

Early Surgical Site Infection after Orthopaedic Implant surgery in HIV – Positive Patients at Kenyatta National Hospital.

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CERTIFICATE OF AUTHENTICITY

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DEDICATION

I dedicate this thesis to my wife Joan, lovely daughter Suki and my mother Elizabeth for their support, and encouragement during this study.

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ACRONYMS

SSI	Surgical Site Infection
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers of Disease Control and Prevention
CD ₄	Cluster Differentiation 4
RNA	Ribonucleic Acid
UNAIDS	The Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
KNH	Kenyatta National Hospital
UON	University of Nairobi
ERC	Ethical Review Committee
ART	Antiretroviral Therapy

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ABSTRACT

Introduction

Surgical Site Infection (SSI) is a disaster both for the patient and the surgeon. SSI related to orthopedic procedures can be associated with serious morbidity, mortality and increased resource utilization. SSI in HIV positive patients post orthopedic implant surgery is an area which is incomprehensively studied. This study seeks to fill in this gap.

Methods

This was a prospective case controlled study carried out over a period of six months at Kenyatta National Hospital. Purposive sampling was applied to select patients admitted for orthopedic implant surgery. Data was collected using a standardized and pretested tool to collect variables such as socio-demographic, HIV status, type of surgery and infection occurrence (SSI). Blood was collected for CD₄ count (the HIV positive patients). Data was keyed into Epi Info and exported to SPSS 17.0 for analysis. Measures of central tendency were calculated and bivariate analysis using Fishers exact test. A multivariate analysis using Mantel Haenszel odds ratio to give a weighted average of the odds ratios was also carried out. Results were presented inform of tables, charts and graphs.

Results

A total of 154 respondents participated in this study. Forty six (30%) were HIV positive (cases) and one hundred and twenty one (70%) were HIV negative (controls). HIV positive state didn't increase the risk of early surgical site infection (OR=0.611, 95%CI=0.0207, 1.798). There was no association between surgical procedure and implant to the likelihood of having early surgical site infection (p value 0.05, 0.33 and 0.74 respectively).

Conclusion and recommendation

HIV status, CD4 count, surgical procedure and implant used were not shown to have any association with prevalence of early surgical site wound infection. A larger prospective study with a longer duration needs to be carried out to reveal a possible correlation between the influences of these variables on surgical site infection.

1.0 BACKGROUND

Trauma has no preference for HIV negative individuals and at times we treat both HIV positive and negative patients without knowing their status.

Surgical treatment of HIV positive patients is necessary for problems both related and unrelated to HIV infection. HIV weakens the immune system and thus negatively influences one's ability to fight infections. It does this by infecting CD4 T Helper cells. This puts HIV positive patients at an increased risk of developing infections.

Due to the negative effect (weakening) on the immune system of HIV positive patients by the virus it is assumed that they may have an increased risk of surgical complications especially infections. Studies from outside orthopedics, suggest that specific risk factors influencing operative morbidity in HIV positive patients, especially infections related to wound-healing, include an absolute CD4 count of <200 cells/mm³ or a viral load of $>10,000$ copies/mL¹.

However, there is currently limited and controversial scientific data on the incidence of surgical complications (post-operative infection) among HIV patients undergoing orthopaedic implant surgery.

It is still not clear whether a HIV positive patient's CD₄ cell count, WHO staging and or viral load influences their risk of post orthopedic implant surgical infections. CD₄ cell count between 600 and 1,200 cells per microliter of blood have been recorded in healthy individuals with no immunosuppressing ailments. The lower the CD₄ count, the weaker the patient's immune system. Some studies have found no correlation between low CD₄ cell counts and surgical complications^{35, 37}, while others have found an increase in complications with lower CD₄ counts^{30, 36}. Further research is needed before a firm conclusion can be made.

The aim of this study was to determine the rate of SSI in HIV positive patients undergoing orthopaedic implant surgery and to investigate the correlation if any between CD₄ count, viral load and WHO staging with early SSI.

2.0 LITERATURE REVIEW

2.1 Introduction

HIV an acronym that stands for Human Immunodeficiency Virus associated with pneumocystis jiroveci pneumonia and Kaposi's sarcoma was first recognized in 1981 in the United States of America among gay men and identified in 1983 by Barre-Sinoussi et al at the Institut Pasteur, Paris^{2, 3}. HIV is a retrovirus which encodes its genome in RNA and transcribes genome copies in DNA using the enzyme reverse transcriptase within host cells such as the human CD₄ (T helper) lymphocyte. HIV infection is marked by a fall in the CD₄ cell count with an associated decrease in immunity, particularly humoral immunity. HIV infection results in a syndrome known as Acquired Immune Deficiency Syndrome (AIDS). Despite the numerous advances made in antiretroviral therapies such as nucleoside analogues, protease inhibitors, fusion inhibitors and integrase inhibitors that reduce the viral load in the host serum and restore the numbers of host CD₄ cells there is still no cure for HIV infection nor is there a vaccine more than 25years since the virus was first identified.

2.2 HIV Epidemiology

HIV Globally and sub-Saharan Africa

Globally around 34 million people are living with HIV. Each year, around 2.7 million more people become infected with HIV and 1.8 million die of AIDS (UNAIDS, 2011) and by year 2010 more than 30 million people around the world had died of AIDS-related diseases (UN, 2011).

HIV is a pandemic with some areas more afflicted than others. The worst affected region is sub-Saharan Africa where rates of HIV infection are still extremely high with an estimated 22.9 million people living with HIV and 1.9 million people in this region newly infected in 2010.

HIV in Kenya

Kenya is home to one of the world's harshest HIV and AIDS epidemics. A national HIV prevalence rate of 6.3% (KAIS, 2007) means an estimated 1.5 million people are living with HIV; around 1.2 million children have been orphaned by AIDS; and in 2009 80,000 people died from AIDS-related illnesses⁴ while its estimated that annually 166,000 people are newly infected with HIV (KDHS, 2008 report). Kenya's HIV epidemic has been categorized as generalized since HIV affects all sectors of the population, although HIV prevalence tends to differ according to location, gender and age.

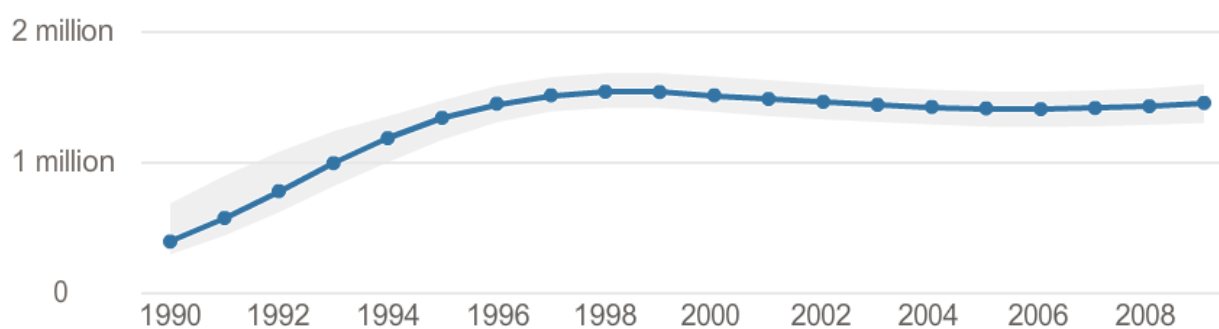


Figure 2.1: Number of people living with HIV in Kenya (UNAIDS, 2010)

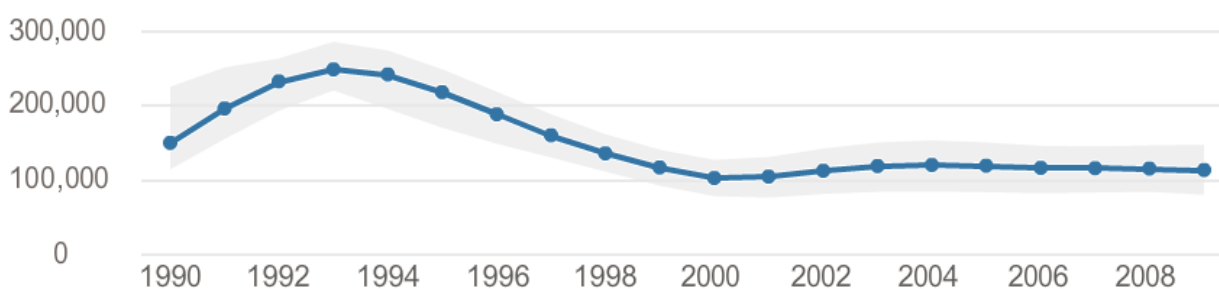


Figure 2.2: Number of new infections all ages (UNAIDS, 2010)

