

UNIVERSITY OF NAIROBI

PIN TRACT INFECTION AFTER UNIPLANAR EXTERNAL FIXATION OF OPEN FRACTURES AT KENYATTA NATIONAL HOSPITAL

BY

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H58/67152/2013

A Dissertation Submitted for Examination in Partial Fulfillment of the Requirements for Award of the Degree of Master of Medicine in Orthopaedic Surgery of the University of Nairobi

2017

DECLARATION

I declare that this dissertation/thesis is my original work and has not been submitted elsewhere for examination, award of a degree or publication. 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 requirements.

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Date.....

DEDICATION

I dedicate this study to my mother, Zuleykha, for her support throughout my education; to my wife, Khadijah, for her unconditional love and support; to my daughters; and to my lecturer, Dr. Gakuya – teacher and mentor.

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ABBREVIATIONS

KNH – KENYATTA NATIONAL HOSPITAL

- UON UNIVERSITY OF NAIROBI
- ERC ETHICAL RESEARCH COMMITTEE
- PTI PIN TRACT INFECTION
- HIV HUMAN IMMUNODEFICIENCY VIRUS
- SPSS STATISTICAL PACKAGE FOR THE SOCIAL SCIENCES

ABSTRACT

Background: Pin tract infection is the most common complication of external fixation accounting for 43% of complications (1). The presence of a pin tract infection reduces the pin-bone interface strength which leads to subsequent pin loosening. Pin tract infection also delays conversion of an external fixator to an internal fixation until clearance of the infection is completed. The incidence of pin tract infections following uniplanar external fixation of open fractures in the local settings is not known. Due to less than ideal circumstances in hospitals in an African setting, there is concern that the incidence of pin tract infection is higher.

Hypothesis: The incidence of pin tract infection in Kenyatta National Hospital is higher compared to the West.

Study Objective: To determine the incidence and microbe profile of pin tract infection in patients who have undergone uniplanar external fixation following open fractures at Kenyatta National Hospital.

Study Design: Prospective cross-sectional study.

Study Setting: This study was conducted at the Orthopaedic Wards and Clinics in Kenyatta National Hospital.

Methodology: Consecutive sampling of patients who had undergone uniplanar external fixation at Kenyatta National Hospital was done between September 2016 and December 2016. Seventy three patients were recruited. Data on presence of pin tract infection was collected. Patients with discharging sinuses had a culture and sensitivity done while those with major pin tract infection (infections that cause loosening of pins) had immediate x-rays done to rule out radiological changes.

Data Processing: The collected data was analyzed using the Statistical Package for the Social Sciences (SPSS) v. 20.

Results: Incidence of pin tract infection was 87.7% (64 of 73 patients). *Staphylococcus aureus* (30.2%) and *coagulase negative staphylococci* (16.3%) were the commonest causative organisms. Other organisms were *Proteus species* and *Pseudomonas species*.

Conclusion: The incidence of pin tract infection after uniplanar external fixation is high. *Staphylococcus aureus* is the leading cause of pin site infection.

CHAPTER 1: INTRODUCTION

A form of external fixation was first described by Hippocrates in the form of two firm leather straps with interconnecting bars made of English dogwood. Lambotte then designed a form of external fixation that involved three fixed pins at either end of a bar without the use of adjustable knobs (2). Hoffman improved the external fixator by introducing adjustable knobs so that pin positioning may be varied and their use made easier (3). Anderson redesigned the external fixator to include through and through pins that traverse the bone and thus improve stability of the construct (4). Strader improved it further by modifying the pin planes' of orientation to improve stability (5).

There are different types of frames of external fixators: uniplanar fixators, ring fixators or hybrid fixators. The uniplanar frame type uses fixator bars, adjustable clamps and pins. Ring fixators, first used by Ilizarov, use wires and ring frames. Hybrid fixators combine use of both monolateral frames and the ring fixators.

External fixators are used for several indications. They may be used as part of damage control orthopaedics - to temporarily stabilize a fracture or even as the definitive management of various fractures. Ring external fixators, as well as uniplanar types may be used for bone transport to fill in bony defects in long bones or in limb lengthening procedures, in acquired or congenital deformity correction, in arthrodesis, and in protection of vascular or nerve repairs.

External fixators do have complications including: Pin tract infections, neurovascular injury, muscle or tendon tethering, delayed union, malunion, bending and psychological trauma. The incidence of pin tract infections in the local settings is not known despite it being quoted as the most common complication following external fixation (1).

CHAPTER 2: LITERATURE REVIEW

The incidence of pin tract infections is highly variable. Parameswaran et al. in a level 1 trauma setting studied 285 patients with external fixators reported the incidence to be 11.2% in his retrospective study (6). Schalamon et al studied the incidence of pin tract infections in 30 patients of the paediatric age group and found it to be 52% (7). Aronson and Tursky in their study of femur fractures involving 42 children found an incidence of 85% (8). Regionally, a study by Jellis et al in Lusaka, Zambia, compared the rate of severe pin tract infection in HIV negative and positive patients, his sample size was 47 patients (13 of whom were HIV-positive) and he found the rate of severe pin tract infection in HIV positive patients to be only 7% (9).

Most pin site infections are secondary to *Staphylococcus aureus*, followed by *Pseudomonas aeruginosa*. Other organisms that are common include *Escherichia coli, Enterobacter aerogenes, Staphylococcus epidermidis and Acinetobacter* (10, 11).

FACTORS ASSOCIATED WITH PIN TRACT INFECTIONS

Multiple factors are associated with the development of pin tract infections. These factors include: construct stability, technique of pin insertion, biomaterials used for the external fixator and post-operative care.

The rigidity of an external fixator is a major determinant of subsequent development of pin tract infection. A stable construct is one that allows just enough micro-motion at the fracture site for bone healing to occur (50-150uM). A pliable construct is more likely to develop pin tract infection than a stable one because of pin site irritation of the surrounding soft tissues.

The stability of uniplanar fixators is dependent on several factors. These include:

- The number of rods used in the external fixator: Increasing the number of rods used increases the stiffness of the construct rendering it more stable.
- The number of pins used: Increasing the pin number increases the stiffness of the construct.
- The core diameter of pins used: Increasing pin core diameter increases the stiffness of the construct making it more stable (12, 13, 14).
- Using a hydroxyapatite coating for the pins: Hydroxyapatite improves bone in growth into the pin and this improves the stability of the bone-pin interface with subsequent decrease in pin loosening (15).
- Tapering the pins: this improves the fixation strength of the pins into the bone as tapered pins can be flushed into depth (16).
- Biomaterial used: Using rods made of carbon fibre improves stability of the construct as compared to stainless steel (17). Carbon fibre is stiffer than stainless steel. A stiffer construct reduces the stress at the bone-pin interface.
- Clamp re-use reduces stability by reducing clamp mechanical performance (18).

