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The clinical efficacy of the negative pressure therapy in critical wound management

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Abstract
Negative pressure assisted wound healing is a recent proven method of fast and better healing of wounds. The application of negative pressure to remove edema fluid from the wound through suction. This results in increased blood flow to the wound (by causing the blood vessels to dilate) and greater cell proliferation. Another important benefit of fluid removal is the reduction in bacterial colonization of the wound, which decreases the risk of wound infections. Through these effects, Negative pressure-assisted closure enhances the formation of granulation tissue, an important factor in wound healing and closure.

Keywords: negative pressure wound therapy, vacuum assisted wound healing, opsite, surgical glove

1. Introduction
Negative pressure, may also be known as vacuum assisted closure (VAC) wound therapy or Micro deformational wound therapy, which has brought a revolution in wound care since past 15 years. This method was first described by Fleischmann *et al*. in 1993 [1]. The basic concept of this method is removal of blood and serous collection from the wound site by the application of negative pressure. This will be done by applying a piece of foam and a drain over the wound surface after debridement and is covered over by a semi permeable plastic adherent membrane securing it to skin margin and the drain is given connection to a vacuum creating unit. The plastic membrane forms like a barrier preventing the contamination from outside environment and the foam will help to distribute the negative pressure uniformly over the entire wound surface area preventing the chance of necrosis at a single place due to high pressure at a single place. The standardized average negative pressure is applied around −125 mm Hg. The interface material used in the Negative pressure therapy stretches the cells at the base of the wound bed, promoting the response for divide and proliferates. It also creates an environment of hypoxia over the surface leading to promotion of angiogenesis in addition to it keeps the wound warm, moist and prevents desiccation.
In the era of modern wound care negative pressure therapy for treatment of wounds has been routinely used and become integral part of the treatment plan. Its usage in acute, chronic, and complex wounds has been proven more effective and promotes for faster healing, early discharge with good quality of life with cost-effectiveness. Main objectives of negative pressure therapy are:
1. To promote rapid healing
2. To decrease the frequency of change of dressings
3. To prepare faster granulation bed for the wound for change to other surgical intervention procedure
4. To promote contraction of the wound edges
5. To minimize the contamination of the wound
6. To decrease the hospital stay.

In this study, we practiced to do the negative pressure dressing by using
VAC machine and routine suction machine.

2. Materials and methods
This prospective comparative study was undertaken at
B J Medical College, Civil Hospitals Ahmedabad, India from January 2015 to December 2015.Ethical approval was obtained for this study from local ethical committee. A total of 70 patients in the study divided into experimental and control groups each of 35 patients in each group and all patients informed consent was taken. Modified method of vacuum dressing applied for the experimental group, and conventional betadine dressing applied for the control group. For vacuum dressing, the inclusion and exclusion criteria are as follows:

Inclusion Criteria
1. Chronic pressure ulcers
2. Neuropathic ulcers
3. Dehisced wounds or wounds with exposed bone/ tendons
4. Partial thickness burns.

Exclusion Criteria
1. Wounds of very large surface area (area more than 30% body surface area, areas like groin, perineum, axilla)
2. Malignancy in wound
3. Cavity or sinus of unknown depth or origin
4. Untreated osteomyelitis within vicinity of the wound
5. Wound with unstable fractures or loose fragments of bone
6. Ulcers over the extremities with peripheral vascular disease
7. Wound with exposed blood vessels or organs
8. Acute burns.

The Technique
Sequence of Procedure (see Fig.1)

