Role of vacuum assisted closure (VAC) in treatment of difficult to heal wounds in lower extremity - our experience in 100 cases

Dr. Dhananjay V Nakade, Dr. Manish Zade, Dr. Jitendra Mehta and Dr. Akhila Pandita

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Abstract
Aims and objectives
1. To study effectiveness of lower limb problems like: lower limb injuries, difficult to heal wounds like amputation stumps, necrotizing fasciitis, diabetic foot, burns wounds and deep electrical burns wounds, cellulitis and extensively oozing wounds.
2. Improvement in take of graft or flap.
3. Reduction of infection and surface bacterial count in wounds reducing morbidity and mortality and making treatment cost effective, also.
4. Salvaging lower limbs.

Methods: Standard method of VAC application is used in our study with step wise manner. Wound debridement, hemostasis done, VAC applied by standard method. Negative pressure around 125 to 150 mmHg is used in our study. Out of 100 cases, 50 cases are lower limb injuries due to trauma, accident, amputation stumps, 40% cases are due to necrotising fasciitis and cellulitis, septicaemia. 10% cases are due to bedsores and its infection management. Lower limb wounds with exposed tendons or bones, orthopaedic implants exposed-are well managed with VAC. Standard method of VAC application is followed in each case.

Result: Out of 100 cases of lower limb problems with difficult to heal wounds, amputation stumps treated, we found infection is effectively reduced, wound discharge is reduced, wounds granulated well and early, and wound bed prepared early for skin graft take or flap take.

Conclusion: Vacuum assisted closure (VAC) is very good modality of treatment, which assists plastic surgeons in healing wounds specially in difficult to treat lower limb wounds.

Keywords: VACuum therapy, topical negative pressure therapy, negative pressure wound therapy (NPWT), wound closure, vacuum assisted wound closure (VAC), sub atmospheric pressure therapy, skin graft in difficult to treat wounds and amputation stumps

Introduction
The application of controlled levels of negative pressure has been shown to accelerate wound debridement and promote wound healing in many different types of wound. The optimum levels of negative pressure appears to be around 125mmHg below ambient and there is evidence that this is most effective if applied in cyclical fashion of five minute on and two minute off (intermittent).

It is believed that the negative pressure assist with removal of interstitial fluid, decreasing localised oedema and increasing blood flow. This reduces bacterial count in the infected or affected tissues. Mechanical deformation of cells is thought to result in protein and matrix molecule synthesis, which increases rate of cell proliferation. The treatment is beneficial in treatments of majority of lower extremity wounds which are difficult to treat. Vacuum assisted closure also called vacuum therapy, vacuum sealing, and topical negative pressure therapy, is sophisticated development of a standard surgical procedure, the use of vacuum assisted drainage to remove blood or serous fluid from a wound or an operation site.

Materials and Methods
Indications in our Studies and Technique
Technique consist of 1. Wound debridement done, hemostasis done, piece of foam with open
structure is called granulofoam, introduced in the wound on a thin bactigrass layer, the entire wound area and foam has covered with a transparent adhesive membrane Ioban, we use which is firmly secured to the healthy skin around wound margin, a half inch whole is made in the appropriate position on the foam and drain, a wound drain with lateral perforators, sensa track pad [KCI], is kept in position on top of it. It has sticker which sticks to the membrane air tightly, then the exposed end of drain is connected to a vacuum source, fluid is drawn from the wound through the foam into a reservoir for subsequent disposal. The plastic membrane prevents ingress of air and allows to form partial vacuum to form within the wound, reducing its volume and facilitating the removal of fluid. The foam ensures that the entire surface area of wound is uniformly exposed to this negative pressure effect, prevents occlusion of perforations in the drain by contact with the base or edges of the wound and eliminates the possibility of localised areas of high pressure and resultant tissue necrosis. (A).

Our Strategy
We debride the wound, then we apply VAC. Hemostasis we achieve after debridement. VAC to be applied for 48 to 72 hours and again second look debridement, inspection of viability of muscles, vessels, and bone assessed, after 48 hrs, again repeat VAC applied for one to 2 sittings of 5 days each, depending upon slough and exudation. Then skin grafting or flap is done whichever is possible and as per requirement. If skin graft done, we use VAC 1-2 sittings after skin graft. Each sittings of 5 days. Our acceptance of skin graft improved to almost 95%.

