OUTCOME OF FOAM VERSUS GAUZE DRESSING IN NEGATIVE PRESSURE WOUND THERAPY FOR THE MANAGEMENT OF ACUTE TRAUMATIC WOUNDS WITH SOFT TISSUE LOSS AT KENYATTA NATIONAL HOSPITAL.

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

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DECLARATION

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ABBREVIATIONS

NPWT……..Negative pressure wound therapy

KNH……..Kenyatta National Hospital

UoN……..University of Nairobi

VAC……..Vacuum assisted closure

VRS……Verbal rating scale

VAS……Visual analogue scale

NRS……Numeric rating scale

KNH/ERC……..Kenyatta national hospital ethical and research committee.

B.C.E……..Before the Common Era.

NIH……National institute of health

S.D……Standard deviation

CDC……..center for disease control

ATLS……advanced trauma life support.

ABSTRACT

Background: Wounds have provided a challenge to the clinicians for centuries and this scenario persists to the 21st century. Negativepressure wound therapy (NPWT) is one of the latest additions in wound management. It has been widely adopted in developed countries with foam as the default wound dressing although it has some limitations. This study aimed to investigate the effectiveness of gauze as wound dressing in NPWT compared to foam and if gauze dressing can overcome some of the shortcomings observed with foam dressing in NPWT.

Objective: To determine the difference in outcome between the use of gauze versus foam as wound dressing in NPWT for the management of acute traumatic wounds with soft tissue loss.

Design: Prospective randomized comparative interventional study.

Methodology: The study involved patients aged 12 years and above admitted in the surgical wards at KNH with class III or IV acute traumatic wounds with soft tissue loss involving the lower limbs. Fifty two wounds from 51 patients were randomized into either the gauze or foam group after surgical debridement. Patient demographics and wound characteristics were recorded after consenting for the study and NPWT applied. After every 72 hours, the wound was exposed, level of granulation assessed, wound surface area estimated and any presence of infection noted.

Outcome measures: The main outcome measure is the time taken to achieve 100% wound granulation. Comparisons were also made on the mean pain scores during dressing change and the percentage change in wound surface area.

Results: Wounds took an average of 8.4 days in the gauze group and 8.1 days in the foam group (p=0.698) to achieve full granulation. The percentage change in wound surface area was 5.3 versus 5.5 (P=0.769) in the gauze and foam groups respectively. The infection rates were comparable between the two groups (28% for gauze and 23.1% for foam, p=0.697) and there was no significant difference in the median pain scores (gauze= 4.5, foam=4.8 with p=0.174). However, outcomes with gauze dressing were influenced significantly by the time to application of NPWT, initial wound surface area and wound infection while with foam dressing outcomes tended to be affected less so by the above factors.

Conclusion: In the use of NPWTfor the management of acute traumatic wounds, there is no difference in terms of time to full wound granulation, change in wound surface area, wound infection and pain during dressing change whether gauze or foam is used as the wound dressing material.

INTRODUCTION

The management of wounds has presented a long standing challenge to health care practitioners. Faced with such a daunting array of wounds, surgeons and other clinicians have sought various methods to achieve healing. Some of the methods employed include use of foams, hydrogels, debriding agents, alginates and topical antimicrobials dressings. These have achieved remarkable results but still better methods are required to shorten wound healing/preparation time[1].

In the management of acute traumatic wounds with soft tissue loss, the aim is to achieve early secondary closure or readiness for surgery. This requires hospital admission in our setting and wound care until it is ready for surgery [2]. To hasten wound healing or shorten time to readiness for surgery, Morykwas and Argenta described NPWT about 15 years ago [3, 4]. The initial study focused on the use of polyurethane foam as the wound dressing material in NPWT and subsequent studies have used the same. These have shown better outcome with NPWT than traditional dressing resulting in wide adoption of NPWT in developed countries. However, foam dressing has been noted to have some complications such as pain during dressing change and ingrowth of granulation tissue [2]. Recent experimental studies and one clinical study suggest that use of gauze as the dressing material in NPWT may have a better outcome and tolerability.

In our institution, wound management is still mainly based on traditional gauze dressing which is associated with a longer duration to achieve wound healing /readiness for surgery and consequently long hospital stays. Considering that gauze is already long established for use in most hospitals, its use in NPWT may speed up the uptake of NPWT in developing countries where only few hospitals have adopted it[2]. The aim of this study is to compare outcome in the use of gauze and that of foam as wound dressing material in NPWT.

LITERATURE REVIEW

The management of wounds has a long history and has provided a challenge to humanity through ages. From the accounts of the Sumerians in 2000 B.C.E of spiritual incantations and applying poultice like materials [5], the techniques have improved to modern day dressings and NPWT with the aim of secondary closure or preparing the wound for further surgical reconstruction.

Wounds are classified as either acute or chronic.

a. **Acute wounds** - these are wounds that heal in a predictable manner and time frame with few complications resulting in a well healed wound. If there is tissue loss, healing can occur following granulation tissue formation and contraction i.e. secondary intention in 6-12 weeks or by delayed primary closure or employment of reconstructive techniques[6, 7].

b. **Chronic wounds**– these are wounds that fail to proceed through an orderly process that provides a satisfactory anatomic and functional integrity or that have proceeded through the repair process without producing an adequate anatomic and functional result [6, 7].

MANAGEMENT OF ACUTE TRAUMATIC WOUNDS

A trauma patient who has an acute traumatic wound should bemanaged as per the advanced trauma life support (ATLS) protocol on presentation. This involves the assessment of the airway, cervical spine, breathing, circulation and other life threatening conditions. These are expeditiously managed and the patient stabilized[5].

Following resuscitation and stabilization, a detailed history is obtained on the patient demographics, mechanism of injury, underlying medical conditions and drug use. The patient is examined, vital signs recorded and all the body systems evaluated. The acute traumatic wound is then evaluated by describing the site, size, contamination and classifying the wound. Tetanus prophylaxis is administered followed by debridement under local or general anesthesia. The wound can then be dressed or reconstructed[5, 6].

Classification of acute traumatic wounds

Acute traumatic are classified into four classes by the American college of surgeons and Centers for Disease Control and Prevention (CDC)[5, 8] based on the level of contamination into:

Class 1 – clean wounds

These are operative wounds for elective procedures in which a normally colonized viscous or lumen of the body is not entered. Elective inguinal hernia repair is an example.The wound infection rates in this class of procedures should be 2% or less.

Class II – clean contaminated wounds.

These are wounds in which the operative procedure enters into a colonized viscous or cavity of the body, but under elective and controlled circumstances. The most common contaminants are endogenous bacteria from within the patient. For example, Elective intestinal resection, pulmonary resection, gynecologic procedures, and head-neck cancer operations that involve the oropharynx. Infection rates for these procedures are in the range of 4% to 10%.

Class III – contaminatedwounds.

They are wounds in which there is:

a. Gross contamination at the surgical site in the absence of obvious infection such as laparotomy for penetrating injury with intestinal spillage.
b. Fresh trauma from a clean source.
c. Entrance into the genitourinary or biliary tract
d. Acute non purulent inflammation.

Infection rates in these wounds are greater than 10% even with preventive antibiotics and other strategies.

Class IV – dirty wounds.

These are wounds in which unusual pathogens are often encountered. They include:

a. Surgical procedures performed when active infection is already present. For example, abdominal exploration for acute bacterial peritonitis and intra-abdominal abscess.
b. Traumatic wounds from a dirty source.
c. Traumatic wounds with delayed treatment.
d. Wounds with devitalized tissue.
e. Wounds with a foreign body or fecal contamination.

The traumatic wounds fall mainly into class III if they are fresh and from a relatively clean source or class IV if they are from a dirty source or treatment is delayed.

In a study by Otieno J. on traumatic wounds with soft tissue loss at KNH, he found that road traffic accidents were the commonest cause at 65.5% followed by assault at 10.9% and animal bites at 7.3%. Other causes were industrial accidents and gunshot injuries. In this study, 85.5% of the patients had class IV wounds while 14.5% had class III wounds [9]. This shows that most of the wounds will require some form of surgical management

SURGICAL TOILET

Under local or general anesthesia, the wound is thoroughly cleaned with normal saline. All hematomas, foreign materials and non-viable tissues are removed. The wound is then irrigated with copious amounts of normal saline and adequate hemostasis achieved. This reduces the bio-burden and prepares the wound for healing. The wound with viable margins is then dressed appropriately[5].

There are newer methods of debridement such as autolytic debridement, enzymatic debridement and pressurized water tools that can be used as adjunct to sharp debridement. They offer advantage of less bleeding and faster debridement [6].

WOUND DRESSING

The goal of wound dressing in acute traumatic wounds is to provide a moist healing environment that facilitates cell migration and prevent desiccation of the wound [6]. This will increase the rate of epithelialization. Traditionally gauze has been used but it is disruptive, dries the wound and causes tissue damage on removal. These factors increase pain and slow wound healing [5].

The ideal wound dressing should have the following characteristics[10]:

1. Maintain a moist environment while removing the excess exudate.
2. Nontoxic and non - allergenic.
3. Protection of the wound from further trauma.
4. Impermeable to bacteria.
5. Allow gaseous exchange.
6. Comfortable and conformable.
7. Requires infrequent changes.
8. Cost effective.
9. Long shelve life.

In search for this ideal dressing,various dressings have been developed to try and capture most of the above characteristics and address the wide array of wounds[5,6, 10]. They include:

a. **Absorbent dressings:** They are meant to absorb the wound exudate. Examples include cotton and sponge.
b. **Non adherent dressings:** They are impregnated with paraffin, petroleum jelly or water soluble jelly. This reduces pain during dressing change but they require a secondary dressing to prevent desiccation and infection. Examples include bactigras and sofratulle.
c. **Semi - occlusive dressing:** They are sheets impermeable to fluids but permit passage of small gas molecules. They are used together with gauze on clean wounds and maintain good moisture content. They include OpSite Flexigrid, OpSite Plus and Tegaderm.
a. **Hydrogel dressings:** They maintain a moist wound bed and rehydrate wounds facilitating healing and autolytic environment. This is appropriate in wounds with a small amount of eschar or those predisposed to desiccation. They are not dependent on wound secretions to maintain a moist environment.Examples include Aquaform, Intrasite and GranuGel.
b. **Hydrocolloids:** These are pastes, powders or sheets placedwithin the wound and covered with a dressing. This forms an occlusive barrier that gels and absorbs mild amounts of exudates. They are impermeable to liquids and gases but provide a moist environment for autolytic debridement and cell migration. They are however inappropriate for highly colonized wounds. They include Alione, CombiDERM, DuoDERM and Tegasorb.
a. **Foam dressings:** They are made of non-adhering hydrophobic polyurethane and an occlusive cover. They are highly absorptive and only useful for exudative wounds. Examples include Allevyn Adhesive, Biatain Adhesive and Tielle Lite.
b. **Aliginates:** Theyare produced from the naturally occurring calciumand sodium salts of alginic acid found in a family of brownseaweed (Phaeophyceae). They are of two kinds: those containing 100% calcium alginate or those thatcontain a combination of calcium with sodium alginate, usuallyin a ratio of 80:20. They absorb about 20 times their dry weight of fluid and are therefore best suited for highly exudative wounds. They reduce the burden of frequent dressing change. They include Algisite, Melgisorb and SeaSorb.
a. **Antimicrobial dressing**: They contain antimicrobial agents such as silver which has broad spectrum microbicidal activity. Others contain povidine iodine and some metronidazole. They reduce wound colonization and the bio-burden. Examples include Acticoat, Actisorb Silver, Arglaes and Iodosorb.
b. **Skin substitutes:** They provide wound coverage and may have living cells. Their use is limited by the high cost.

NEGATIVE PRESSURE WOUND THERAPY

While the traditional wound dressings have been used to manage the wounds after surgical debridement, the introduction of NPWT by Morykwas and Argenta in 1997 which involves application of continuous or intermittent negative pressure on a sealed wound with either foam or gauze dressing has revolutionized the management of wounds in developed countries[3].