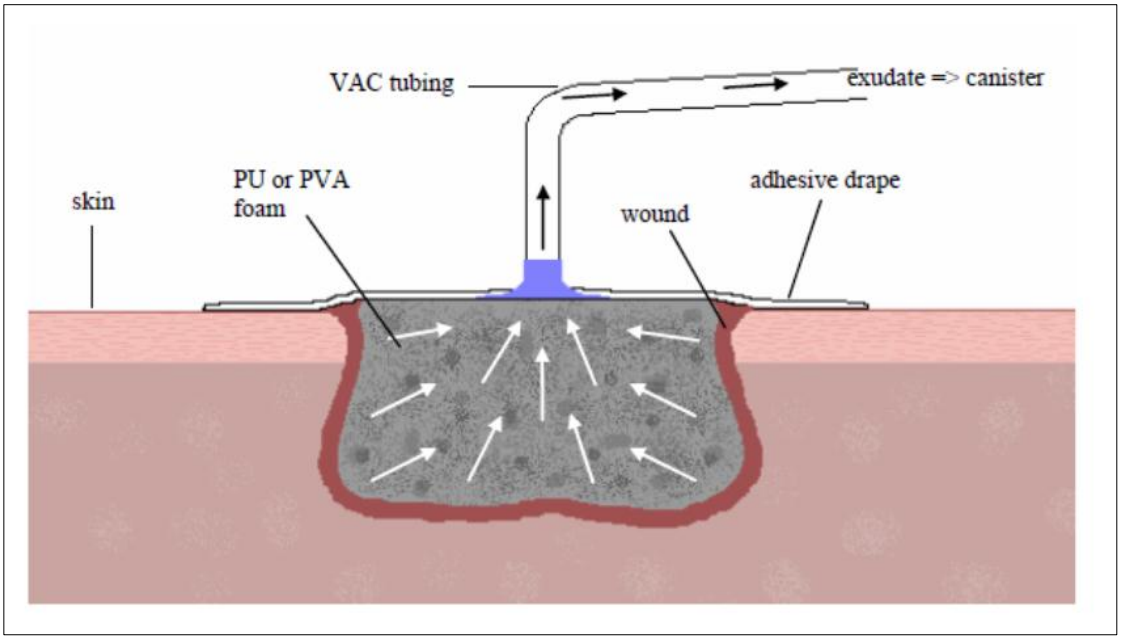

Fig 1: Cross-section of a wound with the VAC dressing in place.

i) Wound Preparation
Any dressings from the wound are removed and discarded. If required, a culture swab for microbiology should be taken before wound irrigation with normal saline. Surface slough or necrotic tissue should be surgically removed (surgical debridement) and adequate haemostasis achieved. Prior to application of the drape, it is essential toprepare the peri-wound skin and ensure that it is dry [2].

ii) Placement of Foam
Sterile, open-cell foam dressing is gently placed into the wound cavity. Open-pore, reticulated medical-grade foams are used as they are the most effective at transmitting mechanical forces across the wound and provide an even distribution of negative pressure over the entire wound bed to aid in wound healing [4]. There are two different types of foam available, black (applied into the wound) or white (applied over the wound) [4]. Black foam, polyurethane ether (PU), has larger pores, is lighter, easily collapsible and hydrophobic with a pore size of 400 to 600 mm. It is used when stimulation of granulation tissue and wound contraction is required. Embedded in the foam is a fenestrated evacuation tube, which is connected to a computer-controlled vacuum pump that contains a fluid collection canister [3]

iii) Sealing with Drapes
The site is then sealed with an adhesive drape.
Drapes should cover the foam and tubing and at least three to five centimetres of surrounding healthy tissue to ensure a seal. The manufacturer recommends dressings (foam + drapes) to be changed every 48 hours or sooner if the wound is infected. Some dressings have been left for four to five days before changing [5]. However, the speed of tissue growth should be monitored to prevent adherence to the wound bed. For meshed grafts, dressings are left in place for four to five days [6]. Care must be taken when removing the adhesive drape to avoid irritating the periwound skin. Normal saline solution can be used to loosen the foam for removal from the wound bed. For patients experiencing pain with dressing changes, 1% lidocaine solution may be introduced either via the tubing or injection into the foam.

vi) The Application of Negative Pressure
Controlled pressure is uniformly applied to all tissues on the inner surface of the wound [7]. The foam dressing should compress in response to the negative pressure. The pump can deliver either continuous or intermittent pressures, ranging from 50 to 125 mmHg (adjustable up to 200 mmHg).[4] Intermittent delivery consists of a seven-minute cycle of two minutes off and five minutes on, while the negative pressure is maintained. The ideal pressure setting is 125mmHg, but particularly painful chronic wounds such as chronic leg ulcers are usually managed with lower therapeutic pressures of 50 to 75 mmHg. Higher pressures of 150 mmHg plus are used for large cavity wounds such as acute traumatic wounds, as they produce copious amounts of exudate.[3] The pressure is set to continuous for the first 48 hours and the pressure is changed as required thereafter.

