Early clinical outcomes of patients wound, using negative pressure wound therapy in wound dressing of patient with open fractures of the tibia and fibula gustilo anderson grade iiib at Muhimbili Orthopedic Institute 2018

Elias Lyimo, MD

MMed (Orthopaedics and Traumatology) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2018
Muhimbili University of Health and Allied Sciences

Department of Orthopedics and Traumatology

EARLY CLINICAL OUTCOMES OF PATIENTS WOUND, USING NEGATIVE PRESSURE WOUND THERAPY IN WOUND DRESSING OF PATIENT WITH OPEN FRACTURES OF THE TIBIA AND FIBULA GUSTILO ANDERSON GRADE IIIB AT MUHIMBILI ORTHOPEDIC INSTITUTE 2018

By

Elias Lyimo

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine (Orthopaedics and Traumatology) of

Muhimbili University of Health and Allied Sciences
October, 2018

CERTIFICATION

The undersigned certify that have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences as a dissertation entitled: ***"Early Clinical Outcomes of Patients Wound, Using Negative Pressure Wound Therapy in Wound Dressing of Patient With Open Fractures of The Tibia and Fibula Gustilo Anderson grade IIIB at Muhimbili Orthopedic Institute 2018"*** in (partial) fulfillment of the requirement for the degree of Masters of Medicine (Orthopedics and Traumatology) of Muhimbili University of Health and Allied Sciences.

_____

Dr. Cuthbert N. Mcharo

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Dr. Elias Lyimo**, I declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for any similar or any other degree award.

Signature…… **Date**……

ACKNOWLEDGMENT

I wish to express my sincere gratitude and appreciation to my supervisors Dr. Cuthbert N. Mcharo for his supervision and encouragement during the development and writing of my dissertation.

I would like to mention Dr. Billy T. Haonga and Dr. Edmund Ndalama Eliezer for their support to make this study success.

I am also grateful to all staff members of Orthopedics and Trauma at MOI/MUHAS for their support during the course of my studies, to mention Dr. Rabi Ndeserua for his tireless support.

I am grateful and indebted to my mother for her unconditional love and support in all aspects of my life. I also thank all my relatives who in different ways supported me morally and physically. Last but of foremost importance I am thankful and indebted to my wife for encouragement, motivation, support and patience throughout my dissertation work.

To all that I have achieved in my life may the glory, honor and praise be to the Almighty God.

DEDICATION

To my beautiful wife Dr. Angela Japhet Lyimo, for her unconditional love and patience for the whole time that I was away from home for my studies.

To my daughter Abigail Elias Lyimo for the joy she brought into our life.

To my Late father Mr. Obadia Lyimo who groomed me to be who I am today.

ABSTRACT

Background: Open fractures are often high-energy injuries and are frequently associated with life-threatening injuries, skin degloving, soft tissue crushing, and contamination. Open Tibia fractures causes great suffering to patients and are an enormous economic burden especially in developing countries.

Negative Pressure Wound Therapy (NPWT) has shown a promising treatment method when managing these wounds. The four primary effects of NPWT are; wound contraction, stabilization of the wound environment, decreased edema and removal of wound exudates, and micro deformation. These effects allow NPWT to speed wound healing; increase blood flow around wounds; improve wound bed preparation for subsequent closure or coverage, and change wound biochemistry, bacterial burden, and systemic response.

Objective: The study aimed at determining the early outcomes; granulation tissue formation, wound site infection, re-debridement and grafting proportion, when using negative pressure wound therapy (NPWT) in the management of wounds in patients with Gustilo-Anderson IIIB fracture of the tibia treated at MOI from June 2017 to March 2018

Methodology: One arm cohort study was conducted at Muhimbili Orthopedics and Trauma Institute (MOI) from June 2017 to March 2018. Twenty four patients meeting the inclusion criteria were enrolled into the study consecutively as they presented to the hospital, data was collected using a structured questionnaire and Bates-Jansen wound assessment tool was used in the assessment of wound on each dressing change,

Results: A total of 24 patients were enrolled during the study period, 18 (75%) were males and 6 (25%) were females, male: female was 3:1, the mean age was 36.67 standard deviation 15.216 years, the majority of patients (54.2%) were in the age group between 21-40 years, the mean time from injury to intravenous antibiotics prophylaxis was 6.54 standard deviation 1.719 hours, the mean time from injury to surgical debridement was 9.79 standard deviation 1.587 hours.

The mean duration of using NPWT was 4.9 standard deviation 1.6 days, and the mean number of dressing change was 2.88 standard deviation 0.338.

The duration for formation of healthy granulation tissues covering more than 90% of the wound bed was found to be 4.92 standard deviation 1.586 days, the infection rate was found to be 16.7 %. The proportion of patients who underwent graft procedure to cover the soft tissue defect was 16.7%, the mean wound area reduction was 10.42 cm^2 (63.46%) p-value <0.001, re-debridement was found to be 20.8% of these, 16.64% was due to infection and 4.16% was due to secondary necrosis. The early infection rate was 16.7% , time from injury to antibiotics of more than 6 hours was associated with development of infection p-value = 0.018, while time from injury to surgical debridement was not associated with development of infection p-value = 0.288.

Conclusion and recommendations: Road traffic accidents (RTA) are in rise, due to poor infrastructures, increase in motorcycles as means of transportation, these contributes to a raise in high energy injuries which pos treatment challenges due to complex soft tissue disruption, the affected age group is between 21-40 years, this group is the working force for the economic growth of our country. New modality of wound dressing using NPWT shows promising early treatment outcomes and lowers the complication rates. There was statistical association between development of early infection and delay in prophylactic antibiotic.

There is need of affirmative action's to advocate early intravenous antibiotics prophylaxis to patients with open fracture to lower the infection burden. This can be achieved by regular training first health care responders who provide the basic life support to trauma victims. A larger multicentre case control study is needed in order to establish the effectiveness of using NPWT in wound management of open fractures compared to wet dressing in Tanzania.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CI	Confidence Interval
CM	Centimeter
FDA	Food and Drug Authority
GHOIS	Ganga Hospital Open Injury Score
IRB	Institute Review Board
K.C.I	Kinetic Concepts Inc
KE	Kinetic Energy
MOI	Muhimbili Orthopedic Institute
MUHAS	Muhimbili University of Health and Allied Sciences
NPWT	Negative Pressure Wound Therapy
PU	Polyurethane
VAC	Vacuum Assisted Closure
VFD	Vacuum Foam Dressing
WHO	World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Open fractures are often high-energy injuries and are frequently associated with life-threatening injuries. They are best managed by a team approach in centers that have appropriate facilities for resuscitation and multispecialty care (1). Apart from severe bone and soft tissue involvement, these injuries have other risk factors such as skin degloving, soft tissue crushing, contamination with dirt and debris and injury to neurovascular structures. Hence, they are associated with a high risk of complications, such as delayed union, osteomyelitis, and amputation. Recent developments such as advances in the management of polytrauma, the availability of broad-spectrum antibiotics, refinement of the techniques of surgical debridement, bone stabilization, and early soft tissue reconstruction have helped to improve the outcome considerably. The present challenge for the trauma surgeon is not simply salvage of the limb but the restoration of maximal function (2).

Open fracture management has evolved over centuries. Tscherne has grouped the developments into four eras of; Life preservation, Limb preservation, Infection prevention, and Functional restoration (2). Ambroise Pare who emphasized the need for cleaning wounds of all foreign matter recognized the problem of contamination in the 16th century and necrotic tissue and leaving the wound open (3). The term "*debridement"* was coined by Desault in the 18^{th} century to describe a procedure that involved surgical extension of the wound and the removal of all necrotic and contaminated tissue.(4) In the absence of antibiotics and aseptic surgical techniques, the incidence of mortality and amputation following infection was very high. "Lose a Limb to save a Life" was an accepted dictum of management as gross infection of open injuries often led to gangrene, septicemia, and death. Meanwhile the principles of treatment were being constantly refined. Gustillo and Anderson published their landmark classification scheme for open fractures that brought attention to the importance of the wound and the need for early soft tissue cover (5, 6). The seminal work of Godina clearly emphasized the advantages of early soft tissue cover (7). The source of the infection was frequently

identified to be from the hospital environment and the principle of “Fix and Flap” and the indications and advantages of primary skin suturing were developed. The huge variability in presentation and the challenges inherent in the management of Gustilo-Anderson IIIb injuries led to the development of the Ganga Hospital Open Injury Score (GHOIS) with specific guidelines for salvage and reconstruction in Gustilo-Anderson IIIb injuries (8).

