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EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY OVER STANDARD WOUND THERAPY FOR THE PATIENTS WITH COMPOUND FRACTURES: A COMPARATIVE STUDY

Kasamsetty Chandu Vidyasagar[1], Ashok Nayak[2], Shrikant Kulkarni[3], Sahebagouda Patil[3]

[1]Junior Resident 3rd Year, Department of Orthopaedics, Shri BM Patil Medical College, Hospital and Research Centre, Bijapur, Karnataka, India
[2]Professor, Department of Orthopaedics, Shri BM Patil Medical College, Hospital And Research Centre, Bijapur, Karnataka, India
[3]Assistant Professor, Department of Orthopaedics, Shri BM Patil Medical College, Hospital And Research Centre, Bijapur, Karnataka, India

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Corresponding Author:
Dr. Sahebagouda Patil,
Email: sahebgoudapatil12@gmail.com

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Abstract

Background: An essential part of treating complicated fractures is wound therapy and infection control. Negative pressure wound therapy (NPWT) is a post-operative wound care technique that uses foam or gauze under negative pressure to accelerate wound healing. Vacuum-assisted closure is the most used NPWT (VAC). The main aim of the study is to prove that negative pressure dressing has better outcome than standard wound dressing. The objectives are to increase the use of vacuum assisted closure in open fractures to reduce the duration of wound healing process. To reduce the incidence of infections, which are very high in open fractures. **Materials and Methods:** A comparative study of efficacy of negative pressure wound therapy over standard wound therapy for the patients with compound fractures in B.L.D.E (DEEMED TO BE UNIVERSITY) Shri B.M patil's medical college, Hospital and Research centre, in Department of orthopaedics from August 1st 2022 to 2024 January. Patients admitted with open fractures of more than gustilo Anderson grade 3a and 3b will be involved in the study, if the patients satisfy the inclusion criteria which includes, Age group: 18 years and above Male and female patients and Open fractures of gustilo Anderson type II and III. And patients will be excluded if Patients with history of previous long bone surgeries, Patients in need for vascular surgery, Pregnancy, Immunosupressive therapy patients, Dermatological conditions and osteomyelitis patients, Male and females below age group of 18 years. The anticipated Mean±SD of dressings in NPWT and SWT 4.32±0.27 and 15.77±0.44 resp. (ref) the required minimum sample size is 27 per group (i.e. a total sample size of 34, assuming equal group sizes) to achieve a power of 95% and a level of significance of 5% (two sided), for detecting a true difference in means between two groups with effect size 1 using G* power software 3.1.9.7. The data obtained will be entered in a Microsoft Excel sheet, and statistical analysis will be performed using statistical package for the social sciences. **Result:** The gender distribution in our sample of 40 participants shows a notable difference between the number of males and females. There are 18 females and 22 males involved in the study. Most of the patients were at age group of 40 – 50 years old. The average hospital stay duration was shorter in patients treated with negative pressure wound therapy compared to individuals treated with standard wound dressing. The comparison of the mean wound area between the two groups reveals important findings regarding wound healing progress. The P value of 0.8142 indicates that there is no statistically significant difference in wound area between the two groups at this initial measurement. **Conclusion:** The present study highlights the superior efficacy of Negative Pressure Wound Therapy (NPWT) over standard wound therapy for patients with compound fractures. The findings suggest that NPWT significantly reduces the number of dressings required, shortens the wound healing time, and decreases the incidence of deep infections compared to standard dressing methods. Specifically, the study demonstrated that NPWT patients required fewer dressings and had a considerably shorter healing time. Overall, the evidence strongly supports the implementation of NPWT as a preferred treatment modality for patients with compound fractures, ensuring better clinical outcomes and improving the overall quality of life for affected patients.

