COMPARISON OF THE VACUUM ASSISTED CLOSURE (VAC) DRESSING AND GAUZE DRESSING IN THE MANAGEMENT OF ACUTE TRAUMATIC WOUNDS


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DECLARATION

I certify that this dissertation is my original work and has not been presented for a degree in any other university.

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<tr>
<td>ACS</td>
<td>American College of Surgeons.</td>
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<td>BMI</td>
<td>Body Mass Index.</td>
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<td>CBER</td>
<td>Center for Biological Evaluation and Research.</td>
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<td>CM</td>
<td>Centimeters.</td>
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<td>CSSD</td>
<td>Central Sterilization Services Department.</td>
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<td>FDA</td>
<td>Food and Drug Administration.</td>
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<td>Hg</td>
<td>Mercury.</td>
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<tr>
<td>KCI</td>
<td>Kinetic Concepts Incorporated.</td>
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<td>KNH</td>
<td>Kenyatta National Hospital.</td>
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<tr>
<td>M.MED</td>
<td>Masters in Medicine.</td>
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<td>MBChB</td>
<td>Bachelor of Medicine, Bachelor of Surgery.</td>
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<td>MM</td>
<td>Millimeters.</td>
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<td>RCT</td>
<td>Randomized controlled trial.</td>
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<td>UK</td>
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<td>UON</td>
<td>University of Nairobi.</td>
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<td>USA</td>
<td>United States of America.</td>
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<td>VAC</td>
<td>Vacuum Assisted Closure</td>
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ABSTRACT

Background: Vacuum assisted closure dressing is a relatively new concept that has been shown to promote wound healing. This study aimed to investigate the effect of vacuum assisted closure therapy on granulation tissue formation, wound size and the limb circumference at the site of the wound, in comparison to gauze dressing on acute traumatic wounds in the lower limbs.

Methodology: Forty-four wounds, on forty-two patients, were randomly allocated to treatment with either vacuum assisted closure or gauze dressing. The end point was 100% granulation tissue. The wound surface area, diameter and limb circumference were measured every three days.

Results: Wounds managed by vacuum assisted closure achieved 100% granulation tissue formation faster (median time 12 days compared with 21 days), had a higher probability of achieving this (hazard ratio 7.6) and had a significant reduction in wound size (0.79 cm² compared to 0.23 cm², P value < 0.001) compared to wounds managed by gauze dressing. There was also a significant reduction of the limb circumference at the site of the wound (0.47 cm compared with 0.09 cm, P value < 0.001) for patients whose wounds were managed by vacuum assisted closure compared to those whose wounds were managed by gauze dressing.

Conclusion: Vacuum assisted closure dressing is more effective than gauze dressing in the management of acute traumatic wounds in terms of formation of granulation tissue, reduction in wound size and reduction of limb circumference at the site of the wound.
INTRODUCTION

The aim of the surgeon is to achieve wound healing in the shortest time possible with no or minimum complication, using the most cost effective method.

Patients who have sustained traumatic wounds with soft tissue loss often require admission, wound care with dressings until the wound heals or until the wound has been adequately prepared for a reconstructive procedure e.g. skin grafting, rotation of flaps or tissue transfer.

In our setting, after the initial surgical toilet, such wounds are dressed with gauze. The wound is usually cleaned with saline, a non adherent dressing e.g. sofrafur maybe applied on the wound. Gauze is often then placed on this and secured with adhesive tape or gauze roll. This dressing is changed when it is soaked – usually daily or on alternate days.

Vacuum assisted closure (VAC) dressing is a relatively new method of wound management having been introduced about 12 years ago (1). It is now widely used in Europe and North America (2). However in Kenya, only a few surgeons have adopted it.

Vacuum assisted closure dressing has been shown to promote healing in many different types of wounds (2,3). However systematic reviews of literature on VAC therapy report lack of sufficient evidence that VAC dressing is superior to other dressings in the management of wounds (4,5). Most of these studies have been done on chronic and difficult to heal wounds. This study focuses on a common problem - the acute traumatic wounds in the lower limb.

The purpose of this study is to investigate the effect of vacuum assisted closure dressing on granulation tissue formation, wound size and limb circumference in comparison to gauze dressing on acute traumatic wounds in the lower limbs.
LITERATURE REVIEW

MANAGEMENT OF ACUTE TRAUMATIC WOUNDS

Wounds are classified as acute or chronic. Acute wounds are those that proceed through an orderly and timely reparative process to achieve restoration of structure and function. The chronic wound on the other hand fails to proceed to restoration of sustained structural and functional integrity (6).

A patient who presents with an acute traumatic wound must first be managed according to the advanced trauma life support protocol of airway, breathing and circulation so as to identify and deal with any immediate life threatening conditions (6).

Once the patient has been resuscitated and stabilized a detailed history should then be obtained. The history should include the mechanism of injury and an exploration of factors that may affect wound healing such as advanced age, poor nutritional state, cigarette smoking, drugs e.g. corticosteroids, cytotoxics and concomitant diseases such as diabetes, cardiac, respiratory or renal disorders.

On examination, the patient’s general condition is assessed – specifically vital signs, nutrition state, cardiac and respiratory functions. Attention is then turned to the wound(s) and the following should be noted- site and size of wound, degree of contamination, anatomical structures that are (or may have been) injured or exposed, the presence of fractures and distal perfusion (7). Proper wound exploration is however done under local anaesthesia or general anaesthesia at wound excision.

If wound excision can not be done immediately, the wound should be covered in sterile or clean dressings. Antibiotics, analgesics and tetanus prophylaxis should be given and arrangements made to do surgical toilet as soon as possible.

The American College of Surgeons has classified wounds according to the degree of contamination into class I (clean), class II (clean contaminated), class III (contaminated) and class IV (dirty). Traumatic wounds (excluding those due to surgery) fall in class III and class IV.
Class III wounds include fresh traumatic wounds from a relatively clean source while Class IV wounds include traumatic wounds from a dirty source or where treatment is delayed (6).

Otieno J. A. found that the commonest cause of traumatic soft tissue loss in patients admitted to Kenyatta National Hospital (KNH) was road traffic accident (65.5%) followed by assault (10.9%), animal bite (7.3%) industrial accidents and gunshot injuries. These injuries affected most commonly people of age 21-40yrs (54.6%) which is the most productive age group. He also found that 85.5% of patients presenting at KNH with acute traumatic wounds with soft tissue loss had dirty (class IV) wounds while only 14.5% had contaminated (class III) wounds(8).

**Wound excision**

The patient is given local or general anaesthesia and the wound is thoroughly cleaned with normal saline. All foreign material, haematoma and non viable tissue are removed. Bone without any soft tissue attachment is also removed. Haemostasis is achieved by either ligature or cautery. The wound is irrigated with copious amounts of saline. Exposed bone and tendon should be covered with soft tissue (muscle). Once a clean wound, with viable easily bleeding tissue is achieved, a decision on how to close the wound is made (6).

