

# Efficacy of Modified Vacuum Assisted Closure in Wound Healing

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## Abstract

**Background:** Vacuum assisted wound healing is a recent trend and proven method of fast and better healing of wounds. The basic concept is the removal of blood and serous collection from the wound site with negative pressure and promoting the healing process rapidly by altering the local microcellular environment.

**Aim:** The aim of this study is to evaluate efficacy of the modified method of vacuum dressing in wound healing in low resource settings.

**Objectives:** To find out the rate of wound contraction, infection clearance, duration of hospital stay in comparison to betadine dressings.

**Materials and Methods:** In our prospective non-randomized comparative study, a total of 100 patients were taken and divided into two groups with 50 each for conventional betadine dressing and modified vacuum assisted dressing. Vacuum dressing done with autoclaved sponge, opsite, glove, sterile plastic cover and creating a vacuum with 50 cc syringe, romovac, pedal suction, portable motorized suction apparatus. Comparison between the groups made in categories of wound cultures, wound area, wound scoring, duration of hospital stay, cost-effectiveness.

**Results:** Among 50 patients of vacuum dressing, 9 patients are excluded due to various reasons. There is 29.72% decrease in wound area in the experimental group than compared to 19.97% decrease in conventional dressing with  $P = 0.000$ . In wound scoring, 68.16% improvement is seen in the experimental group as compared with 57.10% in the control group with  $P = 0.002$ . There is 19.41% decreased duration of hospital stay in the experimental group. There is a significant decrease in wound infection clearance of 63.4% in the experimental group as compared to 34% in the control group with  $P = 0.005$ . The median cost for modified vacuum dressing was Rs. 311.1111 and compared to Rs. 610.5477 in the control group.

**Conclusion:** Modified vacuum assisted dressing in low resource settings proven effective than conventional betadine dressing.

**Key words:** Negative pressure wound therapy, Opsite, Surgical glove

## INTRODUCTION

Vacuum assisted closure (VAC), may also be known as negative pressure wound therapy or Microdeformational 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.<sup>1</sup> 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 applied is around -125 mm Hg. The interface material used in the VAC therapy stretches the cells at the base of the wound bed, promoting the response for divide and

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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

The trademarked VAC therapy belonging to KCI VAC<sup>2</sup> needed a sophisticated equipment with specialized foam and drain and trained personnel for application and maintenance, which is possible at high cost settings.

There are many studies done to make negative pressure dressing more cost effective and can also be practiced in low resource settings, like Danu and Rosadi,<sup>3</sup> Singh *et al.*<sup>4</sup> who have proven their efficacy in using negative pressure therapy in low resource settings.

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 easily available materials to a surgeon and making in cost effective manner than compared to standard method and achieving similar results in a low resource setting.

## MATERIALS AND METHODS

This prospective comparative study was undertaken at Kasturba Medical College Hospitals and Government Wenlock Hospital attached to Kasturba Medical College, Mangalore, India from October 2012 to September 2014. Ethical approval was obtained for this study from local ethical committee. A total of 100 patients in the study divided into experimental and control groups each of 50 patients in each group and all patients informed consent was taken. All patients are of above 18 years of age of both sexes. 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. Dehiscent 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.

### Materials Needed

1. Autoclaved sponge foam (double autoclaved at pressure of 20 PSI, 250°F for 30 min)<sup>4</sup>
2. Disposable syringes (10 cc, 20 cc, 50 cc), romovac, mucus suckers, pedal suction apparatus, portable electrical suction machine
3. Tegaderm/opsite/plastic cover/surgical glove of appropriate size
4. Suction catheter/Ryle's tube/infant feeding tube
5. Transparent adhesive tape/micropore
6. Cling drape
7. Graph paper
8. Plastic sheet
9. Marker pen.

### Method of Application

After thoroughly debriding the wound from necrotic slough after hemostasis wound surface area is measured by imprint of plastic sheet over graph paper and recorded in cm<sup>2</sup>. Sponge foam which is normally available at hardware stores of 8 mm thickness is taken and is autoclaved and is cut in to shape of the wound with slightly larger size than the wound. Wound swab is taken for culture sensitivity.

