

## Original Article

# A comparative study of the efficacy of topical negative pressure moist dressings and conventional moist dressings in chronic wounds

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### ABSTRACT

**Aim:** To assess the efficacy of topical negative pressure moist wound dressing as compared to conventional moist wound dressings in improving the healing process in chronic wounds and to prove that negative pressure dressings can be used as a much better treatment option in the management of chronic wounds. **Materials and Methods:** This is a prospective comparative study of data from 112 patients with chronic wounds, of which 56 patients underwent topical negative pressure dressings (17 diabetic, 10 pressure sores, nine ischemic, two varicose, 10 post-infective raw areas and eight traumatic - six had bone exposed, two orthopaedic prosthesis exposed). The remaining 56 patients underwent conventional moist dressings (20 diabetic, two ischemic, 15 pressure sores, three varicose, eight post-infective raw areas and eight traumatic - five had bone exposed, three orthopaedic prosthesis exposed). The results were compared after 10 days. The variables compared were, rate of granulation tissue formation as a percentage of ulcer area covered, skin graft take up as the percentage of ulcer surface area and duration of hospital stay. The variables were compared using Unpaired Student's t test. A "*P*" value <0.05 was considered significant. **Results:** Out of 56 patients who underwent topical negative pressure dressings, six (10.71%) were failures, due to failure in maintaining topical negative pressure due to defective sealing technique; these were included into the study group. After 10 days, the mean rate of granulation tissue formation was 71.43% of ulcer surface area. All these 56 cases underwent split-thickness skin grafting. The mean graft take-up was 79.29%. The mean hospital stay was 32.64 days. In the remaining 56 patients, the mean rate of granulation tissue formation was 52.85% of ulcer surface area. The mean graft take-up was only 60.45% of the total ulcer surface area. The mean hospital stay was 60.45 days. **Conclusion:** To conclude, topical negative pressure dressings help in faster healing of chronic wounds and better graft take-up and reduce hospital stay of these patients.

### KEY WORDS

Hydrocolloid occlusive dressing, rate of granulation tissue formation, sub-atmospheric pressure, topical negative pressure moist wound dressing, vacuum-assisted closure

Chronic wounds, especially of the non-healing types, are one of the most common surgical conditions a surgeon comes across. Whatever the

management given, chronic wounds, especially pressure ulcers or bed sores refuse to heal. The issue of chronic wound management still remains an enigmatic challenge.

Empirically, the ancient physicians of Egypt, Greece, India and Europe developed gentle methods of treating wounds by removing foreign bodies, suturing, covering wounds with clean materials and protecting injured tissue from corrosive agents.<sup>[1]</sup> During the last two decades a wide variety of innovative dressings have been introduced.

### **Objectives of the study**

To compare the efficacy of topical negative pressure hydrocolloid moist dressing with that of a control group using conventional moist wound dressings, in healing of chronic ulcers, in terms of: 1) Number of days required for healing, 2) Number of ulcers unhealed in either group at the end of trial period. 3) Rate of granulation tissue formation as percentage of ulcer surface area 4) Graft survival as percentage of ulcer surface area 5) Period of hospital stay.

### **MATERIALS AND METHODS**

This prospective comparative study included 112 patients with chronic wounds of varying aetiology, admitted to the Fr. Muller Medical College, Mangalore, from September 2003 to October 2005 satisfying all the inclusion criteria mentioned below after the clearance from the ethical committee was obtained. All chronic wounds where conventional dressings were indicated were included in the study. The main inclusion criteria were (a) Patients with age between two to 75 years, (b) All types of chronic wounds irrespective of aetiology, (c) Wound size <10% Total Body Surface Area, (d) Patients giving consent for topical negative pressure dressings.

The main exclusion criteria for the study included (a) Wounds with necrotic tissue, (b) Untreated underlying osteomyelitis, (c) Fistulas to organs or body cavities, (d) Exposed arteries or veins, (e) Malignancy within wounds, (f) Dry gangrene.