• Increasing the pitch of the threads increases the pull out strength of the pins and improves stability.

Stability may also be improved by using two frames oriented at different planes preferably at ninety degrees to each other. This enables the construct to resist forces from various angles.

The type of external fixator also determines the incidence of pin tract infection. Parameswaran et al quoted that the monolateral and hybrid fixators have a higher incidence of pin tract infections than the ring external fixators (6).

The biomaterials used determine the development of pin tract infection. Piesk at al quoted that titanium alloys have fewer incidences of pin tract infections than steel pins (19). There is a race between tissue cells and bacteria to attach to the pin surface – titanium alloys provide a poor surface for the attachment of bacteria (20). Titanium alloys also provide a poor surface for biofilm formation. The choice of implant biomaterial also can encourage white blood cell degranulation and weaken the immunity at the surface of the pin due to polymorphonuclear cells exhaustion (21). Shirai et al also quoted that titanium alloys had less pin tract infection (22). Coating the pins with silver reduces the incidence of pin tract infection as silver has bactericidal properties (23). Using pins coating with nitrous oxide releasing compounds reduces the incidence of pin tract infection, as nitrous oxide can form reactive by-products that have antibacterial activity (24).

An unstable fracture pattern increases the chances of pin loosening by increasing the stress at the pin-bone interface. This increases the likelihood of pin tract infections.

The method of pin insertion is a determining factor to the development of pin tract infection. Loosening of the pin is associated with thermal necrosis during the drilling process. Matthews et al recommended pre-drilling before pin insertion as it reduces pin insertion heat generation that could cause bone necrosis (25). Temperatures above sixty degrees are associated with thermal necrosis (25). One could also use a start-stop technique or continuous irrigation of drilling site with normal saline to allow for bone cooling (26). Bone swarf during the drilling process should also be removed as this leads to decrease in fixation strength and can lead to loosening (26).

During pin insertion, one should avoid areas of significant soft tissue movement such areas where tendons lie, as pins placed at these sites have a higher risk of pin tract infection (36). Pins passing through muscle compartments should be placed with the muscles under stretch to avoid tethering of the muscles and also to prevent pin movement during muscle contraction (36).

Pin site care can influence the development of pin site infection. Chan et al reported similar incidences of pin tract infection with the use of either diluted povidine iodine or saline and concluded saline may be enough (27). Cam et al reported that the use of chlorhexidine was superior to the use of povidine-iodine to prevent pin tract infection (28). Ogbemudia et al reported that chlorhexidine/sulphadiazine mixture was superior to chlorhexidine alone in minimizing the risk for pin tract infection (29).

Yuenyongviwat et al reported similar incidences of pin site infection whether using silver sulfadiazine dressing or dry dressing alone (30). However, Lee et al reported different findings, that antimicrobial dressing reduces incidences of pin tract infection (31).

Camathias et al reported that routine care of pin tracts in external fixators is unnecessary (32). This is supported by the study of Gordon et al where it was concluded bathing may be enough for pin-site care in children (33).

Ferreira et al adopted a method where an alcoholic dressing is applied over the pin sites and left undisturbed for 7 days followed by twice daily cleaning and dressing with alcoholic agent until pin sites healed. No dressing is required after healing of the pin sites but twice daily cleaning is continued for the duration of the external fixation (34).

Norrish et al reported the incidence of pin tract infection in HIV-positive patient to be relatively similar to HIV negative patients (9). Nando et al did a similar study and reported the same (35).

The longer an external fixator remains in situ, the higher the likelihood of infection. Bibbo et al stated that pin tract infection eventually becomes inevitable as the duration of the external fixator increases (36).

Pins located near the fracture site are expected to have a higher chance of loosening than those located further away as they are exposed to higher stress levels. The greater the stress level at the pin-bone interface, the higher the likelihood of pin loosening with subsequent soft tissue irritation and infection (34). It is therefore expected that pins located near fracture sites have a higher incidence of pin tract infection.

Limb elevation post external fixation reduces oedema and encourages healing at site of pin insertion. This seals the pin tract from the external environment earlier (36).

Patient education on pin site care may be of importance. Patients who are educated on the care of the pin sites are expected to have lower incidence of pin infections. Hospital stay duration may also influence development of a pin site infection. A longer hospital stay may result into a longer duration of exposure to hospital acquired pathogens that may lead to pin tract infection.

In conclusion, multiple factors have been associated with external fixator pin tract infection; in order to reduce the incidence of infections, all these factors have to be taken into consideration starting from the operating theatre where the pins are inserted to the follow up care of the pin sites.

CLASSIFICATION OF PIN TRACT INFECTIONS

There are several ways of classifying pin tract infections. Two examples are the DAHL classification and the Checketts –Otterburn classification. The latter is more commonly used as it also gives treatment guidelines.

Pin tract infections are classified into five groups according to the DAHL classification (37).

- I. Type 1 There is inflammation of the skin at the site of pin insertion, there is neither discharge from the pin site nor any radiological findings.
- II. Type 2 There is inflammation plus a serosanguinous discharge at site of the pin tract. There is no purulent discharge or any radiological findings.
- III. Type 3 There is a purulent discharge at the site of the pin tract; however, there are no radiological findings.
- IV. Type 4 There are radiological findings of bone osteoporosis at the site of pin insertion in addition to a purulent discharge.
- V. Type 5 There is frank bone osteomyelitis with sequestrum and involucrum formation.

The Checketts-Otterburn classification (38) includes minor infections (Grades 1 to 3) and major infections (Grades 4 to 6).

- I. Grade 1 Slight redness and little discharge.
- II. Grade 2- Redness of the skin, discharge, pain and tenderness in the soft tissue.
- III. Grade 3 Grade 2 but no improvement with oral antibiotics. Managed by re-siting affected pins, giving IV antibiotics.
- IV. Grade 4 Severe soft tissue infection involving several pins, sometimes with associated pin loosening.
- V. Grade 5 Grade 4 but with radiographic changes (osteopenia around the pins).
- VI. Grade 6 Infection after fixator removal. Pin tract heals initially but subsequently breaks down and discharge in intervals. Radiographs show new bone formation and sometimes sequestra.