Recently a hydrosurgical system of debridement known as Versajet was introduced by Smith and Nephew of Hull, U.K. This is a device that facilitates simultaneous irrigation and debridement of the wound using a high velocity jet of sterile saline and a vacuum system. Its advantages include minimal bleeding, removal of only non-viable tissue with preservation of healthy tissue and it is a much faster procedure to perform than surgical debridement (9,10).

**Wound Dressing**

Wounds should be dressed until wound closure or healing is achieved. Traditionally wet to dry gauze has been used to dress wounds. Dressings that create and maintain a moist environment are now considered to provide optimal conditions for wound healing. Moisture under occlusive dressings increases the rate of epithelialization (11). Gauze may be disruptive to the healing wound as it dries and causes tissue damage when it is removed. It is therefore not widely used in some developed countries (11).
An ideal dressing should have the following characteristics-
- Capable of maintaining a high humidity at the wound site while removing excess exudate
- Free of particles and toxic wound contaminants
- Non toxic and non allergenic
- Capable of protecting the wound from further trauma
- Can be removed without causing trauma to the wound
- Impermeable to bacteria
- Thermally insulating
- Will allow gaseous exchange
- Comfortable and conformable
- Require only infrequent changes
- Cost effective
- Long shelf life

There is no ideal dressing that has been developed yet. Depending on structure and composition, different dressings are used to absorb exudate, combat infection or odor, relieve pain, promote debridment and provide/maintain a moist environment (6,11).

The following types of dressings exists

1. Absorbent dressings: These include cotton and sponge. They are designed to match the exudative properties of the wound

2. Non adherent dressings: They are impregnated with paraffin, petroleum jelly or water soluble jelly, for example, Bactigras. A secondary dressing must be placed on top to prevent desiccation and infection.

3. Occlusive and semi occlusive dressings: They are water proof and impervious to microbes but permeable to water vapour and oxygen, for example, tegaderm, op site.

4. Hydrocolloid and Hydrogel: They attempt to combine the benefits of occlusion and absorbency. They form complex structures with water and fluid absorption occurs with particle swelling. This aids atraumatic removal of the dressing.

5. Alginates: Calcium alginates turn into sodium alginates through ion exchange in the presence of wound exudates. The polymers swell and absorb fluid.

6. Medicated dressings: Agents delivered in dressings include benzoyl peroxide, zinc oxide, neomycin, bacitracin, povidone iodine and metronidazole. (6,11)
Wound Closure

Wounds can be closed primarily, by delayed primary closure or they can be left to heal by secondary intention. Reconstructive procedures can be used to achieve wound closure for larger wounds. These include skin grafting, rotation of flaps and tissue transfer (6).

Wounds that are treated within 6 hours of injury, are located in a well vascularized region of the body and are not heavily contaminated are treated by primary closure. The edges are apposed accurately using sutures and hence heal by primary intention.

Wounds that are treated 6 hours after the injury and are located in regions of the body that are not well vascularized should be treated by delayed primary closure in the absence of soft tissue loss. The wound is dressed or a vacuum assisted closure system applied for 48hrs to 72hrs. If the wound is clean with no signs of infection, it is sutured and allowed to heal by primary intention (6, 7).

Wounds with full thickness skin loss may be allowed to heal by secondary intention i.e. granulation tissue formation, contraction and epithelialization. During this period when the wound is open, the wound is dressed or a vacuum assisted closure system applied.

Larger wounds require closure using reconstructive techniques including skin grafting, rotation of flaps or use of free flaps (tissue transfer). These procedures are usually not carried out in the acute setting. In such cases the wound is dressed or vacuum assisted closure system applied and when there are no signs of infection and the wound bed has healthy granulation tissue then the reconstructive procedures may be carried out.

The concept of the reconstructive ladder enables the surgeon to choose the simplest and the most effective method to achieve wound closure starting with allowing the wound to heal by secondary intention for smaller wounds to tissue transfer for the more complex wounds (12).
Other factors that influence the method of wound closure include the patient’s general state of health, motivation, as well as the cost – benefit ratio of the proposed reconstruction (12).

**VACUUM ASSISTED CLOSURE (V.A.C)**

Vacuum assisted closure (also called topical negative pressure therapy, vacuum sealing, vacuum therapy or vacuum dressing) was first described by Fleishmann et al in 1993 (1) and has been popularized by Morykwas and Argenta of Wake Forest University, U.S.A (2).

It is now widely used in Europe and North America for wound management by surgeons of all specialties (2). However, in Kenya, it is still a new concept that is practiced only by some plastic surgeons.

**Technique**

The vacuum assisted closure dressing is applied to the wound that has been cleaned, debrided and haemostasis achieved (3).

A sterile sponge is trimmed to the size and geometry of the wound. Embedded in the sponge is a non-collapsible tube drain with multiple lateral perforations. In large wounds, multiple sponges placed in contact with each other may be used.

The sponge is placed in the wound ensuring close contact with all wound surfaces. The entire area is then covered by a plastic membrane that is firmly secured to the surrounding healthy skin around the wound margin to achieve an airtight seal. The exposed end of the tube drain is connected to a canister into which effluent from the wound will collect when the sub-atmospheric pressure is applied (3,13).
The canister is connected to a vacuum source. It has been shown that a negative pressure of 125mmHg is optimal (14). The sub-atmospheric pressure may be applied continuously or it may be applied intermittently in cycles of 5 minutes on / 2 minutes off. Some studies indicate that the intermittent application of negative pressure may be superior in terms of achieving faster wound healing (3, 14).

A partial vacuum is therefore created within the wound, reducing its volume and facilitating the removal of fluid. The foam ensures that the entire surface area of the wound is uniformly exposed to this negative pressure and also prevents occlusion of the perforations in the drain by preventing its contact with the base or edge of the wound (14). The transparent plastic membrane ensures an airtight seal and also allows the surgeon to inspect the tissue adjacent to the wound.

The patient has to remain close to the suction machine, either in bed or on a chair. However the patient/nurse may disconnect the tube drain when the patient needs to go the toilet. The patient/nurse then reconnects it there after (2).

This system (VAC) has been commercialized and is produced in the USA by Kinetic Concepts Inc (KCI) of San Antonio Texas (3,14). Various modifications can be made to this basic system.

1. A second catheter can be installed into the sponge through which fluid can be instilled into the wound. This allows contaminated wounds to be continuously irrigated so that particulate and bacterial matter can be continuously removed (2).

2. The sponge interface used has been refined and made uniform. There are two types of foam available, a polyurethane ‘black’ form with an average pore size of 400-600um and a denser polyvinyl alcohol white foam. The white foam is useful in areas where a rapid rate of granulation tissue is less desirable. Silver coated sponges decrease the odor of the wound and probably also the bacterial counts (2).

3. Various commercial devices include alarms systems that warn of excessive fluid output, bleeding and loss of adequate seal (2).

4. The size of these devices has also reduced and are now available in portable sizes that can be used at home and allow the patient to ambulate (2).
Figure 1. Trimming of the polyurethane sponge.

Figure 2. Placing the suction drain in the sponge.

Figure 3. Adhesive drape being applied over the sponge.