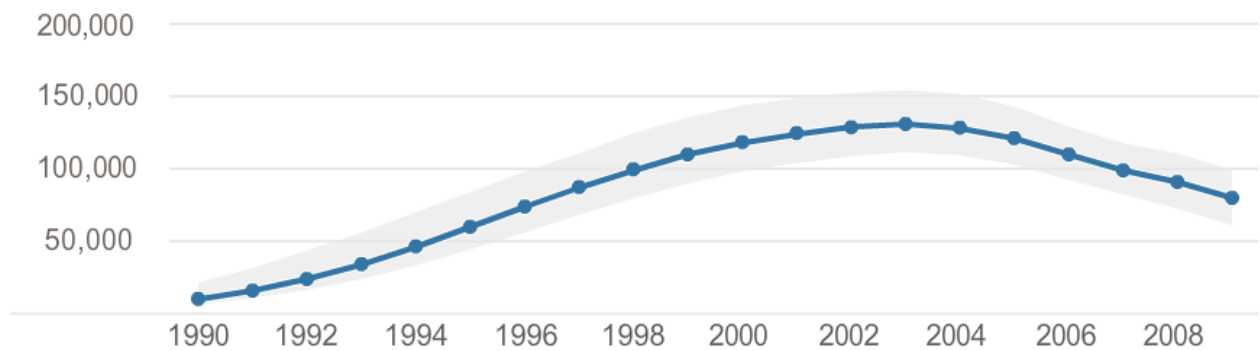


Figure 2.3: Annual number of AIDS deaths (UNAIDS, 2010)

2.3 Pathophysiology of immunity impairment in HIV

HIV primarily targets the CD₄ lymphocytes, which are responsible for cellular immunity and indirectly impairs B lymphocyte differentiation (humoral immunity)⁵. Monocyte macrophage cell lines and production of interferon gamma and lymphokines – products of antigenically stimulated lymphocytes are also affected. Absolute polymorphonuclear leucocytes count drops as the disease progresses, to a level that impairs phagocytosis⁶.

CD₄ Lymphocytes and lymphokines play an important role in wound healing⁹. Migration of CD4 lymphocytes subsets into healing wound body region has been documented¹⁰.

Platelet deficiency also seen in HIV infected patients, may lead to excessive bleeding during surgery. Platelet deficiency is initially treated with corticosteroids and if persistent with splenectomy. Corticosteroids further reduce hosts resistance to infection, and splenectomy is associated with an increased risk of septicemia^{11, 12}.

Neutrophil bactericidal capacity in HIV positive patients has been studied by several groups of researchers. One such study conducted by Murphy et al¹³ using cultures of *Staphylococcus aureus* as the target organism, compared ninety-minute bacterial survival in washed neutrophils from nineteen AIDS patients, who had no active infections and were receiving no

drugs, with that in washed neutrophils from seventeen healthy control subjects. Bacterial survival in the AIDS patients was significantly higher at 32.5% vs. 13.8% in the healthy control group. Another study by Ellis et al⁶ in patients with AIDS and Kaposi's sarcoma demonstrated reduced bacterial killing against *S aureus*. These two studies demonstrated impairment of all three leukocytes bactericidal functions i.e. chemotaxis, phagocytosis, and secretion of microbicides - in patients with AIDS.

Due to the complex immune system impairment patients with advanced HIV infection have high susceptibility to both common pathogens and opportunistic infections. Krumholz et al¹⁵ reported 44 episodes of community acquired bacteremia in 38 AIDS patients at San Francisco General Hospital. Most of these pathogens include those commonly involved in musculoskeletal infections. The most common infecting organisms, in descending order, were *S aureus*, *Streptococcus pneumoniae*, and *Escherichia coli*. Only 57% of the patients were febrile, which is typical of AIDS patients with a bacterial infection, such as septic arthritis or another orthopedic infection. These patients often present with a minimal inflammatory response, which appears deceptively benign but can progress to sepsis and septicemia which can be fatal. It has been shown that carriage rate for *S aureus* in the nose, throat, and perineum in asymptomatic HIV-positive subjects was double that in HIV-negative control subjects (49% vs. 27%)¹⁴.

Malnutrition, which may be a consequence of both the disease process or the administration of therapeutic medication, causes hypoalbuminaemia which leads to further impairment of lymphocyte function and phagocytosis^{7, 8} hence increased propensity to bacterial infections and delayed wound healing.

Clinical and immunological staging systems and criterion have been developed to facilitate proper categorization of patients for quality management. The WHO clinical staging system¹⁶

(Table 1) of HIV infected individuals, that groups individuals into four stages according to clinical features is most commonly followed.

<i>WHO Stage</i>	<i>Characterized by</i>	<i>Examples</i>
1	Acute primary HIV Infection or latent asymptomatic or persistent generalized lymphadenopathy	Acute seroconversion illness in some patients
2	Cutaneous manifestations	Herpes Zoster, Seborrheic dermatitis, Recurrent URI, < 10% weight loss
3		Pulmonary TB < 1 year ago, severe bacterial infection, weight loss > 10%, Chronic diarrhea > 1 month
4	AIDS defining illness	Pneumocystis Carinii Pneumonia, Toxoplasmosis, Cryptosporidiosis, CMV retinitis

Table 1: WHO Staging for HIV Infection and Disease

Impaired defense to common surgical pathogens and delayed wound healing are causes for concern about the outcome of orthopedic procedures on the HIV-positive patient. HIV-positive patients are at higher risk of peri-operative infections, complications, impaired wound healing, and mortality.

2.4 Early Surgical Site Infection

Centers of Disease Control and Prevention (CDC) defines superficial incisional Surgical Site Infection (SSI) as: Infection occurring within 30 days after an operative procedure and involving only skin and subcutaneous tissues of the incision and the patient has at least one of the following;

- a) Purulent drainage from the superficial incision.
- b) Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

- c) At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision are deliberately opened by surgeon, and are culture-positive or not cultured. A culture-negative finding does not meet this criterion
- d) Diagnosis of superficial incisional SSI by the surgeon or attending physician.

NB. If the incisional site infection involves or extends into the fascial and muscle layers, this is reported as a deep-incisional SSI.

SSI related to orthopedic procedures represents a severe and catastrophic complication for patients, surgeons and hospital institutions, as an infection can extend the patient's hospitalization time by up to two weeks, double re-hospitalization rates, increase care costs by more than 300%, besides causing important physical limitations that significantly reduce patients' quality of life after the surgery¹⁷.

Incidence levels of orthopedic SSI can vary widely between 0.8 and 71%^{18, 19, 20, and 21}.

In a study titled Human Immunodeficiency Virus Infection: Complications and Outcome of Orthopedic Surgery, James V. L et al suggested that orthopedic surgeons practicing in areas with a high-prevalence HIV infection may expect that up to 7% of their patients who undergo emergency procedures and 1% to 3% of those who undergo elective surgery will be HIV positive²². The higher infection rate in emergent surgeries was associated with the fact that in an emergent situation, the patient's status is often unknown but could be critical in management of the case. Surgery on the HIV-positive patient, whether elective or emergent, involves special risks, which may be divided into two categories: risk to the patient and risk to health-care personnel.

A number of surgical outcome studies, focusing on early surgical complications, have been published^{10, 23}. Also several studies of orthopedic patients, most of them hemophiliacs, have been published on related topics. These studies can be divided into two categories: those involving early postoperative infections (mostly in surgical wounds) and those involving late infections of hematogenous origin.

2.5 Early postoperative Infections

The mail survey of 115 hemophilia centers by Ragni et al²⁶, to study the rate of early postoperative infection after orthopedic procedures performed on 66 HIV-positive patients with CD4 lymphocyte counts below 200 at the time of surgery. They found that when patients with preoperative evidence of active infection were eliminated, the rate of postoperative infection was 7.5%.

