UNIVERSITY OF NAIROBI

EVALUATION OF DIAPHYSEAL TIBIAL ALIGNMENT FOLLOWING INTRAMEDULLARY NAIL FIXATION AT KNH.

Dissertation submitted in partial fulfillment of the requirements for the award of the Degree of Master of Medicine in Orthopedic Surgery of the University of Nairobi.

By

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H58/7300/2017.

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This is to certify that this dissertation is the original work of Dr. Athuman Mohamed Abdallah, registration number H58/7300/2017, has completed this dissertation in the Department of Orthopedic Surgery, University of Nairobi under the guidance and supervision of Dr. George Museve, Dr. Edward Gakuya and Dr. Ezekiel Oburu. This is to confirm that this thesis has not been presented at the University for the award of any other degree.

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May Allah bless you

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Dedicated to my loving wife, my blessing, Dr. Alawiya Abdulkadir Mohamed, your endless love, impeccable support and encouragement have instilled confidence in me that I am capable of anything.

To my Sons: AbdallahJunaid and AbdulkadirJawwad, to my Daughters: Naima and Fatimah for enduring my long period of absence away from home, thank you so much.

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To Allah the Almighty, who gave me life, wisdom, guidance and strength to overcome all obstacles.

This research is dedicated to you.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS

aADTA – Anatomical anterior distal tibial angle

A & E -Accident and Emergency

AO/OTA - Arbeitsgemeinschaft für Osteosynthesefragen/ Orthopaedic Trauma Association

aPPTA – Anatomical proximal tibial angle

AP - Anteroposterior

ERC - Ethics and Research Committee

II – Image Intensifier

IMN – Intramedullary Nail

KNH- Kenyatta National Hospital

LEA – Lower extremity Alignment

mMPTA -Mechanical medial proximal tibial angle

mLDTA – Mechanical lateral distal tibial angle

ORIF – Open reduction and internal fixation

RTA – Road Traffic Accidents

DEFINITIONS OF KEY TERMS

Alignment: The act of bringing into line; the longitudinal position of a bone or limb.

Angulation: defined by the direction of apex, -anterior/posterior, medial/lateral

Displaced fracture: when the bone breaks into two or more portions and moves so that the bone ends do not line up correctly. (Distal fragment with respect to proximal- anterior, posterior, medial, lateral, overlapping and distraction)

Distal tibial fracture – Defined as a fracture that extended no further than 10 cm from the tibial plafond with or without intraarticular fracture extension

Fracture pattern/morphology: Physical and radiological characteristics of a fracture that may define its management approaches can be transverse, oblique, spiral, comminuted, etc.

Fracture: A break in the continuity of a bone along with partial or complete disruption of blood supply to the region, visible radiologically as a uni- or bicortical break.

Herzog curve: Nail designs curvature

Malalignment/Malunion: defined as shortening > 2cm or coronal angulation >10 degrees or sagittal angulation >5 degrees.

Procarvatum: Angulated anteriorly

Valgus: is a condition in which the bone segment distal to a joint is angled outward, that is, angled laterally, away from the body's midline.

Varus: An excessive inward angulation (medial angulation, that is, towards the body's midline) of the distal segment of a bone or joint.

Xray: A penetrating form of electromagnetic wave of high energy and very short wavelength, which is able to pass through solid objects including the body organs, tissues, and bones to produce images.

ABSTRACT

Background: Intramedullary nailing (IMN) is an approach of fracture fixation and performed since early 20th century. Owing to the variations in type of complications related to fractures of tibia, intramedullary fixation has allowed opportunities for further improvement.

Significant complexities exist in management of diaphyseal tibia fractures with a higher risk of mal-alignment. This contributes to significant disability in patients, declined quality of life and escalates the costs of treatment. Furthermore, there is a disruption of otherwise normal joint kinematics resulting in non-physiologic loading of the knee and ankle leading to significant limitation of function, causing a deformity across the knee and tibiotalar joint resulting in alteration of overall joint biomechanics and post-traumatic arthritis thus limiting both ankle and knee range of motion with gait disturbance. Extremely small amounts of persisting angulation in the fracture that is already united, and as minute angulation as possible, changes the load across the knee and ankle joints. Improved biomechanical understanding of diaphyseal tibia malalignment will help to formulate improved treatment modalities and should be minimized whenever possible.

Objective: The main aim of this study is to evaluate diaphyseal tibial alignment following intramedullary nail fixation at the Kenyatta National Hospital.

Methods and Materials: The study was a cross-section analytical in design involving 72 patients, carried out Kenyatta National Hospital, Orthopedic and radiology imaging Departments. Patients who presented to KNH with Diaphyseal tibial fractures to undergo Intramedullary Nailing (IMN) were recruited into the study. Outcome measures were malalignment, elaborated as varus/valgus angulation (anterior/posterior angulation) of knee

at 5 degrees and sagittal angulation of 10 degrees bases on first anteroposterior and lateral X-rays after fixation surgery. Direct clinical measurements of limb length discrepancy for both injured and uninjured limb were taken and the measurement documented.

Results: Seventy-two patients undergoing diaphyseal tibial fracture fixation, and treated with an intramedullary nail, were consecutively recruited. The respondents were aged between 19 and 59 years of age. The mean age was 31years and 6 months (95% CI; 29.5 to 33.5). The majority of the respondents were male (n=66; 91.7%) and 6 (8%) women. Majority of the patients (n=48; 66.7%) had open fractures and 24 (33.3%) closed fractures. Using AO fracture classification two thirds of the respondents (n=49; 68.1%) had Middle level of fracture, 17 (23.6%) had Lower Level while only six (8.3%) had Upper level. Approximately 42% (n=30) of the respondents had simple transverse fractures(42A3), 31% (n=22) sustained oblique fractures(42A3) and 17% (n=12) comminuted fractures(42B3), complex segmental 4(5.6%), (42A1) simple spiral 4(5.6%). Approximately 92% (n=66) had fibula fractured but not Plated, with 7% (n=5) being intact and only one patient presented with fibula fracture and plated. Two thirds (n=48; 66.7%) were attended by Registrars while a third (n=24; 33.3%) were attended by the Consultants (figure 10). Majority of the patients (n=49; 68.1%) underwent a closed surgical procedure while the rest underwent open surgical procedure. Localization of the entry point was through eye balling in approximately 82% (n=59) of the cases, the others were through Image intensifiers (fluoroscopy). Gravity and manual Traction as a method of achieving reduction was used in approximately 96% (n=69) of the Cases. The most preferred method of maintaining the reduction was Gravity and manual traction at 68.1% (n=49). Manual traction, gravity and clamping was used in 31.9% (n=23) of the cases. The most utilized nail sizes for fracture reduction were 36*10mm, 34*10mm and 36*11mm at 38.9%,

37.5% and 13.9% respectively. Nail size 36*9mm was used in 4.2%, nail size 34*9mm, in 2.8% and nail size 34*11mm and 32*10mm in 1.4% each. In 58.3% (42) of the cases, a reaming diameter of 2mm was used. A reaming diameter of 1mm was done in 25 (34.7%) cases. The overall rate of malalignment was 6.9% in length discrepancy and 1.4% malalignment in sagittal plane. with upper and lower third fractures most affected by malalignment. No middle third fractures had malalignment. Location of fracture, predicted the occurrence of malignment with a p value of 0.001. There was no association between entry point and malalignment.

Conclusion: Middle third diaphyseal tibial fractures can be treated adequately with eyeballing technique, manual traction and gravity as a method of achieving and maintaining reduction and compared to upper and lower third fractures which require use of fluoroscopy to minimize the risk of malalignment. This would help optimize the use of fluoroscopy in the hospital which is a scarce resource.

CHAPTER ONE

1.0 INTRODUCTION

The reference standard for the primary fixation of fractures of the diaphyseal tibia is the Intramedullary Nailing (IMN) since it allows adequate stability and weight bearing in the immediate post-operative period. The index usage of tibial nail was reported by Küntscher in the 1940 and forms the basis of the current technique(1).

In the 20th century, there has been significant progressive change in the technique. In the 1950s there was introduction of medulla reaming as well as usage of interlocking screws. The 1990s saw the introduction of nails made of titanium(2).

The most prevalent long bone injuries are the fractures of the diaphyseal tibia with a yearly reported incidence of 51.7 per 100,000 population in the USA. These resulted in 77,000 patients getting hospitalized, 569,000 total days spent in hospitals with a mean hospital stay of 7.4days. Moreover, there were 825,000 visits to the doctors' office annually(3)(4)

Desirable outcomes for the operative treatment of the diaphyseal tibial fractures is pegged on proper understanding of the indications. Further considerations are the expectations of the patient's based on how soon they desire to return to their optimal functional capacity. Based on the pattern of the fracture, conservative treatment may be considered as an option, however, to reduce loss of earnings as a result of time spent away from working, patients may opt for operative management (5),(6)

Management of diaphyseal tibial fractures with a cast placement has been in use for a long time and continues to be applied widely and successfully in modern times. However, the advantages of intramedullary nailing supersede cast placement in terms of fracture healing and function (7). IMN offers proper biomechanical fracture stabilization, restoring length, alignment, and rotation and permits early patient mobilization after surgery since they allow for adequate load sharing (8)

The key challenge with nail placement in tibial fracture is due to the anatomical disposition of the segment – the upper and lower part of tibia bone have a wide canal cavity assuming the hourglass shape. In diaphyseal tibial fractures, there seems to be a relationship between the inserted nail diameter and the canal which supports the alignment, however, in the metaphysis, there is diminished balance for the bone-nail construct (9)

In the operative fixation, the upper fragment is routinely challenging to manipulate during the fixation / reduction and this can result in malignment due to an attempted medial starting point and proceed posterior and laterally this changes the orientation and the angle of nail insertion(10).

Herzog curve, is the upper bend of the tibia intramedullary nails and can result in the undesirable alignment of the proximal tibia fractures due to "wedge effect." Increased distal Herzog curves in some nails is known to result to anterior translation of the upper fragment. In the frontal plane there are similar orientations of the locking options. Thus, it is difficult to secure remote upper and distal fracture segments because of positioning and locking of the screws in the basis of measurement to either end of the nail. Screws are designed with a low-profile thread, reduce cross-section and single-threaded layout and this allows a weak grip in the cancellous bone (11)(12). Freedman et al elicited higher percentages of malalignment after nailing of the upper third fractures compared to center or lower third of the fractures of tibia, due to inadequate fracture reduction during nail insertion, failure to properly assess extremity rotation, and lack of attention to the entrance site and angle of nail insertion (13).

The bending moment of the distal segment increases due to proximity to the ankle joint. Therefore, leading to fracture progressing into the articular extension ankle joint. Inability to adequately manipulate the lower fragment or reaming away from the center may result in considerable primary malalignment. Placement of nail in the lower third metaphyseal fracture causes no reduction the fracture contrary to placement of a nail in a middle third fracture of tibia (14),(15)

Thus, there is a greater likelihood of malalignment in these fractures and this can contribute to significant disability in patients, lowered quality of life and escalation in the costs of treatment (16)(17). Diaphyseal tibia fracture malunion can disrupt otherwise normal joint kinematics resulting in non-physiologic loading of the knee and ankle leading to significant limitation of function, thus causing a deformity across the knee and tibiotalar joint resulting in alteration of overall joint biomechanics and post-traumatic arthritis thus limiting both the knee and ankle motion with gait disturbance. The importance of residual angular deformity after tibial fractures is still uncertain (18). A very minute degree of angulation in a united fracture can result in load alteration through the knee and ankle joints. Surgeons do not routinely inform patients on the anticipated long-term function following fixation with intramedullary nailing of a diaphyseal fracture of tibial bone. Improved biomechanical understanding of diaphyseal tibia malalignment will help to formulate improved treatment modalities and should be minimized whenever possible (19).

