UNIVERSITY OF NAIROBI

EARLY FUNCTIONAL OUTCOMES OF OPEN ANKLE FRACTURES AT KENYATTA NATIONAL, AGA KHAN UNIVERSITY AND P.C.E.A KIKUYU HOSPITALS

A dissertation submitted for examination in partial fulfillment of the requirements for the award of degree of Master of Medicine in Orthopaedic Surgery of the University of Nairobi

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H58/80964/2015

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Declaration

I hereby declare that this dissertation is my original work and has not been presented at any other University. Where other people‘s work or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi‘s plagiarism policy**.**

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Dedication

I dedicate this work to my dear wife Angel Gustaph, for her unconditional love, patience and encouragement as well as to my son Jayden and Daughter Janelle. I also dedicate it to my parents, for their support throughout my education.

Acknowledgement

I wish to acknowledge the following people:

1. My supervisors, for their guidance, patience and kind advice throughout my research process.
2. Dr. Parmenus Oroko (Consultant Orthopaedic Surgeon and Assistant Professor in the Aga Khan University) for his assistance as the sight supervisor at the Aga Khan University Hospital (AKUH).
3. Dr. Edward Sang (PCEA Kikuyu Head of Orthopaedic and rehabilitation department) for facilitating my approval in conducting this study in PCEA Kikuyu Hospital.
4. Mr. Francis Njiri for his invaluable input in statistics.

Finally, I would like to take this opportunity to thank everyone who played a role in one way or another in facilitating the execution and completion of this dissertation.

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List of abbreviations

A&E	Accident and Emergency
AKUH	Aga Khan University Hospital
AKUN, IERC	Aga Khan University, Nairobi, Institutional Ethics Review Committee
ANOVA	Analysis of Variance
AO	Arbeitsgemeinschaft für Osteosynthesefragen (German for Association for the study of Internal Fixation)
AOFAS	American Orthopaedic Foot and Ankle Society
AO/OTA	Arbeitsgemeinschaft für Osteosynthesefragen foundation/Orthopedic Trauma Association
ARDS	Acute Respiratory Distress Syndrome
ASEPSIS	Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria and Stay as inpatient prolonged over fourteen days
ATLS	Advanced Trauma Life Support
AWSS	ASEPSIS wound scoring system
BOA/BAPRAS	British Orthopaedic Association and British Association of Plastic, Reconstructive and Aesthetic Surgeons
CDC	Centres for Disease Control and prevention
MTRH	Moi Teaching and Referral Hospital
NACOSTI	National Commission for Science, Technology and Innovation
NINSS	Nosocomial Infection National Surveillance Scheme
KNH	Kenyatta National Hospital
KNH-UoN ERC	Kenyatta National Hospital- University of Nairobi Ethics and Research Committee
ORIF	Open reduction and internal fixation
PCEA	Presbyterian Church of East Africa
RUSH	Radiographic Union Score for Hip
RUST	Radiographic Union Score for Tibia
SSI	Surgical Site Infection
STSG	Split Thickness Skin Graft

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Abstract

Background: Open fractures are generally very challenging to treat due to the risk of sepsis, potential soft tissue loss and subsequent delayed or non-union. This challenge is amplified at the ankle joint because of inadequate soft tissue cover and precarious blood supply.

While fractures around the ankle are the second most prevalent in Kenya, the open type are relatively uncommon but have significantly higher rates of ankle stiffness, pain, wound necrosis and infection.

Open fractures are considered emergencies requiring early debridement and stabilization, the time of definitive fixation and wound closure however remains controversial.

Study objective: To evaluate the early functional outcomes of open ankle fractures managed at Kenyatta National Hospital (KNH), Aga Khan University Hospital (AKUH) and Presbyterian Church of East Africa (PCEA) Kikuyu Hospital.

Methods: A prospective study carried out at the A&E departments, orthopaedic wards and orthopaedic outpatient clinics of KNH, AKUH and PCEA Kikuyu Hospital over a period of twelve weeks. Ethical approval was sought from the relevant ethical boards and consent sought from each of the 62 patients recruited.

Data collected included patients' demographics, wound characteristics according to the AO ankle fracture and soft tissue classification. The time antibiotics were commenced, time from injury to initial debridement, stabilization modality and time to definitive wound cover and fracture fixation. The patients were assessed on the fourth and the tenth day to for early infection and the ASEPSIS score was recorded. The wound was reassessed on the sixth and twelfth week determine the degree of delayed and late infection respectively. The fixation modality and whether provisional fixation was converted to definite fixation before discharge were recorded. Ankle radiographs taken at six weeks were analyzed for adequacy of fracture reduction, alignment and stability. Complications, including delayed wound infection, mal-union, stiffness and functional outcome based on AOFAS scoring system were recorded at 12 weeks.

Data Analysis: The compiled data were analyzed using the IBM Corp. Statistical Package of Social Science (SPSS) for Windows version 25. Armonk, NY.

The baseline characteristics were summarized and presented as means, medians and proportions.

Bivariate analysis was used to evaluate factors associated with functional outcome.
Pearson correlation analysis was used to assess the relationship between the intervening variables (time to initial debridement, antibiotic initiation, primary fixation and time to definitive fixation) with outcomes of interest (adequacy of reduction, infection and functional outcome).
The Chi-square test was used for inferential statistics, analyzing categorical data such as the AO fracture and soft tissue category with the AOFAS score.
All statistical tests were performed at 5% level of significance (95% confidence interval). The results of the study were presented in forms of tables, histograms and pie charts.
Results: The age of the patients ranged from19 to 63 years with a mean age of 38 years. Of these, males formed 77%. AO type B and skin lesion IO 3 were the commonest fracture and soft tissue injury seen (64.5% and 47.7% respectively). The incidence of wound infection was 48.4% (early), 19.4% (delayed) and 14.5% (late). The radiological assessment of reduction at 6 weeks showed that 45% of the patients had anatomic reduction, 31% had fair reduction and 24% had poor reduction. At 12 weeks, 49.7% of patients had an AOFAS score above 50%, while 22.6% had poor scores (less than 39%).
The radiological assessment of reduction was poorest among those stabilized with a back slab alone, leading to significantly higher rates of infection and poor AOFAS scores.
The size of initial wound, debridement after 72 hours and the quality of initial fixation had a significantly increased the rate of infection and poor functional outcome. Delay in antibiotic administration beyond 72 hours also led to increased infection but not to a significant degree.
Conclusion: Wound debridement within the first 72 hours, early definitive fixation and definitive fixation within the first two weeks were the main contributors to reduction of infection rates.
Poor reduction and malunion were associated with higher rates of delayed infection and poor functional outcome. Additionally, the loss of reduction and poor stability was noted to be significantly higher with use of a back slab splint alone.
Poor functional outcomes were attributed mainly to infection, poor reduction and failure of conversion of provisional fixation to definitive fixation.

1. Introduction

Background

An open fracture is a discontinuity in bone with disruption of skin and underlying soft tissue leading to a communication of the fracture and fracture haematoma with the external environment (1). Also, there is a varying amount of soft tissue loss and periosteal stripping (2). Open ankle fractures are associated with adverse sequelae such as infection, non-union and skin necrosis. These may result in prolonged hospital stay, re-operation, arthrodesis and even amputation(3–7). The main objectives in open ankle fracture treatment are the prevention of infection, promotion of fracture healing and reestablishment of function (6,8,9).

Open ankle fractures with minimal soft tissue damage (such as from low energy trauma) have a good prognosis. However, other factors influence the outcome, including the degree of contamination, age, nutritional factors and co morbidities such as diabetes and immunosuppresion (2).

Complex ankle fractures pose a great challenge to many surgeons. The challenge is exacerbated by tissue loss. This chapter gives a brief overview of ankle anatomy, epidemiology, pathophysiology, classification and management of open ankle fracture.

Anatomy of the ankle joint

The ankle joint is a hinged synovial joint of the mortise and tenon variety. Stability of the ankle joint is offered by the joint capsule, bony congruency, strong ligaments and crossing tendons (10). The deltoid ligament is the primary restraint to anterolateral talar displacement while the lateral malleolus acts as a buttress preventing lateral talar displacement.

The ankle has minimal muscle mass around it (only the belly of the flexor hallucis longus), and several tendons hence the blood supply is precarious.

The major neurovascular bundle (posterior tibial) is located posteromedial and is well protected. This accounts for the rare occurrence of neurovascular injuries of the ankle joint (10,11).

Although posterior tibial tendon rupture is rare, it has been reported in several case series, and it is paramount that the surgeon checks at the time of debridement, especially in medial malleolar fractures (12).

A sixth of the body weight is transmitted through the fibular. Ramsey et al. (13) reported that a 1mm lateral shift reduces the tibiotalar articular area by 42%.

Epidemiology

Ankle fractures are fairly common, accounting for up to 10% of fractures (2,14). Open fractures of the ankle are less frequent (3%-6%) (15). Of all open articular fractures, the ankle joint is the most frequent accounting for 9.7% of all open articular fractures (1). A study by Kilonzo and Lelei at Moi teaching and referral hospital showed a 3.3% incidence of open ankle fractures and up to 80% of open ankle fractures reported moderate to severe pain three months after injury (16). This was mostly attributed to inadequate reduction with significant talar shift at six weeks post-injury. A similar study by Malagala (17) in Mulago Hospital (Uganda) showed 23% of ankle fractures were open and these were associated with significantly poor functional outcomes compared to closed fractures.

In a systematic review, Saini et al. found that open ankle fractures were commoner in males and usually from direct impact, high energy such as road traffic accidents or skin penetration from a sharp bone spike (2). High energy trauma has been associated with more complications (9,15,18–20).

However, the prevalence of low energy open ankle fractures, especially in the elderly, has been on the rise in the recent past(2,21–23). An epidemiologic study in Sweden showed a steadily increasing prevalence of open ankle fractures in the past decade (0.2% per year), especially among the elderly population. Some researchers are describing low energy open ankle fractures as a type of fragility fracture (24,25). Similar results were found in the United States, where elderly patients with low energy open ankle fractures had high mortality of 27.27%, and 81.81% had associated co morbidities (21). In the UK, 20% of open ankle fractures were of women >80yrs old (23).

In the United Kingdom, Brown (26) reported 47.6% of open ankle fractures were Gustilo III, with 86.7% of the wounds on the medial side. Santhanakumaran et al. (9) in India found that majority of ankle fractures were Gustilo 3 (30.4%) and 60% were bimalleolar.

Pathophysiology

Immediately after soft tissue injury, humoral and cellular mechanisms are activated, and the healing process is initiated. This has 3 phases: exudative/ inflammatory, proliferative and reparative phase. During the inflammatory phase, secretion of adrenalin, thrombaxane A2, cytokines (Platelet derived growth factor and Transforming growth factorβ) lead to vasoconstriction. This leads to under perfusion of damaged tissues, subsequent hypoxia and acidosis (27,28).

Cytokines secreted strongly stimulate macrophage, neutrophil and fibroblast chemotaxis and mitogenesis. The neutrophilic granulocytes move in to remove necrotic debris and produce more cytokines. However, the capacity of macrophages in removing debris is limited. Moreover, the high contamination and necrotic tissue with reduced perfusion increase the risk of infection. The physiologic rationale of surgical debridement is to support phagocytic cells in removing debris and necrotic tissue (1,29,30).

Classification of ankle fractures

The three major classifications of open ankle fractures are:-

i. Lauge Hansen classification (1)
ii. Danis-Weber classification (31)
iii. AO/OTA classification (32)

The Lauge- Hansen classification focuses on describing the injury mechanism and infers the expected ligamentous injuries based on the fracture pattern. Recent studies indicate that Lauge Hansen classification should be used with caution when determining actual mechanism as it has predicted less the 50% of patient-reported mechanisms of injury. It also has high interobserver variability reducing its clinical relevance and does not take into consideration soft tissue status, associated injuries, circumstances of the accident in defining the mechanism of injury (33,34). There were no studies advocating for its use.

The Danis-Weber classification is based on the level of lateral malleolar fracture in relation to the tibiofibular syndesmosis (35). It is relatively simple and reproducible; hence, it has been widely adopted as the classification of choice for ankle fractures (33). It can also be used as a prognostic indicator with Weber C having the poorest outcomes. However, the prognosis applies for unimalleolar / fibular fracture only and will vary in multiple malleolar fractures (34,36). A trimalleolar Weber B will have a worse prognosis than a unimalleolar Weber C (36).

The AO/OTA classification is a complex anatomical classification was described by Muller (27). It uses alpha numerical coding based on:

- The bones involved (tibia and fibula are designated 4)
- The location of the fracture (distal tibia-fibular is designated 4)

- The morphology of the fracture.(A,B or C with each being further subdivided into 3 subgroups based on the degree of comminution)

In an attempt to describe ankle fractures more comprehensively, ankle fractures are classified into 27 subgroups (32). This classification broadened the Danis-Weber classification scheme, developing a classification based on lateral malleolus involvement and the degree of fracture comminution. It describes the extent of instability related to a distinct fracture pattern. It has limited inter and intra-observer variability (33). For this reason, the AO-OTA classification was used in this study (Appendix 8.4).

Classification of open fractures

In choosing an appropriate classification system, consideration to all crucial aspects offers the best support in selecting the appropriate bone and soft tissue treatment. It also reduces complications preventing avoidable treatment errors and offers prognostic value (27).

The most frequently used classifications of open fractures are (28):

i. Gustilo and Anderson classification
ii. Oestern and Tscherne classification
iii. Hannover classification
iv. Soft tissue grading system by AO

The Gustilo and Anderson classification categorizes wounds into three major grades commensurate with increased wound size, tissue injury and higher energy mechanisms (8,30). This classification is relatively easy and helps in prognostication and planning course of management. However, critics of this classification point out that it has been shown to have high interobserver variability especially for grade III injuries (1,37). It also does not take into account neuromuscular and tendon injuries (27,28).

The Oestern and Tscherne classification groups soft tissue injuries into four categories based on the fracture pattern, the size of the wound and degree of contamination (27). The Tscherne classification was found to have higher reliability and better probability in predicting functional outcomes than Gustilo and Anderson (38).

The Hannover fracture scale attempts to improve interobserver reliability and to classify complex open fractures more comprehensively. It evolved from the original Tscherne classification after analyzing 1000 fractures between 1980-1989 (39). The fracture type (based on AO classification), the neurological status, degree of contamination, bone loss, the duration between trauma and treatment and overall injury severity is added up to provide a total score (27).

The score provides three categories to classify the wound: the size of the wound, area of skin loss and deep tissue damage. Neurological assessment during the time of admission is usually difficult, but the examination of reflexes allows gross estimation of neurovascular status. Wound bacterial culture samples are also taken into account (27).

The AO group adopted and developed the Hannover classification system to a more comprehensive system for fractures with accompanying soft tissue damage. This grading system is based on the severity of the injury and categorized into;

i. skin
ii. muscles and tendons,
iii. neurovascular system
iv. AO fracture classification

Given the limitations of previously existing classifications already described, and for ease of merging the soft tissue status with the fracture classification system, the AO soft tissue classification system was used in this study (Appendix 8.4).

Management of open ankle fractures

There has been an evolution of management of open fractures in four stages: Life preservation (where amputation was standard treatment justifiable to save a life), followed by limb preservation (debridement) in the 18th Century described by Desault (1), followed by infection control (the 1970s) to the current functional restoration as described by Tscherne (30). The ortho-plastic approach is now recognized as the standard of care (40).

Treatment of open ankle fractures remains a daunting task because of the complex Osseo-ligamentous complex and paucity of soft tissue envelope. The relatively thin soft tissue cover can easily get damaged, increasing the propensity for wound necrosis, infection and impaired functional ability (2). The goal is prevention of infection, promotion of fracture healing and reestablishment of function (41). To achieve this, effective antibiotic therapy, thorough surgical debridement, fracture reduction and stabilization and wound coverage are of paramount importance (41).