INTRODUCTION

Treating significant open fractures, which typically result in complications, morbidity, and even amputation, is a challenging task for orthopaedic surgeons. High-impact trauma is linked to open fractures. Wound therapy and infection control are crucial components of the management of complex fractures. It is imperative to promptly address these fractures due to the increased risk of infection and complications during therapy. It is a known fact that the infection rate range for serious open fractures was 25–66%.[1-3] When diagnosing and treating compound fractures in the extremities, it is important to consider a number of factors, such as the patient's health, the kind of fracture, antimicrobial therapy, wound debridement, the location and extent of the wound, the neurovascular status, and the extent of muscle tear.[4,5] Compound fractures are often classified using the Gustilo-Anderson classification approach.[6]

According to research, the infection rate in complicated fractures ranges from 0-2% for type I fracture to roughly 2-10% for type II fractures and 10-50% for type III fractures. It is discovered that neither the length of antimicrobial therapy nor the amount of time it takes for the lesion to heal are the cause of this infection.[1,7] A method of wound care following surgery known as negative pressure wound therapy (NPWT) uses foam or gauze under negative pressure to promote wound healing. The most used NPWT is vacuum-assisted closure (VAC).[8–10] Approximately twenty years ago, Morykwas et al. introduced it for the first time.[11]

Using a specific closed wound dressing that is worn either continuously or sporadically, the above approach applies negative pressure to the wound. Furthermore, this has a biological effect that accelerates the healing of wounds.[8] NPWT was initially identified as an adjuvant therapy to help repair complex wounds that are challenging to heal.[12] Following then, a number of research papers and clinical trials provided evidence in favour of this technique for wound healing in the treatment of compound fractures.[12–16] Furthermore, it is a reasonably priced approach that the majority of patients can afford in addition to being an efficient way to promote wound healing. And in many institutions these days, it serves as a therapy guideline.[1,2]

The VAC device works as follows: wound debridement is the initial stage in pulling the borders of the wound together.[7,17] Negative pressure wound care is then used to stabilise the wound and prevent further infection. After the formation of granulation tissue, the patients had follow-up treatments such as skin grafting to seal the wound.[9,10,17] As a result, the NPWT method makes the skin grafting process easier.[18] Continuous wound treatment is still a clinical challenge even with the advent of novel therapeutic approaches for better wound care, such as dressings, local growth factors, hyperbaric oxygen, and systemic and local antiseptic agents.[1] Negative pressure dressings, according to data from multiple studies, offer an adequate environment for the healing of open fractures because they shield the site from infection, which impedes the healing process and lowers wound complications.[7,18] The purpose of this study was to evaluate standard wound dressing against negative pressure wound treatment for open-compound fracture wounds.

MATERIALS AND METHODS

Source of Data: Patients admitted in Department of orthopedics in B.L.D.E(DEEMED TO BE UNIVERSITY)Shri B.M patil’s medical college, Hospital and Research centre, with open fractures of more than gustilo Anderson grade 3a and 3b

Patient will be in informed about the study and written informed consent will be taken.

Period of study: August 1st 2022 to 2024 January

Study design: Comparative study

Inclusion Criteria

Age group: 18 years and above Male and female patients

Open fractures of gustilo Anderson type II and III

Exclusion Criteria

Patients with history of previous long bone surgeries

Patients in need for vascular surgery

Pregnancy

Immunosupressive therapy patients

Dermatological conditions and osteomyelitis patients

Male and females below age group of 18 years

Sample size calculation:

Sample size

The anticipated Mean±SD of dressings in NPWT and SWT 4.32±0.27 and 15.77±0.44 resp. (ref) the required minimum sample size is 27 per group (i.e. a total sample size of 34, assuming equal group sizes) to achieve a power of 95% and a level of significance of 5% (two sided), for detecting a true difference in means between two groups with effect size 1 using G* power software 3.1.9.7

Statistical Analysis

The data obtained will be entered in a Microsoft Excel sheet, and statistical analysis will be performed using statistical package for the social sciences

Results will be presented as Mean±SD, or Median and Inter quartile range, frequency, percentages and diagrams.

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For normally distributed continuous variables between two groups will be compared using
Independent t test For not normally distributed variables Mann Whitney U test will be used. Categorical variables between two groups will be compared using Chi square test/fisher's exact test
Pared data will be compared using Repeated measures of ANOVA or Friedman test
Categorical variables will be compared using chi square test.
p value is less than ;0.05 will be considered statistically significant. All statistical tests will perform two tailed.