Figure 4. Continuous suction within the sponge.
Mechanism of Action

The mechanism of action of the vacuum assisted closure is not completely understood yet (15). However the following have been observed.

1. *Increased blood flow*

   Several animal studies on pigs and rabbits have demonstrated an increase in the local perfusion in the wound to which negative pressure was applied (14, 16, 17).

2. *Increased formation of granulation tissue.*

   Morykwas et al demonstrated an increased rate of granulation tissue formation in wounds treated by vacuum assisted closure (14). In a study to determine synergistic effects of hyperbaric oxygen with vacuum assisted closure device in a rabbit model, Fabian et al found that use of the vacuum assisted closure device caused a significant increase in the rate of granulation tissue formation although they did not find any significant synergistic effects of the combination of vacuum assisted closure and hyperbaric oxygen (18).

   Morykwas et al in another study also found that wounds filled significantly faster with granulation tissue when a negative pressure of 125mmHg was applied to wounds compared with 25mmHg and 500mmHg (19).

3. *Bacterial clearance*

   Morykwas et al reported a significant decrease in the number of organisms per gram tissue after 4 to 5 days treatment of wounds with vacuum assisted closure system (12). Moues et al reported a significant decrease in non-fermentive gram negative rods e.g. pseudomonas but an increase in staphylococcus aureus in biopsy specimen harvested from vacuum treated wounds (20).

The application of sub atmospheric pressure to wounds causes increased blood flow and therefore increased local oxygen levels. This reduces or eliminates the growth of anaerobic organisms the presence of which has been correlated to decreased healing rates. In addition greater amount of oxygen is available to neutrophils for the oxidative bursts that kill bacteria (14, 15).
Physiologic basis

Two broad mechanisms have been proposed to account for the increased rate of healing for the wounds treated with the vacuum assisted closure system—a fluid-based mechanism and a mechanical mechanism (15).

(a) Fluid-based mechanism

Application of a controlled vacuum to the wound interface facilitates the removal of excess interstitial fluid because of the pressure gradient created. This results in a decrease in the interstitial pressure, which falls below the capillary pressure. The capillaries re-open and flow to periwound tissue is restored. This mechanism is also responsible for the success of this technique in decompression of the compartment syndrome (14, 15).

All non bound soluble factors will be removed with the fluid. This includes both the factors that inhibit and those that promote wound healing. Various factors, including growth factors, metalloproteinases, C-reactive proteins in the fluid removed from wounds treated with vacuum assisted closure, have been measured. However due to the complex interaction of the factors and the fact that their roles in wound healing have not been completely elucidated it is difficult to determine the effect of VAC in this area of wound healing at the moment (14).

(b) Mechanical mechanism

The skin (and most tissues) is viscoelastic; it will deform slowly over time when mechanical force is applied to it (21). In addition the mitotic rate of the stretched cells is increased (22, 23). The applied forces deform the extracellular matrix and therefore the cells which are anchored to it. Cell deformation has been shown to cause a wide variety of molecular responses including changes in ion concentration and permeability of membrane ion channels, release of second messengers, stimulation of molecular pathways and alteration in gene expression and therefore increased mitosis. This effect is the basis of tissue expansion and osteogenic distraction (22-26).

Vacuum assisted closure causes deformation of tissues at the wound/sponge interface and also in the periwound area. At the site of the wound, application of vacuum causes collapse of the sponge, drawing the wound edges together. It also causes microdeformation as small mushrooms of tissue are drawn into the pores of the sponge dressings (27). Tissues in the periwound area also
stretched when vacuum is applied. One study showed that surface strain 8cm from the wound edge was still 5% (15). This distant strain may still result in an increased mitotic rate in these periwound areas.

Chen et al have reported an increase in several proto oncogenes, including myc, c-jun and bcl-2 in both acute and chronic wounds treated with vacuum assisted closure (28).

Therefore it appears that vacuum assisted closure applies mechanical forces to wounds resulting in deformations of tissues and their cells. This is followed by activation of pathways resulting in increased mitosis and therefore production of new tissue (15).

An artist rendition of the VAC sponge applied to a wound. It decreases oedema, draws wound edges to the center and increases local perfusion.
Clinical Application

The concept of vacuum assisted closure is now widely accepted in Europe and North America and is used by multiple specialties in the treatment of a wide variety of wounds (2). The clinical conditions for which VAC has been used are discussed below.

1. Chronic wounds
Vacuum assisted closure system was first (and is still) used to treat chronic wounds, so that care of these patients could be simplified and accomplished outside the hospital. It has been used in patients with pressure ulcers, vascular ulcers, venous stasis ulcers and diabetic ulcers (29-32).

Vacuum assisted closure therapy has been found to achieve a faster rate of granulation tissue formation (33) and to decrease the wound depth and volume more effectively than moist gauze dressing in patients with diabetic ulcers (33, 34).

2. Acute wounds
Vacuum assisted closure has become widely accepted in the treatment of large soft tissue injuries (2). Non viable tissue is debrided, foreign bodies are removed, haemostasis achieved and appropriate coverage of vital structures such as major vessels, viscera and nerves by mobilization of local soft tissue accomplished. The wound is then treated by vacuum assisted closure (3).

This technique enables the surgeon to safely and expeditiously prepare the wound bed for the standard reconstructive procedures to be performed (2). This may reduce hospital stay for these patients (35).

The extremities
The extremities (upper and lower limbs) are often exposed to high velocity injuries. This results in acute traumatic wounds often with significant soft tissue loss and sometimes bony and vascular disruption (3).

This may cause significant bleeding and oedema in the surrounding tissue, causing increased pressure. The increased pressure compromises the zone of stasis causing further enlargement of the wound. Exposed bone desiccates and may become infected, requiring debridement. The result is a large wound and a larger bony gap (3).
After cleaning and debridement, VAC is applied to the wounds. This results in a sealed moist environment where the tissue is given an opportunity to survive as excess interstitial fluid is removed and perfusion increased. Viable tissue is drawn together resulting in a smaller wound. Bone is kept in a moist environment minimizing desiccation. Definitive reconstruction can be performed in a stable clean wound on an elective basis (36, 37).

Vacuum assisted closure has been used in wounds with exposed bone. Granulation tissue forms around and over exposed bone. The rate of granulation tissue can be increased by placing drill or bore holes in the cortex of the exposed bone (37). Plates and screws used for bony fixation may become exposed after orthopedic surgery. Directly covering the hardware (plates and screws) with vacuum assisted closure dressing can produce sufficient granulation tissue to cover such hardware (37).

Successful management of degloving injuries using VAC has been reported. There are several reports of degloved parts being defatted to full thickness grafts, fenestrated, re-applied to the patient and covered with a vacuum assisted closure dressing for 5 to 6 days. Good results have been obtained despite large traumatized and contaminated segments of tissue (38, 39).

**Chest wounds**

Post operative sternal infections, sternal instability and mediastinitis dramatically increase morbidity, mortality, hospitalization and expense. Serial debridement of non viable tissue and use of myocutaneous flaps has been the standard of treatment but this unfortunately has to be done in debilitated patients and secondary complications and death are not infrequent (2).