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Indications for the Intramedullary Tibial Nail

The IM Tibial Nail has expanded its indications and is suitable for proximal and distal metaphyseal fractures and certain intraarticular fractures.

The IM tibial nail has many indications, including:

- Proximal tibial fracture with intraarticular extensions
- All fractures of the diaphyseal tibial segments
- Distal tibial fractures with intraarticular extensions

Revision Surgeries such as mal-unions, tumors and non-unions (12).

2.2 Fracture patterns/Morphology

Tibial fractures can simply be classified as either open or closed and if it involves the tibia at the upper, the middle, or lower third. A study in the United Kingdom estimated that seventy-seven percent of fractures of tibia treated by majority of the surgeons in orthopedics are closed, and the rest 23% tend to be open (20). Some authors suggest that integrity of the fibula bone and amount of fracture displacement are key in the prognosis of the fracture hence their consideration in the fracture classification (21). Young patients mostly sustain Closed tibial shaft fractures mainly due to sport-related injuries. In contrast, in the elderly, just a fall can cause most fractures including tibial shaft fractures. A simple fracture pattern is often associated with closed tibial fractures, might have a more or less severe soft-tissue injuries than open tibial shaft fractures. Older and less fit patients with osteoporotic bone are associated with more complex fracture configurations (22).

The common classification system is the AO/OTA classification, it uses numbers as codes to describe the fracture of a particular bone firstly, the bone injured, the portion of the bone involved and the fracture pattern with its complexity (23). This is a morphologic classification based on the initial anteroposterior and lateral radiographs. (See appendix 2). Type A fractures constitute the majority at 54% of all tibial shaft fractures, while type C fractures account for 18.3% (20).

Gustilo and Anderson classification system, modified in 1984 is used for Open fractures (24). The classification depends on increasing soft tissue injury (See appendix 3). About 60% usually types III fractures 19% are type II (20). The extent of soft tissue injury similarly plays a key role in classifying tibial fractures. Tscherne classification system is thus utilized for closed fractures and is well correlated with the prognosis (see Appendix 4) (25). A study done in India reported an incidence of closed fractures at 65% and open type at 35%. Distal 1/3 level was the most affected at 49.2% and the transverse subtype was the most common (26). A study that was exclusively looking at motorcycle injury patterns at a county referral hospital in Kenya reported 75% closed tibia fractures patients (27).

Categorizing of fractures and soft tissue damage assists in standardizing communication and data management and storage. It may also assist in defining fracture management and predicting simple outcome measures (28). OTA classification is predictive of how soon the patients bear weight as well as when they can resume their routine activities. Gustillo classification is predictive of time to union and incidences of nonunion, malunion and infections but does not prognosticate function. On the other hand, the Tscherne classification is predictive of time to union and time to resumption of activities of daily living (29).

2.3 Treatment Methods

Generally, we have non-operative and operative approaches in terms of managing these fractures. Most experienced specialists consider IMN as the implants of choice for treating tibial fractures which are considered both stable and unstable, they could be open or closed (30)(31). Many authors are not agreeing precisely on treatment of slightly displaced and closed tibial shaft fractures, with plaster application and IMN on the forefront with good support (32). For open fractures, surgical debridement is done as an emergency before definitive fixation. Thus, this is very important to prepare the fracture for reduction and to combat infection (33)

While using the intramedullary interlocking nail, the surgeons perform a proximal and distal locking of the nail with screws and this stabilized the length of nail, alignment and prevents rotation if fracture is unstable. Thus fractures of the tibial shaft can achieve over 95% union if treated with this method (34). Several contraindications to surgery in this patient include; an ipsilateral Total knee replacement/fusion, tibia deformity before injury, and a canal diameter of less than 7 mm, because with this you will need to ream so much to get a smooth entry of the nail you desire as a surgeon (35)(36).

The nails we use recently cannulated and not solid as before, and you have to ream to ensure insertion is smooth and a good construct and working length with contact on both nail and bone to enable union. All the nails we use offer proximal and distal locking options. The construct becomes more stable after fixation if the working length is shorter. At our institution, the medial parapatellar and the transpatellar approaches have been used successfully for years (37).

The advantages of the implant usage are that it provides for relevant stabilization of fracture biomechanically and contributes to load sharing hence permitting earlier mobilization after surgery. Further utilities of the IMN fixation have included fixation of upper and lower third fractures of tibia due to recent improvements in design of nail and techniques of fracture reduction. This technique has been well elaborated and is routinely conducted by orthopedic surgeons at all levels (38).

2.4 Diaphyseal tibial alignments post intramedullary nail fixation

The inferior joint surface of the knee is represented by the proximal tibia and has become most frequently operated of all joints. Besides its nearness to the articular surface, it harbors a series of complicated features which are variables in humans. Some of the variable features include, the posterior slope, the axis of joint alignment, and width of metaphysis and such results is significant variations in every individual tibia. Fractures of tibia, tumors and degeneration cause loss of natural bony configuration and can lead to alteration in biomechanical role and result in premature or fastened worsening of the function of the knee joint (39). In addition, proximal third fractures of the tibial shaft do not appear to respond as favourably technically to intramedullary nailing as do fractures in the distal two-thirds of the tibia; they tend to misalign (40).

While attempting reduction, the proximal fragment is difficult to control, thus, errors can occur surgically at any particular point, starting with the entry point when its missed or if medialized; posteriorly and laterally it directs the nail insertion at an angle which contributes to malalignment. Logically, if you ream a fracture then insert your nail in a posterior direction this will result in an anterior gap and also when you have comminution on the posterior aspect of the cortex, it will definitely affect the alignment while inserting the nail it will have an anterior angulation (41). Other challenges are based on the design of the implant. Traditionally, the number of locking options of tibial nails is limited, consisting proximal and distal two holes each (42). The proximal and the distal locking options are in the same orientation and direction in the coronal plane. As a result of the positioning of these locking screws regarding the length to both the proximal and distal end of the nail, they cannot achieve a stable secured isolated fracture fragment of either proximal or distal (11)(12).

Orthopedic surgeons do not agree on how much deviation from anatomic alignment is acceptable for a good functional outcome (43)(44). A study by Merchant and Dietz based on a long-term review of the cases of thirty-seven patients with a tibial shaft fracture treated with a cast concluded that "the clinical and radiographic outcomes were unaffected by the amounts of anterior or posterior and of varus or valgus angulation. Nevertheless, numerous authors have proposed various standards recommending "acceptable alignment." For example, Bridgman and Baird ascertained that 4% or 42% of the tibia in their study would be maligned depending on the parameters used to define alignment (45),(46),(47)

Consequently, alignment parameters published are guidelines without scientific data to substantiate them. Moreover, to avoid factors that result in disability, many surgeons choosing among management options must regard other goals, including conservative, simple management, early weight-bearing, early range of motion of the knee and ankle, early return to work, and cost-effectiveness (7). Typically, used and accepted reduction criteria include a varus/valgus angulation less than 5°, an anteroposterior angulation less than 10°, rotation less than 10° (with external rotation better tolerated than internal rotation), and shortening less than 15 mm. While supine, the anterior superior iliac spine, center of the patella, and the second proximal phalanx base should be in the same linear axis; this provides a rough guide to the alignment of the limb (48),(49).

The direction to which reaming and insertion of the nail has to be in line with the anterior tibial surface of cortex and neutral in both anterior/posterior and varus/valgus planes to maintain the centrality of the nail (50)

2.5 Coronal and sagittal angulation post diaphyseal tibial intramedullary nail fixation

There are opportunities for further advances in the IMN fixation due to the configuration of tibial fractures as well as resulting complications. postoperative when malalignment occurs it creates difficulties and leads to a higher frequency of malunion. However, surgeons have innovated newer methods of addressing this but still every method has its weaknesses(51).

Malalignment arises because the nail fits loosely in the wide metaphysis and cannot control alignment. If there is no cortical contact with nail and bone, the nail will not align with the fracture independent of a stable reduction and careful nail path (52),(53). When a tibial fracture is malalignment after IMN fixation it’s as a result from failure to appropriately reduce the fracture fragments(10).

Lang et al., in their study, found an angulation of 5 degrees in at least one plane in 84% of tibial fractures on proximal segment managed by IMN and also 59% of the fractures that were managed, they presented with a 10 mm or more displacement. Another study found same results in the clinical data published by Ahlers and von Issendorf, and Hansen (10)(45). A study by Freedman and Johnson on radiographs reported that malalignment was commonly found in upper third fracture of the diaphyseal tibia representing (58%), followed by a distal third (8%) and middle third fracture (7%), the malunion rate was 7% in tibial diaphyseal fractures and 8% in distal third fractures (13).

In another study, the intraoperative reduction deteriorated to some degree during the period until union. The authors reported that the reason for this was that the diameter of the screw hole in the nail was more significant than the diameter of the screw (54). The screwing procedure is easier to perform when the screw diameter is smaller than the diameter of the hole. However, this difference causes micro-movements in time, resulting in some reduction loss. In addition, Obremskey and Medina et al. reported angulation problems in distal third tibial fractures (55).

2.6 Tibial Nail Starting Point

The crucial part of IM nailing is the entry point. Various entry sites have been described, but the optimal site remains a topic of debate (56)(57). A study by McConnell et al, found that the optimal entry point is just medial to the lateral tibial spine at the anterior margin of the articular surface, medial aspect of the tibial tubercle in the coronal plane, the midpoint of the tibial shaft both in the anteroposterior and mediolateral plane; (see fig. 1 to 4) (58).

There is a variable anatomic relationship between the patellar tendon and the lateral tibial spine. Thus a routine surgical approach may not give direct access to the ideal nail entry site and a direct approach to the entry site is necessary to minimize soft tissue damage secondary to retraction and prevent nail malposition or intra-articular injury (59).