GUIDELINES FOR PIN INSERTION TECHNIQUE AND PIN SITE CARE

These are adopted from 'Prevention and management of external fixator pin track sepsis' by Nando Ferreira (34).

Pin Insertion Technique guidelines:

- 1. Skin incision size should be equal to the size of the pins to facilitate rapid healing of the skin and thus seal the pin-bone interface from the environment earlier.
- 2. Drilling should be done with soft tissue protectors
- 3. Predrilling should be done to decrease thermal necrosis
- 4. Pins inserted through muscle compartments should be inserted with the muscles stretched.
- 5. A start-stop technique with saline used for cooling should be done to decrease thermal necrosis

Pin site care guidelines:

- 1. Pin-site dressed with chlorhexidine gauze and left undisturbed for 7 days.
- 2. Twice daily dressing with chlorhexidine solution after 7 days until pin sites heals.
- 3. Once healed, no dressing should be applied. Pin sites are cleaned twice a day until the entire duration of external fixation is over.

GUIDELINES ONCE A PIN SITE INFECTION IS DIAGNOSED

These are adopted from the Checketts-Otterburn Classification (38) and are as follows.

- 1. Grade 1 Slight redness and little discharge. Managed by improved pin site care.
- 2. Grade 2- Redness of the skin, discharge, pain and tenderness in the soft tissue. Managed by improved pin site care and oral antibiotics.
- 3. Grade 3 Grade 2 but no improvement with oral antibiotics. Managed by re-siting affected pins, giving IV antibiotics. The external fixator can be continued.
- Grade 4 Severe soft tissue infection involving several pins, sometimes with associated pin loosening.
 Check X-ray must be done to rule out radiographic changes at this point. Managed by

Check X-ray must be done to rule out radiographic changes at this point. Managed by abandoning external fixator, debridement and IV antibiotics.

- 5. Grade 5 Grade 4 but with radiographic changes. Managed by abandoning external fixator, debridement and IV antibiotics.
- 6. Grade 6 Infection after fixator removal. Pin tract heals initially but subsequently breaks down and discharge in intervals. Radiographs show new bone formation and sometimes sequestra. Managed by curettage of pin tract.

STUDY QUESTION

What is the incidence of pin tract infections following uniplanar external fixation of open fractures in Kenyatta National Hospital?

HYPOTHESIS

The incidence of pin tract infection in Kenyatta National Hospital is higher compared to the West

STUDY JUSTIFICATION

Pin tract infection is the commonest complication of external fixation. Presence of a pin tract infection causes pin loosening and thus reduced stability of the external fixator construct. It also delays the conversion of an external fixator to internal fixation until the infection is cleared. The incidence of pin tract infection is highly variable worldwide. Due to less than ideal circumstances in hospitals in an African setting, there is concern that the incidence of pin tract infection locally, neither is no study that has determined the incidence of pin tract infections. Knowledge of the microbe profile of pin tract infections in our local setting can be used to effectively treat pin tract infections once diagnosed.

STUDY OBJECTIVES

MAIN OBJECTIVES

To determine the incidence of pin tract infection in patients who have undergone external fixation at Kenyatta National Hospital.

SPECIFIC OBJECTIVES

1. To determine the incidence of pin tract infection following uniplanar external fixation of open fractures

2. To determine the microbe profile in pin tract infection in KNH.

CHAPTER 3: MATERIALS AND METHODS

STUDY DESIGN

Prospective cross-sectional study, with consecutive patient sampling.

STUDY SETTING

The study was conducted at the Orthopaedic Wards and Clinics at Kenyatta National Hospital. KNH is a metropolitan, tertiary, referral and teaching hospital situated at Upper Hill area along Hospital Road about 5km from Nairobi city centre. It has a 2000 bed capacity and is one of the two main referral hospitals in Kenya, also serving the greater East and Central Africa region.

STUDY DURATION

September 2016 to December 2016.

STUDY POPULATION

Patients who had uniplanar external fixation at Kenyatta National Hospital.

INCLUSION CRITERIA

- 1. Patients aged between 18 65 years who had undergone uniplanar external fixation after open fractures.
- 2. Those who gave consent

EXCLUSION CRITERIA

- 1. Patients with known co-morbid conditions that may increase likelihood of infection such as HIV, diabetes mellitus, liver failure, renal failure, tumours and smoking shall be excluded. Extremes of age were also excluded. These were excluded as they may increase the incidence of pin tract infection.
- 2. Those who were unable or unwilling to give consent
- 3. Patients who had undergone Ilizarov external fixation.

SAMPLING

All eligible patients were enrolled into the study until the required sample size is obtained.

SAMPLE SIZE

The sample size was calculated using Cochran formula (39) because this is a cross-sectional study with the main objective aimed at getting proportions

$$n = \underline{Z^2 \times P(1-P)}{E^2}$$

where ;

n = sample size to be determined

 Z^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 = is the expected prevalence of the event to occur. Value of P was 0.95.

E = is the target margin of error which will be 5 %(0.05) to increase precision.

$$n = \underline{1.96^2 \times 0.95 (1 - 0.95)}$$
$$0.05^2$$

Hence n = 73 patients

DATA COLLECTION

(a)Patient Recruitment

The principal investigator recruited patients who had undergone uniplanar external fixation at KNH. Follow up of patients was done while patients were admitted in the wards and at the Orthopaedic Clinics.

(b) Data Collection

Patient's biodata was taken and duly filled in the questionnaire. Names were not recorded and instead were assigned serial numbers.

Data on presence and grade of pin tract infection was collected. The presence of redness, tenderness, discharge or pin loosening delineated presence of infection, this was graded using a simplified form of Checketts-Otterburn classification. This is shown below:

GRADE	SIGNS
GRADE 1	REDNESS, TENDERNESS AND NO DISCHARGE
GRADE 2	PRESCENCE OF DISCHARGE
GRADE 3	AS IN NO. 2 BUT WITH NO IMPROVEMENT ON ORAL ANTIBIOICS
GRADE 4	PIN LOOSENING PRESENT
GRADE 5	RADIOGRAPHS SHOW OSTEOPENIA AROUND THE PINS
GRADE 6	RADIOGRAPHS SHOW SEQUESTRUM AND INVOLUCRUM

Table 1: Grading of Pin Tract Infection

Follow up of patients was done at 1, 2 and 6 weeks post external fixation for assessment and sample collection.

