



Original Article

A Post-Market Randomized Controlled Trial to Evaluate the Efficacy of VELVERT Antimicrobial Wound Dressing Versus Framycetin Cream in Infected Wounds

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ABSTRACT

Background: The primary objective of this comparative study was to assess the efficacy of a new antimicrobial wound dressing (VELVERT) against infected wound in comparison to standard of care (Framycetin cream). Velvert is a breathable, non-adherent, and topical wound dressing.

Methods: Patients with infected wound were assessed and divided to receive Velvert or standard of care treatment. Wound assessment was carried out using BWAT score and bacterial load assessment. The clinician's opinion of the dressing's performance was surveyed through assessment of surgeon's questionnaire. Pain levels was evaluated using a 0-10 Numeric Pain Chart.

Results: On day 24, the VELVERT dressing group exhibited 58.16% (± 30.15) reduction in wound size whereas, in the standard of care group 55.76 % (± 23.61) reduction was observed. BWAT scores have generally improved (showing lower scores) wound healing. VELVERT was found to be effective in reducing the severity and prevalence of various microorganisms. The assessment of Surgeon's Questionnaire results showed a positive user experience.

Conclusion: The dressing was well-received by patients and resulted in positive clinician experience. VELVERT showed the potential to offer advancements in wound care for patients with infected wounds. This is a promising novel dressing that could offer significant advantages to improve the quality, and convenience of wound care.

Keywords: Infected wound, wound management, antimicrobial dressing, herbal dressing.

INTRODUCTION

A wound is defined as an injury or tear on the skin's surface caused by physical, chemical, mechanical, or thermal damage (Gharibi et al., 2015). Wounds are significant contributor to morbidity and a reduced quality of life. They also consume a substantial portion of healthcare resources, from the initial injury to complete wound healing (Chaby et al., 2007). Wounds are classified into two main categories based on their healing processes: acute and chronic wounds. Additionally, wounds can be categorized as clean, clean-contaminated, or contaminated/infected wounds (Liptak, 1997; Monaco & Lawrence, 2003). Infected wounds can lead to various complications and impede the body's natural healing processes. An infected wound occurs when harmful microorganisms, such as bacteria, breach the body's protective skin barrier through an open wound. These microorganisms can multiply rapidly, resulting in localized inflammation, often characterized by redness, swelling, warmth, and pain at the wound site. Infected wound, when not receiving adequate care, can results in exacerbation of the injury, amputation and sepsis (Brem & Tomic-Canic, 2007; Davenport et al., 2016; Eguia et al., 2019; Ladhani et al., 2021; Nair et al., 2020). Numerous conventional oral and topical medications are available in the market to prevent

wound contamination and promote wound healing. These conventional treatments include local antiseptic agents and antibiotics. Antiseptic agents encompass hydrogen peroxide, chlorhexidine, triclosan, and iodophors (e.g., povidone iodine). Antibiotics consist of aminoglycosides (such as Framycetin and Neomycin) and Polymyxin B, Bacitracin, among others. While these remedies prevent wound infection and help maintain wound cleanliness, they lack wound healing properties. Furthermore, most of these remedies have side effects and drawbacks, including skin irritation, rash, and antibiotic resistance (Burrows, 1958; Dorai, 2012; Lio & Kaye, 2009). The increase of antibiotic resistance in infected wounds has led to the need to develop options that can be used to treat colonized wounds effectively. To manage and facilitate the healing of infected wounds, different dressings have been developed. These dressings are designed to create an optimal environment for wound healing by promoting tissue repair, preventing further infection, and facilitating the removal of dead tissue. Foam-based antimicrobial wound dressings can play a critical role in the treatment of infected wounds. They serve as a barrier against external contaminants; help maintain a moist environment that supports the healing process and can release antimicrobial agents to combat infection.

