EVALUATION OF HIP ABDUCTOR FUNCTION FOLLOWING PIRIFORMIS FOSSA ENTRY ANTEGRADE NAILING IN ISOLATED DIAPHYSEAL FEMUR FRACTURES AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

This research dissertation is my original work and has not been presented in this University or any other in the award of a degree

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ATLS- Advanced Trauma Life Support

AO/OTA - Arbeit Gemeinschaft fur Osteosynthesefragen /Orthopaedic Trauma Association

TEN- Trochanteric Entry Nails

PEN- Piriformis Fossa Entry Nails

BMI- Body Mass Index

GT- Greater Trochanter

ASIS - Anterior Superior iliac Spine

EMG-NCV- Electromyography and Nerve Conduction Velocity

WHO- World Health Organization

KNH- Kenyatta National Hospital

OPERATIONAL TERMS

Abductor muscles – Gluteus Medius and Gluteus Minimus

Range of motion – normal hip range of motion arc 0-45 degrees, functional

ABSTRACT

Background: A standard method of femur shaft fractures fixation is using trochanteric entry antegrade nails. Studies have highlighted the pros and cons of trochanteric entry nails (TEN) and piriformis entry nails (PEN). Many authors have expressed faster union rates, good trochanteric alignment, shorter length of surgery, shorter duration of radiation, and better functional outcomes of TEN than PEN. Very few studies have unequivocally addressed hip abductor function to state if indeed piriformis entry damages hip abductors. In our local setup, many surgeons, including those under training, perhaps due to lack of fluoroscopy, ream the femur fractures in a retrograde manner from the fracture site and then introduce nails in an antegrade fashion through a piriformis entry point. Evaluation of hip abductor function following fixation of femur fracture with piriformis entry nail is necessary to establish and quantify the damage this procedure causes the hip abductor. There are no local studies available on this.

Objective: The study aimed to establish the function of hip abductors among patients with diaphyseal femur fractures post piriformis entry nailing.

Study Design: Prospective cohort study.

Study Setting: Kenyatta National Hospital, Orthopedic Outpatient Clinics

Methodology: Sixty-four patients who underwent fixation of fracture femur were recruited from the clinics to establish the proportion of patients and degree of hip abductor dysfunction following fracture fixation at six weeks and twelve weeks. The patients were assessed based on their gait, hip abductor range of motion, and the power of the hip abductors graded based on their ability to resist elastic loop bands. Values were obtained from the operated and the non-operated limb and compared.

Results: The mean age was 31.75, SD 8.54, Median 31.5 Range 19 – 52. Males were 45 (75.0%) while females were 15 (25.0%). Left sided injuries were 30 (50.0%) similar to right 30 (50.0%). AO32 class A were 19 (31.7%), class B 29 (48.3%), class C 12 (20.0%).

The injured limbs had significantly less MRC scores when assessing power. Similarly, for the right injured limb, there was a significant increase in MRC score (p=0.012) from 6 weeks to 12 weeks. Despite an MRC power increase in the left injured limb, it was not statistically significant (p=0.089).

The injured limbs had significantly less hip abductor ROM both at six and 12 weeks (Right injured limb, p = 0.0034, & p = 0.0361) and left (p = 0.007 & 0.039). However, there were no statistically significant increase in hip abductor range of motion between 6 and 12 weeks.

In terms of Trendelenburg gait, there were significant differences between the normal vs the abnormal limbs, as well as between 6 weeks and 12 weeks.

There was significant reduction in number of patients with a positive Trendelenburg sign from 60 to 54 at 6 weeks and 12 weeks (p=0.014).

There was significant reduction in wasting between 6 weeks and 12 weeks in patients with right injured limb (p = 0.008) and no significant change in those with left injured limb.

Comparing right and left limbs abductor hip strength with the use of loop elastic bands , there were significant differences in right injured limb at six weeks and 12 weeks (p values <0.001 and 0.001 respectively) and left injured limb (p 0.019 and 0.004). However, no significant differences were notable when comparing between 6 weeks and 12 weeks.

There was a reduction in usage of all walking aids, from 6 weeks to 12 weeks.

Significance of the study: This study investigated the hip abductor function following piriformis entry nailing of diaphyseal fractures of femur. Despite the frequent use of antegrade nailing in fracture femur fixation, the degree of abductor dysfunction was significant at 6 weeks with marked improvements at 12 weeks. Rehabilitation techniques could improve abductor dysfunction after antegrade femoral nailing.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Morbidity and mortality resulting from trauma remain a significant concern in low- and middle-income countries with increased development of infrastructure and urbanization. The physical, psychological, and economic burden resulting from trauma is high, as stated by Worlds Health Organization (1). They result from motor vehicle and motorcycles accidents and falls. The World Health Organization (WHO)aims to reduce this burden by 2030 in its sustainable development goals.

Femur fractures result from high energy mechanisms in young patients with young men as the predominant sex (2). Low energy trauma causes femur fractures in the elderly population. The incidence of femur fractures in a study over seven years in the Swedish population documented 10 per 100,000 person-years annually (3).

The prevalence of femur fractures in a population-based study by Enninghorst et al. found a prevalence of 21 per 100,000 in an Australian population, with a majority of the patients having complicated femur fractures (open, associated comorbidities, elderly patients, multiple injuries, etc.) of whom many required transfusion with analysis based on systolic blood pressure, base deficit and lactate levels. In this population-based study, physiologically stable patients underwent early total care with definitive fixation of femur fractures (4).

In East Africa, a paper published in the Pan African Medical Journal documented femur shaft fractures as the most expected fracture pattern in Northern Tanzania. In the young population, femur fractures occurred commonly, with 39 percent being femur shaft in the

540 patients seen in 9 months. About 40% of the patients were managed non-operatively, with a large percentage of midshaft femur fracture patterns managed non-operatively (5).

In Malawi, a Nationwide survey of femoral shaft fractures over 46 days reported four weekly admissions in central referral hospitals and one patient per week admissions for femoral shaft fractures. The incidence is 0.51 per 100,000 patients annually (6).

The introduction of modern intramedullary nails from the advent of Küntscher in the 1940s and interlocking nails has resulted in earlier mobilization with early return to activities compared to patients managed non-operatively or with weight-bearing devices such as plates and screws. Benefits of operatively managed femur fractures in the elderly population, who were able to start early mobilization with more minor complications noted (7). There was, however, no mention of the injury to the surrounding soft tissues as a result of nail insertion techniques.

Antegrade nailing is the gold standard for fixation of shaft fractures, as described by Kumar, where he reported excellent results with closed femur fractures allowing early mobilization and predictable union (8). Antegrade nailing has been replicated in our local setup and has been the basis of the fixation of femoral fractures. Non-operative management of femur fractures is associated with unfavorable outcomes and utility when surgery is not feasible.

Consensus on the effect of different nail designs on hip abductor mechanisms is not fully understood. The Greater trochanter and the piriformis fossa are anatomical landmarks which form the basis of nail entry point designs. The Greater Trochanter is six degrees lateral to the piriformis fossa. Both TEN and PEN cause injury to the abductor muscles, but controversy remains regarding the superiority over the other. In our local setup, surgeons heavily rely on

functional external locking devices as the availability of traction tables and available fluoroscopy machines is still a challenge. This has driven most surgeons to use open reduction techniques with retrograde reaming from fracture site and after that introducing the nail in an antegrade fashion inevitably in the piriformis fossa, which is in line with the canal as studied by Labrocini et al. (9). The use of external locking and distal targeting devices to minimize radiation has driven surgeons to this technique.

This study, therefore, aims to quantify the abductor dysfunction resulting from the use of PEN, which is a common method in the fixation of femur shaft fractures locally. A similar study was conducted in Australia, Adelaide, to assess abductor function of patients following closed femoral shortening and isolated femur shaft fracture compared to a control group with naïve hips. This study concluded that all procedures in which gluteal splitting techniques showed weaker abductor strength and a higher incidence of complaints than the naïve group (10).

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Classification of femoral shaft fractures

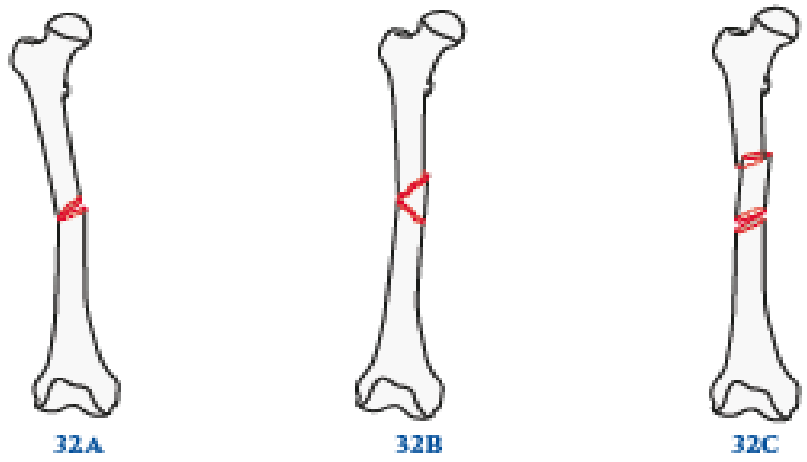
AO/OTA developed a globally acceptable classification system for femoral shaft fracture. The femur is divided into segments; the metaphyseal (two end segments) and diaphyseal (one middle segment). The metaphyseal end segment is defined by a square whose sides have the same length as the widest part of the metaphysis—the exception of the proximal femur.

The diaphysis is the segment cephalad to the lesser trochanter and ends proximal to the metaphyseal flare and condyles. The initial 5cm inferior to the lesser trochanter are termed subtrochanteric area and are managed and classified as a different section due to their precarious blood supply and minimal muscular attachment (2,11)

The diaphysis of the femur is a cylindrical soft bone with a posteriorly located linea aspera with large muscular attachment. The sciatic nerve peroneal division is close to the shaft of the femur and may be at risk of injury during trauma (2).

Therefore, the diaphysis classified A0 32 can have a simple, wedge, and multi-fragmentary fractures described by Kumar et al. (8) and have good outcomes when managed by antegrade nailing (Figure 1).

Figure 1: Classification of diaphyseal femur fractures



32A Femur, diaphyseal segment, **simple fracture**
32B Femur, diaphyseal segment, **wedge fracture**
32C Femur, diaphyseal segment, **multifragmentary fracture**

The abductor muscles surround the shaft proximally, covering the inferior and superior gluteal nerves and vessels as they supply them. Therefore, these are at risk of injury during proximal dissection of the femur (2). The greater trochanter has multiples facets to which the abductor muscles attach. The Gluteus Medius posterior fibers attach to the posterior-superior aspect of the GT, while the anterior fibers and central fibers attach to the lateral facet of the GT. The Gluteus Minimus inserts via its long fibers medial to the Gluteus Medius insertion with some fibers reflecting onto the capsule. The insertions describe the footprint of the abductor muscles on the GT.