Until a century ago, open ankle fractures would almost always lead to sepsis and death (up to 70% mortality seen with open fractures) (27). Thus immediate amputation was the treatment of choice to save life (42). However, with advances in antimicrobial therapy, wound reconstruction and fracture stabilization techniques, there has been a dramatic decline in the rate of mortality and limb loss (42).

The management of open ankle fractures begins with stabilization of the patient following the ATLS guidelines (43,44). After stabilization of the patient, a focused history about the mechanism of injury, location of the injury, and thorough clinical evaluation determining the grade of injury, level of contamination, degree of soft tissue destruction, bone loss and neurovascular injury of the affected extremity. Co-morbid conditions should be assessed and recorded (44).

Early antibiotic administration, aseptic dressing and wound assessment is recommended (45). Orthogonal radiological views of the affected ankle should be done preferably after attempts of reduction and splinting.

The goals of soft tissue management consist of early surgical debridement and restoration of viable soft tissue envelope (46). Given the poor soft tissue cover, preservation of skin viability around the ankle is of paramount importance in the successful management of open ankle fractures.

1.1 Problem Statement

Open ankle fractures pose a major challenge because of the inherent risk of infection, nonunion, compartment syndrome and wound necrosis. These complications are a major clinical burden due to the need of multiple surgeries, prolonged hospital stay and even amputation. The morbidity and impaired functional ability has a detrimental effect to the patients physically, psychologically and socioeconomically.

In order to reduce the rates of complications associated with open ankle fractures, it is paramount to assess the prevalence of these complications the local community and establish a treatment protocol that offers the best overall outcome.

1.2 Study question

What are the early outcomes and complications of open ankle fractures seen in KNH, AKUH and Kikuyu Mission Hospital?

1.3 Justification and Significance

There is limited local data regarding the functional outcome of management of open ankle fractures. This study is expected to help develop a standardized treatment protocol applicable in the local region. It will also provide a platform for further research where modifiable interventions can be evaluated to improve outcomes of open ankle fractures.

2.4 Main/Primary objective

This study aims to evaluate the early outcomes of open ankle fractures managed in KNH, AKUH and PCEA Kikuyu hospital.

2.4 Specific objectives

1. To determine the factors associated with development of infection of open ankle fractures
2. To determine factors associated with Malunion of open ankle fractures
3. To determine factors associated with functional limitation following open ankle fractures

2. Literature review

Open ankle fractures are considered rare and complex injuries, with an incidence ranging from 3% to 6% (2,23,47). Despite numerous advances in surgical management and antimicrobials available, open ankle fractures are still challenging and pose high morbidity. The present challenge is not simply limb salvage but the restoration of maximum function (24).
However, this chapter will focus mainly on complications associated with open ankle fractures and factors related to these complications. These are:

i. Infection
ii. Wound necrosis
iii. Delayed union/non-union
iv. Post-traumatic osteoarthritis.

Open ankle fractures have been associated with high rates of morbidity and mortality. However, recent advancements in infectious disease control, reconstructive surgery, and damage control orthopaedics has helped improve outcomes (48).

2.1 Factors influencing outcome of open ankle fractures

2.1.1 Infection

There is a commensurate relationship between the grade of wound injury and the risk of developing infection. For example, using the Gustilo and Anderson grading, there is a 0-2% risk in type I, 2-12% in type II and 10-50% in type III (3,49). The anatomic location of the fracture may help determine the risk of infection. Experimental studies suggest that neutrophil delivery is lower in wounds of the lower extremity compared to the upper limb (50). Therefore infections of open lower limb fractures occur more frequently compared to the upper extremity.
There are local and systemic factors that increase the risk of infection. The local factors include:

- Organic, farmyard, or sewage contamination.
- Debridement after 24 hours.
- Poor debridement (retention of foreign debris and nonviable tissues)
- Insufficient skeletal stabilization.
- Existence of dead space.

The systemic factors include the following (1,3,30,51):

- Presence of shock and ARDS

- Compartment syndrome and hypo-perfused tissues.
- Co morbid factors like diabetes mellitus and a history of smoking.
- Age above 65 years
- Poor nutrition.
- Extended hospital stay
- Exposure to resistant organisms.

Wound infections are classified into early (within two weeks), delayed (3-10 weeks) and late (after ten weeks) (30). Infections may also be classified as superficial or deep (52). Deep infection occurs when pathogenic organisms invade the ankle joint or surrounding soft tissues (2). It can be prevented by the preservation of soft tissues, thorough and repeated debridement where indicated, and early antibiotic use (49). Deep infection is a major cause of poor functional outcome including chronic pain, ankle arthritis and Osteomyelitis (19,53).

Wound infection assessment system

There is no single method sufficient for infection diagnosis, but multiple methods must be used for proper diagnosis. These include repeated measurements of immune-related markers (erythrocyte sedimentation rate and C-reactive protein), deep wound cultures, histopathology, radiology (may show periosteal reaction, delayed union or nonunion of the fracture, pin or implant loosening indicating the possibility of infection) (6)

There are various subjective ways developed to evaluate and classify the degree of wound infection. The most common classifications are:

i. The United States Centre for Disease Control and Prevention (CDC) (54)
ii. English Nosocomial Infection National Surveillance Scheme (NINSS)
iii. ASEPSIS Wound Scoring System(AWSS) (55)

The CDC system divides SSI into superficial, deep incisional and organ space-related infection occurring within 30 days (51). The NINSS system is a modification of the CDC classification, however, pus cells have to be present for cultures to be considered positive and the surgeons‘ diagnosis is omitted as a criterion for the diagnosis of surgical site infection. Moreover, there is low reproducibility of this scheme (52).

The AWSS scoring system (Appendix 8.4) is a qualitative score computed using impartial criteria based on visual characteristics and consequences of infection. It was developed from a prospective randomized clinical trial in an attempt to objectively assess and take account of factors applicable to the development of wound infection after surgery in a reproducible way. Wound sepsis is defined as the breakdown of a wound in the presence of pus and infecting organism. However, the degree of infection is also of clinical importance.

In this grading system points (from 0-4) are assigned based on the wound characteristics and the proportion (in percentage) of the wound involved. The wound characteristics assessed are:

i. Serous exudate
ii. Erythema
iii. Purulent discharge
iv. separation of deep tissues

Additional points are added based on whether

i. Antibiotics were used to manage wound infection
ii. Pus was drained from the wound under local anaesthesia
iii. Wound debridement under general anaesthesia

After compiling the total points, the wound is graded as:

- No infection (0-10 points)
- Disturbance of healing (11-20 points)
- Minor infection (21-30 points)
- Moderate infection (31-40 points)
- Severe infection (more than 40 points)

Although this scoring system provides more detailed information, it is time-consuming and more costly to perform compared to NINNS and CDC (52). However, this system is the most objective and repeatable (56).

Allami et al. (57) concluded that the CDC criteria was subjective and unreliable. There was low reproducibility in the use of NINNS (58).In a London study, both the CDC and NINNS systems were found to be unreliable (52). Of the three systems, the ASEPSIS was most preferred and was used in this study. Culture samples were taken in all wounds suspected to be infected.

Debridement and infection control

Wound infection is as a result of an imbalance between the host defenses and infective organism (59). The pathophysiologic basis of performing surgical debridement is supporting the phagocytic process of the macrophages in removing necrotic tissue and debris (27).

Wound irrigation plays a key role in preventing infection by decreasing bacterial load and removal of foreign bodies (1,15). High Pulsatile lavage (70 psi @ 1050 pulsations per minute) has been considered the most effective for removal of foreign bodies and bacteria. It reduces bacterial load 100 folds but has a disadvantage of microscopic damage to bone and increasing bacterial dissemination into tissues planes hence precipitating contamination (19,60,61). Low-pressure lavage (14psi @ 550 pulsations) is equally effective in reducing bacterial load without the harmful effects on tissues.

Literature recommends a minimum of 9 liters of saline for type III open fracture.(1,27,30,62) Normal saline is the solution of choice, as antibiotic solutions have been found not to offer any advantage with the risk of impairing wound healing. Antiseptic solutions such as chlorhexidine and hydrogen peroxide have a toxic effect on tissues (1,63,64). Although pressure lavage has been known to be the most efficient method of removing foreign debris from wounds, it has the limitation of causing particulate dissemination further into tissue planes as well as soft tissue and bone damage particularly with high-pressure (61).

Some authors advocate for serial debridement every 48 hours and delay of wound closure until negative post debridement cultures are attained. This would provide lower rates of deep infection (5.7% in grade 2, 1.3% in grade 3A, 10,6% in grade 3B, and 20% in grade 3C).The downside is multiple surgeries required, delay in wound healing and a longer hospital stay with increased risk of Nosocomial infection (46,65).

The timing to surgical debridement has remained controversial over the past. The consensus has been all open fractures are considered an emergency and should be debrided as soon as possible. The rationale behind this was believed to be from Freidrich's study on guinea pigs in 1898 that showed the critical limit of bacterial replication was 6 hours, after which massive bacterial replication was observed (28,66). A local study by Abdulhamid assessing the effects of delay in debridement in open fractures had similar reports, showed that debridement within 6 hours had a significant chance in reducing risk of infection (67).

Recent conflicting reports show that the ‒6-hour rule‖ has no significant evidence in reducing infection rate as long as antibiotics are started early (8,68). Recommendations from BOA/BAPRAS guidelines (69) shift the emphasis from emergency surgery to timely surgery (up to 24 hours) carried out by experts in orthopaedics and plastic surgery (28). The requirement of ortho-plastic collaboration has also been emphasized. This notion has not been accepted in various trauma centres around the world who consider a 24-hour window too long (28). Other supporting studies also dispute the 6-hour rule and attribute deep infection and poor outcome to the type of initial soft-tissue injury severity and loss of reduction, rather than delayed surgical treatment (7,42,70,71).

It has been widely accepted that early surgical debridement remains urgent, reduces risk of infection and provide a stable environment for wound healing. However, it is more important to stabilize the patient and institute antibiotics than rush for surgical debridement (7,42). Retaining marginal viability fragments while removing grossly contaminated or completely devitalized bone fragments is favorable to aggressive debridement in reducing excessive bone loss, delayed union and need for repeat debridement with comparable infectious risk (72).

Wound closure

In the past, surgeons were hesitant to close open fracture wounds primarily or early flap coverage due to the risk of wound necrosis and infection. There is firm evidence that acute infection after open injuries is from hospital-acquired pathogens rather than those acquired at the site of injury (73,74). Patzaki et al. (75) established that only 18% of infections were caused by organisms initially isolated in the perioperative period. It was concluded that during intervals where wounds were left open, the infectious organisms were difficult to control with antibiotics alone. Since the fracture site and wound is probably most sterile after satisfactory debridement, that would be an opportune time to provide soft tissue cover. Studies by Godina (76) emphasized the advantages of early wound cover where there were significantly lower rates of infections (1.5%) and free flap failure (0.75%) when wound cover was performed within 72 hours of injury compared to after 72 hours where infection rates were increased to 2% and flap failure to 12%. This has been corroborated by several recent studies that support early wound coverage (77–80). Early wound coverage may be considered after the wound has been thoroughly debrided and edges are opposable.

Immediate closure refers to closure within 72 hours while delayed closure ranges from 72 hours to three months post injury (44). Primary closure of type I, II and a few type III wounds may be attempted (81). However, caution is taken in grossly contaminated wounds in which case multiple debridement before coverage may suffice(2). Contraindications for immediate closure include the following (8,28,82):

- gross contamination with dirt, farm injuries, freshwater injuries, stagnant water and fecal material
- delay to initiation of antibiotics >12 hours
- delay of more than 24 hours between injury and primary debridement
- questionable skin and soft tissue viability at initial surgery where plastic surgeons intervention is likely required
- very high energy injury, where contamination is likely to have been forced into tissue planes
- Host immunosuppresion

There are advocates for initial debridement followed by delayed wound closure to prevent the potential complication of deep infection (41,62,83) and tissue necrosis. The benefit of a staged approach is allowing re- debridement in cases of development of necrotic tissue and avoid generation of anaerobic environment, which risks the development of Clostridial myonecrosis (84).

Other authors suggest that early closure is beneficial without excessive risks (65,74,85,86). The decision to primarily close a wound, delayed closure or allowing secondary healing remains controversial because there are no guidelines available to determine which wounds can feasibly be closed primarily and which should left open for delayed closure (8,87). Some authors recommend primary closure as long as the wound has been adequately debrided, and edges can be opposed without tension (87). Additionally, others recommend an attempt to primary closure only when the initial injury was a low energy trauma mechanism. They discourage primary closure of grade III open ankle fractures (19,46).

Flap coverage within 72 hours has been shown to have fewer repeat procedures, fewer infection and shorter hospital stay than between 72hours and three months (76,88). Early flap coverage makes the injury amenable to subsequent procedures. Another study by Benson et al. showed significantly fewer infection rates in primary closure compared to delayed closure (89).

Role of fracture fixation in prevention of infection

The importance of fracture fixation is to protect the soft tissues, improved wound care and allow fracture healing and allow early mobilization (2). Timing of internal fixation is dictated by the state of soft tissues (27). Proper stabilization improves venous return, reduces oedema, promotes local neovascularisation and reduce inflammation (90,91).

The choice of skeletal stabilization includes external fixation alone, external fixation with limited internal fixation with screws or K-wires (hybrid) or internal fixation with plates and screws. Stable fractures may be splinted in a back slab. Each option has its own merits and demerits. Plaster cast may make wound inspection difficult and increase the risk of wound infection. Puno et al. reported an infection rate of 15% after the management of open tibial fractures with casting (92).

Internal fixation may be done where there is adequate soft tissue cover. Otherwise, an external fixator may be considered (53). The prevalence of infection after implant fixation of open fractures varies from 8% (19) to 17% (15), compared to 1.9% in closed fractures (30).

External fixation provides an easy and versatile mechanism to address a wide variety of ankle fractures and soft tissue damage (93). They are mainly used temporarily in the initial phase and later converted to definitive fixation. Infection rates are lower when the conversion is done within the first week compared to after three weeks, mainly due to pin tract infection (30,94). With delayed conversion, pin removal and stabilization with a cast before fixation is recommended.

In a local study by Rashid (94) the incidence of Pin tract infections was 87.7%. This may subsequently lead to pin loosening from the reduction of pin- bone interphase. The pins also violate muscle compartments and give rise to joint stiffness (27).

There have been arguments in favour of immediate fixation of open fracture sighting benefits such as protection of the soft tissue envelope, minimizing additional trauma from mobile fracture fragments, improving soft tissue healing, allowing early mobilization and rehabilitation, and reducing infection (11,19,83,95).

Studies on open tibia plateau fracture showed no correlation between any deep infection and distance from plate to pin, pin- plate overlap distance, open fracture classification or status of fracture healing (96). Thus, fears that definitive fracture fixation site is contaminated by external fixator pins appear not to be clinically grounded.

Antibiotic use and infection control

The timing of antibiotic therapy plays an important role in the rate of wound infection, with a significant reduction if antibiotics are initiated within 3 hours from the time of injury(19). The antibiotic chosen depends on the environment the injury occurred and the skin flora (83).

The commonest organisms isolated are gram-positive (mainly *Staphylococcus*), followed by gram-negative, anaerobic and gas forming bacteria (84,97). The pathogen may be primary (present at the time of injury) or secondary (from subsequent contamination) (8). A broad spectrum antibiotic such as a first-generation cephalosporin is recommended. Addition of an aminoglycoside is recommended for Gustilo III open fractures (45,98). The antibiotics are administered up to 48 hours post debridement, as additional antibiotics have been shown not to have any additional benefits in preventing surgical site infection. Prolonged antibiotic use has been associated with bacterial resistance (69,70,99,100).