All patients with pus discharge at pin site had a pus swab for culture and sensitivity.

Method of obtaining a pus swab: The area around the infected pin was cleaned with normal saline to remove excess debris or scab. Excess normal saline after the cleaning process was then removed using sterile gauze. Gloves were changed and sterile ones used. A pus swab was squeezed into the pin site tunnel for collection of soft tissue exudates from the site of the pins.

The swab was placed in Amies transport medium and sent to the lab within 1 hour of collection. Pus swabs taken were incubated at 37 degrees Celsius for 16 – 18 hours. Both aerobic and anaerobic cultures were done. Aerobic culture medium used was the Sheep Blood Agar or MacConkey agar. Anaerobic cultures were done using Wilkins Chalgren Amikacin Agar. Positive aerobic and anaerobic cultures were tested for sensitivity to various antibiotics.

All patients had a check x-ray (antero-posterior and lateral views) done 6 weeks post external fixation to rule out any bony involvement around the pins. In addition, patients with major pin tract infection (Checketts grade 4 and above – associated with pin loosening) had an immediate check x-ray done to rule out radiological involvement. These patients were selected on basis of pin loosening clinically. The check x-rays were carried out at the Radiology Department in Kenyatta National Hospital.

(c) Data analysis

The collected data was analyzed using the SPSS v. 20.

QUALITY CONTROL

The lab used was Pathologists Lancet Kenya, Main Laboratory located at 5th Avenue Building, Ngong Road.

Interpretation of lab results was done by Mrs. Asenath Nyandika, the Head of Department Technician at Lancet Kenya and supervised by Dr. Nasrin Ahmed, a Consultant Microbiologist.

The lab had monthly External Quality Control Tests of the results to ensure results are reliable.

Interpretation of x-rays was done by Dr. Omar Bashaeb, a 4th year radiology resident at the University of Nairobi; all his reports were supervised and counterchecked by a consultant radiologist.

ETHICAL CONSIDERATIONS

Approval to conduct the study was sought from the Department of Orthopaedic Surgery, University of Nairobi as well as Kenyatta National Hospital, Ethics and Research Committee (KNH/UON-ERC). Data collection commenced once the approval was granted.

Participants in this study or their next of kin were required to give a written informed consent. The consent sought enabled the principal investigator to take the patient's bio-data details, mobile phone number as well as history related to the presenting illness. The mobile number provided was used to trace the participant for the 6 weeks of follow-up.

The investigator clarified to the participants the objective of this study.

Participants were also informed that they will not need to pay for any pus swabs taken for culture and sensitivity nor for check x-rays to rule radiological involvement of bone following pin infection. These expenses were incurred by the researcher. There were no financial costs to the patients involved in this study.

Participation in this study was purely voluntary in nature and as such, it was clarified to the participants that they were free to participate or even withdraw their participation at any point during the study without any explanation. Withdrawal of participation did not to affect the participant's treatment or management in any way whatsoever.

Some questions such as patient's immune status were considered invasive by some participants. As such, participants were free to answer or to decline to answer such questions without any prejudice or any consequences whatsoever.

All information obtained was treated with utmost confidentiality. All participants were allocated a study serial number linking them to their bio-database accessible only to the principle investigator. Patients' names were not used.

STUDY LIMITATIONS

1. Patients' sero-status was reported by the patient themselves and there was no attempt made to clarify that report.

2. Mechanical cleansing cannot achieve sterility of skin around the pins during pus swab collection

DELIMITATION

Patients who have undergone Ilizarov external fixation were not included in the study as this type of fixation is rarely done at KNH.

TIME FRAME

	TIMELINE		
BACKGROUND READING, LITERATURE REVIEW AND	JAN 2016 – JULY 2016		
RESEARCH METHODS PLANNING			
STUDY PROPOSAL PRESENTATION	AUGUST 2016		
SUBMISSION FOR ETHICAL APPROVAL	SEPTEMBER 2016		
DATA COLLECTION AND ANALYSIS	SEPTEMBER 2016 TO DECEMBER 2016		
THESIS WRITING AND PRESENTATION	JANUARY 2017		

Table 2: Timeframe

CHAPTER 4: RESULTS

1. BASELINE CHARACTERISTICS

A. GENDER DISTRIBUTION

Seventy three patients (73) were recruited into the study and followed up for 6 weeks. A total of 300 external fixator pins were assessed. pinsNo patient was lost to follow up as the follow up period was short and most patients were admitted in the wards for longer than the follow up period. Fifty (68.5%) patients were male and 23 were female (31.5%).

B. AGE

The patients' age range was 18 to 64 years with a mean age of 34 years. The median age was 32 years with a standard deviation of 11.

C. DIAGNOSIS

The diagnoses of patients recruited is summarized below

SITE	NUMBER OF PATIENTS	PERCENTAGE OF TOTAL PATIENTS
OPEN TIBIA-FIBULAR FRACTURE	57	78.1
OPEN FEMUR FRACTURE	10	13.7
OPEN HUMERUS FRACTURE	1	1.4
OPEN RADIUS ULNA FRACTURE	3	4.1
COMBINED OPEN TIBIA-FIBULAR AND FEMUR FRACTURES	2	2.7
TOTALS	73	100

Table 3: Diagnosis of patients recruited

GUSTILLO ANDERSON GRADE OF OPEN FRACTURE	NUMBER OF ENROLLED PATIENTS
GUSTILLO II	28
GUSTILLO IIIA	38
GUSTILLO IIIB	7
TOTAL	73

Table 4: Gustillo Classification of the Open Fractures

D. DURATION OF HOSPITAL STAY

The duration of hospital stay is summarized in the figure below.

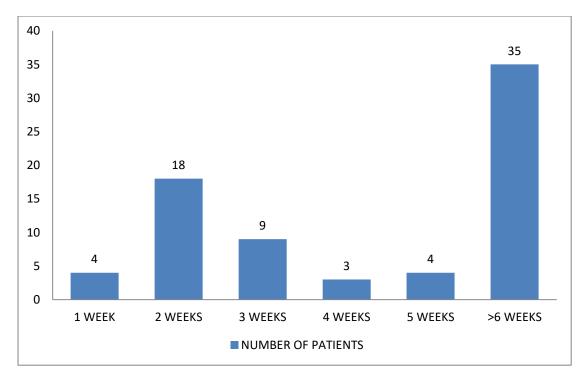


Figure 1: Duration of hospital stay of study patients

2. PIN TRACT INFECTION INCIDENCE

64 (87.7%) of the patients had pin tract infection at some point during the 6 weeks follow up; only 9 (12.3%) of the patients did not develop any grade of pin tract infection throughout the follow up period of 6 weeks. See figure 2 below.

