

**PATIENT SATISFACTION FOLLOWING BELOW KNEE PROSTHESIS  
FITTING**

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**A dissertation to be submitted in part fulfillment for the requirements of the degree  
of Master of Medicine (M.MED) in Orthopedic Surgery of the University of Nairobi**

**2017**

## DECLARATION

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I hereby declare that this study is my original work and has not been presented for dissertation at any other university.

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## **DEDICATION**

I dedicate this dissertation to my wife dr. Lynda Myra Oluoch, son Aiyden Randiga Mugasia and parents Edward Mugasia Amadi and Leah Kavere Amadi without whom it would have been difficult to complete this dissertation. thank you for your continued support.

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## **List of Abbreviations**

KNH	Kenyatta National Hospital
PCEA	Presbyterian Church of East Africa
AIC	African Inland Church
SF-36	Standard Form 36



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## Abstract

**Background:** Prosthesis use has become the main mode of rehabilitation of patients following limb amputation. The main aim of the prosthesis use is for the patient to regain most of their previous function. There is however minimal data on outcome and satisfaction of patients following this rehabilitation in our setting.

**Objective:** The aim of the study was to look at patient satisfaction following below knee prosthesis fitting post amputation patients who have been put on prosthesis over a period of 6 weeks.

**Study design:** This was a descriptive prospective study conducted in Prosthesis clinic at KNH, PCEA Kikuyu and AIC CURE Kijabe hospitals.

**Methods and Materials:** Patients with below knee amputations were recruited in the study consecutively after giving a written informed consent over a period of 6 weeks. The sample size was 45. In minors, consent was sought from parents and /or guardians. The patients were followed over 6 weeks with reviews done at week 0 and 6. Patient satisfaction were assessed using the SF-36 health questionnaire which is a validated questionnaire used to monitor patient satisfaction to treatment. The scores of the form were compared to the different biosocial and physiological characteristics of the patient. Data collected was analyzed using SPSS version 20 and presented as graphs and charts.

**Results:** The participants were mainly male (64.4%), with a mean age of 41.8 years and a range of 14-88 years. Average waiting time between amputation and prosthesis fitting was 5.9 months. Pain was the main complication (44.4% of the participants) and it was graded at different levels. Age was found to be associated with presence of complication (p value 0.032) with patients over 40 years more likely to develop complications.

SF36 form scores calculated for physical and mental health were 64.9% and 75.5% respectively. The physical functioning score was 50.6%. Patient role limitation was more due to physical health (58.9%) as compared to emotional health (81.5%). Social function scores were at 73.1%.

**Conclusion:** The study showed that prosthesis use remains a key element in management of an amputee and ensures good emotional, social and physical functioning scores.

**Recommendation:** A long term study is recommended to enable serial follow up on the satisfaction levels and use of walk tests for better quantitative data. Policy development for management of amputees is also encouraged to allow for better outcomes.

**Limitations:** Patient bias due to use of a questionnaire as a data collecting tool may have occurred. Short duration of the study, although the SF36 form has been shown to be adequate in measuring changes within a minimum of 4 weeks following a health intervention.

## CHAPTER ONE: INTRODUCTION

Lower limb amputations are associated with more morbidity and change in quality of life than upper limb amputations (1). Lower limb amputation in this study is defined as complete loss of any part of the lower limb, for any reason in the following anatomical planes: in the transverse anatomical plane proximal to, and including, the subtalar joint and in the frontal anatomical plane distal to the subtalar joint. A major amputation is defined as through or proximal to the tarso metatarsal joint and a minor amputation as one distal to the joint.(2). A below knee amputation is thus defined as a major lower limb amputation between the knee joint and the ankle joint.

In the Kenyan setting, there are different causes of amputation. In a study looking at lower limb amputations in Kenyatta National hospital, Peripheral vascular disease was the main indication for lower limb amputation(55.3%), diabetes related gangrene(17.5%), tumours(24.3%) with osteosarcoma accounting for 16.2%, while trauma accounted for 18.9%. Above knee amputations accounted for 55% of the amputations, below knee amputations were 31%, hip disarticulations were 5% with foot amputations accounting for the remaining 9% (3).

Amputation is a life altering surgery that affects both the individual and their families. It may be associated with loss of earning power leading to economic, psychological and physical hardships. Amputation thus leads to a permanent disability and brings a dramatic change in the life and function of the individual (1, 4, 5).

Amputations are still viewed in developing countries as a sign of failed treatment and not as a treatment modality thus leading to severe psychological distress (4, 5). Cultural

beliefs are also contributing to the stigma associated with amputation. Some communities believe that once amputated, the patient would lose the limb even in the next life, thus the increased stigma (4). This contributes to late presentation at the hospitals with associated poor outcomes following the amputation. The goal of modern management of patients who have had an amputation is to restore the form and function of the limb in a way that optimizes quality of life (6).

Studies done have shown that lower limb amputees report lower quality of life as compared to the rest of the population(7). The important role of employment status and use of assistive devices in determining quality of life were the key findings of this study (7). Use of a prosthesis, comorbidities, phantom-limb pain and residual stump pain were found to be other important factors affecting quality of life (5, 7).

Generally, post amputation the functional outcomes of the patient are markedly impaired. There is need to improve their daily activities in life and prosthesis assist in that. A study done to compare functional outcomes between the elderly active amputees and those who lived a sedentary life showed that those with a sedentary lifestyle still had better outcomes than the elderly active patients that had undergone amputation(8). This shows the need for use of prosthesis to assist in their daily functions and activities

In a study done by Permont et al , prosthesis use played a major role in improving the quality of life of patients post amputation. The ability to walk was closely related to their daily function and quality of life. Quality of life in this study was measured using the SIP68 and Barthel Index Scores (9).

Studies have also shown patients who have undergone amputations to suffer from low back pain after amputation (10). Some reported the pain to be present daily or several times a week thus reporting moderate or severe disability. Prosthesis plays a role in reducing the low back pain and enabling better quality of life.

A study done by Matson et al showed that most of the factors that correlate with the quality of the perceived result of amputation and the prosthetic management are not necessarily related to the amount of the limb that was amputated. Rather, the most important correlations appear to be related to the function of the prosthesis itself and to the patient's ability to manage social activities and interactions (6).

However, several other studies show that retaining the knee joint ensures better ambulation with patients with below knee prosthesis ambulating faster and getting to their previous functional state faster than those with above knee amputations (11,29).

Prosthesis use is therefore an important component in the management of a patient post lower limb amputation. They also help the patient to view the amputation as a mode of treatment and not failed treatment (5).

There however is very minimal data in our Kenyan set up on rehabilitation of patients post amputation. The aim of this study is to look at the satisfaction and the return to previous level of function post prosthesis fitting in below knee amputees.