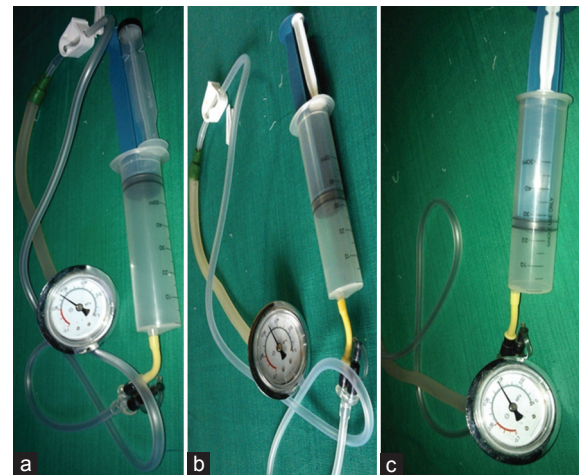
Over the wound surface if there is clean granulation tissue present then bactigrass or Vaseline gauze can be applied so that while removing of dressing the sponge surface will not be adherent to the wound surface and during its removal bleeding can be reduced. A suction catheter/Ryle's tube with adequate number of fenestrations made depending upon the wound size is placed in between the two sponge layers and the whole wound area is sealed with tegaderm/opsite/sterilized polyethylene cover<sup>5</sup>/sterile surgical glove.<sup>6</sup> The exit site of the suction catheter to the opsite T-tailing

should be done to prevent the tubing exit site leakage.<sup>7</sup> The suction catheter on the other end is connected to vacuum creating device and is charged.

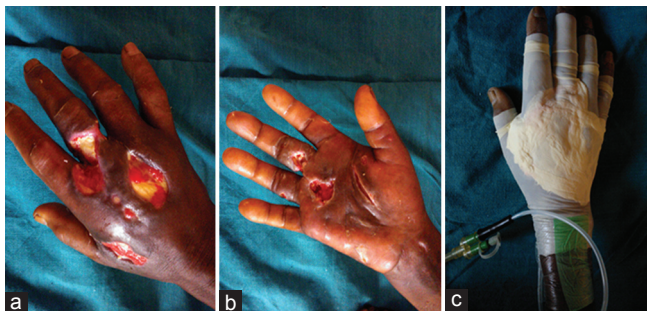
The syringe/romovac/mucus sucker/pedal suction machine is cleared of drainage and recharged with vacuum after each clearance at timely intervals.

The method of application of dressings and the negative pressures that can be created with portable suction, romovac, syringe and mucus sucker are shown in Figures 1-6.

The negative pressure applied will be from  $-75$  mm Hg to  $-200$  mm Hg depending upon the type of modality used to create the vacuum. The characteristic of exuded fluid and quantity is noted down. The wounds surroundings were inspected at time of change of dressing for any spreading cellulitis or maceration. Dressings are changed at intervals of 48-72 h depending upon the amount of exudates



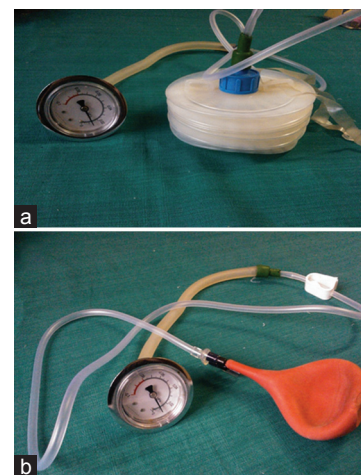
**Figure 3:** (a) Negative pressure created with 50 cc plastic syringe on maximum retraction is 0.06 Mpa = 450 mm Hg pressure, (b) negative pressure created at keeping at level of 30 cc retraction is 0.04 Mpa = 300 mm Hg pressure, (c) negative pressure created at keeping at level of 20 cc retraction is 0.03 Mpa = 225 mm Hg pressure



**Figure 1:** (a) Cellulitis of right hand dorsal aspect post debridement, (b) cellulitis of right hand palmar aspect post debridement, (c) application of vacuum assisted closure dressing using sterile surgical glove with finger tips cut to promote aeration and prevent maceration due to retaining of moisture



**Figure 2:** (a) Traumatic injury to left thumb of 4 days old, (b) after debridement and placement of K-wire and getting infant feeding tube from middle of wound with few serrations outside, (c) application of sponge around the finger and applying negative pressure with help of sterile surgical glove finger and syringe, (d) complete healing seen after seven dressings

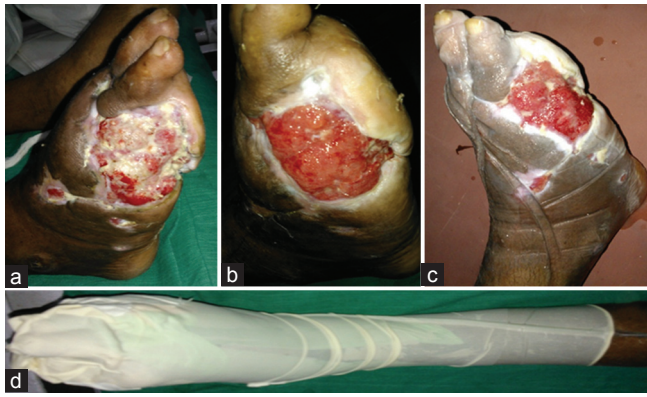


**Figure 4:** (a) Negative pressure created with romovac suction on full compression is 0.02 Mpa = 150 mm Hg, (b) negative pressure created with mucus sucker is 0.01 Mpa = 75 mm Hg