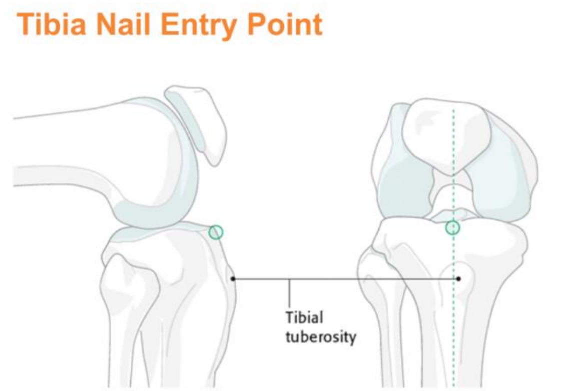


Figure 1. Tibial nail entry point

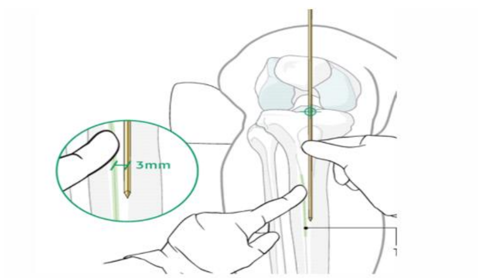


Figure 2. Tibial nail entry point measurement

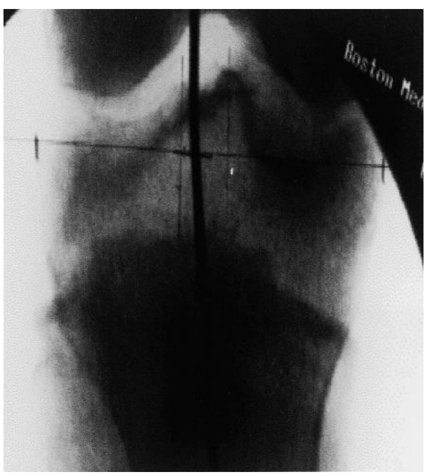


Figure 3: Entry point on Anteroposterior.

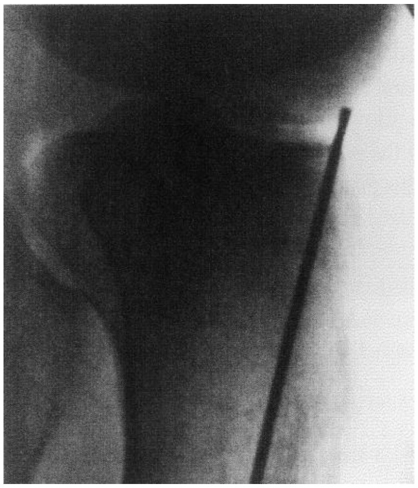


Figure 4: Entry point on Lateral view.

Several surgical approaches are in use, there is no difference in the incidence of damage to intra-articular structures wile choosing either approach (60)(61). If nail entry point is not optimal, there can be malignment, surgical challenges with nail insertion or fracture during fixation (62)

Anterior and posterior displacement can result from a too anterior or too posterior entry points whereas a medial displacement can be due to too lateral nail entry point and this can lead to varus deformity with a lateral displacement occurring due to too medial entry point. Malalignment can occur due to a medially oriented nail entry point that leads to posterior or laterally oriented nail insertion angle (63). Insertion of nails through the lateral and medial third of lateral tibia plateau leads to varus malalignment whereas their insertion at the medial third of the lateral tibial plateau results in valgus and varus malalignment (64).

Studies by O Lembcke et al. indicate that varus deformity can occur due to too lateral entry point and valgus deformity due to too medial entry point (65). The ideal nail entry point as defined by Hernigou P, Cohen D is 2.5mm (+/-1.8mm) lateral to the center of the tibial tubercle. Too distal entry point results in proximal posterior cortex fracture (66).

2.7 Relationship between the fracture location/site and the diaphyseal tibial alignment.

2.7.1 IMN of Proximal third diaphyseal tibial fractures

Fractures of the proximal tibia represent approximately 5–11% of all tibia fractures (67). Intramedullary nail fixation of proximal tibial fractures is associated with a much higher rate of complications than is intramedullary nail fixation of midshaft fractures (10). Causes for this mismatch can be due to an entry point that is too medial, reaming a fracture that is not reduced, or positioning the Herzog bend of the IMN at or distal to the fracture site. It is important that this curve remains proximal to the fracture otherwise a wedge effect can occur on insertion leading to posterior translation of the distal segment. Tornetta and Collins described a semi-extended position for nailing of proximal tibial fractures, utilizing a medial parapatellar approach, with no malunions in their series (68)

It's very important to have a reference starting point which for most orthopaedic surgeons ensures maintenance of a good fixation. This is enabled by having appropriate resources and instrumentations while intraoperatively (69)(70)

A number of modifications to the surgical method had been recommended. To reduce apex anterior angulation of the proximal fragment Tornetta and Collins cautioned lateral subluxation of the patella and positioning the knee in a semi-prolonged position throughout nail creation, to keep away from deforming factors because of patella tendon strain (68).

Poller screws have been investigated and used to solve the varus-valgus instability in the upper third tibial fractures. Krettek et al. utilized them next to the nail with an aim to reduce the size of the medullary canal and reduce nail translation. They are routinely used to achieve reduction and secondarily to minimize instability and hence are proven to be effective in maintaining alignment (71) In proximal metaphyseal fractures using the three spongious locking screws ensures premiere stabilization of the proximal fragment. The cease cap affords angle solid locking of the proximal locking screw. Ensure fracture types extra use of the mediolateral screws may additionally upload to the stableness. thanks to modifications in proximal locking options the prevalence of secondary malalignment is appreciably decreased. but unique attention has to be given to the unique anatomy of the proximal decrease leg. Drilling and creation of the screws ought to be strictly monocortical to avoid lesions of the popliteal artery, the tibial, and common peroneal nerve, and injuries to the proximal tibiofibular joint (72).

2.7.2 IMN of mid-third diaphyseal Tibia fractures

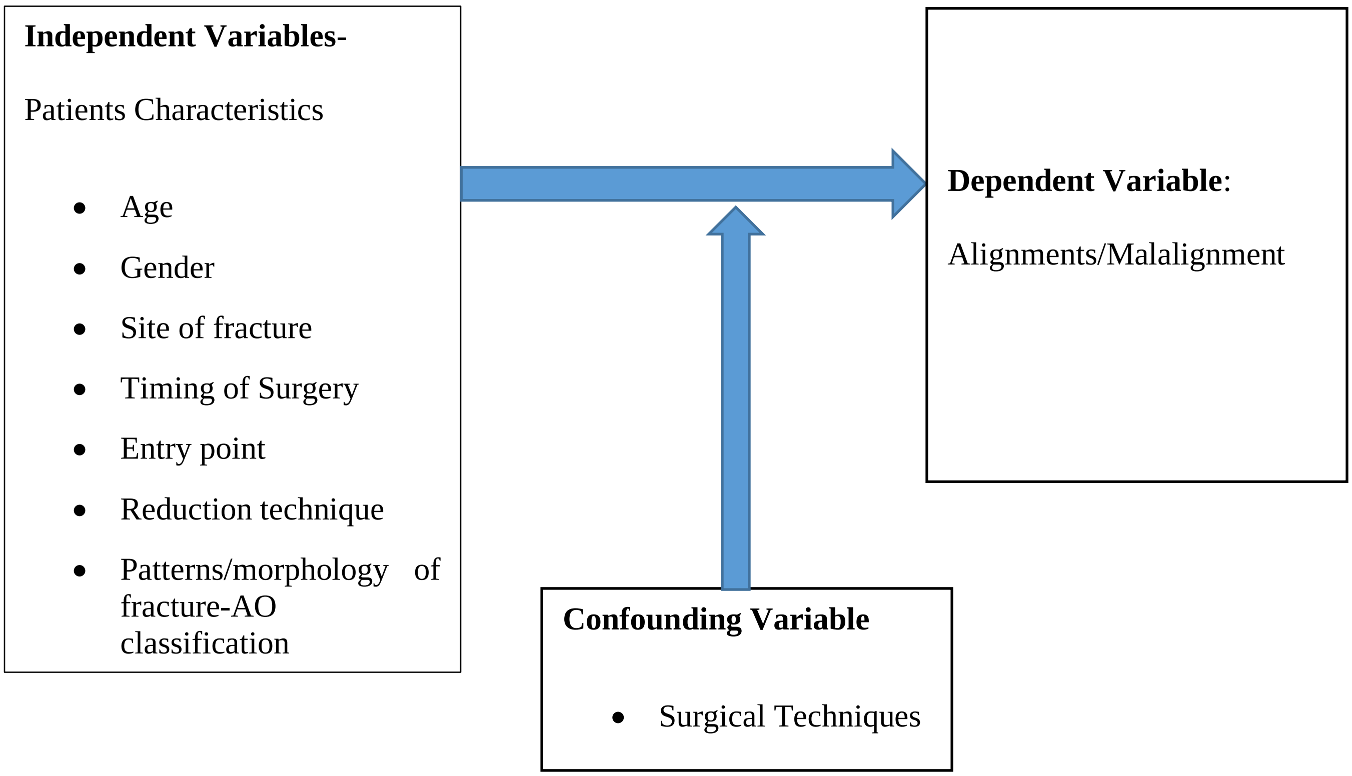
Majority of the problems in IMN of tibial fractures is from the segmental anatomy —the canal is wide on upper and lower segment; forming hourglass appearance. In tibial shaft fractures this is not true, the close touch between the medullary canal and the nail helps in ensuring alignment is well achieved, the metaphyseal anatomy has minimal balance for the bone-nail construct (12).

2.7.3 IMN of distal third diaphyseal tibial fractures

The distal meta-epiphyseal tibial fractures is reported to be 15% of distal tibial fractures (3). When using the IMN the outcome is a solid construct, stable fixed fracture and the incidence of failing and loss of angular alignment are low. Distal tibia fractures nailing is associated with malalignment ranging from 0% to 50% while some studies are at 5%–30%; Valgus deformity being the common residual deformity (73)(74). Most of the literature reports the malaligned distal third tibia to be 3–6 times higher after IMN than after fixation with a plate, however, the tibia being a surface bone with little soft tissue coverage limits open reduction and internal fixation techniques (75)(76)

Various reduction techniques can be used for proper intraoperative reduction: percutaneous reduction clamps limited direct open reduction, traction by means of a femoral distractor, or by the assistant surgeon (77). While inserting the guide wire, you have to ensure it passes at the center of the distal segment without to the cortex in both views when using Image intensifier (78)(79)

2.8 Conceptual Framework



2.9 Problem Statement

Globally, the standard treatment for displace tibial diaphyseal fractures is the reamed IMN. Currently, intramedullary nail fixation is a well outlined and frequently performed surgical procedure by ortho surgeons. Regardless of its acceptance, intramedullary nail fixation of displaced diaphyseal tibial fractures is fraught with difficulties and there are multiple potential challenges such as tibial malalignment. Particularly for proximal third diaphyseal fractures, the deforming forces on the proximal segment are extensor mechanisms extending the proximal fragment (causing apex anterior deformity) and insertion at pes anserine medially (causing valgus). Nail insertion requires that the knee is hyper flexed; thus, deforming forces cause upper-third tibial fractures to orient into valgus and procarvatum.

The slight flexion aids to balance the force of the extensor mechanism on the proximal tibia, hence an apex anterior deformity, thus relaxing the tissues allowing for easier instrumentation in proper alignment. In the distal third diaphyseal tibial fracture, intramedullary nailing is challenging to perform because the diameter of the tibial distal metaphysis is wider than the nail diameter, thus tends to align into valgus angulation. This significantly affects the average sagittal and coronal plane alignment in intramedullary nailing.