This is based on the principle of mechanical stretching of cells which was shown to increase mitosis by Brunette in an experimental study with epithelial cells [11]. Further experimental and clinical studies on NPWT have elucidated and validated the mechanisms by which wound healing is improved.

Mechanisms of action

A.Macro and micro deformation which increase cell proliferation.

Stress induced by the negative pressure applied through the foam or gauze dressing during NPWT therapy producesa three-dimensional stress within the cells (micro-strain) as well as across the whole area of the wound (macro-strain)[12].

Most tissues are viscoelastic and deform slowly over time with applied mechanicalforces[13]. However, in addition to flow of stretchedtissue, these same applied forces also result in anincrease in the mitotic rate of the stretched cells [14,15]. Macro-deformation pulls the periwound area into the wound and encourages wound contraction.

The applied forces deform the extracellular matrixand thus, as cells are anchorage-dependent, deform the cells in the stretched tissues[16, 17]. This cell deformation (micro-deformation)has been shown to cause a wide variety ofmolecular responses, including changes in ion concentrationand permeability of membrane ionchannels, release of second messengers, stimulationof molecular pathways, and alterations in geneexpression[12, 18].

Chen et al showed that mechanicalshear stresses can activate the vascular endothelial cell growth factor (VEGF)pathway without any VEGF being present in theculture fluid[19]. Similar in vivo studies examining both acutewounds in swine and chronic wounds in humans reported an increase in several proto-oncogenes;including myc, c-jun, and Bcl-2, inboth wound populations after NPWT application[20].

Thus, it appears that applied mechanical forcesdeform tissues, which results in deformation ofcells; this is followed by stimulation of growth factorpathways, resulting in increased mitosis and production of new tissue (faster wound granulation).

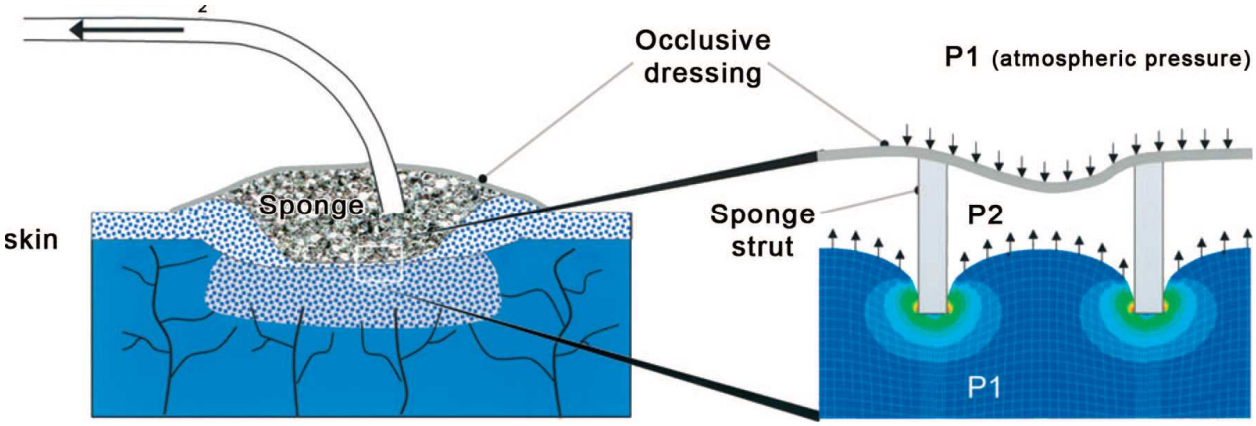


Figure 1. Schematic depiction of NPWT device applied to a wound, overlying adhesive drapethat forms a seal, connecting tube,vacuumsource,andinterface material. The direction of the deforming forces is shown by arrows.ReprintedfromSaxena et al [12].

B.Increasing wound perfusion.

Optimal blood perfusion is necessary todeliver nutrients, oxygen, cells and growthfactors to a healing wound and to removewaste products, free radicals and carbondioxide. This also results in improved delivery of antibioticsto the wound [21].

Multiple studies have reported the positive effects NPWT has on tissue perfusion[3, 22, 23]. Morykwas et alina series of studies using wounds in a pig modelthat were subjected to NPWT observed that Doppler measured blood flowlevels increased fourfold when 125 mmHgnegative pressure was applied to the wounds.The survival of random pattern flaps was significantlyincreased (P =0.05) by 21% comparedwith controls[3].

Wackenfors et al. recorded anincrease in blood flow with 60 minutes of NPWTtherapy accompanied with enhanced wound fluid partial pressuresof oxygen and lactate [24]. The combination ofoxygen and lactate is known to promotewound healing [25].

C.Exudate Removal and Oedema Reduction.

NPWT continuously removes the exudative fluid while keeping the wound moist. Fluid impedes bloodflow and increases diffusion distances for oxygen and nutrients[1, 26]. In patients with lymphedema, compartment syndrome, or an open abdomen, large quantities of fluid can be removed with NPWT devices and significant oedema reduction achieved [27, 28, 29].The mechanism of improved wound healing after fluid removal has not been determined but may be related to improved nutrient transport, removal of toxins, or local blood flow changes[30].

D. Changein the expression of biomarkers in chronic wounds.

It has been shown that fluid from chronicwounds contains abnormally high proteases such as matrix metalloproteinases (MMPs),elastase, plasmin and thrombin [31, 32]. Excessiveprotease activity in chronic woundsresults in abnormal degradation of the extracellularmatrix, negatively impacting wound healing[33].

Shi etal. studied the changes in MMPs in chronic woundsafter treatment with NPWT by quantifying theexpression of messenger RNA encoding theseproteins[34]. They reported a steep decrease in MMPs similar to findings in a study byMoues et.Al[35]. This reduction of both MMPs and TNF-α has also been reported on hospitalisedpatients with pressure ulcers treated with NPWT[36].

Clinical application of NPWT

Since the introduction of NPWT in clinical use about 17 years ago by Argenta and Morykwas, it has found many clinical applications[4]. The standard device has an interface material that fits to the wound, covered with an adhesive transparent drape, and attachedby means of tubing to a vacuum device oncontinuous or intermitted suction. This can be done in an inpatient or outpatient setting[1].The clinical uses include:

a. Diabetic foot

These are difficult wounds and healing time exceeds 2 months with traditional dressing. They are frequently attended bydevastating complications such as deep infection and amputation[56].

Negative-pressure wound therapy has been used asa wound healing therapy after debridement ofdiabetic foot ulcers and non-healing amputationsites [38].Most of the few randomized diabetic footulcer trials comparing NPWT to hydrogel, alginate, or gauzeindicate better wound healing, fewer amputations or faster wound preparation for surgical closure when using NPWT[39,23].

b. Pressure ulcers.

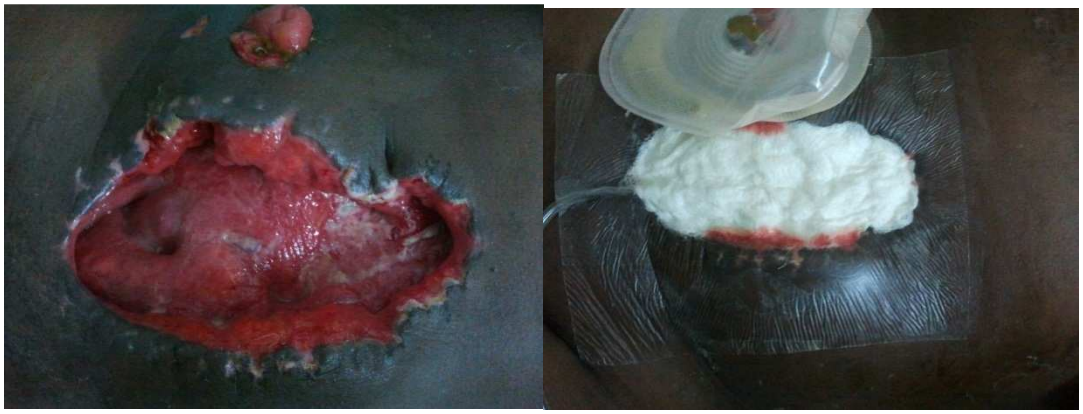
Pressure ulcers develop because of prolonged pressure and relative ischemia to the tissues in bed ridden patients.They pose a challenge to management due to the poor healing[1]. Following debridement, NPWT is used for primary healing or wound preparation for flap surgery. This aids in exudate management, decreasing bacterial load, increases granulation tissue formation, contracts the wound and overall faster healing compared to traditional gauze dressing [40].

c. Open abdomen (laparostomy wounds).

These wounds result from wound dehiscence, damage control laparotomy, abdominalcompartment syndrome, and entero-cutaneous fistulas. Due to the high exudative content in these wounds, they usually require frequent dressing changes.

Heller et al. used NPWT with non-adherent cover over the organs in 21 patients with postoperative abdominal wound dehiscence that could not be closed primarily [41]. Cutaneous coverage was achieved in all patients using flaps, skin grafts, or healing bysecondary intention.The results were comparable to when polyglactin 910 mesh is used. TheSuction system also decreases effluent and protects the surrounding tissues from erosion in entero-cutaneous fistulas [42].

a. Laparostomy wound with ileostomy b. NPWT applied in-situ.



c. Wound 6 days later after two NPWT sessions.

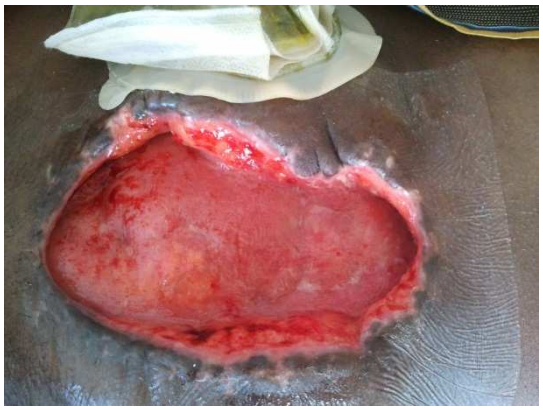


Figure 2:A patient managed with NPWT following post laparotomy wound dehiscence in peritonitis.

d. Chest wounds

Sternal wound complications after mediansternotomy are difficult to manage and cause significant morbidityand mortality. Negative-pressure wound therapy allows for wound drainage,chest wall stabilization, isolation of the chest cavityto prevent contamination, maintenance of amoistenvironment, granulation stimulation, and increasedblood flow to the tissue [43].

The duration in days to closure and size and number of flaps necessaryare decreased when NPWT is used [44, 45]. It also decreases thereinfection rate, length ofhospital stay[46],and mortality rate [47].

e. Skin grafts/wound bed preparation.

To improve skin graft take, a tie over bolster has been traditionally used to immobilize the graft in the post-operative period. Following skin grafting, a non-adherent gauze layer is placed over the skin graftto prevent the graft sticking to the interface material and then NPWT applied for about 5 days [30].

The use of NPWT as a bolster for skin grafts has been shown to increase graft take compared with traditional foam bolsters in small randomized studies [48,49]. It is also used after debridement or surgical excision to prepare the wound bed forskin grafting a few days later [50].

f. Lower Extremity Traumatic Wounds

Traumatic lower extremity wounds are challenging to manage and can lead tochronic infections, non-union, and amputation.The infection rate from severe open fracturesranges from 25- 66% [51].

Studies, both retrospective and prospective, have concluded that NPWT placement after bony fixation and debridement significantly decreases the overall complication and infection rates [52]. There is adecrease in the number of complex soft-tissueprocedures necessary for wound closure[53, 54] andthe rate of flap failure [55]. This is due to the removal of exudates, drawing of the tissue edges together, and providing a moist, contained environment.

