International Journal of Research in Orthopaedics
Lingayat MB et al. Int J Res Orthop. 2023 Sep;9(5):xxx-xxx
http://www.ijoro.org

Original Research Article

DOI: https://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20232503

Assessment of the effect of low-cost negative pressure dressing on wound healing

Maruti B. Lingayat, Abhay M. Kawedia*, Hitarth J. Gathani, Karan Baria, Swapnilkumal Patil

Department of Orthopaedics, Government Medical College, Aurangabad, Maharashtra, India

Received: 07 August 2023
Revised: 10 August 2023
Accepted: 11 August 2023

***Correspondence:**
Dr. Abhay M. Kawedia,
E-mail: akawedia@gmail.com

ABSTRACT

Background: Wound care is a priority element in the management of grade 3 compound fractures and has traditionally relied on the use of dressing products (gauze, foam dressings, alginates, and hydrocolloids) and manual debridement. Paving the way to the future, there are now several alternative therapies, of which negative pressure wound therapy (NPWT) is an emerging treatment. Negative suction dressing has been proven to be superior in wound healing and is faster compared with regular dressing using gauze, hydrocolloids, and local debridement. It leads to faster rates of skin cover spontaneously or with surgical procedures like skin graft and flaps, eventually resulting in early internal fixation of fractured bones, if any. The present study was designed to assess the effect of the negative pressure dressing technique on wound healing and to compare its effect with that of the conventional dressing technique.
Methods: The study was a double-blind randomized control trial conducted after ethics approval. A case record form was used for data collection after obtaining the participants' informed consent, and a total of 120 patients participated in the study.
Results: Low-cost negative pressure dressing has an effect on general conditions, fever, hyperemia, and irregular margins. It was observed to increase granulation tissue formation and decrease pus/serous discharge and was associated with a decreased number of hospital visits due to early healing compared with normal dressing.
Conclusions: The low-cost negative dressing technique was effective in healing wounds in type III open fractures and was associated with early recovery compared with the normal dressing technique.

Keywords: Open fractures, Wound healing, Negative suction therapy, Normal dressing

INTRODUCTION

Wound healing involves a complex interplay. A dozen methods such as cleaning, dressing with povidone-iodine, mechanical debridement, chemical debridement with Eusol or H_2O_2, hyperbaric oxygen therapy, and negative pressure therapy are available and used.[1] Wound care is a priority element in the management of grade 3 compound fractures, which has traditionally relied on the use of dressing products (gauze, foam dressings, alginates, and hydrocolloids) and manual debridement. Paving the way to the future, there are now several alternative therapies, of which negative pressure wound therapy (NPWT) is an emerging treatment. NPWT was first introduced in North America in 1995. It is an adjunctive therapy consisting of a noninvasive wound closure system that uses controlled negative pressure to promote healing.[2] Negative suction dressing has been proven to be superior in wound healing and is faster compared with regular dressing with gauze, hydrocolloids, and local debridement.[3] It leads to faster rates of skin cover spontaneously or with surgical procedures like skin graft and flaps, eventually resulting in early internal fixation of fractured bones, if any. In case of open fractures, early wound healing leads to early chances of internal fixation of compound fractures, resulting in a better range of motion and reduced changes of stiffness,

arthritis, and osteomyelitis.[4] The reported benefits of NPWT are that it provides a closed moist wound-healing environment; decreases wound volume by drawing the wound edges together; removes exudate; reduces infection and chances of chronic osteomyelitis; reduces edema at the wound site, thereby increasing blood flow; and increases mitosis, promoting granulation. Some of its added advantages include the absence of pain during daily dressing and early increased range of motion of the joints. NPWT used worldwide uses a dedicated vacuum pump machine, granulation foam, semi-permeable drapes, suction tubing, and ports that cost around 10,000–20,000 rupees and is usually not affordable for patients coming to the government hospital setup. This gave rise to an alternative, cost-effective method whose results are comparable to those of NPWT – the low-cost negative suction wound therapy, which uses a suction machine, hardware sponge, sterile plastic sheet, suction drain, and an urban sellotape, costing 600–800 rupees on average each time.[5]

The present study was designed to assess the effect of the low-cost negative pressure dressing technique on wound healing and compare the effect with that of the conventional dressing technique.