In a series from Kigali, Rwanda, Hoekman et al²⁷ compared the rate of postoperative infection after open reduction and internal fixation of fractures in 171 HIV-negative patients, 26 asymptomatic HIV-positive patients, and 17 symptomatic HIV-positive patients. None of these patients had hemophilia. The surgeons did not know the patients' HIV status, and no prophylactic antibiotics were used. The infection rates were 5% in the HIV-negative group, 0% in the asymptomatic HIV-positive group, and 23% in the symptomatic HIV-positive group. The infecting organisms were common surgical pathogens: *Staph aureus* in eight cases, *group A streptococci* in two, *E coli* in one, and *Pseudomonas aeruginosa* in one. All infections resolved with antibiotic management, and there were no deaths. The rate of infection in the symptomatic HIV-positive patients in this study was substantially higher than that in the survey by Ragni et al²⁶ of high-risk patients with CD4 lymphocyte counts below 200. The lack of prophylactic antibiotic therapy and other factors related to the patient

population and location may have made a critical difference. The authors did not give the CD4 lymphocyte counts of the symptomatic patients, which would have allowed better correlation of the rate of infection with the degree of immune impairment. Remarkably, the rate of infection in the HIV-negative and asymptomatic HIV-positive patients, who did not receive prophylactic antibiotic therapy, was similar to that in a reported series of open fracture repair in the general population²⁸. On the basis of other studies cited in that report, it appears likely that the symptomatic HIV-positive patients harbored more pathogens and had more severe immunity impairment, which would have made the absence of prophylactic antibiotic administration more critical.

In his study of 44 HIV positive patients who were clinically staged (WHO) supplemented with an absolute lymphocyte count in Lusaka, Zambia Jellis³¹ reported that closed fractures healed normally if treated conservatively but if internally fixed 33% suffered infections, open fractures fared worse with a 72% infection rate and 28% with non-unions. He concluded that major orthopedic surgery in HIV positive patients has increased risk of sepsis which rises steeply in those with physical signs of HIV disease.

Other studies demonstrating contrary results such as conducted by Diettrich et al⁸ reported the data on a series of 120 HIV-positive patients, 56 (47%) of whom had AIDS, who underwent elective or emergency procedures between 1986 and 1990. They found that the 30-day mortality after emergency procedures was 23% for patients with AIDS, compared with 0% for those who did not have AIDS. For elective procedures, it was 4% for AIDS patients, compared with 0% for non-AIDS patients. Of the 7 surviving patients with postoperative complications, one had a wound infection and one experienced a delay in healing; contrary to what might be expected, neither patient had AIDS. The risk of morbidity or mortality was higher if the patient had a history of opportunistic infection and a serum

albumin level below 25 g/L. The study concluded that the results in the HIV-positive patients without AIDS were 0% mortality and 4% postoperative complications are roughly comparable to those in the HIV-negative population.

In another study by Buehrer et al²⁴ on surgical wound-infection rates in HIV-positive and HIV-negative hemophiliacs who underwent 169 surgical procedures, 53 of which were orthopedic they reported two wound infections, but there was no statistically significant difference between the wound-infection rates of the HIV-positive patients (1.4%) and the HIV-negative patients (0%). Also, no wound infections occurred after the 7 procedures performed on patients with AIDS.

Another study with concurrent results by Greene et al²⁵ reviewed 26 orthopedic procedures performed on HIV-positive hemophiliacs between 1984 and 1988. They found no surgical-site infections and five patients had a protracted postoperative fever, but clinical infection did not develop. The outcomes and functional results were similar to those in patients treated before 1982 who were presumed to be HIV-negative.

In a study by Paiement et al²⁹ who reported data on 476 orthopedic surgical trauma patients that underwent at least one open procedure at San Francisco General Hospital. There were 444 HIV-negative patients and 30 HIV-positive patients without AIDS. In the clean and clean-contaminated wound categories, infection occurred in 15 of the 364 HIV-negative patients but in none of the 21 HIV-positive patients. In the open-fracture category, deep infections occurred in 3 of the 80 HIV-negative patients and in 1 of the 9 HIV-positive patients. Because of the retrospective nature of this study, CD4 lymphocyte counts and other indicators of immune status were not available.

Habermann et al³⁰ performed 55 total joint replacements in 41 HIV positive patients. These authors found that while functional outcomes of these patients did not differ from those of HIV negative patients, and total joint replacements appeared safe in hemophiliacs, irrespective of serostatus, intravenous drug users had an increased incidence of infectious complications after total joint replacement. There was no correlation between CD₄ counts and infection.

Few Orthopedic related studies investigating SSI in HIV positive patients in comparison to their immunosuppression status with reference to their CD4 count levels have been carried out and more so in Africa, the continent with the highest HIV prevalence rates. This study sought to address that area of deficiency.

Rationale

- Paucity of studies that correlate CD₄ count and Viral Load to SSI in HIV positive patients undergoing orthopaedic implant surgery
- Conflicting results in studies published on HIV and post-operative infection in patients undergoing orthopaedic implant surgeries.
- Will assist in developing policies on the management of patients requiring orthopaedic implant surgery electively or as an emergency.

Study Question

What is the incidence of post-operative early SSI in HIV positive patients undergoing orthopaedic implant surgery at Kenyatta National Hospital?

Null hypothesis

The incidence of post-operative early SSI is not influenced by HIV

Study Objectives

Primary Objective

- To determine the rate of early SSI in HIV positive patients undergoing orthopedic implant surgery

Secondary Objectives

- To determine the correlation between CD₄ count with early SSI in patients undergoing orthopedic implant surgery
- To determine the correlation between WHO classification of HIV with early SSI in patients undergoing orthopedic implant surgery

3.0 METHODOLOGY

3.1 Study Site

The study took place in Kenyatta National Hospital - Orthopaedic wards.

3.2 Study population

All adult patients admitted to KNH- Orthopedic wards for orthopedic implant surgery.

3.3 Study design

A case control study conducted from June – October 2012.

3.4 Sampling

3.4.1 Sample Size Estimation

The sample size was determined by the use of the following formulae (Fishers formulae) for proportions to achieve an adequate sample.

$$n = \frac{Z^2_{\alpha/2} * PQ}{\delta^2}$$

Where:

n = required sample size

δ = the desired precision level set at 10% (0.1)

P = is the expected sero-prevalence = 7.5%

Q=1-P.

The $Z_{\alpha/2}$ is the cut off points along the x-axis of the standard normal probability distribution that represents probability matching the 95% confidence interval (1.96).

Substituting the above in the formulae we get;

$$\begin{aligned}n &= 26.6 \\ &\approx 27 \text{ patients}\end{aligned}$$

The control group, a ratio of one is to four (Cases: Control) will be applied thus giving a sample size of **108** patients.

Justification of ratio of HIV negative to HIV positive patients

From previous studies infection rate in clean wounds in HIV positive patients post orthopedic implant surgery has been reported to be approximately 7.5 %²⁶. Currently there is no literature on infection rate in the orthopedic wards at KNH. Internationally acceptable infection rate in an orthopedic surgery department is approximately 2%³⁴. This gives a ratio of 2:7.5 \approx 1:4; furthermore there is usually little marginal increase in precision from increasing the ratio of controls to cases beyond four. For these reasons the ratio 1:4 was adopted for this study and not 1:10 which is the approximate ratio of HIV positive to HIV negative individuals in the general population of Kenya.

3.4.2 Sampling design and procedures

All adult patients admitted to the orthopedic unit KNH were counseled and tested for HIV (as per the national algorithm). Purposive sampling was conducted for patients undergoing orthopedic implant surgery (surgery involving the use of devices usually metallic to replace or provide fixation of bone or to replace articulating surfaces of a joint).

The potential study subject was given adequate information about the study by either the principal investigator or the research assistant i.e. purpose, procedure, risks, and benefits. He or she was then allowed ample opportunity to ask questions. Following the verbal explanation the subject was then provided with a written consent form and afforded sufficient time to consider whether or not to participate in the research. After allowing the potential subject time to read the consent form the investigator then met with him or her and answered any additional questions that they had. Once the potential subject had had all of his or her questions answered and had agreed to participate in the study he or she signed and dated the consent form. The investigator who had oriented and took consent from the subject also signed and dated the consent form. The subject was provided with a copy of the consent form to use as continual reference for items such as scheduling of procedures and for emergency contact information.

Patients who consented to the study were enrolled. Patients who were already HIV positive and consented for the study were also enrolled.

WHO clinical HIV infection staging of the HIV positive patient was then done. Venous blood samples were then taken preferably from the superficial veins of one of the upper limbs for CD₄ count prior to surgery (Sample also included blood for baseline investigations prior to surgery. Maximum five milliliters of blood was drawn and put in specific laboratory bottles). The samples were taken between nine and eleven o'clock in the morning and transported to

the laboratory within the hour. The procedure carried out in theatre was recorded for both the HIV positive and negative patients.