Cardiac surgeons in the west are now embracing debridement of the sternum and use of VAC as the primary initial treatment for sternal infections. The chest is stabilized so that the need for ventilator assistance is decreased and fewer painful dressing changes are required. The number of soft tissue flaps needed for closure after VAC is decreased (40-42).
**Abdominal wall defects**

Injuries or surgery to the abdomen may result in difficulties in closure of the abdominal wall. VAC has been used in such conditions where there are abdominal wall defects.

It has the benefit of removing wound contaminants and intra abdominal exudates (thus decreasing oedema) and drawing together the fascia so that delayed primary closure can be achieved (43, 44). This has resulted in successful fascia closure in a high percentage of patients who would otherwise have required hernia repair later. It has increased the rate of survival; decreased time spent in hospital and decreased the rate of enterocutaneous fistula formation (43, 44).

The presence of an enterocutaneous fistula was one of the contraindications for the use of vacuum assisted closure therapy. There are now reports of the successful treatment of patients with enterocutaneous fistula with vacuum assisted closure therapy (45-47).

**Perineum**

Wounds in the perineum are difficult to manage because dressing changes are difficult and risk of contamination is high. Use of vacuum assisted closure is also difficult due to problems achieving an air tight seal (2).

However, there are reports of successful application of vacuum assisted closure therapy to a variety of perineal wounds. It has been useful in treating excised pilonidal sinuses, defects resulting from abdominoperineal resection and pelvic exenterations (48-52).

**Skin grafting**

Split thickness or full thickness skin grafting remains a frequent and necessary reconstructive procedure for many patients. Classically a tie over bolster has been used to immobilize the graft in the postoperative period (2).

Vacuum assisted closure has been applied as bolster dressing after skin grafting with success. Fenestrations are made into the skin graft so that serum and blood can be drawn through the sponge. A non adherent dressing is placed over the graft. The sponge is then placed over the non adherent dressing and the negative pressure of 100-125mmHg applied for 4-5 days (2).
The sponge contours perfectly over the surface of the recipient site and maintains a predetermined pressure on the skin graft minimizing its disruption. Application of negative pressure changes the passive process of inosculation into an active one by creating a pressure gradient, nutrients flow actively from the tissue bed into the transplanted skin (2).

It has been reported that this technique results in a significant increase in successful graft take (53-56). One study noted significantly improved quality of the graft compared to non treated grafts (56). This technique is particularly useful in the difficult areas of the perineum, axilla and lower extremities.

**Burns**

Results from several small studies have demonstrated a decrease in oedema and an increase in perfusion of tissue adjacent to the burn (57-59). However more work needs to be done in this area.

**Others applications**

VAC has also been used successfully for a variety of wounds- in the head and neck (60), infected postoperative wounds in the back after spinal surgery (61) and wounds resulting from necrotizing fasciitis (62).

It may also be used in wounds as a result of insect bites (63) and other animal bites and wounds resulting from extravasation of toxic drugs (64).

Morykwas et al demonstrated a decrease in serum myoglobin levels in patients who had prolonged crush/ischaemic injury and were treated using VAC (65). Therefore, in situations where there is envenomation or release of a toxin as a result of the wound, vacuum assisted closure may have a role in the reduction/removal of such substances from the body.

VAC has been used successfully in children, from the neonate to the older child. The wounds that may be treated this way in children include those due to pilonidal disease, traumatic soft tissue wounds, sacral and extremity ulcers etc (66-68).
Complications
As the VAC is being more widely used and adapted to multiple problems, complications are being reported.

1. Two cases of toxic shock syndrome associated with VAC have been reported (69). In one case it appears the drainage was partially or completely blocked and in the other computer data indicates that the device was never turned on. There is potential for toxic shock in any patient with a foreign body in a wound for several days.

2. Wound healing complications may occur when pieces of sponge is lost in the wound. Use of multiple small sponge fragments should therefore be discouraged (2).

3. Bleeding in the post operative period in patients on anti coagulant therapy has occurred (2). More significant bleeding secondary to disruption of major vessels, vascular grafts, cardiac by pass grafts or the ventricle itself has occurred when the sponges are placed directly on these structures (2,70). These structures should be covered first by non-adherent dressing or adjacent muscle: the sponge of VAC is then placed on top of this. Wall suction should be avoided as the force of negative pressure varies considerably (2). Patients in whom vacuum assisted closure system has been applied close to a major vessel or to the heart should be monitored in high dependency unit (2).

4. Application of vacuum assisted closure dressing to large wounds may result in excessive suction of fluid leading to hypovolemia (71). However, Argenta et al noted that exudate volumes of up to 1000mls of fluid per day can safely be removed without any significant haemodynamic or biochemical imbalance.

5. There is also a report of vacuum assisted closure therapy resulting in hypoalbuminemia and anarsarca (72).

6. Pressure of the evacuation tube on the adjacent tissue may result in erosion of this tissue if the tube is placed over bone or if the patient lies on it (14).

7. Pain especially in the first 20 minutes has been reported, but most patients report being more comfortable with the vacuum closure dressing than the previous gauze dressing (14).

8. Excessive growth of granulation tissue into the foam dressing may occur and this may result in some bleeding but most of this easily controlled by pressure (14).

9. Foul odor may be a problem especially in chronic wounds.
Contraindications

The following are currently considered to be contraindications to vacuum assisted closure therapy.

1. Necrotic tissue in the wounds.
2. Untreated osteomyelitis.
3. Malignancy in the wound.
4. Where haemostasis has not been achieved (3).

It should be used with caution in the following situations.

1. Near major vessels or the heart.
2. Patients on anti-coagulants (3).

Is vacuum assisted closure superior?

Although vacuum assisted closure has become quite popular in the West, Gregor et al have noted that the ‘total number of studies, their sample size and their quality are inadequate’ (73). Vermeulen et al have also noted that this lack of quality research also affected many wound therapies (4). Ubbink et al found only 15 publications on 13 randomized control trials in their systematic review of topical negative pressure therapy and concluded that there was no worthwhile evidence to support the use of topical negative therapy in the treatment of various wounds. However, they noted that individual trial data on chronic and diabetic wounds treated with topical negative pressure therapy appear to be ready for secondary closure surgery between 1 to 10 days earlier than controls (5).
JUSTIFICATION

Vacuum assisted closure (VAC) dressing for the treatment of wounds is a relatively new innovation; the first reports having been published about 12 years ago (1).

It is currently widely used in North America and Europe. However in Kenya, only a few plastic surgeons are currently using it in the management of wounds.

To the best of my knowledge, there is no published data on the use of VAC dressing in sub-Saharan Africa. This study aims to bridge this gap and possibly provoke interest in the use of vacuum assisted closure dressing.

The vacuum assisted closure device in the developed countries is an expensive device. In this study I used cheap, locally available material.