METHODS

The study was a double-blind randomized control trial (RCT) conducted at Government Medical College Aurangabad after approval from the institutional ethics committee (IEC) over four months from August 2022 to December 2022. A case record form was designed by the principal and co-investigator with the help of other faculty members of the department of orthopedics. The case record form comprised three sections: Section A asked for patient demographics; section B elicited medical history; and section C comprised two scales: The Kuppuswamy socioeconomic scale and Gustilo–Anderson classification of open fracture.[6] Characteristics of a healing wound were checked using a checklist. Patients visiting the OT/ST room or orthopedic OPD were screened using the Gustilo–Anderson classification, on meeting the inclusion criteria and ruling out any of the exclusion criteria, the patient was administered the ICD for enrollment into the study

Inclusion criteria

Grade 3a, 3b or 3c wounds according to the GUSTILO classification, patients of age and any gender, patients giving their informed consent to use the negative pressure technique, and patients giving their informed consent to participate in the study were included.

Exclusion criteria

Patients refusing to give their consent, patients on antibiotics/local debridement/other methods of wound healing, and patients withdrawing consent in follow up or losing to follow up were excluded.

A complete sample of 120 patients was drawn and administered sections A and B of the questionnaire. After the enrollment of all participants, they were further matched according to age, sex, and current treatment. The participants were then randomized into two groups, namely the normal dressing group and the low-cost NPT group, by a person separate from using randomization.com using their unique ID generated on enrollment by an investigator not part of the analysis of the clinical outcome. Wounds were treated until the wound was closed spontaneously or surgically, whichever was earlier.

Items required for the low-cost technique of negative suction dressing are as follows: hardware sponge, sellotape, ioban, suction drain, which can be reused, and sterile bedsheet.

First, the wound was thoroughly debrided in the surgical OT to decrease bacterial load and remove foreign materials stuck inside the wound. The hardware foam was then cut in the shape of the wound. Afterward, the suction drain tip was passed longitudinally through the sponge, and the opposite end was attached to a suction machine. The sponge was then covered with an Ioban to make it airtight. A sterile bedsheet was subsequently wrapped around the Ioban, and a layer of sellotape was applied around the entire bedsheet.

The negative suction dressing was given for 1 hour, with a pressure of 50–60 mmHg, kept for a period of five days, and then removed. The wound was then cleaned with normal saline and covered for a day. The negative pressure dressing was reapplied the next day, if required, again for a period of five days. This process was repeated until the wound closed spontaneously or seemed healthy enough for splint skin grafting. There were no ADRs related to the process except the risk of cross infections if not sterilized properly.

Characteristics of the wound were noted using the checkbox technique comprising the general patient's condition, fever spikes, hyperemia around the wound, irregular/regular margins, presence or absence of healthy granulation tissue, foreign body/slough formation, serous/pus discharge, number of hospital visits required to heal or become healthy from an unhealthy/infected wound.

For a clinical superiority trial with continuous variable, the following formula was used for sample size calculation.

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta}}{\delta - \delta_0}\right)^2 \times s^2$$

Here, N = size per group; z_x= the standard normal deviate for a one- or two-sided x; δ_0=a clinically acceptable margin; and S_2=the pooled standard deviation of both comparison groups. Taking α=0.05 and β=0.1, estimating the power of the study at 90%, and considering the clinically acceptable margin as 1 and the SD observed between the two groups (measured in the Alzheimer's

disease assessment scale–cognitive subscale [ADAS-Cog]) as 2, the sample size for single group came to 61 participants, accounting for 50% drop rate due to the intensity of treatment frequency. Factoring in the equal distribution of participants in the control and treatment groups, the total count for the two arms of the study reached 120 participants.[7] The participants were randomized into two arms: experimental (low-cost negative pressure technique) and control (local debridement). The randomization was performed by an investigator not involved in the administration or analysis of the low-cost negative pressure technique on randomization.com, which uses block randomization by a computer-generated random number list. The participants were blinded to the status of the low-cost negative pressure technique. Furthermore, those assessing the clinical outcomes were blinded to the randomization status, and those administering the intervention were not privy to the clinical outcomes. Descriptive statistics (mean, standard deviation, and proportions) were used to summarize the study variables. The study used 95% confidence intervals (CI) for mean difference. A Chi-square test was used to identify an association between the qualitative data and outcome variables. An unpaired t-test was used to compare the two groups in terms of quantitative data and outcome variables