2.2 Surgical technique: antegrade versus retrograde nailing

In the recent concept of early total care and damage control of orthopedic polytrauma patients, emphasis is on tailoring treatment to individual patients. Clinical categorization of patients, stable, in-extremis, and borderline may help determine who may benefit from early

total care and those from Damage Control Orthopaedics. The physiologically stable patient may benefit from Early comprehensive care (3,12).

The positioning of a stable patient with a femur fracture is either supine or lateral decubitus. This consideration is on the availability of fluoroscopy and fracture table. A retrospective study by Wolinsqy reported short operative time for those operated without a fracture table compared to those placed supine (13). Supine position is advocated for multiply injured patients and lateral decubitus for those with high BMI to improve access to the proximal femur.

Antegrade nailing of the femur can be done on a radiolucent table using minimally invasive techniques or on a traction table. Pre-operatively, patients are informed about hip pain due to the proximal entry of antegrade nails. As described by Dodenhoff et al., patients may experience residual hip pain in the scar area, which persists, leading to reduced mobility (14). The author found no relation between nail prominence proximally and pain. Heterotopic ossification was associated with pain. Removing the nail for the patients who opted to do so did not resolve the pain.

The choice of entry point depended on nail design and had been a point of discussion since the 1940s. Kutchner originally described the use of modern antegrade nailing from the greater trochanter in a closed technique. The surgeon directed the nail into the canal under x-ray control (7). Surgeons opted for open methods where the surgeon opened the fracture site and prepared bone ends under direct vision. The femur nail was introduced in a retrograde fashion into the proximal fragment and exteriorized from a separate proximal incision, followed by fracture reduction and introduction of the nail to the distal segment (7).

Surgeons then discovered PEN and a medialized position on the neck and the greater trochanter entry. These techniques inevitably go through the abductor muscle function, and its effect was not fully understood and studied earlier. A minimum of 2 cm incision is made at a point 5-8cm from the tip of the greater trochanter. A single incision is made through the skin and underlying fascia. Muscles are bluntly dissected to access the GT. The awl is introduced at the piriformis fossa /greater trochanter depending on the nail design and a guidewire after that. Reaming to achieve cortical chatter. Nail is introduced after that in an antegrade fashion and locked statically or dynamically based on the fracture configuration (11,12,13).

Nail designs have changed since the introduction of the Kutchner nail. The introduction of an ante-curvature and a lateral bend has improved the design of the trochanteric nail.

The piriformis fossa is anatomically aligned to the femoral canal while the trochanteric fossa has a 6-degree angulation to the canal. A cadaveric anatomical study by Labronici et al. illustrated the central axis of the medullary canal while using wires in a retrograde direction. Labrocini et al. demonstrated the piriformis fossa as the best entry point for straight nails as the anatomical study showed the wires exited in the piriformis fossa (9).

Systematic review studies such as by Kumar et al. in a study comparing piriformis fossa nails and greater trochanter entry points showed statistically significantly shorter duration of surgery with a mean standard difference of 21.01 minutes, shorter exposure to fluoroscopy, less abductor muscle weakness and better functional outcomes for greater trochanter nails. This was from data collected from PubMed, EMBASE and SCOPUS (15). Time to union rates in fractures fixed by the different entry points show comparable union rates. He also found no significant varus malalignment for shaft of femur fractures managed with a nail. In

support of these findings, a study by Hussain et al. in a systematic review to demonstrate the advantage of PEN versus TEN and antegrade vs retrograde nailing systems, of the 52 eligible studies, the author concluded that greater trochanter entry reduced the operative time by 14 minutes. He also did not find any statistical difference in functional outcomes. Hip pain was significantly higher for antegrade nailing and knee pain for retrograde entry nails (16).

The abductor mechanisms can be violated during initial surgery resulting from poor surgical technique during sharp or blunt dissection through the proximal femoral incision, unprotected reaming of the canal resulting in muscle detachment or iatrogenic injury to the superior gluteal nerve. Other causes of decreased abductor muscle strength include prominent hardware limiting ipsilateral truck lean and hip abduction angle, therefore, affecting hip kinematics and kinetics as studied by Archdeacon et al. in which the prospective study measured functional outcome and motion analysis following antegrade femoral nailing. The author studied eight consecutive femur fractures with a follow-up for 24 months (17), contrary to Dodenhoff et al (14) who found no correlation in the prominence of the nail proximally but rather reduction in function as a result of injury to the soft tissue envelope.

Ansari et al., in a cadaveric study of 10 specimens, dissections were done to determine the pattern of the superior gluteal nerve. Seven out of the ten cadavers dissected had the nerve dissecting 1-2 cm from the proximal edge of the piriformis muscle into branches that either create a fan/ spray pattern or a transverse neutral pattern. The author also determined that the last inferior branch of the superior gluteal nerve is at an average of 2.3 to 6.5 from the tip of the greater trochanter. The nerves were not encountered or interfered with during the insertion of femoral nails in these cadavers. The proximal dissection through the fascia Lata and Gluteus Medius was similar for both PEN and TEN, with an additional risk of injury to the

short rotators of the hip and the hip capsule for PEN. The author, therefore, concluded less injury to structures for TEN (18).

In 2016, a study comparing entry points for antegrade femoral nails for 2 level 1 RCT, 1 level two prospective cohort study, and, one level three retrospective study analyzed 510 patients. Follow-up was done for 10 –48 months. Nails were all inserted in a supine fashion. The outcomes evaluated in this study were alignment of the lower extremity, union time operative time, and exposure to fluoroscopy. Functional testing was also conducted using the chair stand test and timed up and go test, gait analysis and intraoperative blood loss. In the study, TEN recorded less operative time by 20 minutes and less fluoroscopy time. The authors also recorded non-union rates of about 4.6% for both fractures and delayed union of 3.6% for both entry points, with no difference in functional outcomes (19).

Quantification of the amount of injury to the abductor muscles in our local set-up has not been documented. This study aims to quantify the commonest entry point, PEN, in our local set-up and form a platform to improve surgical techniques in femur shaft fracture fixation.

2.3 Post-operative follow up

The contractile function of muscles is carried out by myofibers and their corresponding nerves and a framework made of connective tissue with nerves and capillaries, which function as a unit during contraction. Injuries to muscles may occur as contusions, sprains, or lacerations. Splitting of muscles in surgery may mimic muscle lacerations and tears sustained in injuries. The regenerative capacity of muscle healing is limited. Muscles heal in three phases; destruction, repair, and remodeling phase. These steps have been described in multiple texts. Rupture followed by necrosis of myofibers occurs within the second day with inflammatory cells and cytokines which, are released within the central zone of the injured

muscle. This is followed by regeneration as a result of satellite cells from the basal lamina, in which myoblasts fuse to form myotubes. The myotubes, by day 7, pierce the connective tissue scar-forming within the central zone. By day 14, the connective tissue scar in the central zone condenses and reduces in size, and the gap is closed by regenerative myotubes. By the 21st day, since the muscle tear, the interlacing myofibers are fused, and there is minimal intervening scar in-between (20).

Myofibers are innervated by a single point in the neuromuscular junction. If the axon of a nerve falls within the reactive zone of an injury, then a new axon sprouts through the central zone during muscle healing (20).

The connective tissue formed within the muscle injured is the weakest point of the muscle. The tensile strength of the muscles improves as collagen type 1 is deposited into the tissue. By day 10 of the injury, the maturation of the scar reaches a point that it is no longer the weakest point of the muscle. Immobilization within the first few days of injury is necessary until the muscle is able to withstand the contraction-induced forces applied to it without a re-rupture. Muscle immobilization for prolonged periods results in wasting.

Järvinen et al. (2015), in a study published in the American Journal of Sports medicine, reported usefulness of gradual isometric training exercises, which initially the exercises allow muscle length to remain the same and a gradual increase in the tone of the muscles, all limited by pain (20).

Once patients are able to tolerate this, they are subjected to isotonic exercises in which the tone of the muscle is kept constant, but the length changes with the use of loads and counter loads which are increased progressively. Isokinetic exercises are then started last once the patient is able to do both isometric and isotonic exercises without pain (20,22,26).

The study also suggested operative management for severely injured muscles. Rehabilitation protocols in different institutions recommend early mobilization following fixation with rehabilitation programs to promote independence, as described by Brumback et al., which are applicable and replicable in our local setup (21). Protocols differ in surgeons, but a general consensus is weight-bearing as tolerated for AO 32A and 32B and partial weight bearing for AO 32C followed by progressive weight bearing as callus formation is observed. The two-part study by Brumback included a biomechanical phase where a construct to mimic nail locked both proximally and distally was subjected to axial loads and compressive forces to determine points of failure and to estimate the number of cycles before failure. The estimated cycles per week were 50,000 and therefore 500,000 cycles in 10 weeks which is about the time required for callus to mature to begin load sharing. In the clinical part of his study, he included all comminuted fractures of 35 patients with an estimated weight of 102kgs. Patients were expected to fully bear weight by six weeks with or without walking aids. Only 2 of the 28 patients who completed follow-up had not started weight-bearing at six weeks post-operatively (21).

A journal published in 2009 in the Journal of Orthopaedics and Trauma described standard rehabilitation protocols that may be used for patients with femur fractures. The protocols were divided into three phases based on the weight-bearing potential of the patient (22). Residual impairments were related to soft tissue injury. This included hip abductor weakness, knee extensor weakness, and gait abnormalities. Hip pain and knee pain were also significantly reported for antegrade and retrograde nails, respectively. Trendelenburg gait was reported (17,22,23). Injury to the abductor mechanisms was postulated from hardware irritation and inadequate rehabilitation. Computerized gait analyses were done with a reduction of hip and knee motion two months after surgery, with improvement in hip kinematics noted after eight

months (22). The study advocated for an early range of motion a week after surgery, initial weight bearing as tolerated and initial isometric activities of the lower limb. Once fair hip abduction strength was attained, which was defined by the ability of the patient to elevate the lower extremity against gravity from a resting side position, and can apply a minimum of half their body weight with an assistance device, the patient was moved to the next phase.

In the second phase, a single crutch or no crutch was used with neuromuscular electrical stimulation of the muscles. The third phase entailed the normalization of gait and strength-building exercises.

Fracture union with regard to the diamond concept is estimated to show signs of clinical union as demonstrated by non-tender fracture site on palpation and weight-bearing with the formation of callus of good quality radiologically bridging three out of four cortices on both AP and Lateral standard radiological femur view. Clinical union occurs weeks in advance in comparison to radiological union (23). Corrales analyzed 126 studies and listed the different criteria to determine fracture union clinically and radiologically. 49% concurred that a non-tender fracture site on weight-bearing is a high indicator of fracture union, while 53% advocated for callus bridging the fracture site. However, there is a lack of general consensus about the validity of each criterion studied.

Heterotopic ossification after antegrade nailing as studied by Biyani after closed femoral nailing which the authors measured isometric hip abductor function with the amount of heterotopic ossification on AP radiographs in which the hip abductor weakness was expressed as a percentage of the normal limb. There was a positive correlation between the size of the heterotopic ossification and hip abductor weakness. Excision of the HO worsened the

abductor function. The recommendation from the study was for surgeons to shield the abductor muscles to minimize the damage during canal preparation and nail insertion (25).