RESULTS

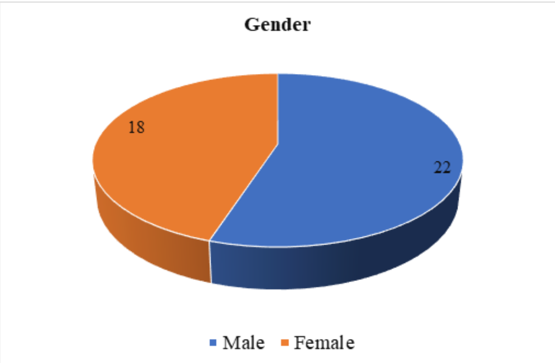

Figure 1: Gender Distribution

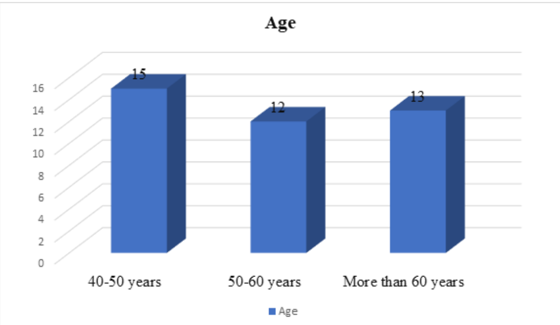

Figure 2: Age Distribution

In our study the gender distribution out of the total sample (40), 22 participants are male, which constitutes 55% of the sample population. This indicates that more than half of the participants are male. On the other hand, there are 18 female participants, making up 45% of the sample. Overall, the data reveals a slight predominance of males over females in this particular sample.
The age distribution in our sample of 40 participants reveals a diverse representation across three age groups. Specifically, 15 participants are between 40 and 50 years old, accounting for 37.5% of the total sample. This indicates that over a third of the participants fall within this age range. The next group, consisting of individuals aged 50 to 60 years, includes 12 participants, representing 30% of the sample. This demonstrates that nearly a third of the participants are within this middle age range. The oldest age group, those over 60 years, comprises 13 participants, making up 32.5% of the sample. This shows that slightly less than a third of the participants are in the oldest age category.
The comparison of fracture types between the group treated with negative pressure dressing and the group treated with standard dressing reveals some notable differences.
For Grade II fractures, 17.5% of the participants in the negative pressure dressing group had this type of fracture compared to 12.5% in the standard dressing group. The P value for this comparison is 0.310, indicating that the difference is not statistically significant.
In the case of Grade IIIA fractures, 32.5% of the participants in the negative pressure dressing group had this fracture type, while 40% of the participants in the standard dressing group fell into this category.
For Grade IIIB fractures, 37.5% of participants in the negative pressure dressing group had this type of fracture, compared to 45% in the standard dressing group. Lastly, Grade IIIC fractures were observed in 12.5% of the participants in the negative pressure dressing group, while only 2.5% of the participants in the standard dressing group had this severe type of fracture.
These observations suggest that while there are variations in the distribution of fracture types between the two groups, the difference for Grade II fractures is not statistically significant. The information provided helps to understand the demographic and clinical characteristics of the sample populations, which is essential for evaluating the efficacy of the different dressing methods.
The comparison of clinical outcomes between the group treated with negative pressure dressing and the group treated with standard dressing shows significant differences in several variables.
The mean number of dressings required was significantly lower in the negative pressure dressing group (4.12±0.26) compared to the standard dressing group (11.26±0.43), with a P value of less than 0.001, indicating a highly significant difference.
Similarly, the mean wound healing time was significantly shorter in the negative pressure dressing group (16.35±2.31 days) compared to the standard dressing group (31.67±2.89 days), also with a P value of less than 0.001, demonstrating a substantial improvement in healing time with the negative pressure dressing.
Acute wound infection was observed in 7.5% of the standard dressing group, while no cases were reported in the negative pressure dressing group. Although the P value of 0.077 suggests this difference is not statistically significant, it indicates a trend towards fewer infections with negative pressure dressing.
Deep infections were significantly lower in the negative pressure dressing group (7.5%) compared to the standard dressing group (30%), with a P value of 0.010, indicating a statistically significant reduction in deep infections.