Early antibiotic therapy (within 6 hours) has been shown to reduce the rate of infection significantly (68,83). The time of initiation of antibiotic is more significant than the time to debridement in preventing deep infections (8,49). Superficial infection usually resolves with regular dressing and a course of oral antibiotic therapy (2).

The degree of bone disruption and soft tissue injury determines the risk of infection (3).

2.1.2 Wound necrosis

Wound necrosis was found to be the most common complication of open ankle fracture in a systematic review with a prevalence of 14% (15) to 18% (19) casting has been associated with increased risk of wound necrosis (92).

In a systematic review assessing open ankle fractures, 81% of patients had satisfactory results after immediate ORIF (15,19).

For periarticular fractures, the decision to convert to definitive stabilization is usually based on the condition of soft tissues. A 10-14 day period of latency is required to allow soft tissues to recover to the extent where definitive fixation can be undertaken safely (1).

2.1.3 Compartment syndrome

This is an emergency that results from tissue swelling and ischemia within a tight osciofascial space after injury or after fracture fixation first described by Volkmann in 1872 (28). It may lead to fibrosis, contracture and loss of function (101). The modern definition is the elevation of interstitial pressure such that it exceeds capillary perfusion pressure. This is an absolute value of more than 30mmhg or difference between diastolic and compartment pressures of more than 30mmhg.

Maintaining a high index of suspicion is of paramount significance to proceed early to operative intervention where the diagnosis is suspected. Casting may compromise early detection of compartment syndrome. Excessive traction across the ankle joint when applying spanning external fixator may lead to stretching of muscle compartments and lead to compartment syndrome (1).

2.1.4 Nonunion/ Malunion

This is more common in open ankle fractures because of the soft tissue damage, poor perfusion, and increased incidence of infection. It often leads to secondary osteoarthritis and need for arthrodesis of the ankle joint (102). This may potentiate the need for multiple surgical debridement, and increase risk of nonunion and ankle arthrodesis (53).

Casting has been associated with an increased rate of up to 70% of non-union (92).

Spanning fixation has been widely accepted as a mode of temporary periarticular fixation. It offers ligamentotaxis and reduces the amount of injury-related oedema by reducing the deformity. The external fixator construct is a simple mono-lateral frame in a triangular construct with two or three pins in the distal tibia and a centrally threaded calcaneal pin through the calcaneal tuberosity. However, this construct is not fully rigid for it can allow rotation around the calcaneal pin. This is often countered by the addition of forefoot pins to the base of the first metatarsal bone. This also maintains the foot in a neutral position (1).

The most common complication encountered when utilizing a spanning external fixator is the inability to re-establish length. The gradual loosening of the external fixator components before definitive reconstruction may occur, causing loss of initial reduction.

External fixator maintained for a long time acts as a definitive skeletal stabilizer with delayed union and Malunion rates as high as 40% (30). Limited internal fixation, in combination with external fixation, has demonstrated to work well with periarticular fractures. Inter-fragmentary screws seek to achieve direct bone healing using compression while external fixator limit the degree of micro-motion (1).

In an attempt to standardize radiological assessment of fracture union, The University of Toronto and McMaster recently developed a scoring system (RUSH and RUST) that has been shown to have increased reliability among surgeons and radiographers in assessing fracture healing (109). This system assesses the presence of callus and fracture line in four cortices to give a score between 4 (no union) and 12 (union). However, there has been no gold standard to compare this system with. Hence, it has not been validated as a clinical tool.

2.1.5 Post traumatic osteoarthritis

This is a well-known complication of ankle fracture and is compounded by open fractures. Horiseberger et al. (102) reported a 70% incidence of post-traumatic ankle arthritis and attributed it to the failure of restoration of normal anatomy. This mainly involves the failure of reduction of lateral talar displacement (16). Ramsey et al. (13) showed that the lateral talar re-displacement of 1 mm reduces the tibiotalar contact area by 42%. Other factors include fibular malunion with shortening and valgus deformity as well as ligamentous injury (5).

Fixation of the fibular with rash pins, k-wire or plate fixation is recommended to maintain length, rotation and lateral wall stability. Fixation failure is high, with spanning external fixator (103).

Burwell et al. (104) came up with an objective classification for assessing ankle reduction Radiologically. More than five posterior or lateral displacement of the talus have been shown to increase the risk of post-traumatic arthritis by five times.

The stabilization techniques are varied, and there is no consensus on which is superior to the other. Some authors recommend stabilization with a cast or a combination of a cast and minimally invasive techniques such as rush pins (10).

The latency time between injury and development of end-stage OA is 20.9 years (102). In this study, time is a limiting factor, but the Burwell radiological assessment score and the AOFAS score have been shown to predict the probability of developing post traumatic arthritis positively.

2.2 American orthopaedic foot and ankle society (AOFAS) outcome classification system

The AOFAS ankle-hind foot score is one of the commonest used instruments of measuring the outcome in patients who have sustained a complex ankle and hind foot injury (105). It combines clinical reported and patient-reported outcome measures (106). Various factors thought to reflect the condition of the ankle and foot were considered (Appendix 8.5). These include:

- Degree of pain
- Functional limitations
- Average maximum continuous walking distance
- Difficulty of walking based on the walking surface
- Gait anomaly
- Range of joint motion
- Ankle- hind foot stability
- alignment

These factors are weighted non-numerically based on a grading between 0 and 100 as follows:

- Excellent= more than 75%
- Good=60-75%,
- Fair=40-59
- Poor= less than 40 (appendix 8.4)

The AOFAS grading system has the advantage of being applicable in a wide variety of ankle disorders while remaining responsive to clinical changes (107). The validity of this scoring system has been put into question by various studies that show poor correlation between AOFAS and F36 (106,108). However, the AOFAS scoring system is the most widely used outcome measure with reliable results and valid conclusions related to foot and ankle quality of life issues (109).

In a study analyzing the outcomes of open ankle fractures in an Indian population (9), 73% of the patients had good outcomes based on AOFAS criteria after being managed with debridement and fixation with external fixators, with wounds healing by secondary intention in 39% and 34% requiring skin grafting and flap cover.

3. Patients and methods

Study design

This was a prospective, cohort study with consecutive patient sampling.

Study setting

In order to obtain data from all socioeconomic categories, and to achieve the desired sample size (considering open ankle fractures are rare), 3 facilities were selected as follows:

- KNH, located in Upper Hill Nairobi: It is the largest referral hospital in East and Central Africa. It mainly caters for patients of low socioeconomic status.
- PCEA Kikuyu Hospital: Located in Kiambu County and caters mostly to patients of middle socioeconomic status.
- AKUH in parklands is a teaching hospital that largely caters for patients of high socioeconomic status.

The study was carried out in the A&E Departments, Orthopaedic Wards and fracture clinics in these facilities.

Study duration

August 2019- May 2020 (Appendix 8.6)

3.1 Patients

All patients of 18 years and above presenting to KNH, AKUH and PCEA Kikuyu between August 2019 and March 2020 with open ankle fractures were considered for the study.

Selection criteria

Inclusion criteria:

1. Patients aged 18 years and above with open ankle fracture
2. Patients who gave consent/guardian for those with head injury.

Exclusion criteria:

1. Patients with tibial plafond fractures
2. Associated crush injury of the foot and mangled extremity
3. Talus fractures

4. Patient with the following co-morbidities that may increase the likelihood of infection and delayed union: diabetes mellitus, immunosuppresion (HIV or prolonged steroid use), liver failure, renal failure, atherosclerosis and cigarette/tobacco use.
5. Patients who did not consent to be part of this study

Ethical considerations

All appropriate institutional and Governmental regulations concerning the ethical use of human volunteers was followed during this research. Approval was sought from the Department of Orthopaedic Surgery, in the University of Nairobi, after which, permission was sought from Kenyatta National Hospital, Ethics and Research Committee (KNH-UoN ERC) (Appendix 8.7) Relevant registration certificates and approvals were sought as follows:

- KNH (Appendix 8.8)
- National Commission for Science and Technology (NACOSTI) (Appendix 8.10)
- PCEA kikuyu Hospital approval (Appendix 8.11)
- AKUH approval (Appendix 8.12)

Data collection commenced after ethical approval was granted.

Study participants or their next of kin were requested to give written informed consent. The consent sought enabled the principal investigator to take the patient‘s bio-data details as well as photos of the wounds and initial ankle radiographs.

The investigator clarified to the participants the objective of this study. Participation in this study was absolutely voluntary. Thus, the participants were informed that they are free to participate or even withdraw their participation at any point during the study without any explanation. Withdrawal from the study did not influence the participants‘ treatment in any way.

Sampling Technique

Patients were recruited into the study by the principal researcher and three trained assistants (fourth year registrars rotating in KNH, AKUH and PCEA Kikuyu who were selected based on those rotating in the respective hospitals) . Consecutive sampling technique was used, and each patient was assessed on the admission day, day 4, day10, 6th week and 12th-week post-injury. Only those satisfying the inclusion criteria and gave informed consent were recruited. The data sheet (Appendix 8.4 and 8.5) was filled accordingly.

On admission, all patients were reviewed and managed by the surgeon on call. They were initially assessed and stabilized according to the ATLS protocol, antibiotics were initiated and tetanus toxoid or hyper-immune globulin was administered as indicated. The fracture classification, soft tissue injury (AO) and the time of initial antibiotic administration was recorded in the data sheet.

The type of initial stabilization was at the discretion of the surgeon on call. The time of initial debridement, time and type of initial stabilization modality and soft tissue injury were recorded in the data collection sheet after the initial debridement.

The patients‘ wounds were assessed on day 4, day10, 6th week and 12th week. Their condition was recorded on the data sheet as per the ASEPSIS score criteria. Culture specimens were collected from septic wounds and recorded in the data sheet.

The condition of the wound determined whether primary closure, STSG or flap cover was done. The stabilization modality at the time of discharge was considered definitive.

All patients were assessed at six weeks for radiological adequacy of reduction and at 12 weeks where the degree of ankle stiffness, pain and functional limitation were assessed using AOFAS score.

Sample size

The formula below was used to estimate the sample size (110):

$$n_0 = \frac{Z^2(1-\infty/2) \times P(1-P)}{d^2}$$

The *d* value considered to be significant was below 0.05(absolute error of 5%) giving us a standard normal variant (*Z)* of 1.96

Where;

n_0 = sample size determined

Z^2 $(1-\infty/2)$ =is the standard error of the mean corresponding to a 95% confidence interval and the corresponding value from a t-table is 1.96.

P = Expected prevalence of good functional outcome, anatomic reduction and absence of infection. In this case, the value of P was 0.5, the best average estimate for predetermined outcomes.

d = Target margin of error, which will be 5 %(0.05) to increase precision.

$$n_0 = \frac{1.96^2 \times 0.5(1 - 0.5)}{0.05^2}$$

Hence $n_0 = 384$

However, given the small population, the Fischer's formula was modified by including the finite population correction factor (FPC) as;

$$\mathbf{n = \frac{n_o}{1 + \frac{(n_o - 1)}{N}}}$$

Where;

n= the sample from the finite population

N= Total population; data from KNH registry between Aug and October 2018 showed a total of 30 open ankle fractures admitted in KNH(average of 10 patients per month). Considering a 4-months data collection period, total of 40 patients is expected, with an addition of 18 patients from AKUH (8 patients) and PCEA Kikuyu Hospital (10 patients), bringing the total to 58 as the total population.

n_0 retains its earlier definition

Therefore;

$$\mathbf{n = \frac{384x58}{384+(58-1)}}$$

N=50.5~51

With the assumption of an attrition rate of 10%, the expected sample size was 56.

Purposive/convenient sampling was utilized based on the defined inclusion criteria until the appropriate sample was reached, or a statistically sound level possible under the circumstances was attained.

3.2 Methods

Data collection and analysis

Data were coded, entered and managed in a Microsoft Access database and at the end of data collection exported to IBM Corp. SPSS for Windows version 25 for analysis. The baseline characteristics were summarized and presented as means, medians and proportions

Bivariate analysis was used to evaluate factors associated with functional outcome

Pearson correlation analysis was used to assess the relationship between the intervening variables with outcomes of interest (Appendix 8.1).

The Chi-square test was used for inferential statistics, analyzing categorical data such as the AO fracture and soft tissue category with the AOFAS score.

All statistical tests were performed at 5% level of significance (95% confidence interval). The results of the study were presented in forms of tables, histograms and pie charts.

All information obtained was confidential. All participants were allocated a study serial number linking them to their bio-database accessible only to the principal investigator. Patients‘ names were not be used.

4. Results

Demographic patterns of patient with open ankle fractures

A total of 65 patients were recruited for this study (48 patients from KNH, 14 from PCEA Kikuyu Hospital and 3 from AKUN). However, three were lost to follow up due to relocation. The mean patients' age was 38 years with a standard deviation (SD) of $\pm$ 12. The range was between 19 and 63 years.

Majority of open ankle fractures occurred in male patients (77%). This is summarized in table 1 below.

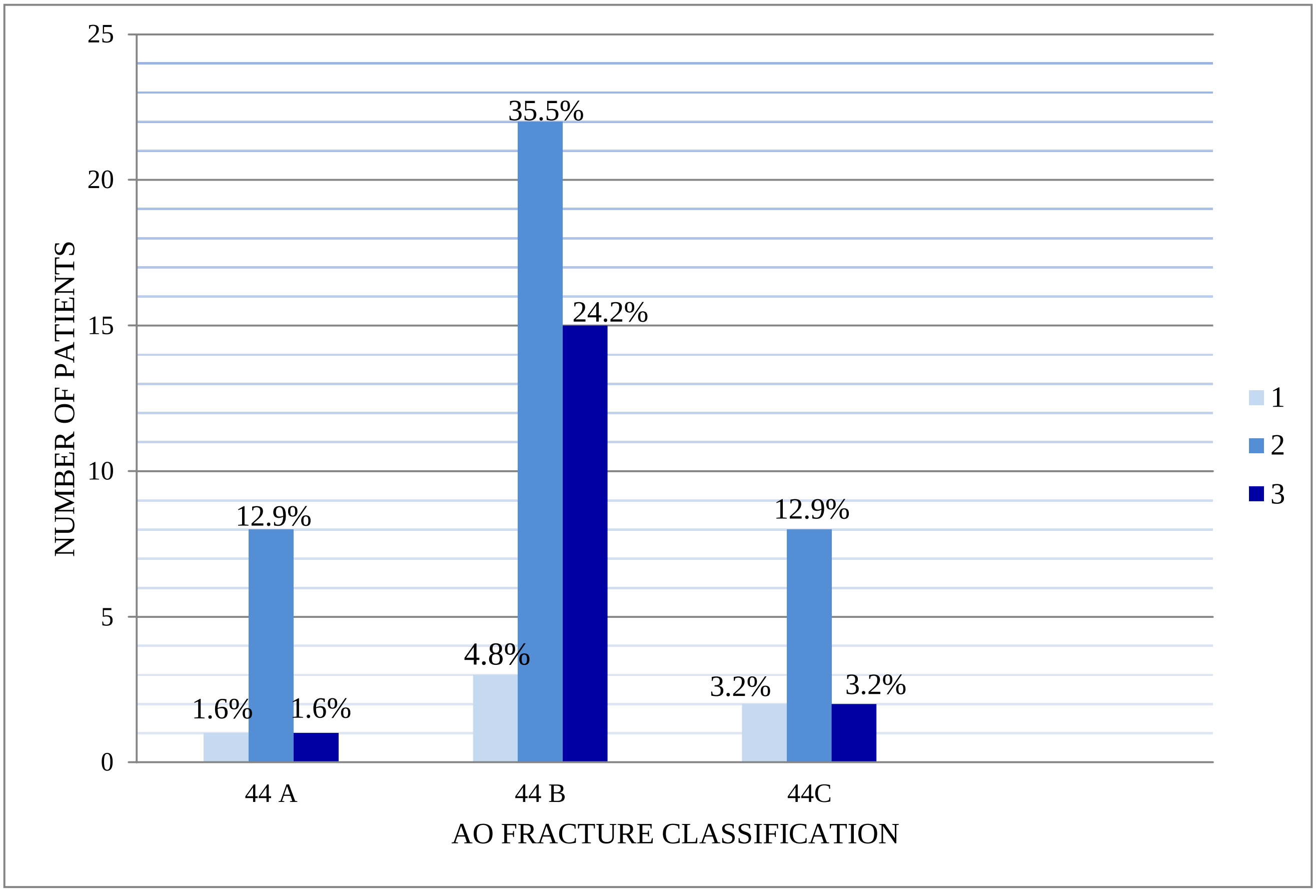
Table 1: Open ankle fracture distribution

Demography	**n**	**%**
Age (years)		
18-30	22	35.5
31-40	18	29
41-50	11	17.8
51-60	9	14.5
≥61	2	3.2
Hospital		
KNH	45	72.6
AKUH	3	4.8
PCEA Kikuyu	14	22.6
Sex		
Male	48	77
Female	14	23

AO/OTA fracture and soft tissue distribution

Forty patients (64.5%) had type B (transyndesmotic) fractures, 12 patients (19.4%) by type C (suprasyndesmotic), and 10 patients (16.1%) had type A (Infrasyndesmotic) fractures (figure 1)

Figure 1: Proportions of open ankle fractures



(Note: 1, 2 and 3 represent the sub-categories of AO grade 44A, 44 B and 44C)

The largest majority of patients (48.3%) had skin wounds of greater than 5cm with contusions and devitalized edges (IO3), majority of the patients had no muscle or tendon injury (62.9%) and no neurovascular injury (96.8%).This is illustrated on table 2 below.