In Sweden, 23 patients were evaluated for abductor muscle dysfunction through isometric muscle strength with the use of a mechano-electric transducer was done with the comparison group being young individuals, less than 30 years. Hip abductors were noted to be most affected compared to other muscle groups. Full weight-bearing at 1.8 months after surgery was expected for most fracture types (26).

Larsen et al., in a study done demonstrated muscle function and strength measured by disease-specific questionnaires on 48 candidates. The quality-of-life assessment in patients, isokinetic muscle testing, and clinical evaluation were done following intramedullary nailing of the femur concluded that the long-term outcome was multifactorial. Worse outcomes were reported for patients with poor muscle strength in knee flexion and extension and reduced hip abduction (27). There are no local studies to quantify the amount of injury to the abductor mechanisms.

Moghtadei et al. studied EMG-NCV of patients following antegrade femoral nailing to determine the proportion of patients with superior gluteal injury. The author studied a population size of 25 patients. The results of the study were interpreted by a neurologist. Patients were evaluated for hip abduction weakness and limping, which were recognized complications following iatrogenic injuries to the superior gluteal nerve and the Gluteus Medius muscle. The conclusion of his findings from the EMG-NCV indicated that superior gluteal nerve injury occurred in 8% of the patients' studies, while myogenic muscle damage occurred in 20% of the studies' sample size. Therefore, a total of 7 patients (28%) of patients developed hip abductor dysfunction (28).

A comparison study of isokinetic hip abductor function among elite uninjured football players before the beginning of a season compared their kicking limb/dominant limb, and authors noted standard limb/ non-dominant limb to be symmetrical for both limbs (29,30).

2.4 Statement Problem

Given the importance of hip abductors in hip function, it is essential to establish if the commonly employed piriformis entry interferes with the abductor function.

Currently, there is a lack of objective literature assessing the function of hip abductors following antegrade femoral nailing. Failure to understand the degree of interference with abductor function limits the employment of different fixation methods of fracture femur, which could have better patient outcomes. Therefore, quantifying the degree of abductor dysfunction resulting from antegrade nailing will raise discussion on whether this technique is optimal for treating patients with femur fractures.

2.5 Justification of the Study

There are currently no local studies or regional studies addressing the probable injury to the abductor muscles following piriformis fossa antegrade nailing. This study aims to shed a light on the abductor muscle status following surgery of isolated diaphyseal femur fractures.

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2.6 Hypothesis

i. Piriformis entry nailing does not affect abductor muscle function

2.7 Study Objectives

2.7.1 Broad Objective

To evaluate the hip abductor function of patients managed for isolated shaft femur fractures with piriformis fossa entry antegrade nails at KNH

2.7.2 Specific objectives

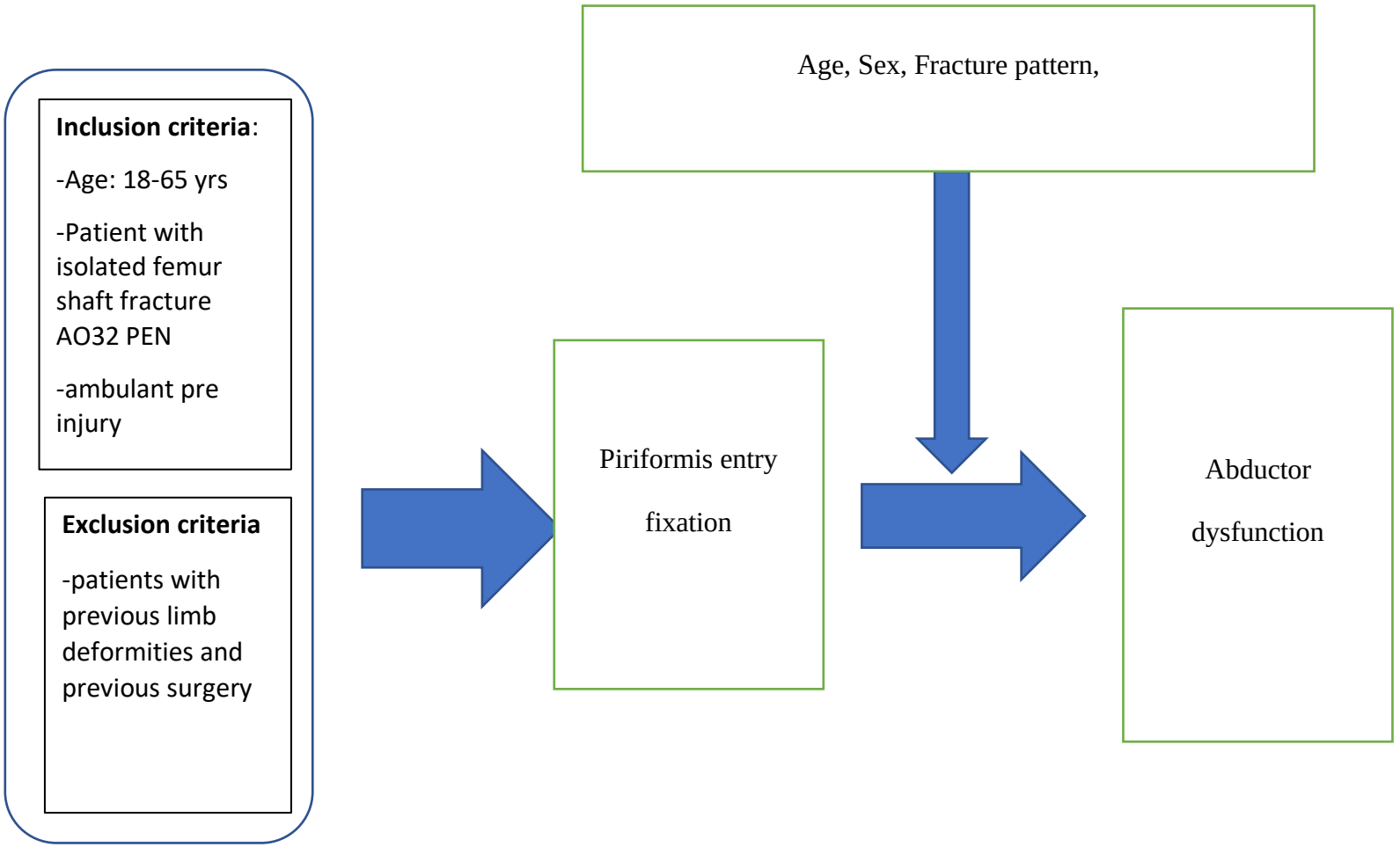
i. To determine and measure the power of abductor muscles of patients managed for isolated femur fractures with piriformis antegrade nail at six weeks and twelve weeks after surgery

ii. To measure passive hip abductor range of motion following isolated femoral fracture antegrade nailing at six- and twelve weeks post-surgery with piriformis fossa antegrade nailing

iii. To assess for Trendelenburg gait following operatively managed isolated femur fractures at six weeks and twelve weeks following piriformis fossa antegrade nailing

2.8 Conceptual Framework

Figure 2: Diagram showing the conceptual framework



CHAPTER 3

3.0 METHODOLOGY

3.1 Study design

Prospective Observational Study. Patients were recruited in the clinic following surgery during their first clinic visit.

3.2 Study setting

The study was conducted at Kenyatta National Hospital (KNH), Nairobi, Kenya, at the Orthopaedic clinic KNH is a national referral hospital offering specialist orthopedic services. It is the largest referral facility in the region.

3.3 Target Population

This study involved patients who were surgically managed for femur shaft fractures AO32 and aged 18 to 65 years with piriformis fossa antegrade nailing

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion Criteria

i. Patients aged between 18-65yrs
ii. Patient with isolated unilateral femur shaft fracture AO 32 managed operatively with a PEN
iii. Ambulant patient pre injury

3.4.2 Exclusion Criteria

i. Patients with previous limb deformities, hip and knee osteoarthritis, lower back pain, ankle deformities
ii. Patents with neuromuscular disorders
iii. Previous femur fractures and pelvic fractures
iv. Chronic osteomyelitis patients requiring surgery

v. Radiological presence of heterotopic ossification

vi. Patients with psychological disorders unable to consent independently

vii. Deaf and Blind patients

3.5 Sample size calculation

The sample size for the study was calculated as follows using the Cochrane formula. The sample population is random, and the population standard deviation was estimated by the confidence interval. The z figure (normal standard deviation) was obtained from the z tables.

Cochrane's formula: $n_{\circ} = Z^2pq/\ e^2$

$n_{\circ}$ = sample size
z = critical value for 95% confidence interval = 1.96
e = Desired level of precision (margin of error)
p = estimated proportion of the population
q = 1-p
Therefore n= 384

Using the prevalence of 28% as per Moghtadei et al. (28), the sample size was **310** patients KNH saw and managed 16, 22, 23, and 20 patients with diaphyseal femur fracture in the months of Dec 2021, January, February, and March 2022, respectively. This gave a total of 81 patients over the last four months. The adjusted sample size for finite population was

n(adj)= (N*n)/ (N+n)

N=310*81/ (310+81)
= 64 patients

The sample size was **64** patients.

3.6 Sampling Procedure

Consecutive sampling method was used on all patients with operatively managed for diaphyseal femur shaft fractures with piriformis entry antegrade nails. Patients who had been operated and presented to the clinic were recruited as they presented to the clinic till the desired sample size was achieved.

3.7 Data collection methods

A structured data form shall be used for data collection. The data form was administered by the research assistants as per the study protocol.

3.8 Variable definition and assessment

3.8.1 Exposure Variable

Independent variables in this study included, age, sex, type of fracture pattern, baseline muscle strength,

3.8.2 Outcome variable

The outcome variable was the range of abductor motion and abductor power at six- and twelve-weeks following surgery.

3.9 Study Procedure

3.9.1 Recruitment of study participants

The patients were taken through an overview of the study before going through the eligibility criteria to determine their eligibility for the study. Those who met the criteria and consented for the study were recruited.

Recruitment of patients took place at six weeks post-surgery and followed up at twelve weeks post-surgery.

3.9.2 Clinical Evaluation

i. Gait assessment

Following consenting, the patients were subjected to a gait assessment. Assessment was clinical. Patients presented with a severe limp with a lurch or a compensatory bend on the side of the affected hip to balance the body's center of gravity, therefore, producing a lurching gait. If this occurred bilaterally, then the patient presented with a waddling gait. The patient then walked a 6-meter distance to and fro while the examiner observed for waddling or lurching.

For mild cases in which the gait was not apparent, the examiner performed a Trendelenburg test. The examiner stood in front of the patient and asked the patient to lift one foot off the ground. Both limbs' liftoff was done, sustaining the hold for 30 seconds.

The negative Trendelenburg test was a typical result when the pelvis on the unsupported side remained on the same level. For a positive Trendelenburg test, the unsupported pelvis dropped towards the affected side, and in severe cases, the patient's trunk tilted towards the affected side. This suggested abductor muscle weakness. The patient ought to have had a painless hip pathology and was able to balance (31).