Recently, the availability of vacuum foam dressings (VFD) using negative pressure wound therapy (NPWT) has also proved to be very useful in wounds that cannot be covered early. It acts as a bridge between the index procedure and the definitive soft tissue cover procedure. NPWT progresses a wound towards healing by maintaining a moist wound environment, improving micro-vascular blood flow, controlling exudates, stimulating tissue formation and reducing wound size by pulling the wound edges together (9). Additionally NPWT can reduce bacterial load, eliminate wound odor and improve quality of life for patients (10). There are two types of foam dressings available to use with the V.A.C Therapy. The Granufoam is a black, polyurethane (PU) foam dressing with reticulated (open) pores to help evenly distribute negative pressure across the wound bed, assisting in tissue granulation formation in wounds and aiding wound contraction. It is hydrophobic (or moisture repelling), which enhances exudates removal. There is also an antimicrobial option, which includes 10% silver for the use of infected wounds (11).

Mechanism of action of Negative Pressure Wound Therapy

In an extensive systematic review of the literature on NPWT, Orgill et al described the four primary effects of NPWT: wound contraction, stabilization of the wound environment, decreased edema and removal of wound exudates, and micro deformation. These effects allow NPWT to speed wound healing; increase blood flow around wounds; improve wound bed preparation for subsequent closure or coverage; and change wound biochemistry, bacterial burden, and systemic response. (40)

Wound Contraction

After traumatic or surgical skin disruption, the tensile forces of the surrounding soft tissues can lead to wound gapping. Prolonged wound gapping leads to soft-tissue contraction, thereby jeopardizing the capability to obtain primary wound closure, even in the absence of soft-tissue loss. NPWT exerts a contracting effect on the wound that pulls the edges together (40)

Stabilization of wound environment

There is accumulation of exudates in traditional wet dressing, however in NPWT there is continuous drainage of excess exudates in the wound bed thus maintaining osmotic and oncotic gradient between the wound bed and the surrounding soft tissue. (40)

Decrease edema

Following trauma, edema develops, the use of NPWT leads to constant evacuation of excess exudates, and this promotes cell proliferation and tissue perfusion (41)

Micro deformation

Improved interstitial fluid flow through the extracellular collagen matrix, secondary micro deformation stimulates cellular growth factors synthesis such as vascular endothelial growth factor (VEGF). (42)

Classification of open fractures of the extremities

Various classification systems exists which explains the degree of injury to the extremities, these classification system helps to plan management and predicts the outcome of the treatment according to the grade of the injury. The two famous systems are Gustilo and Anderson, and the other system is Ganga Hospital Open Injury Score, which was described by Rajasekaran in 2005.

For the purpose of this study, Gustilo and Anderson classification was used.

In 1976 Gustilo and Anderson proposed a classification for open fractures of the tibia, it consists of three types;

Type I injuries are associated with minimal soft tissue injury

Type II injuries are associated with moderate injury

Type III injuries are associated with severe injuries which expose the fracture site and were associated with muscle damage and periosteal stripping

In 1984, type three III open fractures were subdivided again into three types which are;

Type III A injuries are associated with wound more than 10cm, high level of contamination, severe soft tissue crushing, comminuted bone injury with possible coverage of bone

Type III B injuries are associated with wound more than 10cm, high level of contamination, poor coverage of bone which usually requires soft tissue reconstruction

Type III C injuries are associated with wound more than 10cm, high level of contamination, very severe loss of cover and vascular injury requiring repair, poor bone coverage which usually require soft tissue reconstruction.

This classification system has contributed in the management of open fractures as it focuses the importance of soft tissue injury and wound contamination. Infection rate was 1.9% in type I injuries, 8% in type II injuries and 41% in type III injuries, this implies that need for early surgical debridement and wound coverage after controlling the infection. (14)

Management of open fracture

Tendon and/or bone exposure commonly occurs in the leg (15). The conventional treatment method used for these non-closable wounds is skin grafting after the formation of healthy granulation tissue by wet dressing (16). However, the duration of treatment may be prolonged, and patients may experience severe pain during dressing changes, furthermore, it is difficult to form healthy granulation tissue by simple wet dressing, when a tendon, bone, or implant is exposed. Accordingly, free flap surgery is often required, which requires substantial effort and introduces the issue of donor site morbidity (17).

Surgical debridement is important to minimize the risk of infection. Surgical debridement is an active surgical procedure whereby a dirty contaminated wound is converted into a surgically clean wound. All foreign material and tissues that are contaminated or suspected to be avascular are systematically removed so that whatever is left behind is vascularized living tissue, devoid of contamination. Another aim of debridement is also to minimize risk factors for infection such as dead space or hematoma so that the incidence of infection is at minimum as possible.

Lavage is used before and after debridement as it clears the debris and hematoma and provides optimal exposure and reduces contamination and the bacterial count (18, 19). Adequate quantity of lavage fluid must be used for cleaning on the principle that the "solution for pollution is dilution." Typically more than 9 L of fluid is required in Type IIIb injuries.

Stable skeletal stabilization must be achieved as it helps to alleviate pain and prevent further soft tissue damage. During skeletal stabilization the length of the limb must be restored as this restores the correct tension to the soft tissues and this decreases swelling, improves circulation, and aids venous and lymphatic return. It also increases the comfort of the patient during wound inspection and facilitates early rehabilitation and movement of joints. (19)

Skeletal stabilization should be undertaken quickly especially in the setting of vascular deficit and it must be designed to allow future soft tissue reconstruction. Different techniques for skeletal stabilization are available; the choice depends on the morphology of the fracture and the planned reconstructive procedures. In high-energy injuries associated with contamination, the preferred method is to use a temporary external fixation followed by secondary internal fixation at a later operation. (19)

1.2 Literature review

Negative pressure wound therapy (NPWT) was first described by Argenta and Morykwas (19). This technique can be used to cover exposed bone or soft tissue defects without frequent dressing changes, and reduces chronic edema and increases local blood supply, which enhances the formation of healthy granulation tissue. Several reports have been issued on the application of NPWT to soft tissue defects of the extremities, abdomen and chest (19, 20). There was significant granulation tissue associated with NPWT which enabled them to treat a high proportion of wounds with split skin graft as opposed to a more complex flap reconstruction (21).

With conventional dressing methods, patients with wounds with soft tissue defects, flaps are almost needed to cover the defects, however with the use of NPWT there is reduction in the need for flaps to cover the soft tissue defects, (22, 23, 24, 25, 26, 27) with data regarding flap rates and extended negative pressure wound therapy use have reported a decrease in flap procedures. Before the introduction of NPWT, it was reported free flap rates of 42%, however after its approval by the FDA in 1997 the rate of free flap went down to a mean of 11% (27).

Following high energy trauma as in grade III Gustilo and Anderson, secondary necrosis used to happen due to the knowledge that a crushed tissue demarcates during a 72-hour period and this may change the status of the wound and lead to secondary wound exploration and re-debridement, however NPWT has shown to minimize secondary tissue necrosis when it is employed in the management of crushed injuries (28). Another study reported no need for flaps and no infections in the 88 high energy wounds sustained by 77 patients in the Iraq war, this was due to avoidance of secondary necrosis after using the NPWT in the management of these causalities (29).