Patient Group
Vacuum therapy can be applied to various types of wounds to patients of all ages. However the wound must have the basic capacity to heal. Vacuum therapy should not be initiated in patients who have an inadequate nutritional status, an untreated infection, or if death is imminent (i.e. the patient is unlikely to live more than six months).
Wounds treated with Negative pressure include:

- diabetic foot ulcers
- pressure sores
- skin graft fixation
- burns
- hand injuries

- exposed tendon in lower limb trauma
- venous stasis ulcers

3. Results & Discussion

3.1 Result

In our study, among the experimental group 2 patients were considered as failure (one patients expired, two patient was not willing to continue) and these patients were excluded from study population of vacuum dressing, thereby experimental group *n* = 47, control group *n* =50. The mean age distribution in the experimental group is 37.11 ± 9.95 and in control group 39.4 ± 7.63 and sex distribution in experimental group 31 patients (65.9%) are males and 16 patients (34.1%) females, in control group 37 patients (74%) males and 13 patients (26%) females. The ulcers are located predominantly over lower limbs and other sites also like upper limb, abdomen, amputation stump, sacral and trochentric region.

The efficacy of wound healing indicated by clearing the infection is measured by sequential wound swab cultures in both experimental and control group and the results are shown in Table 1.

Table 1: Sequential wound cultures swabs

Wound culture	Absent (%)	Presen (%)
Culture 1		
Experimental group	6.4	93.6
Control group	14	86
Culture 2		
Experimental group	68.1	31.9
Control group	26	64

In Culture 1 the predominant organisms being pseudomonas in 21(44.68%) and 11 (22%) cases in experimental and control group and *Klebisiella*in 7(14.89%) and 1 (2%) cases in experimental and control group respectively.

Number of mechanicaldebridment is 37 and 69 times in experimental and control group. On comparison by mode of healing in both groups split skin grafting was done in 45 (90%) cases and 46 (97.8%) cases in control and experimental groups, and the results are shown in Table 2. Healing by secondary intention in 2 (10%) and 1 (2.2%) cases in control and experimental groups.

The wound healing is also compared between the experimental and control groups in the parameters such as wound areas initial and final, number of debridements, number of dressings, number of days of hospital stay, wound scoring assessment by photographic wound assessment.

Total time of the treatment of the patient more than 10 cm2 area of wound is reduced in experimental group and the results are shown in Table 3.

Table 2: Wound coverage following VAC therapy

	Skin graft	Secondary intention
Experimental group	97.82	2.18
Control group	90	10

Table 3: Total hospital stay in days

	Minimum	Maximum
Experimental group	15	37
Control group	28	58

3.2 Discussion

Wound healing is a complex interdependent and intricate process involving many cellular interactions, release of biochemical mediators, changes in the microenvironment and extracellular matrix resulting in structural and functional restoration of the wound [8]. Locally acting growth factors influence healing in the events of angiogenesis, formation of extracellular matrix, migration of neutrophils, macrophages, fibroblasts, increasing collagen and protein production thereby enhancing the healing of wound [9, 10].

Any disturbance in this mechanism will delay in healing and lead to chronic non healing wounds. Application of sub atmospheric pressure decreases the bacterial colonization over the wound and increases the blood flow [11]. Increase in oxygenated blood flow to the damaged tissues increases the wound resistance to the infection [12]. Increased oxygenated blood flow to the wound healing promotes the oxidative bursts in neutrophils and there by promoting the killing of microbes and preventing infection [13]. Negative pressure therapy decreases the interstitial edema and increases the capillary blood flow, promotes granulation tissue formation and produces a traction force whereby decreases the wound surface area and increases the mitoticity in cells around the area [14]. It has been proposed four primary mechanisms for healing by negative pressure therapy

1. Macro deformation or wound shrinkage at the base
2. Micro deformation near the interface sponge
3. Removal of excess fluid
4. Optimizing the wound environment [15].