Delayed closure and the need for skin grafts were more frequent in the standard dressing group, though the differences were not statistically significant, with P values of 0.077 and 0.314, respectively. No flap procedures were required in either group.
These results indicate that negative pressure dressing significantly reduces the number of dressings needed, shortens wound healing time, and decreases the incidence of deep infections compared to standard dressing. The findings support the effectiveness of negative pressure dressing in managing wound healing more efficiently and with fewer complications.
The comparison of the mean wound area between the two groups reveals important findings regarding wound healing progress. At baseline, the mean wound area for the negative pressure dressing group was 213.43±23.57 square centimeters, while the standard dressing group had a mean wound area of 214.67±23.46 square centimeters. The P value of 0.8142 indicates that there is no statistically significant difference in wound area between the two groups at this initial measurement.
However, at the end line, the mean wound area in the negative pressure dressing group significantly decreased to 123.14±12.38 square centimeters, compared to a mean wound area of 147.86±14.68 square centimeters in the standard dressing group. The P value of less than 0.001 indicates a highly significant difference, suggesting that the negative pressure dressing was more effective in reducing wound area over time.
These results highlight the superior effectiveness of negative pressure dressing in promoting wound closure compared to standard dressing, as evidenced by the significant reduction in wound area by the end of the treatment period.

Table 1: Comparison of Fracture Types Between Dressing Groups.

Type of fracture	Group with negative pressure dressing n=40 (%)	Groupwith standard dressing n=40 (%)	P value
Grade II	7 (17.5)	5 (12.5)	0.310
GRADE III A	13 (32.5)	16 40	
Grade IIIB	15 (37.5)	18 45	
Grade IIIC	5 (12.5)	1 2.5	

Table 2: Clinical Outcomes Comparing Negative Pressure Dressing and Standard Dressing

Variable	Group with negative pressure dressing (%)	Group with standard dressing (%)	P value
Mean number of dressing	4.12±0.26	11.26±0.43	<0.001
Mean wound healing time	16.35±2.31	31.67±2.89	<0.001
Acute wound infection	0	3(7.5)	0.077
Deep infection	3 (7.5)	12 (30)	0.010
Delay closure	0	3 (7.5)	0.077
Skin graft	0	1 (2.5)	0.314
Flap	0	0	

Table 3: Wound Area Comparison Between Dressing Groups.

Mean area of the wound (sq cm)	Group with negative pressure dressing	Group with standard dressing	P value
Base line	213.43±23.57	214.67±23.46	0.8142
End line	123.14±12.38	147.86±14.68	<0.001

DISCUSSION

The current study employed two approaches, namely VAC dressing and conventional dressing, to manage open fractures. This resulted in the division of study participants into two groups. No statistically significant differences were found between the two groups in terms of basic demographic factors such as age, gender, height, and weight. Several studies have reported comparable findings when the intervention groups were matched based on fundamental demographic factors.[19,20] The average hospital stay duration wasshorter in patients treated with negative pressure wound therapy compared to individuals treated with standard wound dressing. The findings from our investigation were consistent with those of Kaushik et al,[21] who reported a 27% decrease in average hospitalisation duration, compared to a 34% reduction observed in our study. The utilisation of negative pressure wound therapy is presumed to promote accelerated soft tissue healing, leading to a reduced duration of hospitalisation.
The mean number of dressings in patients from the negative pressure wound therapy group was 7.14+0.17 dressing episodes less than that of individuals from the standard wound dressing group. The findings of our investigation were similar to those of Kaushik et al,[21] who reported an 84% decrease in the average number of dressings, compared to a 73% reduction in our study. The reason for this is that negative pressure wound therapy establishes a favourable wound environment by decreasing swelling, enhancing blood circulation, minimising factors that impede healing, and stimulating the growth of new tissue, which results in a decrease in the amount of fluid discharged from the wound.
The mean duration for wound healing was significantly shorter in patients treated with negative pressure wound therapy is 16.35+2.31 compared to