Method Step by Step
Technique of step by step use of VAC assisted closure is: (A):

Step 1: Wound debrided, hemostasis achieved. Foam granulofoam, cut to the approximate size of the wound with scissors and placed gently in position. Skin staplers used to fix the foam, second piece of the foam used to keep on top of the first foam on which we put sensa TRAC end of tube with lateral holes which connects to the canister-the collecting vessel. (Fig. 1 a and 1b)

Step 2: Ioban is an adhesive transparent sticky dressing membrane, used to seal the foam and wound to its healthy skin surrounding the ulcer. The foam and the surrounding area of healthy skin is then covered with the adhesive transparent membrane Ioban. At this stage it is important to ensure that the membrane forms a good seal both with the skin and the drainage tube. (Fig 2.)

Stage 3: A coin size hole is made at top of topmost foam on which sensa trac is stuck which is surrounded by round shape umbrella shape adhesive material airtight seal is ensured. (Fig 3.)

Step 4: Other end of tube of sensa track is connected with tubing from canister, which in turned connected with VAC machine, which is programmed to produce the required level of pressure. (Fig 4.)

Step 5: Once the vacuum is swiched on, the air is sucked out of the foam causing it to collapse inwards drawing the edges of the wound in with it.

Step 6: The fluid within the wound is taken up by the foam and transported into the disposable container within the main vacuum unit called canister. (Fig 5.)

Observation and Result
Of 100 cases we studied, of lower limb injuries due to trauma and accidents and infected cases of cellulitis, necrotising
fasciitis, diabetic foot, amputation stumps and bed sores.

1. 50 cases (50%) of lower limb injuries with extensive defects, difficult to heal wounds, slowly healing or delayed healing wounds.
2. 40 cases (40%) of lower limb cellulitis or necrotising fasciitis.
3. 10 cases (10%) of bedsores.

Result
All 50 cases (50%) of lower limb injuries healed well, except two cases ended amputation due to extensive tissue damage. Skin graft take improved in all injuries, flap acceptance is increased in 25 cases of lower limb injuries. All 35 cases of cellulitis and necrotising fasciitis showed good result, 3 cases of diabetic foot needed amputation and one case of necrotising fasciitis need amputation. All cases showed improved wound healing and graft take. Except 3 cases showed skin graft loss in margin of the wound. 5 cases of lower limb electrical burns with raw area shows good healing after VAC except one patient showed graft loss because of underlying infection.

10 (10%) cases of bed sores - shows after debridement and VAC application good improvement of wound and after that, good graft take in 2 cases and good flap coverage in 8 cases. 10 cases for comparison in which VAC was not used, in which infection took lot of time to cure, wound granulation took more time, 3 cases out of 10 land up in septicaemia of which one required amputation to save his life from septicaemia.

Table 1: Comparison in between cases treated with VAC and those treated without VAC:

| Parameters                        | With VAC                        | Without VAC                     |
|-----------------------------------|---------------------------------|---------------------------------|
| Duration of the hospital stay      | 10 to 21 days (100 Cases)       | 18 to 38 days (10 cases)        |
| Morbidity                         | Less                            | More                            |
| Amputation of limb to save life    | Less Chance                     | More Chance                     |
| Skin graft or flap take           | Early wound bed preparation and good acceptance of graft take Majority of wounds in one sitting good granulation tissue grown | Wound bed preparation takes more time. |
| Healthy granulation tissue formation | Formed in 1 to 2 weeks.         | 3 to 4 weeks.                  |
| Pus swab culture report           | Bacterial count/tissue gm reduced | more aggressive bacterial count/per tissue gm |
| Joined work or duties in days.    | 35 to 45 days in 80% cases      | 65 to 90 days in 80% cases      |

Cases and Photos
Case 1: 26 yrs old person had met with an accident, crush injury of leg, badly damaged and exposed bones with complex compound fractures of tibia and fibula, fixation of bones by orthopaedic surgeon, debridement done, two sittings of VAC for 5 days each. ALT free flap done and skin grafting done, limb salvage possible. Patients is performing duties in paramilitary.

Case 2: 27 yrs old male, had run over injury with bus tyres and badly devolving injury of rt leg. We debrided the right leg, dead skin removed, VAC 2 sittings given, 5 days each. Once wound granulated well skin grafting done. Later free ALT flap done for TA contracture.

Case 3: A case of bilateral lower limb amputation in 55 yrs old female where she met with a roadside accident, run over by small truck. She landed in sever septicaemia, we have debrided her frequently with 2 sittings of VAC 5 days each. Wound granulated well, skin graft applied and again VAC applied on skin graft, patient came out of septicaemia and skin graft taken well, she is now walking on prosthetic limbs.

