT**

My name is Benny Tettei Adjei, a MMed student with the registration number HD/MUH/G148/2021. I am writing to request a waiver of informed consent for a retrospective study entitled "The Prevalence, Associated Factors, and Complications of Peri-Implant Femur Fracture Following Retrograde Intramedullary Nailing at Muhimbili Orthopaedic Institute." The study aims to investigate the aforementioned subject to contribute to the existing body of knowledge in orthopaedics and improve patient care. I kindly request your consideration for this waiver based on the following justifications:

**Nature of the Study:** This study is designed as a retrospective analysis of existing medical records and radiographs, which involves no direct interaction with patients or alteration of their treatment plans. The research will solely rely on de-identified data, ensuring the privacy and confidentiality of patients' personal information.

**Minimal Risk and Confidentiality:** As a retrospective study, this research entails minimal risk to the participants as it does not involve any interventions or alterations to the standard medical practices employed at Muhimbili Orthopaedic Institute. Moreover, utmost importance will be placed on maintaining strict confidentiality and preserving patient privacy. All personal identifiers will be either removed or encrypted to ensure complete anonymity. The handling, access, and storage of data will adhere to stringent privacy

regulations and ethical guidelines, safeguarding patient confidentiality at all stages of the study.

**Scientific and Clinical Relevance:** The outcomes of this study hold immense scientific and clinical significance in the field of orthopaedic medicine. By comprehensively investigating the Prevalence, associated factors, and complications of peri-implant femur fractures, we aim to contribute to the existing orthopaedic literature and directly inform clinical practice. The findings from this study will aid orthopaedic surgeons in making informed decisions regarding surgical techniques, implant selection, and patient management strategies. Additionally, the results may foster the development of evidence-based guidelines and protocols, ultimately enhancing patient outcomes and minimizing the occurrence of complications.

In accordance with ethical guidelines, I assure you that all data collected for this study will be treated with the utmost confidentiality and will be stored securely. No personally identifiable information will be disclosed or published, ensuring strict adherence to patient privacy regulations.

I kindly request the Institutional Review Board to consider the justifications presented above and grant a waiver of informed consent for this retrospective study.

Thank you for your attention and consideration.

Sincerely,

Benny Tettei Adjei

(Principal Investigator)