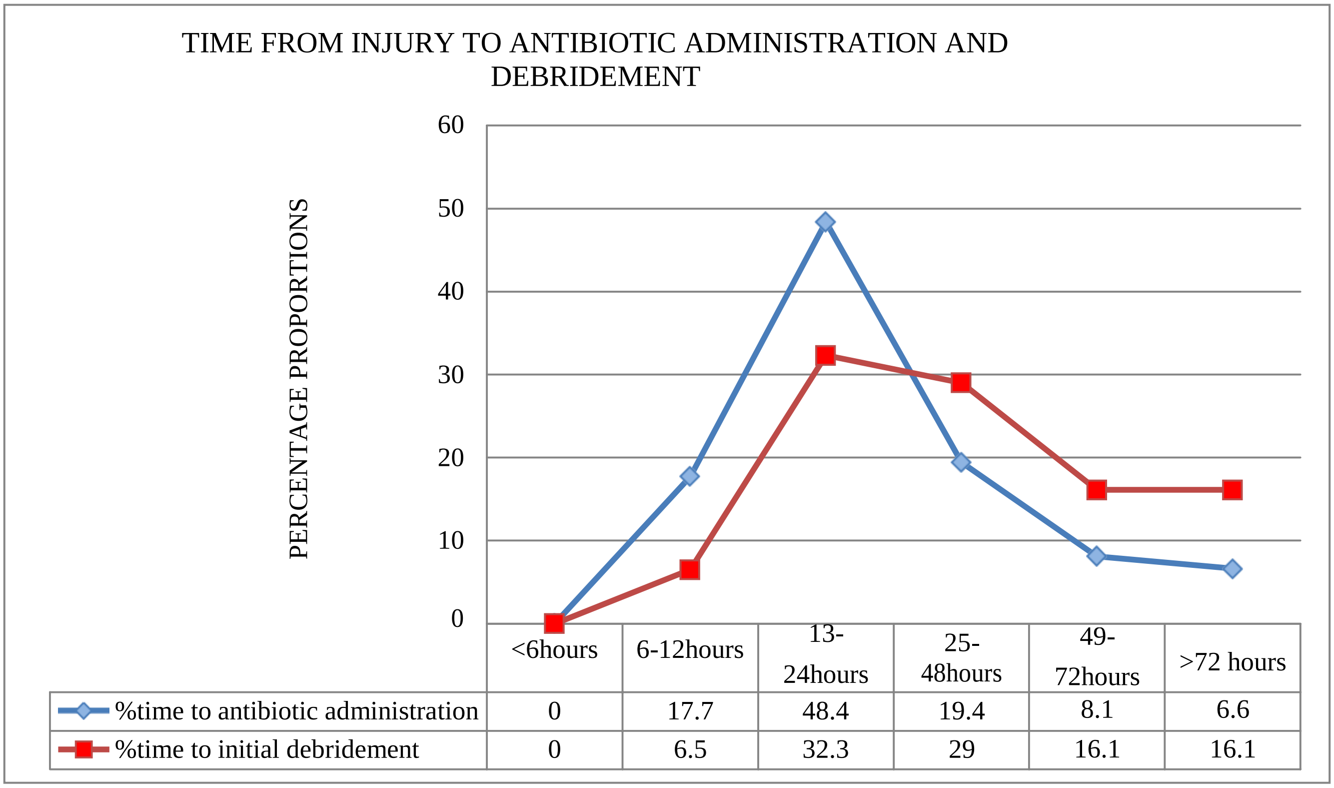
Table 2: Proportions of skin lesion, muscle, tendon and neurovascular injury severity

		n	%
SKIN LESION	IO 1	6	9.7%
	IO 2	20	32.3%
	IO 3	30	48.3%
	IO 4	6	9.7%
MUSCLE/TENDON INJURY	MT 1	39	62.9%
	MT 2	13	21.0%
	MT 3	4	6.5%
	MT 4	4	6.5%
	MT 5	2	3.1%
NEUROVASCULAR INJURY (NV)	NV 1	60	96.8%
	NV 2	0	0.0%
	NV 3	2	3.2%
	NV 4	0	0.0%
	NV 5	0	0.0%

Time from injury to initial debridement

No patient received antibiotics or debridement before 6 hours in all hospitals that the study was conducted. Majority of patients received antibiotics and initial debridement 13-24 hours after injury (48.4%) and 32.3% respectively. This is illustrated in the graph below.

Figure 2: Proportions of time taken to initial antibiotic administration and debridement



Wound debridement

A total of 30 of the patients (48.4%) had their wounds left open after primary debridement while 32(51.6%) wounds were closed primarily. Of those closed primarily only 1 had a primary flap coverage done. Only 7(11.3%) of the patients were debrided with tourniquet and no debridement was done with Pulsatile lavage.

Fixation after initial debridement

A total of 21 patients (33.9%) had a back slab placed after initial debridement. Only 3(4.8%) patients had a hybrid fixation with k-wires and external fixator combined. The proportions of fixation modality after initial debridement is illustrated in table 3.

Table 3: Proportions of fixation modalities used after initial debridement.

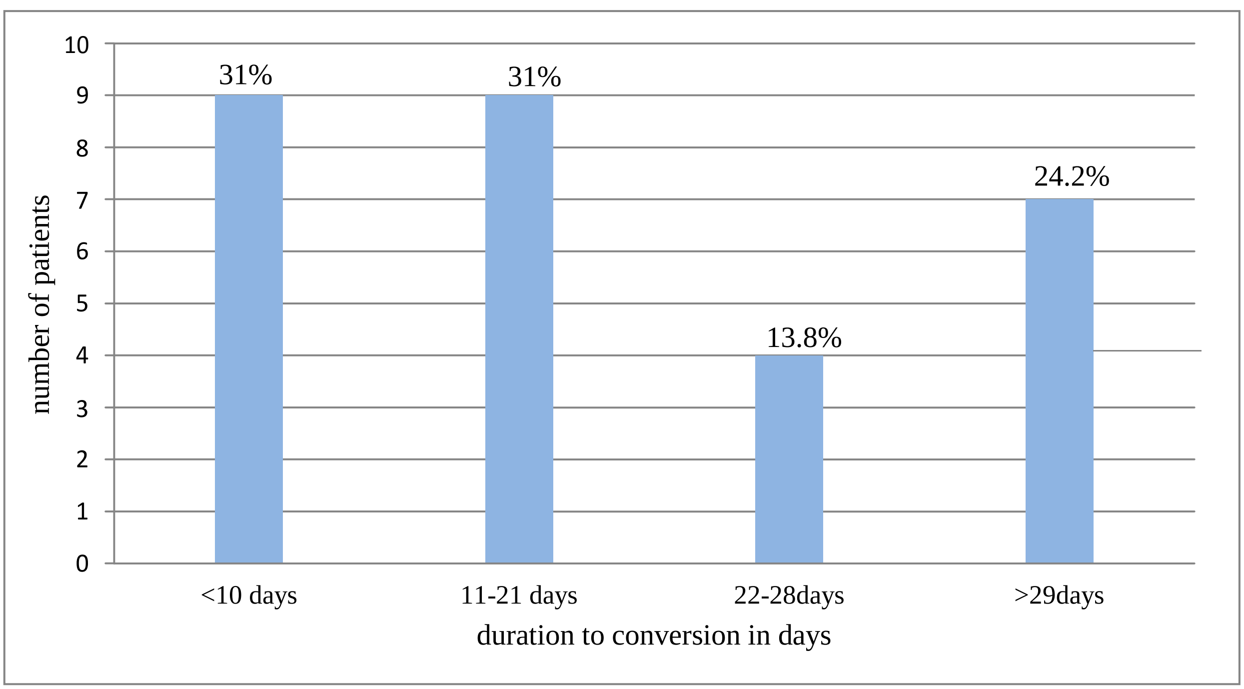
Fixation after initial debridement	**n**	**%**
Back slab splint	21	33.9%
K-wires/ rash pin/ screws & back slab	17	27.4%
K-wires/ rash pin/screws & external fixator	3	4.8%
Internal fixations with plate and screws	6	9.7%
External fixator alone	15	24.2%

Conversion from temporary fixation to definitive fixation

There were 6 (9.7%) patients who had primary internal fixation (with plates and screws) and primary closure immediately after initial debridement. A total of 21 (33.9%) patients had the initial fixation converted to definitive fixation prior to discharge at a rate illustrated on figure 4.The rest of the patients (56.4%) maintained the initial fixation or splint as the definitive treatment until they were discharged.

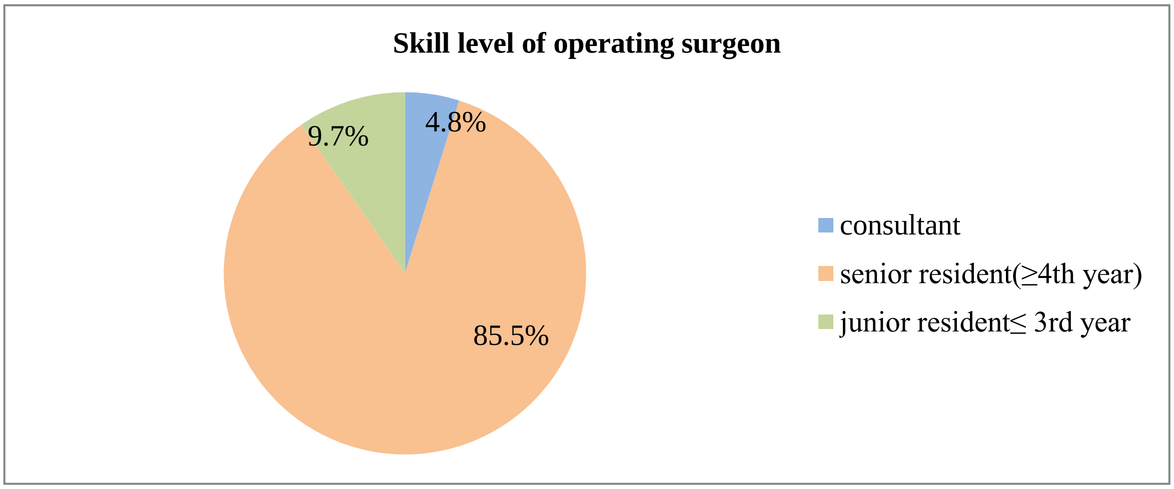
The graph below illustrates the average time it took to convert to definitive fixation

Figure 3: Mean duration of conversion to definitive fixation



Majority of the initial debridement was carried out by senior residents (≥ 4th year). This was followed by junior residents and consultants. They operated on 53, 6, and 3 patients respectively.

Figure 4: Operating surgeon performing initial debridement and fixation



Incidence of infection

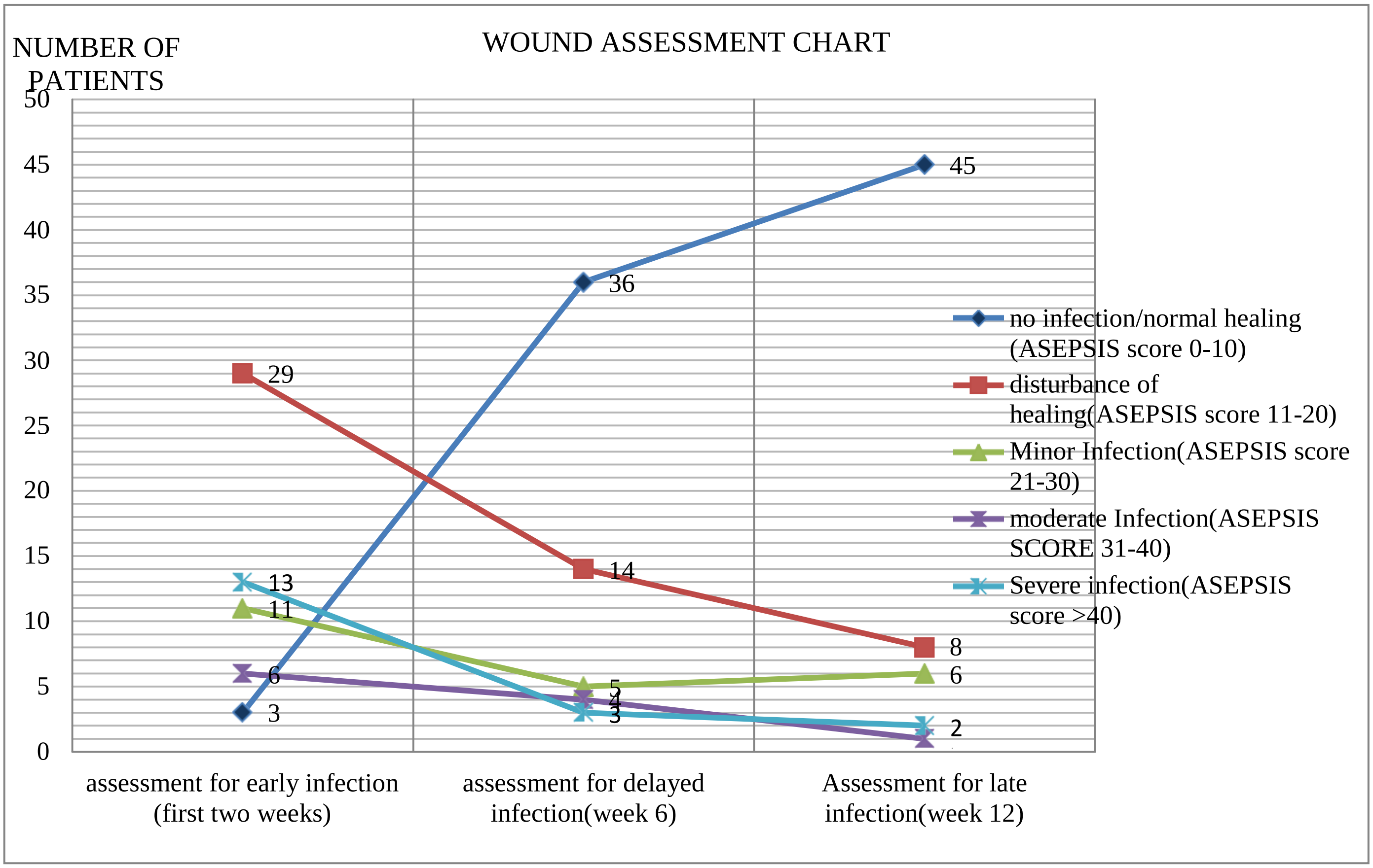
Early infection rates were based on wound assessment on day 4 and day 10 to represent the first two weeks. A total of 29 of the patients (46.8%) had disturbance of healing (ASEPSIS score 11-20). Another 6 (9.7%) patients had moderate infection (ASEPSIS score 31-40) while 13 (21.0%) patients had severe infection (ASEPSIS score >40). Only 3 patients (4.8%) had no infection (ASEPSIS 0-10)

The rate of delayed infection was based on evaluation of the wounds at 6 weeks after injury. The number of patients with normal healing (ASEPSIS score ≤10) increased to 36 (58.1%). There were 14 (22.6%) patients who had disturbance of healing (ASEPSIS score 11-20). Moderate and severe infection was reported in 4 (6.5%) and 3 (4.8%) patients respectively.