The examiner assessed for incision scar tenderness and examiner took measurements with a standard tape from the proximal tip of the scar to the most prominent point of the GT.

Examiner thereafter assessed true limb length by measuring the distance from the ASIS to the medial malleoli of each limb and recorded.

ii. Range of motion assessment

With the pelvis squared and the patient lying supine in anatomical position, the examiner placed the hand on the iliac crest and grasp the ankle of the contralateral leg and passively abduct the hip. The endpoint of this abduction was at the point where the start of a pelvic tilt was felt by the hand on the iliac crest. The arch formed by this movement was measured by a standard orthopedic goniometer.

The fulcrum of the goniometer was placed on the ASIS of the measured limb. The moving arm of the goniometer was aligned with the midpoint of the patella and the stationary arm with the opposite limb. A mark was placed on the thigh. The goniometer reading, which at this position read 90 degrees, was used as the zero scale. The goniometer was then be read at the end position aligning with the initial mark and degree determined. This was done for both lower limbs.

iii. Power assessment

The patient after that, lay on their side. With the examiner's hand on the ASIS, the patient was asked to abduct the lower limb. The patient flexed the contralateral hip and knee at 30 degrees for comfort and stability. The patients were not be allowed to use their upper limbs for truncal stabilization. Hip abductor strength was thereafter be graded based on the medical research grading system as the patient passively abducts the hip with the knee fully extended. This was the strength value of the movement. The same procedure was repeated for the opposite limb and documented. For patients unable to actively abduct against gravity on the side position, the patient returned to the supine position and was assessed for abductor function in the supine position.

Table 1: Power grading of the abductor muscles

Muscle Grade	Observation
0	No contraction
1	Flicker or trace contraction
2	Active movement with gravity eliminated
3	Active movement against gravity
4	Active movement against gravity and resistance
5	Normal power

For an objective assessment of abductor dysfunction, the examiner used loop elastic resistive bands. These were restive bands of similar length and color representing different thicknesses. Therefore, the different thicknesses demonstrated different resistance levels for each band. The manufacturer provided a maximum limit in which the elastic limit of the band was exceeded once the stated weight was applied.

The following methodology intended to achieve the next objective as they related to this study:

1. Measured the hip abduction of one hip relative to the other hip.

To attain the fore mentioned objectives, we used the following apparatus.

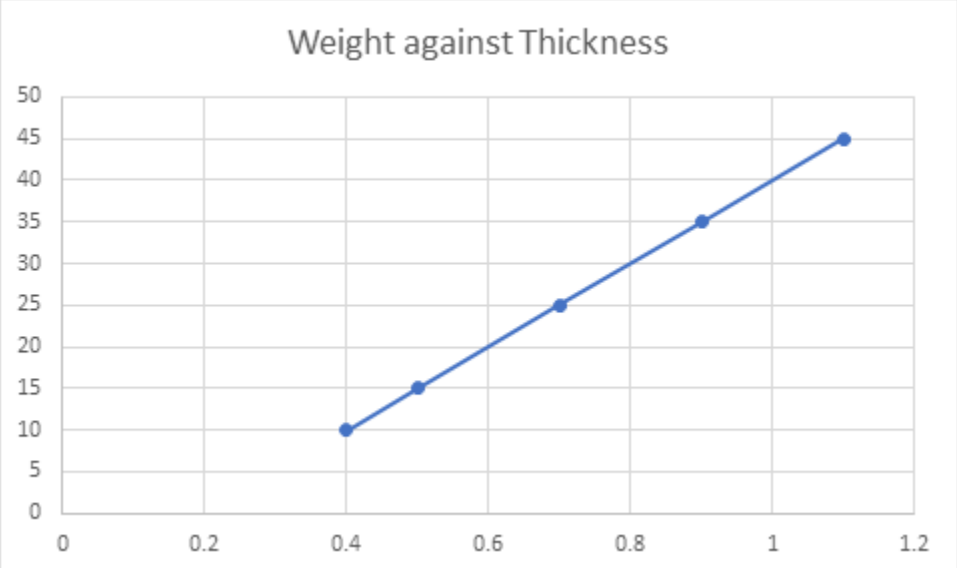
1. Loop elastic resistive bands
2. A standard digital weighing machine
3. Varying weights. (1kg, 2kg …., 20kg)
4. Tape measure

Procedure

a. Purchase a set of elastic loop bands from a reputable company. The examiner used elastic loop bands of varying thickness with the following weight ranges for this procedure. The manufacturer gave the values on the table. From this data, we generated the graph below.

Colors	Thickness(mm)	Weight(lb.)
Green	0.4	10
Yellow	0.5	15
Red	0.7	25
Blue	0.9	35
Black	1.1	45

Figure 3: Weight against thickness



The graph showed a linear relationship between the bands; therefore, the bands were of the same material and the same grade of material with the thickness being the only difference.

The specifications from the manufacturer and a data sheet from them were also attached.

b. To measure the hip abduction, we generated a scale. Steps to do this were given below:

I. Fix the elastic loop band onto an unmovable object, fixed 2m above the ground and let the loop elastic band hang loosely.

II. Measure the length of the elastic loop band with the hanging lace. This measurement is M1.

III. Starting with a 1kg weight and continuously loading to failure with increments of 1Kg while recording for any change in initial band length

IV. Record the corresponding weights and measurements of the length of the elastic loop band starting from M1 to the failure weight. (Using the measurement sheet attached)

V. Repeat this procedure three times for each loop elastic band and calculate the average value.

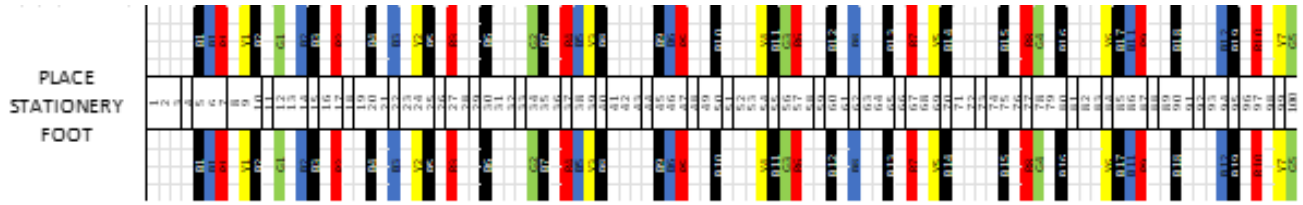
VI. From this data, create a scale that can be mounted on the ground and used to measure hip abduction.

MEASUREMENT SHEET

	GREEN				YELLOW				RED				BLUE				BLACK			
Weight (kg)		1	2	3	1	2	3		1	2	3		1	2	3		1	2	3	
1	M1				M1				M1				M1				M1			
2	M2				M2				M2				M2				M2			
3	M3				M3				M3				M3				M3			
4	M4				M4				M4				M4				M4			
5	M5				M5				M5				M5				M5			
6	M6				M6				M6				M6				M6			
7	M7				M7				M7				M7				M7			
8	M8				M8				M8				M8				M8			
9	M9				M9				M9				M9				M9			
10	M10				M10				M10				M10				M10			
11	M11				M11				M11				M11				M11			
12	M12				M12				M12				M12				M12			
13	M13				M13				M13				M13				M13			
14	M14				M14				M14				M14				M14			
15	M15				M15				M15				M15				M15			
16	M16				M16				M16				M16				M16			
17	M17				M17				M17				M17				M17			
18	M18				M18				M18				M18				M18			
19	M19				M19				M19				M19				M19			
20	M20				M20				M20				M20				M20			

A sample scale that we will generate be is shown below.

Figure 4: Band length with weight



The change in the band length in comparison to the weight applied was simplified on the above scale. The tension a patient needs to apply to the band to attain a certain band length was a surrogate marker of abductor strength. The patient was required to hold the band position for 3 seconds.

Comparison was made of both injured and non-injured limb.

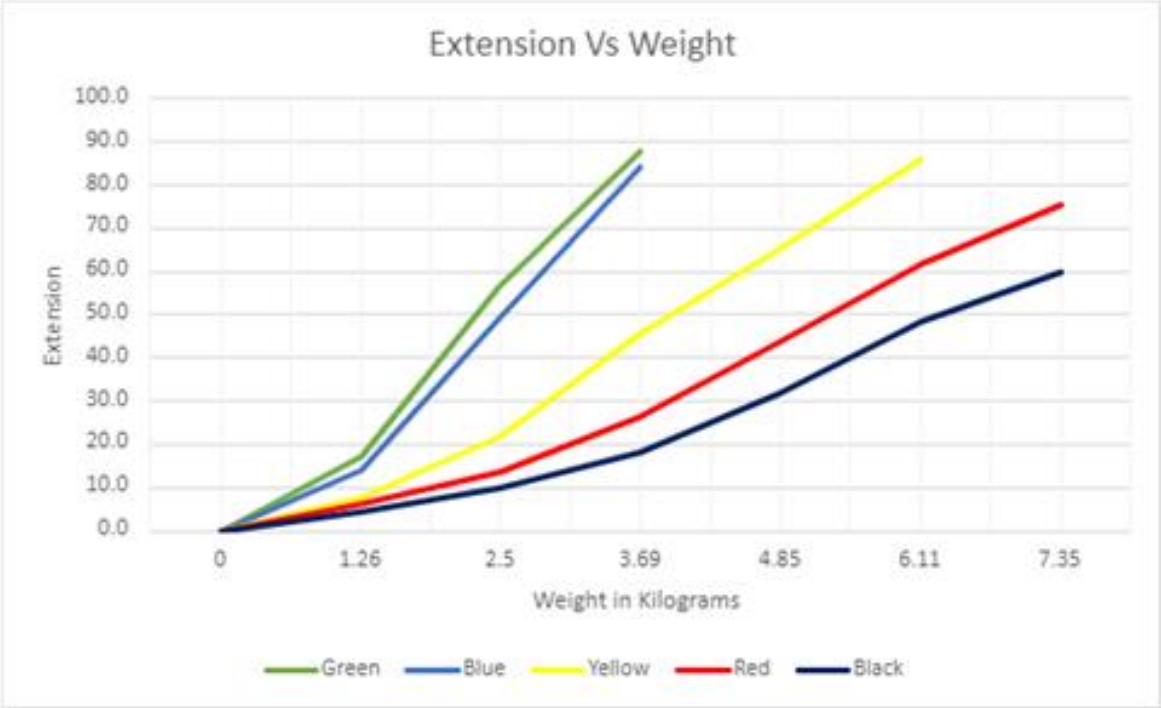
Conclusion

From the experiment conducted the following data was obtained;

Loading Conditions	Manufacturers Weight	Actual Measured Weight	Green		Blue		Yellow		Red		Black	
			Reading	Extension	Reading	Extension	Reading	Extension	Reading	Extension	Reading	Extension
Unloaded	0	0	19.0	0.0	18.0	0.0	18.0	0.0	17.5	0.0	18.0	0.0
W1- 1.25	1.25	1.26	36.0	17.0	32.0	14.0	25.5	7.5	23.5	6.0	22.5	4.5
W2- 1.25+1.25(1)	2.5	2.5	75.5	56.5	67.5	49.5	40.0	22.0	31.0	13.5	28.0	10.0
W3- 1.25+2.5	3.75	3.69	107.0	88.0	102.0	84.0	63.5	45.5	44.0	26.5	36.0	18.0
W4- 2.5+2.5(1)	5	4.85					83.5	65.5	61.5	44.0	50.0	32.0
W5- 2.5+2.5(1) +1.25	6.25	6.11					104.0	86.0	79.0	61.5	66.5	48.5
W6- 2.5+2.5(1) +1.25+1.25(1)	7.5	7.35							93.0	75.5	78.0	60.0

The data obtained was used to generate the following graph.