All patients in this study were given intravenous cloxacillin (Floxapen) as prophylaxis against infection pre and post operatively.

Patients were followed up for a maximum of thirty days post operatively. Assessment of healing and infective complications was made using a modified version of the asepsis wound scoring system³² (Table 2) as recommended by the Surgical Infection Study Group.³³ This describes the appearance of the wound and the necessity for further treatment, such as the administration of antibiotics. The maximum score is 65. It is very sensitive and allows objective appraisal of infection, and its severity. For the purpose of this study, a score of 0 to 10 would be considered to represent normal wound healing and a score of more than 10 an infection. This confers a sensitive, if arbitrary, definition of infection. The scores would be recorded at 5 days, 14 days and 28 days after operation. The highest score for each patient was adopted.

Appearance of wound	<i>% wound involved</i>					
	0	< 20	20 - 39	40 - 59	60 -79	≥ 80
Serous exudates	0	1	2	3	4	5
Purulent exudates	0	1	2	3	4	5
Separation of deep tissues	0	2	4	6	8	10
Erythema	0	1	2	3	4	5
Additional treatment						
Antibiotics						10
Drainage of pus (LA*)						5
Debridement of wound (GA†)						10
Isolation of bacteria						10
Inpatient stay >14 days						5
Maximum score						65
* LA, local or no anaesthetic						
† GA, general or regional anaesthetic						

Table 2: Asepsis scoring system used to assess wound healing and infective complications after implant surgery

The research assistant (a clinical officer) aided in recruiting study subjects and in the follow up of the subjects during the study period. He also assisted in collecting blood samples from the study subjects for laboratory evaluation.

Enrolment of study subjects stopped on the fifth month of the study i.e. thirty days before the end of the six months study period so that the study duration did not exceed six months.

Each of the three orthopedic firms operates at least three patients per theatre day, each firm has four theatre days in a week, and thus thirty six patients are operated each week from all the firms. This facilitated the enrolment of at least more than six study subjects per week.

Inclusion and Exclusion criteria

- **Inclusion**

- Individual who is 18years of age and above
- consent to HIV testing and participation in the study
- Admitted to KNH orthopaedic wards for orthopaedic trauma surgery

- **Exclusion**

- Individuals less than 18 years of age
- Individuals who decline to be tested for HIV
- Patients with compound fractures or contaminated wounds
- Patients with previous implant surgery on the same surgical site
- Patients with systemic diseases that cause immune suppression.

3.5: Data Handling

3.5.1: Data collection

Data was collected in the form of a pre-tested questionnaire administered face to face by the investigator (See Appendix). The questions included both open – ended coded and close – ended questions designed in light of the objectives. The questionnaire was in English. Laboratory results and wound scores were also recorded.

Study Variables

Data on the following variables was collected.

- Age, sex
- Drug abuse
- WHO Staging
- CD₄ count
- Procedure carried out
- Type of implant used
- Wound Score

3.5.2: Data Entry and Storage

Data collected for the study was thoroughly checked and validated for accuracy and completeness. It was stored in compact discs and external hard disks for back up before and after analysis.

Data on the questionnaires and disks was kept under lock and key at the Principal investigators office, while electronically stored data was password protected.

3.5.3: Data analysis

Data was keyed in through Epi Data and exported to SPSS 17.0 for analysis. Data was analyzed for central tendency results, bivariate analysis using Fishers exact test and multivariate analysis using Mantel Haenszel odds ratio was used to give a weighted average of the odds ratios in the different strata.

3.5.4: Data presentation

The results were presented in form of tables, bar graph and pie charts.

3.6: Ethical Considerations

Ethical approval and permission was provided by the Kenyatta National Hospital Ethical and Research Committee. The purpose, procedure, rights and benefits of the study were explained to the patient by the principal investigators and research assistant. Written consent to participate in the study was obtained from the patient. Denial of consent did not interfere with the treatment of the patient in any way whatsoever. Confidentiality of patient data was upheld and no names were put on any of the data sheets. At the end of the study, the data sheets shall be shredded by the investigators to ensure complete destruction. The study shall be considered to be completed when the results have been disseminated.

3.7: Assumptions/Limitations

Other diseases or conditions that may not be easily ruled in or out e.g. malnutrition, diabetes mellitus, drug abuse etc. that may contribute to immune suppression may affect outcome of the study

3.8: Expected application of results

The findings obtained from this study will provide invaluable information on the influence if any of patients CD₄ count, viral load and WHO staging on SSI post operatively. This would help in the development of policies on the management of such patients requiring orthopaedic implant surgery. The study will also provide information on the incidence of early surgical site infection in HIV positive patients undergoing orthopaedic implant surgery in KNH.

The information obtained will also be used for purposes of obtaining a Masters degree in Orthopedic Surgery for the principal investigator.

4.0 RESULTS

A total of 154 patients participated in this study. Majority 87% were between the ages of 18-49 years and 13% were above 50 years of age (Figure 4.1).

The number of male patients was four times that of females at 80%.

Fifty respondents reported substance use on the multiple response questions; Forty four reported alcohol use and twenty eight smoking.

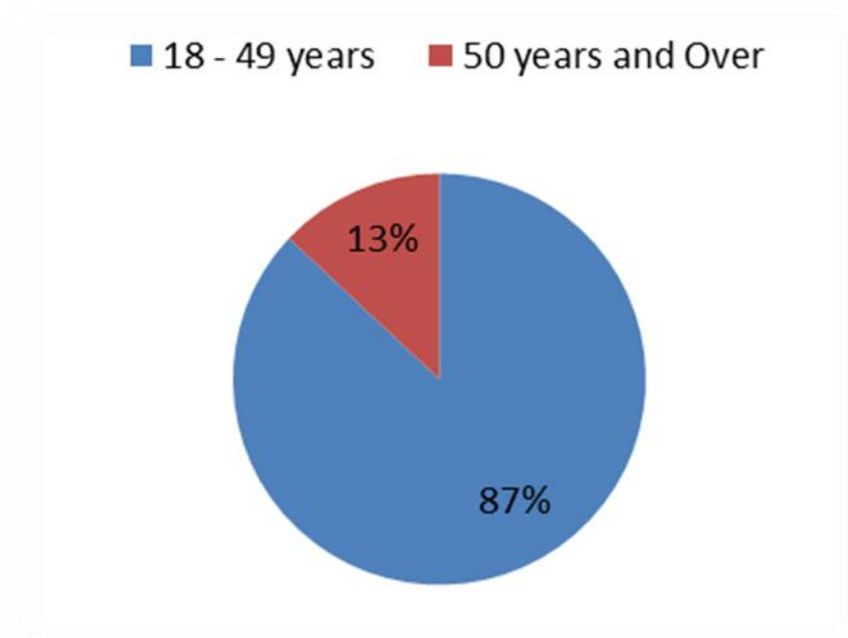


Figure 4.1: Age distribution of respondents

Forty six patients (30%) were HIV positive (cases) and one hundred and eight (70%) were HIV negative (controls) (Figure 4.2). Of the 46 cases, 22 (48%) were on Anti retro viral therapy (ART) (Figure 4.3)

Respondents HIV status

■ Positive ■ Negative

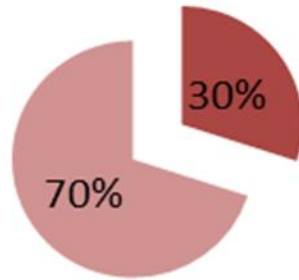


Figure 4.2: Respondents HIV status

ART distribution

■ Yes ■ No

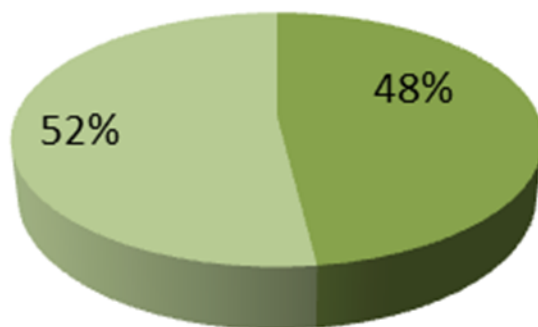


Figure 4.3: ART distribution

On WHO clinical staging 45% of the respondents were in Stage 2 followed by 32% in Stage 3 and 5% in Stage 4 (Figure 4.4).