Macro deformation

It refers to decrease in the wound surface due to shrinkage of sponge and action of centripetal forces over the wound surface. In studies made by Borgquist *et al*. in porcine models, exposing the sponge to negative pressure of 125 mm Hg will decrease the foam volume by 80% leading to decrease in wound surface area [16]. Due to the inherent tension which is present in the dermis near the wound and underlying attachments of different wounds over different sites contract to a different extent. The macro deformation effects depend upon the variety of tissues, amount of negative pressure, volume of the interface material, and the surrounding tissues deformability [15].

Micro deformation

The negative pressure transmitted through interface material acting over the undulated surface of the wound produces changes occur in µ to mm range scale. Depending on the common diameters of pores of interface material in range of 400-600µm, on application of the negative pressure there will be 5-20% tissue strain over the wound surface.[17]These mechanical forces are transmitted to every cell through the extracellular matrix and lead to cell deformation causing modifications in cell function for adaptation of stress [18, 19].

Removal of Excess Fluid

The total body fluid is distributed in three compartments. They are: (1) Intracellular, (2) extracellular (3) intravascular. Translocation of fluid in between these compartments across the semi permeable membrane is governed by the differential between osmotic and hydrostatic pressures derived by Starling's equation. Extracellular compartment is the most variable compartment among the three. Excess fluid in this

compartment leads to edema and deprivement leads to signs of dehydration. This compartment is drained by lymphatics; abnormality in this may lead to lymphedema. Chronic wounds and edema are often concomitant more commonly in lower limbs. Excess of fluid will lead to delay in healing due to the compressive effect exerted over the tissues. While healing intrinsic tension will be developed within the individual cells through their cytoskeleton and extracellular matrix interactions, increased fluid pressure will dampen the building up intrinsic tension and prevent proliferative response [15]. Removal of this excess fluid will decrease the compression of microvasculature there by promoting the perfusion to the local area [20]. The semi permeable nature of the occlusive drape will allow a little leakage of air into the system, which helps in preventing the fluid lock and thereby allowing the evacuation of fluid continuously. Along with excess extracellular fluid toxins formed over the wound and microbes were also cleared by the negative pressure therapy [21]. Negative pressure therapy also allows for developing of lymphatics at the wound edges thereby improving the fluid drainage [22]. The semi occlusive drape is not permeable to microorganisms thereby significantly reducing the contamination and also helps in maintaining moist and warmth environment, which promotes the healing response [23, 24].

Conditions where negative pressure therapy is contraindicated are:

1. Untreated osteomyelitis
2. Unexplored and nonenteric fistulas
3. Necrotic tissue along with eschar
4. Exposed blood vessels
5. Wounds with malignancy
6. Exposed nerves
7. Exposed anastamotic sites
8. Exposed internal organs.

FDA has proposed risk factors and other warrant conditions before consideration of a patient of negative pressure therapy. They are:

1. Treatment with platelet aggregation inhibitors or anticoagulants
2. High risk for bleeding
3. Infected blood vessels, wounds, osteomyelitis, exposed blood vessels, nerves, tendons, ligaments, anastomosis, spinal cord injuries, enteric fistulas, sharp edges at wound edges
4. Patient requirement for hyperbaric oxygen therapy, magnetic resonance imaging, defibrillation
5. Patient size and weight
6. Circumferential dressing application
7. Proximity of foam to the vagus nerve
8. Continuous or intermittent suction application.

Negative pressure therapy treated wounds in the proliferation phase there will be robust granulation tissue, proliferation of cells, angiogenesis and the maturation of collagen exhibit mast cell dependence in proliferation and remodeling phases. Morykwas *et al*. studies showed a decrease in the bacterial load in wounds treated with negative pressure therapy [25], Mouës *et al*. studies showed there is a decrease in non fermentive Gram-negative bacilli and *S. aureus*increased [26], The effect of negative pressure therapy on bacterial culture from the wounds should be more studied particularly in responses of different strains that are elicited. Traditional VAC dressing's uses polyurethane ether foam, reduction of bacterial load can be achieved in the wound by silver coating added to the foam. Stinner *et al*. study in the goat model with silver dressings placed beneath the foam in complex wounds with high bacterial load demonstrated reduction in bacterial growth particularly *S. aureus* when compared to standard VAC dressings [27].