Open injuries are associated with high infection rates, and among the factors that impairs wound healing is the infection which cause persistent inflammatory reaction at the wound site, this will cause prolonged hospitalization and high cost of treatment to the institute and the patient side, however it was observed, when using NPWT there is nearly 80% reduction in deep infection (30). A case series of 35 where NPWT was used, these cases included wounds

associated with tibia fracture, foot and ankle trauma and hip revision surgery. All cases were identified as being high risk for post operative complications with prolonged wound drainage or swelling. NPWT was employed for a mean duration of just over 3 days, two key benefits were reported. Firstly, over the same period four dressing changes would have occurred if conventional techniques were employed, hence patients were less troubled by dressing changes and nursing time required to manage the wounds was reduced. Secondly, there were no cases of infection in this high risk group (31). Another study which look at NPWT in the management of open tibia fractures, the infection rate for all grade III was about 24% and increased to 50% in grade IIIB fractures. In this study 49 adult patients who had sustained grade III open tibia fracture, after initial debridement and skeletal stabilization, NPWT was employed, almost 30% of those predicted to need flap coverage did not require it. About half of the wounds were closed by skin grafting, primary closure or secondary intention (32). A retrospective study which reviewed 111 open tibia fractures treated with free flaps reconstructions which were performed between days 8-42. This group of patients is at increased chances of having complications related to flap reconstruction when compared to those who were managed by definitive surgery. However the NPWT group had a lower overall complication rate 35% versus 53%, the infection rate of 6% versus 18% and flap complication rate of 12% versus 21%. The authors recommended NPWT to be used as a bridging treatment in cases where definitive flap was delayed (33)

1.3 Problem Statement

Motor traffic crash is the leading cause of the injuries affecting the young and productive generation of the nation. These injuries caries a high percentage of complications such as, deep infection, delayed union and non-union (34). Deep infection rates of a range 8-12% have recorded (35-38). Thus it is associated with prolonged hospitalization, high cost of treatment, and work burden to the health system. With the advent of NPWT in the management of Gustilo Anderson IIIB wounds of the tibia/fibula it is expected to improve the treatment outcome.

There is paucity of data on outcome of using NPWT in managing patients with Gustilo Anderson IIIB in our setting and the, proposed study will help to address the gap.

1.4 Rationale

Proposed study will help to fill the knowledge gap in the management of patients with open fracture Gustilo Anderson IIIB of the tibia/fibula in our institution using NPWT as the dressing modality.

It will also be a baseline study of the use of NPWT in managing traumatic wounds at our institute and be used for future scientific research in our setup.

1.5 Research question

What are the early clinical treatment outcomes of NPWT as a means of dressing wounds of patients with fracture of the tibia/fibula Gustilo Anderson IIIB at MOI?

1.6 Objectives

1.6.1 Broad objective

To determine the treatment outcomes of using NPWT in the management of wounds in patients with Gustilo Anderson IIIB fracture of the tibia treated at MOI from June 2017 to March 2018.

1.6.2 Specific objectives

1. To determine the duration of formation of healthy granulation tissue of wounds in patients with Gustilo Anderson IIIB fracture of the tibia treated by NPWT at MOI, using Bates-Jensen tool.
2. To determine the infection rate of wounds in patients with Gustilo Anderson IIIB fracture of the tibia treated by NPWT at MOI, using Bates-Jensen tool.
3. To determine the rate of re-debridement of wounds in patients with Gustilo Anderson IIIB fracture of the tibia treated by NPWT at MOI.
4. To determine proportion of patients who required flap to cover soft tissue defect of wounds in patients with Gustilo Anderson IIIB fracture of the tibia treated by NPWT at MOI.

CHAPTER TWO

2.0 METHODOLOGY

2.1Study design

One-arm observational cohort study.

2.2 Study area

The proposed study will be conducted at Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania for a period of nine months as from June 2017 to March 20187.

Muhimbili Orthopaedic Institute (MOI) is the largest Orthopaedic and trauma referral center in Tanzania, which offer both Orthopaedic and Neurosurgery services, with a capacity of 270 beds (30 privates and 240 general). There are thirty five Orthopaedic surgeons, five anesthesiologists, three radiologists, thirty one residents, 115 operating room nurses and ward nurses.

In the department of Orthopaedic and Traumatology, there are three firms (A and B), and Paediatrics Orthopaedic firm which carryout clinical activities.

In Orthopaedic and Traumatology, the admitting firm has a team of one consultant, one specialist, two residents and one registrar who is the medical officer and one intern doctor and a nurse at the emergency department.

2.3 Study Period

The study was conducted for a period of eight month from June 2017 to March 2018 inclusive.

2.4 Study population

The study includes all patients presented at MOI during the study period with the diagnosis of Gustilo Anderson IIIB fracture of the tibia.

2.5 Inclusion criteria

- All patients with isolated limb Gustilo Anderson IIIB fracture of the tibia/fibula at MOI during the study period.

2.6 Exclusion criteria

- Wounds with exposed blood vessel
- Wounds with exposed nerves
- Infected wounds
- Patients with bleeding disorders
- Patients who were on anticoagulation therapy
- Patients with pre-medical conditions such as Diabetes mellitus

2.7 Sample size estimation

From a pilot study at MOI from October to November 2016 the prevalence of Gustilo-Anderson IIIB fracture of the tibia was found to be 1.9%. Considering the study power of 95%, a random likely error is estimated to be 5%, thus the sample size of this study is calculated from the formula

$$n \quad \frac{Z^2P(1-P)}{E^2}$$

Where;

N Sample size

P Prevalence

E Marginal error

Z Confidence level

$$N \quad \frac{1.96^2 \times 0.019x(1-0.019)}{0.05^2}$$

N $23.64 \approx 24$. Thus, the minimum sample size of this study was 24 patients

Patients who meet the study criteria and consented to participate in the study were enrolled in the study.

2.8 Sampling technique

Convenient sampling technique was used to obtain the required sample

2.9 Technique

Surgical debridement was done and fracture stabilization with either internal or external fixation as per MOI protocols, intravenous antibiotic (I/V Ceftriaxone 1gm) was administered pre-operative as a prophylactic dose and post operative as per MOI guideline, Tetanus toxoid (T.T) vaccination status was reviewed for each patient, and they received (T.T 0.5mls) as per guideline. Wound parameters were recorded after initial surgical debridement, these included; anatomical distribution, size, status of soft tissues and fracture type.

Aseptic techniques were observed in all dressing change. NPWT was applied to the patient the same day in the ward from operating theatre, a pressure of -120mmHg was set as per guideline of pressure set for traumatic wounds, continuous mode was selected to all patients as the VAC machines used had only one mode, the model of the machine used was aquarium air pump model no. pr-7500. The NPWT consist of a suction tube, a collecting canister, a vacuum pump, and a sterile gauze. Size of the sterile gauze used was 1-2 cm larger than wound size and sealed with Smith and Nephew opsites to maintain the seal. Dressings were changed every 48 hours. At each dressing change, Bates-Jansen wound assessment tool was used to assess the wound and scoring was done at every dressing change. On day seven final wound assessment using Bates Jensen wound assessment tool was done and recorded.

Surgical site infection surveillance post-operative data collection form of WHO was used to capture patients who developed wound infection. The infection rate was determined by taking a proportion of patients who developed wound site infection in a period of seven days in which NPWT was used.

Treatment was stopped when there was

- Formation of healthy granulation tissue which is in level with the surrounding skin,
- When there is no reduction in wound size following two consecutive dressing changes,
- Presence of signs of systemic infection or localized cellulitis, this necessitated the patient to be sent for another surgical debridement in the operating theatre as per MOI protocol

2.10 Data collection process

Informed consent was obtained before patient enrollment; data were collected using a structured questionnaire. Patient demographics information's were captured standard treatment information was also obtained all enrolled patients received standard treatment as per guidelines for management of open fracture. Wound status measurements were recorded on day one and at consecutive dressing change using the Bates-Jansen wound assessment tool until completion of NPWT. Scores of wound regeneration were observed at every dressing change, and scores which indicated that there were signs of wound degeneration when noted, prompt actions were done, which included stopping the treatment and re-surgical debridement was done and treatment was continued. Raw data cleaning was done every month, and entered to the structured template in the SPSS version 20.