VELVERT, an antimicrobial dressing manufactured by Datt Mediproducs Private Limited, is indicated for use in Diabetic Foot Ulcers (DFUs), trauma, infected wounds, and burn wounds, among others. It is a non-adherent topical wound dressing loaded with an antimicrobial formulation of F-10 (extracts from *Curcuma longa*, *Phyllanthus emblica*, and *Camellia sinensis*) on a polymeric sponge made from biopolymers (gelatin and chitosan). The dressing is highly porous, facilitating exudate absorption from wounds. The unique antimicrobial formulation combats infections within the wound, aiding the healing process. Furthermore, the dressing is biocompatible and biodegradable. VELVERT has previously demonstrated effective treatment outcomes in venous leg ulcers (VLUs) and shows promise in broader wound care applications (Kumar et al., 2024).

The present study majorly aims to compare the efficacy of VELVERT with framycetin. The primary objectives of the current study are: 1) To assess the efficacy of a new antimicrobial wound dressing (VELVERT) compared to framycetin in infected wound with respect to healing rates based on clinical evaluation and evaluation of wound photographs, 2) To assess the microbial load in wounds. The secondary objectives included: 1) Assessment of safety based on adverse events and incidences of wound complications like infection associated with the use of dressings (VELVERT and Standard of care) in infected wound, 2) Assessment of dressings in infected wound by Investigators based on surgeon's questionnaire, 3) Assessment of VELVERT efficacy based on reduction in subject's pain levels.

Material and methods

Study design and Participants

This study was a prospective, single center, two arm, randomized open label, post market surveillance study on infected wound. 50 patients with infected wounds were screened for the study and then randomized into two groups: the standard group, receiving the Standard of care with Framycetin cream and the test group, receiving Velvert dressing. No changes to the clinical investigation plan were made during trial, study was performed as per approved protocol. Electronic Data Capture (EDC) was used in study.

Patient enrolment in the study occurred following the receipt of ethical approval from the institutional ethics committee (Institutional Ethics Committee, EC registration Number: ECR/1409/Inst/UP/2020, Investigational Site: S.N Medical College, Agra, India) and CTRI registration (CTRI/2022/05/042407). Subject confidentiality was maintained throughout the study while obtaining data. The study was conducted after meeting all the local ethical requirements and was in accordance with International Conference on Harmonization Guideline-Good Clinical Practice E6 (ICH-GCP), the Declaration of Helsinki, ISO 14155:2020 and applicable regulatory requirements.

After evaluating the eligibility criteria, patients with infected traumatic and post-surgery wounds were enrolled in the study after getting written consent and randomised using an Interactive Web Response System (IWRS) to one of two arms. The maximum duration of each participant in the current study was 24 days after first dressing application (either Standard or Velvert Dressing) including all visits. All potential patients with infected wound of both genders between 18-70 years of age, and patients of all socio-economic status who met the study related inclusion and none of the exclusion criteria were enrolled in the study (Table 1). Demographic characteristics of the study participants are defined in Table 2. Sample size was calculated as defined previously (Schmiedova et al., 2024), with 0.05 probability of type I error, 80% power and 10 per cent anticipated drop-out rate. None of the participants, resident surgeons, and outcome assessors were blinded to the interventions.

Outcome

The study period involved a total of 8 visits for VELVERT (dressing was changed every 4th day) and 14 visits for standard of care (changed every alternative day). Screening, informed consent, and baseline data was collected on visit 1. The primary endpoint of the study was the incidence of wound healing status with 50% or more coverage in up-to 24 days. The wound area was measured by calculating the length (longest part of the wound) and width (widest part of the wound) of the wound using a sterilize, single-use paper ruler. Photographs of wound were taken before and after the application of

the investigational VELVERT on day 0, 8, 20, and day 24. The second primary endpoint was comparative evaluation of wounds through BWAT in terms of wound size, depth, edges, location, undermining, necrotic tissue, exudate type and amount, skin color around the wound, peripheral tissue edema and induration, granulation, epithelialization. Principal investigator assessed the wounds throughout the trial. The third primary endpoint was bacterial load assessment, carried out through cultures from swab test on day 0 and day 24 or upon device removal due to wound closure. The culture plates are examined thoroughly and the various colony morphotypes present are identified. Culture load was evaluated in semi-quantitative way with grading of microorganisms' presence in wounds as scanty, mild, moderate or heavy. Mild growth was defined as the presence of growth only on the primary quadrant/streak, moderate growth as presence of growth up to the second quadrant/streak and severe as presence of growth on tertiary quadrant/streak.