The whole sample population was divided into two equal and comparable groups of 56 patients, based on the willingness for undergoing topical negative pressure dressing (Group I). Those who were not willing were subjected to conventional moist wound dressings and formed the control group (Group II). Selection of patients was done by purposive sampling method. Care was taken so that both the groups had a comparable distribution of patients with regards to age as well as aetiology of the ulcer.

All patients underwent detailed clinical examination and relevant investigations and the wounds were thoroughly

debrided and the ulcer dimensions as well as the surface area assessed using vernier calipers, before both types of dressings were applied. The patients were followed up on a daily basis for 10 days in both the test and control groups. The control group was subjected to twice-daily dressings by conventional methods i.e., cleaning with hydrogen peroxide and normal saline, dressing the wound with povidone iodine and saline-soaked gauze; whereas the test group consisting of patients on topical negative pressure dressings, was left undisturbed for 10 days and wound was inspected twice daily.

### **Materials used**

The application of topical negative pressure moist dressings needs the following materials: synthetic hydrocolloid sheet, vacuum suction apparatus, transparent semi-permeable adhesive membrane sheet.

### **Technique of application**

The topical negative pressure wound dressing is a combination of composite synthetic hydrocolloid sheet dressing with vacuum-assisted wound closure systems. The technique involves six steps. All the patients included in Group I were subjected to these six steps. These were as follows:

1. The wound was thoroughly debrided and devitalised tissue removed [Figure 1]. A perforated drain tube was placed on top of the wound bed and the other end was brought out subcutaneously a little away from the main wound.
2. The hydrocolloid foam dressing soaked in povidone iodine solution was cut to the size of the wound and applied over the drain tube.
3. The foam with the surrounding normal skin was covered with adhesive, semi-permeable, transparent membrane. A good air seal was thus ensured around the wound.
4. The distal end of the drain tube was now connected to a device which provided a negative pressure suction in the range of -25 to -200 mmHg (-100 to -175 mmHg in most of the cases). This was achieved by wall suction apparatus or simple suction drain devices. Suction was applied continuously or intermittently based on amount of wound discharge.
5. Once vacuum is applied, the foam must be seen collapsed into the wound bed, thus giving the surface a concave appearance [Figures 2a-c].
6. The fluid from the wound is absorbed by the foam and is removed from the wound bed by suction.

The negative pressure was maintained for an average of 10-14 days for maximum benefit as other studies have proved.<sup>[2]</sup> Once adequate granulation tissue was formed



**Figure 1:** Photograph showing post-traumatic wound over the leg with exposed tibia

the dressing was removed [Figure 3] and definitive wound closure achieved by skin grafts, flaps or suturing [Figure 4]. At the end of 10 days the wounds in both the groups were inspected. [Figures 5a-b]. The wounds were compared based on the following parameters: rate of granulation tissue formation as percentage of the ulcer surface area, quality of ulcer bed, present dimensions and surface area of the ulcer. Once these parameters were assessed, both the groups were subjected to split-thickness skin grafting. Both groups were given the same systemic antibiotics during the postoperative period. The wounds were reassessed at the end of the fifth postoperative day and the following parameters were accounted for: skin graft take-up as a percentage of ulcer surface area, number of days of hospitalization.

After discharge, patients were followed up in the outpatient department after one month to assess post-



**Figure 2a:** Photograph showing negative pressure dressing with collapsed foam following vacuum application (concave appearance of surface)



**Figure 2c:** Photograph showing the pressure gauge of the wall suction apparatus



**Figure 2b:** Photograph showing the wall suction apparatus used for vacuum application



**Figure 3:** Photograph showing healthy granulation tissue after opening the negative pressure dressings on the 10th day

skin-grafting complications like contractures, itching, pain and infection, wound dimensions. The results obtained were statistically evaluated and the main parameters analysed, were rate of granulation tissue formation,

graft survival and take-up, duration of hospital stay. The mean rate of granulation tissue formation, graft survival and hospital stay was calculated and compared for both groups. The variables were compared using the Unpaired Student's t-test. A "P" value <0.05 was considered significant.