In our setting vacuum assisted closure dressing has mainly been used on complex, difficult to manage wounds, which are often chronic. In this study I seek to demonstrate its usefulness in the management of acute traumatic wounds, which is one the commonest type of wounds we encounter in our daily surgical practice.
OBJECTIVES

Broad Objective
To establish if the vacuum assisted closure dressing is more effective than gauze dressing in the management of acute traumatic wounds.

Specific objectives
1. To determine if the vacuum assisted closure dressing significantly reduces the time to achieve 100% granulation tissue cover of the wound compared to gauze dressing.

2. To determine if the vacuum assisted closure dressing is more effective than gauze dressing in achieving reduction in wound surface area.

3. To determine if the vacuum assisted closure dressing significantly reduces lower limb circumference in the limb with an acute traumatic wound compared to gauze dressing.

HYPOTHESIS

Vacuum assisted closure dressing is not more effective than gauze dressing in the management of acute traumatic wounds.
METHODOLOGY

1. Study design
Randomized control study

2. Study setting
Kenyatta National Hospital, general surgery and orthopaedic wards.

3. Sample size
Braakenburg et al reported a 4 day shorter median healing time in patients with acute and chronic wounds, treated with vacuum assisted closure dressing compared with those treated with other dressings (74). Using this and a standard deviation of 2.08, we calculate that a total sample size of at least 42 patients (21 in each group) are required to find a difference of 4 days in healing time at 5% significance level with a power of 90%. The following formula was used for this calculation.

\[ n = \frac{(A+B)^2 \times 2 \times SD^2}{DIFF^2} \]

\( n \) = the sample size required in each group.
\( SD \) = standard deviation of the difference in the mean of the primary outcome.
\( DIFF \) = size of difference to be detected.
\( A \) depends on the desired significance level – here is 1.96.
\( B \) depends on the desired power – here is 1.28.

4. Patients

Inclusion Criteria
1. Patients with acute trauma to the lower limbs.
2. Injury should have occurred less than 48 hours prior to the recruitment into the study.
3. They must have full thickness soft tissue loss.
4. They must have undergone a surgical toilet to remove all non-viable tissues and foreign bodies.
5. The patients must be aged above 18 years.
6. Patients who are haemodynamically stable.
Exclusion Criteria

1. Patients in whom injury occurred more than 48 hours prior to the recruitment into the study.
2. Partial thickness wounds.
3. Wounds with exposed major blood vessels or those in which haemostasis has not been achieved.
4. Wounds that have non-viable tissue or are contaminated with foreign bodies, (i.e. those that have not been debrided).
5. Wounds in patients who have vascular injury or those with signs of ischemia.
6. Wounds due to causes other than trauma.
7. Patients 17 years and below.
9. Patients who have psychosis, diabetes mellitus or are known to have renal failure.
10. Patients on anti-coagulants, chemotherapy or corticosteroids.
11. Patients who refuse to give consent.
12. Patients who are haemodynamically unstable.

Method

Once every week, two patients who met the above criteria and accepted to participate in the study were recruited. One patient was allocated to the vacuum assisted closure group and the other to the gauze dressing group. They were randomly allocated to the two groups by tossing a coin.

Group 1- Vacuum assisted closure group

This group of patients was managed using vacuum assisted closure dressing as per the protocol outlined below.

Group 2- Gauze dressing group

The wounds of these patients were dressed by the nursing staff as per the existing protocol in the surgical wards at the Kenyatta National Hospital.

The following information was then collected and recorded in a data collection sheet.

1. Age.
2. Sex.
3. Height, weight, calculated body mass index (BMI)
4. Date and time of injury.
5. Date and time of recruitment into study.

The wounds shall be assessed on the day after surgical toilet (day 1), on day 3 (i.e. after 48 hours) and subsequently on every third day (i.e. after every 72 hours), that is, day 6, 9, 12, 15 etc.

On day 1 the following information was collected.

a) Class of the wound (according to the American College of Surgeons)
   (i) Class III—contaminated
   (ii) Class IV—dirty.

b) Site of wound - thigh, leg, or foot.

c) Surface area-
   A tracing paper was used to trace the margin of the wounds. This was then placed on a graph paper and the number of boxes within this margin counted to calculate the surface area.

d) Limb circumference at the site of the wound.
   The limb circumference was measured at the point where the wound was widest.
   The distance from this point to a fixed point on the limb, for example, medial malleolus or tibial tuberosity was noted so that the limb circumference at the same point was taken at subsequent measurements.

On day 3 and every subsequent 3rd day (i.e. day 6, 9, 12, 15 etc.) the following information on the wound was collected and recorded.

   a. Wound surface area as above.
   b. Limb circumference as above.
   c. The presence of necrotic tissue was noted. The patient was debrided under local or general anaesthesia in conjunction with the ward team when necrotic tissue was found in the wound.

The wound management and assessment of each patient was continued until the following end point are achieved - wound with 100% granulation tissue.
Group 1: Vacuum Assisted Closure group

The patients who were recruited into this group had their wounds assessed as described above. The vacuum assisted closure dressing was then applied as follows.

1. The wound was cleaned with normal saline.
2. A sterile sponge (foam mattress) was trimmed at the bedside to the size of the wound.
3. The sponge was placed on the wound.
4. A suction catheter, on which additional lateral perforations had been made, was then placed on the sponge.
5. A second sponge was placed on these (the first sponge and suction catheter) ensuring that all the holes on the suction catheter were covered within the two sponges.
6. A plastic membrane (cling film) was then be placed over the above (and where possible wrapped around the limb) to achieve an air tight seal.
7. The other end of the suction catheter was connected to a suction machine.
8. The suction machine was turned on and set at a pressure of negative 125mmHG. The fluid withdrawn from the wound was collected in a canister in the suction machine.

- When the suction machine was turned on, the sponge on the wound collapsed and remained collapsed as long as the airtight seal was maintained and the suction machine was on. This indicated that negative pressure was being applied on the wound.
- The vacuum assisted closure dressing was changed on day 3 (i.e. after 48 hours) and subsequently on every third day (i.e. after every 72 hours—day 3, 6, 9, 12 and so on).
- The vacuum assisted closure dressing was also changed whenever the airtight seal was lost as indicated by failure of the sponge to remain collapsed.
- Analgesics were given to the patient as required when the patient was in pain.
- The patient was taught how to switch off the suction machine and to disconnect the suction tube from the suction machine. He/she would do so whenever he/she wished to visit the toilet.
- The wounds were assessed as described above and measurement recorded in the data collection sheet.
- Vacuum dressing was be stopped when,
  a) There are signs of excessive bleeding.
  b) The patient requested or opted out of this form of treatment.
  c) There were signs of complications or adverse events as a result of this treatment.
- Complications, complaints and adverse events were noted and recorded.
Group 2: Gauze Dressing Group (Control Group)

The patients who were recruited into this group had their wounds assessed as described above. These patients’ wounds were dressed by the nurses, as per current practice at Kenyatta National Hospital. Currently at Kenyatta National Hospital wounds are cleaned with saline; sofratulle may be used as a primary dressing and gauze is applied on this as a secondary dressing. The dressings are changed every day or on alternate days.