2.10 Justification and Significance of The Study

The lower limbs play very important functional roles: stability, upright posture, walking, and other movements. A tibial fracture is the most common long bone fracture encountered all over the world. The effect of postoperative tibial alignment on the clinical and radiographic outcome requires further investigation. Globally, studies have been done on alignment but there are several questions and shortcomings: in measuring technique, (i.e) centering of the x-ray not mentioned in the studies. The design of our tibial nails at KNH is different from other hospitals around the region. The Image Intensifier (II) is not a routine in our center KNH, we use the jig for locking, this is a small shortcoming that needs improvement. A study has not been conducted to evaluate the diaphyseal tibial alignment following intramedullary nail fixation at Kenyatta National Hospital; thus, there is a paucity of data to support tibial alignment and outcomes after intramedullary nail fixation in patients seen at the Kenyatta National Hospital. This would form the basis upon which other studies can be formulated and can as well as be important information in policy formulation. The aim of this study is to determine alignment following diaphyseal tibial nailing at Kenyatta National Hospital.

2.11 Research question

1. What are the common types of diaphyseal tibial alignments among patients post diaphyseal tibial intramedullary nail fixation at KNH?
2. What is the prevalence of coronal and sagittal angulation among patients post diaphyseal tibial intramedullary nail fixation at KNH?
3. What is the association between the entry point of reaming and alignment?
4. What is the relationship between the fracture location/site and the diaphyseal tibial alignment using the AO classification?

2.12. Objectives

2.12.1 Broad Objective

To evaluate diaphyseal tibial alignment following intramedullary nail fixation on patients seen at the Kenyatta National Hospital (KNH).

2.12.2. Specific Objectives

1. To determine common types of diaphyseal tibial alignments among patients post diaphyseal tibial intramedullary nail fixation at KNH;
2. To determine the prevalence of coronal and sagittal angulation among patients post diaphyseal tibial intramedullary nail fixation at KNH;
3. To determine the association between the entry point of reaming and alignment;
4. To determine the relationship between the fracture location/site and the diaphyseal tibial alignment using the AO classification.

2.13 Null Hypotheses

There is no association between the fracture location /site and the diaphyseal tibial alignment.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

This was an Analytical Prospective Cross-sectional study.

3.2 Study setting

Kenyatta National Hospital in Nairobi, a level six National teaching of the University of Nairobi, College of Health Sciences, and referral hospital in the country and East Africa as well located in Nairobi, Kenyan's largest capital city. Kenyatta National Hospital handles a high number of trauma cases admitted in 3 Orthopaedics wards on the 6th floor in the main hospital through A & E. The A & E Department receives emergencies on a 24-hour basis. Most of the patients admitted with tibia fractures are managed operatively in theatres. At KNH, there are three orthopaedics theatres One-Trauma theatre next to the A & E department and two Main theatres within the main hospital.

3.3 Study duration

The study took a period of four months. A census approach was employed with patients being recruited consecutively until the sample size for the study was reached.

3.4 Study population

All patients with diaphyseal tibial fractures admitted to KNH.

3.5 Eligibility criteria

3.5.1 Inclusion criteria

a) Patients with diaphyseal tibial fracture admitted at KNH;
b) A patient presenting with unilateral closed diaphyseal and Gustillo I & II fracture of the tibia;
c) All patients 18 years of age and above;
d) Patients are willing and able to consent to participate in the study voluntarily.

3.5.2 Exclusion criteria

a) Fractures with intra-articular extension
b) Pathological fractures.

3.6 Sample size Calculation

The sample size was calculated as follows (80):

$$N = \frac{{Z_{0.975}}^2 P(1-P)}{\Delta^2}$$

$$N=\frac{1.96^2 \times 0.247(1-0.247)}{0.1^2} = 71.45 \approx 72 \ patients$$

N represents the sample size of the study

P is the proportion of patients with an incidence of malrotation 20 (24.7%) from the latest study (81).

$Z_{0.975}$ is the reliability coefficient, given a 95% confidence level (1.96)

Δ is the precision of the proportion (10%)

N= 72

Therefore, the sample size was 72 patients.

3.7 Sampling procedure:

A convenient sampling technique was used to sample respondents during the study period.

3.8 Recruitment and consenting

Patients were recruited into the study by the principal researcher and two assistants who were clinicians with experience in orthopedic practice. Patients were recruited from KNH wards. An AP and lateral x-rays were done post-operatively for those treated operatively with intramedullary nailing. Written informed consent adopted from the KNH-UoN ERC Participant Information Consent form was administered to eligible respondents.

3.9 Informed consent and consenting procedures

Approval was obtained from KNH to allow for data collection from respondents. Written informed consent was obtained from those enrolled. This was done in a private space provided by Ward to ensure audio and visual privacy and confidentiality. The location of the interview room was in the KNH Orthopedic Ward or elsewhere depending on what was available in the facility at the time of data collection. The interviews were conducted in English or Kiswahili and entered into a questionnaire. Respondents were informed that they had the right to decline participation or withdraw from the study at any point and this would not affect the care they were entitled to at KNH. This guaranteed voluntary participation during the study period.

3.10 Data collection procedure/tool

All patients were assessed post-operatively for alignment/angulation using the same limb's radiographic images of the knee and ankle. We obtained full-length standardized post-operative anteroposterior (AP) and lateral (L) images of the tibia. We took a true AP while the patient was standing on a square piece of sponge, creating a false weight-bearing x-ray-leg internally rotated 15 degrees position, film centered to include knee and ankle joints with visualization of tibiofibular overlap. A true lateral was obtained by ensuring knee and ankle in the lateral position, condyles perpendicular to film, and foot in lateral position; ankles stabilized in the gutter to optimize reproducibility. With the leg held stationary, the x-ray machine unit rotated 90 degrees. Using a two-line method for creating a long axis of tibial bone from proximal and distal fracture fragments cortical ends. We measured the anatomical angle and the Lateral mechanical angle. Radiograph imaging to compare the opposite uninjured limb was taken as described above, measured, and recorded. The point of intersection of the two lines was considered the site of malalignment, and the angle was measured. Furthermore, anything way out of the standardized radiograph in AP was considered malalignment.

As described by Haines et al., fracture gapping was measured at the perimeter of the cortical bone on the anterior, posterior, medial, and lateral cortical projections on the first available post-operative full-length tibia radiograph. Displaced but retained fragments were not considered in the bone gap measurement. All the Fractures were classified using the OTA classification system. Quality of reduction was assessed using the following three parameters: (1) < 10°of angulation in orthogonal radiographic views, (2) < 5 mm of displacement between the major fracture fragments, and (3) < 5 mm of the gap between the major fracture fragments (82).

Measurements were done in the ward, privacy of the patient observed and a chaperone present. Direct measurements of limb length discrepancy clinically were done. Mmeasurements were taken while the patient was in supine position: the pelvis was squared. The two lower limbs were aligned (same orientation). Both limbs, the injured and uninjured, were aligned, measured and recorded in centimetres.

The principal investigator analysed the radiographs using Mediview Web Viewer (3.6.8 version)[1].

The principal investigator and trained research assistants at the Kenyatta National Hospital administered the questionnaire. The questionnaire/Checklist has questions on the patient's socio-demographic factors, the detailed injury mechanism, the age at which the patient was injured, also whether a patient was primarily seeking treatment or referred from another facility. In addition, morphological classification of the fracture was documented as discerned from the radiological investigation and clinical evaluation. Surgical techniques and implants used were also noted.

[1] It is a Java-based web-enabled radiology viewer. Supports image measuring tools including distance, area, angle, etc. Supports side-by-side image comparison and synchronized scrolling between two multi-frame study series.

3.11 Training procedures

Two Research assistants; holders of Diploma in orthopedic trauma surgery from Kenya Medical Training College, underwent 2 (two) days of training on study procedures and the protection of human subjects. Study procedures ensured confidentiality. Human subjects training covered the principles of beneficence, autonomy, and justice in research regarding this study.

3.12 Quality assurance & quality control procedures

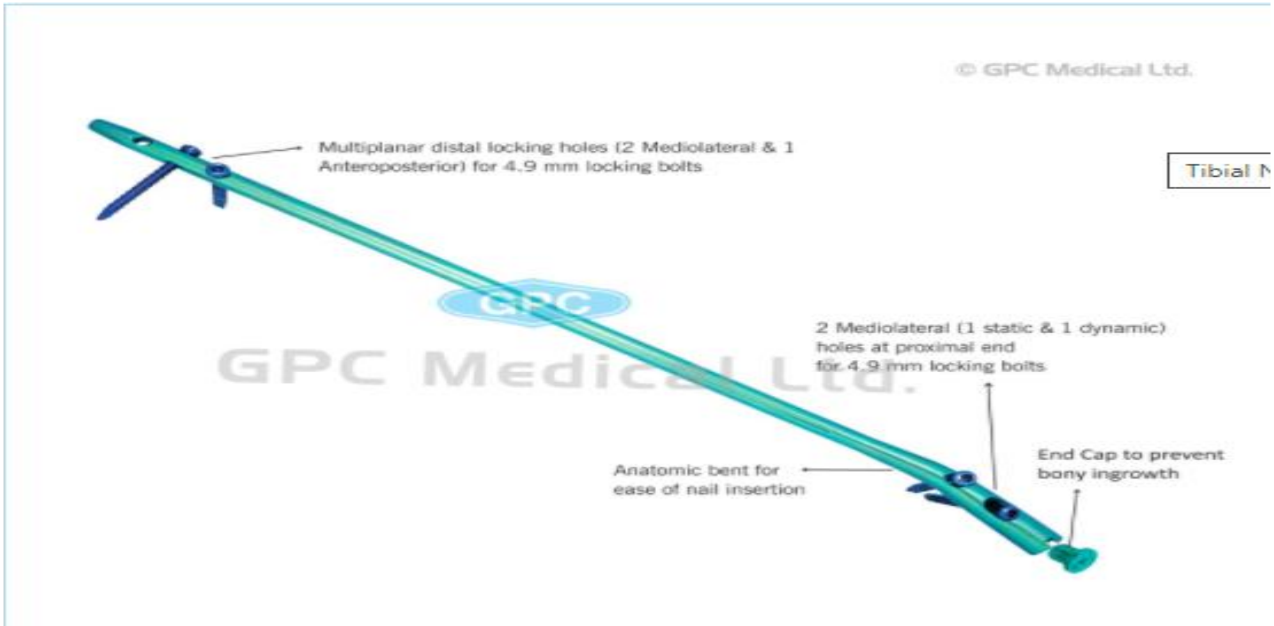
We conducted a pilot study to test the data collection tools for relevance, appropriateness to answer the research questions and adjustments of the data collection tools made as necessary. Quality assurance was maintained throughout the process of data collection. The 2 research assistants participating in the survey were provided with training on data collection. The Principal Investigator reviewed daily for the first 2 weeks all the data collected for accuracy, completeness, and compliance to the research protocol. Thereafter, twice-weekly checks were done during the remainder of the data collection period. Every month, the principal investigator sampled 10% of the collected data and reviewed it for accuracy, completeness, and compliance with the research protocol.