**Figure 5:** (a) Left lower limb necrotizing fasciitis wound, (b) application of dressing with sterile plastic cover, sponge, and sterile gauge, (c) healing response after eight dressings





**Figure 6: (a) Right diabetic foot post debridement, (b) healing response after eight dressings, (c) maceration seen over the foot due to retaining of moisture, (d) application of dressing with sterile gynaecological glove**

drained, leakage from the sealed area due to fluid logging in and also upon the state of the wound and pictures of the wound and measurements are taken.

If maceration present then the next dressing will be applied after 12-24 h interval period to allow the skin to get back to the normal state. When surgical glove is used for dressing then, by creating small fenestrations in the distal end of the glove will allow the minimal air leak and decrease the maceration.

Wound swab and also the exudates obtained in the vacuum device are sent for culture at weekly intervals. The size of the wound is measured every time on change of dressing over the graph paper, and successive measurements will be recorded. The improvement in the wound is assessed by revised photographic wound assessment tool<sup>8</sup> and the scores are noted. The total cost analysis of the dressing for each patient is analyzed separately and recorded.

The vacuum dressing are done till the granulation tissue of the wound fills till to the skin surface and left to healing by secondary intention or as secondary method of wound closure as secondary suturing, split skin grafting, flap repair.

## RESULTS

In our study, among the experimental group nine patients were considered as failure (two patients underwent amputation, two patients developed leak in vacuum, one patient was not willing to continue, four patients not improved and changed to other modality of dressing) and these patients were excluded from study population of vacuum dressing, thereby experimental group  $n = 41$ , control group  $n = 50$ . The mean age distribution in the experimental group is  $45.39 \pm 9.95$  and in control group  $46.72 \pm 7.63$  and sex distribution in experimental

group 34 patients (82.9%) are males and 7 patients (17%) females, in control group 41 patients (82%) males and 9 patients (18%) females. The ulcers are located predominantly over lower limbs and other sites also like upper limb, clavicular region, abdomen, amputation stump, back, neck and scrotum.

The modality to create vacuum are by portable suction machine in 28 cases (68%), by using syringe in 10 cases (24%), pedal suction 2 cases (5%) and using romovac in 1 case (3%), by comparing with Fischer's exact test  $P = 0.0001$  proving highly significant. The materials used for vacuum dressing are with opsite in 21 cases (51%), surgical glove in 12 cases (29%) and plastic cover in 8 cases (20%). On comparison by mode of healing in both groups split skin grafting was done in 41 (82%) cases and 22 (53.7%) cases in control and experimental groups, respectively and healing by secondary intention in 9 (18%) and 17 (41.5%) cases in control and experimental groups respectively, scrotum reconstruction done in 1 (2.4%) case in experimental group, and secondary suturing in 1 (2.4%) case in experimental group with  $P = 0.008$  proving highly significant.

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.

In Culture 1 the predominant organisms being pseudomonas in 16 (40%) and 19 (38%) cases in experimental and control group and *Staphylococcus aureus* in 16 (40%) and 24 (48%) cases in experimental and control group and *Klebsiella* in 4 (10%) and 2 (4%) cases in experimental and control group. In Culture 3 *S. aureus* in 12 (80.0%) and 27 (81.8%) cases in experimental and control group and *Klebsiella* in 3 (20%) cases in experimental group and proteus in 3 (9%) cases and pseudomonas in 3 (9%) cases of control group.

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,

**Table 1: Sequential wound cultures swabs**

Wound culture	Absent (%)	Present (%)	P value
Culture 1			
Experimental group	2.4	97.6	0.451
Control group	0	100	
Culture 2			
Experimental group	29.3	70.7	0.075
Control group	14	86	
Culture 3			
Experimental group	63.4	36.6	0.005
Control group	34	66	

wound scoring assessment by photographic wound assessment tool, pain assessment by visual analog scale has been shown in Table 2.

In our study diabetic patients in experimental and control groups are 15 (36.6%) and 13 (26.0%). Due to vacuum dressing in the experimental group in 4 (9.8%) patients maceration of the skin was observed due to moisture retainment.

The cost-effectiveness of modified vacuum dressing compared with the conventional betadine dressing is measured by comparing to a 20 cm<sup>2</sup> area of wound and the median cost of modified vacuum dressing is much less compared to conventional betadine dressing as shown in Table 3.