## CHAPTER TWO: LITERATURE REVIEW

### 2.1 Burden of Lower Limb Amputations in Kenya and other region

Lower limb amputations remain a common procedure in Kenya and sub Saharan Africa. Several studies have shown different indications for the amputations. Children are also affected with a study done in Kenya by Ogeng'o et al, showing that children and adolescents account for up to 30% of the amputations. Indications included trauma being the most common cause (42%), followed by congenital defects (29.5%), infection (12.5%), and tumors (11.4%). The commonest cause of trauma was burns (27%), followed by animal bites (18.9%), road traffic accidents (16.2%), and falls (13.5%). In this study, 77.2% of the patients presented after the age of 5 years (12).

Another study conducted at Kikuyu mission hospital by Ogeng'o et al, showed in adults trauma was the leading cause (35.7%), followed by congenital defects (20%), infection (14.3%), tumours (12.8%) and diabetes vasculopathy (11.4%) (13). A dissertation done at the Moi Teaching and Referral Hospital by Birech showed that 48% of the amputations were due to vascular aetiology while trauma constituted another 23.5% and tumours accounted for 8%.(14). The mean age was 49.6 years with males accounting for about 65.9% of the amputated patients.

A study by Muyembe VM et al at the Nyeri Provincial General Hospital showed that Trauma, tumours and complications of diabetes mellitus each accounted for 26.5% of all amputations done (15). They also discovered that only 21.5% of the amputees had prosthesis fitted. The study thus revealed that a low percentage of the amputees underwent rehabilitation with the prosthesis which has been shown to be the most

important factor in rehabilitation of amputees (7, 9). This was thought to be due to limited manpower and expertise in management of an amputee.

In Nigeria, Yinusa et al showed that trauma was the main indication of lower limb amputation at 39% (4). They also found out that most of the patients failed to get prosthesis fitted and were left to ambulate on walking sticks. This markedly altered their economic power as most of the amputees were manual, unskilled labourers. Forty nine percent of the amputees (49%) received adequate physiotherapy while in hospital, with only 21% being assessed by the prosthetics on the ward. However, only 16% had prosthetic fitting. Average time for provision of prosthesis in these 13 patients was 4.7 months.

A study done in Tanzania showed that the most common indication for major limb amputation was diabetic foot complications in 41.9%, followed by trauma in 38.4% and vascular disease in 8.6% respectively (16). Lower limbs were involved in 86.4% of cases and upper limbs in 13.6% of cases. Males were also most commonly affected at a ratio of 2:1. This was significant as males form the major workforce in the East African region. In the Ivory Coast, trauma (49.9%) and diabetic foot (31.4%) were the main indicators with peripheral vascular disease accounting for 13 % ( 20). They also concluded that most of these cases were preventable.

Amputations secondary to trauma and tumour will mainly affect younger aged people who tend to be healthy. This is significant due to the fact that with proper rehabilitation,

they are more likely to readjust and return to their normal life (2). Studies done in the west where the population is elderly still show that prosthesis use helped the elderly amputees to get back to mobility and thus retain their social interaction(5). This was associated with an improvement in their quality of life.

## **2.2 Use of SF-36 to measure prosthesis outcomes and quality of health**

Prosthesis use remains one of the mainstays in rehabilitation of a patient post amputation. However, despite the huge burden of amputations in our settings, there is a relatively small percentage of patients who receive prosthesis and even fewer studies on the functional outcomes following prosthesis fitting (15). Birech at MTRH showed that only 7.1% of amputees were reviewed by prosthesis officers despite 79% having had a discussion with the surgeon on prosthesis use (14). This result were similar to a study done by Lin et al which concluded that successful prosthesis rehabilitation was dependent on both careful patient selection and a coordinated multidisplinary effort(17).

Prosthetic function outcome of lower limb amputees describes the patient's performance by means of health, illness, function and quality of life. This is because amputation affects not only the physical activity of the patient but also the behavioural and psychological functions of the patient. This can be measured by reported assessment instruments and performance-based assessment tools (11, 18).

Several tests and measures have been used to measure prosthesis outcome. However it is important to note that prosthesis function is not dependent only on physical outcome but also emotional and psychological outcomes due to the psychological aspect associated with loss of a limb (11, 18). Prosthesis rehabilitation post amputation has been shown to

have a significant psychological impact (19). Others have shown that the patients satisfaction and prosthesis use is not necessarily determined by level of amputation and energy use during movement but rather by social interaction and psychological satisfaction (6). The tools used in measuring prosthesis outcome function must thus be able to measure the psychological aspect too.

Successful prosthesis rehabilitation depends on patient selection and a multidisciplinary approach. Despite a low immediate mortality, the overall long-term results of lower limb amputation remain dismal. The SF-36 form was developed as a simple measure to assess the health status of an individual and the changes in quality of health following an intervention.

Several studies have been done to assess the validity. Brazier et al showed the SF-36 to be a promising new instrument for measuring health perception in a general population (21). It was noted to be easy to use, acceptable to patients, and fulfils several criteria of reliability and validity.

During the Whitehall II study, Harry Hemingway et al showed that the SF-36 is sensitive to changes in health in general population and could thus be used to measure change in population health (22). Jenkinson et al even reduced the number of fields in the SF-36 form to the SF-12 form (23). The SF-12 form was still shown to be as valid in assessing changes in the health status of the subjects being assessed.

A study by Hagberg et al used the SF 36 to determine quality of life post amputation and prosthesis use (24). They concluded that Transfemoral amputation, due to non-

vascular causes, has an evident impact on quality of life and there are considerable problems related to the amputation and the prosthesis. Efforts to improve the physical and the psychological well-being for this group, with a long life expectancy, are needed.

The SF 36 offers the advantage of looking at all the aspects of health of an individual. This is necessary in analyzing the quality of life and satisfaction post prosthesis fitting as amputation and the intervention of prosthesis fitting will affect all the aspects of a patient's health.

The SF-36 form has been used in several studies. A study by Cees P et al used the Dutch version of the form to assess for phantom limb and health related quality of life in lower limb amputees (25). They noted that in general, the most important amputation-specific determinants of health-related quality of life were 'walking distance' and 'stump pain.' Both of these could be improved by the use of lower limb prosthesis.