3.13 Nail design

Model No: ITLD09-14

Description: Tibial Nails (Stainless Steel)

Fig 5: GPC/Kemsa Tibial Nails



Features

- Universal nail available in both Titanium and stainless steel
- Superior biomechanical intramedullary stabilization of the tibial fracture
- Distal most screw situated at the distal tip of the nail
- Static and dynamic locking options
- 10-degree Herzog bend in the proximal third of the nail
- Biplanar distal locking options provide rotational stability
- Diameter from 8mm to 14mm
- Length from 22cm to 44cm

3.14 Ethical considerations

3.14.1 Ethical Approval

3.14.1.1 Permits

Ethical permissions were sought from the Department of Surgery, the Orthopaedic section University of Nairobi as well as Kenyatta National Hospital, Ethics, and Research Committee (KNH/UON-ERC) and KNH administration before the commencement and its conducted while observing the law and with respect for the participants. All the participants received a thorough description of the study including the objectives and data to be collected from them and during the surgery. Individual informed consent was sought from all patients who were participating without coercion or bribery.

3.14.1.2 Confidentiality

Any and all the information collected from the research project were kept confidential. Participants were allocated serial numbers that were used to record their individual information as no names were used. All hard copy Information about the participants that were collected during and after the research and were put away under lock and key for five years and no one, apart from the principal researcher, supervisors, statistician, and Ethics & Research board, had access to the database, thereafter destroyed by fire. All the information stored in soft copy was kept secured and password protected.

3.14.1.3 Non-maleficence:

The researcher was responsible for the physical, mental, and social well-being of the research participant and the study did not cause any harm or discomfort to the patient.

3.14.1.4 Beneficence:

The researcher's intentions are of benefit to the patient, ought to do and promote good and reduce the hospital stay for the patients.

3.14.1.5 Justice:

The study results were presented in the Department of Orthopedics of UoN and KNH. Additionally, to be presented in seminars, workshops, abstracts, and used to compile a thesis which shall be available at the University of Nairobi Department of Orthopaedics, as well as the University's Libraries. Manuscripts submitted to reputable peer-reviewed journals with open access for wide readership for publication. The findings shall also be presented in scientific conferences whenever opportunities arise.

3.14.1.6 Recruitment and consenting

After obtaining ERC approval, data were gathered from patients who consent to use the data collection tool. Patients were recruited into the study by the principal researcher and two assistants: - clinicians with experience in orthopedic practice. The principal researcher and/or his research assistants reviewed the patient's checking for eligibility of being recruited into the study. Those that meet inclusion criteria were recruited into the study. There will be no coercion to participate.

3.15 Data analysis and management

Data were cleaned and entered on an MS access database then exported to SPSS Version 23.0 for data analysis. Descriptive statistics (Measures of central tendency and dispersions) will be computed for continuous variables, i.e., age, and frequency and percentage will be used for categorical variables, i.e., gender, site, side type of fracture. The common types of tibial alignments were analyzed using proportions. The prevalence of angulation were calculated by dividing the number of new cases with malalignment by sample size (n) multiplied by constant (k e.g.,100). The association between the entry point for reaming and the center of IMN placement were analyzed using the Student T test for association. The association between fracture location and alignment was analyzed using Chi square test of independence. Fracture patterns were classified using AO/OTA classification. Statistical significance was determined using an alpha of 0.05 at a 95% confidence interval. A p-value of less than 0.05 was said to be statistically significant hence rejecting the null hypotheses.

3.16 Study results dissemination plan

The study results were presented in the Department of Orthopedics of UoN and KNH. Additionally, presented in seminars, workshops, abstracts, and used to compile a thesis which shall be available at the University of Nairobi Department of Orthopaedics, as well as the University's Libraries. Manuscripts submitted to reputable peer-reviewed journals with open access for wide readership for publication. The findings shall also be presented in scientific conferences whenever opportunities arise.

3.17 COVID -19 safety measures

The lead researcher ensured that all members of his research team were trained on all aspects of COVID-19 infection prevention and adhere to the provided protocols and guidelines by MOH. Proper and adequate personal protective gear: i.e gloves, hand sanitizers, N95 masks, and face shields/goggles were provided for all members of the research team during data collection.

CHAPTER FOUR

RESULTS

4.1 Response rate

A sample size of 72 patients was targeted. The number of respondents recruited was 72, making a response rate of 100%. All patients' measurements were accounted for in the statistical analysis.

4.2 Characteristics of the study participants

The age of respondents in our study ranges from 19 and 59 years; 31years and 6 months was the mean age (95% CI; 29.5 to 33.5). Figure 6 illustrates the respondents age at presentation.

Most of the patients who responded were male (n=66; 91.7%). The skin status of all the clients was intact i.e., none of the patients had blisters. Majority of the patients (n=48; 66.7%) had open fractures and 24 (33.3%) closed fractures. Using AO fracture classification, two thirds of the respondents (n=49; 68.1%) had Middle level of fracture, 17 (23.6%) had Lower Level while only six (8.3%) had Upper level. Figure 7 shows the means of age based on location of injury.

Figure 6: Age distribution

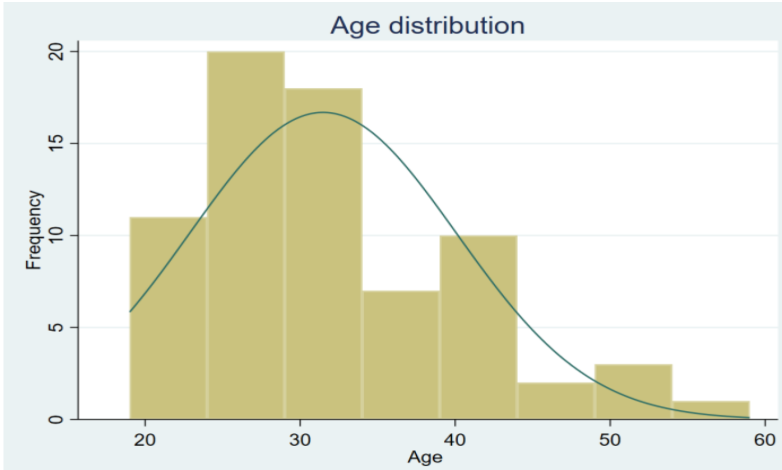
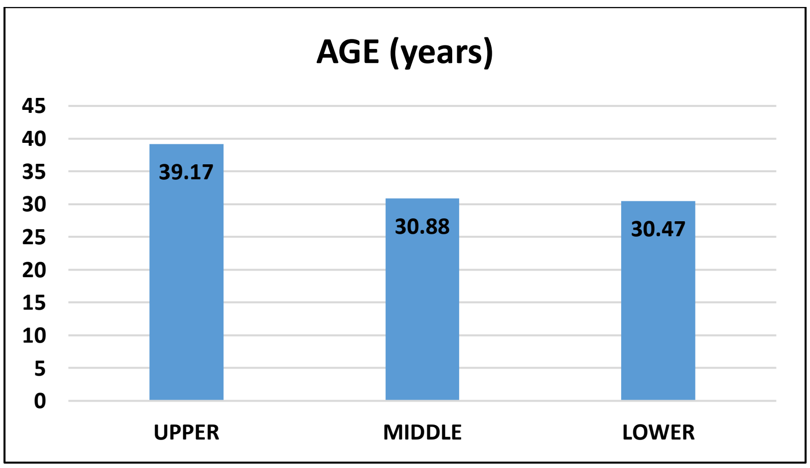


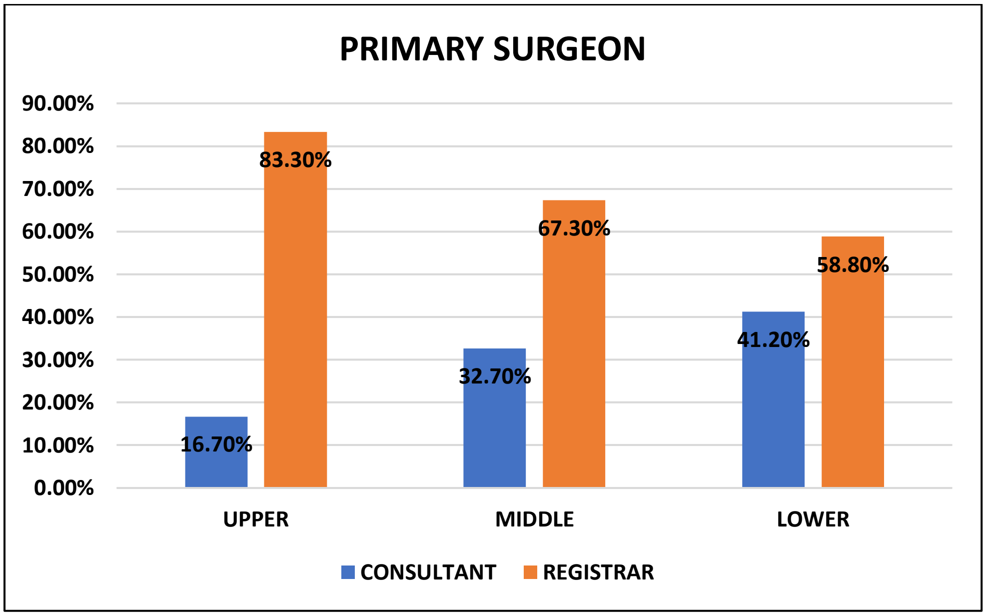
Figure 7: Means of age based on location of injury.



Approximately 42% (n=30) of the respondents had simple transverse fractures (42A3), 31% (n=22) sustained oblique fractures (42A3) and 17% (n=12) comminuted fractures (42B3), complex segmental 4(5.6%), (42A1) simple spiral 4(5.6%). Approximately 92% (n=66) had fibula fractured but not Plated, with 7% (n=5) being intact and only one patient presented with fibula fracture and plated (FLP). Males were more likely to have fractures

(92%) than females (8%). Two thirds (n=48; 66.7%) were attended by Registrars while a third (n=24; 33.3%) were attended by the Consultants as shown in figure 8 below.

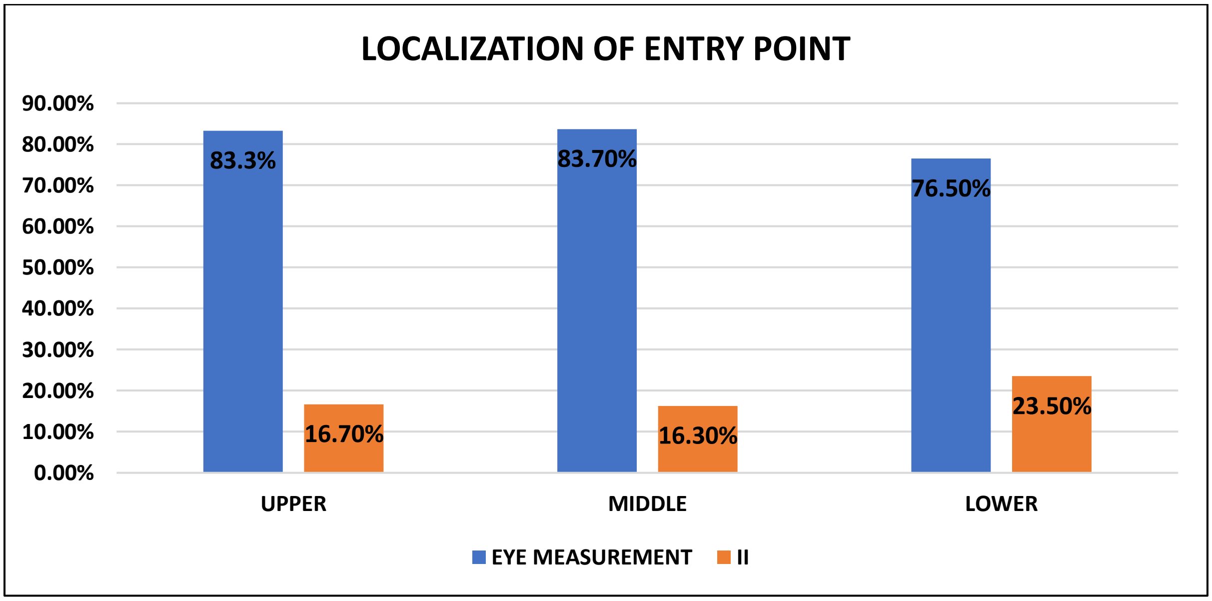
Figure 8: Experience of the surgeon



Majority of the patients (n=49; 68.1%) underwent a closed surgical procedure while the rest underwent open surgical procedure. Localization of the entry point was through eye balling in approximately 82% (n=59) of the cases, the others were through Image intensifiers (fluoroscopy). In the eyeballing technique based on location of fracture, after making an incision representation was as follows: upper tibial fracture 5(83.3%), middle tibial fracture 41(83.7%) and lower tibial fracture 13(76.5%).