RESULTS

The total number of patients who cleared the screening test and participated in the trial was 120, of which 60 belonged to the low-cost negative pressure technique group and 60 to belonged the normal dressing group.

Table 1: Demographic distribution of all participants.

Age group (years)	Low cost negative pressure dressing	Normal dressing
	No. of patients	No. of patients
18 to 30	15	11
31 to 40	14	15
41 to 50	18	8
51 to 60	10	16
61 to 70	3	9
71 to 80	0	1
Total	60	60

Group A

Low-cost negative pressure technique, n=60.

The age range of the participants was 20–65 years with a mean age of 41.3±12.4 years. All patients were male. Of the 60 participants, two had a history of comorbidities, three had a history of addiction, and none had a significant contributing family history. Further, three patients had a good general condition and the remaining 57 had a moderate general condition at first visit. Tables 2 and 3 illustrate the effect of the low cost negative pressure technique on clinical and laboratory parameters.

Null hypothesis

The low-cost negative pressure dressing has no effect on wound healing.

Alternate hypothesis

The low-cost negative pressure dressing has an effect on wound healing.

As the calculated t-value is greater than the t-tabulated value at $p<0.05$, where df=59, the null hypothesis H_0 should be rejected and the alternate hypothesis H_a accepted. In other words, low-cost negative pressure dressing has an effect on Hb, platelet, sr. creatinine, SGOP, and SGPT.

As the calculated t-value is lower than the t-tabulated value at $p<0.05$, where df=59, the null hypothesis H_0 should be accepted and the alternate hypothesis H_a rejected. In other words, low-cost negative pressure dressing has no effect on the total leucocyte count (TLC).

Group B

Normal dressing, N=60.

The age range of the participants was 19–80 years with a mean age of 45.9±14.5 years. All patients were males. Of the 60 patients, four had a history of comorbidities, one had a history of addiction, and none had a significant contributing family history. Moreover, from the patients, one had a good general condition and the remaining 59 had a moderate general condition at first visit. Tables 4 and 5 illustrate the effect of normal dressing technique on clinical and laboratory parameters.

Null hypothesis

Normal dressing has no effect on symptoms.

Alternate hypothesis

Normal dressing has an effect on symptoms.

As the calculated t-value is greater than the t-tabulated value at $p<0.05$, where df=59, the null hypothesis H_0 should be rejected and the alternate hypothesis H_a accepted. This suggests that normal dressing has an effect on Hb, platelet, sr. creatinine, SGOP, and SGPT.

As the calculated t-value is lower than the t-tabulated value at $p<0.05$, where df=59, the null hypothesis H_0 should be accepted and the alternate hypothesis H_a rejected. This suggests that normal dressing has no effect on TLC.

Table 2: Effect of low-cost negative pressure technique on clinical parameters.

Parameter	BT	AT	Chi-square tabulated	Chi-square calculated	Significant
GC					
Moderate	57	8	3.84	80.59	Significant association
Good	3	52			
Fever					
Yes	43	0	3.84	60.01	Significant association
No	17	60			
Hyperemia					
Yes	50	1	3.84	81.87	Significant association
No	10	59			
Irregular margins					
Yes	56	2	3.84	97.30	Significant association
No	4	58			
Presence of healthy granulation tissue					
No	51	0	3.84	88.69	Significant association
Yes	9	60			
Presence of pus discharge					
Yes	33	2	3.84	38.76	Significant association
No	27	58			
Presence of serous discharge					
Yes	10	0	3.84	10.90	Significant association
No	50	60			
Presence of slough					
Yes	24	0	3.84	30.00	Significant association
No	36	60			

Table 3: Effect of low-cost negative pressure technique on laboratory parameters.