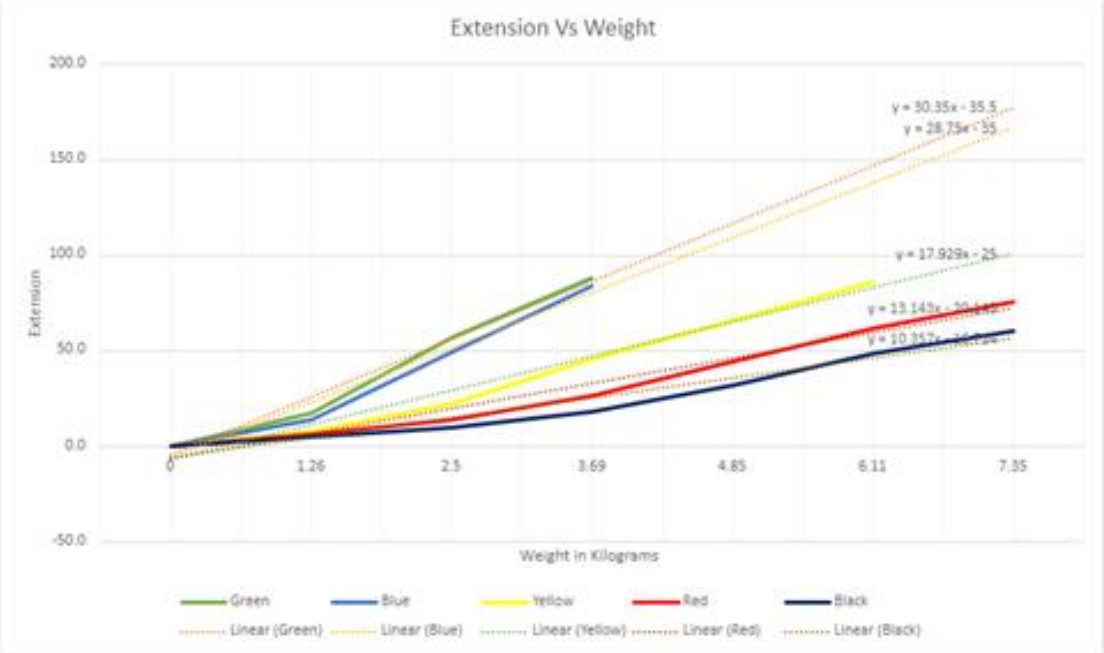
Figure 5: Extension with weight



Conclusions derived from the experiment are listed below

1. The bands follow a similar trend when loading, and trend analysis can be used to extrapolate the data for other weight values, as shown below.

Figure 6: Extrapolated extension with weight



Thus, the trendlines were used to establish the extension parameters for weight ranges from 1 Kilogram to 15 Kilograms. The data thus obtained is displayed below.

Loop elastic Band	Green	Blue	Yellow	Red	Black
Equation	y=30.35x-35.5	y=28.75x-35	y=17.929x-25	y=13.143x-20.143	y=10.357x-16.714
Weight in Kilograms					
1	-5.15	-6.25	-7.071	-7	-6.357
2	25.2	22.5	10.858	6.143	4
3	55.55	51.25	28.787	19.286	14.357

4	85.9	80	46.716	32.429	24.714
5	116.25	108.75	64.645	45.572	35.071
6	146.6	137.5	82.574	58.715	45.428
7	176.95	166.25	100.503	71.858	55.785
8	207.3	195	118.432	85.001	66.142
9	237.65	223.75	136.361	98.144	76.499
10	268	252.5	154.29	111.287	86.856
11	298.35	281.25	172.219	124.43	97.213
12	328.7	310	190.148	137.573	107.57
13	359.05	338.75	208.077	150.716	117.927
14	389.4	367.5	226.006	163.859	128.284
15	419.75	396.25	243.935	177.002	138.641

2. A scale can now be generated based on the extensions shown for various weight ranges. The interpretation of this scale was used to measure hip abduction. For example, if a patient can extend the yellow loop elastic band by 65 centimeters, then the strength value is 4 Kilograms.
3. Extensions above 100cm will not be featured on the scale as if a patient can attain this extension, they should move to the next loop elastic band color.
4. The negative values are also not considered as negative extensions are not possible. Therefore, if a patient cannot extend a band, the examiner should move them to the immediate lower band class.

3.10 Quality Assurance Procedure

The principal investigator; an Orthopedic Resident assisted by two holders of a Diploma in Clinical Medicine from Kenya Medical Training College undertook data collection. The team trained for one day on how to recruit respondents, consenting procedures, and administered the structured data collection form, including conducting measurements required in this study.

3.11 Data management

Once data was collected, data entry was done using the Microsoft Access software, where it was cleaned for accuracy prior to entry to avoid errors, and analysis was done with the help of a statistician. The entered data was password protected and only accessible to study participant and the statistician.

Hard copy data collection forms were stored in a locked safe to avoid access by unauthorized personnel.

3.12 Data Analysis

SPSS version 26 was used for data analysis.

For continuous variables such as age, and abductor range of motion, descriptive statistics such as mean, median, and standard deviation were used to elaborate on the patient and clinical characteristics. For categorical variables such as gender, abductor power, and gait characteristics, proportions and frequencies were used.

For hypothesis testing, to assess association between muscle strength, wasting and hip abduction for injured vs uninjured limb and at 6 weeks vs 12 weeks, student t-test was used

with Chi-square test of independence used for assessing counts of Trendelenburg gait. P values of <0.05 were considered statistically significant.

The results were presented using bar graphs, pie charts, frequency tables, and scatter plots.

3.13 Study Result Dissemination

Results from this study were disseminated to the University of Nairobi (UON) Department of Orthopedic Surgery, and the UON Library and thereafter planned for publication in a peer-reviewed journal.

3.14 Ethical considerations

i. Approval for this study was sought from the Kenyatta National Hospital – University of Nairobi Ethics and Research Committee (KNH-UON ERC), a copy of which was attached in the appendices.
ii. The study was conducted in accordance with the Declaration of Helsinki regarding the use of human subjects.
iii. Verbal explanation of the objective of the study and written informed consent was obtained from patient of all the study participants.
iv. Information about the patients that was collected during the research was strictly confidential. Any information about the patient had a number on it instead of the patient's name. Only the researcher knew the patient numbers and they were constantly kept under lock and key.
v. All the information stored in soft copy was kept secured using a password.
vi. Participation in this research was entirely voluntary. It was the patient's/parents' choice whether to participate or not, and he/she can withdraw from the study without any consequences.
vii. COVID – 19 prevention measures were observed at all times.

3.15 Study Limitations

Loss to follow-up: However, patients were encouraged to adhere to follow-up clinics after surgery. Their personal numbers were recorded to remind them to continue follow-up.

Confounding factors: Previously lower limb function state prior to the injury. The patients were required to consent for a normal functioning limb prior to the injury to enable us to exclude any previous pathologies such as knee and hip osteoarthritis, polio, and lower back pain. However, only patients with a normal function limb prior to injury were included.

CHAPTER FOUR

4.0 RESULTS

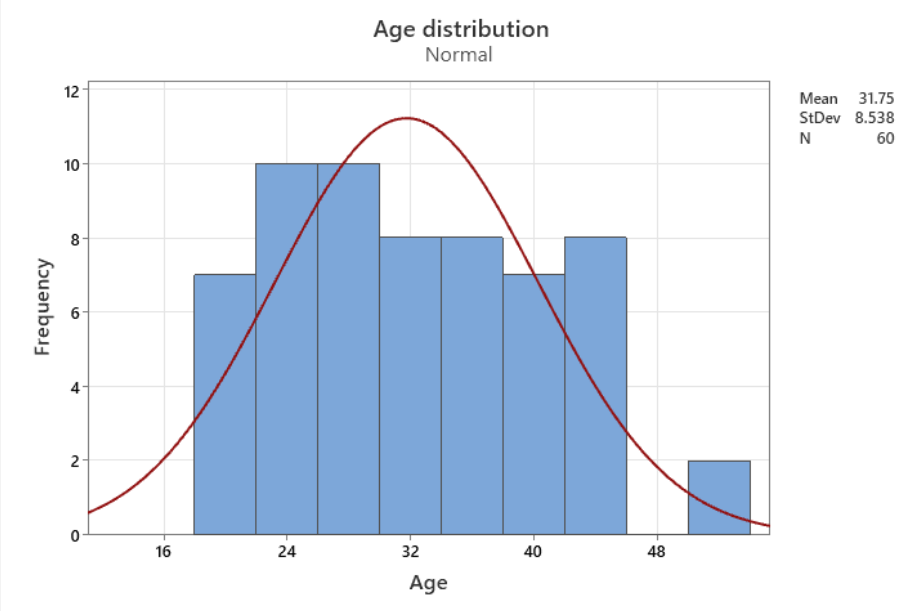
There were 61 participants in this study who were on follow up at the Orthopedics clinic. One study participant was excluded for analysis due to missing data. Thus, data for 60 study participants was analyzed and presented in this chapter.

4.1 Demographic and clinical Characteristics

4.1.1 Age

The mean age was 31.75, SD 8.54, Median 31.5 Range 19 – 52 (Figure 7).