Using image intensifier and basing on location of fracture, representation was as follows: upper tibial fracture 1(16.7%), middle tibial fracture 8(16.3%) and lower tibial fracture 4(23.5%) as illustrated in figure 9 below.

Figure 9: Localization of entry point



Gravity and manual traction as a method of achieving reduction was used in approximately 96% (n=69) of the cases. Only 4% (n=3) underwent minimum opening as a method of achieving reduction. The most preferred method of maintaining the reduction was Gravity and manual traction at 68.1% (n=49). Manual traction, gravity and clamping was used in 31.9% (n=23) of the cases. The most utilized nail sizes for fracture reduction were 36*10mm (38.9%), 34*10mm (37.5%), and 36*11mm (13.9%). Nail size 36*9mm was used in 4.2%, nail size 34*9mm in 2.8% and nail size 34*11mm and 32*10mm in 1.4% each. In 58.3% (42) of the cases, a reaming diameter of 2mm was used. A reaming diameter of 1mm was done in 25 (34.7%) cases. A reaming diameter of 3mm was used in minority (n=5; 6.9%) of the cases. Other surgical interventions done were; debridement (n=43; 59.7%), IMN (n=1; 1.4%) & Fibula Plating (n=1; 1.4%). The average gap of the cortices was calculated from the average difference between the anterior, posterior and lateral measurement and was noted to be 1.17 mm (95% CI: 1.04 to 1.29). Table 4.1 displays the summary of the descriptive statistics.

Table 1: Patient's age

Variables	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Error**	**SD**	**95% Confidence Interval**	
							Lower	Upper
Age in years	72	19	59	31.47	1.014	8.606	29.5	33.5
Gap of the cortices - Average (mm)	72	0.27	2.28	1.1661	0.06232	0.52877	1.04	1.29

Table 2: Characteristics of the study participants

		Frequency	Percent
Gender	Female	6	8.3
	Male	66	91.7
Skin Status	Intact	72	100
	Blisters	0	0
Fracture Morphology	Open	48	66.7
	Closed	24	33.3
Level	Middle	49	68.1
	Lower	17	23.6
	Upper	6	8.3
Fracture pattern	Simple	30	41.7
	Oblique	22	30.6
	Spiral	4	5.6
	comminuted	12	16.7
	Segmental	4	5.6
Fibula status	Fractured Level Plated (FLP)	1	1.4
	Intact	5	6.9
	Fractured Level Not Plated (FLNP)	66	91.7
Primary surgeon	Registrar	48	66.7
	Consultant	24	33.3
Surgical procedure	Open	23	31.9
	Closed	49	68.1
Localization of entry point	Eye Balling	59	81.9
	Image Intensifier	13	18.1
Method of achieving reduction	Gravity, manual Traction	69	95.8
	Minimum Opening	3	4.2
Method of maintaining reduction	Manual traction, Gravity and Clamping	23	31.9
	Manual traction and Gravity	49	68.1

Nail size	36 x 11mm	10	13.9
	34 x 10mm	27	37.5
	36 x 10mm	28	38.9
	34 x 9mm	2	2.8
	34 x 11mm	1	1.4
	36 x 9mm	3	4.2
	32 x 10mm	1	1.4
Reaming Diameter	1mm	25	34.7
	2mm	42	58.3
	3mm	5	6.9
Other Surgical Interventions	Debridement	43	59.7
	IMN	1	1.4
	None	27	37.5
	Fibula Plating	1	1.4

4.3 The common types of diaphyseal tibial alignments among patients post diaphyseal tibial intramedullary nail fixation

Only 6.9 % of the patients had malalignment. This was determined by comparing the injured limb with the uninjured limb. A discrepancy of 2mm and above was considered as a malalignment. Figure 10 below displays proportion of patients with aligned and malaligned fractures.

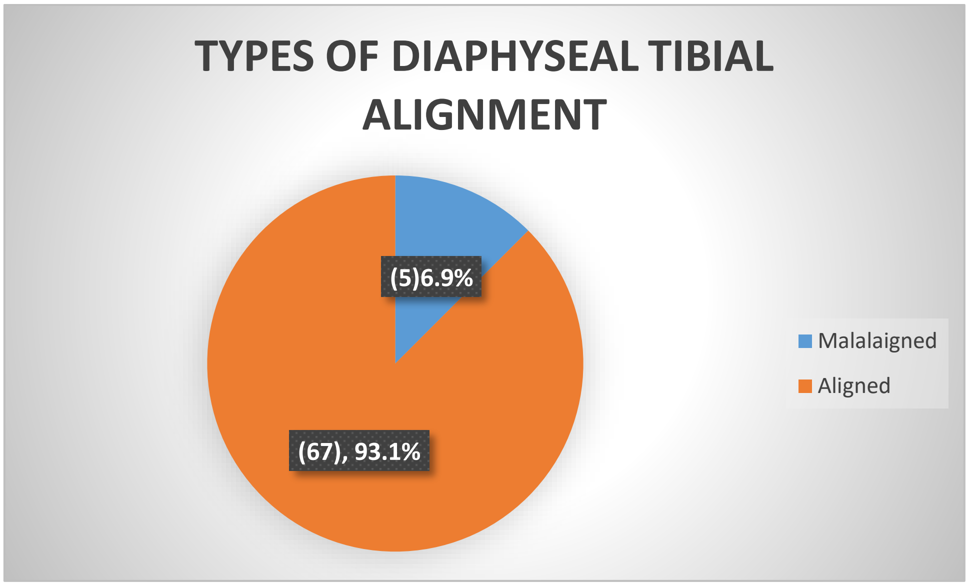


Fig 10: Types of diaphyseal tibial alignment

4.4 Prevalence of coronal and sagittal angulation among patients post diaphyseal tibial intramedullary nail fixation

Undesirable angulation was measured by angulation greater than 10 degrees of coronal view and greater than 5 degrees of angulation in the sagittal view.
There was no displacement shown as per the measure of coronal angulation.

We reported a sagittal displacement in 1.4% of the cases.

4.5 Association Between the Entry Point of Reaming and Alignment

We report no statistically significant in association between the entry point of reaming and the alignment (p-value = 0.362). With every increase of one millimeter in diameter of the entry point of reaming, the reduction was 1.8 times (95% CI: 0.513 to 6.206) more likely to be aligned. Hence, the increase in the entry point reaming diameter was not associated with the alignment.

Table 3: Association between the Entry Point of Reaming and Alignment

	B (Beta)	Standard Error	Wald	Degree of freedom	Sig.	Odds Ratio	95% C.I. for Odds Ratio	
							Lower	Upper
Reaming Diameter	0.579	0.636	0.829	1	0.362	1.785	0.513	6.206
Constant	0.99	1.066	0.863	1	0.353	2.692		

4.6 Relationship Between the Fracture Location/Site and the Diaphyseal Tibial Alignment Using the AO Classification

This study reported no statistically significant in association between the fracture site/ level and the alignment by using AO classification/ Fracture pattern (P-value 0.471).

Table 4: Relationship between the Fracture Location/Site and the Diaphyseal Tibial Alignment Using the AO Classification

		Fracture Site/level			Total	Fischer's exact
		Middle	Lower	Upper		P-Value
Fracture pattern/ AO Classification	**Simple**	21	7	2	30	0.001
	Oblique	13	5	4	22	
	Spiral	2	2	0	4	
	Comminuted	9	3	0	12	
	Segmental	4	0	0	4	
Total		49	17	6	72	

CHAPTER FIVE

5.0 DISCUSSION

Diaphyseal tibial alignment is an important measure of outcome and effectiveness of surgical intervention following intramedullary nail fixation. This study was aimed at investigating the alignment level; aiming to identify gaps in management of patients with tibial fractures. Moreover, we sought to establish the prevalence of coronal and sagittal angulation in patients post diaphyseal tibial intramedullary nail fixation as well as the relationship between the fracture site and the diaphyseal tibial alignment using the AO classification.

5.1 Response rate

The number of the respondent was at 100%.

5.2 Characteristics of the study participants

The outcome of this research showed that; 31 years was the mean age of patients and 29 years the median. This implies that younger patients are routinely affected by these kinds of injuries. In a study by Wanjema S et al, 2020, conducted in Moi University indicated a median age of 28 years. Thus, there appears to be a similarity in the age of presentation across the country as indicated by these two studies. In addition, a study outside Kenya by Grutter et al, in 2000 (83) demonstrated a varying age with younger patients, 20 – 30 years being more affected.

A study by Wanjema S (2019) demonstrated a ratio of male to female involvement as 3.2:1. However, findings of this study showed a male to female ratio of 11:1. Thus, men appear to be generally affected by the tibial fractures. More men are involved in RTA which has been shown to be a leading cause of diaphyseal tibial fractures. This occurs due to more men being involved as motorist. Other mechanisms of injuries documented in literature include falls, assaults, sports and gunshot injuries.(84)

On the other hand, the findings of this study indicate that majority of fractures were open fractures, 48 (66.7%) and minority were closed fractures, 24 (33.3%). This contradicts the recent findings in literature which show that closed fractures were majority at 59.1% compared to open at 40.9% (85). The probable reason for this contradiction is the nature of the study design, where patients in our study were undergoing surgical intervention for the diaphyseal tibial fractures thus likely to have an open wound unlike the comparative study by Wanjema which prospectively looked at patients undergoing overall treatment for diaphyseal tibial fractures (84).

5.3 The common types of diaphyseal tibial alignment among patients post diaphyseal tibial intramedullary nail fixation

Adequate alignment was achieved in 93.1% of the cases compared to 6.9% of cases where there was no adequate alignment. In all the cases of malalignment, shortening was the main contributor of malalignment as compared to coronal and sagittal angulation. A study by Freedman EL et al, 1995, demonstrated a malalignment rate of 12% of patients who underwent intramedullary nailing of diaphyseal tibia fractures (13). Midshaft fractures were not affected by malalignment compared to upper third and lower third. This association was significant at p value 0.001. This shows that if surgeons were to use image intensifier, they can focus the resources to fractures of upper third and lower third which nevertheless occurred in a lesser frequency. This would help optimize the utilization of fluoroscopy in the hospital. Contemporary literature demonstrates high rates of malignment of upper and distal third (13). In the Freedman et al, 1995, study, out of 16 cases with malalignment, 58% were proximal third, 7% middle third and 8% lower third. Such findings mirror our findings that fractures of upper and distal third are most affected by malalignment. The authors recommended a meticulous attention to detail in operative technique and also taking into consideration the entry angle for proximal third or comminuted fractures. However, in our series, there were no cases of malalignment of the middle third fractures (13). Another study by Lang G et al al 1995, similarly demonstrated unacceptable levels of malalignment in treatment of proximal third fractures with locked intramedullary nails (10).