2.11 Data analysis

Obtained data were analyzed using SPSS version 20. Statistics included were; means and SD were computed for all demographics. Proportion were determined for categorical variables while means/median and standard deviation were determined for numerical variables. Student t-test were used for comparisons of numerical variables while for categorical variables, Chi square test or Fisher exact test were used. The differences were considered statistically significant at P value of less or equal to 0.05.

2.12 Ethical consideration and Consent

Ethical clearance was sought from the IRB of MUHAS. An Introductory letter from MUHAS was sent to MOI administration, prior to commencement of the study; all enrolled patients were instructed about the study and asked for consent. The procedures followed observed the principles as described by MUHAS Institutional Review Board. These include telling the patients the right and freedom to participate or not and, the protection of the patient's data and privacy. Patients were instructed about the study and consented privately.

CHAPTER THREE

3.0 RESULTS

3.1 Socio-demographics

A total of 24 patients were enrolled in the study for a period of nine month, from June 2017 to March 2018, the mean duration of using negative pressure wound therapy (NPWT) was 4.9 standard deviation 1.6 days, minimum of 4 days and maximum of 7days. The mean number of NPWT dressing change was 2.88 standard deviation 0.338 times, median was 3 times.

Of the study participants, 18 (75%), were males and 6 (25%) were females, the male: female (m: f) ratio 3:1, the mean age was 36.67 standard deviation 15.216 years, the median age was 33.5 years, youngest age was 5 years and the oldest was 64 years. Majority of patients 54.2% were in the age group between 21-40 years. The mean time to I/V Ceftriaxone was 6.54 standard deviation 1.719 hours, 79.2% of patients received antibiotics within first six hours post injury. The mean time from injury to surgical debridement was 9.79 standard deviation 1.587 hours.

Table 1: Patient characteristics

Variables	Frequency	%
Age groups in years		
5-20	3	12.5
21-40	13	54.2
41-60	6	25.0
>61	2	8.3
Sex		
Male	18	75
Female	6	25
Standard treatment		
Tetanus toxoid	24	100
I/V Ceftriaxone	24	100
Surgical debridement	24	100
Time from injury to antibiotics		
First 6 hours	19	79.2
More than 6 hours	5	20.8
Time from injury to surgical debridement		
Within 6 hours	6	25
More than 6 hours	18	75
Mechanism of injury		
Road traffic accident	**24**	**100**

A large proportion of patients 75% that had surgical debridement done more than six hours after injury, and 20.8% received I/V Cefrtiaxone more than six hours post injury.

3.2 Duration to formation of health granulation tissue

Table 2: Granulation tissue formation

Variable	Frequency	%	P-value
Granulation formation day 3			
Excellent	5	20.8	
Good	14	58.4	0.04
Poor	5	20.8	
Granulation formation day 5			
Excellent	19	79.2	
Good	2	8.3	0.04
Poor	3	12.5	
Granulation formation day 7			
Excellent	22	91.7	
Good	2	8.3	0.04
Poor	0	0.0	
Total	**24**	**100**	

At day seven, majority of patients 91.7%, had formed excellent granulation in the wound bed, which covered > 90%, p-value 0.04.

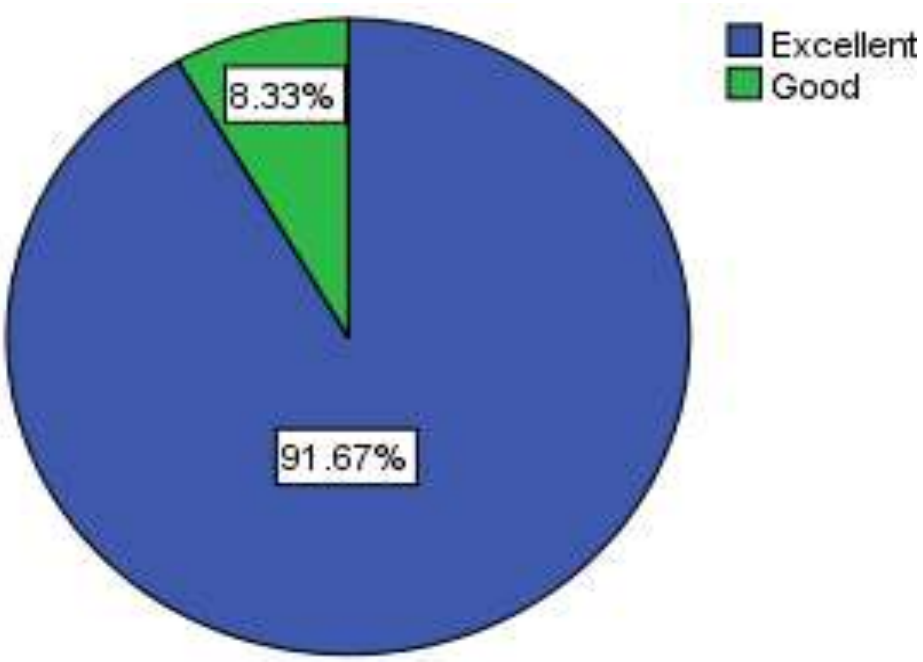


Figure 1: Pie chart percentage wound granulation on seventh day

At day seven, all study participants had formed acceptable granulation tissue in their wound beds, of which; 91.67% had excellent granulation tissue formed and 8.3% had good granulation tissue formed. The mean duration to formation of health granulation tissue was 4.92 standard deviation 1.586 days, the minimum duration for formation of health granulation tissues was 2 days and the maximum duration was 7 days and the median was 5 days. A healthy granulation tissue was defined as the one which is beefy and bright red.

3.3 Infection rate

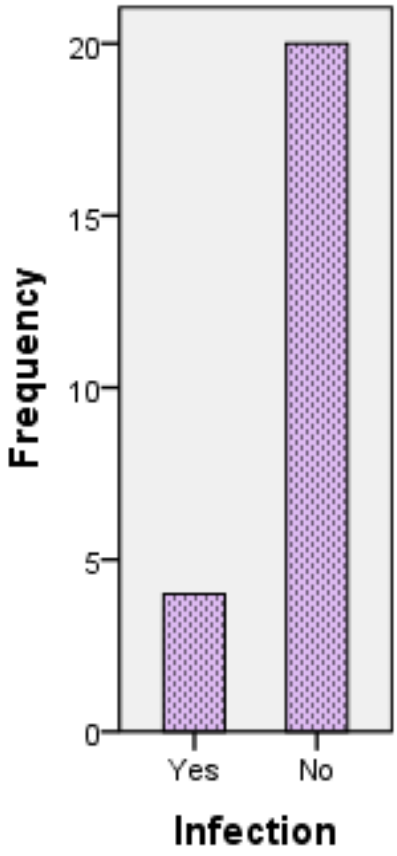


Figure 2: Bar graph showing the infection frequency

Among 24 study participants, 4 of them developed infection which account for 16.7%, of whom 3 were male participants and one was a female. There was statistical association between delay in prophylactic antibiotics of more than 6 hours and development of early infection, p-value 0.018. However there was no association between late surgical debridement of more than 6 hours and development of early infection, p-value 0.288, wound size on day one was not found to be associated with development of infection p-value 0.233.

Table 3: Infection determinants

Variable	Infection	No infection	P-value
Time from injury to antibiotics			
< 6 hours	1(4.16%)	18(75%)	0.018
>6 hours	3(12.5)	2(8.33)	
Time from injury to surgical debridement			
< 6 hours	0(0.0%)	6(25%)	0.288
>6hors	4(16.67%)	14(58.3%)	
Wound size after initial surgical debridement			
4-16 cm^2	1(4.16%)	12(50%)	0.233
16-<36 cm^2	3(12.5%)	8(33.3%)	

There was statistical association between time from injury to prophylactic I/V, antibiotics of more than six hours and development of early infection.