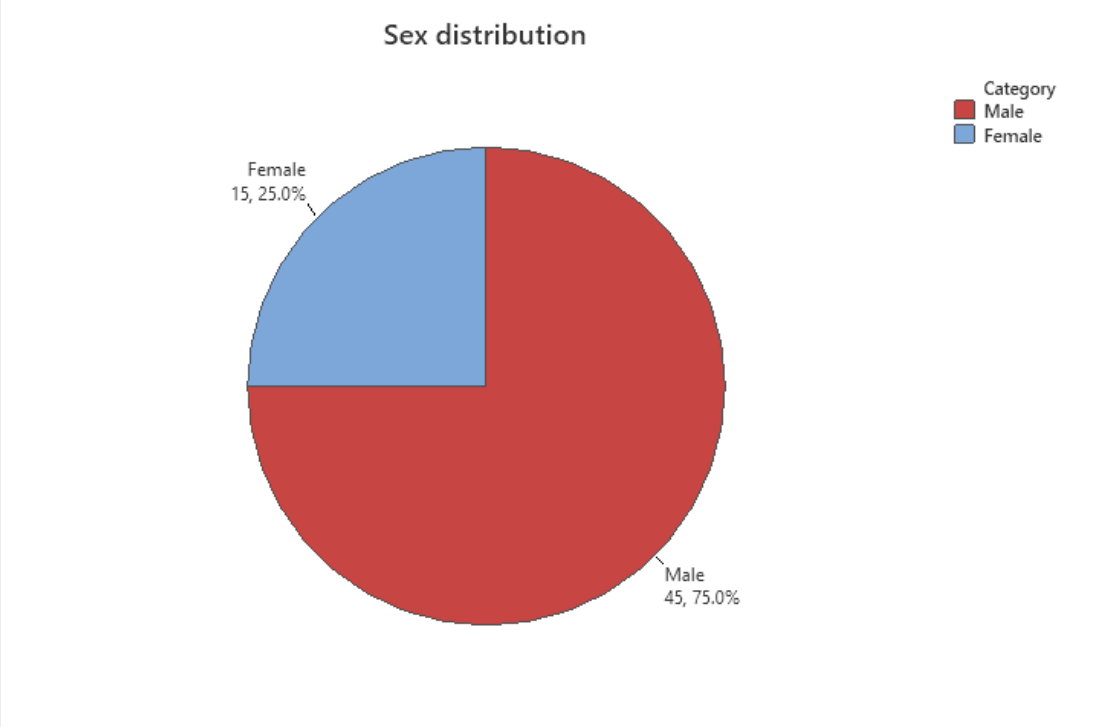
Figure 7: Histogram showing age distribution



4.1.2 Sex distribution

Males were 45 (75.0%) while females were 15 (25.0%) (Figure 8).

Figure 8: Pie chart showing sex distribution



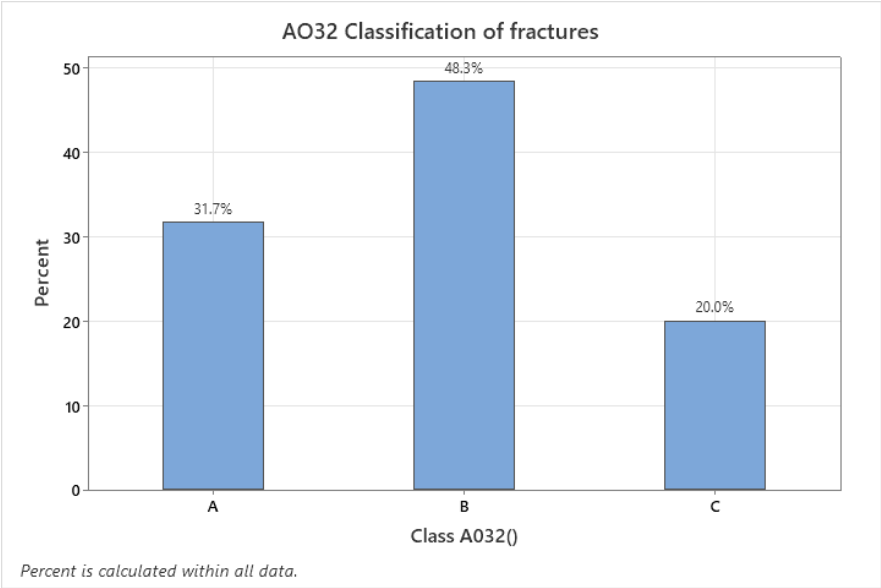
4.1.3 Laterality of Injury

Based on side of injured limb, left sided were 30 (50.0%) compared to right 30 (50.0%)

4.1.4 AO32 Classification of fractures

AO32 class A were 19 (31.7%), class B 29 (48.3%), class C 12 (20.0%) (Figure 9).

Figure 9: Bar-graph showing AO32 femoral fractures classification



Socio-demographic and clinical characteristics are shown in table 2

Table 2: Summary table showing demographic and clinical characteristics

Variable	**Category**	**Frequency (%)**
Age	18 – 35 36 – 62	38 (63.3) 22 (36.7)
Sex	Male Female	45 (75.0) 15 (25.0)
Laterality of injured limb	Left Right	30 (49.2) 31 (50.8)
Type of femur fracture	AO 32A AO 32B AO 32C	19 (31.7) 29 (48.3) 12 (20.0)
Tenderness on incision site	YES NO	12 (20.0) 48 (80.0)

4.2 Power of abductor muscles after surgery

The injured limbs had significantly less MRC scores as shown in the table. Similarly, for the right injured limb, there was a significant increase in MRC score (p=0.012) from 6 weeks to 12 weeks. Despite an increase in the left injured limb, it was not statistically significant (p=0.089) (Table 3).

Table 3: Power of abductor muscles at six weeks and twelve weeks after surgery

Injured Limb	Category	Mean MRC Score _ 6 weeks (SD)	Mean MRC score_ 12 weeks (SD)	P values (Student t test): 6vs12 wks.
Right (n = 30)	Right	3.097 (0.712)	3.5 (0.572)	0.012
	Left	4.903 (0.403)	4.933 (0.365)	0.764
	P value Rt vs Lt (T test)	<0.001	<0.001	
Left (n = 30)	Right	4.9 (0.305)	4.933 (0.254)	0.651
	Left	3.067 (0.583)	3.333 (0.606)	0.089
	P value Rt vs Lt (T test)	<0.001	<0.001	

4.3 Passive hip abductor range of motion post-surgery.

The injured limbs had significantly less hip abductor ROM at both at six and 12 weeks (Right injured limb, p = 0.0034, & p = 0.0361) and left (p = 0.007 & 0.039). However, there were no statistically significant increase in hip abductor range of motion between 6 and 12 weeks (see Table 4).

Table 4: Passive hip abductor range of motion

Injured Limb	Category	Hip abductor ROM _ 6 weeks (SD)	Hip abductor ROM _ 12 weeks (SD)	P value (t test) 6 vs 12 weeks
Right (n = 30)	Right	32.27 (7.017)	35.1 (5.108)	0.079
	Left	36.94 (4.574)	37.5 (3.381)	0.592
	P value Rt vs Lt (T test)	0.0034	0.0361	
Left (n = 30)	Right	35.9 (6.294)	36.57 (5.642)	0.666
	Left	30.8 (7.774)	33.03 (7.218)	0.254
	P value Rt vs Lt (T test)	0.007	0.039	

4.4 Trendelenburg gait following operatively managed isolated femur fractures at six weeks and twelve weeks.

In terms of Trendelenburg gait, there were significant differences between the normal vs the abnormal limbs, as well as between 6 weeks and 12 weeks (Table 5).

Table 5: Trendelenburg gait comparing normal and injured limbs and different time intervals.

Injured Limb	Category	Trendelenburg gait status	Trendelenburg gait _6 weeks	Trendelenburg gait _12 weeks	P value (Fishers' exact) 6 vs 12 weeks
Right (n = 30)	Right	Positive Negative	28 (93.3) 2 (6.7)	16 (53.3) 14 (46.7)	<0.001
	Left	Positive Negative	1 (3.3) 29 (96.7)	1 (3.3) 29 (96.7)	0.754
		P value (Fishers' exact) Rt vs Lt	<0.001	<0.001	
Left (n = 30)	Right	Positive Negative	1 (3.3) 29 (96.7)	0 (0) 30 (100)	0.5
	Left	Positive Negative	29 (96.7) 1 (3.3)	21 (70.0) 9 (30)	0.006
		P value (Fishers' exact) Rt vs Lt	<0.001	<0.001	

4.1.1 Trendelenburg sign

There was significant reduction in number of patients with a positive Trendelenburg sign from 60 to 54 at 6 weeks and 12 weeks (p=0.014) (Table 6).

Table 6: Trendelenburg sign changes at 6 weeks and 12 weeks

Variable	Category	6 weeks	12 weeks	P value
Trendelenburg sign	Positive Negative	60 0	54 6	0.014

4.5 Wasting

There was significant reduction in wasting between 6 weeks and 12 weeks in patients with right injured limb (p = 0.008) and no significant change in those with left injured limb (Table 7).

Table 7: Assessment of wasting at 6 weeks and 12 weeks

Injured Limb	Category	Wasting	6 weeks	12 weeks	P value
Right (n = 30)	Right	Positive Negative	23 (76.7) 7 (23.3)	13 (43.3) 17 (56.7)	0.008
Left (n = 30)	Left	Positive Negative	20 (66.7) 10 (33.3)	15 (50.0) 15 (50.0)	0.190

4.6 Abductor hip strength

Comparing right and left limbs, there were significant differences in right injured limb at six weeks and 12 weeks (p values <0.001 and 0.001 respectively) and left injured limb (p 0.019 and 0.004). However, no significant differences were notable when comparing between 6 weeks and 12 weeks (Table 8).

Table 8: Abductor hip strength

Injured Limb	Category	Mean weight 6 weeks (SD)	Mean weight 12 weeks (SD)	P values (T test): 6 vs12 weeks
Right (n = 29)	Right	4.033 (1.450)	4.933 (1.570)	0.027
	Left	6.1 (1.936)	6.4 (1.694)	0.533
	P value Rt vs Lt (T test)	<0.001	0.001	
Left	Right	5.517 (2.165)	6.133 (1.717)	0.235

(n = 30)	Left	4.103 (2.273)	4.7 (1.932)	0.278
	P value Rt vs Lt (T test)	0.019	0.004	

4.7 Type of walking aid

There was a reduction in usage of all walking aids, from 6 weeks to 12 weeks (Table 9).

Table 9: Use of walking aids at 6 and 12 weeks.

Walking Aid	**6 weeks**	**12 weeks**
Double crutch	29 (49.2)	18 (30.5)
Single crutch	29 (49.2)	22 (37.3)
Wheelchair	1 (1.7)	0 (0)
None	0 (0)	19 (32.2)

CHAPTER FOUR

5.0 DISCUSSION

The study sought to determine the hip abductor function following piriformis fossa entry antegrade nailing in isolated diaphyseal femur fractures, at Kenyatta National hospital.

5.0.1 Socio-demographic and clinical characteristics

The prevalence femur fracture in internationally and regionally has a young male sex predominance as found in this study to be at 45 out of the 60(75%) patients recruited (2, 5) Patients under 35 years of age were 38/60 participants which is similar to the prevalence in a study conducted in Northern Tanzania by Hollis et all that where majority of patients were less than 30 years (5).

The AO classifies diaphyseal fractures into simple AO32A, Wedge Fractures AO32B and AO32C to represent multi-fragmentary fractures. In our study, the majority of femur fractures sustained were AO32B at 29 out of 60 (48%). These patterns of injury were previously described by Kumar et al however percentage prevalence was not discussed of each sub category (8,11).

In this study, walking aids were used at the initial six week visit and a record follow up was done. 59 out of 60 patients had started weight bearing at the 6-week mark with only one patient who was on a wheel chair at six weeks. At the 12-week mark, all patients were weight bearing using crutches with 19 out of the 60 patients with complete follow up using no aids by twelve weeks. These findings are consistent with similar studies which promoted early mobilization and independence and patients expected to be full weight bearing aided or not by 6 weeks (21).