5.4 Prevalence of coronal and sagittal angulation among patients post diaphyseal tibial intramedullary nail fixation

We reported only 1.4% of angulation malalignment in sagittal plane. This demonstrates that despite the unavailability of fluoroscopy, surgeons in the local hospital are able to achieve adequate alignment of most of the diaphyseal tibial fractures. Guichet et al and Ryan et al found limb length discrepancy incidence of 14% from both the femur or tibia diaphyseal fractures managed operatively (68). A recent study by baker et al reported no significant in displacement, angulation, or gapping in respect to part of the segment fractured (85).

Out of 32 patients, 27 (84%) had angulation of more than 5 degrees in the frontal or sagittal plane. The authors found that the principal cause of malalignment was surgical technical errors (10). The authors in this study went ahead to advocate for usage of other ways of fixation (plate or fixation) rather than intramedullary nailing for treatment of proximal third fractures (10). Alternative techniques advocated for in fixation of upper third fractures to avoid malalignment include the use of blocking screws, medial plating and also proximal interlocking bolts placement while extending the knee. The extension position is hypothesized to remove the effect of extensor mechanism on fracture angulation (86),(87). Recommended further in upper third fractures, are the new designs of nail which have multidirectional locking options (54).

For distal third fractures, there is generally no clear agreement on its fixation amongst surgeons however, some choose to fix the fibula first with AO technique, lag screws and neutralization plating (88). It is argued that with fibula fixation, it is easier to fix the tibial fracture with less worries about the sagittal angulation of the tibia due to shortening of fibula (67).

5.5 Association between entry point of reaming and alignment

In all the cases done, the primary and consultant surgeon used transpatellar access. Localization of entry point was largely carried out through the eyeballing technique in 59(82%) of the cases compared to use of Image intensifier in 13(18%) of cases. Localization of entry point was largely carried out through the eyeballing technique in 82% of the cases compared to use of Image intensifier in 18% of cases. Despite using an eyeballing technique to localize the entry point, average point for the aligned tibia was at 2.27mm and malaligned cases at 2.93mm. All this were within the acceptable and normal reported entry point. Hernigou P & Cohen D revealed that 2.5mm (+/-1.8mm) while Tornetta et al found that its approximately 2.29 mm (56),(89).

The unavailability of fluoroscopy equipment at the national referral hospital is a key contributor to the increased usage of eyeballing technique. Reduction of fractures was largely achieved by manual traction and gravity and maintained by traction, gravity and clamping. This is explained by lack of adequate equipment to achieve this task in the local set up.

5.6 Relationship between the fracture site and the diaphyseal tibial alignment using the AO classification

According to the AO classification of fractures, two thirds of the respondents (n=49; 68.1%) had Middle level of fracture, 17 (23.6%) had Lower Level while only six (8.3%) had Upper level. Approximately 42% (n=30) of the respondents had simple transverse fractures (42A3), (42A1) simple spiral 4(5.6%), 31% (n=22) sustained oblique fractures (42A3), 17% (n=12) comminuted fractures (42B3), complex segmental 4(5.6%). This pattern follows what is reported in literature where simple transverse fractures are most common (85).

The middle third fractures were the most prevalent, followed by the upper third and least prevalent were lower third. Other literature has demonstrated similar patterns of location of the diaphyseal tibial fractures This may be as a result of mechanisms involves such as RTA having a direct impact on the mid diaphysis (85).

Alignment was unaffected by the reaming entry point as evidenced by p value of 0.471. This demonstrates the proficiency of the eyeballing technique in achieving adequate reduction in majority of these fractures. However, medial entry point of nailing has been shown to result in unfavorable outcomes (54).

CONCLUSION

Tibial fractures are common and mostly affect young males. Open fractures are the most prevalent in this hospital with simple transverse and simple oblique patterns being the most common patterns of occurrence. Most of these fractures involve the middle third of tibia.

Many of open diaphyseal fractures Gustillo I and II can be managed with IMN after undergoing a first thorough debridement or in the same sitting.

Eyeballing technique, manual traction and gravity was the most common method used in achieving alignment. All fractures of the middle third achieved adequate alignment yet some of the fractures in the lower third and upper third did not achieve adequate alignment.

5.7 Recommendations

The utilization of image intensifier for intraoperative reduction and alignment can be allocated to fractures of the upper and lower third whereas middle third fractures do not necessarily need use of Image intensifier since eyeballing technique achieves adequate reduction. This would help in resource management in a hospital where fluoroscopy resources are scarce.

Adoption of newer implant designs and fixation techniques is recommended to reduce the incidence of diaphyseal fractures malalignment. This would be most beneficial in the fractures of proximal and distal third.

Further studies are required in addressing the long-term impact of eyeballing and fluoroscopy techniques in achieving adequate alignment, magnitude of limb length discrepancy and assessing the prevalence of malunion after diaphyseal tibial fractures treatment. Further evaluation of better implants and fixation techniques is similarly recommended to reduce the incidence of malalignment.

Lower limb discrepancy occurs in fractures of tibia despite fixation and should be given attention it deserves. Long term effect of mild asymptomatic discrepancy should be looked into appropriately. The outcome will form a core base for instilling appropriate treatment based on severity, age, level of physical activity and co-morbidities.

5.8 Limitations

Our limitation was a sample smaller size of 72 participants. Thus, inability to adequately assess the prevalence of malalignment especially in the middle third fractures. single-centre study.

This was a single-centre study and given the numbers of patients was small, than would be available in a long duration or do a multicentered study to cater for the numbers, also most of the patients with closed diaphyseal fractures opted to be managed conservatively.

Long-term follow-up was lacking in our study, which limits assessing the long-term effects of the treatment and comparing the eyeballing technique to usage of fluoroscopy in management of these fractures. Future studies can aim to address the issue of follow-up until union occurs with measurement taken in the follow-up visits. Patients follow up with radiographs at 2 weeks, 4 weeks, 3 months, 6 months, 9 months, and 12 months and after union as the last follow-up visit; since this study was assessing immediate postoperative malalignment and not loss of alignment or functional outcome over a period of time.

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APPENDICES

Appendix 1: Consent Information

PART I: CONSENT INFORMATION DOCUMENT

The informed consent is for the patients who are admitted at KNH Orthopaedic wards scheduled to undergo orthopaedic surgery: - tibial intramedullary nailing during the study period.

Title of the study: Evaluation of tibial alignment following intramedullary nail fixation at KNH.

My name is Dr. Athuman Mohamed Abdallah, a postgraduate student in the Department of Orthopaedic Surgery at the University of Nairobi. I am conducting a study on evaluation of diaphyseal tibial alignment following intramedullary nail fixation in patients with unilateral tibial fracture at the Kenyatta National Hospital. This is a prospective descriptive cohort study.

Study benefits

• The findings of this study may not be of direct/immediate benefit to you but may help in management decisions for future patients.

• All the questions you will be asked in the study and the subsequent physical examination are part of the management process of your injuries. Refusal to participate in the study will not affect the quality of your treatment in any way.

• There will be no financial benefits for participating in this study. You will also not incur any extra financial costs for participating in this study. The information obtained will be used for research only.

• The findings in this study will provide data for health planning, improvement in the management of tibial fracture, less hospital stay, and overall better quality of life thus helping inform the future standard of care for orthopedic patients.

Inconvenience, risks, and right of withdrawal from the study

• You may experience inconvenience due to the personal questions in the interview.

•You may decide to opt-out of the study at any time, temporarily or permanently as your involvement in the study is purely voluntary. This will not affect the quality of your treatment in any way.

• There are no dangers or risks associated with participating in this study.

• If you accept to participate, you will be asked to provide personal information. You will also be interviewed by the research assistant (medical officer) or myself; Dr. Athuman Mohamed (Primary Investigator).

Confidentiality

•Strict confidentiality and privacy of the patient participating in this study shall be maintained. The questionnaire will not bear your name and all the data obtained shall be securely stored. The information about you will only be identified by a study number.

• We will seek to share our findings with other people undertaking similar studies. Any publication of our findings in scientific journals or presentations in scientific meetings will have no information that can identify you. Your identity will not be revealed in any publication.

Questions and choices

• Any questions you may have may be addressed to the principal investigator via the contact information provided below. Your participation in the study is voluntary. You may choose to decline to participate or withdraw your participation from the study at any time without any repercussions.

PART II: CONSENT CERTIFICATE

I…...…………………………………………………………………………… freely give consent of myself to take part in the study conducted by Dr. Athuman Mohamed, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to me. The results of the study may not directly be of benefit to me and may assist in the management of future patients undergoing orthopaedic surgery.

Signature/Thumbprint of (participant)…………………. Date: ……………….

Statement by the witness if participant illiterate:

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

Name of witness: ……………………………………………………………………..……

Signature of witness: ………………………. Date: ……………………………….

Thumbprint of the participant if illiterate

(Witness must sign below)

PART III: STATEMENT OF THE RESEARCHER/PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of

my ability made sure that the participant understands what the research is all about.

• Refusal to participate or withdrawal from the study will not in any way compromise

the quality of treatment.

• All information given will be treated with confidentiality.

• The results of this study might be published.

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

A copy of this document has been provided to the participant.

Name of Researcher taking consent: …………………………………………..

Signature of the researcher taking consent: ….…………………………………….

Date: ………………………………………

STUDY CONTACTS:

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SEHEMU I: HATI YA HABARI ZA MAJALI

HABARI YA IDHINI

Idhini ya habari ni kwa wagonjwa ambao wanawasilishwa kwa KNH A&E, wodi za Mifupa au ICU / HDU waliopangiwa kufanyiwa upasuaji wa mifupa wakati wa kipindi cha utafiti.

Mada ya utafiti: Tathmini ya unyooshaji sahihi na utengenezaji wa mfupa wa mguu kwa wagonjwa wanaofanyiwa upasuaji na kuwekwa chuma baada ya kuvunjika katika Hospitali ya Kitaifa ya Kenyatta.

Jina langu ni Dk Athuman Mohamed, mwanafunzi wa uzamili katika Idara ya upasuaji wa Mifupa katika Chuo Kikuu cha Nairobi. Ninafanya utafiti ili kubaini unyooshaji sahihi na utengenezaji wa mfupa wa mguu kwa wagonjwa wanaofanyiwa upasuaji na kuwekwa chuma baada ya kuvunjika katika Hospitali ya Kitaifa ya Kenyatta.

Faida za Utafiti

• Matokeo ya utafiti huu hayawezi kuwa ya faida ya moja kwa moja / ya haraka kwako lakini inaweza kusaidia katika maamuzi ya matibabu kwa wagonjwa wa baadaye.