Case 4: 7 yrs old girl child met with an accident roadside, run over by truck wheel on foot, skin loss, partial bone loss, we have debrided her foot and leg, VAC applied, two sittings, 5 days each, skin grafting done again applied for two sitting of VAC 5 days each. Skin graft taken well. Patient came out of trauma, infection controlled well, we have planned for flap in second stage if required.
Case 5: Degloving injury of sole of foot, sole debrided, VAC applied 2 sitings, 5 days each sitting, then skin graft done with VAC 2 sittings done, then sural flap done at heel. Patient recovered well.

Case 6: VAC used in bilateral cases of necrotising fasciitis of lower limbs with patient in septicemia, VAC used to save his life from septicemia and reducing chances of ARDS due to septicemia.

Case 7: VAC used in lower third leg injury with defect with exposed implant, debridement, VAC done one sitting, parascapular flap done to cover the defect.

Case 8: 23 yrs old lady got run over injury by tractor in a road traffic accident, and got crush and devolving injury rt lower limb, was in septicema, VAC used to save her, after debridement and two sitting of VAC, wound granulated then skin grafting done. Now she is working, walking. VAC machine used in these study are:
1. KCI VAC machine.
2. NPWT VAC machine.
3. PRASADITI VAC machine these 3 types of VAC machines we used in our study.
4. We used wall suction machine in very poor patients initially but in this study we have not used wall suction machine.

Discussion
Surgical site infections (SSI) has prevalence of 2% to 5% and increase the cost of surgical patients care by approximately 20%. Diabetes mellitus and Obesity are two of the main risk factors of such infections. Another important factor that may comprise the SSI healing is impaired tissue perfusion. Clinical application of negative pressure was first used in Chinese medicines techniques with acupuncture for its ability to
cause hyperaemia, resulting in increased local circulation through vasodilatation. Historically, different systems have been developed to use the negative pressure in the treatment of wounds. Vacuum-assisted closure (VAC) is a system first reported in 1997 in plastic surgery. The polyurethane foam used with a regular pattern of large holes (400-600 mcm) allows an even distribution of pressure over the entire surface of the wound.

The practice of exposing a wound to sub atmospheric pressure for an extended period to promote debridement and healing was first described by Fleischmann et al. in 1993. Following the successful use of this technique in 15 patients with open fractures, they reported that the treatment resulted in efficient cleaning and conditioning of the wound, with marked proliferation of the granulation tissue. No bone infection occurred in any patients.

In two further papers, Fleischmann W. And colleagues described the treatment of 25 patients with compartment syndrome of the lower limb, 313 patients with acute and chronic infections of various types. The average duration of the vacuum therapy treatment for patients with compartment syndrome was 12 days (4 to 31 days). With 1 to 8 dressing changes per patient. Theses wounds were subsequently either closed by secondary suturing or by skin graft.

The average duration of vacuum therapy in the treatment of the 313 patients with infected wounds was 16 days, with average 3 dressing changes per patient. Of the 203 suturing 65.5%, remained 27.2% by spontaneous epithelialisation, skin grafting 12.3% or flap transfer 2%. Six patients 3% died. Infection recurred in 3.9% and was managed using another treatment. Unstable scar formation 1% is treated by free flap transfers. Mullhers et al. from Germany treated successfully 300 cases with infected wounds. They have shown several advantages. Clean and sterile wound dressing, safe wound healing, they advised VAC in septic wounds in surgery.

1998 Kovacs et al. described how vacuum sealing could be used for the treatment of chronic radiation ulcer. Mullner et al. The results of prospective trial involving 45 patients with soft tissue injuries including sacral pressure ulcers, acute traumatic soft tissue defects and infected soft tissue defects following rigid stabilisation of lower extremity fractures were described by Mullner et al. They reported that in 38/45 patients (84%), the use of the vacuum sealing technique following irrigation and debridement decreased the dimensions of the initial wound, thus facilitating healing time and the eradication of any preexisting infection.

In the early studies, negative pressure within the wound was achieved by the use of conventional methods such as wall suction apparatus or surgical vacuum bottles. Both these systems are associated with practical problems in terms of the delivery, control and maintenance of the required levels of negative pressure, as discussed by Banwell et al. [7].

In 1995, a commercial system for promoting vacuum assisted closure VAC, was introduced into their United States market. This equipment, called VAC. The heart of the system is a microprocessor controlled vacuum unit that is capable of providing controlled levels of continuous or intermittent sub atmospheric pressure ranging from 25 to 100mm Hg.