- The wounds were assessed as described above on day 1, day 3 (i.e. after 48hrs) and subsequently on every third day (i.e. day 6, 9, 12 and so on) until the end point was reached.
- Wound debridement was done as required whenever there is necrotic tissue in the wound.
- Analgesics were given to the patient as required.
- Complications and adverse reactions were noted.
DATA ANALYSIS

Data was collected between February 2008 and October 2008. It was collected by the chief researcher and two assistants and recorded in a data collection sheet (appendix I).

Descriptive statistics was performed for patients' characteristics. Kaplan-Meier survival curve was used for the description of the distribution of healing time and to estimate the median healing time for each group. Linear regression was used to analyze secondary objectives with continuous variables.
RESULTS

Forty-five patients, who were eligible, were recruited into the study. The data of three patients who dropped out of the study before reaching the endpoint was excluded from the data analysis. Two of these patients (one in the gauze group and the other in the vacuum assisted closure group) were discharged, due to social reasons, before achieving 100% granulation tissue. The third patient, whose wound was being managed by vacuum assisted closure dressing, did not achieve 100% granulation tissue because the suction machine in his ward broke down. His wound was subsequently managed by gauze dressing.

Data from wounds of forty-two patients, (34 male, 8 female) was analyzed. Two patients had two wounds, one on either lower limb. Data from forty-four wounds was thus analyzed. (figure 1)
Table 1. Summarizes the patients’ characteristics.

<table>
<thead>
<tr>
<th>MEASURES</th>
<th>VAC</th>
<th>GAUZE</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE (yrs)</td>
<td>Mean</td>
<td>34.0</td>
<td>31.5</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>32</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>20-62</td>
<td>23-46</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>23.5</td>
<td>24.9</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>23</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>19-31</td>
<td>21-31</td>
</tr>
<tr>
<td>Wound surface area (cm²)*</td>
<td>Mean</td>
<td>204.6</td>
<td>135.8</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>124.9</td>
<td>95.0</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>59-1153.4</td>
<td>46.6-536.0</td>
</tr>
<tr>
<td>Wound diameter (cm)*</td>
<td>Mean</td>
<td>15.3</td>
<td>11.7</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>12.5</td>
<td>9.8</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>7.1-47.2</td>
<td>5.5-27.6</td>
</tr>
<tr>
<td>Limb circumference (cm)*</td>
<td>Mean</td>
<td>36.0</td>
<td>37.1</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>35.7</td>
<td>35.8</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>23.5-58.1</td>
<td>24.6-78.3</td>
</tr>
</tbody>
</table>

* wound measurements at recruitment into study

There was no statistically significant difference between the two groups of patients (all the p values are >0.05).

The Kaplan-Meier survival plot (figure 2, below) shows the time taken to achieve full granulation. Patients with vacuum assisted closure took shorter time in achieving 100% granulation as compared to patients who received gauze dressing. The median number of days achieving full granulation in VAC group was 12 days as compared to 21 days in the gauze group. This was statistically significant (P value <0.0001)
The results from the Cox regression model reveal that patients in the Vacuum assisted closure dressing group had a higher probability of achieving 100% granulation tissue formation (hazard ratio 7.6, 95% confidence interval 3.27 - 17.9). Patients with class 3 wounds also had a higher probability of achieving 100% granulation tissue formation compared with patients who had class 4 wounds (hazard ratio 2.35, 95% confidence interval 1.09 - 5.04).
Linear regression was used to compare data of the wound surface area, wound diameter and the limb circumference at the site of the wound (table 2).

Table 2: VAC vs Gauze – change in wound size and limb circumference

<table>
<thead>
<tr>
<th></th>
<th>Average Change in size</th>
<th>P - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wound surface area (cm²)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAC</td>
<td>-0.789</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Gauze</td>
<td>-0.233</td>
<td></td>
</tr>
<tr>
<td><strong>Wound diameter (cm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAC</td>
<td>-0.101</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Gauze</td>
<td>-0.032</td>
<td></td>
</tr>
<tr>
<td><strong>Limb circumference (cm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAC</td>
<td>-0.473</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Gauze</td>
<td>-0.089</td>
<td></td>
</tr>
</tbody>
</table>

There was an average reduction in wound surface area of 0.79cm² for the VAC group compared with 0.23cm² for the gauze group (figure 3). This was statistically significant (P value <0.001).
The average reduction in wound diameter in the VAC group was 1.01 cm compared with 0.03 cm in the gauze group (figure 4). This was also statistically significant (P value 0.001). A slight increase in the wound size was noted in the first three 3 days of treatment in the gauze group (figure 5 & 6).

Figure 4
Figure 5.

The individual wound surface area profiles

Figure 6.

The individual wound diameter profiles
The average limb circumference at the site of the wound was 38.36cm. On average the limb circumference reduced by 0.47cm in the vacuum assisted closure group compared with 0.09cm in the gauze group. This was statistically significant (P value 0.001). None of the patients in this study developed signs and symptoms of compartment syndrome.

Figure 7

The presence of erythema or pus was considered to be a sign of infection. Table 3 shows the rates of infection in the two groups. There were clinical signs of infection in 13.6% of the wounds managed by vacuum assisted closure dressing compared 72.7% in the gauze group.
Table 3

<table>
<thead>
<tr>
<th></th>
<th>NO</th>
<th>YES</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAC</td>
<td>19 (86.4%)</td>
<td>3 (13.6%)</td>
<td>22</td>
</tr>
<tr>
<td>GAUZE</td>
<td>6 (23.3%)</td>
<td>16 (72.7%)</td>
<td>22</td>
</tr>
<tr>
<td>TOTAL</td>
<td>25 (56.8%)</td>
<td>19 (43.2%)</td>
<td>44</td>
</tr>
</tbody>
</table>

Figure 8: Infection rate
DISCUSSION

The results of this study show that vacuum assisted closure dressing is more effective than gauze dressing in the management of the acute traumatic wounds. Wounds managed by vacuum assisted closure achieved 100% granulation tissue formation faster (median time 12 days compared with 21 days), had a higher probability of achieving this (hazard ratio 7.6) and had a significant reduction in wound surface area (0.79 cm² compared to 0.23 cm², P value < 0.001). There was also a significant reduction of the limb circumference at the site of the wound (0.47 cm compared with 0.09 cm, P value < 0.001).

There is no published randomized control trial comparing vacuum assisted closure to gauze dressing in the management of acute traumatic wounds. Most randomized control trials have been done on chronic wounds and they compare vacuum assisted closure to modern dressings (i.e. hydrocolloids, hydrogels, alginates and foams). These type of dressings are rarely used in our country.

The only published randomized control study on acute wounds is by Armstrong et al who investigated diabetic foot amputation wounds. They report that in a 16 week period 43 of 77 (56%) VAC treated wounds versus 33 of 85 (38%) controls achieved complete wound closure. The patients in the control group were managed using hydrocolloids, hydrogels, alginates and foam (34).