Secondary endpoint was evaluation of safety by monitoring adverse events and incidents of wound complications. Another secondary endpoint was clinician's opinion of the dressing's performance was surveyed through assessment of surgeon's questionnaire. The questions were posed on a five-point Likert scale in relation to the ease of handling, appropriateness of instruction for use, ease of application, conformance to tissue surfaces and overall performance of device. On this scale of one to five, 1 represents "Easy" and 5 represents "Difficult" related to experience during use of devices. The third secondary endpoint was systematic evaluation of pain relief during each patient visit using a 0-10 Numeric Pain Chart, with the numerical scale ranging from 0 (indicating no pain) to 10 (representing the worst pain imaginable).

Statistical Analysis

Categorical data was presented as frequencies and ratios (%) and as means for continuous data. All statistical tests were performed using R Software, Version 4.3.0. Between group p-values are based on two-sample t-test.

Results

Primary Outcome

The flow of patients during enrollment, allocation, follow-up, and analysis is shown in Figure 1 as per the CONSORT protocol. All participants were followed for a period of 24 days after enrollment. Primary outcomes shows whether VELVERT treatment results in achieving wound healing status of 50% or more wound coverage in up-to 24 days (Figure 2), comparative evaluation of wounds through BWAT score, and comparative evaluation of wound infection. The outcomes show that by Day 24, the VELVERT dressing group demonstrated a comparable reduction in wound size 58.16 % ($\pm$ 30.15%) to that of the standard of care group 55.76 % ($\pm$ 23.61). Notably, during the early treatment phase (Day 0 to Day 8), the VELVERT dressing group exhibited a greater reduction in wound surface area 24.74 % ($\pm$ 17.48) compared to the standard of care group 19.56 % ($\pm$ 26.07) (Figure 3 and 4). While the differences are not substantial, they support the effectiveness of both dressings in promoting wound healing. At the end of the treatment (day 24), 13 patients in both the group showed 50% or more wound healing. However, among these patients, 9 (40.09%) patients achieved 75% or more wound closure in VELVERT group whereas in control group only 4 patients (18.18%) achieved this value, including 2 patients with complete wound closure in both the group.

Secondary Outcome

The wounds of each enrolled patient were also assessed using BWAT score (Figure 5). The BWAT score is a systematic tool used to assess wounds, and it involves the consideration of 15 different parameters (mentioned earlier). Out of these 15 parameters, 13 are scored items, and 2 are non-scored items. Each of these parameters was assessed on a modified Likert scale, ranging from 1 to 5. On this scale, a score of 1 indicates the least severe or favourable condition, while a score of 5 indicates the most severe or unfavourable condition for the specific wound characteristic being assessed. The BWAT scores have generally improved (showing lower scores) indicating gradual wound healing (Figure 5). Notable improvement was seen in the 21-25 score range for VELVERT group, where number of patients increased from 0 to 9 (attaining a lower score from higher score) (Figure 5). On the completion of treatment, around 86.36 % patients attained a score within the range of 21-25 or less, whereas, in the standard of care group, 72.72% attained these scores (Figure 5). Moreover, approximately 9% of patients from control group showed a higher BWAT score (36-40 category), however no patient from VELVERT group had shown this BWAT score at the end of the study. Another primary outcome assessed was presence of infection at the wound site (Figure 6). Each patient underwent a comprehensive and meticulous evaluation of their wound cultures to assess the infection. On day 0, different strains of microorganisms were found in all the enrolled patients in both the groups (Figure 6). On Day 24, the data demonstrates effectiveness of VELVERT in mitigating the presence of *Klebsiella pneumoniae* across all severity categories, as compared to the standard of care. In VELVERT group, no increase in infection in any category was observed, however, in Framycetin group infection was observed on Day-24 that was not present initially. Moreover, VELVERT completely reduced the *Klebsiella pneumoniae* in patients with heavy levels. VELVERT also exhibited efficacy against *Staphylococcus aureus* infections, particularly in preventing their heavy proliferation. These findings collectively suggest that VELVERT is effective in reducing the severity and prevalence of various microorganisms in infection wounds. Secondary outcomes show the overall performance of the product in terms of ease of handling and application, and conformance to the tissues based on surgeon's questionnaire, adverse events monitoring and patient comfort in terms of pain reduction. The efficacy of VELVERT was assessed based on the reduction in subjects' pain levels. Comparative evaluation of patients' recording their pain level on a scale of 0- 10 Numeric Pain