The incidence of late infection was recorded on the twelfth week. The number of patients with no infection increased further to 45 (72%) and 8 (12.9%) had disturbance of healing. There were 6 (9.7%) patients who had minor infection. Only 1 (1.6%) patient had moderate infection and 2 had severe infection at this time.

This has been illustrated in the chart below (Figure 5).

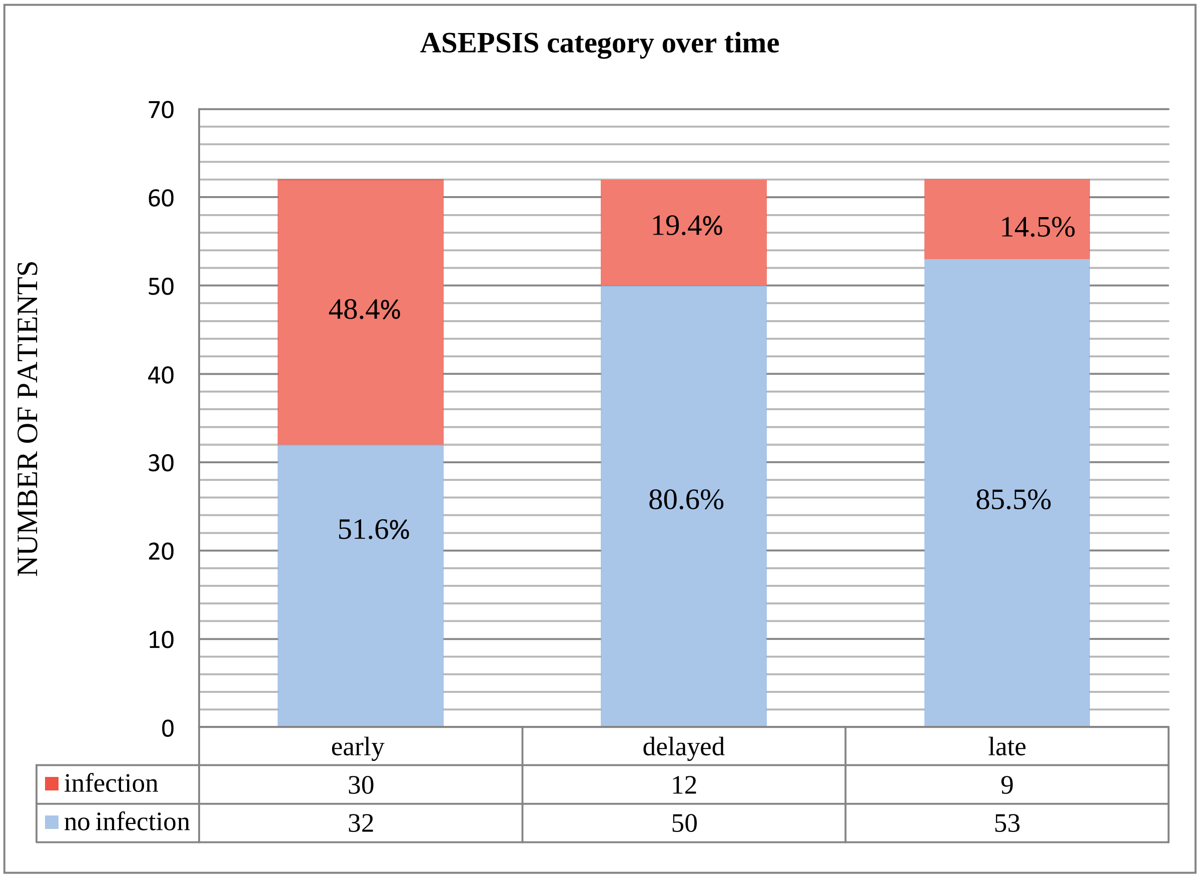
Figure 5: Incidence of infection over time



Factors associated with development of infection

In order to have bivariate outcome measures, the ASEPSIS score was categorized into ―infection‖ (scores ≥20) and ―no infection (scores <20) categories. The table below summarizes the respective proportions of these categories.

Figure 6: Proportions of infection over time



The Chi-square test was used to evaluate predictors of poor ASEPSIS score. There was no significant difference of infection rates based on sex in all stages of wound assessment (P-value 0.281-0.978) or the hospital where the patient was managed (P-value 0.413-0.908). There was proportional increase in the infection rates with increase in injury severity based on AO fracture classification, but not to a significant degree (P-value 0.331-0.56).

The size of skin lesion had a significant bearing to the risk of early infection (p-value 0.002) but not as significant for delayed (p-value 0.427) or late infection (p- value 0.163)

The time to antibiotic treatment had a negative impact on the rate of early, delayed and late infection. There was notable increase in infection rates with delay of more than 24 hours in antibiotic administration but not to a significant degree (p-value 0.17-0.2)

Delay to initial debridement more than 72 hours had a significant influence on the rate of early infection (P-value 0.008) but less significant in delayed (P-value 0.79) and late (P-value 0.117).

There was a notable significant difference in early infection based on the initial fixation chosen (p value 0.028) with internal fixation producing the least ASEPSIS scores throughout the study duration. The use of K- wires with a back slab produced the highest infection rates throughout the study period. However the differences were less significantly associated with delayed and late infections. There was significantly higher rates of early infection (p-value<0.0001) and delayed infection (P- value 0.014) but this did not have significant influence on late infection (p-value 0.328)

The quality of reduction has a significant influence on propensity to delayed infection (p-value 0.01) but less significant attribute to early and late infection (p-value 0.11 and 0.38 respectively)

It was observed that there is a significant relationship between early infection and prolonged hospital stay (p-value 0.004).However, the relationship was less significant for delayed and late infection (p- value 0.18 and 0.57 respectively)

There was no significant relationship between infection rates at every stage with the skill level of the surgeon performing the initial debridement (p-value 0.2-0.4).

Delayed and late infection was significantly associated with poor functional outcome at 12weeks (p-value <0.0001 and 0.037 respectively). Early infection had less significant influence to poor functional outcomes (p-value 0.237)

Table 4 summarizes the bivariate analytical results of factors associated with infection of open ankle fractures.

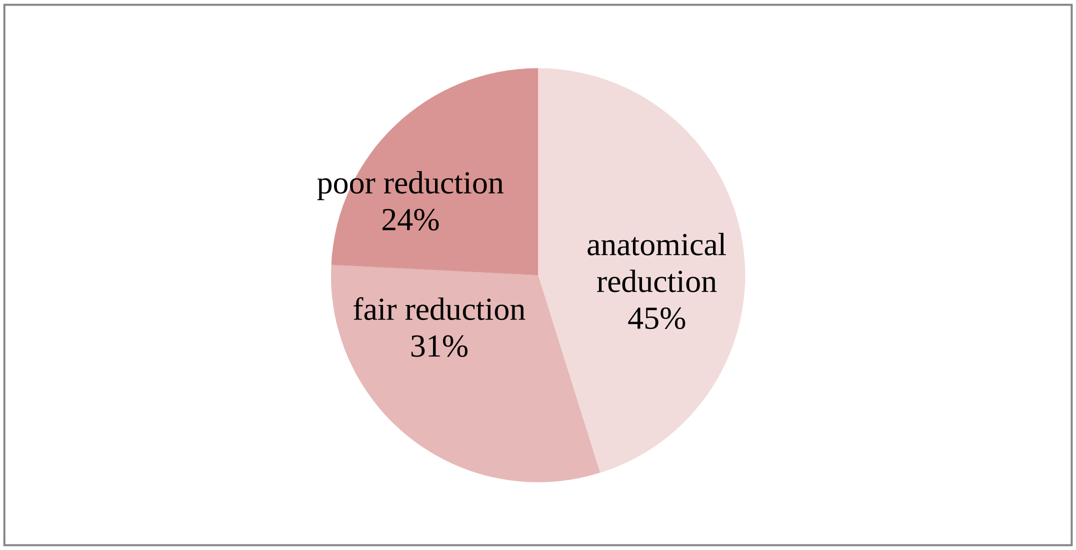
Table 4: Factors associated with infection (poor asepsis scores)

		EARLY INFECTION		DELAYED INFECTION		LATE INFECTION	
		% Infected	p-value	% Infected	p-value	% Infected	p-value
MEAN AGE		39	0.400	44	0.043	35	0.529
SEX	Male	52.1	0.281	20.8	0.585	14.6	0.978
	Female	35.7		14.3		14.3	
AO SCORES	A	38.5	0.562	0	0.331	7.7	0.550
	B	48.8		22		14.6	
	C	62.5		23.1		25	
SKIN LESION	IO 1 and IO 2	25.9	0.002	14.8	0.427	7.4	0.163
	IO 3 and IO 4	65.7		22.9		20	
TIME FROM INJURY TO ANTIBIOTIC ADMINISTRATION	<6 hours	0	0.208	0	0.213	0	0.172
	6-12 hours	27.3		18.2		0	
	13-24 hours	43.3		13.3		10	
	25-48 hours	58.3		41.7		25	
	49-72 hours	80		0		40	
	>72 hours	75		25		25	
TIME FROM INJURY TO INITIAL DEBRIDEMENT	<6 hours	0	0.008	0	0.790	0	0.117
	6-12 hours	0		25		25	
	13-24 hours	30		15		5	
	25-48 hours	55.6		22.2		11.1	
	49-72 hours	50		10		40	
	>72 hours	90		30		10	
FIXATION AFTER INITIAL DEBRIDEMENT	Back slab splint	33.3	0.028	23.8	0.423	14.3	0.616
	K-wires/ rash pin/ screws & back slab	70.6		29.4		23.5	
	K-wires/ rash pin/screws & external fixator	100		0		0	
	Internal fixations with plate and screws	16.7		0		0	
	External fixator alone	46.7		13.3		13.3	
WOUND	left open	71.9	<0.0001	31.2	0.014	18.7	0.328
	closed primarily	23.3		6.7		10	
DEFINITIVE FIXATION	Yes	45.5	0.732	4.5	0.029	13.6	0.884
	No	50		27.5		15	
SKILL LEVEL OF PERSON OFFERING SERVICE	consultant	0	0.228	0	0.477	0	0.317
	senior resident	50.9		18.9		13.2	
	junior resident	50		33.3		33.3	
RADIOLOGIC CRITERIA OF REDUCTION	Anatomical	39.3	0.111	3.6	0.010	10.7	0.308
	Fair	68.4		26.3		10.5	
	Poor	40		40		26.7	
HOSPITAL STAY	≤14 days	26.9	0.004	11.5	0.186	11.5	0.572
	>14 days	63.9		25		16.7	
AOFAS SCORE	≥75% (Excellent)	33.3	0.237	0	<0.0001	4.2	0.037
	60-74% (Good)	71.4		0		0	
	40-59% (Fair)	52.9		11.8		17.6	
	≤39% (Poor)	57.1		71.4		35.7	

Adequacy of reduction

The adequacy of reduction was evaluated at 6 weeks using the radiological criteria of union (see appendix 8.1). A total of 28 patients had anatomical reduction, 19 and 15 patients had fair and poor radiological outcomes respectively. This is illustrated in figure 7 below.

Figure 7: Radiological criteria of reduction



The analysis of variance (ANOVA) was used for inferential statistical analysis between Malunion rates and possible contributing factors.

Although females had a higher poor radiological outcome (42.9% in females versus 18.8% in males) this difference was not statistically significant (p value 0.051). There was no statistically significant difference based on the hospital that the patients were managed (p value 0.745).

AO group A had better radiological outcomes (57%) than B (39%) and C (46.2%). However the overall difference in anatomic, fair and poor outcomes was not significant (p-value 0.382).there was a significant relationship between the wound lesion and the radiological outcome at 6 weeks (P value 0.038). There were 55.6% of IO 1 and 2 who had anatomical reduction while 37.1% of IO 3 and 4 had anatomical reduction. This is illustrated in table 4.

The modality of initial fixation had a significant impact on the radiological outcome at 6 week (P value <0.0001. Anatomical reduction was seen in 100% of patients who had internal fixation with plates and screws. Most of the patients with poor radiological reduction had been fixed with a back slab splint alone (42.9%).This is illustrated in figure 8.There was significant improvement after conversion from all temporary fixation modalities to fixation with plates and screws (p value <0.001). This is summarized in table 5.