Early signs of residual impairments were noted for patients in this study such as persistent incision site pain for 20% of the patients. As noted in a study published by the Journal of Orthopaedics and Trauma in 2009, these residual impairments were related to the soft tissue injury and a longer duration of follow up would be needed for such patients (14, 22).

5.0.2 Wasting

Wasting of the gluteal muscles observed in this study improved significantly for those with right sided leg injuries compared to those with left sided injury. This is contrary to the study on elite football players as isokinetic hip abductor function was found to be symmetrical in both kicking or dominant limb and the standard or non-dominant limb hence the recovery pattern expected to be even (29)

5.0.3 Trendelenburg gait

Patients initially recruited all tested positive for Trendelenburg gait at 6 weeks. There was noted improvement of this gait by the 12^{th} week with significant improvement noted for the right than the left limb. Of those who tested negative for Trendelenburg gait, they were subjected to Trendelenburg test (23,31). Trendelenburg test was noted to reduce from 60 to 54 by the 12^{th} week in patients included in the study which was statistically significant ($p=0.014$). Of these patients who had no Trendelenburg by 12 weeks, only one was using a single crutch while the rest had none. None of these patients underwent physiotherapy following femur fracture fixation with intramedullary nail but had information on progressive weaning off of walking aids. A study by Archdeacon et al on functional outcome and motion analysis evaluating hip abductor function after antegrade nailing found gait alterations at 2 months improved by 7 months if deficits in stride and gait early improved the overall outcome at 2 years for patients therefore suggesting the soft tissue issues could be addressed early (17).

5.0.4 Hip abduction range

The abduction range was compared between the injured and non-injured limb. We found a significant difference between the injured and non-injured limb and no significance in improvement of abduction range at six and twelve weeks. The difference in abduction range

could be as a result of the soft tissue envelope injured proximally similar to the study findings noted by Dodenhoff et al. (14) and Larsen et al. (27) poor range of motion resulted in long term poor outcomes.

Muscle healing in a study by Järvinen et al. was suggested to be possible for those with smaller gaps talking an average of 21 days from the time of injury for myotubes to interdigitate and fuse forming a scar. The quality of the connective tissue is based on the deposition of collagen type 1 fibers and within 2 weeks of the muscle injury, the muscle is able to withstand contraction induced forces without re-rupture (20). This would therefore encourage early range of motion exercises even before weight bearing starts. Initially isometric muscle exercises would be encouraged to allow the muscle length to remain the same then eventually strength training to be introduced (20,22,23)

5.0.5 Muscle strength

This study also employed the use of elastic loop bands to determine the tension applied on the bands as a marker of the strength of the abductors. These different tensions applied were based on a predetermined scale in which different weights were applies to the different bands and a scale developed. The patient abduction power was also determined using the MRC score. The findings were that the injured limb had a significantly lower MRC at 6 weeks which slightly improved by the 12th week. These findings correlated with the abduction power measured by weight as lower weight were recorded for patients with a lower MRC score. The difference was significant when comparing the left and right limb versus at the 6 week and the 12th week suggesting the study duration to determine full muscle strength recovery would need to be longer. In Sweden, a comparison group of younger patients tested abductor muscle dysfunction using mechano-electric transducers found abductors to be most affected following intramedullary nailing (26). The study on

rehabilitation protocols published in the Orthopedics and Trauma Journal in 2009 used protocols in which the patient was objectively subjected to isometric activities of the lower limb and hip abduction strength were tested using patients' ability to resist gravity from a side position and can apply minimum of half their body weight with assistance devices (22). The mean weights ranged from 4-6 kilograms in our study suggesting a lag in strength training within our set up.

5.1 CONCLUSION

This study concludes that abduction muscle strength is reduced with those patients managed for antegrade femoral nailing using piriformis fossa antegrade nailing technique with improvement proportional to level of ambulation independency.

5.2 RECOMMENDATION

1.Full adoption of rehabilitation protocols and self-training exercises may result in early detection of soft tissue deficits and aggressive management in strength training exercises for proper rehabilitation.

2.Local guidelines with adoption from international can be formulated to improve and standardize patient care.

3.A long term follow up of the said patients can be done to determine delayed outcomes.

4. A follow up study on avoiding iatrogenic injury to abductor muscles intraoperatively can be carried out. Informed improvement of techniques such as protective reaming, using fluoroscopy where feasible, and reducing the amount of dissection proximally can be gained.

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APPENDICES

i)Appendix 1: Data collection Sheets

Study Title: **EVALUATION OF HIP ABDUCTOR FUNCTION FOLLOWING PIRIFORMIS FOSSA ANTEGRADE NAILING IN ISOLATED FEMUR FRACTURES**

Biodata

1. Form Number: _____
2. Age: _____ years
3. Sex: male / female
4. Injured limb: Right / Left
5. Fracture classification: AO32A () / AO32B() / AO32C()

Clinical assessment at 6 weeks

6a.	Trendelenburg gait	Right	Y() N()	Left	Y() N()
6b.	Trendelenburg test(positive/negative)				
7.	Gluteal muscle wasting	Y() N()			
8.	Abductor muscle power MRC score				
9.	Range of Motion Hip abduction in degrees (Use goniometer)	Right hip		Left hip	
10	Maximum Band color on scale and weight attained (green/Blue/Yellow/Red/Black)	Right hip		Left hip	
11	Walking aid: Walking Frame/Single crutch/Double Crutch	Y ()		N ()	

Clinical assessment at 12 weeks

11a.	Trendelenburg gait	Right	Y() N()	Left	Y() N()
11b.	Trendelenburg test (positive/negative)				
12.	Gluteal muscle wasting	Y () N ()			
13.	Abductor muscle power MRC power				
14.	Range of Motion Hip abduction in degrees (Use goniometer)	Right hip		Left hip	

15.	Maximum Band Color on scale and weight attained (green/blue/yellow/ red/black)	Right Hip		Left Hip	
16.	Walking Aid: Frame/ Single Crutch/Double Crutch	Y ()		N ()	

ii) Patient Consent form:

a. English version

PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY

This Informed Consent form is for patients undergoing follow up in the Orthopaedic clinic following surgery of isolated femur fractures with antegrade intramedullary nails at KNH. It were administered to eligible patients. We are requesting you to participate in this research project whose title is "Evaluation of Hip Abductor Function Flowing Piriformis Fossa Entry Antegrade Nailing in Isolated Diaphyseal Femur Fractures"

Principal Investigator: Dr. Dorothy Jepkoech Torutt

Institution: Department of Surgery, Orthopaedics Unit, Faculty of Health Sciences, University of Nairobi.

This Informed Consent Form has three parts:

I. Information Sheet (informs you in a brief overview about the research with you).

II. Certificate of Consent (for you to sign if you agree to take part).

III. Statement by the researcher/person taking consent.

A copy of the informed consent form was provided.

PART I: Information Sheet

Introduction

My name is Dr. Dorothy Jepkoech Torutt, a postgraduate student in Orthopaedic surgery at the University of Nairobi. I am carrying out research to evaluate hip abductor function in operatively managed diaphyseal shaft femur fractures in patients seeking treatment at the Kenyatta national hospital.

Purpose of the research

I will provide information and invite you to be a participant in this research. There may be some words that you don't comprehend. Please ask me to explain as we go through the information and I will explain. After receiving the information concerning the study, you are encouraged to seek clarification in case of any doubt. This study will elucidate the effect of surgery on abductor hip function. The study will also aim to justify the establishment of appropriate management protocols on operatively managed shaft femur fractures.

Type of Research Intervention

This research will involve use of questionnaires and medical records with your doctor's permission [or their representative], imaging results.

Voluntary participation/right to refuse or withdraw

It is your decision to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you decide against participating, you will be offered the treatment that is routinely provided in this hospital for your condition. You have a choice to refuse or withdraw your participation in this study at any point.

Risks and benefits.

This study confers no risks to the participant and therefore no harmful effects will be encountered. The measurement procedures are part of the routine clinical procedures that should be undertaken in a patient on follow-up after interlocking nail fixation. Equally, there will be no direct benefits to the participants.

Confidentiality

The information obtained in this study will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any personal information will have a number on it instead of your name. We will not be sharing the identity of those participating in this research.

Study procedure

After agreeing and consenting to participate in the study, various measurements shall be taken from you including your stride length, range of motion and gait.

Sharing the results

The knowledge obtained from this study will be shared with the policymakers in KNH and doctors through publications and conferences. Confidential information will not be shared.

Benefits

The benefits of joining the study include:

- Contribution to the advancement of patient management.
- Improvement in the management of patients presenting with trauma
- There will be no risk involved by enlisting for this study

Cost and compensation

There will be no extra cost incurred for participating in this study nor is their compensation offered.

This research proposal has been reviewed and approved by the Uon/KNH Ethics Committee, which is a committee whose task is to make sure that research participants are protected from harm.

Who to contact

If you wish to ask any questions later, you may contact:

PRINCIPAL RESEARCHER:

DR. Dorothy Jepkoech Torutt; DEPARTMENT OF SURGERY, ORTHOPAEDIC UNIT, Faculty of Health Sciences, Department of Orthopedic Surgery, UNIVERSITY OF NAIROBI

Phone: 0727878598

Email; dorothytorutt@gmail.com

OR

University of Nairobi /Kenyatta national hospital Supervisors:

1. Dr. Vincent Mutiso, Consultant Orthopaedic Surgeon, Senior Lecturer- Department of Orthopaedics, University of Nairobi

2. Dr. John King'ori, Consultant Orthopaedic Surgeon, Lecturer- Department of Orthopaedics, University of Nairobi,

OR

Kenyatta National Hospital _ University of Nairobi (KNH_UON) Ethical Review Committee

Email: uonknh_erc@uonbi.ac.ke

Website htttp://www.erc.uonbi.ac.ke

Facebook: https://www.facebook.com/uonknh.erc

Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERCs

PART II: Certificate of Consent

I have read and understood the above information/the above information has been read out to me. I have had the opportunity to ask questions and the questions that I have asked have been answered satisfactorily. I voluntarily agree and consent to participate in this research.

Print unique ID of Participant

_____

Signature of Participant _____

Date _____

If Non -literate:

I have witnessed the reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I can confirm that the individual has given consent voluntarily.

Print Unique ID of witness_____ Thumb print of participant

Signature of witness _____

Date _____

PART III: Statement by the researcher

I have read out the information sheet to the participant, and made sure that the participant understands that the following will be done:

A decision to refuse to participate or withdrawal from the study will not in any way compromise the care of treatment.
All information given will be handled with confidentiality.

The results of this study might be published to facilitate research and improved clinical guidelines. I can 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 approval has been given voluntarily.

A copy of the Informed Consent Form has been provided to the participant.