3.4 Proportion of Graft

Table 4: Shows the frequency of patients who had grafting procedure

Variable	Frequency (%)
Graft procedures	
Yes	4(16.7%)
No	20(83.3%)
Graft type	
FTSG	1(4.2%)
STSG	0(0.0%)
Rotational flap	3(12.5%)

Among 24 study participants, 4 underwent graft procedure which mount to 16.7%, of these 3 underwent rotational flaps equal to 12.5% and 1 underwent full thickness skin grafting 4.2%. The mean reduction of wound size was 10.42$cm^{2,}$ standard deviation 0.568, this is equal to 63.46% reduction in wound size achieved. The mean wound size reduction was statistically associated with rate of graft, p-value 0.016. Hence 20 (83.3%) study participants wounds were left to heal by secondary intention.

3.5 Rate of Re-Surgical debridement

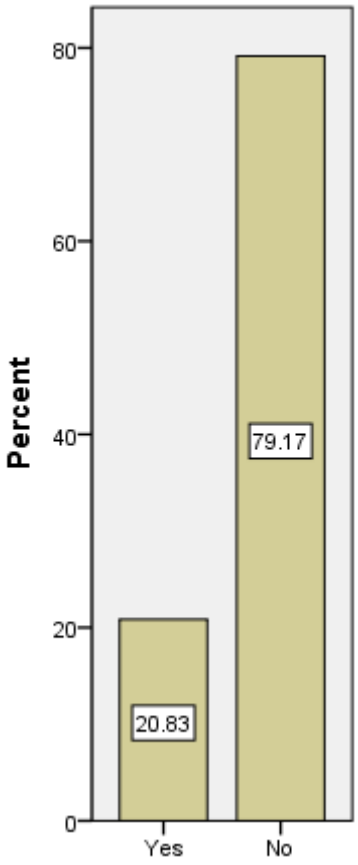


Figure 3: Bar graph shows frequency of patients who underwent re-surgical debridement

Of the 24 study participants, 5 (20.8%), underwent second debridement procedure, of these, 1 (4.16%) had secondary necrosis and 4 (16.64%) developed infection. On day three signs of infections were noted, NPWT was stopped, and secondary debridement was done and NPWT was re-continued, on day seven their wound characteristics were; 3 (12.5%) had good granulation tissue covering the wound bed and 2 (8.3%) had excellent granulation tissue covering the wound bed, 3 (12.5%) had edema <4cm around the wound margin and 2 (8.3%) had no edema around the wound margin.

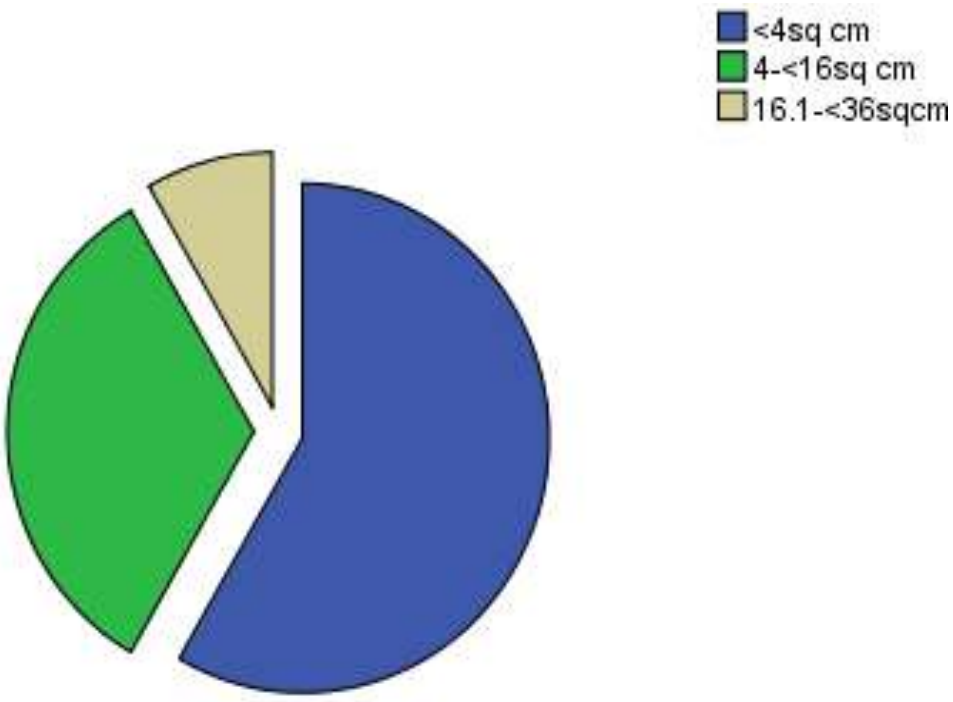


Figure 4: Wound size on day seven

It was observed the mean wound size at the start of negative pressure wound therapy to be 16.42cm^2 standard deviation 1.274, median size was 18 cm^2, and at day seven, the mean was 6.0cm^2 standard deviation 0.712, the median size was 14cm^2 the mean reduction was 10.42cm^{2,} standard deviation 0.568, this is equal to 63.46% reduction in wound size achieved. This mean reduction in wound area was statistically significant, paired sample t-test 95% C.I, p-value 0.001. Also the mean duration of edema reduction to normal around the wound was 4 standard deviation 1.18 days, and the median was 4 days

CHAPTER FOUR

4.0 DISCUSSION

In this study, a higher proportion of males were observed to compare to females, the male: female ration was 3:1. This finding is expected in our setting due to the reason that, males are the ones involved in high risk activities to raise family income and are thus subjected to sustain road traffic accidents (RTA) compared to females. Similar findings were observed in another study (43).

The current study showed that, 54.2% of patients were in the age group 21-40 years, this is the bread earner group in our community, and are taking part in the economic activities which predispose them to sustain RTA, related results were also observed (44).

It was observed in this study, 6 patients (25%) had surgical debridement within first 6 hours of injury and 18 (75%) had surgical debridement more than 6 hours and the mean time to surgical debridement was 9.79 standard deviation 1.58 hours, there was no statistical association between development of infection and time from injury to surgical debridement, p-value 0.288, similar findings were observed also (44), (45).

In this study, it was observed the median time from injury to intravenous antibiotics initiation was 8 hours, mean time was 6.54 standard deviation 1.719 hours, also 79.2 % of patients received intravenous antibiotics within the first 6 hours, there was a statistical association between delay in antibiotics prophylaxis of more than 6 hours and development of infection, p-value 0.018, similar findings were observed in a study done in Kwazulu natal, and found that the median time was 7.5 hours but majority 60.5 % received antibiotics more than 6 hours (46), similar findings were also observed in another study in which the median time was 7.75 hours (47)

It was observed in this study, the mean time to formation of health granulation tissues covering more than 90% of the wound bed was 4.92 standard deviation 1.58 days, the median was 5 days and the minimum duration was 2 days and the maximum duration was 7 days, in a

study done by bolero et al found good granulation formation which helps to reduce the number of complex flap to cover the wounds and instead they used split thickness skin graft (7), another study found the mean duration to formation of health granulation tissue covering the wound bed >90% was found to be 13.71 days, this is contrary to what has been observed in this study, the difference may be explained by the fact that, they enrolled 13 participants of whom; 1 had open fracture, 11 had cellulitis and 2 had diabetic foot ulcer (48), this might confound the results.

This study found early infection rate among 4 out of 24 patients (16.7%) and, all of them went for second debridement and at the end of the NPWT all of them had no signs of infections. The present study was not designed to do bacteriological analysis to find the bacteria strain and antibiotics sensitivity, it has been observed in other study done by Dedmond et al, described the prevalence of infection in patients with Gustillo IIIB of the tibia/fibula to be 45.8 %, when the use of NPWT was instituted in this patients reduction in infection rate by 80%, (9).