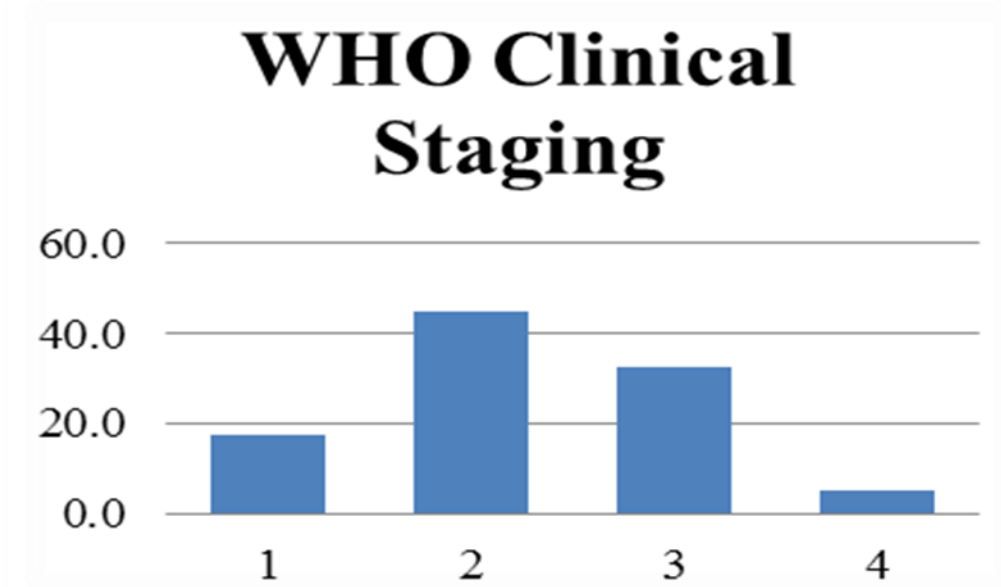


Figure 4.4: WHO clinical staging for HIV positive respondents

Respondents CD4 count levels were highest in 45% of patients at >500 cells/uL and lowest at <200 cells/uL in 22% (Figure 4.4 & 4.5)

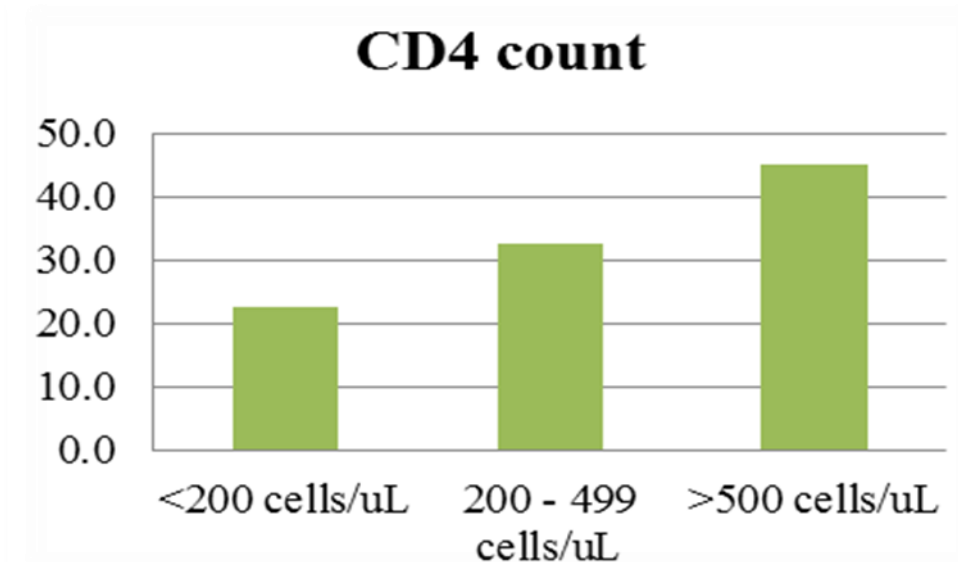


Figure 4.5: CD4 count levels for HIV positive respondents

10.4% of patients in the study developed early superficial surgical site infection. (Figure 4.6)

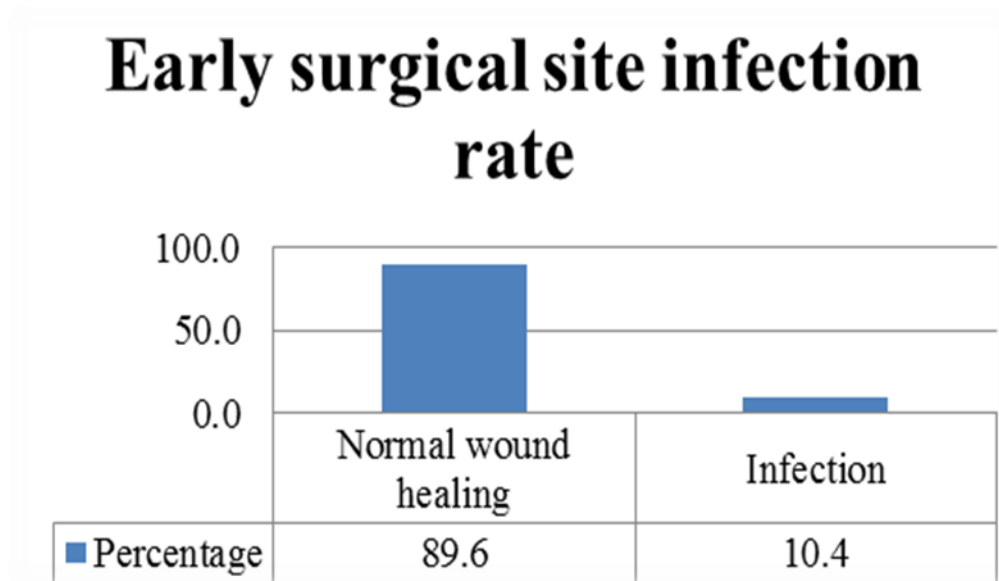


Figure 4.6: Early surgical site infection

Majority of the orthopedic procedures were ORIF for fresh fracture (77.1%) followed by reconstruction for non-union (13.1%). The least was arthrodesis at 3.9% (Figure 4.7).

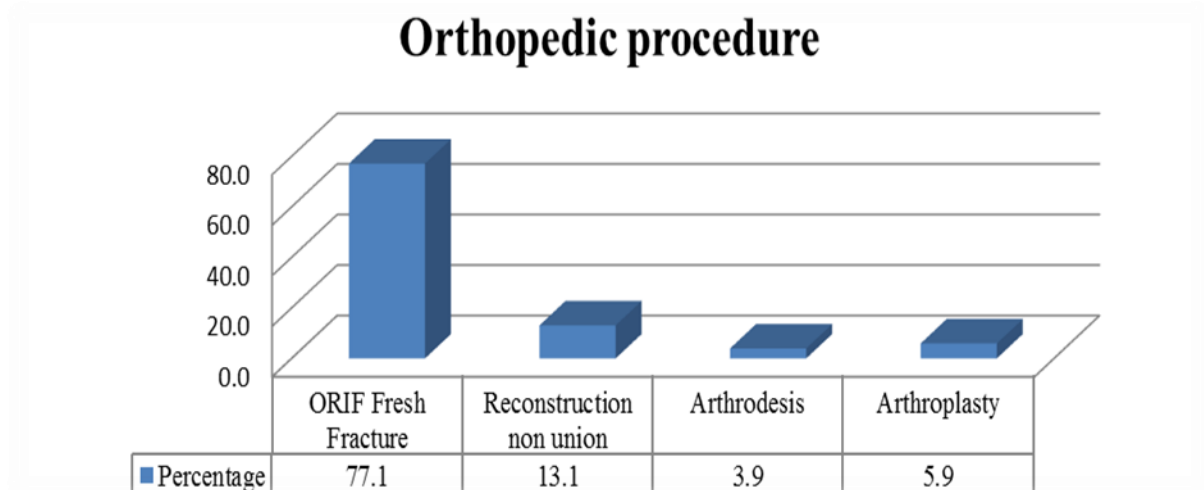


Figure 4.7: Orthopedic procedures conducted on the respondents

Of the orthopedic implants utilized in the study, 35.7% were intramedullary nails, 29.9% were plate and screws and only 5.8% were arthroplasty implants (Figure 4.8).