In a follow up on transtibial amputations post the Vietnam war the SF-36 form was used to compare health status and functional outcomes for those who sustained the amputations (26). They came to a conclusion that those who had fewer injuries had a better quality of life than those with multiple injuries. In a meta-analysis study to check outcomes in different levels of lower limb amputation following trauma, the SF-36 form was again used alongside other tools (27). The study showed that patients who sustained more proximal amputations had poorer quality of life than those who had distal amputations. Taghipour et al (29) used the form to analyse long term quality of life in patients who had prosthesis fitted following lower limb amputations associated with war. They analyzed 141 war veterans over an average period of 21.6 years. He noted that

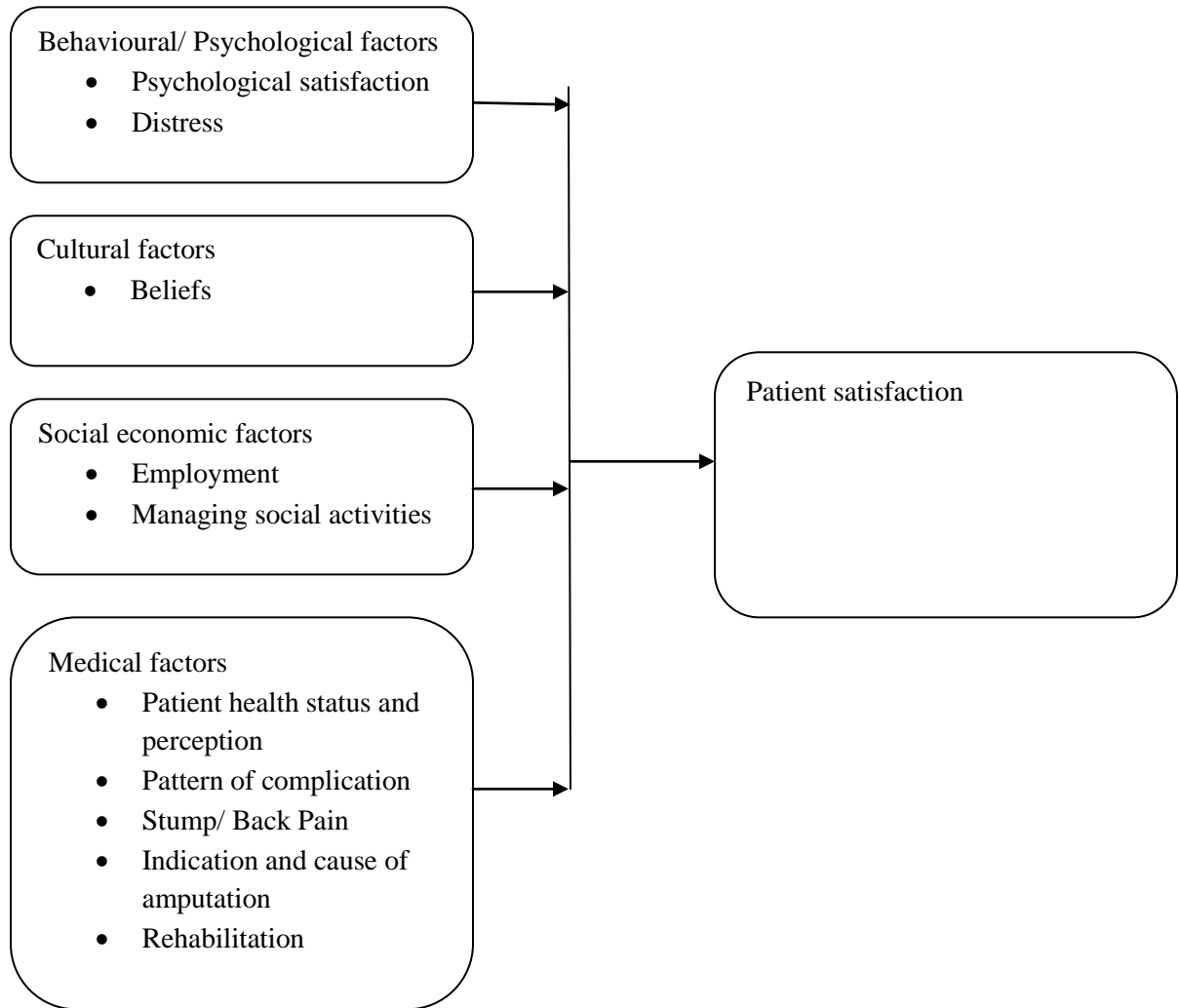
those with transtibial amputations and knee disarticulations tended to have higher physical function scores than those with transfemoral amputations. They however had similar mental scores on the SF36 forms.

Overall, the health related quality of life was significantly lower than that of the general Iranian community. Low back pain was also a common complaint in the study and was found to be the most important factor associated with reduction of physical health related quality of life(OR = 9.1).

## 2.3 Theoretical/ Conceptual framework

### Independent variables

### Dependent variable



### 2.5 Conceptual framework:

Major limb amputations remain a common procedure in our set up with prosthesis fitting being one of the ways of improving function, mobility and independence. Of the patients who have a prosthesis fit, very few have been studied to see their satisfaction following this assistive intervention.

## **2.6 Justification**

In our set up, there is paucity of knowledge about the outcome and satisfaction following prosthesis use, rehabilitation, complications associated with the prosthesis and follow-up of these amputees. This study therefore, seeks to bridge this gap.

## **2.7 Study Question**

What is the patient satisfaction following below knee prosthesis fitting?

### **Objectives**

#### **2.7.1 Primary Objective**

To determine patient satisfaction following below knee prosthesis fitting.

#### **2.7.2 Specific Objectives**

1. To determine the socio demographics of the patients coming for below knee prosthesis fitting
2. To determine patients health status and perception using the SF-36 form
3. To determine pattern of complications associated with prosthesis use



## **CHAPTER THREE: METHODOLOGY**

### **3.1 Study Methods**

This was a cross sectional prospective study that started from July 2016 to November 2016. Patients with below knee amputations fitting the criteria below were recruited in the study after giving a written informed consent. In minors, consent was sought from parents and /or guardians.

The patients were recruited by the principal researcher and his assistants (prosthesis technologists in the clinics) by convenient sampling technique. Follow up was over a 6 week period with reviews done at week 0 and 6. The patient details were captured in the data sheet at the first visit. The SF-36 form was then filled at week 6 and the scores computed and analyzed. Any new complications arising were also noted and included.

### **3.2 Location of the Study**

The study was conducted at the prosthesis clinic of AIC CURE Kijabe Mission hospital, PCEA Kikuyu Mission Hospital and The Kenyatta National Hospital. These three clinics act as a catchment area for provision of both prosthetics and orthotics around the region of Nairobi, Central, Eastern and The Rift Valley provinces of Kenya.