Lower extremity compartment syndromewounds as the result of trauma can also betreated with NPWT.The device is placed into the fasciotomywounds decreasing oedema and promoting granulationtissue formation [30]. Yang et al. retrospectivelycompared 34 patients with fasciotomy woundstreated with NPWT and34 patients without NPWT. The NPWT group took an average of 6.7 days to definitive closure as opposed to16.1 days in the control group [56].

g. Lymphatic fistula and lymphocele.

Lymphaticinjury can result from vascular procedures, resulting in a chronic lymphocele or a lymphatic fistula. This causes significant morbidityand risk of infection [57].Case studies using NPWT for afemoral lymphocele and lymphatic fistula achievedcomplete resolution of the drainage in a mean of14 to 18 days in comparison to more than 47 days of lymphatic drainagenot treated with NPWT or surgery [57, 58].

h. Other clinical applications

Morykwas et al. showed that NPWT can prevent tissue injury progression in swine after partial-thickness burns[3] although clinical trials have not been conducted to assess theoretical benefit ofoedema reduction, improved tissue perfusion, or less scarring with negative- pressure wound therapy in burn wounds [1, 59] . This might be an area of future application.

Negative-pressurewound therapy has also been used on spinal wounds after post-operativeinfection. Ploumiset al. reviewed 73 consecutive patients treatedwith NPWT and noted the therapy was safe [60].

The NPWT has been used in closed incisions for oedema reduction. Foam is placed directly over the incisionand suction applied. This has been shown to decrease the risk of infection, oedema, hematoma formationand fluid collections within the closed incision[61, 62].

Complications

With the increasing adoption of NPWT, different complications have been noted. These include:

1. Foam may be too adherent to the wound bed and somepieces may be retained[2, 63].
2. Toxic shock syndrome can occur if the drainage is completely or partially impaired [64].
3. Bleeding can occur in the immediate postoperativeperiod and in patients being treated with anticoagulant therapy. Most significant bleeding has occurred secondary to disruption of major vessel grafts, cardiac bypass grafts, or the ventricle itself when sponges are placed directly on the structures. Therefore, patients being treated with the NPWT in proximity to major vessels should be monitored in the high-acuity setting [30].
4. The evacuation tube may cause tissue erosion and pain if the patient lies on it or is placed over bone[3].
5. Excessive granulation tissue growth into foam which causes bleeding and pain [2, 3].

Can gauze be used as interface dressing?

Most of the current studies were performed at negative pressures of 125mmHg and using foam as the interface dressing, conditions that were established in the pioneering studies and confirmed by other subsequent studies [3, 22, 65, 66].

In the study by Wandera O. comparing use of vacuum assisted closure (VAC) to gauze dressing in the management of acute traumatic wounds with soft tissue loss involving the lower limbs, the VAC group took a median time of 12 days to achieve full granulation compared to 21 days in the gauze group ($p<0.001$)[2].These results were similar to other studies which demonstrated the superiority of NPWT [3, 4, 67, 68]. However, the use of foam dressing in NPWT was noted to cause pain during dressing change especially in patients with large wounds and bleeding from the wound bed. In some cases pieces of foam were lost in the wound due to growth of granulation tissue into foam [2, 63].

Amir et al, in a comparative study between gauze suction NPWT and standard vacuum assisted closure [63], found that the gauze based system;

- Is at least as effective as the foam based system in changes in wound volume and surface area.
- Decreases pain per dressing change and medications required ($P<0.01$ with median pain scores of 2.7 versus 4, n=87). Similar observations were made by Campbell et al [69].
- Forms thin and dense granulation tissue compared to the thick and fragile granulation tissue formed with foam dressing.

They also found that gauze did not stick into wound unlike foam which sticks causing pain and disruption of the wound surface. Besides, there was more leucocyte infiltration and tissue disorganization when using foam compared to gauze. However, they did not report on the difference in time to readiness for surgery or wound healing.

Experimental studies byOla Borgquist et al on wound dressing in NPWT found that pressures needed to remove wound filler from the wound bed after NPWT were greater with foam than gauze. There was tissue growth into foam but not gauze and beneath foam, there was more leucocyte infiltration, tissue disorganization and disruption of contact among cells [67].These effects may translate to different outcomes in a clinical setting.

Malmsjo etal found in an experimental study that pressure transduction to the bottom of the wound is similar with either polyurethane foam or gauze. They were both equally effective at delivering negative pressure and creating mechanical deformation at the wound tissue[70]. In another experimental study, they found that there was no difference in the micro-vascular blood flow regardless of the wound filler (foam or gauze) and besides gauze is easier to apply on the wound as it does not require cutting into specific sizes as foam does [39]. These studies

show that the underlying physiological and mechanical forces that underpin the mechanism of action in NPWT do not change with a change in interface dressing.

To reduce pain and tissue ingrowth into foam, interface dressing such as sofratulle may be applied to the wound bed before filling with foam. However, this was shown by Jones et al to reduce transmission of pressure recorded on the wound surface (mean pressure change of 11 – 76mmHg) [23].

Most of the clinical studies have looked at a mixed population of wounds (acute, chronic, diabetic and pressure ulcers) and used commercially produced vacuum assisted device from Kinetic Concepts International, San Antonio Texas (KCI INC). While gauze has been found to cause less pain during dressing change, the main outcome which is duration to readiness for surgery or wound healing has not been reported. It is also unknown whether similar results will be reproduced when using a suction machine to apply negative pressure and locally available cling film as vacuum seal. Therefore, by selecting similar wound types and using the same instruments, in a clinical setting the study intended to find out if gauze will have similar or different outcomes to that of foam as wound dressing for NPWT.

Contraindications of NPWT.

Some of the contraindications for NPWT are:

a) Exposedvasculature, nerves, anastomotic sites, andorgans[1].
b) Patientsat high risk of bleeding and haemorrhage.
c) Patients onanticoagulants or platelet aggregation inhibitors.
d) Patientswith wound infection before debridement.
e) Sharpedges in thewound from bone fragments or hardware[71].

PAIN RATING SCALES

Rating pain is very subjective and this provides a big challenge to researchers in getting an objective measure. To overcome this, different pain rating scores have been developed such as the numeric rating scale (NRS), visual analogue scale (VAS) and verbal rating scale (VRS).

In a review of the three most widely used pain rating scales, Williamson and Hoggart concluded that:

- All the three scales are valid, reliable and appropriate for use in clinical practice.
- The NRS has a good sensitivity and generates data that can be statistically analyzed for audit purposes.
- Patients who seek a sensitive pain rating scale would probably choose the NRS.
- As a tool for pain assessment as well as for audit and research, the NRS is probably more useful than the VRS or VAS [72].

The national institute of health on a study of pain sensitivity instruments also concluded that the NRS was the most appropriate for pain studies [73].

JUSTIFICATION

Wound management still poses a challenge to all clinicians despite use of various products and methods currently available [1]. NPWT is a relatively new technique developed in the last 15 years for the management of acute and complex chronic wounds and has helped to accelerate granulation tissue formation and wound recovery, reduce infection rates and save on cost for wound management [3, 4, 30, 74, 75, 43, 44, 76].

The majority of the studies are based on foam as wound dressing material in NPWT. However, foam has its shortcomings such as more pain during dressing change, formation of friable thick granulation tissue and foam pieces can get lost into the wound bed [67]. Experimental studies using gauze as wound dressing[66, 69, 39] and a few clinical studies[2, 77, 54] have shown that gauze may overcome those shortcomings. Whether this will translate in improved clinical outcome has not been studied in any randomized comparative study.

In our market, standard Bobmil® foam costs on average sh5/1000cm^2. This is twice the cost of medical gauze such as Cosmos® which costs about sh2.5/1000cm^2. Therefore, adoption of gauze in NPWT will reduce material costs by about 50%.

While NWPT has been widely adopted in the developed countries, there are limited published studies in sub-Saharan Africa on the same and it has not been widely adopted in our health system. Therefore, more studies on various aspects of its materials and application are necessary to improve the NWPT system and incorporate materials already in use in our hospitals such as gauze.

Traumatic soft tissue loss with class III and IV wounds constitutes a large percentage of the acute traumatic wounds seen at KNH. These require admission and more complex wound management hence the need to develop better and cheaper ways to manage them [9].

OBJECTIVES

MAIN OBJECTIVE

To determine if there is a difference in outcome between the use of gauze and that of foam as wound dressing material in NPWT for the management of acute traumatic wounds.

SPECIFIC OBJECTIVES

1. To determine the time difference in achieving 100% granulation for class III and IV acute traumatic wounds with soft tissue loss involving the lower limbs when using gauze or foam dressing material in NPWT.
2. To determine the difference in pain scores during wound dressing change when using gauze or foam dressing in NPWT for acute traumatic wounds with soft tissue loss.
3. To determine the difference in the percentage change of wound surface area for acute traumatic wounds with soft tissue loss when using gauze or foam dressing in NPWT.
4. To determine the difference in wound infection rate between gauze and foam dressing use in NPWT for the management of acute traumatic wounds with soft tissue loss.

HYPOTHESIS

There is no difference in the outcome of lower limb acute traumatic wounds management when using gauze or foam wound dressing in NPWT.

METHODOLOGY

1. STUDY DESIGN

Prospective randomized interventional comparative study

2. STUDY SETTING

Kenyatta National Hospital orthopedics and surgical wards.

3. STUDY POPULATION

The study involved all the patients aged above 12 years with class III or IV acute traumatic wounds and soft tissue loss involving the lower limbs admitted in the surgical wards at KNH.

4. SAMPLE SIZE

Bolleroet al in a prospective study of 37 patients treated with NPWT using foam for lower limbs trauma and soft tissue loss found that they took an average of 22 days to achieve full granulation[52]. In a similar study, Hyun-Joo Lee et al reported an average of 18.4±5.24 (SD)days[78].

Considering the above studies with a confidence interval of 95% and power of 80%, the sample size for each group is estimated using the formula below.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta/2})^2 \sigma^2}{\delta^2}$$

n = the desired sample size in each group

$Z_{1-\alpha/2}$ = 1.96 for 95% confidence interval

$Z_{1-\beta/2}$ = 0.84 for 80% power

σ = overall standard deviation of mean time to granulation = 5.24 days

δ = difference in the mean time to granulation between the two groups to be detected = 3 days

when substitued in the formula

n = 24 for each group and therefore a total of 48 patients. A 10% addition of sample done to cover for possible drop out. The final sample size is 26 in each group.

5. PATIENTS

INCLUSION CRITERIA

- Patients with class III or IV acute traumatic wounds with soft tissue loss involving the lower limbs.
- Injury must have occurred less than 72 hours prior to recruitment into the study.
- Soft tissue loss involving the full thickness of the skin and deeper.
- Patients must have undergone surgical toilet to remove all non-viable tissues and foreign bodies
- Patients who are 12 years of age and above.

EXCLUSION CRITERIA

- Wounds with exposed major blood vessels or where hemostasis has not been achieved.
- Non – trauma wounds.
- Patients who smoke cigarettes.
- Patient with diabetes mellitus, psychosis or chronic renal failure.
- Patients on corticosteroids, chemotherapy or anticoagulants.
- Patients who refuse to give consent.

6. SAMPLING PROCEDURE AND ALLOCATION OF TREATMENT.

Patients who met the inclusion criteria were recruited into the study by the principal researcher and assistants by convenient sampling procedure.

Block randomization wasused to allocate treatments to the participants after they consented to participate in the study. The patients were considered in blocks of four at a time which gave 6 possible ways of allocating treatments. Block **A** for gauze and **B** for foam. The six options were as follows:

1. AABB 2. BBAA 3. ABAB. 4. BABA 5. ABBA 6. BAAB.

Randomization and allocation sequence was accomplished by generating numbers from http://www.randomization.com (Appendix VIII).

7. WOUND MANAGEMENT.

The wounds were assessed 12 hours after surgical toilet and NPWT applied with either gauze or foam as the wound dressing. This was changed after every 72 hours until the wound achieved full granulation.