Treatment by negative pressure therapy provides cosmetic as well as functional outcomes by promoting the local vascularity and decrease in scar height. Negative pressure therapy can be used for preparation of recipient sites for dermal scaffolds and skin grafts over exposed bones or tendons which provide complete vascularized wound bed before skin grafting.

For the treatment with negative pressure therapy, many factors to be considered in view of goal of therapy, type of dressing, suction pressure application. For different types of wounds, there is different amount pressure protocols and the duration of treatment changes. In acute wounds, it is beneficial to start within 48 h initially with continuous suction followed by intermittent suction therapy. For chronic wounds they benefit more by continuous negative pressure therapy. Short and intermittent negative pressure therapy [28] shows improved tissue response than compared to the continuous effect, but it may not be applicable for all types of cases. Intermittent negative pressure therapy may not be tolerated by some patients due to discomfort. The optimal pressure to be applied for improvement of the wound is not yet currently known, there are different studies with application from −75 mm Hg to −150 mm Hg pressure and achieved good healing responses. Frequent change of vacuum dressings may be required for wounds with increased risk of infection. All wounds are not amenable to negative pressure therapy.

Due to hypersensitivity for the adhesive drape and pain caused due to the suction effect some patients may not tolerate the therapy. Pain can be reduced by modalities like decreasing the negative pressure, and if pain is from the surrounding skin then framing the wound with hydrocolloid dressing at the borders and adhesive drape can be placed over hydrocolloid so that the friction force is relieved over the skin. Tissue integrity must be checked during every change of dressing. If hematoma or bruises appears over the wound negative pressure should be decreased, if still persists then negative pressure therapy should be discontinued/substituted by alternative type of dressing.

Fig 2: (a) Traumatic injury to right upper limb of 5 days old, after debridement and placement of external fixator(b) application of VAC at 125mmHg negative pressure after 13days of vac therapy skin grafting was done (c) follow up

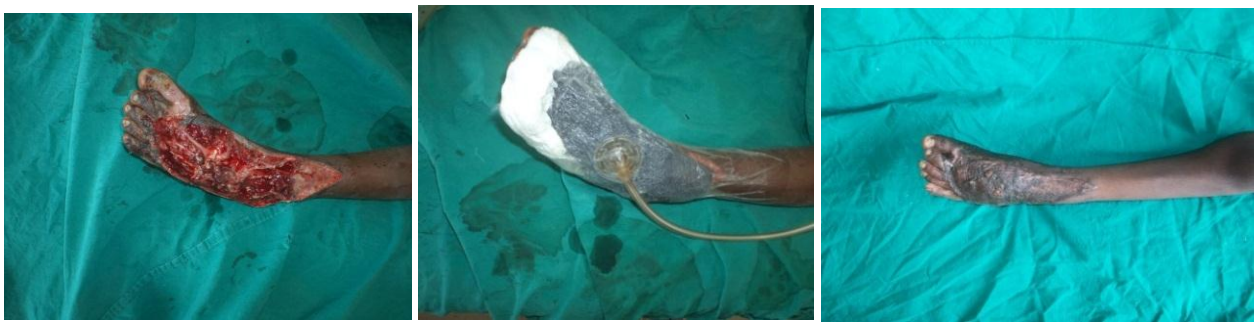

Fig 3: (a) Traumatic injury to left foot of 3 days old, after debridement (b) application of VAC at 125mmHg negative pressure after 2 cycle of vac therapy skin grafting was done (c) follow up