The prosthesis type used in KNH, AIC Kijabe and PCEA Kikuyu clinics are the manual, single axis prosthesis with a socket that is made of either plastic or lamination material. Padding is done using a soft insert for comfort. The endoskeletal shank is made of metal and covered with either plastic or laminated material for protection. The solid ankle

cushion heel (SACH) is used for the foot ankle assembly. This is a single axis foot that allows for wearing of a shoe by the amputee.

In these centres, once a patient pays for the prosthesis as an inpatient, they have a temporary prosthesis fit to assist in mobilization as the stump heals while awaiting the permanent prosthesis. However, most patients are unable to afford this and are thus followed up in the outpatient clinics. Fitting is done in the clinics once the payments are made.

All the prosthesis are manufactured at their individual prosthesis workshop. For rehabilitation, patients are referred to the physiotherapy clinic and reviewed 3 monthly or when complications arise.

### **3.3 Study Population**

All amputees attending the above named prosthesis clinics with the aim of fitting a new below knee amputation prosthesis.

### **3.4 Sample Size and Sampling Procedure**

#### **3.4.1 Sample Size Determination**

The average monthly number of patients visiting prosthesis clinic of AIC Kijabe Mission hospital, PCEA Kikuyu Mission Hospital and The Kenyatta National Hospital is 17. The sample size for patients was computed using the Yamane (1967:886) formula for a study period of 3 months. The margin of error allowed in the estimate was 5% which meant the study was conducted at 95% confidence level.

$$n = \frac{N}{1 + N(e^2)}$$

Where: N- Target population, n - sample size; e - margin of error (5%)

Therefore:

$$n = \frac{51}{1 + (51 \cdot 0.05^2)} = 45.2 \approx 45 \text{ patients}$$

The study was able to follow up 45 patients and thus there was no need to include the 10% attrition.

### **3.4.2 Sampling Procedure**

The study utilized the statistical target population to attain maximum possible response rate. This was because target population is small.

### **3.5 Inclusion and exclusion criteria**

#### **3.5.1 Inclusion criteria**

The study population included all patients presenting to the clinics for the first time with a below knee amputation for prosthesis fitting.

#### **3.5.2 Exclusion Criteria**

The study excluded:

- Patients who had used a prosthesis before
- Patients who require bilateral prosthesis fitting
- Patients, parents and guardians who were unwilling, unable or declined to give consent due to any reason

- Patients requiring prosthesis fit on the upper limbs

### **3.6 Data collection and management**

Data was collected using a standard data sheet. Data collected included:

- Patient demographics
- Data concerning initial amputation
  - Date of amputation
  - Cause of amputation
  - Previous profession or work status
  - Current work status following amputation
  - Duration between amputation and acquiring of prosthesis
  - Reasons of delay, if any on acquiring the prosthesis
- The SF-36 form was then filled and scored at week 6.

At the end of each interview the filled questionnaire was cross checked for completeness and any missing entries corrected. The quantitative data collected was coded, processed and cleaned off current inconsistencies and outliers. The qualitative data was analyzed through the selection of concepts, categories and themes. This involved reading through the data and developing codes that draw similar connections between categories and themes. Data analysis was done using SPSS (Statistical Package for the Social Sciences) version 21. Descriptive statistics were presented using frequencies and percentages. The baseline characteristics were summarized and presented as means/medians and proportions. Relationship between variables were established using Chi-square test for

categorical variables (proportions) and Student's t test for continuous variables (means) at 95% confidence level. Findings were presented in the form of text, charts, graphs and tables.

### **3.7 Ethical considerations**

Approval for the study was sought from the department of orthopedic Surgery, University of Nairobi and the KNH ethics and research committee (KNH/ERC). Once approval was received, the letter was presented to the Kikuyu and Kijabe hospitals for clearance. Patients were given a clear explanation of the study before they decided to consent. For those who did not consent, they were managed as per the regular prosthesis management protocol in the specific institutions.

### **3.8 Study limitations**

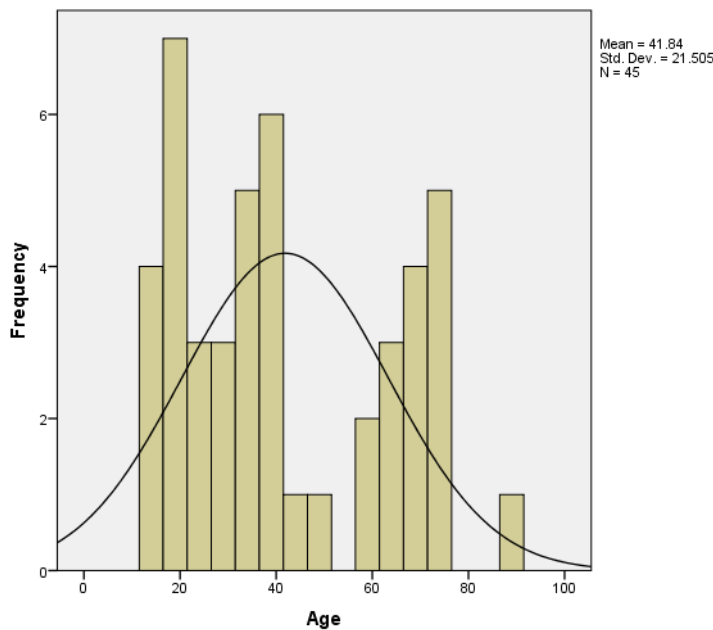
- Difficulty recruiting and monitoring the prosthesis patients. This was covered by ensuring adequate training of the prosthesis technologists.
  - The training was done at each individual prosthesis clinic before data collection starts. It was a 2 hour session that included:
    - Introduction of the study (15 minutes)
    - Aims and objectives of the study (20 minutes)
    - Significance of the study (20 minutes)
    - Methodology of the study (10 minutes)
    - Inclusion and exclusion criteria (10 minutes)
    - How to fill the study questionnaire and the SF 36 form (20 minutes)
    - Follow up at week 0 and 6 (20 minutes)

- Assistants were provided with the principal investigator's contacts to allow for communication at any time when needed (5 minutes)
- Different sites for collection of the data. This was mitigated by at least visiting the sites twice weekly.
- Patient inability to afford the prosthesis thus the limitation in numbers
- Patients opting out of the study –this was prevented by ensuring all patients were educated well on enrollment to the study.

## CHAPTER FOUR: RESULTS

### 4.1 Socio demographics

This study used a sample 45 patients who presented to the clinics for the first time with a unilateral below knee amputation for prosthesis fitting. The sample comprised of 64.4% males and 35.6% female patients. The mean age was 41.8 (SD= 21.5) within the range of 14 to 88 years (Figure 4.1). Majority (51.1%) patients were aged 37 years and below.