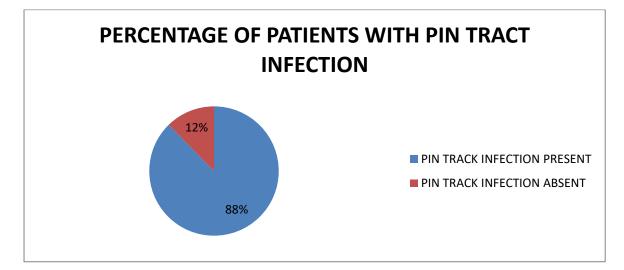
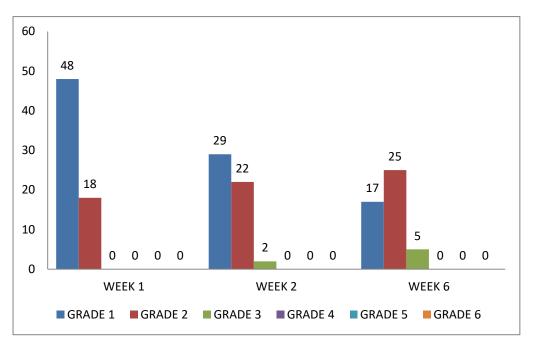


Figure 2: Incidence of pin tract infection in study patients



The pin tract infection grades at different periods of follow up are shown below.

Figure 3: Grades of pin tract infections in the patients during follow up

The commonest grade of pin tract infection was grade 1 infection followed by grade 2 then grade 3. No patient had grade 4, 5 or 6 pin tract infections.

3. PIN TRACT INFECTION INCIDENCE IN DIFFERENT FRACTURE AREAS

SITE	NUMBER ENROLLED	NUMBER INFECTED	PERCENTAGE INFECTED
OPEN TIBIA – FIBULAR FRACTURE	57	49	85.7
OPEN FEMUR FRACTURE	10	10	100
COMBINED OPEN TIBIA – FIBULAR AND FEMUR FRACTURES	2	1	50
OPEN HUMERUS FRACTURE	1	1	100
OPEN RADIUS – ULNA FRACTURE	3	3	100
TOTALS	73	64	87.7

The incidence of pin tract infection in the various fracture regions is shown below.

Table 5: Incidence of Pin Tract Infection in various fracture regions

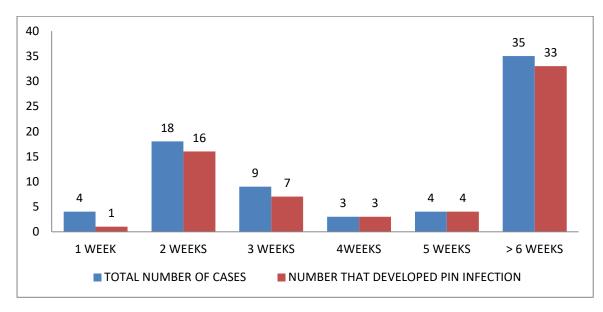
4. PIN TRACT INFECTION AND GUSTILLO CLASSIFICATION OF THE FRACTURES

The incidence of pin tract infections in the various Gustillo Classifications is shown below:

GUSTILLO ANDERSON GRADE OF OPEN FRACTURE	NUMBER ENROLLED	NUMBER INFECTED	PERCENTAGE INFECTED
GUSTILLO II	28	20	71.4
GUSTILLO IIIA	38	37	97.4
GUSTILLO IIIB	7	7	100
TOTAL	73	64	87.7

Table 6: The incidence of pin tract infections in the various Gustillo Classifications

5. PIN TRACT INFECTION AND DURATION OF HOSPITAL STAY



The incidence of pin tract infection and duration of hospital stay is shown below:

Figure 4: Pin tract infection and duration of hospital stay

6. CAUSATIVE ORGANISMS IN PIN TRACT INFECTION

The distribution of bacteria based on culture results is shown below:

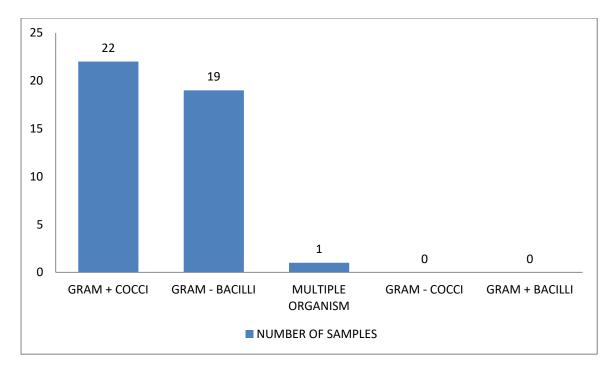


Figure 5: Distribution of bacteria on culture results

Organisms responsible for pin tract infection are shown below.