## RESULTS

The 112 patients admitted for the study were divided into two equal and comparable groups. Patients subjected to topical negative pressure moist dressings were classified under Group I and those who underwent conventional moist wound dressings were classified as Group II. The patient's characteristics of the two groups were well matched as given in the table below [Table 1].

The age-wise distribution of the patients in this study is as given below [Table 2]. The mean age in Group I was 47.59 years and in Group II was 47.42 years.

In the study group six patients (10.71%) were considered as failures due to vacuum leakage. These patients were included into the study group and grafted at the same time as the non-leakers.

All the patients included in the study were suffering from chronic ulcers of varied aetiology. The aetiology-wise distribution of the ulcers in both groups is shown below [Table 3]. The main aetiology in both groups was diabetes mellitus followed by pressure ulcers.

The sex-wise distribution of Group I was as follows: 31 were males and 25 were females. In Group II, there were



Figure 4: Photograph showing post-STSG third postoperative day with 100% graft take



Figure 5a: Photograph showing two weeks post-STSG with 100% graft take



Figure 5b: Photograph showing one year post-STSG with 100% graft take

Table 1: Basic patient data

	Group I	Group II
No. of patients	56	56
Range of age(years)	4-75	15-75
Male-female ratio(M:F)	31:25	34:22
Range of ulcer surface area (cm <sup>2</sup> )	6-200	4-160

Table 2: Age-wise distribution of patients

Age group	No. of patients	
	Group I	Group II
<15	1	0
15-25	2	3
25-35	4	8
35-45	16	12
45-55	17	15
55-65	14	16
65-75	2	2

**Table 3: Aetiology-wise distribution of patients**

Aetiology	No. of patients	
	Group I	Group II
Diabetic ulcer	17	20
Ischemic ulcers	9	2
Pressure sores	10	15
Venous ulcers	2	3
Post-infective raw area	10	8
Traumatic	8	8

34 males and 22 females. All the patients belonged to the middle and low socioeconomic groups.

The efficacy of the dressing was assessed as the percentage of ulcer surface area covered by healthy granulation tissue after 10 days. The mean rate of granulation tissue formation in Group I was 71.43%  $\pm$  26.45 (SD) of total ulcer area and in Group II was 52.85%  $\pm$  21.37 (SD) of total ulcer area [Table 4].

The patients in both groups were subjected to split-thickness skin grafting as the final treatment modality. The graft take-up was then assessed at the end of the fifth postoperative day as the percentage of ulcer surface area. In Group I and II graft take-up was 80-100% in 42 and 19 patients; 60-80% in 6 and 22 patients, <60% in 8 and 15 patients respectively.

The mean graft take-up in Group I was 79.29%  $\pm$  21.22 (SD) and in Group II was 60.45%  $\pm$  19.34 (SD). The quality of life of the patients in both the groups as assessed by total stay in the hospital is as follows [Table 5].

The mean hospital stay in Group I was 32.64  $\pm$  13.81 (SD) days and that in Group II was 60.32  $\pm$  16.48 (SD) days. In both the groups, no complications occurred during the application of dressings, skin grafting or in the postoperative period. The patients were followed up after one month of discharge. The main postoperative parameters noted in both the groups during follow-up were wound size, contractures, pain, and infection. All

**Table 4: Distribution of patients based on rate of granulation formation**

Group	>90%	80-90	70-80	60-70	50-60	40-50	<40%
I	22	6	6	5	6	3	8
II	5	5	3	6	2	8	27

**Table 5: Distribution of patients based on number of days of hospital stay**

Group	10-20	20-30	30-40	40-50	50-60	60-70	70-80	80-90
I	7	30	6	5	4	3	1	0
II	0	6	2	4	7	24	8	5

these parameters were less in Group I as compared to Group II.