Variables	Hb	TLC	Platelet	Sr. creatinine	SGOT	SGPT
Mean score, BT	10.31	7560.00	2.54	0.95	29.35	36.93
Mean score, AT	11.23	7316.67	3.25	0.86	27.37	35.13
SD (±)	0.63	1010.9	0.48	0.105	2.79	2.33
SE (±)	0.08	130.5	0.06	0.013	0.36	0.301
t	-11.32	1.86	-11.42	6.62	5.49	5.97
P	<0.05	>0.05	<0.05	<0.05	<0.05	<0.05
Result	Significant	Insignificant	Significant	Significant	Significant	Significant

Table 4: Effect of normal dressing on clinical parameters.

Parameters	BT	AT	Chi-square tabulated	Chi-square calculated	Significant
GC					
Moderate	59	25	3.84	45.87	Significant association
Good	1	35			
Fever					
Yes	51	0	3.84	88.69	Significant association
No	9	60			
Hyperemia					
Yes	54	10	3.84	64.52	Significant association
No	6	50			
Irregular margins					
Yes	59	20	3.84	56.35	Significant association
No	1	40			

Continued.

Parameters	BT	AT	Chi-square tabulated	Chi-square calculated	Significant
Presence of healthy granulation tissue					
No	55	5	3.84	83.3	Significant association
Yes	5	55			
Presence of pus discharge					
Yes	39	7	3.84	36.09	Significant association
No	21	53			
Presence of serous discharge					
Yes	19	3	3.84	14.24	Significant association
No	41	57			
Presence of slough					
Yes	35	0	3.84	49.41	Significant association
No	25	60			

Table 5: Effect of normal dressing on laboratory parameters.

Variables	Hb	TLC	Platelet	Sr. creatinine	SGOT	SGPT
Mean score, BT	10.28	7465.00	2.23	0.96	28.82	37.35
Mean score, AT	11.44	7523.33	3.06	0.90	27.38	35.93
SD (±)	0.748	1330.26	0.538	0.17	2.48	2.75
SE (±)	0.096	171.73	0.069	0.02	0.32	0.355
t	-11.96	-0.33	-11.90	2.87	4.46	3.97
P	<0.05	>0.05	<0.05	<0.05	<0.05	<0.05
Result	Significant	Insignificant	Significant	Significant	Significant	Significant

Table 6: Comparison of normal dressing and low-cost negative pressure dressing on clinical parameters.

Parameters	Low-cost negative pressure dressing	Normal dressing	Chi-square tabulated	Chi-square calculated	Significant
GC					
Moderate	2	25	3.84	12.07	Significant difference
Good	58	35			
Fever					
Yes	0	0	3.84	Cannot be calculated	
No	60	60			
Hyperemia					
Yes	1	10	3.84	8.10	Significant difference
No	59	50			
Irregular margins					
Yes	2	20	3.84	18.03	Significant difference
No	58	40			
Presence of healthy granulation tissue					
No	0	5	3.84	5.21	Significant difference
Yes	60	55			
Presence of pus discharge					
Yes	2	7	3.84	3.03	No significant difference
No	58	53			
Presence of serous discharge					
Yes	0	3	3.84	3.07	No significant difference
No	60	57			
Presence of slough					
Yes	0	0	3.84	Cannot be calculated	
No	60	60			

Comparative statistical analysis

Tables 6-8 compare the effects of low-cost negative pressure technique and normal dressing on clinical and laboratory parameters.

Null hypothesis

There is no significant difference between the effects of low-cost negative pressure dressing and normal dressing on symptoms.

Alternate hypothesis

There is a significant difference between the effects of low-cost negative pressure dressing and normal dressing on symptoms.

Table 7: Comparison of normal dressing and low-cost negative pressure dressing on laboratory parameters.