**Figure 1: Age distribution of patients**

Majority 53.3% patients had a consistent source of income as farmers (22.2%), drivers (11.1%), masons (6.7%), a teacher, an accountant and businessmen. The rest included students (26.7%), casual labourers (6.7%), persons retired (6.7%) and unemployed (6.7%).

**Table 1: Demographic characteristics**

Variable	Categories	Frequency	Percent
Age groups	<18	6	13.3
	18-27	9	20.0
	28-37	8	17.8
	38-47	6	13.3
	48-57	1	2.2
	58-67	7	15.6
	68-77	7	15.6
	>78	1	2.2
Gender	Male	29	64.4
	Female	16	35.6
Employment status	Unemployed	21	46.7
	Employed	24	53.3

**4.2 Amputation**

The main reasons for amputation were road traffic accidents (46.7%) and diabetic feet (26.7%). Two patients suffered amputations following an attack by wild animals (hippopotamus and crocodile) and were thus grouped under animal bites.

Patients waited for an average of 5.9 (SD=3.1) months with a range of 1 to 13 months before prosthesis fitting after amputation. Main reasons for the waiting time included healing stump/ wound (50.0%) and lack of finances to buy the prosthesis (43.2%). There was no relationship between duration before amputation and reason for amputation ( $\chi^2$ , p value=0.99). The distribution of the number of months before prosthesis fitting was similar across all the reasons of amputation (Kruskal-Wallis, p value=0.283). This implied that no specific reason of amputation would be related to specific duration before amputation.



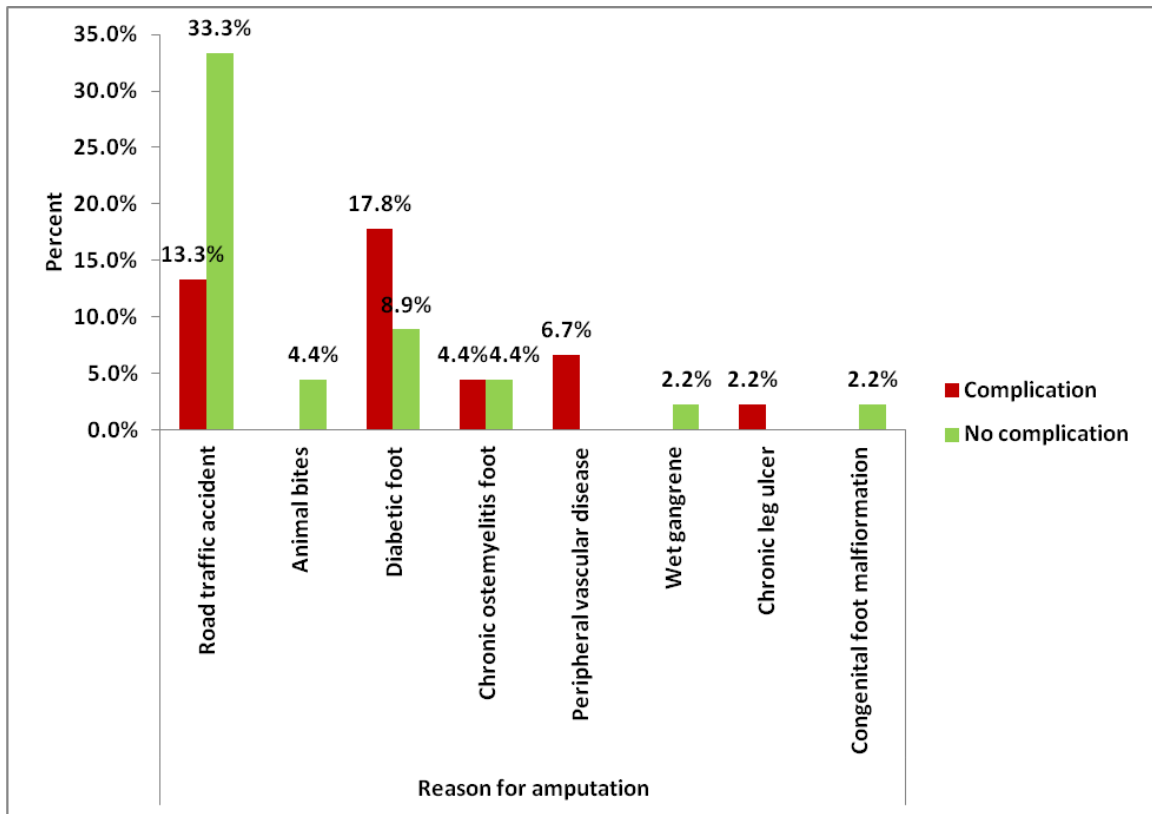
**Table 2: Amputation**

Reason for amputation	Number of months between amputation and prosthesis		Total
	1-4	Over 4 months	
Road traffic accident	7	14	21
Diabetic foot	2	10	12
Chronic osteomyelitis foot	2	2	4
Peripheral vascular disease	0	3	3
Animal bites	1	1	2
Wet gangrene	0	1	1
Chronic leg ulcer	1	0	1
Congenital foot malformation	1	0	1
Total	14	31	45

**4.3 Complications**

Majority of the patients (55.6%) reported no complications at the sixth week. The rest reported pain which they graded as pain (33.3%), mild pain (6.7%) and occasional pain (2.2%). A small group also complained of occasional loss of balance (2.2%).

A proportion of 26.67 % patients could work normally, 46.7% had limited ability to work, and 13.3% were unable to work. There was no significant relationship between diagnosis and complication at week six (Kruskal wallis test, p value=0.077). Road traffic accident and diabetic foot were the diagnosis with the highest number of complications (Figure 4.2).



**Figure 4.2: Relationship between diagnosis and complication**

#### **4.3.1 Relationship between social demographics and complication**

Age and presence of complication at week 6 were significantly related ( $\chi^2$ , p value=0.032). Patients above 40 years were more likely to develop complications as compared to those below 40 years (OR 5.9, 95% CI 1.61 to 21.55). Gender and employment status did not significantly influence occurrence of complications ( $\chi^2$ , p value>0.05).

#### **4.4 Patient's health status**

Cronbach alpha rating ranged from .838 to .935 for the SF-36 eight subscales which implied that the information was reliable. The physical and mental health measures were 64.9% and 75.5%. Physical functioning score was 50.6% which implied that the patients

were moderately functional. Patients were limited in their roles more due to physical health (58.9%) as compared to emotional problems (81.5%).

Bodily pain was reduced at a significant magnitude (82.2%) and the patients scored above average on energy to perform their roles (69.8%). Patient social functioning was moderately good (73.1%) (Table 4.3).