Two types of units are available, a mains operated systems with a canister volume of 300ml for patients with limited mobility or heavily exuding wounds and a lightweight, battery powered unit with a canister volume of 50ml that can delivery therapy to the fully ambulatory patients with minimal to moderate levels of exudate. This system has a battery life of 17 hours. The large system is fitted with various audible and visual alarms to indicate if the unit is tipped greater than 45 degrees, the canister is full, or the dressing has an air leak.

To study mode of action of the VAC, animal studies-Morykwas et al. [8]. Studied the physiological basis of VAC and to determine the optimum level of pressure required in VAC application they studied in animal studies on pigs, a laser Doppler technique was used to measure blood flows in the subcutaneous tissues and muscle surrounding the wounds as these were exposed to increasing levels of negative pressure, applied both continuously and intermittently. Their results indicated that increase of blood flow four times the baseline value occurred with negative pressure values of 125mmHg, blood flow was inhibited by the application of negative pressure of 400mmHg and above. A negative pressure of 125mm Hg was therefore selected for VAC. In our study, Nakade et al., we use 125 to 150mm Hg negative pressure.

The rate of granulation tissue production under negative pressure was determined by measuring the reduction in the wound volume over the time. Compared with control wounds dressed with saline soaked gauze, significantly increased rates of granulation tissues formation occurred with both continuous 63% and intermittent 103% application of negative pressure.

Microbiological studies-Inoculation of punch biopsy wounds with large numbers of microorganisms, compared with control values, tissue bacterial counts of vacuum treated wounds decreased significantly after 4 days. [8]. The effect of vacuum therapy was found to increase flap survival by 21% compared with control values. [9].

Philbeck et al. [9]. The intermittent or cycled treatment appears more effective than continuous therapy is interesting although the reasons for this are not fully understood. Two possible explanations are

1. Intermittent cycling results in rhythmic perfusion of the tissue which maintained because of the process of capillary autoregulation is not activated. As cells which are undergoing mitosis must go through cycle of rest, cellular component production and division
2. Constant stimulus may cause the cells to ignore the stimulus and thus become ineffective.
3. Intermittent Stimulation allows the cells time to rest and prepare for next cycle. For this reason it is suggested that cyclical negative pressure should be used clinically, although some authors [10, 11], suggests that initial 48 hours continuous vacuums-to exert rapid initial cleansing effect, then intermittent or cyclical therapy can be applied. In our study Nakade et al we have used intermittent method in which we use 5 mins on and 2 mins off, setting.

Philbeck et al [9] claimed that treatment with VAC therapy is very cost effective in treatment of pressure ulcers in extremities and trunk. In retrospective study, they compared the treatment costs of VAC with those of a more conventional therapies. By comparing the results of an analysis of the healing rates achieved with the vacuums techniques with those recorded for similar wounds in a previously published study. From these data, the healing rates of the patients nursed on a low air loss surface (LAL) with 43 pressure ulcers stages III and IV, located on the trochanter and trunk were abstracted and compared with previously published values for a comparable group of patients also nursed on a LAL surface and whose wounds were dressed with saline gauzes. Prior to treatment, the VAC dressed wounds averaged 22.2 square cm compared with 4.3 square cm for the saline soaked gauze wounds. Wounds dressed with VAC closed with using these healing rates they calculated that the time to
Vacuum assisted closure has also been used in conjunction with split thickness skin graft STSG in the treatment of burns and is particularly useful for body sites with irregular or deep contours such as the perineum, hand and axilla [20, 21]. In all these situations the vacuums helps to hold the graft securely on to the wound bed thus preventing pooling of tissue fluids which would otherwise make graft unstable. In our study, we used VAC after skin grafting of wounds and we found skin grafting. “Take” was very good.

To get good effect of VAC, and to function it properly, the adhesive membrane applied over the foam (we use Ioban in our study) must form an airtight seal with the skin. Obtaining such a seal can be particularly difficult near the anus or vagina or where the surrounding skin is moist. These problems can sometimes overcome by the use of a hydrocolloid dressing such as Duoderm [15], which is first applied around the wound and used as a base for the adhesive membrane. We (Dr. Nakade et al.) in our study use ointment used with colostomy bags called Coloplast to prevent leakage of air from such difficult areas like perineum, perianal area, vagina, around external fixators in limbs to prevent leakage.

Bauer P. et al. [16] studied 28 cases and showed that advantages of this vacuums sealing procedures are-protection against wound contamination, complete evacuation of wound fluids independent of gravity, and rapid stimulation of dense well vascularised granulation tissue. Relief of pain, early mobilisation, improve patient’s comfort.