The proportion of patients who required graft among the patients enrolled in this study was 4 (16.7%), of these; 1 (4.2%) had full thickness skin graft and 3 (12.5%) underwent rotational flaps, similar findings were observed in which the flap rate was found to be 11% after introducing NPWT (27). NPWT helps to decrease wound edema, facilitates wound contraction, and increase rate of formation of health granulation tissues, in this study, the mean wound size at the start of NPWT was 16.42 cm^2 standard deviation 1.274 cm^2 , median size 18 cm^2 , at end of NPWT treatment it was 6.0 cm^2 standard deviation 0.7112 cm^2 , median size was 14 cm^2 , hence the mean wound size reduction was found to be 10.42 cm^2 , standard deviation 0.568 cm^2 , this equals 63.46% reduction in wound area achieved, p-value <0.001. Similar findings have been observed in which they found the mean reduction in wound area to be 10.55 cm^2 (50).

In this study, the rate of re-debridement was found 5 patients (20.8%), this was contributed in a large extent by infection 4 patients (16.64%) and 1 patient (4.16%) developed secondary necrosis necessitated second debridement, Another study found the rate of re-debridement to

be 13% (13), another study establish the use of NPWT to decrease the rate of secondary necrosis and hence re-surgical debridement procedure (28)

4.1 Study limitations

Only early infections were studied in this study, after patients have been discharged from the hospital, wound status was not followed to look for the late development of infection.

Challenges of getting the consumables on time in few instances was encountered, this is because this technique of wound dressing is not routinely done by most of health facilities in our setup.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Road traffic accidents is the leading cause of high energy injuries which are associated with poor treatment outcomes. The affected age group is between 21-40 years, (54.2%) which is the nation working force. The use of NPWT in dressing these wound yields promising outcomes, decrease in wound size, improved duration to granulation tissue formation, 79.2% of patients received prophylactic antibiotics within first six hours after injury, and it was found late antibiotic prophylactic of more than 6 hours after injury is associated with development of infection, Technique of vacuum assisted closure therapy using negative pressure is effective in treating soft tissue injuries in open musculoskeletal trauma which after debridement, may present with exposed tendon, fascia or bone. NPWT acts as a bridge between first procedure and second procedure by providing a sterile, controlled environment that can lessen the duration of wound healing and decreases the number of secondary procedures for soft tissue coverage and can be used as alternative method in treating soft tissue injuries in patients with open fracture of Tibia/fibula Gustilo-Anderson IIIB with better patient compliance.

5.2 Recommendations

1. This dressing method of NPWT when used as a dressing modality in patients wounds with soft tissue defect at MOI will help to improve treatment outcomes, thus decrease hospital stay and number of multiple surgeries.
2. A Randomized control trial study to compare between NPWT and traditional wet dressing need to be done.

REFERENCES

1. Dabezies EJ, D'Ambrosia RD. Treatment of the multiply injured patient: Plans for treatment and problems of major trauma. *Instr Course Lect.* 1984;33:242–252
2. Tscherne H. Management of open fractures. *Hefte zur Unfallheilkunde.* 1983;162: 10–32.
3. Kocher MS. Early limb salvage: Open tibia fractures of Ambroise Pare (1510-1590) and Percivall Pott (1714-1789). *World J Surg.* 1997;21:116–122.
4. Guthrie HC, Clasper JC. Historical origins and current concepts of wound debridement. *J R Army Med Corps.* 2011;157:130–132.
5. Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: Retrospective and prospective analyses. *J Bone Joint Surg Am.* 1976;58:453–538.
6. Gustilo RB, Mendoza RM, Williams DN. Problems in the management of type III (severe) open fractures: A new classification of type III open fractures. *J Trauma.* 1984;24:742–746.
7. Godina M. Early microsurgical reconstruction of complex trauma of the extremities.*Plast Reconstr Surg.* 1986;78:285–292
8. Rajasekaran S, Naresh Babu J, Dheenadhayalan J,.A score for predicting salvage and outcome inGustilo type-IIIA and type-IIIB open tibial fractures. *J Bone Joint Surg Br.* 2006;88:1351–1360.
9. Abbots, J. (2010) Patients Views On Topical Negative Pressure: 'Effective But Smelly'. *British Journal of Nursing,* 19 (20), 37-41
10. Stephen-Haynes, J., Woodrow, T., Wharton, S. (2011a) V.A.C Therapy. *Wounds UK,* 7 (4), 1-4
11. Banwell, P. (2007) *V.A.C. therapy clinical guidelines: a reference source for clinicians*. London, KCI Medical Ltd
12. Durham RM, Mistry BM, Mazuski JE, et al. Outcome and utility of scoring systems in the management of the mangled extremity. *Am J Surg.* 1996;172:569–573

13. Gregory CF, Chapman MW, Hansen ST. Open fractures. In: Rockwood CA, Green Deds. *Fractures in Adults.* Philadelphia, PA: J.B. Lippincott; 1984: 169–218
14. Dawson J, Carr A. Outcomes evaluation in orthopaedics. *J Bone Joint Surg Br.* 2001;83(3):313–315.
15. Mendonca DA, Cosker T, Makwana NK: Vacuum-assisted closureto aid wound healing in foot and ankle surgery. *Foot Ankle Int* 2005, 26:761-766.
16. Argenta LC, Morykwas MJ: Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. *Ann Plast Surg* 1997, 38:563-576.
17. McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP: Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. *Ostomy Wound Manage* 2000, 46:28-32.
18. DeFranzo AJ, Argenta LC, Marks MW, Molnar JA, David LR, Webb LX, Ward WG, Teasdall RG: The use of vacuum assisted closure therapy for the treatment of lower-extremity wounds with exposed bone. *Plast Reconstr Surg* 2001, 108:1184-1191.
19. DeFranzo AJ, Marks MW, Argenta LC, Genecov DG: Vacuum assisted closure for the treatment of degloving injuries. *Plast Reconstr Surg* 1999, 104:2145-2148.
20. Webb LX: New techniques in wound management: vacuum assisted wound closure. *J Am Acad Orthop Surg* 2002, 10:303-311.
21. Bollero D, Carnino R, Risso D, Acute complex traumas of the lower limbs: a modern reconstructive approach with negative pressure therapy. Wound Repair Regen 2007; 15: 589-94
22. Bhattacharyya T, Mehta P, Smith M, Pomahac B. Routine use of wound vacuum-assisted closure does not allow coverage delay for open tibia fractures. Plast Reconst Surg. 2008;121:1263–1266.
23. Dedmond BT, Kortesis B, Punger K, Simpson J, Argenta J, Kulp B, Morykwas M, Webb LX. Subatmospheric pressure dressings in the temporary treatment of soft tissue injuries associated with type III open tibial shaft fractures in children. J Pediatr Orthop. 2006;26:728–732.

24. Dedmond BT, Kortesis B, Punger K, Simpson J, Argenta J, Kulp B, Morykwas M, Webb LX. The use of negative-pressure wound therapy (NPWT) in the temporary treatment of soft-tissue injuries associated with high-energy open tibial shaft fractures. J Orthop Trauma. 2007;21:11–17.
25. Hou Z, Irgit K, Strohecker KA, Matzko ME, Wingert NC, De- Santis JG, Smith WR. Delayed flap reconstruction with vacuumassisted closure management of the open IIIB tibial fracture. J Trauma. 2011;71:1705–1708.
26. Liu DS, Sofiadellis F, Ashton M, MacGill K, Webb A. Early soft tissue coverage and negative pressure wound therapy optimizes patient outcomes in lower limb trauma. Injury. 2012;43:772–778.
27. Parrett BM, Matros E, Pribaz JJ, Orgill DP. Lower extremity trauma: trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. Plast Reconstr Surg. 2006;117:1315–1322; discussion 1323–1314.
28. Brumback RJ. Wound Debridement. In: Yaremchuk MJ, Burgess AR, Brumback RJ, eds. Lower Extremity Salvage and Reconstruction: Orthopaedic and Plastic Surgical Management. Amsterdam, Netherlands: Elsevier; 1989:71–80.
29. Leininger BE, Rasmussen TE, Smith DL, Jenkins DH, Coppola C. Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq. J Trauma. 2006;61:1207–1211.
30. Blum ML, Esser M, Richardson M, Paul E, Rosenfeldt FL. Negative pressure wound therapy reduces deep infection rate in open tibial fractures. J Orthop Trauma. 2012;26:499–505.
31. Gomoll AH, Lin A, Harris MB. Incisional vacuum-assisted closure therapy. J Orthop Trauma 2006; 20: 705-9.
32. Dedmond BT, Kortesis B, Punger K, The use of negativepressure wound therapy (NPWT) in the temporary treatment of soft-tissue injuries associated with high-energy open tibial shaft fractures. J Orthop Trauma 2007; 21(1): 11-7.