**Table 4.3: Prosthesis outcome measured using SF-36**

Scale	Items	Cronbach Alpha	Mean	Std. Deviation
Physical functioning	10	0.921	50.556	22.4930
Role limitations due to physical health	4	0.935	58.889	45.2755
Bodily pain	3	0.870	82.222	18.4269
General health	4	0.838	68.111	14.1135
Energy/ fatigue (Vitality)	5	0.871	69.778	12.7456
Social functioning	2	0.867	73.056	11.2927
Role limitations due to emotional problems	2	0.859	81.481	34.4917

#### **4.5 Relationship between social demographics and health status**

There was a statistically significant difference ( $F(1, 43) = 13.514, p = .001$ ) in the physical health scores between patients aged below 40 years (mean=73.2, SD=17.6) and those aged above 40 years (mean=53.6, SD=18.3). The effect size of age on physical health scores was large (eta squared= .484). This implied that patients aged below 40 years had better physical health compared to the rest. There was no significant relationship between mental health score and age (Spearman = -.105,  $p = .494$ ).

Gender did not have any significant relationship with physical health score (Mann-Whitney U test,  $p=0.053$ ). There was a statistically significant difference ( $F(1, 43) = 5.091, p = .029$ ) in the mental health scores between male (mean=72.2, SD=15.6) and

female (mean=81.5, SD=7.2) patients. The effect size of gender on mental health scores was large (eta squared= .106). This implied that female patients coped better following prosthesis fitting as compared to the males.

There was a statistically significant difference ( $F(1, 43) = 4.274, p = .045$ ) in the physical health scores between employed (mean=59.3, SD=19.8) and unemployed (mean=71.4, SD=19.1) patients. The effect size of employment status on physical health scores was large (eta squared= .301). This implied that unemployed patients had better physical health compared to the employed. Employment status was not related to mental health scores ( $\chi^2, p \text{ value} = 0.106$ ).

#### **Relationship between health status and other variables**

The distribution of physical health was different across different reasons for amputation (Kruskal Wallis,  $p \text{ value} = 0.044$ ). There was a statistically significant difference ( $F(7, 37) = 2.307, p = .047$ ) in the physical health mean scores between across different categories of diagnosis (Table 4.4). The effect size of diagnosis on physical health scores was large (eta squared= .304). This implied that patients diagnosed with chronic osteomyelitis foot and animal bites had better physical health compared to the rest. The distribution of mental health was similar across different reasons for amputation (Kruskal Wallis,  $p \text{ value} = 0.107$ ). This implied that there was no relationship between the two.

**Table 4.4: Physical health means and diagnosis**

<b>Reason for amputation</b>	<b>Physical health Mean Score</b>	<b>N</b>	<b>Std. Deviation</b>
Road traffic accident	67.381	21	20.2046
Animal Bites	82.500	2	5.3033
Diabetic foot	53.906	12	18.2356
Chronic osteomyelitis foot	84.375	4	4.5357
Peripheral vascular disease	55.625	3	17.3656
Wet gangrene	35.625	1	
Chronic leg ulcer	65.625	1	
Congenital foot malformation	90.000	1	

There was no significant relationship between physical functioning and waiting time before prosthesis fitting after amputation (Spearman =  $-.153$ ,  $p = .315$ ).

## CHAPTER FIVE: DISCUSSION

Findings from the study showed that majority of the patients who presented to the prosthesis clinics were relatively young (mean age 41.8 years, with 51.1% being under 37 years). It also indicated that most of the patients were of the male gender (64.4%). This was similar to the study done by Birech et al where the average age of amputation was 49.6 years with majority being males (65.9%), (14). In Tanzania, Chalya et al showed the mean age to be even lower at 28.3 years with males being the majority at a ratio of 2:1 (16). At the Kenyatta National Hospital, K O Awori noted a mean age of 44.8 years with a male majority of 62.1% (3).

Causes of below knee amputations were noted to be road traffic accidents (46.7%) and diabetic feet (26.7%). Other causes included chronic osteomyelitis (8.9%), Peripheral vascular disease (6.7%), animal bites (following wild animal attacks-4.4%), Wet gangrene (2.2%), chronic leg ulcer (2.2%) and congenital foot malformation (2.2%).

This finding was different from a study done in KNH by K O Awori where peripheral vascular disease was the main indication for lower limb amputation (55.3%), Diabetes related gangrene(17.5%), tumours (24.3%) with osteosarcoma accounting for 16.2%, while trauma accounted for 18.9% (3).

In comparison to other studies conducted in our setting on amputations, it differed from a dissertation done at the Moi Teaching and Referral Hospital by Birech which showed that 48% of the amputations were due to vascular aetiology while trauma constituted another 23.5% and tumours accounted for 8% (14).

There were however comparisons with the study done by Ogeng'o et al and Muyembe et al which showed trauma to be the leading cause of amputations (13,15). Similar findings were also found in Nigeria where Yinusa et al showed that trauma was the main indication of amputation at 39% (4).

Patient waiting time before prosthesis was quite varied with a range of 1 to 13 months. The average waiting time was 5.9 (SD=3.1) months. It was however noted that there was no relationship between waiting time and indication for amputation ( $\chi^2$ , p value=0.99).

The times compared to Nigeria where Yinusa et al showed that the average time for provision of prosthesis in these 16% of patients post amputation was 4.7 months(4). In Finland, a study by T. Pohojolanien showed that the waiting time was a average of 16 weeks (5).

A study by Olunglade et al showed that 91.5% of the patients did not receive a prosthesis due to financial reasons (28). This was different from our study where finances were the second common cause of delay of prosthesis fitting (43.2%). There were however very few studies in our setting that checked for the waiting time and reasons for the wait between amputation and prosthesis fitting. This further showed the necessity behind conduction of this study.

Majority of the patients (55.6%) reported no complications at the sixth week. The rest reported pain which was graded as pain (33.3%), mild pain (6.7%) and occasional pain (2.2%). A small group also complained of occasional loss of balance (2.2%). It was noted

that patients with diabetic foot and peripheral vascular disease were noted to have the highest proportions of those with complications. This was significant as a study by Van der Schans et al showed that stump pain and phantom limbs were the most important factors in detecting quality of life among amputees (25).

It was also noted that majority of the patients were not able to go back to their normal levels of activities after prosthesis fitting. Only 26.67% could return to work normally while 13.3% were unable to return to work at all. This compared with the findings of Pernot et al where the amputees were generally found to have poor functional scores using the SIP68 and the Barthel scores (9). This was despite the fact that the amputees underwent an average of 35 weeks physiotherapy unlike in our setting where minimal physiotherapy was done prior to and after prosthesis fitting.