(a) Including vacuum leakers (six patients) into the study group. The ulcers included in this study in both the groups had diverse aetiologies but the diabetic ulcers formed the major component of each group. Both groups had comparable age and sex distribution. The mean rate of granulation tissue formation in both the groups were 71.43% (SD = 26.45) for Group I and 52.85% (SD = 21.37) for Group II. The results were analyzed by Unpaired Student's t-test which showed highly significant difference in the rate of granulation tissue formation ( $P < 0.000082$ ). The mean graft take-up in both the groups was 79.29% (SD = 21.22) for Group I and 60.45% (SD = 19.34) for Group II. Analysis of the data by Unpaired Student's t-test revealed highly significant difference in graft take-up ( $P < 0.000003$ ). The total days of hospital stay for the patients were also compared. The mean number of days of hospital stay was 32.64 days (SD = 13.81) for Group I and 60.32 days (SD = 16.48) for Group II. Analysis of the data showed highly significant difference in the hospital stay in both groups with a negligibly low  $P$  value obtained in the Unpaired Student's t-test.

(b) Excluding vacuum leakers (six patients) from the study group. The mean rate of granulation tissue formation in both the groups was 79.9% (SD = 18.45) for Group I and 52.85% (SD = 21.37) for Group II. The results were analyzed by Unpaired Student's t-test which showed highly significant difference in the rate of granulation tissue formation ( $P < 0.00000001$ ). The mean graft take-up in both the groups was 80.6% (SD = 15.14) for Group I and 60.45% (SD = 19.34) for Group II. Analysis of the data by Unpaired Student's t-test revealed highly significant difference in graft take-up ( $P < 0.0000001$ ).

## DISCUSSION

World War I resulted in rapid discoveries regarding the care of wounds, the foremost among these being the use of extensive debridement.<sup>[1]</sup> Antoine Depage,<sup>[3]</sup> a Belgian surgeon, was largely responsible for the development and proper use of debridement. The entire category of skin ulcers is now included in the term chronic wound. The management of chronic wounds includes the correction of the underlying disease processes also.<sup>[4]</sup> The concept of moist wound dressings which came into vogue in the 1960s revolutionized wound care.<sup>[5]</sup> Hydrocolloid dressings remain popular even today. The

reason for this is that they provide a convenient and cost-effective treatment option for those who deal with the management of chronic wounds such as pressure sores and leg ulcers. Tegaserb Thin from 3M (hydrocolloid) can create the optimal moist wound healing environment.<sup>[6]</sup>

In the early 1990s, the concept of topical negative pressure moist wound dressing was introduced into the field of chronic wound care. This type of dressing involved a combination of hydrocolloid dressings with topical negative pressure dressings.<sup>[7]</sup> The concept of applying a sub-atmospheric environment on wounds to accelerate the healing process came into practice in 1993 and was first described by Fleischmann *et al.*<sup>[6]</sup> The science behind topical negative pressure dressings is to apply a sub-atmospheric pressure over a wound bed and maintain the negative pressure environment by means of a semi-permeable occlusive coverage. Since the wound is occluded from the surrounding environment it is also called "Limited Access Dressing (LAD)".<sup>[7,8]</sup>

The fundamental principle behind topical negative pressure dressing is the application of sub-atmospheric pressures ranging from -25 to -200 mmHg at the wound bed.<sup>[7-9]</sup> A number of factors are found to be involved in delayed wound healing in chronic wounds, when conventional methods of wound dressings are used. These factors mainly include:

- 1) Peripheral oedema and circulatory compromise at wound bed,
- 2) Bacterial colonization,
- 3) Retarded granulation tissue formation.