Chart on day of dressing and its final removal (0=no pain, 10=worst pain imaginable) was done. At the baseline, both groups exhibited high pain levels, thereafter, there was a gradual decrease in both the group. Pain alleviation from severe to moderate (defined as 5 on the scale) was achieved following 3 applications of VELVERT dressing, while same reduction in pain was achieved with 5 applications of standard of care. On day 24, the mean change in pain levels from the baseline for the VELVERT dressing group is $-5.77 (\pm 1.78)$, while the Standard of care group shows a mean change of $-5.64 (\pm 1.92)$ (Table 3). Surgeon's Questionnaire was used to evaluate data on various characteristics related to the performance and user experience of VELVERT dressing. The data indicates a consistently positive user experience, with users finding the device easy to handle, appropriate in terms of instructions, easy to apply, and effective in conforming to tissue surfaces (Table 4, data is shown only for initial and last application of the dressings). Overall, it was observed that VELVERT dressing generally performed slightly better than standard of care. Notably, VELVERT seems to have a slight advantage in conformance to tissue surfaces on Day 24. Two adverse events headache and emesis, both were moderate in nature, was observed in the standard group, which recovered by next day.

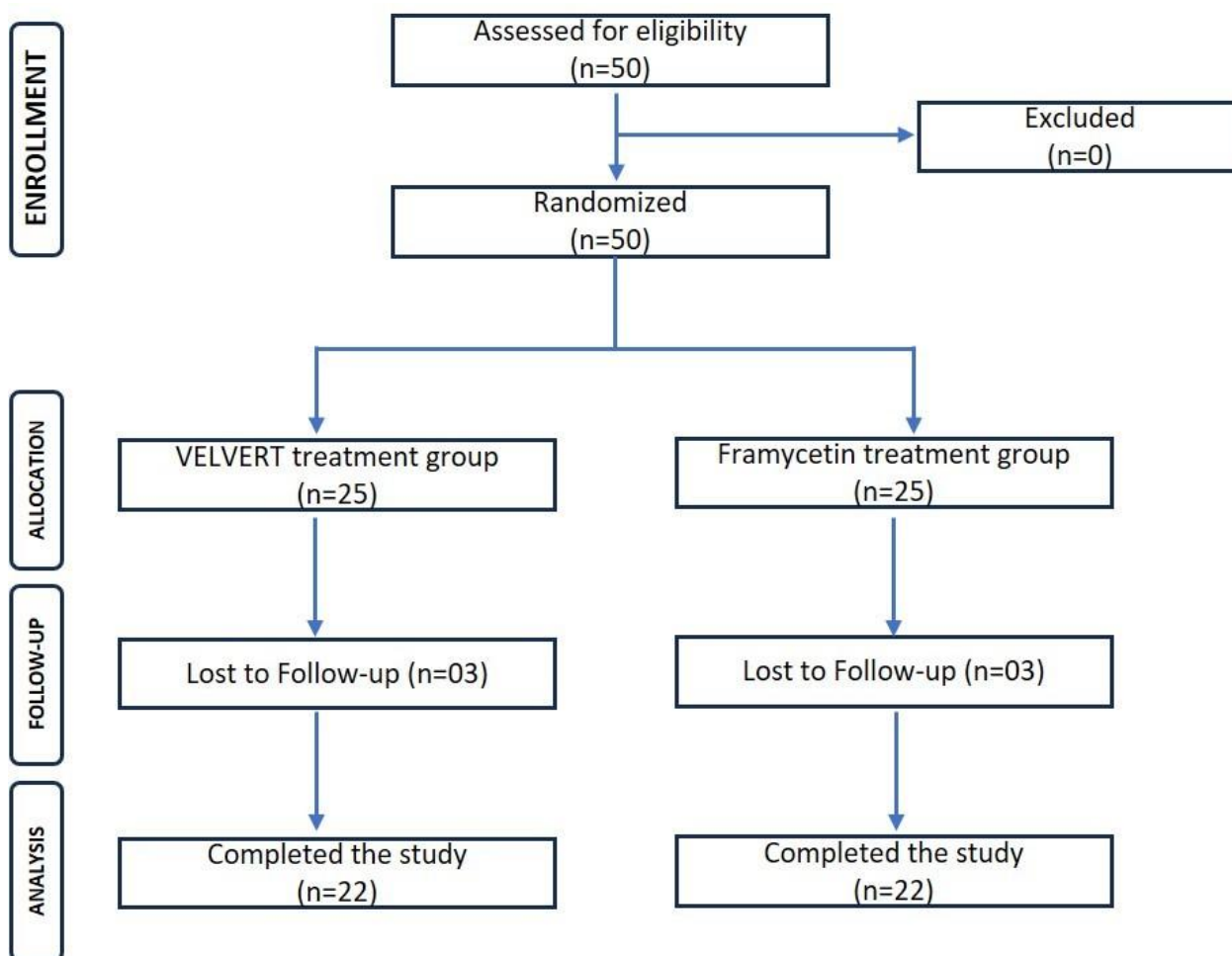


Figure 1: Study flow chart.

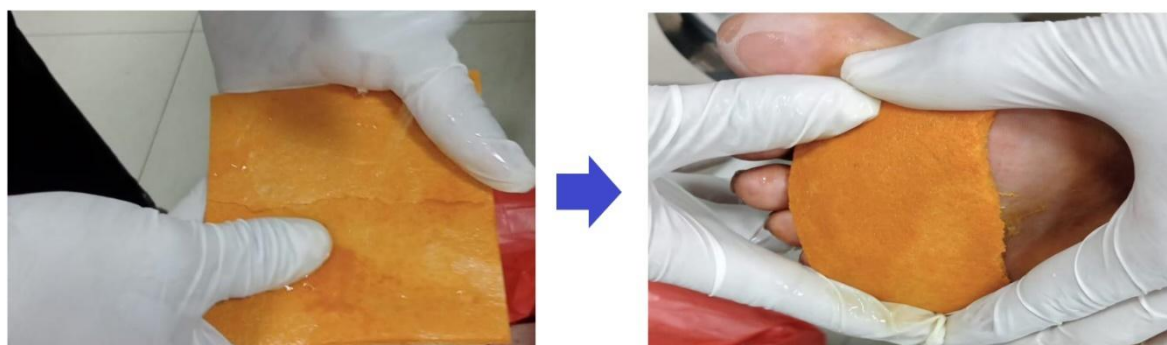


Figure 2: Pictorial representation of application of Velvert dressing on wound site.