33. Rinket B, Amspacher JC, Wilson PC, Vasconcz HC. Subatmospheric pressure dressing as a bridge to free tissue transfer in the treatment of open tibia fractures. Plast Reconstr Surg 2008; 121: 1664-73.
34. Zannis J, Angobaldo J, Marks M, Comparison of fasciotomy wound closures using traditional dressing changes and the vacuum assisted closure device. Ann Plast Surg 2009; 62(4): 407-9.
35. Harley BJ, Beaupre LA, Jones CA, The effect of time t definitive treatment on the rate of non-union and infection in open fractures. J Orthop Trauma 2002; 16: 484-90.
36. Singer RW, Kellam JF. Open tibial diaphyseal fractures. Clin Orthop Relat Res 1995; 315: 114-8.
37. Fleischmann W, Strecker W, Bombelli M, Vacuum sealing as treatment of soft tissue damage in open fractures [in German]. Unfallchirurg 1993; 96: 488-92.
38. Griffin M, Malahias M, Hindocha S, Khan W. Update on the management of compound lower limb fractures. Open Orthop J 2012; 6: 518-24.
39. Philbeck TE, Whittington KT, Millsap MH, Briones RB, Wight DG, and Schroeder WJ: The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999; 45: 41.
40. Orgill DP, Manders EK, Sumpio BE,: The mechanisms of action of vacuum assisted closure: More to learn. *Surgery* 2009;146(1):40-51**.**
41. Yang CC, Chang DS, Webb LX: Vacuum-assisted closure for fasciotomy wounds following compartment syndrome of the leg. *J Surg Orthop Adv* 2006;15(1):19-23.
42. Labler L, Rancan M, Mica L, Härter L, Mihic-Probst D, Keel M: Vacuumassisted closure therapy increases local interleukin-8 and vascular endothelial growth factor levels in traumatic wounds. *J Trauma* 2009;66(3):749-757
43. Arti HR, Khorami M, Ebrahimi-Nejad V. Comparison of negative pressure wound therapy (NPWT) & conventional wound dressings in the open fracture wounds. Pak J Med Sci. 2016;32(1):65-69.

44. Marissa Srou,r BS; Kenji Inaba, Obi Okoye, Carney Chan, BS; Dimitra Skiada, prospective evaluation of treatment of open fractures effect of time to irrigation and debridement. *JAMA Surg*. 2015;150(4):332-336.
45. Khatod M, Botte MJ, Hoyt DB, Meyer RS, Smith JM, Akeson WH. Outcomes in open tibia fractures: relationship between delay in treatment and infection. *J Trauma*. 2003; 55(5):949-954
46. J.K. McCaul , M.G. McCaul, Pre-hospital antibiotics for open fractures: Is there time? A descriptive study, African Journal of Emergency Medicine 3 (2013) S11–S25
47. McCaul, MG McCaul, pre-hospital antibiotics for open fractures: is there time?, SA Orthopaedic Journal Autumn 2014 | Vol 13 • No 1
48. Sandhya Nagaraj, Ramesh Hosmani, Ravi Shankar J C, Negative Pressure Wound Therapy versus Conventional Wound Therapy in Large Wounds, International Journal of Scientific and Research Publications, Volume 5, Issue 5, May 2015.
49. *Janna Joeth1*, *Sandeep J Sebastin2*, *Alphonsus Khin Sze Chong*, *Yeong Pin Peng*, *Mark E Puhaindran*, effect of negative-pressure wound therapy on open fractures of the lower limb, Singapore Med J 2013; 54(11): 620-623.
50. Manish Raj, S.P.S. Gill, Sunil Kumar Sheopaltan, Pulkesh Singh, Dinesh, JasveerSigh, Prateek Rastogi, L.N. Mishra, Evaluation of Vacuum Assisted Closure Therapy for Soft Tissue Injury in Open Musculoskeletal Trauma, Journal of Clinical and Diagnostic Research. 2016 Apr, Vol-10(4):
51. Jean M. de Leon, Sunni Barnes, Melody Nagel, Michelle Fudge, Adora Lucius, RN, and Betty Garcia cost-effectiveness of negative pressure wound therapy for postsurgical patients in long-term acute care, advances in skin and wound care March 2009, vol. 22.No.3

APPENDICES

Appendix I: Consent Form (English Version)

Study Title: EARLY CLINICAL OUTCOMES OF PATIENTS WOUND, USING NEGATIVE PRESSURE WOUND THERAPY IN WOUND DRESSING OF PATIENT WITH OPEN FRACTURES OF THE TIBIA AND FIBULA GUSTILO ANDERSON GRADE IIIB AT MUHIMBILI ORTHOPEDIC INSTITUTE 2018

Part A:

Introduction

My name is Dr. LYIMO Elias, MMed. Student at MUHAS, department of Orthopaedic and Traumatology I am conducting a study on management of wounds in patients with Gustilo-Anderson IIIB tibia fracture by using NPWT. Kindly you are invited to take part in this study, read this form and understand it well before agreeing to the study

Purpose of the study

The purpose is to obtain data on the best way of managing wounds in patients with Gustilo-Anderson IIIB.

This will also help in changing of management policy of these injuries in the hospital and the country at large. It is also a partial fulfillment of my MMed degree in Orthopaedic and Traumatology.

Study procedures

The main information required from you is your social demographics and wound characteristics particulars as in the data collection sheet, wound characteristics will be recorded in each dressing change until discharge from the ward.

Risks and benefits to the participant

No risks are directly expected from the study because the technique has been approved by the FDA and has been in use for the past more than twenty five years.

Confidentiality

The data collection sheet is strictly confidential. Your name will not appear in it.

Participant information

Your participation in this study is voluntary and failure to participate or withdrawal from the study will not affect your management in any way at any stage.

Contacts and Questions

Dr. LYIMO Elias
+255653-452464
ndekilyimo@gmail.com

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher, you are encouraged to contact **Dr. Joyce Masalu**, the Chairman of the University Senate research and publications, MUHAS P.O.BOX 65001, Dar es Salaam. Telephone (+255) 222-152-489

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 II: Consent Form (Swahili Version)

Study title: Study Title: EARLY CLINICAL OUTCOMES OF PATIENTS WOUND, USING NEGATIVE PRESSURE WOUND THERAPY IN WOUND DRESSING OF PATIENT WITH OPEN FRACTURES OF THE TIBIA AND FIBULA GUSTILO ANDERSON GRADE IIIB AT MUHIMBILI ORTHOPEDIC INSTITUTE 2018

Idhini ya Kushiriki:

Sehemu A:

Utambulisho

Mimi ni Dr. LYIMO Elias, mwanafunzi wa Chuo kikuu cha Afya cha Muhimbili (MUHAS) Idara ya Mifupana Ajali, Nachukua shahada ya uzamili ya Tiba (MMed) ninafanya utafiti juu ya matibabu ya vidonda kwa wagonjwa waliovunjika mfupa mrefu chini ya goti (Tibia) aina Gustilo-Anderson IIIB kwa kutumia kifaa cha pump kwa kufunga vidonda hivyo.

Hivyo unakaribishwa ushiriki kwenye utafiti huu. Tafadhali soma dodoso hili vizuri na kuelewa kabla hujashiriki.