## 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.<sup>9</sup> 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.<sup>10,11</sup> 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.<sup>12</sup> Increase in oxygenated blood flow to the damaged tissues increases the wound resistance to the infection.<sup>13</sup> 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.<sup>14</sup>

Negative pressure therapy decreases the interstitial edema and increases the capillary blood flow, promotes granulation tissue formation and produces a traction force whereby

**Table 2: Comparisons on wound area, number of debridements, number of dressings, number of days of hospital stay, wound scoring, pain scoring by VAS**

Group	N	Min	Max	Mean	Standard deviation	Median	Mann-Whitney test Z value	P value	% change
Wound area initial									
Experimental	41	10	458	136.6341	115.9021	128	2.760906	0.005764	-156.928
Control	50	17	106	53.18	20.22091	48			
Wound area final									
Experimental	41	3	437	96.02439	97.0514	78	1.180796	0.237684	-125.621
Control	50	13	90	42.56	17.34189	39.5			
Number of debridements									
Experimental	41	0	5	1.634146	1.444924	2	3.537858	0.000403	44.79235
Control	50	1	6	2.96	1.689825	3			
Number of dressings									
Experimental	41	4	25	10.70732	4.691716	10	7.214766	5.4E-13	59.19468
Control	50	10	47	26.24	9.707056	25			
Number of days of stay									
Experimental	41	15	83	32.17073	14.18433	28	2.491042	0.012737	19.41199
Control	50	15	71	39.92	15.69328	38			
Wound scoring initial									
Experimental	41	15	30	22.36585	4.699766	23	0.104052	0.917128	0.684486
Control	50	14	28	22.52	3.882141	23			
Wound scoring final									
Experimental	41	1	13	7.121951	3.001626	7	3.668592	0.000244	26.2738
Control	50	4	15	9.66	2.811129	9.5			
Pain score VAS									
Experimental	41	2	6	3.853659	0.882071	4	0.427268	0.669184	2.68539
Control	50	2	7	3.96	1.087217	4			

VAS: Visual analog scale

**Table 3: Comparison between costs per 20 cm<sup>2</sup> area of wound**

Group	N	Minimum	Maximum	Mean	Standard deviation	Median	Mann-Whitney test value	P
Experimental	41	41.13	3750	505.3146	701.45988	311.1111	4.072	0.000
Control	50	238.81	1058.82	646.4833	205.17792	610.5477		
Total	91	41.13	3750	582.8798	496.58367	529.4118		

decreases the wound surface area and increases the mitoticity in cells around the area.<sup>15</sup>

It has been proposed four primary mechanisms for healing by negative pressure therapy

1. Macrodeformation or wound shrinkage at the base
2. Microdeformation near the interface sponge
3. Removal of excess fluid
4. Optimizing the wound environment.<sup>16</sup>

### Macrodeformation

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.<sup>17</sup> 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 macrodeformation effects depend upon the variety of tissues, amount of negative pressure, volume of the interface material, and the surrounding tissues deformability.<sup>16</sup>

### Microdeformation

The negative pressure transmitted through interface material acting over the undulated surface of the wound produces changes occur in  $\mu$  to mm range scale. Depending on the common diameters of pores of interface material in range of 400-600  $\mu$ m, on application of the negative pressure there will be 5-20% tissue strain over the wound surface.<sup>18</sup> 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.<sup>19,20</sup>

### 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.<sup>16</sup>

Removal of this excess fluid will decrease the compression of microvasculature there by promoting the perfusion to the local area.<sup>21</sup> 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.<sup>22</sup> Negative pressure therapy also allows for developing of lymphatics at the wound edges thereby improving the fluid drainage.<sup>23</sup> 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.<sup>24,25</sup>

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 anastomotic sites
8. Exposed internal organs.<sup>26</sup>

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.<sup>26,27</sup>

The negative pressure therapy will cause deformations in the cell cytoskeleton architecture leading to cellular proliferation, differentiation, and migration. This has been supported by studies in diabetic mouse model by application of short term intermittent negative pressure there is increased expression of Ki67 which is a marker for proliferation.<sup>28</sup>

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,<sup>29</sup> Mouës *et al.* studies showed there is a decrease in non fermentive Gram-negative bacilli and *S. aureus* increased.<sup>30</sup> 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.<sup>31</sup> Instillation therapy adding of fluid to the wound through a tubing in form of normal saline or other antimicrobials like sodium hypochlorite solution, dilute betadine, doxycycline, phenytoin, lactoferrin are done but trials are needed to prove its efficacy.

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<sup>32</sup> 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.

## CONCLUSION

Through our study it has been proven that modified vacuum assisted therapy is more beneficial when compared to the conventional moist betadine dressings, compared in parameters of granulation tissue formation, clearance of the infection over the wound, decreasing the duration of hospital stay, and cost effectiveness than compared to moist dressings.

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