8. NPWT APPLICATION

- The wound was cleaned using normal saline by the principal investigator.
- Sterile standard Bobmil® foam was trimmed to the wound size and placed on the wound for the foam group or gauze for the gauze group avoiding normal tissue.
- A suction catheter with additional lateral perforations was placed on the gauze or foam.
- A second gauze or foam was placed on top of the catheter.
- Stat wrap® cling film was then used to cover the dressing and strapping applied to achieve an airtight closure.
- The suction catheter was connected to a suction machine and pressure set at 125mmhg. The fluid drained from the wound was collected in a canister connected to the suction machine.
- The seal was confirmed by observation of collapsing of the sponge or gauze with the suction machine turned on.
- Inspections were done 12 hourly by the principal researcher and assistant to confirm the integrity of the vacuum seal.
- Patients were taught how to switch off the machine and disconnect the suction whenever they wanted to visit the bathroom. They switched on the machine and reconnected the suction tube on returning.

Patients were on a regular dose of analgesics with additional analgesiagiven as required if in pain. They also received a prophylactic dose of antibiotics; floxapen 500mg four times a day for 48 hours.

The NPWT was stopped if:

- There was a contraindication to continue with the treatment.
- The patient opted out of treatment.
- The wound achieved 100% granulation – clean, red granulating bed i.e. 'ready for surgical therapy' on inspection by the principal investigator and confirmed by one of the ward surgeons[68].

9. DATA COLLECTION.

Data was collected using a standard data sheet (Appendix III). Information collected on day 1 included:

a. Patient demographics.
b. Height, weight and calculated body mass index (BMI).
c. Date and time of injury.
d. Date and time of the recruitment into the study.
e. Class of the wound according to the American college of Surgeons classification i.e.
    i. Class III – contaminated
    ii. Class IV – dirty.
f. Site of the wound
g. Wound surface area – A sterile paper used in the packaging of sterile gloves was used to trace wound margins.This was then transferred toa graph paper and the surface area calculated by counting boxes.

On the subsequent dressing change after every 72 hours, data was collected on:

a. Wound surface area.
b. Pain experienced – based on the NRS.
c. Presence of necrotic material. If present debridement was done under local anesthesia before NPWT application.
d. Infection as seen from presence of pus or periwound erythema.
e. Duration of NPWT in days to 100% granulation.
f. Complications
g. Discontinuation.

DATA ANALYSIS

Datawas collected between May 2012 and August 2012 by the principal researcher and assistants.This was coded, entered and managed in a Microsoft excel database until the end of data collection when it was exported to SPSS version 17.0 for analysis.

Descriptive statistics was performed for patient'sbaseline characteristics and comparability done using chi square test for categorical variables (proportions) or Student's t test for continuous variables (means).

The mean time to full granulation, average percentage change in wound surface area and wound infection rate were compared between the two groups using Student's t test for normally distributed data or Mann Whitney U test for non-normally distributed data. Linear regression and Pearson correlation was used to relate the different continuous variables. All statistical tests were performed at 5% level of significance (95% confidence interval).

RESULTS

Fifty one patients who were eligible for the study were recruited and all had class IV wounds. One patient in the gauze group was dropped from the study because he was found smoking. One patient had two wounds, one on either lower limb. The data from the fifty one wounds was analyzed as shown in figure 3 below.

Figure 3.Summary of wound allocation

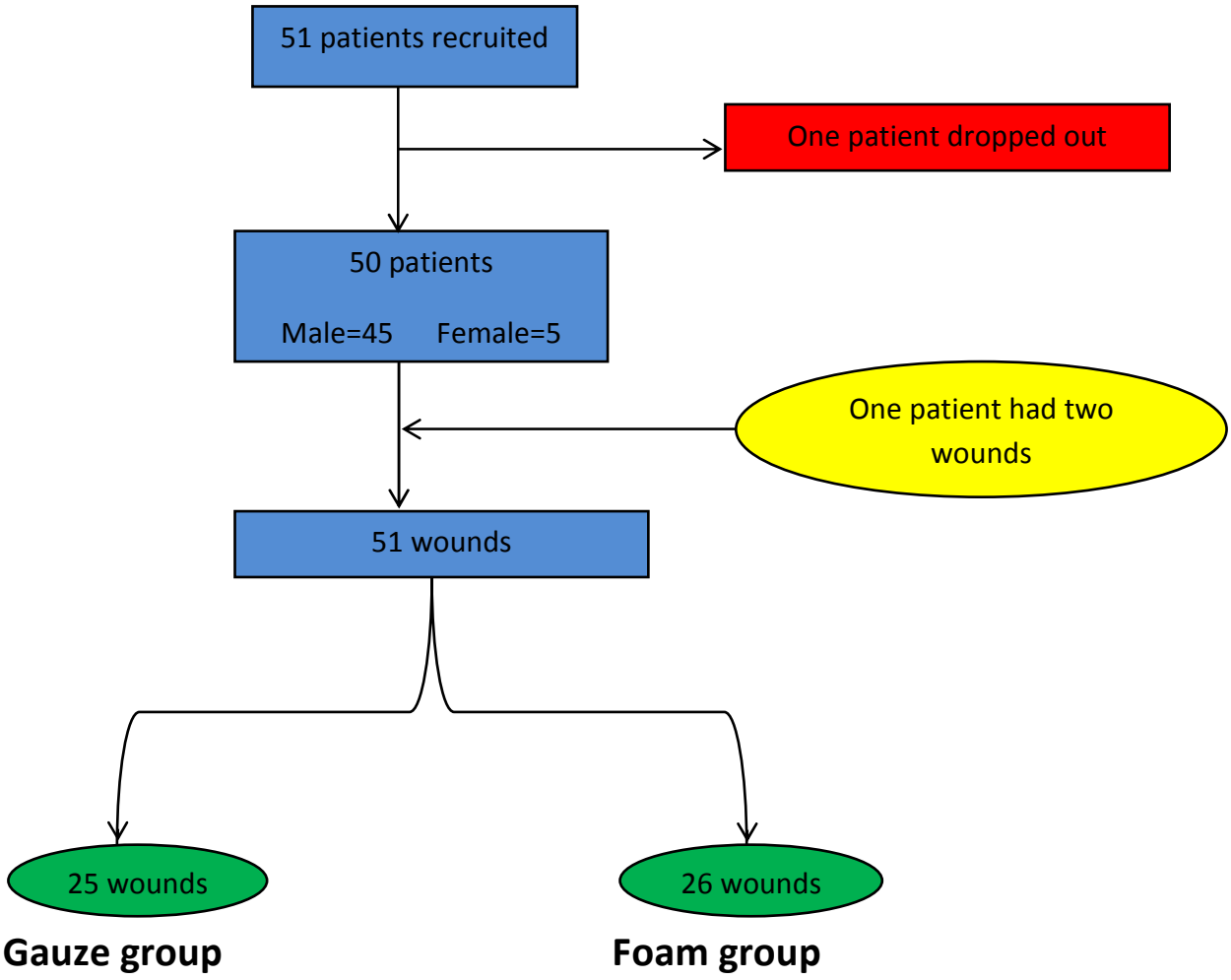


Table 1. Summary of the baseline characteristics

Parameter	Measures	Gauze	Foam	P value
Age (years)	Mean (SD)	37.2 (14.5)	31.5 (8.8)	0.096
	Median (IQR)	34.0 (27.0-45.0)	28.5 (25.0-37.0)	
	Range	18.0-70.0	21.0-60.0	
Sex	Male Female	21 (84.0%) 4 (16.0%)	25 (96.2%) 1 (3.8%)	0.191
BMI	Mean (SD)	22.0 (2.1)	22.1 (2.0)	0.979
	Median (IQR)	22.3 (20.0-23.5)	21.8 (21.0-23.0)	
	Range	18.9-26.7	18.9-26.6	
Time to NPWT (hours).	Mean (SD)	48.4 (14.5)	42.8 (12.0)	0.145
	Median (IQR)	46.0 (39.0-61.0)	41.8 (35.0-51.0)	0.139
	Range	16.0-72.0	17.0-66.0	
Initial wound surface area (cm^2)	Mean (SD)	78.9 (45.9)	73.7 (31.5)	0.636
	Median (IQR)	65.0 (53.0-98.0)	66.0 (54.0-77.0)	
	Range	25.0-210.0)	35.0-165.0	

NB: SD = standard deviation.

IQR = interquartile range.

The mean comparisons were done using Students t test, medians for time to NPWT were compared using Mann Whitney U test and sex distribution between the two groups analyzed using Fisher's exact test.

There was no statistically significant difference between the two patient groups in all the baseline characteristics. All the p-values are more than 0.05.

Table 2: Comparison of the wound site distribution.

Wound site	Gauze	Foam	P value
Thigh	3 (12.0%)	3 (11.5%)	0.238
Knee joint area	4 (16.0%)	0 (0.0%)	
Leg	13 (52.0%)	13 (50.0%)	
Ankle joint area	3 (12.0%)	6 (23.1%)	
Foot	2 (8.0%)	4 (15.4%)	

Most of the wounds (50%) in each group were located in the leg region as shown in table 2 above and figure 4 below. However, there was no significant statistical difference on the wound site distribution between the two groups (p=0.238, Fischer's exact test).

Figure 4. Bar charts on wound site in the two groups

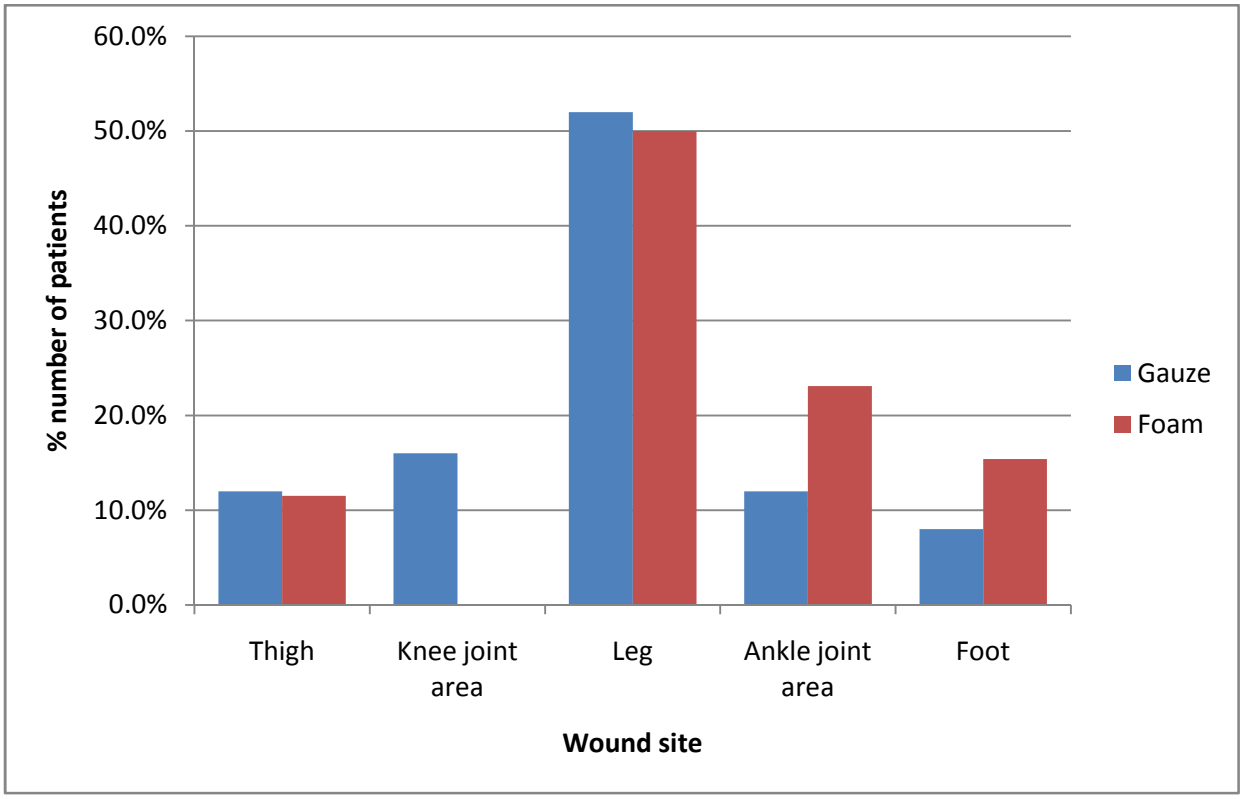


Table 3. Summary of the wound results

Parameter	Measures	Gauze	Foam	P value
Change in wound surface area (cm^2)	Mean (SD)	-3.6 (1.1)	-3.7 (0.7)	**0.937**
	Median (IQR)	-3.0 (3.0-5.0)	-4.0 (3.0-4.0)	
	Range	-2.0 to -6.0	-2.0 to -5.0	
% change in wound surface area	Mean (SD)	5.3 (1.9)	5.5 (1.6)	**0.769**
	Median (IQR)	5.2 (4.5-5.7)	5.6 (4.5-6.5)	
	Range	2.4-12.0	2.4-8.5	
Time to end point (days)	Mean (SD)	8.4 (3.5)	8.1 (2.4)	**0.698**
	Median (IQR)	6.0 (6.0-12.0)	9.0 (6.0-9.0)	
	Range	6.0-18.0	6.0-15.0	