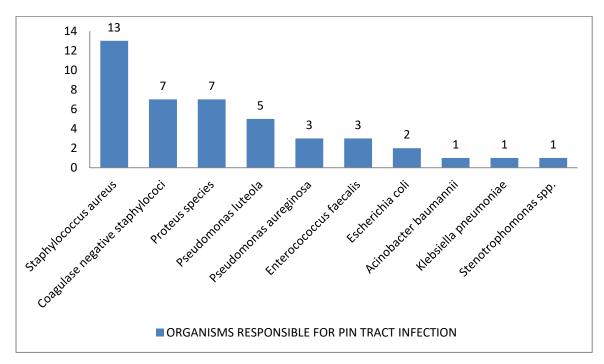


Figure 6: Organisms responsible for pin tract infection

7. ANTIBIOTIC SENSITIVITY PATTERNS OF CAUSATIVE ORGANISMS

	Staph. aureus	Coagulase Negative Staph.	Pseudomonas spp.	Esch. Coli	Proteus spp.	Entero- cocci	Klebsiella spp.	Acinebacter spp.	Stenotrphomonas. spp.
Cefuroxime	-	-	-	1(1)	2(5)	-	0(1)	-	-
Cefrtriaxone	-	-	-	1(1)	3(4)	-		-	-
Cefepime	-	-	4(4)	1(1)	3(4)	-	0(1)	0(1)	-
Cloxacillin	10(3)	3(4)	-	•	-	-	-	-	-
Ampicillin	9(4)	3(4)	-	1(1)	2(5)	3(0)	0(1)	-	-
Penicillin	1(12)	0(7)	-	1(1)	-	-	-	-	-
Amoxiclav	10(3)	3(4)	-	-	2(5)	3(0)	0(1)	-	-
Meropenem	-	-	6(2)	2(0)	7(0)	-	1(0)	1(0)	-
Gentamicin	11(2)	2(5)	5(3)	1(1)	3(4)	3(0)	0(1)	0(1)	-
Ciprofloxacin	-	5(2)	6(2)	1(1)	-	-	1(0)	1(0)	-
Clindamycin	11(2)	-	-	-	-	-	-	-	-
Erythromycin	11(2)	-	-	-	-	-	-	-	-
Cotrimoxazole	8(5)	-	-	-	1(6)	-	0(1)	-	1(0)
Fusidic acid	13(0)	-	-	•	-	-	-	-	-
Rifampicin	11(2)	-	-	-	-	-	-	-	-
Linezolid	13(0)	-	-	-	-	3(0)	-	-	-
Vancomycin	3(0)	-	-	-	-	3(0)	-	-	-

The sensitivity patterns are summarized in the table below:

Number of resistant organisms is given in brackets

Table 7: Antibiotic sensitivity patterns of isolated bacteria

CHAPTER 5: DISCUSSION

The incidence of pin tract infection was quite high at 87.7%. This compared to a similar study done by Aronson and Tursky (8) who quoted an incidence of 85% - this study involved 132 pediatric age group patients.

The incidence was however significantly higher than that quoted by Parameswaran et al of 11.2% (6). His study involved 285 patients in a level 1 trauma centre but was retrospective.

Despite the high incidence, all the infections were minor – either grade 1, 2 or 3 infection based on the Checketts-Otterburn classification system. Grade 1 Checketts-Otterburn pin tract infection is more of a soft tissue inflammation rather than actual presence of bacterial infection. The grade 2 and 3 infections are soft tissue infections characterized by discharge of pus. None of the infections in the study involved the bone. This may be possibly explained by the limited follow up period of only 6 weeks as bone infection may take longer to occur.

In keeping with other studies done by Mahan et al (10) and Antoci et al (11), *Staphylococcus aureus* was the commonest organism responsible for pin tract infection. Other common organisms isolated - *coagulase negative staphylococci, Pseudomonas species, Enterobacter species, Escherichia* coli-were also the same ones quoted by these studies.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

CONCLUSION

The incidence of pin tract infection after uniplanar fixation of open fractures in KNH is high (87.7%) when compared to other international studies. Grade 1 pin tract infection is the commonest grade of infection. *Staphylococcus aureus* and *coagulase negative staphylococci* are the main causative agents of pin tract infection accounting for almost half the cases of infection.

RECOMMENDATIONS

1. Better surgical technique and pin site care is needed to reduce the incidence of pin tract infection.

2. Anaerobic organisms seldom cause pin tract infection and anaerobic cover may not be necessary when treating such.

DISCLAIMER

I, Dr. Mohammed Rashid, have not received any financial benefits or incentives from any party or individual that may benefit from this study.

CHAPTER 7: REFERENCES

- 1. Clifford RP, Lyons TJ, Webb JK. Complications of external fixation of open fractures of the tibia. Injury, 1987 May; 18(3):174-176.
- 2. Lambotte A. The operative treatment of fractures: report of fractures committee. Br Med J 1912;2:1530.
- 3. Hoffmann R. Closed osteosynthesis with special references to war surgery. Acta Chir Scand 1942;86:255-261.
- 4. Anderson R. An automatic method of treatment for fractures of the tibia and the fibula. Surg Gynecol Obstet 1936;62:865-869.
- 5. Lewis KM, Breidenbach L, Stader O. The Stader reduction splint for treating fractures of the shafts of the long bones. Ann Surg 1942;116(4):623-636.
- 6. Parameswaran AD, Roberts CS, Seligson D, Voor M. Pin tract infection with contemporary external fixation: how much of a problem? J Orthop Trauma. 2003;17(7):503–507.
- Schalamon J, Petnehazy T, Ainoedhofer H, Zwick EB, Singer G, Hoellwarth ME. Pin tract infection with external fixation of pediatric fractures. J Pediatr Surg. 2007 Sep;42(9):1584-1587.
- 8. Aronson J, Tursky EA. External fixation of femur fractures in children. J Pediatr Orthop. 1992 Mar-Apr;12(2):157-163.
- 9. Norrish AR, Lewis CP, Harrison WJ. Pin tract infection in HIV-positive and HIVnegative patients with open fractures treated by external fixation: a prospective, blinded, case-controlled study. J Bone Joint Surg Br. 2007 Jun;89(6):790-793.
- 10. Mahan J, Seligson D, Henry SI, Hynes P, Dobbins J. Factors in pin tract infections. Orthopaedics 1991; 14(3):305-308.
- 11. V Antoci, Craig M, Valen Antoci Jr, Ellen M. Pin tract infection during limb lengthening using external fixation. American Journal Orthop. 2008;37(9): E150-E154.
- 12. Behrens F, Johnson WD, Koch TW, et al. Bending stiffness of unilateral and bilateral fixator frames. Clin Orthop Relat Res. 1983;(178):103-110.
- Seligson D, Donald GD, Stanwyck TS, et al. Consideration of pin diameter and insertion technique for external fixation in diaphyseal bone. Acta Orthop Belg. 1984;50(4):441-450.
- 14. Willie B, Adkins K, Zheng X, Simon U, Claes L. Mechanical characterization of external fixator stiffness for a rat femoral model. J. Orthop Res, 2009;27 (5):687-693.
- Piza G, Caja VL, Gonzalez-Veijo MZ, Navarro A. Hydroxyapatite-coated externalfixation pins. The effect on pin loosening and pin tract infection in leg lengthening for short stature. J Bone Joint Surg [Br] 2004;86(6):892–897.
- 16. Moroni A, Faldini C, Pegreffi F, et al. Fixation strength of tapered versus bicylindrical hydroxyapatite-coated external fixation pins: An animal study. J Biomed Mater Res. 2002;63(1):61-64.
- 17. Kowalski M, Schemitsch EH, Harrington RM, et al. Comparative biomechanical evaluation of different external fixation sidebars: Stainless-steel tubes versus carbon fiber rods. J Orthop Trauma. 1996;10(7):470-475.
- 18. Gilley RS, Beason DP, Synder DN, Boston RC et al. External fixator clamp re-use degrades clamp mechanical performance. Vet Surg. 2009 June; 38(4):530-536.
- 19. Piesk O, Geleg P, Zaspel J, Piltz S. Titanium alloy pins versus stainless steel pins in external fixation at the wrist: A randomized prospective study. J. Trauma 2008 May;64(5):1275-1280.