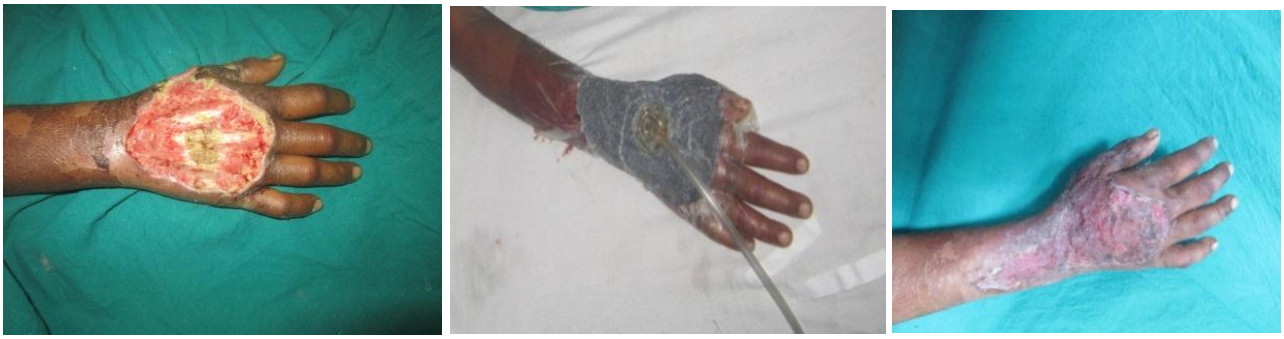

Fig 4: (a) Right dorsum of hand necrotizing fasciitis wound,
(b) VAC AT 125mmHg negative pressure after 2 cycle of vac therapy skin grafting was done, (c)follow up at 5 th day dressing

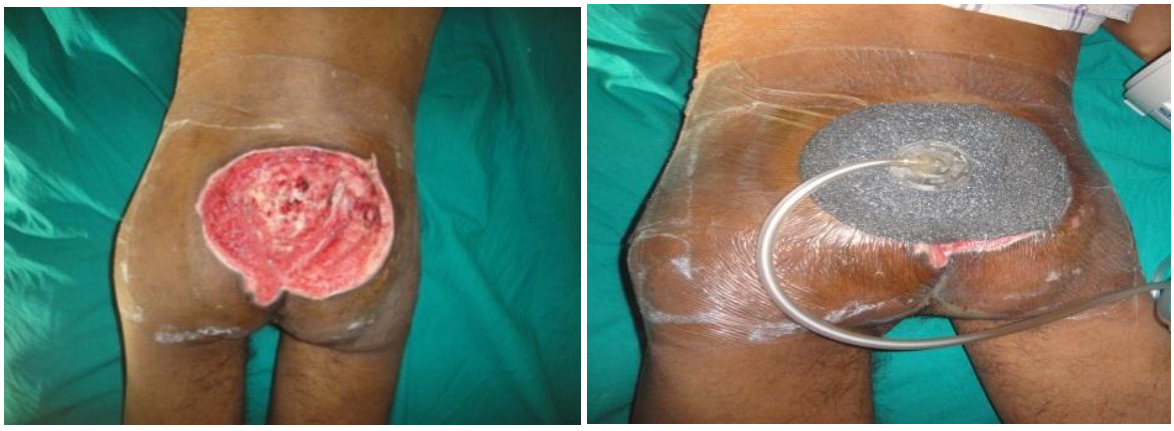

Fig 5: (a) Large sacral sore in paraplegic patient (b) VAC AT 125mmHg negative pressure after 5 cycle of vac therapy wound was contract and bilateral gluteal rotation flap was done.

5. Conclusions

Through our study it has been proven that Negative pressureassisted therapy is more beneficial when comparedto the conventional moist betadinedressings in critical large complicated and non-healing wound, comparing parameters of granulation tissue formation, clearanceof the infection over the

wound, decreasing the durationof hospital stay, and cost effectiveness than compared tomoist dressings.