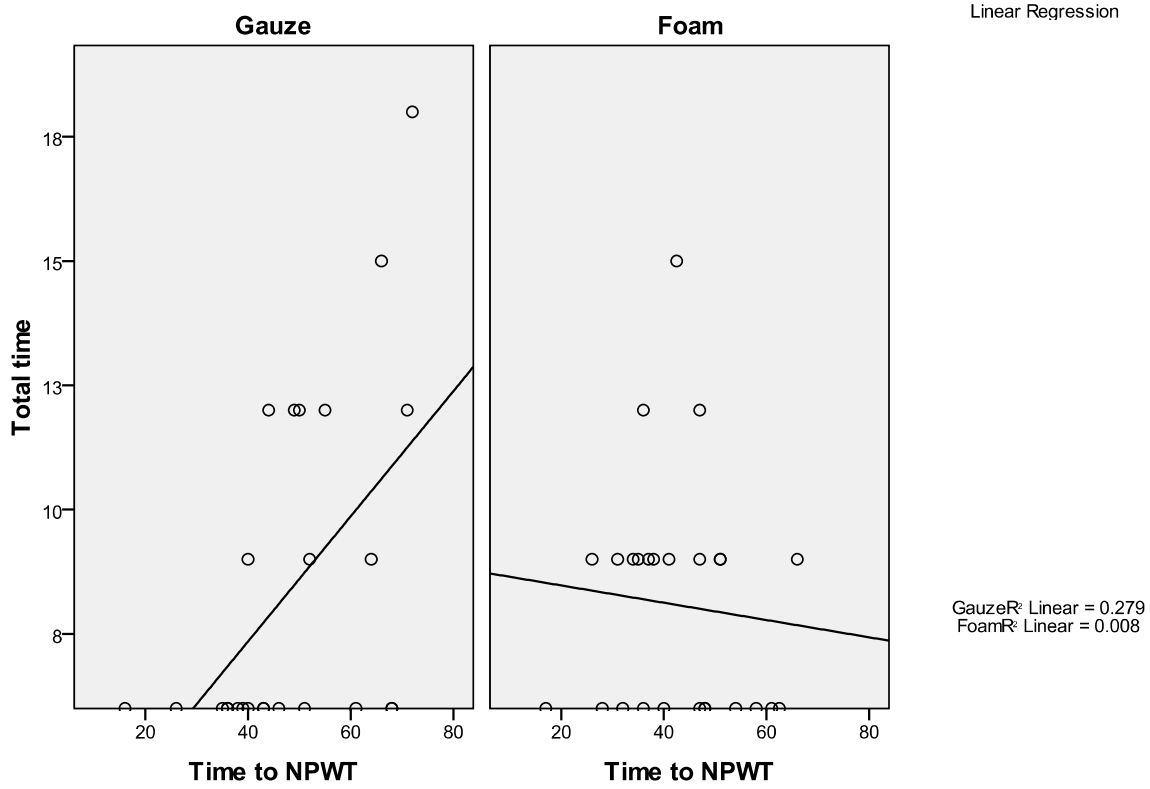
The mean reduction in wound surface area was 3.6cm^2 in the gauze group compared to 3.7cm^2 in the foam group which is not statistically significant (p=0.937). The mean proportional change in the wound surface area was 5.3% in gauze group versus 5.5% in the foam group. This too was not statistically significant (p=0.769).

There was no difference in the average time taken to full granulation between the two groups. The gauze group took a mean of 8.4 days compared to 8.1days in the foam group, p=0.698. However, the time taken to application of NPWT had positive correlation with time to full granulation in the gauze group (p=0.007) but did not affect duration in the foam group (p=0.669). These results are summarized in table 4 below and illustrated in figure 5.

Table 4.Pearson correlation between time to NPWT and time to full granulation.

Variable	Gauze		Foam	
	Correlation coefficient (r)	P value	Correlation coefficient (r)	P value
Time to NPWT	0.528	0.007	-0.088	0.669

Figure 5.Linear regression analysis on time to NPWT versus time to full granulation.

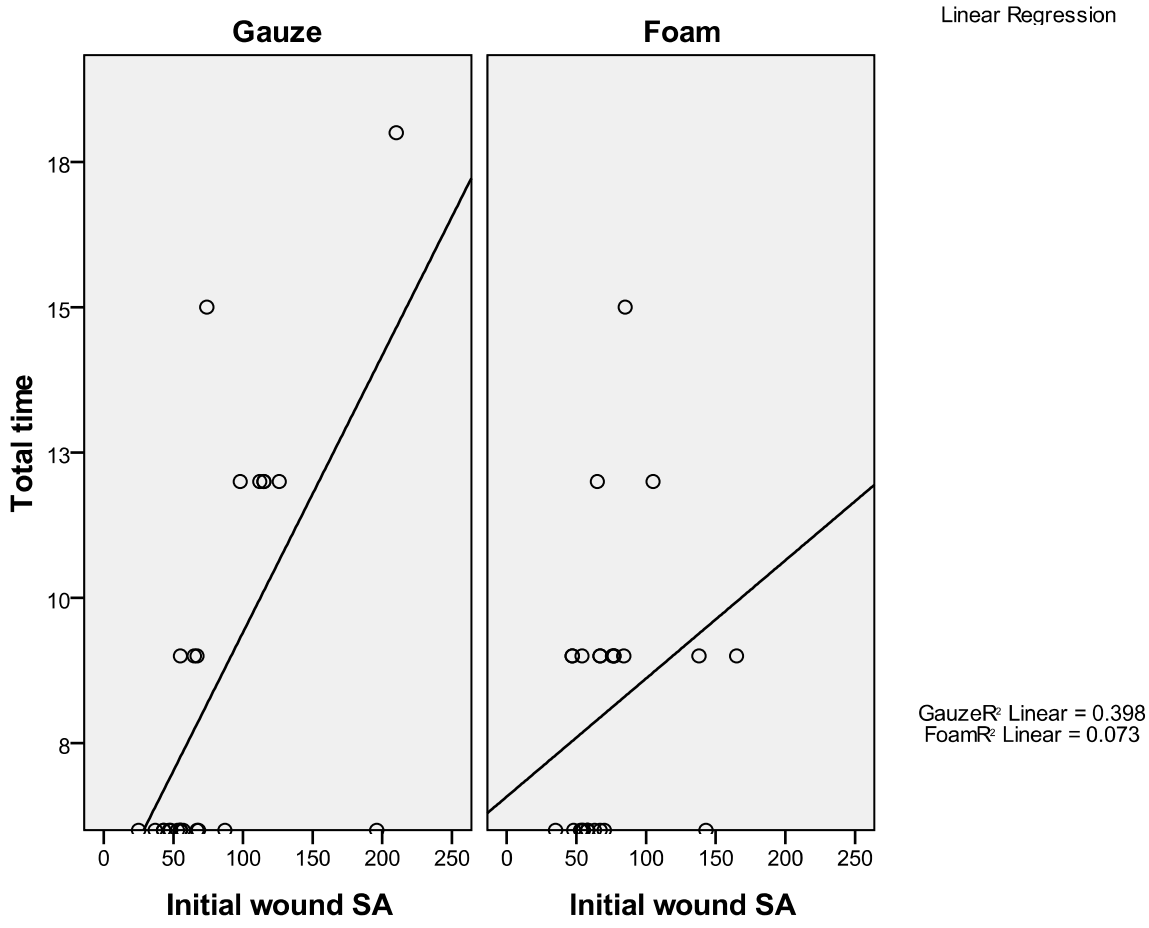


The initial wound surface area had a significant effect on the time to full granulation in the gauze group, p=0.001 but not a statistically significant effect in the foam group, p=0.182 as shown in table 5. However, linear regression analysis in figure 6 below shows a positive trend in both groups.

Table 5. Pearson correlation between initial wound SA and time to full granulation.

Variable	Gauze		Foam	
	Correlation coefficient (r)	P value	Correlation coefficient (r)	P value
Initial wound SA	0.631	0.001	0.270	0.182

Figure 6.Linear regression analysis on initial wound surface area and time to full granulation.

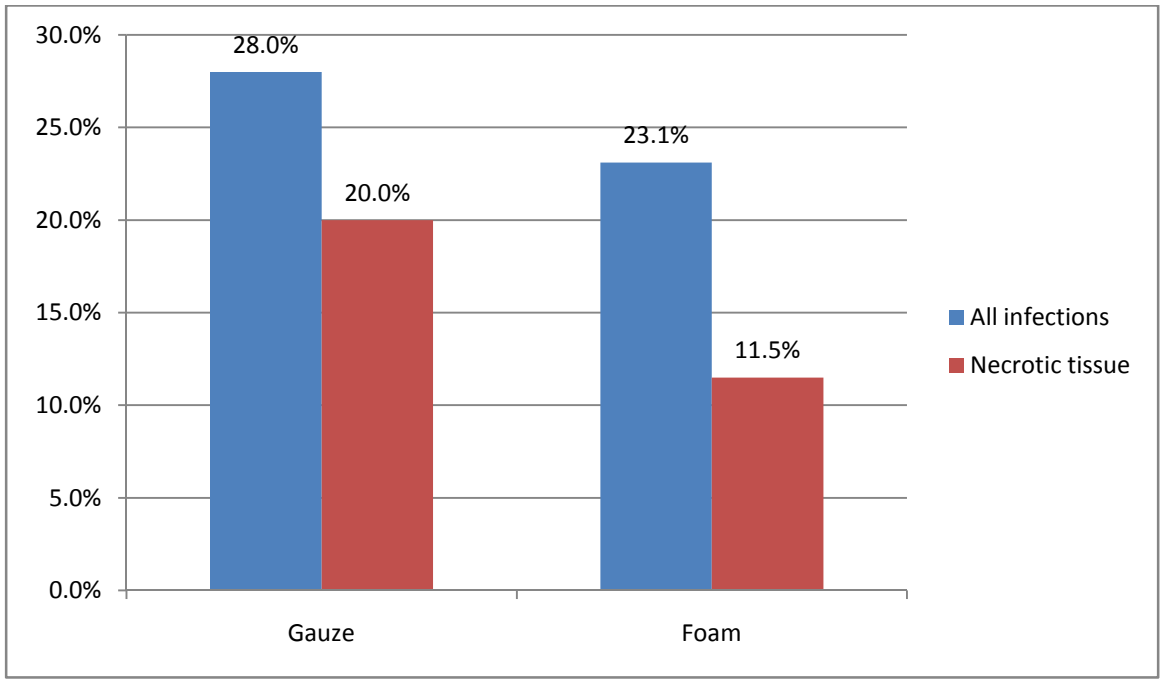


The gauze group had a higher infection rate at 28% versus 23.1% in the foam group but this was not statistically significant, p=0.687 for infection rate and p=0.465 for debridement rate. These results are summarized in table 6and figure 7 below.