• Maswali yote utakayoulizwa katika utafiti na uchunguzi wa mwili unaofuata ni sehemu ya mchakato wa matibabu yako. Kukataa kushiriki katika utafiti haitaathiri ubora wa matibabu yako kwa njia yoyote.

• Hakutakuwa na faida za kifedha kwa kushiriki katika utafiti huu. Pia hautapa gharama zozote za kifedha kwa kushiriki katika utafiti huu.

Habari iliyopatikana itakuwa kutumika kwa utafiti tu.

• Matokeo katika utafiti huu yatatoa data kwa upangaji wa afya, uboreshaji wa matumizi ya bidhaa za damu na damu, na kusaidia kuarifu kiwango cha matibabu wa siku zijazo kwa wagonjwa wa mifupa.

Usumbufu, hatari na haki ya kujiondoa kwenye utafiti

• Unaweza kupata usumbufu kwa sababu ya maswali ya kibinafsi kwenye mahojiano.

• Unaweza kuamua kutoka kwenye utafiti wakati wowote, kwa muda mfupi au kabisa.

Kushiriki katika utafiti ni kwa hiari tu. Hii haitaathiri ubora wa matibabu yako kwa njia yoyote.

• Hakuna hatari au hatari zinazohusiana na kushiriki katika utafiti huu.

• Ukikubali kushiriki, utaulizwa kutoa maelezo ya kibinafsi. Pia utahojiwa na msaidizi wa utafiti (afisa wa matibabu) au mimi mwenyewe; Dkt. Athuman Mohamed (Mchunguzi wa Msingi).

Usiri

• Usiri mkali na faragha ya mgonjwa anayeshiriki katika utafiti huu utadumishwa.

Hojaji haitachukua jina lako na data zote zilizopatikana zitapatikana kuhifadhiwa salama. Habari juu yako itatambuliwa tu na nambari ya utafiti.

• Tutanuia kushiriki matokeo yetu na watu wengine wanaofanya tafiti kama hizi.

Uchapishaji wa matokeo yetu katika majarida ya kisayansi au mawasilisho katika mikutano ya kisayansi haitakuwa na habari inayoweza kukutambulisha. Utambulisho wako hautafunuliwa katika chapisho lolote.

Maswali na uchaguzi

• Maswali yoyote ambayo unaweza kuwa nayo yanaweza kushughulikiwa kwa mchunguzi mkuu kupitia njia ya mawasiliano iliyotolewa hapa chini. Ushiriki wako katika utafiti ni wa hiari. Wewe unaweza kuchagua kukataa kushiriki au kuondoa ushiriki wako kutoka kwa utafiti huuwakati wowote bila athari yoyote.

SEHEMU YA II: CHETI CHA KUKUBALI KUSHIRIKI KATIKA UTAFITI,

HATUA YA UKUBALI.

Mimi, …………………………………………… (Jina kamili kwa herufi kubwa)

nimepeana ridhaa ya mimi kushiriki katika utafiti uliofanywa na Dkt Athuman Mohamed, asili ya ambayo nimeelezwa na yeye / msaidizi wake wa utafiti. Nimearifiwa na nimepata kuelewa ya kwamba kushiriki kwangu ni kwa hiari yangu na nikipenda naweza kujiondoa wakati wowote katika utafiti huu bila kuadhiri na hii haitabadilisha kwa njia yoyote matibabu ninayopewa..Matokeo ya utafiti huu huenda yasinifaidi kibinasi kwa sasa lakini Habari itakayopatikana itasaidia kupata njia nzuru zaidi za kupunguza, kuzuia na kutibu majeraha ya mifupa yanayotokana na ajali na pia kusaidia katika matibabu ya wagonjwa wa baadaye wanaofanyiwa upasuaji wa mifupa.

……………………………………… ..

Saini / Uchapaji wa kidole gumba wa (mshiriki)

Tarehe: ………………………………….

Sehemu III: Kauli ya shahidi ikiwa hiriki hajui kusoma na kuandika:

Nimeshuhudia usomaji sahihi wa fomu ya idhini kwa mshiriki, na binafsi.

Nimepata nafasi ya kuuliza maswali.

Ninathibitisha kwamba mgonjwa huyo ametoa idhini kwa hiari yake.

Jina la shahidi: …………………………………….

Saini ya shahidi: …………………… Tarehe: ………………………

Uchapishaji wa kidole gumba cha mshiriki.

MAWASILIANO

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WASIMAMIZI WA UTAFITI CHUO KIKUU CHA NAIROBI: -

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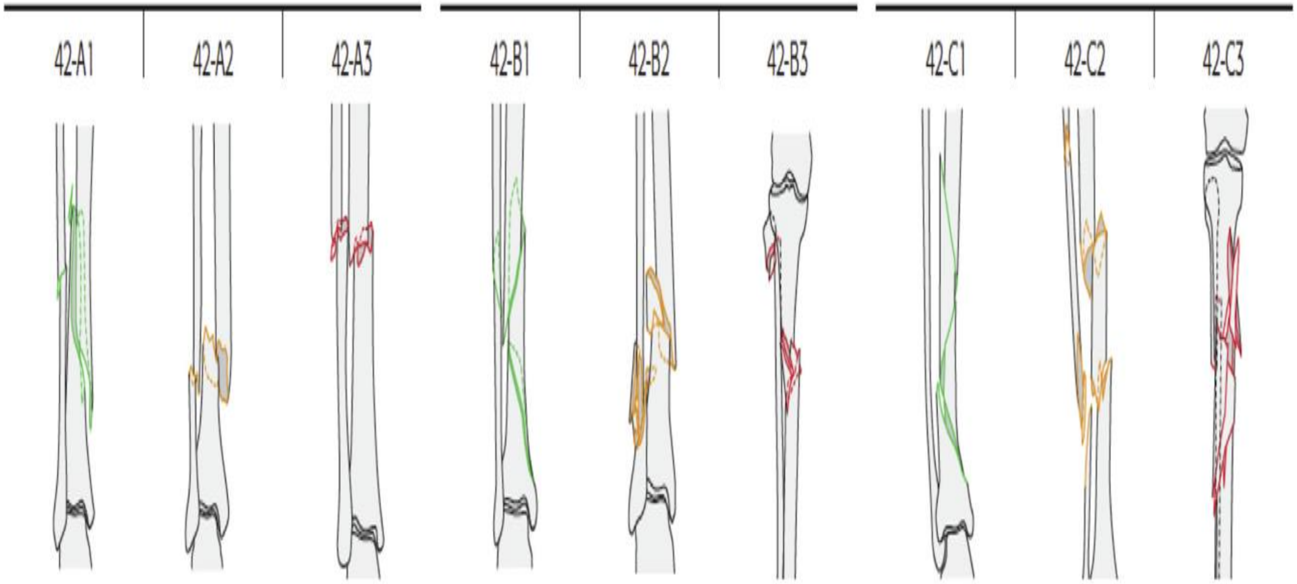
Appendix 2: AO/OTA classification of tibial diaphyseal fractures.(100)

42 diaphyseal



42-A simple fracture

42-A1 spiral

42-A2 oblique (≥ 30°)

42-A3 transverse (< 30°)

42-B wedge fracture

42-B1 spiral wedge

42-B2 bending wedge

42-B3 fragmented wedge

42-C complex fracture

42-C1 spiral

42-C2 segmental

42-C3 irregular

OTA Classification	Subgroups	Open	Closed	n(%)
Unifocal-A	Spiral			
	Oblique Transverse			
Wedge-B Type	Intact spiral wedge			
	Intact bending wedge			
	Comminuted wedge			
Complex-C Type	Spiral wedge Segmental			
	Comminuted			

Appendix 3: Gustilo Anderson Classification(101).

Gustilo and Anderson classification	
Grade I	Clean skin opening of <1 cm, usually from inside to outside; minimal muscle contusion; simple transverse or short oblique fractures
Grade II	Laceration >1 cm long, with extensive soft tissue damage; minimal to moderate crushing component; simple transverse or short oblique fractures with minimal comminution.
Grade III	Extensive soft tissue damage, including muscles, skin and neurovascular structures: often a high energy injury with severe crushing component.
Grade IIIA	Extensive soft tissue laceration, adequate bone coverage; segmental fractures, gunshot injuries, minimal periosteal stripping.
Grade IIIB	Extensive soft tissue injury with periosteal stripping and bone exposure requiring soft tissue flap closure ;usually associated with massive contamination
Grade IIIC	Vascular injury requiring repair.

Appendix 4: Tscherne classification of tibial soft tissue injuries(102).

Tscherne classification	Description
Type 0	Minimal soft-tissue damage due to an indirect mechanism of injury and a simple fracture
Type 1	Superficial abrasion or soft-tissue contusion due to pressure from the bone injury and a mild to moderately severe fracture pattern
Type 2 A	deep and contaminated abrasion with local skin and muscle contusion, an impending compartment syndrome, and a high-energy fracture pattern
Type 3	Extensive skin contusion, severe muscle damage, compartment syndrome, and a severe fracture pattern

Appendix 5: Data Collection Sheet

a) **PATIENT DATA**

a) Study number…………………………
b) Age in years ……………………………………………………
c) Sex M ………… F ……...
d) Date of admission ………………. Time of admission ………………………
e) Date of injury ……………………
f) Ward …………………………………………
g) Surgery to be performed……………………..

b) PRE-OPERATIVE PATIENT DATA

a) Date of surgery……………………………………...
b) Skin Status before surgery
   a. Intact
   b. Blister formation

c) FRACTURE MORPHOLOGY

a) Open ☐ Closed ☐

b) Levels: Upper 1/3☐ Mid 1/3☐ Lower 1/3 ☐

d) FRACTURE PATTERN

Simple………. Oblique…………. Spiral………… Comminuted……….

Segmental……….

e) STATUS OF FIBULA

i. Intact- ………………….
ii. Fractured, level and plated- …………...
iii. Fractured, level, and not plated…………

f) Primary Surgeon

a. Consultant…..

b. Registrar……

g) Surgical procedures (ORIF)

a) Open/closed tibial nailing………………...
b) Other Surgical intervention………………
c) Fibula fixation………………...
d) Poller screws……………….
e) Plating of fracture……….

h) Localization of Entry Point

Done using:

a) II……….
b) Eyeballing……….
c) Measurement……...

i) Methods of reduction

State reduction achieved by:

a. Manual Traction then reaming…………
b. Gravity + Manual Traction then reaming…………...
c. Minimal opening, holding with a temporary plate/clamp then reaming………...
d. None……….

State reduction maintained by:

a. Manual+ Gravity………………
b. Clamps……………………
c. Plate + verbrugge clamp………………

j) Size of the nail used………..

k) Reaming; how many millimeter above the nail diameter………..

l) Malalignment measurements

a. Shortening (cm)……

i. Injured Limb (cm)……….

ii. Uninjured Limb (cm)………

b. Angulation (degrees)….

Injured limb

i. Coronal….

ii. Sagittal……

Uninjured limb

i. Coronal….

ii. Sagittal……

m) Fracture gap

a. AP…….

b. Lateral….

c. Average……

Appendix 6: Plagiarism report

EVALUATION OF DIAPHYSEAL TIBIAL ALIGNMENT FOLLOWING INTRAMEDULLARY NAIL FIXATION AT KNH.

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