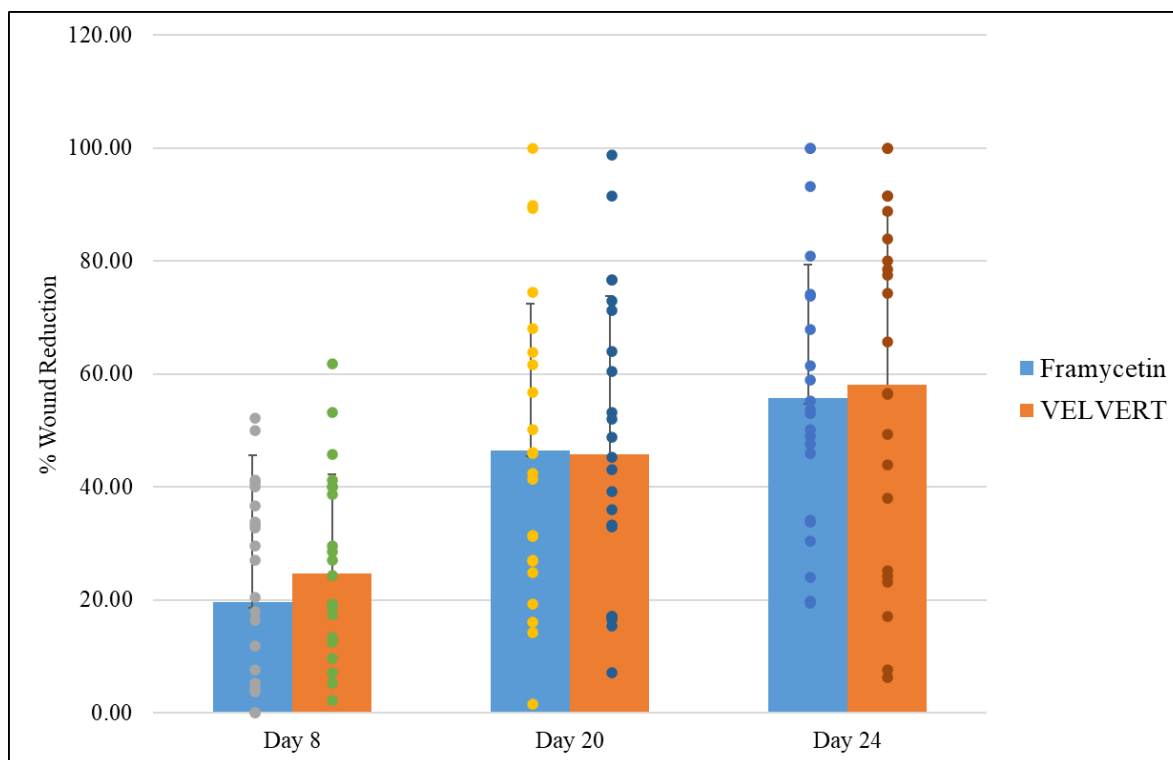


Figure 3: Percentage reduction in wound surface area with respect to time.

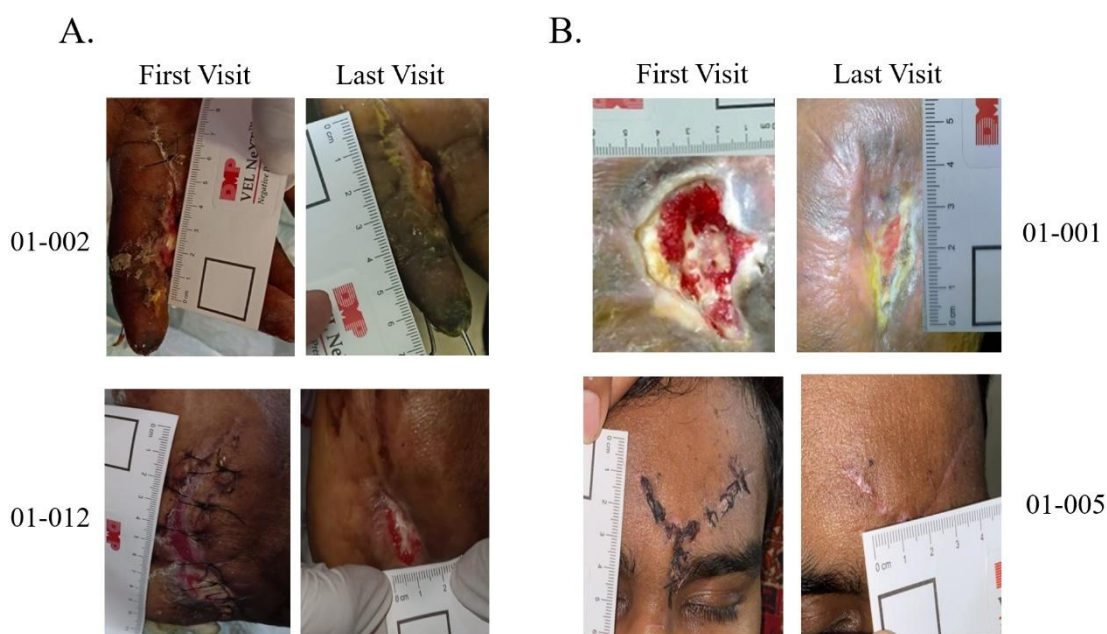


Figure 4: Clinical representation on the first and last day of visit: (A) VELVERT dressing and (B) Framycetin (Standard of care).