Table 6: Comparison of infection rates between the gauze and foam groups

Infection	Gauze group	Foam group	P- value
Erythema/Pus	7 (28.0%)	6 (23.1%)	0.687
Necrotic tissue/debridement	5 (20.0%)	3 (11.5%)	0.465
All infections	7 (28.0%)	6 (23.1%)	0.687

Figure 7.Infection rates by treatment group



The time to NPWT had a significant effect on the infection rate in the gauze group, p=0.03 butnot statistically significant effect in the foam group, p=0.534 as shown in table 7 below.

Table 7.Effect of time to NPWT on infection rates.

	Gauze			Foam		
	Presence of pus or erythema		P value	Presence of pus or erythema		P value
	Yes	No		Yes	No	
Time to NPWT	58.1 (11.4)	44.6 (14.1)	0.033	45.6 (12.3)	42.0 (12.0)	0.534

The presence of wound infection significantly increased the time to full granulation in both groups, 13.3 days versus 6.5 (p<0.001) in gauze group and 11 days versus 7.2 in the foam group (p<0.001). These results are summarized in table 8 below.

Table 8.Effect of wound infection on time to full granulation.

	Gauze			Foam		
	Presence of pus or erythema		P value	Presence of pus or erythema		P value
	Yes	No		Yes	No	
Time to full granulation mean (SD)	13.3 (2.4)	6.5 (1.2)	<0.001	11.0 (2.4)	7.2 (1.5)	<0.001

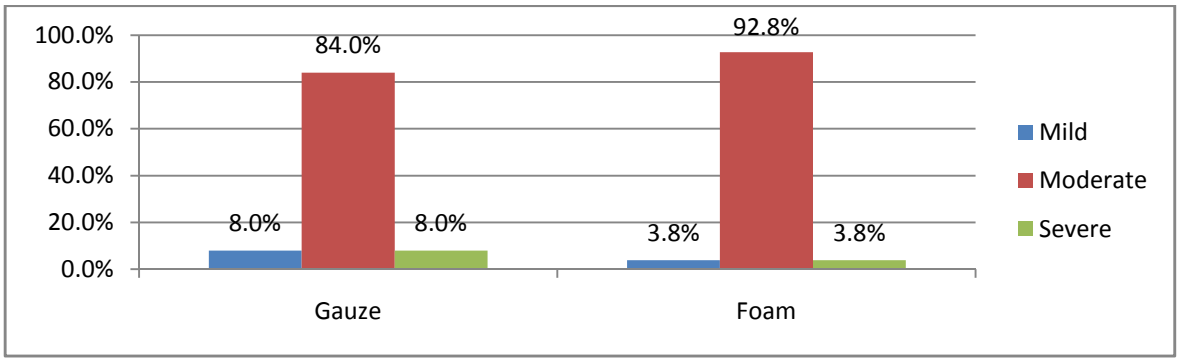
The median pain scores were comparable between the two groups, 4.5 for gauze and 4.8 for foam, as shown in table 9 below. The difference was not statistically significant (p=0.174). Most patients in both groups experienced moderate pain (84% gauze versus 92% foam) as shown in figure 8 below.

Table 9: Comparison of the pain score

Group	Gauze	Foam	OR (95% CI)	P - value
Pain score, Median (IQR)[a]	4.5 (3.5-5.0)	4.8 (4.0-5.0)	-	0.174
Pain score, Mean (SD)[b]	4.4 (1.0)	4.7 (0.9)	-	0.245
Pain score[c]				
Mild	2 (8.0%)	1 (3.8%)	1.0	
Moderate	21 (84.0%)	24 (92.3%)	0.4 (0.0-5.2)	0.512
Severe	2 (8.0%)	1 (3.8%)	1.0 (0.0-29.8)	1.000

[a]Mann Whitney U test [b]Student's t test [c]Chi square test reporting odds ratios

Figure 8.Comparing pain categories between the two groups.

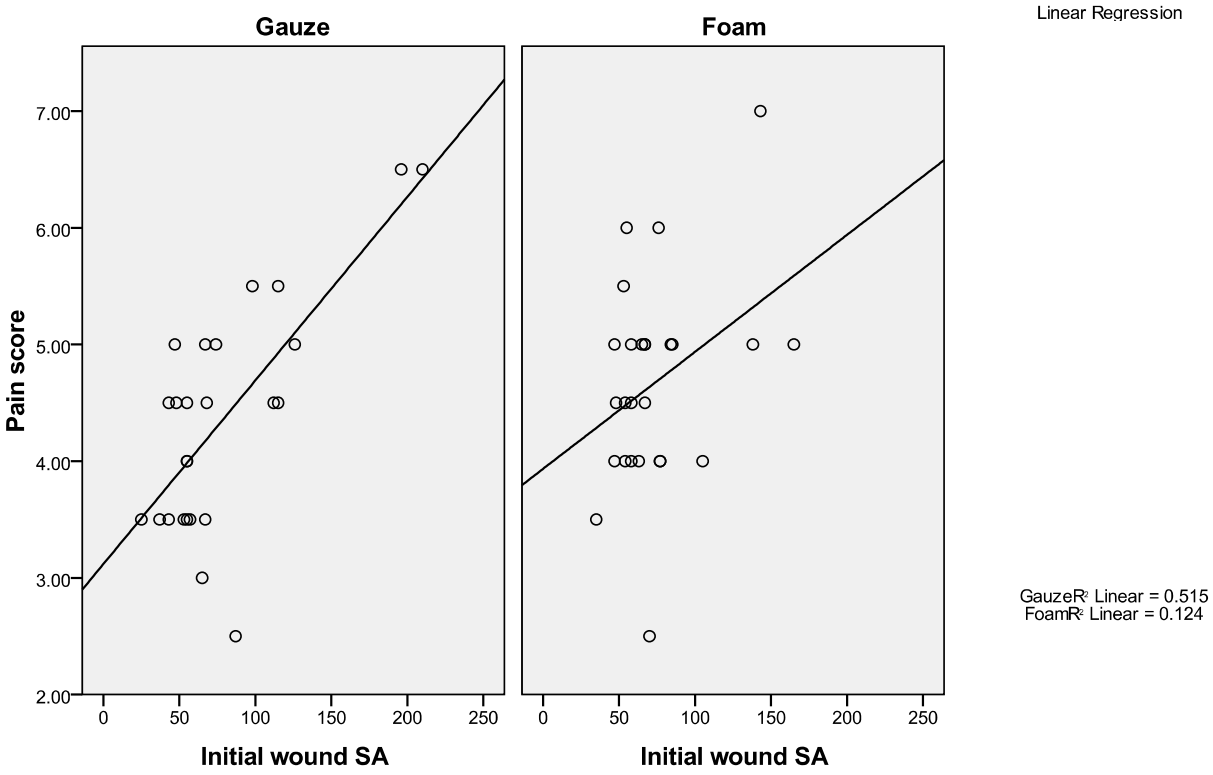


There is a positive correlation in both groups between the initial wound surface area and the pain scores as shown in table 10 and figure 9 below. This is significant in the gauze group, p<0.001 but not in the foam group p=0.077 although both show a positive trend.

Table 10. Pearson correlation between initial wound SA and pain score

Variable	Gauze		Foam	
	Correlation coefficient (r)	P value	Correlation coefficient (r)	P value
Initial wound SA	0.718	<0.001	0.353	0.077

Figure 9. Linear regression on initial wound surface are and pain scores.



DISCUSSION

This study results show that in the management of acute traumatic wounds using NPWT, there is no difference in outcome whether gauze or foam is used as the wound dressing material. Wounds took an average of 8.4 days in the gauze group compared to 8.1 days in the foam group ($p=0.698$) to achieve full granulation. The mean reduction in wound surface area was comparable in the two groups (5.3% with gauze versus 5.5% with foam, $p=0.937$). Infection rates of 28% with gauze versus 23.1% with foam ($p=0.687$) were no different. Pain during dressing change was mainly of moderate category in both groups and there was no difference in the median scores (4.5 versus 4.8, $p = 0.174$).

The outcomes in the gauze group were more influenced by the time to NPWT and initial wound surface area than the foam group although both showed a positive trend. In this regard, the time to full granulation was significantly related to time to NPWT ($p=0.007$) and initial wound surface area ($p=0.001$) in the gauze group. In the foam group, the p values of 0.669 and 0.182 respectively are not statistically significant. There was no observable underlying parameter to account for the difference and it may be due to the dressing material characteristics.

The infection rate in both groups was influenced by how long it took before application of NPWT (gauze, $p=0.03$ foam, $p=0.534$). However, this is evidently statistically significant in the gauze group only. Once infection set in, the duration to full granulation was significantly prolonged in both groups, $p<0.001$. On the pain scores, although there is a positive correlation between the wound surface area and the pain score in both groups, it is only significant with the gauze group ($p<0.001$) but not in the foam group ($p=0.077$). This also suggests that outcomes with foam dressing may be less influenced by wound and patient characteristics compared to gauze dressing in NPWT.

The analysis of various correlations suggests that although in the main outcomes there is no difference between the two dressing materials in NPWT, foam dressing outcomes are less influenced by time to NPWT and the initial wound surface area compared to outcomes with gauze dressing.

There is no published randomized control trial comparing the use of gauze versus foam in NPWT for the management of acute traumatic wounds.Although the bulk of the literature regarding NPWT describes one vacuum-assisted closure system (V.A.C. Therapy®, KCI, San Antonio, TX), the use of gauze as an alternative dressing interface and other vacuum sources also has been presented. There are some randomized experimental studies comparing various aspects of wound healing between the two dressing materials and they have not shown significant differences.

Campbell et alpublished a retrospective analysis of gauze based NPWT inwhich granulation was clinically noted in all patients by day 5. This showed the effectiveness of gauze as a wound filler material in producing a healthy, granulating tissue bed[77]. In a similar study of 75 patients with open wounds of the lower extremity (of which 49 were the result of trauma),granulation tissue was present by day 4 of vacuum therapy, with decreased edema and bacterial counts [79]. These results are comparable to the current study.

In the study by Bollero et al on VAC therapy using foam dressing for acute complex wounds of the lower limbs, it took an average of 22 days to achieve full granulation. This is longer compared to the 8 days in the current study mainly due to the complex wounds involved in his study, 86% had exposed bone[52]. However, in another study by Wandera O. on lower extremity trauma wounds, the median time to full granulation using VAC therapy with sponge was 12 days which is also slightly longer than 8 days in the current study[2]. This could be due the larger starting average wound surface area of 135.8cm^2 in Wandera's study versus 73.7cm^2 in this study.

Morykwas et al in an experimental study on acute wounds with foam dressing, full granulation took an average of 8 days [66] which compares well with this study while a clinical study on acute wounds by Moues et al reported an average of 5 days to full granulation [68].

There was no statistically significant difference in the change of wound surface area between the two groups in this study, p=0.769. This is similar to experimental findings in the study by Malmsjo et al comparing the two dressing materials in NPWT [70]. This finding is expected if the underlying mechanical and physiological basis for NPWT is similar in the two dressing materials as shown in experimental studies[39]. In the study by Moues et al referred above [68], the mean percentage change in wound surface area was 3.8% which compares closely to the 5% in this study. However, Lee et al in a study of acute wounds around the ankle joint and foot treated with NPWT using foam dressing noted a greater average reduction of wound surface area of 24%. This could be due to the different complexity of the wounds and the longer duration of NPWT in that study, 18.4 days [78].

In a study by Amir et al on 87 patients with acute wounds, the median percentage decrease in wound surface area was 10.1 versus 6.7 in the gauze and foam groups respectively (p=0.32) [63]. This is close to results in the current study and also shows that there is no difference in outcome between the two dressing materials.