**Human Studies**

The same research groups described the clinical use of the commercial VAC in 300 wounds of varying aetiology [15]. These were treated until completely closed or could be covered with a split thickness skin graft or were suitable for surgical reconstruction by rotating a flap on to healthy granulation wound bed. Overall 296 wounds responded favourably to the treatment and authors concluded that VAC is extremely efficacious modality for treating chronic and difficult to heal wounds. In our study as shown in table, we found same findings as skin graft or flap survival and early recovery of patients seen when we use VAC.

Fabian et al. [13], investigated that sub atmospheric pressure might act synergistically with hyperbaric oxygen therapy (HBO2). [28]. They found that negative pressure increased the rate of healing compared with the control values, HBO2 therapy did not offer any significant benefits.

Wong L K et al. (2006) [16] managed a 58 years old case of large circumferential lower limb degloving injury with debridement and VAC to prepare the wound bed for skin grafting. After 3 weeks of VAC therapy, the wound bed was revascularised with granulation tissues and was ready for skin grafting. The patient underwent a successful split thickness skin graft on hospital day 23 and was discharged home. Follow up visit revealed no scar contractures or functional limitations in our study, Dr Nakade et al. we have operated such cases of devolving injuries of lower limb by rollover injuries by bus or truck and shown VAC as very good modality of treatment in devolving injuries with skin loss. In our cases, skin graft accepted well and patient survived and came out of sepsicaemia and graft take improved upto 95% in more than 90% cases.

Other papers have described use of VAC in the treatment of the variety of wounds including extensive devolving injuries, [16, 17], various soft tissue injuries, prior to closure by surgery [20]. Surgical closure, skin grafting or reconstructive surgery [21].
infection rate is reduced in majority of patients and patients came out of septicaemia early. In cases of post accidental amputation of bilateral lower limbs especially above knee infection has been reduced. In bilateral above knee amputations and bed sores, hold for Ioban to keep granulofoam of VAC is difficult, also normal dressing is also difficult, but we have used Ioban (plastic adhesives) wisely to fix this problem and tincture benzoin applied previously to skin to improve adhesions.

Greer et al. [27] discussed practical problems associated with the application of the VAC systems, he developed techniques to allow it to be used successfully on sacral pressure ulcer close to anus and to multiple large ulcers on the lower extremities. We in our study of Dr. Nakade et al. use COLOPLAST in such cases, near anus and vagina, and in lower limbs when external fixator, where problem of leakage in vacuums can arises, so we use coloplast and on which we use Ioban as adhesive plastic and leak proof material. When compared to above studies, our study shows good results and well compared to above studies.

Conclusion
In conclusion, we found VAC therapy a lifesaving method for the management of acute traumatic wound like devloving injury to whole lower limb due to trauma, crush injury, high velocity road traffic accidents leading to poly trauma to salvage extremities. Cases of lower limb extensive cellulitis, necrotising fascitis can be very well treated and salvaged with VAC uses. In infected bedsores, electrical burns of lower extremities and acute burns, thermal and electrical burns lower extremities VAC is useful and lifesaving. Specially VAC is very useful in treatment of bilateral above knee amputees with severe infection where dressing is very difficult and painful. In difficult to heal wounds, we use VAC to granulate wounds faster and then we use VAC on skin graft to improve take of the graft for two sittings means for 2 weeks. We use continuous pressure in VAC with skin graft. On the skin graft we use lower pressure, in continuous mode. In our study we used 100mm Hg negative pressure on skin graft in continuous mode. With VAC, skin graft take is possible with amputation stumps in above knee amputation with lot of infection in Railway or road traffic accidents. VAC dressing sucks out all exudates in exuding wounds and reduces infection, reduces bacterial colonization and count, reduces antibiotic doses. It reduces septicaemia and chances that patient going to septicemia or ARDS thus it is lifesaving. So use of VAC is promising, further studies require to improve VAC systems like adding hyperbaric oxygen to wound along with VAC system, adding pulsed lavage with normal saline for hydrodebridement of wound with VAC system to remove slough early, adding enzymatic debridement with VAC system also useful in early debridement. Ability to change PH of wound to reduce bacterial loads of certain bacteria like pseudomonas we can use certain acids like acetic acids 0.1%. Vinegars, to reduce their growth or multiplications. We need further studies to know more indications of VAC in wound management in lower limb wounds.

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Conflict of interest:
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