Parameters	Hb	TLC	Platelet
Mean difference score, group A	-0.92	243.33	-0.708
Mean difference score, group B	-1.15	-58.33	-0.827
Combined SD (±)	0.69	1181.4	0.51
SE (±)	0.126	215.69	0.093
Unpaired t	1.85	1.39	1.27
P	>0.05	>0.05	>0.05
Result	Insignific-ant	Insignific-ant	Insignif-icant

As the calculated t-value is lower than the t-tabulated value at p<0.05, where df=118, the null hypothesis should be accepted and the alternate hypothesis rejected. In other words, there is no significant difference between the effects of low-cost negative pressure dressing and normal dressing on Hb, TLC, and platelet.

Table 8: Comparison of normal dressing and low-cost negative pressure dressing on laboratory parameters.

Parameters	Hb	TLC	Platelet
Mean difference score, group A	0.09	1.98	1.8
Mean difference score, group B	0.063	1.43	1.41
Combined SD (±)	0.141	2.64	2.55
SE (±)	0.025	0.48	0.466
Unpaired t	1.02	1.13	0.82
P	>0.05	>0.05	>0.05
Result	Insignific-ant	Insignific-ant	Insignif-icant

As the t-value calculated is lower than the t-tabulated value at p<0.05, where df=118, the null hypothesis should be accepted and the alternate hypothesis rejected. In other words, there is no significant difference between the effects of low-cost negative pressure dressing and normal dressing on sr. creatinine, SGOP, and SGPT.

Table 9 lists the number of visits required for adequate wound healing in both groups.

Table 9: Overall assessment of the result.

Discharged on	Low cost negative pressure dressing	Normal dressing
	No. of patients	**No. of patients**
1st visit	0	0
2nd visit	54	31
3rd visit	6	27
4th visit	0	2
Total	60	60

DISCUSSION

An open fracture is a prevalent problem routinely encountered in almost every trauma center, and Gustilo grade III fractures have a poor prognosis. The patients in the current study were divided into two groups: group A, subject to a low-cost negative pressure technique, and group B, given conventional normal dressing soaked in betadine and involving the use of H_2O_2.[8] Patients of both groups A and B were mostly middle-aged elderly males, with few having addiction or comorbidities. Only two patients from group A and four patients of group B reported a history of comorbidities such as DM, and HTN, and three from group A and one from group B had a history of addiction. The presence of comorbidities like HTN, DM, CKD, CLD, and CVA, hampers and delays wound healing due to various pathological factors. In this study, almost all patients had a moderately fair general condition at the first visit. Moreover, all patients were male, which could be a limiting factor of the study.

The statistical analysis using the Chi-square test to identify an association between the qualitative data and outcome variables revealed that the low-cost negative pressure dressing technique, like normal dressing, was effective in improving the general condition, decreasing the hyperemia around the wound, reducing fever, regularizing the irregular margins of the wound, decreasing pus and serous discharge from the wound, and increasing the granulation tissue formation in the wound, similar to the findings of Yusuf et al and Achten et al, where the negative pressure technique was found to be effective in healing wounds in an open fracture.[9,10]

Similar to the findings of Kumar et al, where a statistically significant difference was found in favor of the group using the negative pressure technique compared with the group using normal dressing in terms of hospital stay, number of dressings required, wound size reduction, wound healing time, and deep infection rate, the comparative analysis in the current study revealed that the

low-cost negative pressure technique was found to be superior to normal dressing in improving the general condition, regularizing the irregular margins, reducing the hyperemia around the wound, and favoring healthy granulation tissue.[11] By end of the third visit, none of the patients in either group had a fever. Hyperemia was present only in 1 out of 60 (1.6%) patients in group A, whereas it was present in 10 out of 60 (16.6%) patients given normal dressing (group B). Further, only 2 (3%) patients had irregular margins compared with 20 (33.3%) in group A. All patients had healthy granulation tissue in group A compared with 5 (8.3%) patients in the normal dressing group who did not, and only 2 (3.3%) patients had pus discharge as opposed to 7 (11.6%) patients in group A. Serous discharge was not observed in any patient in group A, whereas it was still present in 3 (5%) patients in the normal dressing group. Further analysis revealed there was no significant difference between the effects of low-cost negative pressure dressing and normal dressing on Hb, TLC, platelet, sr. creatinine, SGOP, and SGPT. Hardly any authentic medical research has examined the effect of the low-cost negative pressure technique on the following variables. Thus, the present study was the first of its kind to do so.