The infection rate was noted to be about 13.6% in the VAC group with foam dressing of the study by Wandera O[2] which is lower than 23% in the current study. However, he did not report on time to application of NPWT which has effect on infection rate as seen in the analysis of results in this study above.

Stannard et al reported a 5.4% infection rate on 35 patients treated with VAC for acute traumatic wounds [51]. This low infection rate could be because the study was done in a level one trauma centre and there were repeated debridement's and irrigations done every 48 to 72 hours until wound closure was attained. There is need for further randomized controlled trials to evaluate the differences in infection rates.

Amir et al reported median pain scores during and after dressing changes (2.7 during and 1.9 after in gauze group vs. 4 during and 3 after in the VAC foam group; $p<0.01$ for both comparisons) [63]. This suggested less pain with gauze as interface material. However, in the present study there was no difference between the groups (4.5 for gauze and 4.8 for foam $p=0.174$). Due to the lack of other randomized studies comparing pain scores between the two dressing materials currently, it is difficult to conclude if the differing result is due to methodology or other patient characteristics. More clinical studies are necessary in evaluating pain in relation to dressing material in NPWT.

There was no major complication noted in this study. In the foam group, granulation tissue growth into the dressing material was noted from the second dressing change. This caused slightly more bleeding from these wounds than those with gauze dressing but all were easily controlled by application of wound dressing. As noted from the results above, this also did not translate into significantly more pain.

The other complication noted was noise from the suction machines and patients complained of the noise disturbance at night. However, all patients were educated on the importance of keeping the machine on and none switched it off.

The foam dressing used in this study costs twice as much as gauze dressing material (standard Bobmil® foam costs sh5/1000cm^2 versus sh2.5/1000cm for Cosmos® medical gauze). Considering that there is no difference in time to full granulation and it is easier to apply gauze on the wound, it may be more economical and easier to use gauze as dressing material in NPWT. In our set up, since gauze without NPWT is still the main wound dressing material, adopting it in NPWT may improve wound management.

This study has some limitations. There was no blinding between the two groups since the researcher could see which dressing material was being used on a particular wound during dressing change. This may cause bias in some observations like evaluation of pain. The study also did not consider wound depth which may influence granulation formation. Wound infection was determined by clinical assessment which may give different results from bacteriological cultures. However, in clinical practice the clinical assessment method is what determines if further microbiological analysis is required.

CONCLUSION

This study provides evidence that there is no difference in the clinical outcome between the use of foam or gauze dressing in NPWT for the management of acute traumatic wounds. Both wounds dressing materials produce comparable results in terms of time to full granulation, change in wound surface area, infection rates and pain during wound dressing change. However, the results also suggest that outcomes with foam dressing in NPWT are less influenced by time to NPWT, initial wound surface area and woundinfection compared to gauze dressing.

RECOMMENDATIONS

1. Gauze wound dressing material in NPWT should be adopted in the management of wounds using NPWT as a suitable alternative to foam dressing.
2. All surgeons and nurses in training should be well trained on the use of both dressing materials in NPWT.
3. Further research to follow up patients to complete wound healing is necessary to find out if there is any difference in outcome between the two dressing materials in NPWT.

ETHICAL CONSIDERATIONS

Approval for the study was obtained from the department of Surgery, University of Nairobi and the KNH ethics and research committee (KNH/ERC) before commencement.

Informed consent was obtained from the patients who accepted to participate in the study (See appendix IV).For those who did not consent; they were managed as per the regular wound management protocol in the respective ward.

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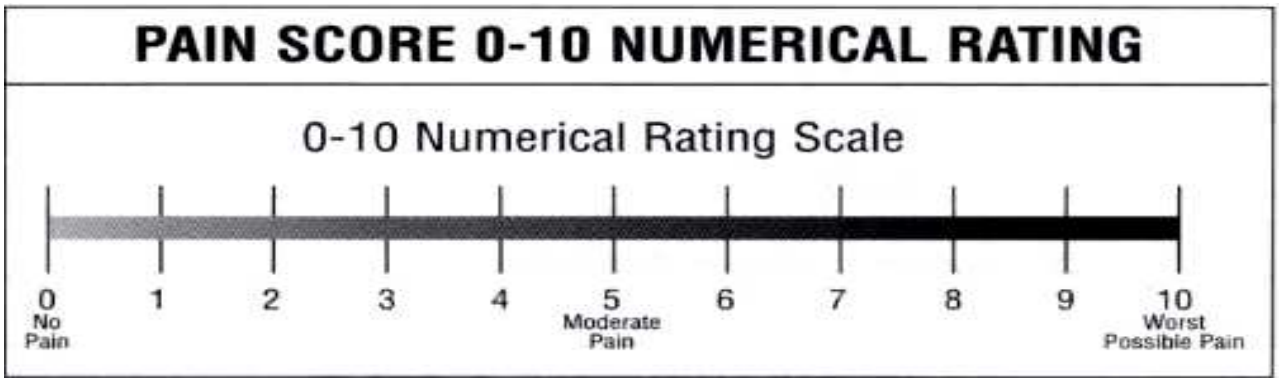
APPENDIX I

NUMERIC RATING SCALE - adapted from the national institute of health on a study of pain sensitivity instruments [73].



Instructions:

1. The patient is asked any one of the following question after completion of dressing change: What number on a 0 to 10 scale would you give your pain when it is the worst?

2. If the above question is not sufficient for the patient, further clarification for the Numeric Rating Scale is sought in the following manner:

0 = No Pain

1-3 = Mild Pain (nagging, annoying, interfering little with activities of daily living)

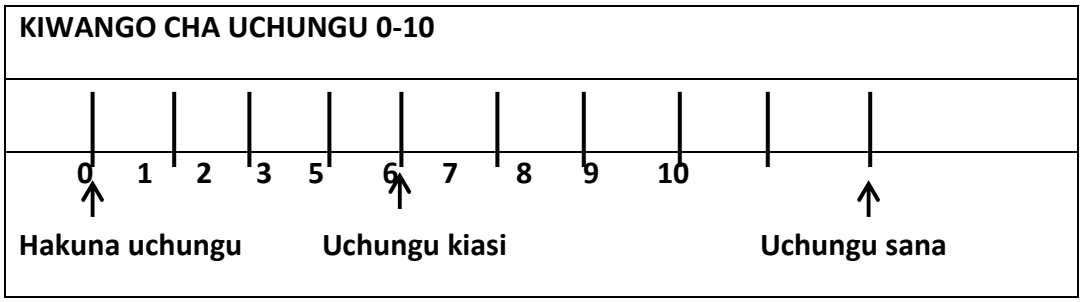
4–6 = Moderate Pain (interferes significantly with activities of daily living)

7-10 = Severe Pain (disabling; unable to perform activities of daily living)

APPENDIX II

KIWANGO CHA KUKADIRIA UCHUNGU

Hiki ni kiwango cha kukadiria kiasi cha uchungu utakaohisi wakati wa kidonda kuvishwa.



MAAGIZO

1. Mgonjwa ataulizwa swali lifuatalo baada ya kidonda kuvishwa.
    a. Kwa kukadiria kati ya 0 na 10, ni kiasi gani cha uchungu umehisi?

2. Ikiwa hilo swali halijatosha, basi mgonjwa ataelezewa zaidi kuhusu makadirio ya uchungu kama ifuatavyo;
    a. 0 = hakuna uchungu.
    b. 1 - 3 = kuna uchungu kidogo ambao hauwezi kumzuia mgonjwa kufanya kazi za kawaida kama kuoga au kuvaa nguo.
    c. 4 - 6 = uchungu kiasi ambacho kitamzuia mgonjwa kwa kiasi kufanya kazi za kawaida kama kuoga au kuvaa nguo.
    d. 7 – 10 = uchungu mwingi sana ambao utamzuia mgonjwa kabisa kufanya kazi za kawaida kama kuoga au kuvaa nguo.

APPENDIX III

DATA COLLECTION SHEET.

Study number……..

Group: Gauze ☐

Foam ☐

PATIENT DATA

1. In patient number…….
2. Age in years …….
3. Sex : M ☐
   F ☐
4. Height in CM……..
5. Weight in KG …….
6. BMI KG/M2…….
7. Date of injury …… time of injury……..
8. Date of application of NPWT ……time of application of NPWT…….
9. Hours from the time of injury to the application of NPWT……

WOUND DATA

Day 1 – at the time of recruitment into the study

1. Site of the wound
   a. Thigh ……..
   b. Knee joint area……..
   c. Leg…….
   d. Ankle joint area ……..
   e. Foot…….
2. American college of surgeons class
   a. Class III ☐
   b. Class IV ☐
3. Wound surface area…….cm^2

After every 72 hours

Study number……..

Number of dressing change…….

1. Wound surface area …… cm^2
2. Presence of pus or erythema
    a. Yes……..
    b. No……..
3. Necrotic tissue
        i. Present……..
        ii. Absent……..

    b. Debridement done
        i. Yes……..
        ii. No ……..
4. Any adverse event
    ……
    ……
5. End point achieved (100% clean granulation)
        i. Yes ……
        ii. No……..
6. Time duration in days taken to achieve end point……..

PATIENT DATA ON PAIN DURING DRESSING CHANGE.

Scale on the numeric rating scale;

a. 1st dressing change…….
b. 2nd dressing change……
c. 3rd dressing change…….
d. 4th dressing change…….
e. 5th dressing change…….
f. 6th dressing change…….
g. 7th dressing change…….
h. 8th dressing change…….
i. 9th dressing change…….
j. Average score…….

APPENDIX IV

CONSENT FORM

Study number…….

My name is Dr. Julius Gisore Ondieki a master's of surgery student at the University of Nairobi, department of surgery. I am carrying out a six months study on the management of acute traumatic wounds using either gauze or foam (sponge) as wound dressing in negative pressure wound therapy (NPWT). This will involve selected patients admitted in the surgical wards at Kenyatta national hospital. 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 which of the two dressings results in faster wound healing and less pain during dressing change. This information will help improve wound management in patients.

Foam is the current wound dressing used in our hospital during NPWT. Gauze dressing can also be used and am seeking to find out its advantages and disadvantages compared to foam. 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 hospital. 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 randomly allocated for your wound to be dressed with either foam or gauze in NPWT. Measurements of the affected wound will be taken and information stored in a data collection sheet. Your wound will be dressed and then connected to a suction machine. This dressing and measurements will be taken every third day until the wound is ready for further surgical closure or up to a maximum 28 days. The management of the wound after this will be by the appropriate method selected by the ward doctors.

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

Name _____

Signature_____ Date_____

Witness_____

Signature_____Date_____

For further information, enquiries or complaints please contact;

1. Dr. Julius Gisore Ondieki mobile number 0721680689 – principal researcher.
2. Chairman, UON/Kenyatta National Hospital ethics and Research committee on Tel 020-2726300 Ext 44355.

APPENDIX V

CHETI CHA KUKUBALI

Nambari ya kushiriki……

Jina langu ni daktari Julius Gisore Ondieki mwanafunzi wa shahada ya juu ya upasuaji katika chuo kikuu cha Nairobi. Nafanya utafiti kwa muda wa miezi sita kuhusu kutibu vidonda kwa kutumia gauze au foam kuvisha kidonda katika negative pressure wound therapy (NPWT). Utafiti huu utahusisha wagonjwa watakaochaguliwa kushiliki ambao wamelazwa kwenye wodi za upsuaji katika hospitali kuu ya Kenyatta. Utafiti huu umeidhinishwa na kamati ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta.

Utafiti huu unalenga kubainisha ni ipi kati ya foam na gauze itachukua muda mfupi kutayarisha kidonda na kupunguza uchungu wakati wa kuvisha kidonda. Matokeo hayo yatasaidia kuimalisha huduma za kutibu vidonda kwa wagonjwa wengi.