Using the SF 36 scores, Sinha et al also found the quality of life of amputees to be significantly lower than that of the general public (7). This indicated that the findings got from my study correlated with previous studies done even though the follow up time was relatively shorter. In our setting, inability to return back to work normally could have been due to poor rehabilitation or prosthesis design both reasons which indicate a need for more research into this subject.

There was also a correlation noted between age and complications at 6 weeks ( $\chi^2$ , p value=0.032). Patients above 40 years were more likely to develop complications as compared to those below 40 years (OR 5.9, 95% CI 1.61 to 21.55). It was noted that



gender and employment status did not significantly influence occurrence of complication ( $\chi^2$ , p value>0.05). There were however no local studies that had looked at this correlation. This could thus be used as a baseline for future studies in our setting concerning prosthesis use post amputation.

From data collected from the SF 36 form, physical and mental health measures were 64.9% and 75.5%. Physical functioning score was 50.6% which implied that the patients were moderately functional. Patients were limited in their roles more due to physical health (58.9%) as compared to emotional problems (81.5%). Their general health percentage score stood at 68.11%. This noted that prosthesis played a major role in the psychologic and emotional status of the patient. It also pointed towards the fact that resumption of previous physical activity may take a longer duration than emotional and psychological status. This was different from the findings of Thagipour H et al who showed in their study that role limitation following emotional problems was 68.3% while that resulting from physical problems was at 57.9%. Their general health score was 47.9%(29). Their relatively poor mental and emotional scores could however have been due to the study's cohort which looked at post war injury amputees as the only participants.

However, Dougherty et al in a similar cohort showed that patients who had only suffered a trans tibial amputation had physical and mental health measures of 81.6% and 79.5%. Their general health scores were at 74.1% (26). Akarsu et al concluded that inspite of the different types of lower limb amputations and aetiology, patients could achieve a

better life standard with good rehabilitation and prosthesis. His patients scored 48.8% for physical function and 43.6% for mental health. The general health score was 50.9%(30).

Comparison of physical health mean scores and the diagnosis leading to amputation seemed to imply that post traumatic amputation patients tend to have better physical scores than those who had amputations following diabetic foot and peripheral vascular disease. This is likely to indicate that the cause of amputation may actually play a major role in determining the functional outcomes post prosthesis fitting.

## **CHAPTER SIX: CONCLUSION**

The results from the study shows that prosthesis use remains a key element in the management of an amputee. This remains so even though availability of the prosthesis may not be easy especially due to financial reasons.

It also showed that despite the absence of return to optimum physical function, most of the amputees developed a better emotional and social health status following amputation use.

## **CHAPTER SEVEN: RECOMMENDATIONS**

1. Need to undertake a study to look at long term outcomes and satisfaction of prosthesis use following below knee amputations
2. Improve availability of the prosthesis by reducing the cost. This will enable shorter waiting periods before prosthesis fitting.
3. Improve public health measures to reduce rates of road traffic accidents and diabetic foot which are the commonest cause of amputations that lead to need for prosthesis rehabilitation.
4. Develop policy for a multidisciplinary approach to the amputee post discharge from the wards. This is likely to help in earlier detection of complications and enable improvements in patient satisfaction and functional outcomes post prosthesis fitting.

## **CHAPTER EIGHT: LIMITATIONS**

1. By use of a questionnaire, there may have been patient bias during data collection.  
It is recommended that a follow up study be done to measure functional outcomes using various walk tests that are available.
2. The duration of time may have been relatively short, despite the fact that the SF36 form has been shown to be adequate in measuring changes within a 4 week period. The next study should have a longer follow up and compare results with the ones obtained here.

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**APPENDICES**

**Appendix I: Data Collection Sheet**

Study number.....

Age.....

Gender.....

Reason for amputation.....

Date of amputation.....

Date of prosthesis fitting.....

Reason for delay (if any).....

Occupation.....

Current work status.....

Complications at week 6

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-----  
-----  
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## Appendix II: The SF-36 Form

### SF-36 QUESTIONNAIRE

Name: \_\_\_\_\_ Ref. Dr: \_\_\_\_\_ Date: \_\_\_\_\_  
ID#: \_\_\_\_\_ Age: \_\_\_\_\_ Gender: M / F

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

#### GENERAL HEALTH:

In general, would you say your health is:

Excellent  Very Good  Good  Fair  Poor

Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago  
 Somewhat better now than one year ago  
 About the same  
 Somewhat worse now than one year ago  
 Much worse than one year ago

#### LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

**Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Lifting or carrying groceries**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Climbing several flights of stairs**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Climbing one flight of stairs**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Bending, kneeling, or stooping**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Walking more than a mile**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Walking several blocks**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Walking one block**

Yes, Limited a Lot  Yes, Limited a Little  No, Not Limited at all

**Bathing or dressing yourself**

Yes, Limited a Lot

Yes, Limited a Little

No, Not Limited at all

**PHYSICAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

**Cut down the amount of time you spent on work or other activities**

Yes

No

**Accomplished less than you would like**

Yes

No

**Were limited in the kind of work or other activities**

Yes

No

**Had difficulty performing the work or other activities (for example, it took extra effort)**

Yes

No

**EMOTIONAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

**Cut down the amount of time you spent on work or other activities**

Yes

No

**Accomplished less than you would like**

Yes

No

**Didn't do work or other activities as carefully as usual**

Yes

No

**SOCIAL ACTIVITIES:**

**Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all

Slightly

Moderately

Severe

Very Severe

**PAIN:**

**How much bodily pain have you had during the past 4 weeks?**

None

Very Mild

Mild

Moderate

Severe

Very Severe

**During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all

A little bit

Moderately

Quite a bit

Extremely

**ENERGY AND EMOTIONS:**

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

**Did you feel full of pep?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you been a very nervous person?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt so down in the dumps that nothing could cheer you up?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt calm and peaceful?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you have a lot of energy?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt downhearted and blue?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you feel worn out?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you been a happy person?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you feel tired?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**SOCIAL ACTIVITIES:**

**During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?**

- All of the time
- Most of the time
- Some of the time
- A little bit of the time
- None of the Time

**GENERAL HEALTH:**

How true or false is each of the following statements for you?

**I seem to get sick a little easier than other people**

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

**I am as healthy as anybody I know**

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

**I expect my health to get worse**

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

**My health is excellent**

Definitely true

Mostly true

Don't know

Mostly false

Definitely false



### **Appendix III: Consent Form**

Study number.....

My name is Dr. Edgar Hezekiah Amadi a master's of orthopaedic surgery student at the University of Nairobi, department of orthopaedic surgery. I am carrying out a three months study on patient satisfaction following below knee prosthesis fitting. This study has been approved by the University of Nairobi and Kenyatta national hospital ethical and research committee. The aim of the study is to find out if patients are satisfied following below knee prosthesis fitting and the complications they incur during use of their prosthesis. This information will help improve management of patients who have undergone major lower limb amputations.