Figure 8: Radiological outcome based on initial fixation modality

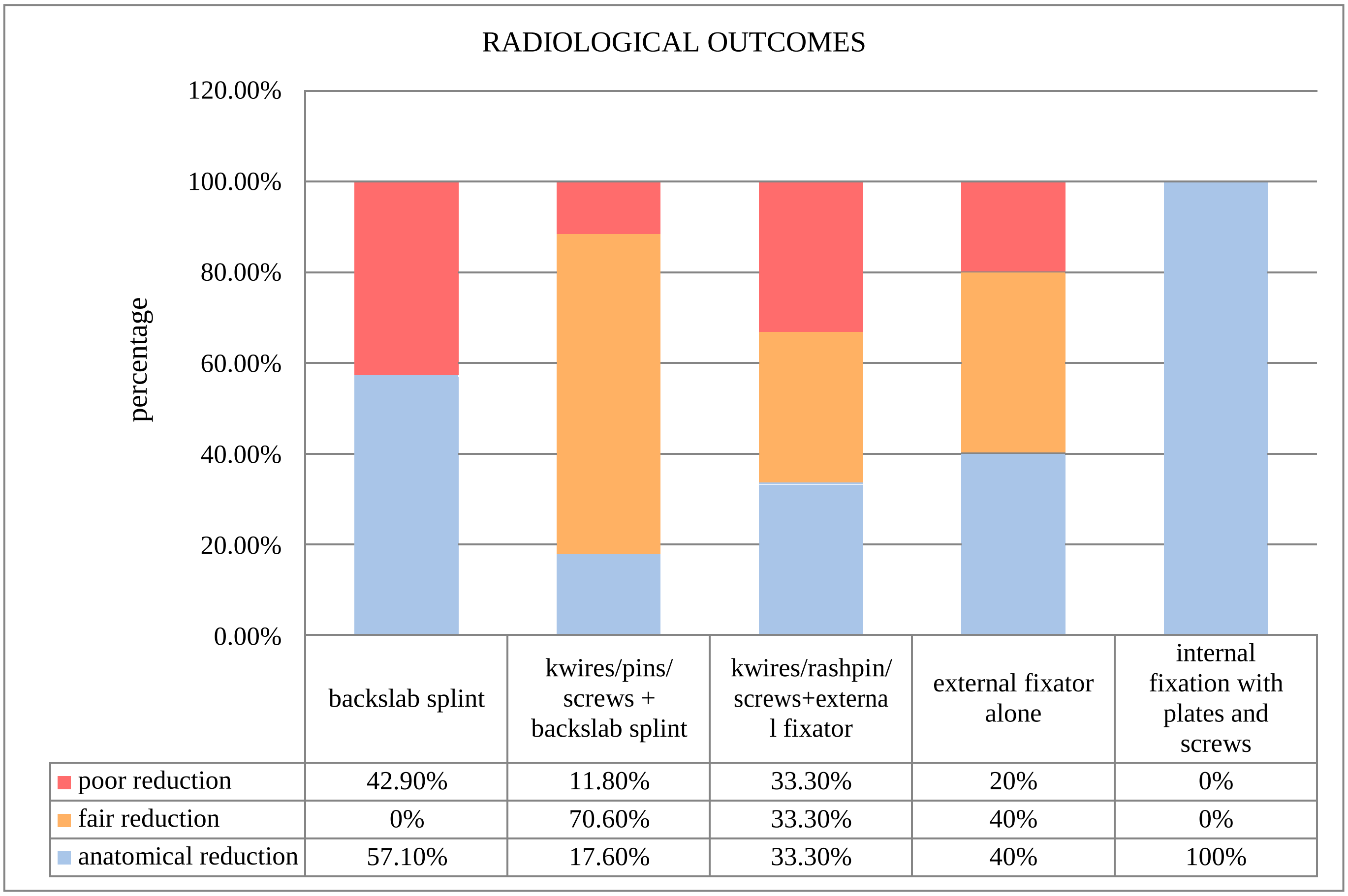


Table 5: Factors associated with radiological outcome at 6 weeks

			RADIOLOGIC CRITERIA OF REDUCTION			
			Anatomical	Fair	Poor	p-value
SEX	Male	%	43.8	37.5	18.8	0.051
	Female	%	50.0	7.1	42.9	
AO SCORES	A	%	75.0	12.5	12.5	0.382
	B	%	39.0	36.6	24.4	
	C	%	46.2	23.1	30.8	
SKIN LESION	IO 1 and 2	%	55.6	18.5	25.9	0.174
	IO 3 and 4	%	37.1	40.0	22.9	
TIME FROM INJURY TO ANTIBIOTIC ADMINISTRATION	<6 hours	%	.0	.0	.0	0.471
	6-12 hours	%	63.6	18.2	18.2	
	13-24 hours	%	53.3	23.3	23.3	
	25-48 hours	%	16.7	50.0	33.3	
	49-72 hours	%	40.0	40.0	20.0	
	>72 hours	%	25.0	50.0	25.0	
TIME FROM INJURY TO INITIAL DEBRIDEMENT	<6 hours	%	.0	.0	.0	0.264
	6-12 hours	%	100.0	.0	.0	
	13-24 hours	%	40.0	20.0	40.0	
	25-48 hours	%	38.9	44.4	16.7	
	49-72 hours	%	50.0	30.0	20.0	
	>72 hours	%	40.0	40.0	20.0	
FIXATION AFTER INITIAL DEBRIDEMENT	Back slab splint	%	57.1	.0	42.9	<0.0001
	K-wires/ rash pin/ screws & back slab	%	17.6	70.6	11.8	
	K-wires/ rash pin/screws & external fixator	%	33.3	33.3	33.3	
	Internal fixations with plate and screws	%	100.0	.0	.0	
	External fixator alone	%	40.0	40.0	20.0	
WOUND	Left open	%	31.3	43.8	25.0	0.038
	Closed primarily	%	60.0	16.7	23.3	
DEFINITIVE FIXATION	Yes	%	81.8	18.2	.0	<0.0001
	No	%	25.0	37.5	37.5	
SKILL LEVEL OF PERSON OFFERING SERVICE	consultant	%	100.0	.0	.0	0.189
	senior resident	%	43.4	34.0	22.6	
	junior resident	%	33.3	16.7	50.0	
Hospital stay	≤14days	%	53.8	23.1	23.1	0.448
	>14days	%	38.9	36.1	25.0	
AOFAS SCORE	≥75% (Excellent)	%	95.8	4.2	.0	<0.0001
	60-74% (Good)	%	28.6	71.4	.0	
	40-59% (Fair)	%	11.8	58.8	29.4	
	≤39% (Poor)	%	7.1	21.4	71.4	

Functional outcome

The functional outcome was assessed at 12 weeks using the AOFAS scoring system. Twenty four (38.4%) patients had an excellent AOFAS score (>75%). Seven (11.3%) patients had a good AOFAS score of 60-74%. 17(27.4%) and 14(22.6%) of the patients had a fair (40-59%) and poor (≤39%) AOFAS score respectively.

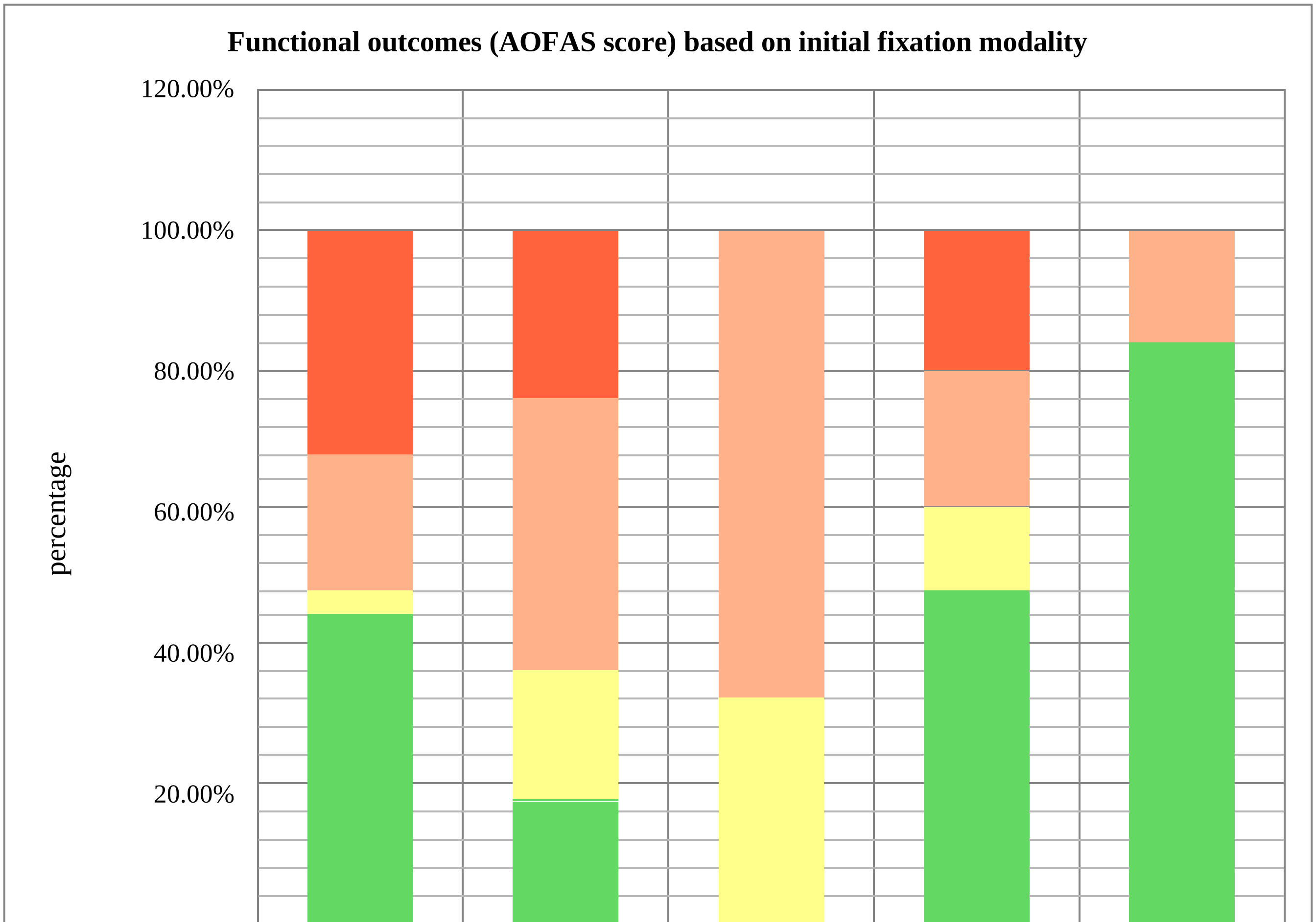
Chi square test was used for bivariate analysis between the AOFAS scores and the age and sex. Although there was a worsening AOFAS score with increase of age, the relationship was not significant (p value 0.336).There was no significant association between patients‘ gender (p value 0.49)

ANOVA was used to analyze associations between the AOFAS scores and other categorical data such as ASEPSIS score, fixation modality and quality of reduction. There was a significant correlation between AOFAS score and early, delayed and late ASEPSIS scores (p values of 0.004, <0.0001 and <0.0001 respectively).

There was better AOFAS score in those treated with immediate internal fixation (83.3% had AOFAS scores above 75%) followed by external fixation (46.7%).Majority of patients fixed with minimal internal fixation (k wires) had good and fair AOFAS score regardless of whether a back slab or external fixator was used to supplement the fixation. However, these differences were not significant (p-value 0.147). Figure 9 summarizes these associations.

Patients who had initial provisional fixation converted to a definite fixation had an overall better functional outcome than those who had the initial fixation maintained until healing (p value 0.013).There was a significant correlation between anatomical reduction and excellent functional outcome (p-value <0.0001).However, there was no significant correlation between the functional outcome and the skill level of the operating surgeon or the duration of hospital stay. This has been illustrated on table 6.

Figure 9: Functional outcomes based on initial fixation modality



	backslab splint	kwires/rashpin/ screws +backslab	kwires/rashpin/ screws +externa fixaor	external fixator alone	internal fixation with palte and screws
poor(≤39%)	33.30%	23.50%	0%	20%	0%
fair(40-59%)	19%	41.20%	66.70%	20%	16.70%
good(60-74%)	4.80%	17.60%	33.30%	13.30%	0%
excellent(≥75%)	42.90%	17.60%	0%	46.70%	83.30%

Table 6: Factors associated with functional outcomes

		AOFAS SCORE								
		>=75% (Excellent)		60-74% (Good)		40-59% (Fair)		<=39% (Poor)		
		n	%	n	%	n	%	n	%	p-value
SEX	MALE	18	75	7	100	13	76.5	10	71.4	0.490
	FEMALE	6	25	0	0	4	23.5	4	28.6	
FIXATION AFTER INITIAL DEBRIDEMENT	Back slab splint	9	42.9	1	4.8	4	19.0	7	33.3	0.147
	K-wires/ rash pin/ screws & back slab	3	17.6	3	17.6	7	41.2	4	23.5	
	K-wires/ rash pin/screws & external fixator	0	.0	1	33.3	2	66.7	0	.0	
	Internal fixations with plate and screws	5	83.3	0	.0	1	16.7	0	.0	
	External fixator alone	7	46.7	2	13.3	3	20.0	3	20.0	
Definitive fixation	Yes	14	63.6	2	9.1	5	22.7	1	4.5	0.013
	No	10	25.0	5	12.5	12	30.0	13	32.5	
SKILL LEVEL OF PERSON PERFORMING PROCEDURE	consultant	3	100.0	0	.0	0	.0	0	.0	0.450
	senior resident	19	35.8	6	11.3	16	30.2	12	22.6	
	junior resident	2	33.3	1	16.7	1	16.7	2	33.3	
HOSPITAL STAY	≤14 days	13	50.0	3	11.5	5	19.2	5	19.2	0.424
	>14 days	11	30.6	4	11.1	12	33.3	9	25.0	
RADIOLOGIC CRITERIA OF REDUCTION	Anatomical	23	82.1	2	7.1	2	7.1	1	3.6	<0.0001
	Fair	1	5.3	5	26.3	10	52.6	3	15.8	
	Poor	0	.0	0	.0	5	33.3	10	66.7	

4.1 Study limitations

1. During this study, a large majority of cases were initially managed by Junior and senior residents. Only 3 patients had their debridement done by consultants. This made it impossible to make inference on the outcomes based on the level of expertise
2. This study was carried out in multiple centres in an attempt to include a number of patients who would have been managed using uncommon wound debridement techniques such as VAC dressing and lavage debridement. However, none of the patients had their wounds debrided using these techniques.
3. There were numerous ways of constructing a spanning external fixator, and some may have been more rigid than others. However, no way was found to assess the rigidity of an external fixator objectively and attempting to classify this was beyond the scope of this study; thus it was assumed that they all had equal rigidity. This study only assessed whether minimal internal fixation with screws or wires were used in conjunction with external fixation as detailed in the methodology.
4. For the cases that underwent internal fixation, stainless steel reconstruction plates, a 3^{rd} tubular plates and titanium-locked plates were used. Although it is known that these plates have different biomechanical properties and rates of infection, the patients were not stratified based on the implant used as this was deemed to be beyond the scope of this study.
5. This study was limited to patients without co morbidities that are known to increase the risk of infection. These include diabetes mellitus, atherosclerosis, smoking, and immunosuppresion. Patients with an associated tibial plateau or talus fracture were also excluded as outlined in the exclusion criteria.
6. Due to time constraints, it was not possible to follow up the patients for more than 12 weeks to assess for overall nonunion, and union. Therefore, an assumption was made that the adequacy of reduction at 6 weeks had a direct correlation to the degree of malunion once healing was achieved as described in the literature review.

5. Discussion

Open ankle fracture management remains a daunting task due to the increased risk of wound infection, wound necrosis, fracture nonunion and resultant impaired functional ability.
The aim of this study was to determine the functional outcomes of open ankle fractures seen in KNH, PCEA Kikuyu hospital and AKUH. Majority of the patients were managed in KNH, with only 3 patients from AKUH included in the study. This limited the ability to infer or compare outcomes based on the hospital the patients were being managed.
In this study, the mean age was 38 years. This is slightly less than the average age found in the Indian population (41.7 years) (9).Majority of the patients were male (77%).This is in keeping with a study done by Saini et al (2) that found a higher incidence in males. This was attributed to the higher incidence of high energy trauma among males which is the leading cause of open ankle fractures.
AO fracture class B was the most common (64.5%) which is comparable with studies in Finland (12) and India (14) that also found Danis- Weber B (similar to AO type B) as the most common. Majority of the skin lesions were type 3(47.7%) i.e. skin breakage from outside being more than 5 cm with increased contusion and devitalized edges. This was similar to studies by Brown (15) and Dhillon (2) who reported 47.6% and 30.4% of open ankle fractures being Gustilo 3 respectively. Most of the fractures had no muscle injury or nerve injury. There were only two cases of vascular injury (posterior tibial artery) and no case of nerve injury in the study group.
No patient had antibiotic administration or debridement in the first 6 hours in all hospitals that the study was conducted. This was attributed to delay in arrival to hospital. However, majority of the patients (66.1%) had antibiotics administered within the first 24 hours. Most of the patients had initial debridement between 24 and 48 hours.

Factors associated with developing infection of open ankle fractures

In this study, the injured ankle was assessed on the first two weeks (day 4 and day 10), the sixth week and the twelfth week to ascertain early, delayed and late infection respectively.

Patients that had a higher AO fracture severity and soft tissue injury severity developed early delayed and late infection more than those with less severe injuries, with the soft tissue injury being a more significant factor than the fracture severity. This was also reported by Boylston

(10), Neubauer (49) and locally by Admani (67). It is attributed to the higher energy involved and more tissue injury attained.