Foam ndiyo inayutumika kwa wakati huu kuvisha vidonda katika NPWT lakini gauze pia inaweza kutumika. Kusudi langu ni kuelewa uzuri na ubaya wa gauze ikilinganishwa na foam. Kushiriki kwako katika utafiti huu ni kwa kujitolea kwa hiari. Sio lazima ushiriki na kutoshiriki kwako hakutabadilisha jinsi utakavyohudumiwa katika hospitali hii. Maelezo yote yatakayokusanywa yatawekwa kwa siri na jina lako halitatumiwa katika uchapishaji wowote au kutolewa hadharani.

Ikiwa utakubali kushiriki katika utafiti huu utawekwa kwenye kundi litakalovishwa na foam au gauze kwa njia ya kibahati. Kidonda chako kitapimwa na maelezo hayo kujazwa katika kijikaratasi cha utafiti. Baadaye kidonda kitavishwa na kuunganishwa na mashine ya NPWT. Upimaji huu wa kidonda na kuvishwa utarudiwa kila baada ya masaa 72 hadi kidonda kiwe tayari kwa matibabu zaidi ya kukifunika au hadi siku 28 ziishe. Baada ya hapo, kidonda kitafunikwa kwa namna inoyofaa itakayochaguliwa na madaktari wa wodi utakoyokuwa.

Kumbuka ya kwamba una uhuru wa kujiondoa toka kwa utafiti huu wakati wowote ule. Uamuzi huu hautadhuru kwa vyovyote vile ile huduma utakayoipata katika hospitali hii. Kwa kutia sahihi hapa chini unaidhinisha kukubali kushiriki katika utafiti huu kwa hiari yako.

Jina_____

Sahihi/Kidole_____ Tarehe_____

Shuhuda_____

Sahihi_____Tarehe_____

Ikiwa unahitaji maelezo zaidi au una swali au malalamishi unaweza kuwasiliana na;

1. Mtafiti mkuu – Dkt. Julius Gisore Ondieki kupitia nambari ya simu 0721680689.
2. Mwenyekiti wa kamati ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta kupitia nambari ya simu 0202726300 ext 44355.

APPENDIX VI.

ASSENT TO PARTICIPATE IN RESEARCH

Study number……

My name is Dr. Julius Gisore Ondieki a master's of surgery student at the University of Nairobi, department of surgery. I am carrying out a six months study on the management of acute traumatic wounds using either gauze or foam (sponge) as wound dressing in negative pressure wound therapy (NPWT). This will involve selected patients admitted in the surgical wards at Kenyatta national hospital. 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 which of the two dressings results in faster wound healing and less pain during dressing change. This information will help improve wound management in patients.

Foam is the current wound dressing used in our hospital during NPWT. Gauze dressing can also be used and am seeking to find out its advantages and disadvantages compared to foam. 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 hospital. 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 randomly allocated for your wound to be dressed with either foam or gauze in NPWT. Measurements of the affected wound will be taken and information stored in a data collection sheet. Your wound will be dressed and then connected to a suction machine. This dressing and measurements will be taken every third day until the wound is ready for further surgical closure or up to a maximum 28 days. The management of the wound after this will be by the appropriate method selected by the ward doctors.

Please talk about this study with your parents/guardian before you decide whether or not to participate. I will also ask your parents/guardian to give their permission for you to participate. However, even if your parents say "yes" you can still decide not to participate. You may also withdraw from the study at any time. This will not compromise the treatment you receive in the ward.

By signing below, you are agreeing to participate in this study with the understanding that your parents/guardians have given you permission to do so. You parents/guardian will be given a copy of this form after you have signed it.

Name _____

Signature_____ Date_____

Parent/Guardian name _____

Signature_____Date_____

Witness_____

Signature_____Date_____

For further information, enquiries or complaints please contact;

1. Dr. Julius Gisore Ondieki mobile number 0721680689 – principal researcher.
2. Chairman, UON/Kenyatta National Hospital ethics and Research committee on Tel 020-2726300 Ext 44355.

APPENDIX VII

CHETI CHA KUKUBALI KWA WALIO CHINI YA UMRI WA MIAKA 18.

Nambari ya kushiriki……

Jina langu ni daktari Julius Gisore Ondieki mwanafunzi wa shahada ya juu ya upasuaji katika chuo kikuu cha Nairobi. Nafanya utafiti kwa muda wa miezi sita kuhusu kutibu vidonda kwa kutumia gauze au foam kuvisha kidonda katika negative pressure wound therapy (NPWT). Utafiti huu utahusisha wagonjwa watakaochaguliwa kushiriki ambao wamelazwa kwenye wodi za upsuaji katika hospitali kuu ya Kenyatta. Utafiti huu umeidhinishwa na kamati ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta.

Utafiti huu unalenga kubainisha ni ipi kati ya foam na gauze itachukua muda mfupi kutayarisha kidonda na kupunguza uchungu wakati wa kuvisha kidonda. Matokeo hayo yatasaidia kuimalisha huduma ya kutibu vidonda kwa wagonjwa wengi.

Foam ndiyo inayutumika kwa wakati huu kuvisha vidonda katika NPWT lakini gauze pia inaweza kutumika. Kusudi langu ni kuelewa uzuri na ubaya wa gauze ikilinganishwa na foam. Kushiriki kwako katika utafiti huu ni kwa kujitolea kwa hiari. Sio lazima ushiriki na kutoshiriki kwako hakutabadilisha jinsi utakavyohudumiwa katika hospitali hii. Maelezo yote yatakayokusanywa yatawekwa kwa siri na jina lako halitatumiwa katika uchapishaji wowote au kutolewa hadharani.

Ikiwa utakubali kushiriki katika utafiti huu utawekwa kwenye kundi litakalovishwa na foam au gauze kwa njia ya kibahati. Kidonda chako kitapimwa na maelezo hayo kujazwa katika kijikaratasi cha utafiti. Baadaye kidonda kitavishwa na kuunganishwa na mashine ya NPWT. Upimaji huu wa kidonda na kuvishwa utarudiwa kila baada ya masaa 72 hadi kidonda kiwe tayari kwa matibabu zaidi ya kukifunika au hadi siku 28 ziishe. Baada ya hapo, kidonda kitafunikwa kwa namna inoyofaa itakayochaguliwa na madaktari wa wodi utakoyokuwa.

Tafadhali ongea na wazazi/walezi wako kuhusu utafiti huu kabla ya kuamua kama utashiriki. Mimi pia nitaongea nao kuwauliza kama watakupa ruhusa kushiriki. Kumbuka ya kwamba hata ikiwa wazazi/walezi wako watakubali bado unaweza kuamua kutoshiriki. Vilevile, una uhuru wa kujiondoa toka kwa utafiti huu wakati wowote ule. Uamuzi huu hautadhuru kwa vyovyote vile ile huduma utakayoipata katika hospitali hii.

Kwa kutia sahihi hapa chini unaidhinisha kukubali kushiriki katika utafiti huu baada ya kuruhusiwa na wazazi/walezi wako. Wazazi/walezi wako vile vile watapewa kopi ya fomu hii baada ya wewe kuitia sahihi.

Jina_____

Sahihi/Kidole_____ Tarehe_____

Mzazi/mlezi_____

Sahihi/kidole_____Tarehe_____

Shuhuda_____

Sahihi_____Tarehe_____

Ikiwa unahitaji maelezo zaidi au una swali au malalamishi unaweza kuwasiliana na;

3. Mtafiti mkuu – Dkt. Julius Gisore Ondieki kupitia nambari ya simu 0721680689.
4. Mwenyekiti wa kamati ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta kupitia nambari ya simu 020-2726300 ext 44355.

APPENDIX VIII

RANDOMIZATION CHART

A Randomization Plan from**http://www.randomization.com**

1. A_____
2. B_____
3. B_____
4. A_____
5. B_____
6. B_____
7. A_____
8. A_____
9. A_____
10. A_____
11. B_____
12. B_____
13. A_____
14. A_____
15. B_____
16. B_____
17. A_____
18. B_____
19. B_____
20. A_____
21. A_____
22. A_____
23. B_____
24. B_____
25. B_____
26. B_____
27. A_____
28. A_____
29. A_____
30. A_____
31. B_____
32. B_____
33. A_____
34. B_____
35. B_____
36. A_____
37. B_____
38. B_____
39. A_____
40. A_____
41. B_____
42. A_____
43. B_____

44. A
45. A
46. B
47. B
48. A
49. B
50. B
51. A
52. A

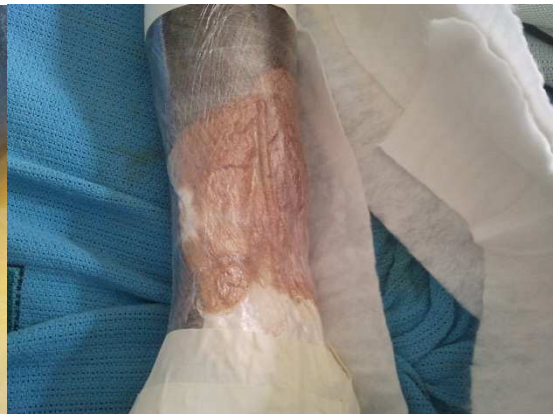
52 subjects randomized into 13 blocks
To reproduce this plan, use the seed 23503
Randomization plan created on Sat Apr 21 2012 10:49:53 GMT+0300 (E. Africa Standard Time)

APPENDIX IX

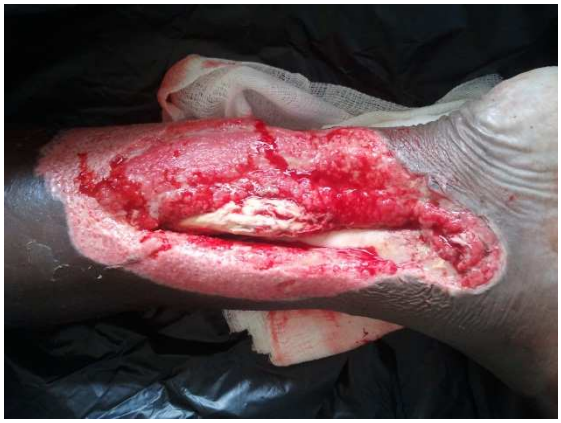
PHOTOS

1. Degloving leg wound

2. NPWT with gauze.

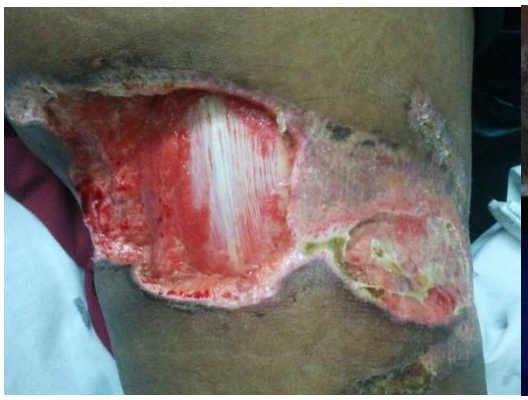
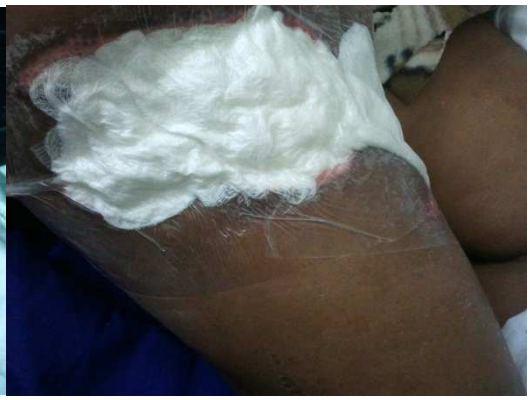


2. Wound after 6 days of therapy. It was later covered with a reverse sural flap.



1. Degloving thigh wound

2. NPWT with gauze dressing.

2. Wound after two NPWT sessions (6 days later). It has contracted and granulated ready for grafting.