It has been shown that amputees who have prosthesis have a better outcome in their daily activities as opposed to those who don't. I would like to find out how you as an amputee cope after prosthesis fit and if you are satisfied with your quality of life following prosthesis fitting. Your participation in this study is on a voluntary basis. It is not a must that you participate in this study and your decision will not affect the treatment you receive in this clinic. All the information collected will be kept strictly confidential and your name will not be used in any publication.

If you agree to be included in this study, you will be followed up at 2 weeks and 6 weeks where you will fill a questionnaire to assess your satisfaction with your prosthesis.

You are free to withdraw from the study at any time. This will not compromise the treatment you receive in the clinic. By signing below, you are agreeing to participate in this study voluntarily.

Name \_\_\_\_\_

Signature\_\_\_\_\_ Date\_\_\_\_\_

Witness\_\_\_\_\_

Signature\_\_\_\_\_ Date\_\_\_\_\_

**DR. EDGAR HEZEKIAH AMADI 0722281256 edgaramadi@gmail.com**

## **FORMU YA RUHUSA**

Nambari ya mhusika.....

Habari yako, jina langu ni Dr. Edgar Hezekiah Amadi, mwanafunzi ninayesomea shahada ya upasuaji we mifupa. Nafanya utafuti wa miezi tatu kuhusu kutosheka kwa wagonjwa waliowekewa visaidizi vya kutembea baada ya kukatwa mguu. Utafuti huu unahusu wale wanaotumia hospitali za KNH, AIC Kijabe na PCEA Kikuyu. Utafuti huu umepewa ruhusa na chuo kikuu cha Nairobi na kamati ya utafuti ya hospitali kuu ya Kenyatta.

Lengo la utafuti huu ni kugundua ikiwa waliowekwa visaidizi hivi hutosheka na husaidika navyo wanapoendelea na kazi zao za kila siku. Majibu tunayopata yatatumiwa kusaidia wale wanaopoteza miguu yao.

Utafuti unaonyesha kuwa wanaotumia visaidizi hivi hufanya kazi zao vyema kuliko wale wasiokuwa navyo. Ningependa kujua vile wagonjwa wetu wanafanya kazi baada ya miezi tatu.

Kuweko kwako katika utafuti huu ni kwa hiari yako na si kwa kulazimishwa na hutadhuru matibabu yako hospitalini. Majibu tunayoyapata kutoka kwako yatawekwa kwa siri na majina hayatatumiwa pahali popote.

Utakapokubali kuwa katika utafuti huu, tutakufuatilia baada ya wiki 0, 2 na 6 kuona unavyoendelea. Utaulizwa maswali kuhusu afya yako ili kuona kama umesaidika na kutosheka na chombo hicho cha kukusaidia kutembea.

Waweza toka katika huu utafuti wakati wowote na kutoka kwako hutadhuru matibabu utakayopata. Kwa kuweka sahihi hapa, unakubali kuhusika katika utafuti huu bila kulazimishwa.

Jina \_\_\_\_\_

Sahihi \_\_\_\_\_ Tarehe \_\_\_\_\_

Mwenye

Kushuhuda \_\_\_\_\_

Sahihi \_\_\_\_\_ Tarehe \_\_\_\_\_

**DR. EDGAR HEZEKIAH AMADI 0722281256 edgaramadi@gmail.com**

**Appendix IV: Implementation Timetable**

	January 2016 – June 2016	July 2016 – November 2016	November 2016– January 2017	February 2017
Proposal writing and submission for ethical approval				
Data collection and analysis				
Dissertation writing				
Presentation of results				

**Appendix V: Budget estimates**

<b>ITEM</b>	<b>COSTS</b>
Research Fee (KNH/ERC)	1500
Stationery costs(printing, binding of proposal, dissertation and patient results)	10,000
Statistician and research assistants	50,000
Transport costs to the different centres	10,000
Contingencies	10,000
<b>TOTAL</b>	<b>81,500</b>

The study was funded by the principal investigator

## Appendix VI: KNH-UoN ERC Approval letter



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
P O BOX 19676 Code 00202  
Telegrams: varsity  
Tel:(254-020) 2726300 Ext 44355

KNH-UoN ERC  
Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)  
Website: <http://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: @UONKNH\_ERC [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)



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

Ref: KNH-ERC/A/308

10<sup>th</sup> August, 2016

Dr. Amadi Edgar Hezekiah  
Reg. No. H58/79628/2012  
Dept. of Orthopaedics  
School of Medicine  
College of Health Sciences  
University of Nairobi



Dear Dr. Amadi

REVISED RESEARCH PROPOSAL: PATIENT SATISFACTION FOLLOWING BELOW KNEE PROSTHESIS FITTING (P468/06/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above proposal. The approval period is from 10<sup>th</sup> August 2016 – 9<sup>th</sup> August 2017.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

“Protect to discover”

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN  
The Deputy Director, CS, KNH  
The Assistant Director, Health Information, KNH  
The Chair, KNH- UoN ERC  
The Dean, School of Medicine, UoN  
The Chair, Dept. of Orthopaedics, UoN  
Supervisors: Dr. George Museve, Dr. John Kingori

## Appendix VII: ACIH IRB Ethics approval letter



**AIC CURE International Hospital**  
P.O.Box 52 - 00220 Kijabe, Kenya  
Tel: 020 3246620, 0733 770 653  
Email: info@curekenya.org

ACIH Institutional Research and Ethics Board (IRB) Ethics Approval Letter

19<sup>th</sup> September 2016

To Dr. Edgar Amadi, Orthopedic Surgery Registrar  
University of Nairobi


**RE: Ethical Approval for Your Study**

The Ethics and Research Board of AIC Cure Hospital has gone through your submitted request to undertake a non-invasive study titled **PATIENT SATISFACTION FOLLOWING BELOW KNEE PROSTHESIS FITTING**

and grants the approval for the study to be carried between Sept 2016 and Nov 2016.

Any variations to the protocol or dates of the study must have prior permission of the IRB. Any severe adverse effects on patients or bad outcomes must be reported within 24 hours to the IRB using the Incidence Reporting Forms. We expect at the end of collecting results you will alert IRB and that you will share the final study outcomes copy with us to facilitate transfer of knowledge and future decision-making. Should you abandon your study mid-way, kindly alert us in writing giving the reasons for such a decision.

We wish you well in your study. Feel free to seek further guidance from the IRB during your study.

Signed:   
Dr. Jeff M. Mailu  
Consultant Orthopedic and Arthroscopic Surgeon  
IRB Chair, AIC Cure Hospital.