Braakenburg et al compared vacuum assisted closure with other dressings (hydrocolloids, hydrogels and alginates) on patients with acute and chronic wounds. Only 7 out of 65 patients had acute wounds. They reported a median healing time (end point - 100% granulation tissue / healing by secondary intension) of 16 days with vacuum assisted closure versus 20 days with the control group (74). This compares well with this study (vacuum assisted closure - 12 days versus 21 days in the gauze group), considering that all the wounds in our study were acute wounds. Vuerstaek and colleagues, who compared vacuum assisted closure with other dressings (hydrogels and alginates), in chronic leg ulcers report a median heal time of 29 days for the vacuum assisted closure group and 45 days in the control group (32).
Gregor et al performed a meta-analysis on eight studies (5 RCTs and 3 non RCTs) on changes in wound size. They reported a significant reduction in wound size in favour of negative pressure wound therapy (RCTs: SMD, -0.57 for VAC to -0.20 for controls) (73). Our study also reports a significant reduction in wound surface area in favour of vacuum assisted closure (-0.79cm² versus -0.23cm²). In our study, a slight increase in wound surface area in the initial 3 days was noted in the wounds managed by gauze dressing. This phenomenon was also noted by Braakenburg et al but they offered no explanation for its occurrence (74). In our study it may be partly attributed to more wounds in the gauze group undergoing debridement of necrotic tissue and partly due to swelling of tissues around the wound due to oedema as postulated by Argenta et al (3).

Acute trauma to the limbs is one of the known causes of compartment syndrome. VAC dressing has been recommended for decompression of compartment syndrome (15). However, there is no published study on the use of VAC in the treatment or prevention of compartment syndrome. In this study we measured the changes in the limb circumference as an indirect measure of the changes in the pressures within the limb at the site of the wound. None of our patients had clinical signs of compartment syndrome. However we demonstrated a significant reduction in limb circumference in the patients whose wounds were managed by VAC compared to those managed by gauze dressing (-0.47cm versus -0.09cm, P value <0.001). Indeed we noted that in some of our patients who had large wounds, the limb circumference of the affected limb in the patients managed by vacuum became smaller than the opposite normal limb in the same patient. This provides some evidence that vacuum assisted closure may be effective in the prevention of compartment syndrome in patients with acute traumatic wounds to the lower limbs. Further research is required in this area.

We found that 13.6% of wounds treated with VAC dressing had clinical signs of infection compared to 72.7% of those treated with gauze dressing. The gold standard for determining colonization of a wound by bacteria is to measure the number of organism per gram tissue. Our findings, therefore, only suggest a lower infection rate in wounds treated with vacuum assisted closure compared with gauze dressing. There are conflicting reports on the effect of vacuum assisted closure dressing on wound infection (3, 20, 74) and this therefore is another area that requires further research.
The main complication experienced with the VAC was in growth of granulation tissue into the foam. This caused significant pain during change of dressing and some patients required opioid analgesics. The pain was worse in patients with large wounds. However the pain would subside within 30 minutes of application of the vacuum assisted closure dressing and most patients reported being comfortable in between dressing changes. In the developed countries there is commercially available medical grade foam which prevents excessive in growth of the granulation tissue (3). In our study we attempted to reduce this complication by applying soffratulle on to the wound before applying the foam.

The other complication experienced included foul odor of the effluent sacked from the wound and of the foam at the time of dressing change. Many patients complained of the noise made by the suction machine especially at night. This prevented them from getting a good night’s sleep. Indeed some patients switched off the suction machine at night. We also experienced difficulties in achieving and maintaining an air tight seal in patients with fractures who had external fixators at the site of the wound. This perhaps requires further refinement in technique and equipment.

It should be noted that this study used materials and equipment that are locally available for the vacuum assisted closure dressing and we compared this with gauze dressing which is the standard for wound dressing in our country. Gauze dressings dry up, cause tissue disruption when it is removed, causes more patient discomfort and has been found to have a significantly higher growth of pathogens when compared to hydrocolloids (4,11). In the developed countries, it is therefore falling out of favour. In our country, we should perhaps, consider the use of vacuum assisted closure in the absence of the other more expensive modern dressings such as hydrocolloids, hydrogels and alginates.

This study has some limitations. It was not blinded and the researcher and his assistants knew which patient was treated by which method as they took measurements of the wounds. Whether the end point had been achieved or not for each wound was based on the subjective assessment of the researcher. This may have introduced bias in favour of the vacuum assisted closure dressing. This study did not consider the depth of the wounds and yet this may have had an influence in the wound healing. The patients who were recruited into the gauze dressing group, had their wounds dressed by the nurses in the wards. This may also have
introduced some bias as some of these patients may not have been dressed as per protocol due to staff shortages regularly experienced in our hospital.

Finally the end point of this study was 100% granulation tissue formation. The Food and Drug Administration (F.D.A) of U.S.A recommends that 'complete wound closure is the most objective and clinically meaningful wound healing endpoint' (75). Measurement of granulation tissue formation and changes in wound size are considered to be surrogate markers of wound healing. Future studies in this area therefore should perhaps follow up the patients for a longer period i.e. until complete wound closure is achieved either surgically or by secondary closure.
CONCLUSION

This study provides evidence that suggests that managing acute traumatic wounds using vacuum assisted closure dressing results in faster granulation tissue formation and a significant reduction in wound size compared with using gauze dressing. Vacuum assisted closure also resulted in a significant reduction in limb circumference at the site of the wound compared with gauze dressing. This suggests that vacuum assisted closure dressing may be useful in the prevention of compartment syndrome.
RECOMMENDATIONS

1. Vacuum assisted closure dressings using locally available materials should be adopted as an alternative to gauze dressing in the management of acute traumatic wounds in our country.

2. All surgeons, medical students, and nurses should be trained on the use of vacuum assisted closure.

3. Further research that would follow up patients to complete wound healing and investigate wound infections in patients treated with vacuum assisted closure dressing is recommended.
The approval of the Ethics and Research Committee of the Kenyatta National Hospital was obtained before commencement of the study.

Informed consent was obtained from the patients who accepted to participate in the study. (See appendix II).
REFERENCES


Appendix 1
DATA COLLECTION SHEET

Group.
1. 
2. 

Patient Data
1. Study number________________________

2. Age___________ 3. Sex  M   F

4. Height_________________________ 5. Weight_________________________

6. Body mass index_______________ BMI = \frac{\text{weight (kg)}}{\text{Height (m2)}}

7. Date of injury__________________ time of injury_______________________

8. Date of recruitment into study____ time of recruitment into study_____________

9. Hours from time of injury to recruitment into study_________________________

Wound data
Day 1 - wound assessment (at the time of recruitment into the study).

1. Site of wound  
   Thigh
   Knee joint area
   Leg
   Ankle joint area
   Foot
2. Wound surface area ___________ cm$^2$

3. American college of surgeons class
   III [ ] IV [ ]

4. Limb circumference: Measurement from fixed point (e.g. tibial tuberosity, medial malleolus) to the point on the wound where its transverse diameter is widest ______ cm.
   Widest transverse diameter of the wound ______ cm
   Limb circumference at this point ______ cm

WOUND DATA

DAY 3 and every subsequent 3$^{rd}$ day (i.e. day 6, 9, 12, 15 etc.)