In this study, the majority of patients belonging to group A, i.e., 54 out of 60 (90%), required only two visits, and merely 6 (10%) patients required three visits for wound closure and healing. This is in contrast with the normal dressing group, where 31 out of 60 (50%) patients visited twice, 27 (45%) visited thrice, and 2 [3.3%] visited four times for wound closure and healing. This result is similar to the findings of Kaushik et al, where the time between injury and complete closure as well as the duration of hospital stay was significantly less in the negative pressure group and the normal dressing group, and contrary to findings of Virani et al, where no significant difference was seen in the time required for the wound to be ready for delayed primary closure or coverage.[12,13]

Limitations

The study has limitations that the author acknowledges. The study has only 120 participants; this subject requires a larger study to accurately depict the effect of low cost negative pressure dressing on wound management. The study was also conducted in a short span of 4 months and requires a longer duration and follow-up for the same for better analysis and long term effectiveness of this method.

CONCLUSION

The low-cost negative pressure technique was effective in healing wounds in type III open fractures and was associated with early recovery compared with the normal dressing technique. Further, a significant difference was observed between the effects of low-cost negative pressure dressing and normal dressing on the general condition, granulation tissue formation, hyperemia, and pus discharge, whereas there was no significant difference in decreasing serous discharge, fever, or slough formation or reducing the total leucocyte count.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet. 2005;366(9498):1704-10.
2. Noble-Bell G, Forbes A. A systematic review of the effectiveness of negative pressure wound therapy in the management of diabetes foot ulcers. Int Wound J. 2008;5(2):233-42.
3. Han G, Ceilley R. Chronic wound healing: a review of current management and treatments. Adv Ther. 2017;34(3):599-610.
4. Kundu ZS, Kamboj P, Sangwan SS, Siwach RC, Singh R, Walecha P. Management of open olecranon fractures using clamp-cum-compressor device. Indian J Orthop. 2009;43(1):50.
5. Chaput B, Garrido I, Eburdery H, Grolleau JL, Chavoin JP. Low-cost negative-pressure wound therapy using wall vacuum: a 15 dollars by day alternative. Plast Reconstr Surg - Glob Open. 2015;3(6).
6. Kim PH, Leopold SS. In brief: Gustilo–Anderson classification. Clin Orthop Relat Res. 2012;470(11):3270-4.
7. Zhong B. How to calculate sample size in randomized controlled trial? J Thorac Dis. 2009;1(1):51-4.
8. Sop JL, Sop A. Open Fracture Management. In: StatPearls. Treasure Island (FL): StatPearls Publishing. 2022.
9. Yusuf E, Jordan X, Clauss M, Borens O, Mäder M, Trampuz A. High bacterial load in negative pressure wound therapy (NPWT) foams used in the treatment of chronic wounds. Wound Repair Regen. 2013;21(5):677-81.
10. Achten J, Parsons NR, Bruce J, Petrou S, Tutton E, Willett K, et al. Protocol for a randomised controlled trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients with an open fracture of the lower limb: UK Wound management of Lower Limb Fractures (UK WOLLF). BMJ Open. 2015;5(9):e009087.
11. Kumaar A, Shanthappa AH, Ethiraj P. A comparative study on efficacy of negative pressure wound therapy versus standard wound therapy for patients with compound fractures in a tertiary care hospital. Cureus. 2022;14(4):e23727.
12. Kaushik D, Joshi N, Kumar R, Gaba S, Sapra R, Kumar K. Negative pressure wound therapy versus gauze dressings for the treatment of contaminated

traumatic wounds. J Wound Care. 2017;26(10):600-6.
13. Virani SR, Dahapute AA, Bava SS, Muni SR. Impact of negative pressure wound therapy on open diaphyseal tibial fractures: A prospective randomized trial. J Clin Orthop Trauma. 2016;7(4):256-9.

Cite this article as: Lingayat MB, Kawedia AM, Gathani HJ, Baria K, Patil S. Assessment of the effect of low-cost negative pressure dressing on wound healing. Int J Res Orthop 2023;9:xxx-xx.