Name of researcher/person taking consent _____

Signature of researcher/person taking consent_____

Date_____

b. Fomu ya Idhini: Swahili version

Jina langu ni Dorothy Jepkoech Torutt, mwanafunzi wa shahada ya uzamili katika chuo kikuu cha Nairobi, sekta ya upasuaji wa mifupa

Nafanya utafiti kuhusu uhusiano wa upasuaji na chuma kwenye mfupa wa paja kwa misuli za nyonga. Utafiti huu utachukuliwa katika harakati ya matibabu yako. Utafiti huu utatumia vipimo za uwezo wako kuisongesha nyonga baada ya upasuaji na nguvu ya misuli zinazoizunguka nyonga.

Utafiti huu hauna madhara yoyote kwako.

Matokea tukoka utafiti huu utatusaidia kuboresha matibabu ya wangonjwa wa shida kama yako kwenye hospitali yetu.

Ni muhimu kuelewa kuwa ushiriki ni wakujitolea na sio lazima kushiriki. Pia waweza kubadili nia yako kuhusu kuendelea kushiriki wakati wowote, bila kuathiri huduma zako za afya.

Nimekubali kwamba nimeelezwa kikamilifu kuhusu utafiti huu na nimekubali kushiriki.

Sahihi ya mshirika_____

Tarehe _____

Nimethibitisha ya kwamba nimetoamaelezo sahihi kwa mhusika pana ya utafiti, naye mhusika ametoa uamuzi wa kushiriki bila ya kushurutishwa.

Sahihi ya mchunguzi_____

Tarehe_____

iii) administrative consent to conduct study

Dr Dorothy Jepkoech Torutt

H58/10924/2018

Department of Surgery, Orthopaedic Unit

Faculty of Health Sciences, University of Nairobi

Phone: 0727878598

Email:dorothytorutt@gmail.com

Date: 12/12/2021

To,

Deputy Director,

Medical Research,

Kenyatta National Hospital.

Dear sir/ma'am

Re: AUTHORIZATION TO CONDUCT RESEARCH STUDY

I am an Orthopaedic resident at the University of Nairobi undertaking Masters of Medicine Orthopaedic and Trauma surgery and equally the principal researcher in this study. This research is undertaken as a thesis for part fulfilment of my requirements for graduation. I hereby seek authorization to conduct research study entitled, "Evaluation of Hip Abductor Function Flowing Piriformis Fossa Entry Antegrade Nailing in Isolated Diaphyseal Femur Fractures". The study aims to identify how the abductor muscles are injured during surgery with a goal of improving outcomes, policy and practice in our set up.

The data for this research will be collected from Orthopaedic clinics using a structured data collection tool. The study will be carried out at KNH. The principal researcher, and research assistants myself, will be the one collecting the data.

To prevent Covid 19 transmission during data collection, hand sanitizer will be provided to the patient and research participants and masks will be won out throughout the examination process

This study was approved by the KNH-UON ERC under approval number _____ in a letter referenced, _____ dated _____ as seen in the attachments.

Yours sincerely,

Dr Dorothy Jepkoech Torutt

Orthopedics Registrar, University of Nairobi

Loop elastic bands- manufacturer description

Product Description | Company Info. | Customer Question & Answer

Product keyword:	*resistance loop band set*	Product Origin:	Guangdong, China
Function	• Resistance Bands Have 5 Different Levels of Resistance - Light, Medium, Heavy, x-heavy,xx-heavy • Great Resistance Loop Bands for Arms & Legs and Upper & Lower Body Exercises • Loop Bands are 12" x 2"/12"x3" in size • Reinforced latex rubber loops to ensure no ripping or tearing! • Resistance loop band training will transformer your body by creating lean, strong muscles and burning fat!	Advantages:	1.Good quality and competitive price. 2.Widely used; 3.Elegent looking and comfortable usage.
Feature:	1.High Quality Exercise Loop Bands for Legs, Arms, Core 2.Latex material Lifetime Guarantee 3.Ensure no ripping or tearing	Maintenance:	Health work out
Packing:	a:1pc/box b: According to the requirement of clients.		
Our Sevrice:	We have 12 years experience in this optical line ,we produce all kinds of products (OEM &ODM), we sell our goods to many countrires ,including the Europe,the South America ,the Middle East and the Asia.		

5pcs Training Fitness Gum Exercise Gym Strength Resistance Bands Pilates Sport Rubber Fitness Bands Crossfit Workout Equipment

Basic Info.

Appliance	Community, Park, Gymnasium, Home	Material	100% Natural Latex Resistence Bands
Usage	Home Exercise, Yoga Exercise	Length	50cm, 60cm or Customized
Size	600*50*0.35/0.5/0.7/0.9/1.1mm	Thickness	0.35mm,0.5mm,0.6mm,0.7mm,0.8 mm,0.9mm,1.0mm,11mm
Feature	Great for Exercise, Pilates, Rehabilitation	Colour	Yellow, Blue, Red, Black, Green, Purple, Orange
HS Code	4007000000	Production Capacity	15000/Pieces Per Month

Digital weighing scale

- TemperedGlass-the weight scale is made of temperedglass, 5 times stronger than ordinary glass, firm and anti-scratch High Accuracy-In accordance with the correct instructions to placed the weight scale
- High technology of the product design make it accuracy Digital-It is easy and convenient to reading the number with the digital display Considerate Design-Auto-on/off the weight scale with the design of LED backlight weight induction
- The base black support has a non-slip function and you can use it safely
- Exquisite packaging- it can reduce the damage in transit with foam and colored packaging, you can purchase trustingly

1 x bathroom scale

SPECIFICATIONS

SKU: GE840FD1F150XNAFAMZ

Size (L x W x H cm): 28x28x3

Weight (kg): 0.4

Main Material: glass

Product details

Feature:

Auto-on/off the weight scale with the design of LED backlight weight induction. Just directly stand on the scale can turn on the hine and about 10 seconds will shutdown automatically.

Applicable: adult

Item diameter: 26cm, glass thickness: 6mm.

Package weight: 1kg

Material: temperedglass + electronic components.

Maximum weighing: 180kg.

Minimum induction weight: 5kg.

Function: weight measurement.

Battery type: button battery (included).

Package: foam+colored box

Package Included:

1 * weight scale

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/174

10th May, 2022

Dr. Dorothy Jepkoech Torutt
Reg. No H58/10924/2018
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

10 MAY 2022

Dear Dr. Torutt,

RESEARCH PROPOSAL: EVALUATION OF HIP ABDUCTOR FUNCTION FOLLOWING PIRIFORMIS FOSSA ENTRY ANTEGRADE NAILING IN ISOLATED DIAPHYSEAL FEMUR FRACTURES AT KENYATTA NATIONAL HOSPITAL (P68/02/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P68/02/2022.** The approval period is 10th May 2022– 9th May 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **227151**

Date of Issue: **14/May/2022**

RESEARCH LICENSE

This is to Certify that Dr., Dorothy Jepkoech Torutt of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: EVALUATION OF HIP ABDUCTOR FUNCTION FOLLOWING PIRIFORMIS FOSSA ENTRY ANTEGRADE NAILING IN ISOLATED DIAPHYSEAL FEMUR FRACTURES AT KENYATTA NATIONAL HOSPITAL for the period ending : 14/May/2023.

License No: **NACOSTI/P/22/17564**

227151

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

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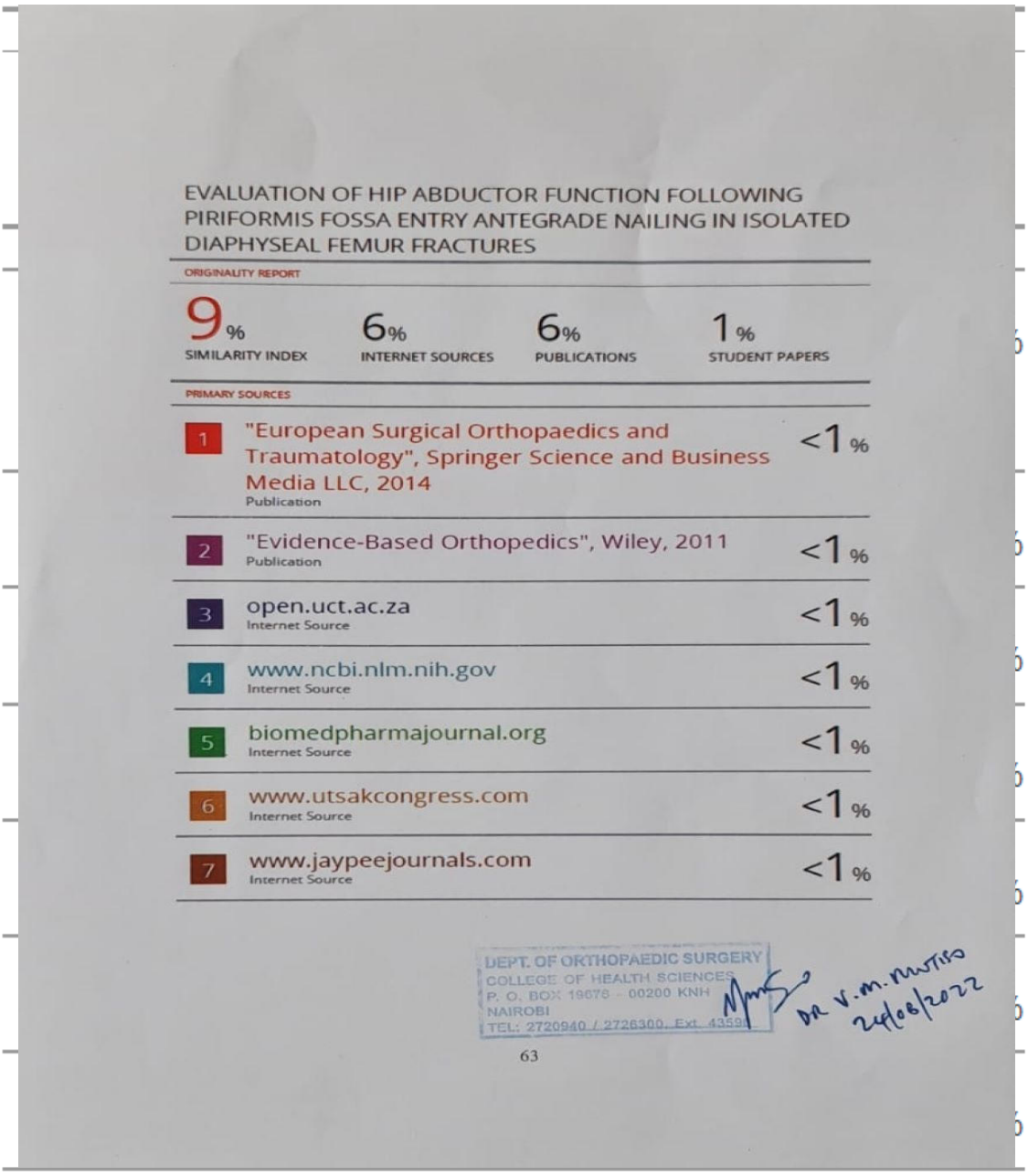

EVALUATION OF HIP ABDUCTOR FUNCTION FOLLOWING PIRIFORMIS FOSSA ENTRY ANTEGRADE NAILING IN ISOLATED DIAPHYSEAL FEMUR FRACTURES

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24/08/2022

63