1. Wound surface area ___________ cm$^2$

3. Limb circumference
   Confirm measurement from fixed point (tibial tuberosity or medial malleolus) to the point where the transverse diameter was widest on day 1 (as above) ______ cm.
   Transverse diameter at this point ______ cm
   Limb circumference at this point ______ cm.

4. Necrotic tissue ______ present [ ] absent [ ]
   Debridement done YES [ ] NO [ ]
Note any adverse events _____________________________________________________________

5. Has end point been achieved?

- Wound with 100% granulation tissue.

6. Comments. _____________________________________________________________

CONSENT BY THE PARTICIPATING PATIENT
Appendix 2

CONSENT BY THE PARTICIPATING PATIENT

My name is Dr Andrew Wandera. I am a postgraduate student in General Surgery at the University of Nairobi. I am carrying out a research study on the treatment of wounds using either vacuum assisted closure dressing or gauze dressing. The aim of this study is to find out which of the two methods of dressing results in faster wound healing.

Gauze dressing is the usual method of dressing used at the moment in our hospital. Vacuum assisted closure dressing is an experimental method of dressing, whose advantages and disadvantages compared to gauze dressing, I aim to study.

You are not obliged to accept to be enrolled in this study. Your decision will not affect the treatment you may receive in this hospital.

You will be enrolled into the study upon giving consent. You will randomly be allocated to either the group of patients to be treated by vacuum assisted closure or by gauze dressing. You will then undergo history taking and physical examination. Measurements of the wound and the affected limb will be taken. This information will be stored in a data collection sheet. Your wound will then be dressed using either vacuum assisted closure dressing or gauze dressing (see below for further information).

Measurements will be taken again on the third day (i.e. after 48 hours) and on every subsequent 3rd day (after every 72 hours) until the wound heals or is ready for surgical closure (i.e. skin grafting etc.).
Part 2

A) VACUUM ASSISTED CLOSURE GROUP.

(Patient Information.)

You have been randomly selected to have your wounds treated using vacuum assisted closure dressing. Your wound will be dressed in the following manner.

1) Measurement of your wound(s) and the circumference of affected part of your limb will be taken.

2) Your wound will be cleaned with normal saline.

3) Foam mattress (sponge) will be trimmed to the size of your wound and applied on to it.

4) A tube (suction catheter) will be placed on the sponge and another sponge will be placed on top of this, covering all the holes of the suction tube.

5) A plastic sheet (cling film) will be used to cover the sponge with the tube in it. The aim is to achieve an air tight seal. One end of the suction tube will stick out of this dressing.

6) The exposed end of the suction tube will be connected to a suction machine which will then be turned on.

When the suction machine is turned on the sponge will collapse and therefore negative pressure will be applied on the wound.

You will be connected to this suction machine throughout except for brief periods when you wish to visit the toilet or during dressing changes.

When you wish to visit the toilets, you (or the nurse) in the ward may switch off the suction machine and disconnect the suction tube from the suction machine. Leave the rest of the dressing as it is and when you are back to the bed reconnect the tube to the suction machine and switch the machine on.

The vacuum assisted closure dressing will be inspected daily by the research team. It will be changed on day 3 and on every 3rd day (after 72 hours) until wound healing occurs or it's ready for closure. It will also be changed when there is loss of the airtight seal i.e. when the sponge fails to remain collapsed despite the suction tube being connected to the suction machine which has been turned on.
When the wound is ready for closure the surgical team in the ward will decide on how best to close it. This may include suturing, skin grafting, or leaving the wound to close on its own (secondary intention).

Please note the following:

1. This treatment will usually take several days to allow your wound to heal or be ready for closure by surgical means.

2. Feel free to ask for pain medicine should you feel that the pain is severe enough to require painkillers.

3. You are free to opt out of this form of treatment at any time in the course of the treatment.

4. Please feel free to ask Dr Wandera (phone no. 0722843611) any questions that you may have regarding this treatment.
B) GAUZE DRESSING

(Patient information)

You have been randomly selected to have your wounds treated using gauze dressing. This is the usual method of wound dressing at Kenyatta National Hospital. Your wound will be dressed by the ward nursing staff as per the ward protocol.

The dressing will be applied in the following manner:

1. The wound measurements and the circumference of affected part of your limb will be taken.
2. Your wound will be cleaned with normal saline.
3. Sofratulle will be applied onto your wound.
4. Gauze will be applied on this.
5. The gauze will then be secured with strapping or with a gauze roll.

The dressing will be changed at the discretion of the ward staff. This may be daily or on alternate days or when stained or soiled.

Please note the following:

1. Feel free to ask for pain medicine should you feel that the pain is severe enough to require pain killers.
2. You are free to opt out of this study at any time during the course of this treatment.
3. Please feel free to ask Dr A. Wandera (phone no. 0722843611) any questions that you may have regarding this treatment.
Part 3
CONSENT FORM
1) I accept to participate in this study on my own free will.
2) I accept to be interviewed concerning my illness and the answers recorded by Dr A.O. Wandera.
3) I accept to be physically examined.
4) I accept to have my wounds treated using vacuum assisted closure dressing / gauze dressing.
5) I understand that my participation in this study is strictly voluntary and I can withdraw my consent at any point in the study and that such withdrawal will not affect my treatment in any way.
6) I understand that the information I give will be treated with utmost confidence and that my name will NOT be published in the results.
7) I understand that I can raise any issue related to the study with Dr A. Wandera (Telephone no. 0722843611).

Patient name:____________________ Signature:____________________

Witness:____________________ Signature:____________________
CHETI CHA KUKUBALI

Nimeelewa maelezo yote kutoka kwa Daktari Wandera.

1) Nimekubali kuhusishwa kwenye utafiti kwa hiari yangu.
2) Nimekubali kutoa habari kuhusu ugonjwa wangu na majibu yake kurekodiwa.
3) Nimekubali kupimwa mwili wangu.
4) Nimekubali vidonda vyangu kutibiwa kwa njia ya vacuum assisted dressing / gauze dressing.
5) Nimeelewa ya kwamba ninaweza kujiondoa wakati wowote kutoka utafiti na kujiondoa kwangu hakutadhuru matibabu yangu kwa njia yeyote.
6) Nimeelewa ya kwamba habari yeyote kuhusu ugonjwa wangu itahifadhiwa kwa siri na kwamba jina langu halitachapishwa hadharani.
7) Nimeelewa ya kwamba ninaweza kumuuliza Daktari Wandera swali lolote kuhusu utafiti huu.(Nambari ya simu 0722843611).

Jina la mgonjwa: ____________________  Sahihi:______________________

Shahidi: ________________________  Sahihi:______________________
Appendix 3: Pictures

1.) Wound at recruitment into study (Day 1)

2.) VAC dressing applied

3.) Day 9 after vacuum assisted closure dressing

4.) Measuring wound surface area dressing

5.) Another patient after 6 days of VAC