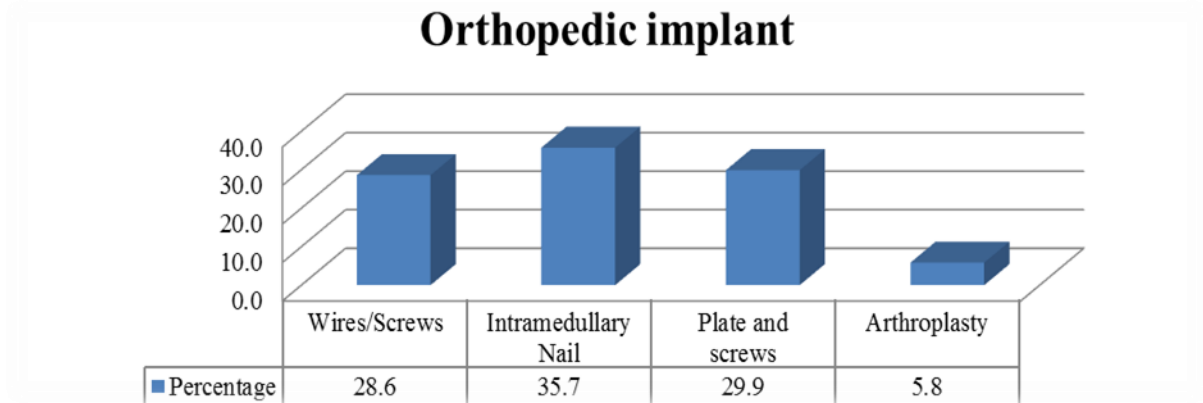


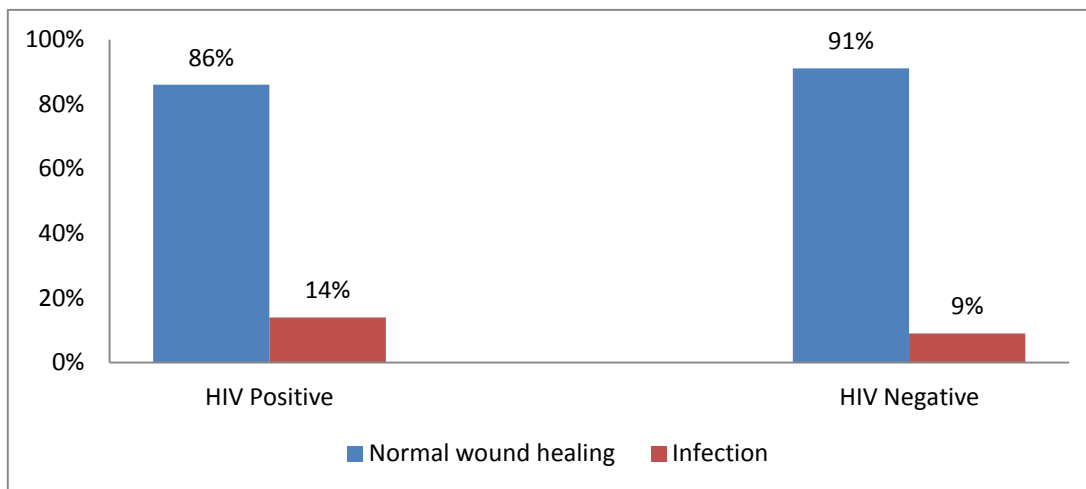
Figure 4.8: Orthopedic implants used in the study

Bivariate analysis

Bivariate analysis on five variables; HIV status, WHO clinical staging, CD4 count level, orthopedic procedure and orthopedic implant used against status of early surgical site infection were conducted using Pearson Chi square test with the following results.

86% of HIV – Positive patients had normal wound healing and 91% of HIV – Negative patients had normal wound healing.

Figure 4.9: HIV status versus infection state



Majority of respondents experienced normal wound healing at WHO stage 1, 2 and 3 as well as in all CD4 count levels.

Figure 4.10: WHO staging versus infection state

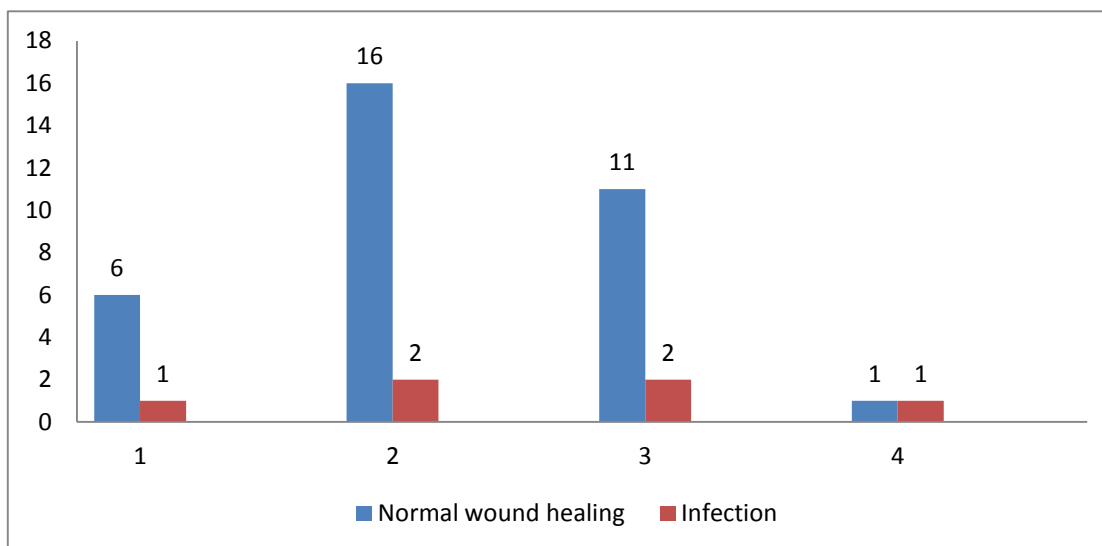
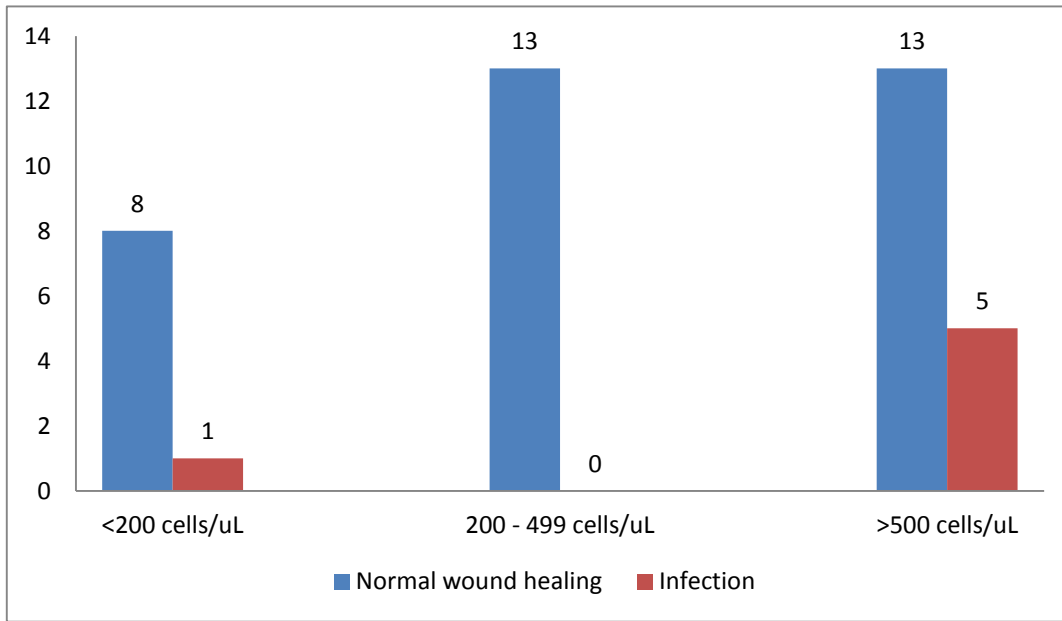


Figure 4.11: CD4 levels versus infection state



Normal wound healing predominated all the types of orthopedic procedures and orthopedic implants used.