*Peripheral oedema and circulatory compromise:* Local oedema fluid build-up produces a localized rise in the interstitial pressure, which leads to impaired local perfusion due to back pressure effects on capillary and lymphatic flow. Oedema fluid promotes bacterial colonization of the wound, impaired lymphatic clearance of growth-inhibiting factors and cellular wastes. When negative pressure is applied over the wound bed, the oedema fluid is evacuated along with all growth-inhibiting factors. This relieves the back pressure effect on the healing tissues leading to improvement in local perfusion, local immunity, cellular waste disposal and tissue nutrition and oxygenation. The most optimum negative pressure range is, as per studies, -25 to -200 mmHg.<sup>[7-9]</sup> A study by Morykwas *et al.*<sup>[10]</sup> proves -125 mmHg to be the optimum negative pressure. Much lower or excessively high pressure levels lead to a significant reduction in the formation of granulation

tissue. This level of vacuum suction pressure was also found to increase the rate of granulation tissue formation by 64% when applied continuously compared with wet-to-moist dressing changes and increased granulation tissue formation 103% with intermittent application compared with saline wet-to-moist gauze dressing changes.

*Bacterial colonization:* The accumulated oedema fluid acts as a good medium for bacterial proliferation at the wound site. The impaired circulation and the resultant reduced local immunity also contribute to this. The microbial infection delays the healing process by a number of mechanisms. The microbes consume oxygen and nutrients from the healing wound environment. Moreover, they express certain proteases and enzymes that break down cytokines which are necessary for the proper progress of healing. Topical negative pressure application is believed to achieve reduction of bacterial load and faster wound healing by removal of accumulated interstitial fluid, improved local circulation and oxygenation and improved local immunity.

*Retarded granulation tissue formation:* Retarded granulation tissue formation is mainly due to the combined effect of interstitial fluid accumulation, circulatory compromise and local bacterial colonization. Topical negative pressure application has been proved to be effective in improving granulation tissue formation and maturation. Studies conducted by Morykwas and colleagues,<sup>[9-12]</sup> Falanga<sup>[13]</sup> and Fabian, *et al.*<sup>[14]</sup> have shown that the mechanical stress that is applied on tissues by topical negative pressure has a stimulatory action on granulation tissue. This is by multiple mechanisms like, a) Stimulation of mitosis b) Enhanced angiogenesis c) Increased protein and matrix synthesis d) Improved epithelialisation.

Clinically, the treatment of chronic wounds such as venous stasis ulcers, with lower levels (-25 to -50 mmHg) of sub-atmospheric pressure is very effective. Initially, higher levels of sub-atmospheric pressure often cannot be used with these patients because of pain issues. Although low vacuum pressure levels produce granulation tissue in these patients, the rate of granulation tissue formation is definitely slower than that observed in other clinical settings.<sup>[10]</sup>

The patient selection is very important prior to application of topical negative pressure therapy. The conditions mentioned in the exclusion criteria are the contraindications, where this mode of wound management either fails or is dangerous.<sup>[2,15]</sup>

The Table 6 shows a comparison of the present study to a similar study conducted by Joseph *et al.*<sup>[16]</sup> The important difference between the present study and the one shown above is that the present study has a higher sample size. Moreover, the above-mentioned study also used local irrigation of the wound with iodine solution in the topical negative pressure group which was not followed in the present study. In two other studies by Eginton *et al.*<sup>[17]</sup> and Isago *et al.*<sup>[18]</sup> it has been shown that the ulcer dimensions have been significantly reduced by topical negative pressure moist dressings. Page *et al.*<sup>[19]</sup> conducted a retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defect and concluded that negative pressure wound therapy reduced the risk of complications, subsequent foot surgeries and hospital readmissions by 70% or more. Length of hospital stay, rate of granulation and wound healing were faster with negative pressure wound therapy.

### Cost consideration

Various studies conducted by Philbeck *et al.*<sup>[20]</sup> have shown the cost effectiveness of topical negative pressure dressing. The cost-effectiveness of this modality of treatment over conventional dressing techniques is believed to be due to 1) Lesser time required for wound to heal or granulate, 2) Better response to definitive treatment modalities like grafting, flaps etc. after removal of topical therapy, 3) Less frequency of dressing changes thus reducing service as well as material charges.