- 20. Gumprakash S, Roel K, Dirk W. Microbial biofilm growth vs tissue integration: 'The race for the surface' experimentally studied. Acta Biomaterialia 2009 June; 5(5): 1349 1404.
- 21. Biomaterials: Silver Jubilee Compendium: Edited by David F. Williams.
- 22. Shirai T, Tsuchiya H, Shimizu T, et al. Prevention of pin tract infection with Titanium-Copper alloys. J. Biomed Mater Res B Appl Biomater. 2009 Oct;91(1):373 380.
- 23. Lisa M Coester, MD, James V Nepola, MD, Judy Allen, RN, and J Lawrence Marsh, MD. The Effects of Silver Coated External Fixation Pins. Iowa Orthop J. 2006;26:48–53.
- 24. Holt J, Hertzberg B, Weinhold P, et al. Decreasing bacterial colonization of external fixation pins through nitric oxide release coatings. J. Orthop Trauma. 2011 Jul; 25(7):432-437.
- 25. Matthews LS, Green CA, Goldstein SA. The thermal effects of skeletal fixation-pin insertion in bone. J Bone Joint Surg Am. 1984;66(7):1077-1083.
- 26. Davies R, Holt N, Nayagam S. The care of pin sites with external fixation. J Bone Joint Surg (Br). 2005; 87-B; 716 719.
- 27. Chan CK, Saw A, Kwan MK, Karina et al. Diluted povidine-iodine versus normal saline for dressing metal-skin interfaces in external fixators. J. Orthop Surg (Hong Kong). 2009 April;17 (1):19—22.
- 28. Cam R, Demir Korkmaz F, Oner Sarks. Effects of two different solutions used in pin site care on development of infection. Acta Orthop Tramatol Turc. 2014; 48(1):80-85.
- 29. Ogbemudia AO, Bafor A, Edomwonyi E, Enemudo R. Prevalence of pin tract infection: the role of combined silver sulphadiazine and chlorhexidine dressing. Niger J Clin Pract. 2010 Sep;13(3):268-271.
- 30. Yuenyongviwat V, Tangtrakulwanich B. Prevalence of pin-site infection: the comparison between silver sulfadiazine and dry dressing among open tibial fracture patients. J Med Assoc Thai. 2011 May;94(5):566-569.
- 31. Lee CK, Chua YP, Saw A. Antimicrobial gauze as a dressing reduces pin site infection: a randomized controlled trial. Clin Orthop Relat Res. 2012 Feb;470(2):610-615.
- 32. Camathias C, Valderrabano V, Oberli H. Routine pin tract care in external fixation is unnecessary: a randomised, prospective, blinded controlled study. Injury. 2012 Nov;43(11):1969-1973.
- 33. Gordon JE, Kelly Hahn J, Carpenter CJ. Pin site care during external fixation in children: results of a nihilistic approach. J Pediatr Orthop. 2000 March-Apr;20(2):163-165.
- 34. Ferreira N, Marais LC. Prevention and management of external fixator pin tract sepsis. Strategies Trauma Limb Reconstr. 2012 August; 7(2):67-72.
- 35. Nando Ferreira and Leonard Charles Marais. The effect of HIV infection on incidence and severity of circular external fixator pin tract sepsis; a retrospective comparative study of 229 patients. Strategies Trauma Limb Reconstr. Aug 2014;9(2):111-115.
- 36. Bibbo C, Brueggeman J. Prevention and management of complications arising from external fixation pin sites. J Foot Ankle Surg. 2010;49(1):87–92.
- 37. Dahl MJ, Gulli B, Berg T. Complications of limb lengthening; a learning curve. Clin Orthop 1994;(301):10-18.
- Checketts RG, MacEachern AG, Otterburn M. Pin tract infection and the principles of pin-site care. In: Goldberg A, De Bastiani A, Graham Apley A, editors: Orthofix external fixation in trauma and orthopaedics. Berlin, Heidelberg, New York: Springer; 2000 pp 97 – 103.
- 39. William G. Cochran. The estimation of sample size. In Cochran, Editor. Sampling Techniques. New York: Wiley & Sons; 1977. Pg 75 76.

CHAPTER 8: APPENDICES

APPENDIX 1: DATA COLLECTION SHEET

PATIENT BIODATA

STUDY NUMBER:	
SEX:	
AGE:	

DIAGNOSIS AT ADMISSION:

DATE WHEN FIXATOR APPLIED:	
DURATION OF HOSPITAL STAY:	

ARE THERE ANY SIGNS OF PIN TRACT INFECTION? (TICK IF PRESENT)	WEEK 1	WEEK 2	WEEK 6
1. REDNESS, TENDERNESS AND NO DISCHARGE (GRADE 1)			
2. PRESCENCE OF DISCAHRGE (GRADE 2)			
3. AS IN NO. 2 BUT WITH NO IMPROVEMENT ON ORAL ANTIBIOICS (GRADE 3)			
4. PIN LOOSENING PRESENT (GRADE 4)			
5. RADIOGRAPHS SHOW OSTEOPENIA AROUND THE PINS (GRADE 5)			
6. RADIOGRAPHS SHOW SEQUESTRUM AND INVOLUCRUM (GRADE 6)			

IF PUS DISCHARGE IS PRESENT, WHICH ORGANISMS WERE CULTURED:

MICRO-	
ORGANISM	
ANTIBIOTIC	
SENSITIVITY	

APPENDIX II (a): CONSENT FORM CONSENT INFORMATION DOCUMENT

<u>Title</u>

Pin tract infection after uniplanar external fixation at Kenyatta National Hospital

Investigator

Dr. Mohammed Rashid Mohammed

Supervisors:

Prof. Atinga E.O. and Dr. Sitati F.C

Introduction

Pin tract infection is the most common complication following external fixation. The presence of such infection loosens the external fixator at the site of the pin insertion to the bone and creates instability. It may also lead to frank bone infection.

Objectives of Study

This study aims to determine the incidence of such infections in our local setting. It also aims to find out the microorganisms responsible for such infections and which antibiotics they are sensitive to.