Figure 4.12: Orthopedic procedures versus Infection

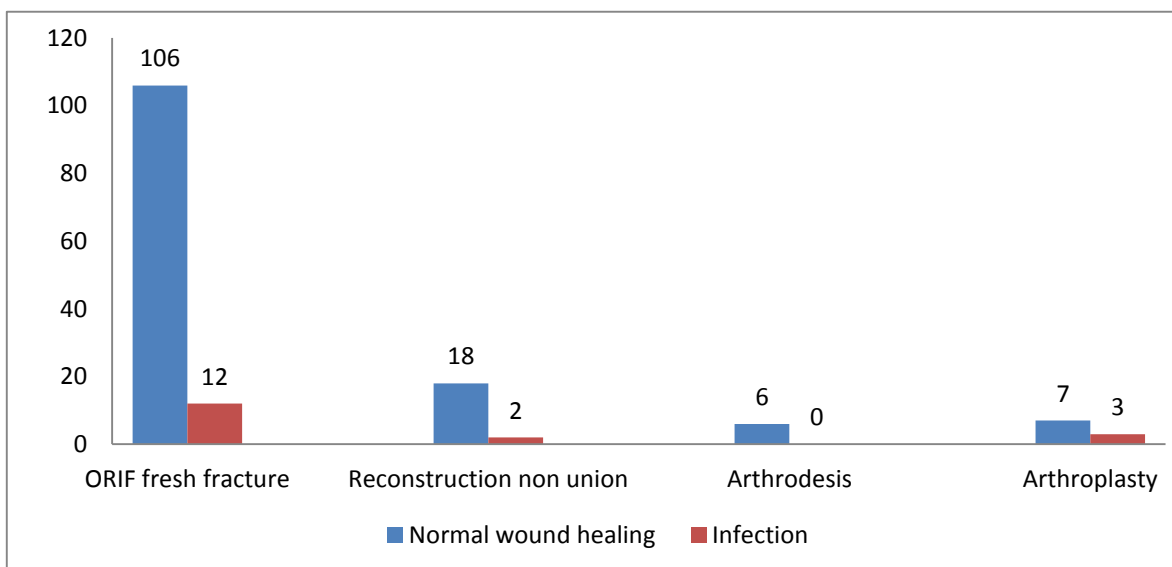
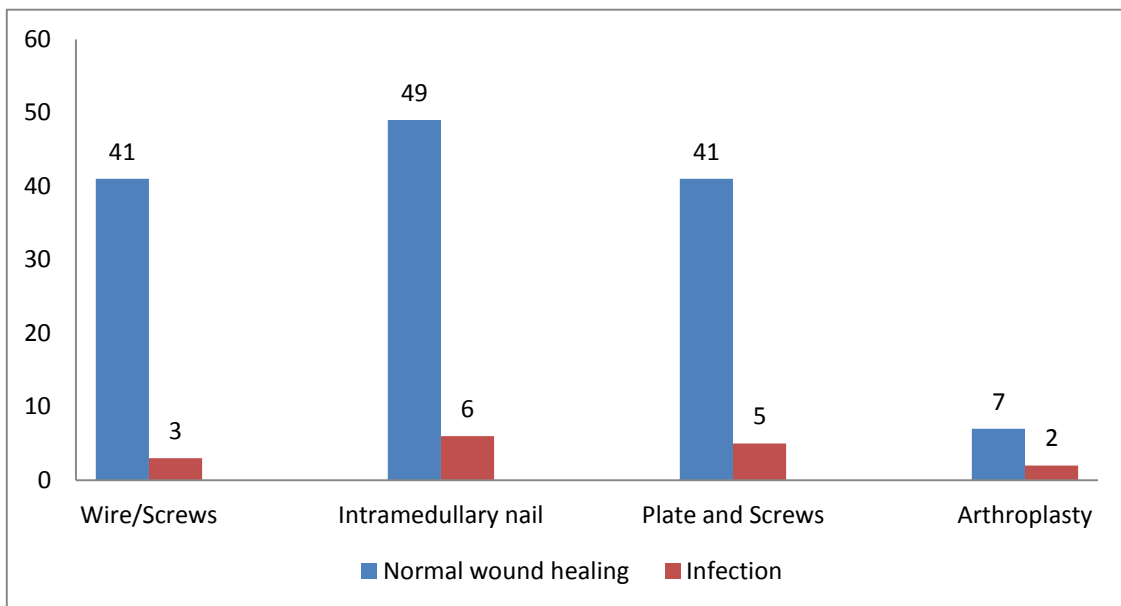


Figure 4.13: Orthopedic Implants versus Infection



Multivariate analysis

Logistic regression analyzing the relationship between HIV status, orthopedic procedure and type of implant used with Wound infection was run. The results are shown in table 1 below.

Table 3: Variables in the Equation

	B	S.E.	Wald	Degrees of freedom	Sigma	Odds Ratio
Implant	.108	.326	.111	1	.740	1.114
Procedure	.315	.326	.936	1	.333	1.371

5.0 DISCUSSION

A total of 154 patients were recruited into the study. Majority of the patients in this study (87%) were within the 18-49 years age bracket, which is the reproductive age group at most risk being HIV-positive (Kenya Demographic and Health Survey 2008). This is also the age group that drives the economy as it's the most productive. Most were also males (80%) which correspond to the male admission rates in KNH trauma wards as well as the global morbidity from orthopedic injuries where almost three times (2.7) as many males as compared to females are affected⁴⁰.

Majority of the patients in this study were staged as WHO stage 2 and 3 and close to half of them (48%) were on ARVs. Kenya's HIV/AIDS guidelines recommend that ARVs be initiated in patients who fit WHO stage 3 & 4 classification and/or have a CD4 count of < 350 cells/ml and/or one is HIV positive and pregnant⁴³. Forty five percent of them had CD4 counts of >500cells/UI unlike those in the study by Ragni et al²⁶ who had CD4 counts below 200 though both studies showed similar results irrespective of this.

Of all respondents; cases and controls, 10.4% had early surgical site infection of these, 14% were HIV-positive and 9% were HIV negative. These results were reflected in a study by James V. L et al²² on complications and outcome of Orthopedic surgery where they found that orthopedic surgeons practicing in areas of high prevalence HIV infection may expect that up to 7% of their patients who undergo emergency procedures will result in surgical site infection.

Another study conducted by Ragni et al²⁶ on the rate of early post-operative infection after orthopedic procedures performed on 66 HIV-positive patients found that the rate of

postoperative infection was 7.5% once patients with preoperative evidence of active infection were eliminated.

Normal wound healing is known to be influenced by several factors including presence of co morbidities, nutrition status, age of patient and substance use among others³⁹. Few studies have been conducted looking into whether the type of orthopedic procedure practiced or orthopedic implant used on a patient impacts healing of the surgical site.

This study analyzed six variables against the risk of early surgical site infection in HIV-positive and HIV-negative patients undergoing orthopedic procedures. These were: influence of HIV status, WHO clinical staging CD4 count, ARTs use, orthopedic procedure and orthopedic implant used. All these variables had no association to early surgical site infection.

Majority of HIV positive patients (86%) had normal wound healing which was a similar result to majority of HIV negative patients (91%) with normal wound healing. Therefore there was no association between HIV positive state and risk of early surgical site infection following an orthopedic implant procedure (P value 0.814, sig. 0.367).

Majority of respondents experienced normal wound healing at WHO stage 1, 2 and 3 as well as in all CD4 count levels. There was no association between WHO stage and CD4 count levels with risk of early surgical site wound infection (P value 2.139; 4.706, Sig. 0.544; 0.095). Similar findings were reported by Bates et al³⁵ and from an Italian prospective multicentre observational study.³⁷

Normal wound healing dominated all types of orthopedic procedures and orthopedic implants used. There was no association between type of orthopedic procedure/orthopedic implant used and risk of early surgical site infection (P value 2.046; 1.984, Sig. 0.563; 0.576).

Several studies have indicated an association between HIV-positive patients who are symptomatic and a high incidence of post-surgical site infections. Hoekman et al³⁸ and Jellis³¹ found in their studies that the incidence of such infections was 24% and 40% respectively after implant surgery. Though, these studies were based solely on clinical staging of HIV disease without reference to CD4 counts. Also no prophylactic antibiotics were used.

A retrospective study by Baochi et al⁴² of sepsis and surgical site infections (SSIs) was conducted in 266 HIV-infected patients showed contrary results with the levels of CD4 count varying in incidence of SSIs. The study team divided the patients into 3 groups based on CD4+ T cells counts in the preoperative period: group A (0–199 cell/ul), group B (200–349 cell/ul) and group C ([greater than or equal to] 350 cell/ul). When the CD4 count was below 350 cells/uL, anti-retrovirus therapy was started. For patients whose preoperative CD4 counts were [less than or equal to] 200 cells/uL, preoperative antibiotic medication was also started. Patients in group A were more likely to get sepsis than patients in the other two groups (p0.01). Sepsis appeared in 110 patients (41%). They concluded that a complete evaluation of surgical risk and suitable perioperative anti-infective treatment may lead to better outcome for HIV-infected surgical patients.