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those treated with standard wound dressing is 31.67 + 2.89. The findings obtained in the present investigation were consistent with the results of previous studies, which reported a 35-54% decrease in average wound healing time, compared to a 47% reduction observed in our study.[22-24] The fundamental principles of negative pressure wound therapy are the maintenance of haemostasis, the reduction of inflammation, the promotion of dominant fibroblast activity, the regeneration of collagen fibres, and the contraction of the wound through the activity of myofibroblasts. These principles together contribute to the acceleration of wound healing time. The prevalence of deep infection was 22 percentage points lower in individuals treated with negative pressure wound therapy compared to those treated with standard wound dressing. The results of our investigation were similar to those of Costa et al,[19] who reported a 69% decrease in the incidence of deep infections, compared to 56% in our study. Applying negative pressure wound therapy correctly leads to almost complete removal of dead tissue and sufficient cleaning of the wound before it is closed, thereby preventing germs from entering the wound. This can significantly decrease the likelihood of a severe infection. The average wound area decreased significantly in patients treated with negative pressure wound therapy compared to patients treated with standard wound dressing. The findings of our study were consistent with those of Quatman et al,[25] who reported a 28% decrease in the average wound area, compared to the 36% reduction observed in our study.

Prior to conducting this experiment, a thorough examination of existing literature indicated that there was only one randomised clinical study that compared traditional wound dressing with negative pressure wound therapy for the first treatment of patients with severe open fractures of the lower leg. Stannard et al,[26] found that patients treated with negative pressure wound therapy had a higher health-related quality of life and a lower rate of deep wound infection compared to the control group (5.4% vs 20%; relative risk, 0.20 [95% CI, 0.05 to 0.87]). Nevertheless, it is important to note that the study was limited in size, consisting of only 59 patients with 63 fractures. Additionally, the control group experienced 7 cases of deep infections, whereas thenegative pressure wound therapygroup had 2 cases. The disparity in the incidence of severe infection may be attributed to potential variations in patient characteristics and/or treatment protocols between a single centre in the United States and the WOLLF study, which encompassed a larger and more diverse sample of 24 major trauma centres. Nevertheless, due to the limited number of individuals in the Stannard et al,[26] experiment, it is plausible that the outcome reflects an imprecise estimation of the occurrence of deep infection. In 2016, an RCT was reported that compared negative pressure wound therapy with conventional dressings for the treatment of open fractures. This research was conducted in Pakistan and employed negative pressure dressings for an extended duration (weeks) to diminish the size of the wound.[27] This is a distinct use of negative pressure wound therapythat deviates from the current recommendations for treating open fractures. The current guidelines suggest early definitive wound closure, often within 72 hours.[28,29] Hence, it remains uncertain if the outcomes of that experiment are relevant to alternative healthcare systems. The use of Negative Pressure Wound Therapy results in the effective removal of dead and necrotic tissues through debridement. This plays a crucial role in the initiation of the healing process and accelerates the reduction of the wound area.

CONCLUSION

In conclusion, our study highlights the superior efficacy of Negative Pressure Wound Therapy (NPWT) over standard wound therapy for patients with compound fractures. The findings suggest that NPWT significantly reduces the number of dressings required, shortens the wound healing time, and decreases the incidence of deep infections compared to standard dressing methods. Specifically, the study demonstrated that NPWT patients required fewer dressings and had a considerably shorter healing time. The mean wound healing time was notably shorter for the NPWT group, averaging 16.35±2.31 days compared to 31.67±2.89 days for the standard dressing group. This acceleration in healing can be attributed to the fundamental principles of NPWT, such as maintaining hemostasis, reducing inflammation, promoting dominant fibroblast activity, regenerating collagen fibers, and contracting the wound through my fibroblast activity.

Additionally, the prevalence of deep infections was significantly lower in the NPWT group, supporting the notion that NPWT effectively prevents severe infections by promoting thorough debridement and cleaning of the wound, thus preventing germ entry. The study also showed a significant reduction in wound area for the NPWT group compared to the standard dressing group, with the NPWT group exhibiting a mean wound area decrease from 213.43±23.57 square centimeters at baseline to 123.14±12.38 square centimeters at the end of the treatment period.

These findings align with previous research, further validating NPWT as a highly effective method for managing complex wounds and promoting faster, more efficient healing. The use of NPWT should be considered a standard practice for treating severe open fractures, given its benefits in reducing complications, minimizing infection risks, and facilitating quicker recovery times. Overall, the evidence strongly supports the implementation of NPWT as a preferred treatment modality for patients with compound fractures, ensuring better clinical outcomes and improving the overall quality of life for affected patients. Further research with larger sample sizes and diverse populations is recommended to confirm these findings and expand the generalizability of the results.

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