Shabaha ya Utafiti

Shabaha ya utafiti huu ni kukusanya taarifa muhimu ili kutafuta njia bora za kutibu vidonda kwa wagonjwa wa mvunjiko wa mfupa mrefu wa chini ya goti (tibia) kwa kutumia pump, matokeo ya utafiti huu yanaweza kusaidia mabadiliko ya sera kwa hospitali na nchi nzima katika utoaji wa matibabu. Aidha taarifa hizi zitamsadia mtafiti kuhitimu shahada yake ya uzamivu ya tiba katika upasuaji wa mifupa.

Taratibu za Utafiti

Taarifa muhimu zinazohitajika zitaingizwa kwenye dodoso maalum ya kukusanyia taarifa aidha taarifa juu ya maendeleo ya kidondo zita rekodiwa kila mara kidonda kitakapo fanyiwa dress hadi utakaporuhusiwa wodini.

Athari na Faida za Kushiriki kwenye Utafiti

Hakuna athari zozote zinazotarajiwa kujitokeza kutokana na utafiti huu, matibabu haya ni salama na yameidhinishwa na mamlaka ya chakula ma dawa, yamekuwepo takribanai zaidi ya miaka ishirini.

Siri

Taarifa zote zitakazo kusanywa zinatajazwa kwenye fomu maalum na zitakua siri, Jina lako au namba yako ya simu zitatumika kwa madhumuni ya matibabu na kufuatilia maendeleo yako.

Taarifa za Mshiriki

Ushiriki wako kwenye utafiti huu ni wa hiari, unaweza kushiriki au kutoshiriki , Aidha unaweza kujiondoa kushiriki na hautaathiri matibabu yako

Kwa maswali

Jina la mtafiti ni Dr. LYIMO Elias,

Barua pepe ndekilymo@gmail.com

Namba ya simu +255653-452464

Kama una maswali kuhusu utafiti huu unaweza kuwasiliana na **Dr. Joyce Masalu**, Mwenyekiti wa baraza la utafiti na machapisho, chuo kikuu cha afya shirikishi MUHAS P.O.BOX 65001, Dar es Salaam. (+255) 222-152-489

Sehemu B

Kiapo cha ridhaa ya Kusiriki

Nimesoma na kuelewa taarifa zilizotolewa hapo juu kama zilivyo fafanuliwa na mtafiti na kwa ridhaa yangu mwenyewe nimeamua kushiriki.

Sahihi……

Au alama ya dole gumba

Tarehe……

Sahihi ya Shaihidi…….

Appendix III: Questionnaire

A. Patient demographics

1. Patient ID_____
2. Age in years_____
3. Sex M/F
4. Address_____
5. Date and time of admission_____

B. Injury assessment

1. Date and time of injury_____

Mechanism of injury,
- a. Road traffic
- b. Fall from height
- c. Gunshot
- d. Assault
- e. Other_____

C. Standardized treatment as per protocol

1. Time in hours from injury to antibiotic prophylaxis_____
2. Antibiotic prophylaxis [ ] Yes [ ] No
3. Antibiotic regime used
   - Ceftriaxone only [ ]
   - Ceftriaxone + Gentamycin [ ]
   - Ceftriaxone + Gentamycin + metronidazole [ ]
4. Tetanus prophylaxis [ ] Yes [ ] No
5. Surgical debridement [ ] Yes [ ] No
6. Time in hours from injury to surgical debridement_____
7. Method of fracture stabilization
   a. External fixation
      a. Intramedullary nail
8. Date and time of commencement of NPWT__/__/_____

9. Re-debridement procedure(s) [ ] Yes [ ] No

10. Reasons for re-debridement

    a. Secondary necrosis
    b. Infection in the wound site

11. Graft/flap used to cover soft tissue defect [ ] Yes [ ] No

12. Type of graft/flap used to cover the soft tissue defect

    a. Full thickness skin graft
    b. Split thickness skin graft
    c. Gastro rotational flap
    d. Soleus rotational flap
    e. Reverse sural flap

13. Date of completion of NPWT_____

14. Date of discharge from hospital_____

BATES-JENSEN WOUND ASSESMENT TOOL

Location: Anatomic site, identify right (R) or left (L) leg

----Anterior ----Lateral

----Medial ----Posterior

Shape: Overall wound pattern

----Irregular ----Linear or elongated

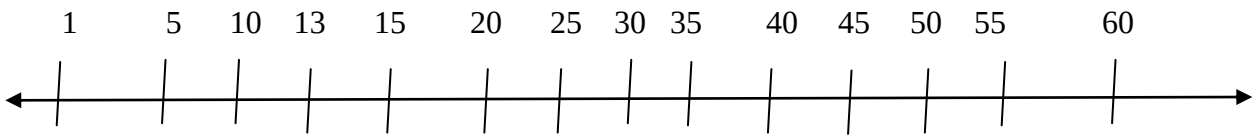
----Round ----Square

Item	Assessment	Date Score	Date Score	Date Score	Date Score	Date Score
1.Size	1= Length× width <4 sq cm 2= Length× width 4-<16 sq cm 3= Length× width 16.1-<36 sq cm 4= Length× width 36.1-<80 sq cm 5= Length× width >80 sq cm					
2.Depht	1= Non-blanchable erythema or intact skin 2= Partial thickness skin loss 3= Full thickness skin loss 4= Obscured by necrosis 5= Full thickness skin loss with damage to muscle, bone or supporting structures					
3.Edge	1=Indistinct, diffuse, non clearly visible 2= Distinct, clearly visible, attached to wound base 3= Well defined, not attached to wound base					

	4= Well defined, not attached to wound base, rolled under 5= Well defined, fibrotic, or hyperkeratotic					
4.Undermining	1=None present 2= Undermining <2cm in any area 3= Undermining 2-4cm involving <50% wound margin 4= Undermining 2-4cm involving >50% wound margin 5= Undermining >4cm or tunneling in any area					
5.Necrotic tissue type	1. = Non visible 2. = White/grey non-viable tissue 3. = Loosely adherent yellow slough 4. = Adherent, soft, black eschar 5. = Firmly adherent, hard, black eschar					
6. Necrotic tissue amount	1. = Non visible 2. = <25% of wound bed covered 3. = 25%-50% of wound covered 4. = >50% and <75% of wound covered 5. = 75%-100% of wound covered					
7. Exudate type	1. = None 2. = Blood 3. = Serosanguinous 4. = Serous 5. = Purulent					

8. Exudate amount	1. = None 2. = Scant, wound moist no observable exudates 3. = Small 4. = Moderate 5. = Large					
9.Skin colour surrounding wound	1. = Pink or normal for ethnic 2. = Bright red & or blanches to touch 3. = White or grey pallor or hypopigmented 4. = Dark red or purple& or non-blanchable 5. = Black or hyperpigmented					
10.Peripheral tissue edema	1.= No swelling 2. = Non-pitting edema <4cm around wound 3. = Non-pitting edema >4cm around wound 4. = Pitting edema <4cm around wound 5. = Crepitus and/or pitting edema >4cm around wound					
11.Peripheral tissue induration	1. = None present 2. = Induration <2cm around wound 3. = Induration 2-4cm <50% around wound 4. = Induration 2-4cm >50% around wound					

	5. = Induration >4cm in any area around the wound					
12.Granulation tissue	1. = skin intact or partial thickness wound 2. = Bright, beefy red 75%-100% of wound 3. = Bright, beefy red <75% &>25% of wound 4. = Pink & or dull, dusky red <25% of wound 5. = No granulation					
13.Epithelialization	1.= 100% wound covered, surface intact 2. = 75%-<100% wound covered, >0.5cm extend into wound bed 3. = 50-75% wound covered, <0.5cm extend into wound bed 4. = 25%-50% wound covered 5. = <25% wound covered					
TOTAL SCORE						
SIGNATURE						



Health wound Regeneration Wound
degeneration
Tissue

Plot the total score on the wound status continuum by putting an “X” on the line and the date beneath the line. Plot multiple score within their dates to see-at-a-glance regeneration or degeneration of the wound