In this study, among the HIV Positive patients the rate of infection was highest in the group with CD₄ count greater than 500cells/ul. This could be due to a high viral load e.g. in patients who have been recently infected with the HIV virus (Phase of Acute infection). The Phase of Acute infection in the natural history of HIV viral infection (within about 9 weeks of infection) is the phase where the CD₄ count is gradually falling but is greater than 500cells/ul and the viral load is rapidly rising.

A cross-sectional prospective study by Brian et al⁴¹ at Bugando Medical Centre Mwanza (BMC), Tanzania involving all patients who underwent major surgery in surgical wards

between July 2009 and March 2010 shows similar results to the previously quoted study. Surgical site infection (SSI) was detected in 65 (26.0%) patients. A total of 37/250 (14.8%) patients were HIV positive with a mean CD4 count of 296 cells/ml.

In this study multivariate logistic regression analysis also showed no association between a person's HIV status, the orthopedic implant used and orthopedic procedure used in the operation to the likelihood of having an early surgical site infection. Thus the null hypothesis 'the incidence of post-operative early SSI is not influenced by HIV' is accepted.

6. CONCLUSION AND RECCOMENDATIONS

6.0 Conclusion

Patients at the KNH orthopedic trauma wards are likely to be within the reproductive age group of 18 to 49 years of age and to be of the male gender. Most of these patients are likely to have been admitted for ORIF for fresh fractures. The commonest implants used on these patients are intramedullary nails.

Early surgical site infection of patients admitted to KNH orthopedic trauma ward is not influenced by HIV status of the patient, CD₄ count or WHO staging if the patient is HIV positive, substance use, orthopedic procedure performed and the implant used.

6.1 Recommendations

Based on the findings of this study, the following recommendations are made:

- Orthopedic implant surgery can be safely undertaken in HIV positive patients without the fear of them getting early superficial surgical site infection regardless of their CD₄ count or WHO staging provided that the surgical conditions are optimal and they have intact skin.
- A larger study would be required to reveal a possible correlation between low CD₄, WHO staging and an increasing risk of early surgical site infection since infections are rare in these groups regardless of the CD₄ count or WHO staging.
- A longer period prospective study would be required to reveal a possible correlation between CD₄ count, WHO staging and late surgical site infection

- Viral load testing and albumin level testing could help in explaining why patients with CD₄ cell counts greater than 500cells/ul had the highest incidence of superficial surgical site infection among the HIV positive patients.

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APPENDIXES

APPENDIX 1: Informed Consent Letter

Title of the study: Early Surgical Site Infection after Orthopaedic Implant surgery in HIV – Positive Patients at Kenyatta National Hospital.

PART A

Introduction

Surgical Site Infection (SSI) is a debilitating complication to wound and fracture healing and more so in HIV positive patients. SSI in HIV positive orthopaedic patients is an area which is incomprehensively studied. This study seeks to fill in that gap.

You are therefore invited to participate in this study whose main objective is to determine the rate of early SSI in HIV positive patients undergoing orthopedic implant surgery at Kenyatta National Hospital Orthopaedic wards. This study will involve two groups of patients (HIV Positive and HIV Negative). The HIV negative group will be the case control group for the study. We request you to read this form and ask any questions you may have before agreeing to participate in the study.

This study is being conducted by Edward Sang (Medical Doctor, Master student) from the University of Nairobi School of Medicine department of Orthopedic Surgery. I will be working with a research assistant who will be a clinical officer.

Purpose of the study

The findings obtained from this study will provide information on the influence if any of patients CD₄ count, viral load and WHO staging on SSI post operatively. This would help in the development of policies on the management of such patients requiring orthopaedic implant surgery. The study will also provide information on the incidence of early surgical site infection in HIV positive patients undergoing orthopaedic implant surgery in KNH. Lastly information obtained will be used for purposes of obtaining a Master degree in Orthopedic Surgery for the principal investigator.

Study procedures

If you agree to participate in this study and you are: HIV positive you will be expected to answer a few questions, staged as per WHO staging system, blood samples will be taken for CD₄ count and viral load levels estimation prior to surgery (A maximum of five milliliters of blood will be drawn, this will include blood for baseline investigations prior to surgery), procedure and implant used in theatre will be recorded and you will be followed up for a maximum of 30 days where the surgical wound will be staged in three occasions. HIV negative you will be expected to answer a few questions, blood samples will be taken for baseline investigations prior to surgery (A maximum of three milliliters of blood will be drawn), procedure and implant used in theatre will be recorded and you will be followed up for a maximum of 30 days where the surgical wound will be staged on three occasions.

Risks and benefits of study participation

You may suffer psychological stress arising from the result of the HIV test. To counteract this adequate pre and post counseling will be offered to every patient as per national HIV testing and counseling guidelines. You will also suffer needle prick pain at the site of venous blood withdrawal.

If you are HIV positive you will be linked to the KNH Comprehensive Care Center (CCC) unit and your CD₄ count and viral load will be done at no cost to you.

During the follow up you will have the advantage of early diagnosis of SSI if you develop any and appropriate treatment will be offered

Study costs

If you accept to take part in this study, there will be no payment expected from you or to you.

Confidentiality

All your responses to the questions are confidential. Your name will not appear on the questionnaire, so that no specific responses can be attributed to you. Your telephone number will only be used for follow up purposes. A copy of this consent document will be given to you to take home if you so wish.

Participant Information

Your participation is entirely voluntary and you are free to withdraw from the study at any moment without any ill consequences befalling you.

Contacts and Questions

The researcher conducting this study is Edward Sang. You may ask any questions you have now or if you have any questions later, you are encouraged to contact him through mobile number: 0722 933301, or email drsangek@gmail.com.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the following:

The Director,

KNH/University of Nairobi – Ethical Review Committee

Telephone: 726300 – 9 or (254 - 020) 2726300 Ext 44102

PART B

Participant consent form

I have understood the above information which has been fully explained to me by the investigator and I voluntarily consent to participate.

Signature.....

Or participants thumb print.

Date.....

Witness signature.....

APPENDIX 2: QUESTIONNAIRE

In patient Number

Mobile number

Age (yrs.)

HIV Status (+/-)

Gender (M/F)

1. ARV's (Yes/No)

Skip if HIV Negative

2. Drugs

a. Alcohol

b. Smoking

c. Other (Specify)

.....

.....

3. WHO Staging

Skip if HIV Negative

4. CD₄ Count (Counts/ μ l)

Skip if HIV Negative

5. Procedure

a. ORIF fresh fracture

b. Reconstruction Non Union

c. Arthrodesis

d. Arthroplasty

6. Type of Implant

a. Wires/Screws

b. Plate and Screws

c. Intramedullary Nail

d. Arthroplasty

7. Wound score

- a. 5 days post op
- b. 14 days post op
- c. 28 days post op

Appearance of wound	% wound involved						Day 5	Day 14	Day 28
	0	< 20	20 - 39	40 - 59	60 - 79	≥ 80			
Serous exudates	0	1	2	3	4	5			
Purulent exudates	0	1	2	3	4	5			
Erythema	0	1	2	3	4	5			
Separation of deep tissues	0	2	4	6	8	10			
Additional treatment									
Antibiotics							10		
Drainage of pus (LA*)							5		
Debridement of wound (GA†)							10		
Isolation of bacteria							10		
Inpatient stay >14 days							5		
Maximum score							65		

* LA, local or no anesthetic, † GA, general or regional anesthetic

WHO Stage	Characterized by	Examples
1	Acute primary HIV Infection or latent asymptomatic or persistent generalized lymphadenopathy	Acute seroconversion illness in some patients
2	Cutaneous manifestations	Herpes Zoster, Seborrheic dermatitis, Recurrent URI, < 10% weight loss
3		Pulmonary TB < 1 year ago, severe bacterial infection, weight loss > 10%, Chronic diarrhea > 1 month
4	AIDS defining illness	Pneumocystis Carinii Pneumonia, Toxoplasmosis, Cryptosporidiosis, CMV retinitis

APPENDIX 3: ETHICAL APPROVAL