Procedure

If you agree to participate in the study, I will observe the pins in your external fixator, prescribe x-ray films if necessary and take pus samples for culture and sensitivity. I will review you after 1 week, 2 weeks and after 6 weeks following the application of your external fixator.

Benefits

You will not pay for the pus swabs I take for culture and sensitivity nor for the check x-rays to rule out radiological involvement of bone following pin infection. The lab and radiological results I get may benefit you in your management.

<u>Risks</u>

There will be no risks to you when you participate in the study

Voluntarism

Please also note that your participation is voluntary and you have a right to decline or withdraw from the study. Your withdrawal of participation will not affect your treatment or management in any way whatsoever.

Confidentiality

The information obtained from you will be treated with confidentiality and will be handled by me.

CONSENT CERTIFICATE

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

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:

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4. Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

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Nairobi

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APPENDIX II (b): FOMU YA IDHINI MAELEZO YA FOMU YA IDHINI

<u>Kichwa</u>

Maambukizi ya pini baada ya kuwekea chuma cha nje cha kushikilia mfupa

<u>Mpelelezi</u>

Dkt. Mohammed Rashid Mohammed

<u>Wasimamizi</u>

Prof. Atinga E.O and Dkt. Sitati F.C

<u>Utangulizi</u>

Maambukizi ya pini baada ya kuwekewa chuma cha nje ni tatizo ambalo hutokea sana baada ya kuwekewa chuma hicho. Maambukizi haya hayajawahi kufanyiwa utafiti katika maeneo yetu na utafiti huu utasaidia kujua zaidi kuyahusu.

<u>Madhumuni ya Utafiti</u>

Utafiti huu utasaidia kujua zaidi kuhusu tatizo la maambukizi ya pini na ni bakteria zipi ambazo husababisha maambukizi haya.

<u>Utaratibu</u>

Utafiti huu nitaufanya kwa kutazama hizo sehemu za pini za chuma ulichowekewa na kuangalia ikiwa kuna usaha ama uchafu wowote unaotoka, na pia kwa kutazama picha zako za x-ray na kuchukua usaha kuupima kwa maabara ikiwa utakuwa unatoa usaha. Nitakufuatiliza wiki ya kwanza, ya pili na wiki ya sita baada ya kuwekewa hicho chuma.

<u>Faida</u>

Matokeo ya kipimo cha usaha na picha za kutazama maabukizi ya pini yanaweza kukusaidia katika tiba yako. Hutolipa malipo yoyote zaidi ya kifedha kwa kushiriki kwa huu utafiti. Malipo ya kupima usaha na picha za kutazama maambukizi ya pini yatasimamiwa na mimi.

<u>Madhara</u>

Hakuna madhara yoyote ambayo yanaweza kukupata kwa kushiriki kwa utafiti huu.

<u>Uhuru wa Kushiriki au Kutoshiriki</u>

Ushiriki ni wakujitolea, sio lazima kushiriki katika huu utafiti, na pia unaweza kubadili nia yako wakati wowote kuhusu kuendelea kushiriki, bila ya kuathiri huduma zako za kiafya.

<u>Usiri</u>

Haki zako zitalindwa, habari utakayotoa au ile itakayopatikana kukuhusu itakuwa siri wakati wote na utatumika kwa huu utafiti pekee yake.

FOMU YA IDHINI

Nimekubali kwamba nimeelezwa kikamilifu kuhusu utafiti huu na nimekubali kushiriki.

Sahihi.....Tarehe.....

Ninathibitsha ya kwamba 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.....Tarehe

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

Ukiwa na maswali yeyote kuhusu utafiti huu, wasiliana na:

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APPENDIX III

BUDGET

ITEM	QUANTITY	UNIT PRICE	TOTAL
Operating Costs:			
Internet: Orange 3 month	3	3000/-	9000/-
subscription			
Stationery:			
Pens (Box)	1	400/-	400/-
Writing pads	5	200/-	1000/-
Printing paper (rim)	1	1200/-	1200/-
Printing Cartridges	4	1200/-	4800/-
Binding Fees	5	100/-	500/-
Approval:			
Ethical Review Fee	1	2000/-	2000/-
Consultation:			
Statistician	1	25000/-	25000/-
Culture and Sensitivity	73	1,250/-	91,250/-
X-rays	73	1,000/-	73,000/-
Patient Cost	-	-	-
TOTAL			208,150/-

APPENDIX IV

KENYATTA NATIONAL HOSPITAL –UNIVERSITY OF NAIROBI ETHICAL RESEARCH COMMITTEE APPROVAL



Yours sincerely,

PROF MLL CHINDIA SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN The Deputy Director, CS, KNH The Assistant Director, Health Information, KNH The Chairperson, KNH- UoN ERC The Dean, School of Medicine,UoN The Chairman, Dept. of Orthopaedic Surgery, UoN Supervisors: Prof. Atinga E.O, Dr.Sitati F.C.

Protect to discover

APPENDIX V

KNH STUDY REGISTRATION CERTIFICATE

Ser In	KENYATTA NATIONAL HOSPITAL P.O. Box 20723-00202 Nairobi	KNH/R&P/FORM/01 Tel.: 2726300/2726450/2726565 Research & Programs: Ext. 44705 Fax: 2725272 Email: <u>knhresearch@gmail.com</u>
	Study Registration	n Certificate
	Name of the Principal Investigator/Researcher DR- MOHAMMED RA-SHID	***************************************
2.	Email address: Mohdrashid 828 Ogmail.c	om Tel No. 4254707179285
3.	Contact person (if different from PI)	AL INVESTIGATOR
4.	Email address:	Tel No
5.	Study Title PIN TRACT INFECTION AFTER FIXATION AT KENYATTA N	
6.	Department where the study will be conducted027 (Please attach copy of Abstract)	THOPAEDIC SURGERY (WARDS & CLINC
7.	Endorsed by Research Coordinator of the Department	where the study will be conducted.
8.	Name:	conducted.
9.	Name:	//
	(Please attach copy of ERC approval)	
	I DR. MOHAMMED RAIHID MOHAMMED findings to the Department where the study will be co and Programs. Signature	onducted and to the Department of Research
11.	Study Registration number (Dept/Number/Year)() (To be completed by Research and Programs Departme	vthopaedics 108/2016 ent)
12.	Research and Program Stamp	NATION
All Res	studies conducted at Kenyatta National Hospital <u>m</u> earch and Programs and investigators <u>must commit</u> to	nust be registered and response partment of share results with the hospital.