### Limitations of the study

The most important limitation of the present study is its sample size. Although a sample size of 112 patients is sufficient for statistical analysis, a randomized controlled comparative study with a much larger population may help to further substantiate the findings or reveal variations which were not observed in the present study. The cost burden on the patient is also not analyzed in this study as this can be influenced by various factors other than the cost

of dressings. The quantitative assessment of postoperative parameters like wound contraction, pain and residual raw ulcer area was also not included in the present study, which if included, might have given a much better analysis of the efficacy of topical negative pressure moist dressings as compared to conventional moist dressings.

The gold standard in topical negative pressure therapy is the vacuum-assisted closure V.A.C<sup>®</sup> system operated by Kinetic Concepts Inc. (KCI) Company,<sup>[10]</sup> San Antonio, TX. Because of its high cost, we have not used this device in our study.

In this study, the study group was treated by using a perforated drain tube covered with Hydrocolloid, a membrane and a seal. This design could lead to blockade of the tube's perforation due to the hydrocolloid above or the wound tissue from below. Therefore the application of the negative pressure to the whole area of the chronic wound may be very limited. Hence in our study, positive effect shown may be related to hydrocolloid wound therapy. To prove the effectiveness of our study setup the control group should have been treated with sealed hydrocolloid instead of conventional wet wound dressings.

Despite recent clinical success with the use of Vacuum-Assisted Closure (VAC) in a variety of wound types, problems may occur with the application of VAC system in certain areas of the body. The main limitation occurs when attempting to maintain an airtight seal over irregular surfaces surrounding a wound. For example, application of the adhesive drape and creation of a seal are particularly difficult in the hip and perineum. In addition, wounds of the lower extremity can occur in multiple sites, posing the problem of providing a vacuum dressing to more than one wound from one suction pump machine. Greer *et al.*<sup>[21]</sup> developed a technique of VAC dressing to wounds in difficult regions like above.

Singh *et al.*<sup>[22]</sup> have conducted a meta analysis of randomized controlled trials on hydrocolloid occlusive dressing (HCD) versus the conventional gauze dressing in the healing of chronic wounds. All available controlled clinical trials published before December 2001 that compared HCD to conventional gauze dressing in the healing of chronic wounds were systematically reviewed. They identified and analysed 12 randomized trials comprising 693 patients with 819 ulcers. Overall odds ratio under the fixed effect model was 1.72, i.e. 72% more ulcers healed completely with HCD than

**Table 6: Comparison of present study to study by Joseph *et al.***

Variables	Joseph <i>et al.</i>		Present study	
	Vacuum group	Control group	Vacuum group	Control group
Sample size	18	18	56	56
Mean age	52.41	53.2	47.59	47.42
	years	years	years	years
Rate of granulation	81.56%	54.3%	71.43%	52.85%
Graft take-up	85.3%	56.43%	79.29%	60.45%
Hospital stay	36.24	70.4	32.64	60.32
	days	days	days	days

with conventional gauze dressing. This result was both clinically and statistically significant.

Air leak in VAC leads to continual flow of air over the surface of the wound which dehydrates the tissue causing the formation of a layer of necrotic eschar. This eschar effectively seals the wound, retains exudates and prevents contracture of the wound. The commercially developed system (VAC-KCI) includes an elaborate sensor that warns of an air leak in the system and turns off the pump if the leak is not corrected.

In our study, we have not used the commercially developed VAC-KCI system due to the cost factor. We have used wall suction apparatus for creating vacuum suction. The negative pressure used in our study ranged from -25 to -200mmHg (commonly used pressure is -100 to -175mmHg) depending on the aetiology of the ulcers. We have not done any study on the optimal negative pressure and we have not maintained a record of specific pressures used in individual cases.

## CONCLUSION

In our present study it was concluded that the rate of granulation tissue formation, overall graft survival and patient compliance was better in the topical negative pressure dressing group as compared to the conventional dressing group. It was also seen that the overall hospital stay and postoperative complications were less in the topical negative pressure dressing group. Topical negative pressure dressing was found to be totally safe, although technically demanding, by virtue of one time application of dressing. Thus, topical negative pressure moist wound dressing can be considered as a superior option in the management of chronic wounds. But further studies with a larger population will be needed in the future before topical negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of chronic wounds.

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