6. References

1. Fleischmann W, Strecker W, Bombelli M, Kinzl L. Vacuum sealing as treatment of soft tissue damage in open fractures. Unfallchirurg. 1993; 96:488-92.
2. KCI VAC, Available from: http://www.kci1.com/KCI1/educationtraining. [Last accessed on 2014 Nov 11], 2014.
3. Collier M. Topical negative pressure therapy. Nursing Times. 2003; 99(5):54-55.
4. Vacuum therapy in wound management. Vacuum Therapy. Last updated http://www.vacuumtherapy.co.uk/woundcare.htm Accessed June, 2001-2003.
5. Banwell PE. Topical negative pressure therapy in wound care.Journal of Wound Care.1999; 8(2):79-84.
6. Patel CT, Kinsey GC, KoperskiMoen KJ, Bungum LD. Vacuum-assisted wound closure. AJN, American Journal of Nursing. 2000; 100(12):45-48.
7. McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP. Vacuum-assisted closure versus saline-moistened g-auze in the healing of postoperative diabetic foot wounds. Ostomy/Wound Management. 2000; 46(8):28-32.
8. Clarkeand RA, Henson PM. editors. The Molecular and Cellular Biology of Wound Repair. New York, NY, USA: Plenum Press, 1988.
9. Laiho M, Keski-Oja J. Growth factors in the regulation of pericellularproteolysis: A review. Cancer Res, 1989 15; 49:2533-53.
10. Whitby DJ, Ferguson MW. Immunohistological studies of the extracellular matrix and soluble growth factors in fetal and adult wound healing. In: Adzick NS, LongakerMT, editors. Fetal Wound Healing. New York, NY, USA: Elsevier Science, 1992, 161-77.
11. Argenta LC, Morykwas MJ. Vacuum-assisted closure: A new method for wound control and treatment: Clinical experience. Ann PlastSurg, 1997; 38:563-76.
12. Hunt TK. The physiology of wound healing. Ann Emerg Med, 17:1265-73.
13. Ryan TJ. Microcirculation in psoriasis: Blood vessels, lymphatics and tissue fluid. PharmacolTher. 1980; 10:27-64.
14. Leininger BE, Rasmussen TE, Smith DL, Jenkins DH, Coppola C. Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq. J Trauma 2006; 61:1207-11.
15. Orgill DP, Manders EK, Sumpio BE, Lee RC, Attinger CE, Gurtner GC, *et al.* The mechanisms of action of vacuum assisted closure: More to learn. Surgery. 2009; 146:40-51.
16. Borgquist O, Ingemansson R, Malmsjö M. The influence of low and high pressure levels during negative-pressure wound therapy on wound contraction and fluid evacuation. PlastReconstrSurg. 2011; 127:551-9.
17. Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber D, Orgill DP. Vacuumassistedclosure: Microdeformations of wounds and cell proliferation. PlastReconstrSurg. 2004; 114:1086-96.
18. Ingber DE, Levin M. What lies at the interface of regenerative medicine and developmental biology? Development. 2007; 134:2541-7.
19. McLeod KJ, Lee RC, Ehrlich HP. Frequency dependence of electric fi eldmodulation of fi broblast protein synthesis. Science. 1987; 236:1465-9.
20. Adámková M, Tymonová J, Zámecníková I, Kadlcík M, Klosová H. First experience with the use of vacuum assisted closure in the treatment of skin defects at the burn center. ActaChirPlast. 2005; 47:24-7.
21. Lancerotto L, Bayer LR, Orgill DP. Mechanisms of action of microdeformational wound therapy. Semin Cell DevBiol. 2012; 23:987-92.
22. Labanaris AP, Polykandriotis E, Horch RE. The effect of vacuum-assisted closure on lymph vessels in chronic wounds. J PlastReconstrAesthetSurg. 2009; 62:1068-75.
23. Winter GD, Scales JT. Effect of air drying and dressings on the surface of a wound. Nature 1963; 197:91-2.
24. Hinman CD, Maibach H. Effect of air exposure and occlusion on experimental human skin wounds. Nature 1963; 200:377-8.
25. Morykwas MJ, Simpson J, Punger K, Argenta A, Kremers L, Argenta J. Vacuum-assisted closure: State of basic research and physiologic foundation. PlastReconstrSurg 2006; 117:121S-6.
26. Mouës CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE. Bacterial load in relation to vacuum-assisted closure wound therapy: A prospective randomized trial. Wound Repair Regen 2004; 12:11-7.
27. Stinner DJ, Waterman SM, Masini BD, Wenke JC. Silver dressings augment the ability of negative pressure wound therapy to reduce bacteria in a contaminated open fracture model. J Trauma 2011; 71:S147-50.
28. Mendez-Eastman S. Guidelines for using negative pressure wound therapy. Adv Skin Wound Care 2001; 14:314-22.