There was a commensurate relationship between delay in antibiotic administration and debridement (more than 24 hours) with development of infection. There was a significant increased risk of developing early infection if debridement was done after 72 hours compared to before 48 hours. This confirms the recommendation by BOA/BAPRAS guidelines (69) that early debridement (within 24 hours) has significant benefits in reduction of infection.

The modality of fixation had a significant influence on the risk of early infection. Fixation with k wires and hybrid fixation had a significantly higher risk of early infection than use of an external fixation or a back slab alone. This risk drastically dissipated with conversion to internal fixation and wound cover. There was no case of wound necrosis, dehiscence or infection in all cases that were fixed and wound closed primarily. There was also a significant reduction in hospital stay and better reduction with early wound closure and internal fixation. These findings assent the advantages of early wound closure and primary fixation described by Bowen (3).

Poor reduction and Malunion has been associated with delayed infection to a significant degree. This exemplifies the argument in favour of immediate or early internal fixation because it improves soft tissue healing and allows early mobilization (18,25,83,95).

There was a progressive reduction of infection over time. This was attributed to repeat debridement and antibiotic treatment as well as wound closure and definitive fracture fixation within the first month.

Factors associated with malunion of open ankle fractures

The radiological criteria described by Burwell (104) was used to assess the adequacy of reduction at 6 weeks. It was assumed that by this time the fixation used was applied for definitive fixation. There was a significantly better reduction with internal fixation with plates and screws than all other fixation modalities. This was followed by use of hybrid fixation and use of external fixation alone respectively. The use of a back slab splint had the highest percentage of poor reduction at 6 weeks. There was significant improvement in quality of reduction after conversion. This emphasizes the importance of conversion to internal fixation as this ensures maintenance of anatomic reduction and minimizes the risk of loss of reduction and malunion (102).

Factors associated with poor functional outcomes of open ankle fractures

The AOFAS grading system (105) was carried out 12 weeks after injury to assess factors that are considered to have a bearing on the functionality of the ankle joint (such as pain, range of motion, ability to walk unaided etc).

A total of 49.7% of the patients had an excellent to good scores while 27.4% of the patients had fair outcome scores and 22.6% had poor scores(less than 39%).The proportions of good outcomes are considerably less than those reported by Santhanakumaran (9) in an Indian study who reported a 73.1% good and 26.9% poor outcome. The study indicates that all patients had surgical debridement within 24 hours and early skeletal stabilization and this may have contributed to the better outcomes seen (9).

Poor reduction, infection (especially delayed and late infection) and maintaining initial provisional fixation had a significant correlation with poor functional outcome. There was a proportionate increase in poor outcomes with increase in age but not to a significant degree. There was no correlation between the AOFAS score and the initial fixation after debridement. In this regard, no provisional fixation is deemed superior over another. The main influence to better outcome was primary internal fixation or conversion to internal fixation. This has been emphasized in previous studies (90,91,93).

6. Conclusion and recommendations

Conclusion

The following factors were associated with significant reduction in infection:

i. Beginning antibiotic administration within the first 24 hours after injury
ii. Wound debridement within the first 72 hours
iii. Early (within the first 2 weeks) definitive fixation and wound closure
iv. Conversion from provisional to definitive fixation within the first two weeks

Regarding fracture fixation, the following was noted:

i. Poor reduction and malunion was associated with higher rates of delayed infection and poor functional outcome
ii. Loss of reduction and poor stability was noted to be significantly higher with use of a back slab splint alone.

Poor functional outcomes were attributed to the following:

i. Infection
ii. Poor reduction
iii. Failure of conversion of provisional fixation to definitive fixation

Recommendations

In order to obtain good functional outcomes, the treatment of open ankle fractures should be tailored to preventing infectious complications and Malunion. The following guidelines should be applied:

- Early antibiotic administration:

Administration of antibiotics within 24 hours significantly reduces the risk of wound infection. However, patients tend to arrive to tertiary hospitals more than 24 hours after injury. Paramedics and primary care givers should be sensitized on the need to offer prophylactic antibiotics as soon as possible prior to referral.

- Early surgical debridement:

The initial debridement should be done within 72 hours and involve an ortho-plastic team. The plastic surgery team should be involved early so as to plan early wound closure where applicable.

- Early conversion to internal fixation. Aim for anatomic reduction:

Since most wounds are not amendable to primary closure, the fixation modality chosen on initial debridement should only be temporary especially where the fracture was comminuted or unstable. Conversion to internal fixation yields better results with reduced infection rates.

Disclaimer

I, Dr. Joseph Irungu Muchugu, have not received any financial benefit or incentives from any party or individual that may benefit from this study.

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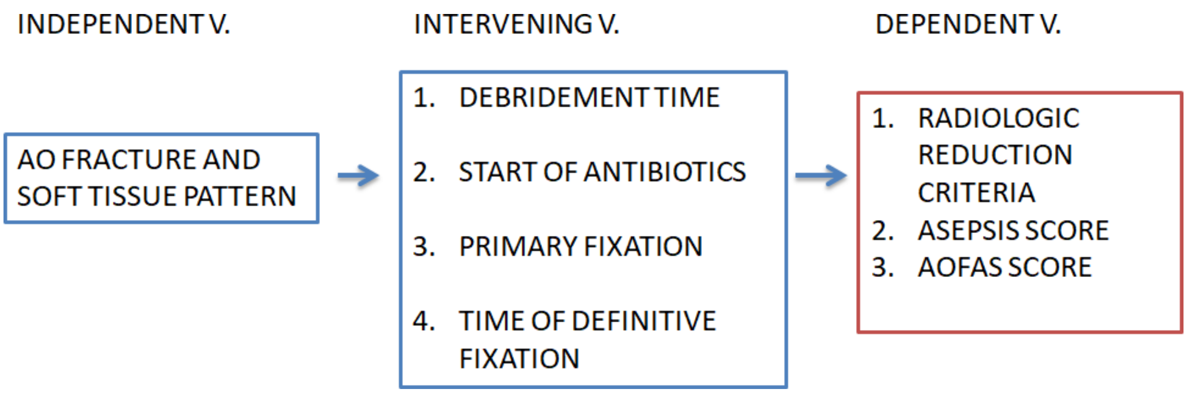
8. Appendices

8.1 Conceptual framework



8.2 Consent form

STUDY ON EARLY FUNCTIONAL OUTCOMES OF OPEN ANKLE FRACTURES AT KNH, AGA KHAN UNIVERSITY HOSPITAL AND PCEA KIKUYU HOSPITAL

STUDY NUMBER……………………………………………………………………….

I am Dr. Joseph Irungu Muchugu; a master of surgery in orthopaedic surgery at the University of Nairobi. I am conducting a study on the early functional outcomes of open ankle fractures at KNH, AKUH and PCEA Kikuyu Hospital. 1would like to recruit you into the study. Your participation will involve you giving information concerning your age and your progress and functional outcome after twelve weeks. This information will help in analysing and improving the management of open ankle fractures

Your participation in this study will be kept in confidence and your actual name will not be used in the study. Confidentiality of information obtained from you will be protected through such processes as using code numbers for concealed identity and limiting the number of people with access to the information.

Your participation in this study voluntary and should you wish to withdraw from the study at any point then you will be at liberty to do so.

The benefits to you for being involved in the study include proper immobilization of your injured limb to the recommended protocol as well as proper wound care and antibiotic coverage.

There are no risks from you getting involved in this study. The study findings will not be used for any monetary gains.

Should you decide to withdraw from the study at any point, you will not be subjected to any discriminatory treatment. Should you require any further information or clarification then the main researcher may be contacted using the contacts on the consent certificate/form.

8.3 Consent Certificate

I certify that the study has been fully explained to me and I am willing to participate in it.

Participant's Signature (or thumbprint)……………………….

Date……………………………………………

I confirm that I have clearly explained to the participant the nature of the study and the contents of this consent form in detail and the participant has decided to participate voluntarily without any coercion or undue pressure.

Investigator's Signature ....Date

…………………………..………………

Witness Signature..Date..

For Any Enquiries, please contact:

1. Dr. Joseph Irungu Muchugu,

   Principle investigator

   Mobile number: 0724171746

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   Senior Lecturer, Department of Orthopaedic surgery, University of Nairobi.

   Mobile number: 0733619775

   Email: gkmuseve@gmail.com
4. Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

   College of Health Sciences

   P.O. Box 19676-00202

   Nairobi

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   Email: uonknh_erc@uonbi.ac.ke

FORMU LA IDHINI

NAMBARI YA

KUSHIRIKI……………………………………………………………………………………..

Jina langu ni daktari Joseph Irungu Muchugu, mwanafunzi wa shahada ya juu ya upasuaji wa mifupa katika chuo kikuu cha Nairobi. Nafanya utafiti kuchunguza jinsi mbalimbali amabavyo mifupa kwenye kifundo cha mguu kiliyovunjiika kikiwa na kidonda pahala palipovunjika.Pia nitatathmini aina mbalimbali ya matibabu utakayopata na matokeo yake baada ya wiki kumi na mbili, Utafiti huu utahusisha wagonjwa watakaochaguliwa kushiriki ambao wamelazwa kwenye wodi za upasuaji ya mifupa katika hospitali kuu ya Kenyatta. Utafiti huu umeidhinishwa na kamati ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta..

Kuhusishwa kwako katika upelelezi huu ni jambo la siri baina yako na mpelelezi, na jina lako halite tumika kwenye upelelezi. Matokeo ya upelelezi huu yatakua ni ya siri kati yako na mpelelezi mkuu, na siri hii itawekwa kwa njia tofauti kama vile kutumia nambari za siri badala ya majina yako, pamoja na kuhusisha wasaidizi wachache katika upelelezi huu.

Kuhusika kwako katika upelelezi huu ni kulingana na mapendeleo yako na sio lazima, naisitoshe, unaweza kujiondoa kutoka upelelezi huu kwa wakati wowote.

Faida utakayoipata nikusitirishwa mfupa wa paja kwa njia inayofaa kama utapatikana kutositirishwa vyema.

Hakuna hatari au mashaka yanayoweza kutokana na upelelezihuu. Hakuna faida ya pesa zozote ambazo zitapatikana kutokana na upelelezi huu.

Ukihitaji maelezo zaidi unaweza kuwasiliana na mpelelezi mkuu kwa anwani, baruapepe au simu zilizoandikwa hapa chini.

Hati ya Ruhusa

Sahihi ya mshiriki..Tarehe..

Ninathibitsha yakwamba nimetoa maelezo sahihi kwa mhusika kuhusu huu utafiti na yale yote yaliyomo kwa ustadi, naye mhusika ametoa uamuzi wa kushiriki bila ya kushurutishwa.

Sahihi ya mchunguzi………………………………Tarehe………………………

Sahihi ya shahidi…………………………………...Tarehe……………………..

Ukiwa na maswali yoyote kuhusu utafitihuu, wasiliana na:

Dtr. Joseph Irungu Muchugu, mtafiti kanuni

Simu ya rununu: 0724171746

Barua pepe: irungumuchugu@gmail.com:

Dtr. Kirsteen O. Awori , Mhariri Mkuu Orthopaedics, Chuo Kikuu cha Nairobi.

Simu ya rununu: 0722812499

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Dtr. George K. Museve,Mhariri Orthopaedics, Chuo Kikuu cha Nairobi.

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hospitali ya kitaifa ya Kenyatta /Chuo Kikuu cha Nairobi,Kamati ya maadili na utafiti

Chuo cha sayansi ya afya

Sanduku la posta 19676-00202

Nairobi

simu: +254202726300-9 Ext 44355

barua pepe: uonknh_erc@uonbi.ac.ke

8.4 Data collection sheet

1. INITIAL ASSESSMENT

PATIENT BIODATA

IP NO…………………………………….

STUDY NO……………………………

AGE…………………………………..

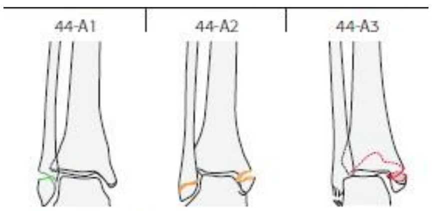
SEX ☐ Male ☐ Female

TEL NO………………………………

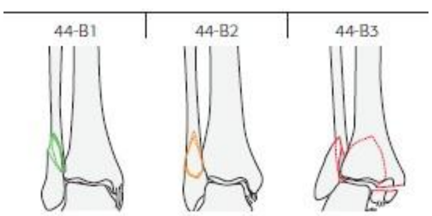
DATE……/……/…. (DD/MM/YY)

AO/OTA FRACTURE

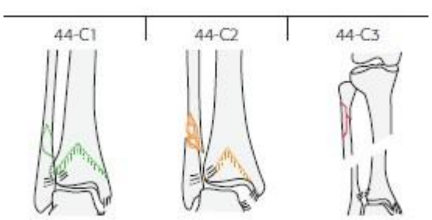
(circle one)



44-A infrasyndesmotic lesion
44-A1 isolated
44-A2 with fractured medial malleolus
44-A3 with posteromedial fracture



44-B transsyndesmotic fibular fracture
44-B1 isolated
44-B2 with medial lesion
44-B3 with medial lesion and Volkmann's fracture



44-C suprasyndesmotic lesion
44-C1 fibular diaphyseal fracture, simple
44-C2 fibular diaphyseal fracture, multifragmentary
44-C3 proximal fibular lesion

SKIN LESION

(Circle one)

IO 1	Skin breakage from inside out
IO 2	Skin breakage from outside in < 5 cm, contused edges
IO 3	Skin breakage from outside in > 5 cm, increased contusion, devitalized edges
IO 4	Considerable, full-thickness contusion, abrasion, extensive open degloving, skin loss

MUSCLE/ TENDON INJURY

(Circle one)

MT 1	No muscle injury
MT 2	Circumscribed muscle injury, one compartment only
MT 3	Considerable muscle injury, two compartments
MT 4	Muscle defect, tendon laceration, extensive muscle contusion
MT 5	Compartment syndrome/crush syndrome with wide injury zone

NEUROVASCULAR INJURY (NV)

(Circle one)

NV 1	No neurovascular injury
NV 2	Isolated nerve injury
NV 3	Localized vascular injury
NV 4	Extensive segmental vascular injury
NV 5	Combined neurovascular injury, including subtotal or even total amputation

TOTAL SCORE

44…… IO…… MT…... NV…......

Data collection sheet (2)

2. INITIAL MANAGEMENT

TIME FROM INJURY TO ANTIBIOTIC ADMINISTRATION

	6-12 hours
	12-24hours
	24-48hours
	48-72hour
	>72hours

TIME FROM INJURY TO INITIAL DEBRIDEMENT

(*Tick one*)

	< 6 hours
	6-12 hours
	12-24hours
	24-48hours
	48-72hour
	>72hours

FIXATION AFTER INITIAL DEBRIDEMENT

(*Tick one*)

	Back slab splint
	K-wires/ rash pin/ screws & back slab
	K-wires/ rash pin/screws & external fixator
	Internal fixations with plate and screws
	External fixation alone

WOUND DEBRIDEMENT

(*Tick one each*)	yes	no
tourniquet		
Pulsatile lavage		
Primary closure		
Primary flap/STSG		
Wound Left open		

If Pulsatile pressure was used indicate pressures used below

………psi at............... revolutions

Definitive fixation (circle one)		
Was the temporary fixation converted to definitive fixation before discharge	yes	no

If yes after how long was conversion done

<10days	(Tick one cell)
11-21days	
22-28weeks	
≥29weeks	

SKILL LEVEL OF SURGEON PERFORMING THE INITIAL DEBRIDEMENT AND FIXATION

PROFFESSIONAL LEVEL	*(TICK ONE)*
CONSULTANT	
SENIOR RESIDENT(≥ YR.4)	
JUNIOR RESIDENT(< YR. 4)	

Data collection sheet (3)

3. WOUND ASSESSMENT FOR EARLY INFECTION IN THE WARD

ASEPSIS SCORE DAY 4

(Circle one in each row)

	The proportion of wound affected (%)					
	0	>0-19	20-39	40-59	60-79	80-100
Serous exudates	0	1	2	3	4	5
erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10
TOTAL SCORE	……………/30					

ASEPSIS SCORE DAY 10

	The proportion of wound affected (%)					
	0	>0-19	20-39	40-59	60-79	80-100
Serous exudates	0	1	2	3	4	5
erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10
TOTAL SCORE	……………/30					

ANY TIME WHILE PATIENT IS ADMITTED

Additional treatment	yes	no
antibiotics	10	0
Drainage of pus under local anaesthesia	5	0
Debridement of wound under general anaesthesia	10	0
Isolation of bacteria	10	0
TOTAL SCORE	………./35	

TOTAL ASEPSIS SCORE

(PICK THE HIGHER SCORE BETWEEN DAY 4 AND DAY 10 AND ADD ‗ADDITIONAL TREATMENT‘)

SCORE… ..../65

ASEPSIS SCORE CATEGORY(first 2 weeks)

SCORE	MEANING	TICK ONE CELL
0-10	No infection, normal healing	
11-20	Disturbance of healing	
21-30	Minor infection	
31-40	Moderate infection	
≥41	Severe infection	

Data collection sheet (4)

4. ASSESSMENT AT 6 WEEKS (DELAYED INFECTION AND REDUCTION)

ASEPSIS SCORE WEEK 6

	The proportion of wound affected (%)					
	0	>0-19	20-39	40-59	60-79	80-100
Serous exudates	0	1	2	3	4	5
erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10
TOTAL SCORE	……………/30					

ANY TIME AFTER PATIENT IS DISCHARGED

Additional treatment	yes	no
antibiotics	10	0
Drainage of pus under local anaesthesia	5	0
Debridement of wound under general anaesthesia	10	0
Isolation of bacteria	10	0
TOTAL SCORE	………./35	

TOTAL ASEPSIS SCORE

(ASEPSIS SCORE PLUS _ADDITIONAL TREATMENT‘ SCORE)

…………………./65

RADIOLOGIC CRITERIA OF REDUCTION

Circle 1(anatomic/fair/poor)

Anatomical • no angulations • no more than 1mm longitudinal displacement of medial/lateral malleolus • no more than 2mm displacement of posterior malleolus
Fair • no angulations • 2-5mm posterior displacement of a large posterior fragment • No displacement of the talus
Poor • Any medial/lateral displacement of medial/lateral malleolus • >5mm posterior displacement of posterior malleolus • Talus displacement/tilt

ASEPSIS SCORE CATEGORY (week 6)

SCORE	MEANING	TICK ONE CELL
0-10	No infection, normal healing	
11-20	Disturbance of healing	
21-30	Minor infection	
31-40	Moderate infection	
≥41	Severe infection	

Data collection sheet (5)

5. 12-WEEK ASSESSMENT (LATE INFECTION AND AOFAS SCORE)

ASEPSIS SCORE WEEK 12

	The proportion of wound affected (%)					
	0	>0-19	20-39	40-59	60-79	80-100
Serous exudates	0	1	2	3	4	5
erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10
TOTAL SCORE	……………/30					

ASEPSIS SCORE CATEGORY (week 12)

SCORE	MEANING	TICK ONE CELL
0-10	No infection, normal healing	
11-20	Disturbance of healing	
21-30	Minor infection	
31-40	Moderate infection	
≥41	Severe infection	

ANY TIME BETWEEN 6-12 WEEKS

Additional treatment	yes	no
antibiotics	10	0
Drainage of pus under local anaesthesia	5	0
Debridement of wound under general anaesthesia	10	0
Isolation of bacteria	10	0
Hospital stay >14days	5	0
TOTAL SCORE	………./45	

AOFAS SCORE

EXCELLENT	≥75%	
GOOD	60-74%	
FAIR	40-59%	
POOR	≤39%	

TOTAL ASEPSIS SCORE............ **/75**

Total Number of surgeries before discharge
…………

8.5 AOFAS scale

Data collection Sheet (6)

PAIN(40 POINTS) *(tick one cellin each category)*		
None		40
Mild/occasional		30
moderate		20
Severe/almost always present		0
FUNCTION(50 POINTS)		
No limitation, no support		10
No limitation of daily activity, limitations of recreation activities, no support		7
Limited daily recreational activity, uses a cane for support		4
Severe limitation of daily activities, uses walker/crutches/wheelchair/brace		0
AVERAGE MAXIMUM CONTINOUS WALKING DISTANCE(IN METRES)		
>500 metres		5
300-499 metres		4
100-299 metres		2
<100metres		0
WALKING SURFACES		
No difficulty on any surface		5
Some difficulty on uneven terrain, stairs, inclines, ladders		3
Severe difficulty on uneven terrain, stairs, inclines, ladders		0
GAIT ABNORMALITY		
None/slight		8
obvious		4
marked		0
SAGGITAL MOTION (FLEXION PLUS EXTENSION) *compare with opposite ankle*		
Normal/mild restriction(75%-100% of normal)		8
Moderate restriction(25%-74% of normal)		4
Marked restriction(<25% of normal)		0
HINDFOOT MOTION(INVERSION AND EVERSION) *compare with opposite foot*		
Normal/mild restriction(75%-100% of normal)		6
Moderate restriction(25%-74% of normal)		3
Marked restriction(<25% of normal)		0
ANKLE-HINDFOOT STABILITY(ANTEROPOSTERIOR,VALGUS AND VARUS) *compare with opposite foot*		
Stable		8
Definitely unstable		0

ALIGNMENT(10 POINTS)		
Good plantar grade foot, ankle and hind foot well aligned		10
Fair, plantergrade foot, some degree of ankle hind foot malalignment, no observable symptoms		5
poor, non plantergrade foot, severe malalignment, observable symptoms		0
TOTAL SCORE	**/100**	

8.6 Time frame: Gantt chart

Year	2019									2020						
Month	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06	07
Proposal Writing and Presentation																
Ethical approval																
Data Collection and analysis																
Dissertation writing																
Presentation of results																

8.7 Budget

ITEM	QUANTITY	UNIT PRICE	TOTAL(KSH)
Stationery:			
• Pens	1 box	400	400
• Writing pads	5	250	1250
• Printing fees	9	500	4500
• Binding fees	9	100	900
ERC Approval:			
Ethics review fees	1	2000	2000
Consultation:			
Statistician	1	30000	30000
Lab oratory:			
Culture and sensitivity	34	1500	51000
Contingencies	-	-	15000
TOTAL			105,050

This study was funded by the principal investigator.

8.8 KNH/UON-ERC Approval

KENYATTA NATIONAL HOSPITAL
APPROVED
24 SEP 2019
KNH/UoN-ERC
P. O. BOX 20723 - 00202 NAIROBI

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
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Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/352

24th September, 2019

Dr. Muchugu Joseph Irungu
Reg. No. H58/89864/ 2015
Dept. of Orthopaedic Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Muchugu

RESEARCH PROPOSAL: EARLY FUNCTIONAL OUTCOMES OF OPEN ANKLE FRACTURES AT KENYATTA NATIONAL HOSPITAL, AGA KHAN UNIVERSITY HOSPITAL AND P.C.E.A. (P559/07/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 24th September 2019 – 23rd September 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect 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.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
g. Submission of an *executive summary* report within 90 days upon completion of the study.
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UON
The Chair, Dept.of Orthopaedic Surgery, UoN
Supervisors: Dr. Kirsteen Awori, Dept. of Human Anatomy, UoN
Dr.George K. Museve, Dept.of Orthopaedic Surgery, UoN

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8.9 KNH study registration certificate

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
JOSEPH IRUNGU MUCHUGU
2. Email address: irungumuchugu@gmail.com Tel No. 0724171746
3. Contact person (if different from PI) —
4. Email address: — Tel No. —
5. Study Title
EARLY FUNCTIONAL OUTCOMES OF OPEN ANKLE FRACTURES AT KENYATTA NATIONAL HOSPITAL, AGA KHAN UNIVERSITY HOSPITAL AND PCEA KIKUYU HOSPITAL
6. Department where the study will be conducted ORTHOPAEDIC SURGERY
(Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
Name: Dr. D. G. Kinyanjui Signature Date 25/10/19
8. Endorsed by KNH Head of Department where study will be conducted.
Name: Dr. D. G. Kinyanjui Signature Date 25/10/19
9. KNH UoN Ethics Research Committee approved study number P559/07/2019
(Please attach copy of ERC approval)
10. I JOSEPH IRUNGU MUCHUGU commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
Signature Date 25/10/2019
11. Study Registration number (Dept/Number/Year) Orthopaedic 24 / 2019
(To be completed by Research and Programs Department)
12. Research and Program Stamp 28 OCT 2019

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Research and Programs and investigators **must commit** to share results with the hospital.

Version 2: August 2014

8.10 NACOSTI approval

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 956177

Date of Issue: 16/December/2019

RESEARCH LICENSE

This is to Certify that Dr.. Joseph Muchugu of University of Nairobi, has been licensed to conduct research in Kiambu, Nairobi on the topic: EARLY FUNCTIONAL OUTCOMES OF OPEN ANKLE FRACTURES AT KENYATTA NATIONAL HOSPITAL, AGA KHAN UNIVERSITY HOSPITAL AND P.C.E.A KIKUYU HOSPITAL for the period ending : 16/December/2020.

License No: NACOSTI/P/19/2818

956177

Applicant Identification Number

Director General

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

8.11 PCEA Kikuyu Mission Hospital approval

P.C.E.A Kikuyu Hospital

P.O. Box 45-00902 Kikuyu, Tel:(020) 2044766-68, (020)2044769-71
Fax: (020)2044765/772 Mobile:0722-207636 / 0733-606133 / 0736-270192

December 2, 2019

Dr. Muchugu Joseph Irungu
Department of Orthopaedic Surgery
The University of Nairobi
School of Medicine
P O Box 33294-00600
Nairobi

Dear Dr. Muchugu

RE: REQUEST TO COLLECT DATA IN PCEA KIKUYU HOSPITAL

Your request to collect data on 'Early functional outcomes of Open Ankle Fractures' is hereby granted. You are required to submit a copy of your findings to the undersigned.

Wishing you the best in your work!

Yours faithfully
For: PCEA Kikuyu Hospital

Mr. P. Kimpiatu MD, FRCSI, FCS-ECSA, LeHHO
CHIEF EXECUTIVE OFFICER

Cc Dr. E. Sang – Rehab Unit Manager

*Receipients of the **Golden Jubilee** Award year 2013 awarded by His Excellency **Uhuru Muigai Kenyatta**, President & Commander-in-chief of the Armed forces of the Republic of Kenya*

General Hospital Eye Unit Orthopaedic Rehabilitation Centre Dental Unit

Email: kikuyu@pceakikuyuhospital.org / Website: www.pceakikuyuhospital.org

PCEA Kikuyu Hospital @PceaKikuyu

"The love of Christ through healing"

8.12 AKUN, IERC and research committee approval

THE AGA KHAN UNIVERSITY

Ref: 2019/IERC-141 (v3)
March 3, 2020

Dr. Parmenus Oroko – AKU Site Investigator,
Faculty, Department Of Surgery,
Aga Khan University.

Dr. Joseph Irungu Muchugu,
Orthopaedic Surgery Registrar,
School Of Medicine, University of Nairobi

Dear Dr. Oroko and team,

RE: EARLY FUNCTIONAL OUTCOMES OF OPEN ANKLE FRACTURES AT KENYATTA NATIONAL HOSPITAL, AGA KHAN UNIVERSITY HOSPITAL AND P.C.E.A KIKUYU HOSPITAL

The Aga Khan University, Nairobi (AKUN), Institutional Ethics Review Committee (IERC) and Research Committee (RC) are in receipt of your protocol resubmitted to the Research Office on February 10, 2020. With reference to our earlier communication Ref: 2019/IERC-141 (v2) dated February 03, 2020 the IERC & RC note that the researcher has addressed concerns earlier raised. Further the committees' record that the Investigator has correctly moved to a proportion estimate for numbers, however, the Fisher's correction is not relevant here. Ideal would have been to indicate that there is no way to obtain 384 participants and to say that because of that limitation, the precision will be less than 0.05.

The committees have granted approval for this project {*as per attached official stamped protocol and attachments - version 2019/IERC-141 (v3)*}. As per the KNH.UON ERC letter Ref: KNH-ERC/A/352, you are authorized to conduct this study at Aga Khan University Hospital Nairobi from **March 03, 2020** to **September 23, 2020.** Prior to commencing the study, you will be expected to ensure compliance with relevant institutional administrative regulations.

The study should be conducted in full accordance with all the applicable sections of the IERC guidelines and you should notify the IERC immediately of any changes that may affect your research project. All Serious Adverse Events (SAEs) and the interventions undertaken should be reported as soon as they occur but not later than 48 hours. A report from the Hospital Patient Safety Committee should also be submitted. All consent forms must be filed in the study binder and patient hospital record. Further, you must provide an interim report **60 days before expiration** of the validity of this approval and request extension if additional time is required for study completion. You must advise the IERC when this study is completed or discontinued and a final report submitted to the Research Office for record purposes. The hospital management should be notified of manuscripts emanating from this work.

If you have any questions, please contact Research Office at research.supportea@aku.edu or 020-366 2148/1136.

With best wishes,

Prof. Rodney Adam
Chair – Research Committee (RC)
Aga Khan University, (Kenya)

Copies:
Chair - Institutional Ethics Review Committee, AKU (*Nairobi*)
Associate Dean - Clinical services and Chief of Staff, AKUH (*Nairobi*)

3rd Floor, Park Place Building, 2nd Parklands Avenue, Off Limuru Road
P. O. Box 30270, GPO 00100, Nairobi, Kenya
Tel: +254 20 366 1200; Website: www.aku.edu

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

The Grant of Research Licenses is Guided by the Science, Technology and Innovation (Research Licensing) Regulations, 2014

CONDITIONS

1. The License is valid for the proposed research, location and specified period
2. The License any rights thereunder are non-transferable
3. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research
4. Excavation, filming and collection of specimens are subject to further necessary clearence from relevant Government Agencies
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8. NACOSTI reserves the right to modify the conditions of the License including cancellation without prior notice

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Mobile: 0713 788 787 / 0735 404 245
E-mail: dg@nacosti.go.ke / registry@nacosti.go.ke
Website: www.nacosti.go.ke

8.13 Originality report

Early Functional Outcomes Of Open Ankle Fractures At Kenyatta National Hospital, Aga Khan University Hospital And P.C.E.A Kikuyu Hospital

ORIGINALITY REPORT

9%	2%	5%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to University of Nairobi Student Paper	2%
2	Mikko T. Ovaska, Rami Madanat, Maija Honkamaa, Tatu J. Mäkinen. "Contemporary demographics and complications of patients treated for open ankle fractures", Injury, 2015 Publication	1%
3	www.ajol.info Internet Source	1%
4	Hannigan, Geoffrey D., Nicholas Pulos, Elizabeth A. Grice, and Samir Mehta. "Current Concepts and Ongoing Research in the Prevention and Treatment of Open Fracture Infections", Advances in Wound Care, 2014. Publication	<1%
5	www.jfasap.com Internet Source	<1%
6	Rajasekaran, Shanmuganathan, P Kanna, and Jayaramaraju Dheenadhayalan. "Open injuries	<1%