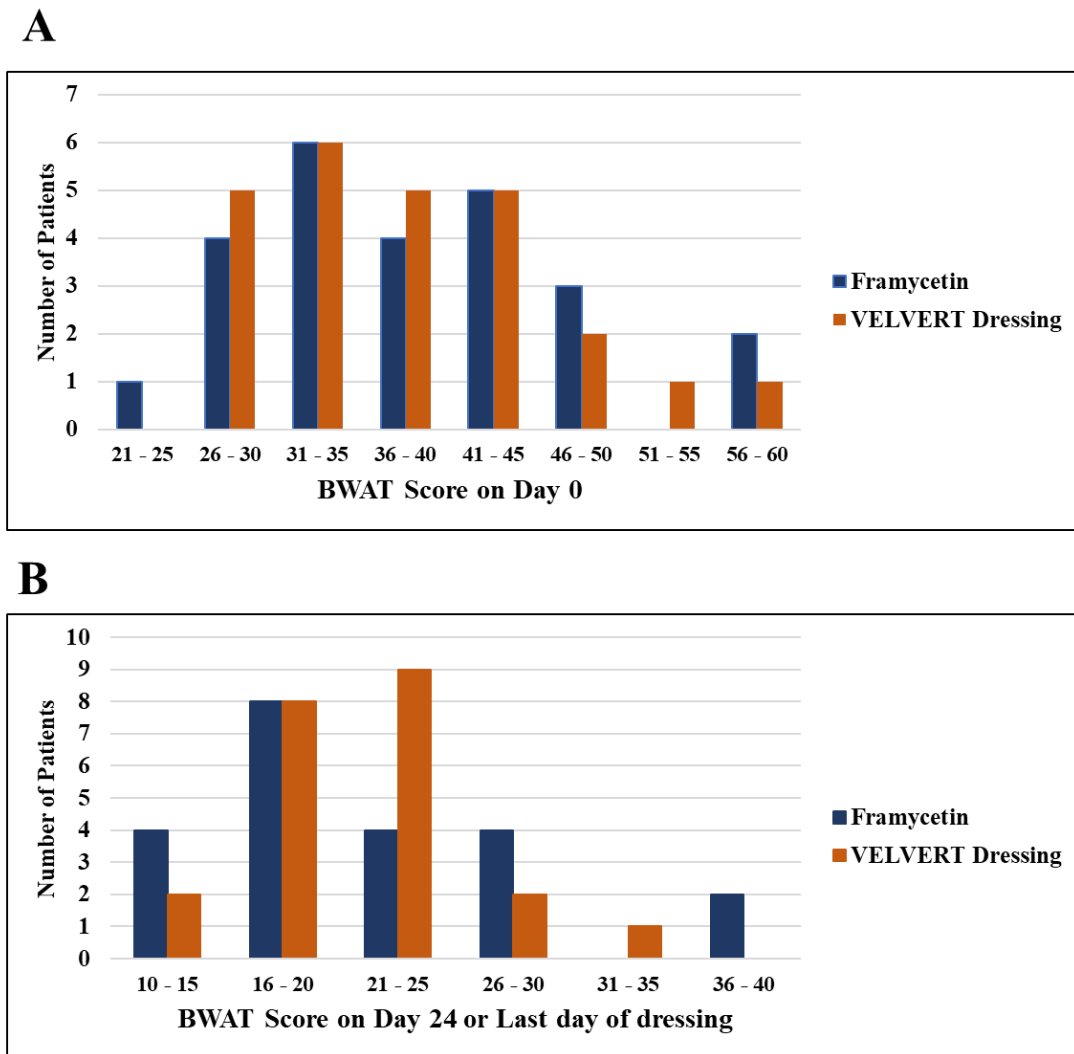


Figure 5: BWAT Score: A comparison between the score at the start of the study (A) and at end of the study or last day of dressing (B) vs number patients falling in a particular range of score.

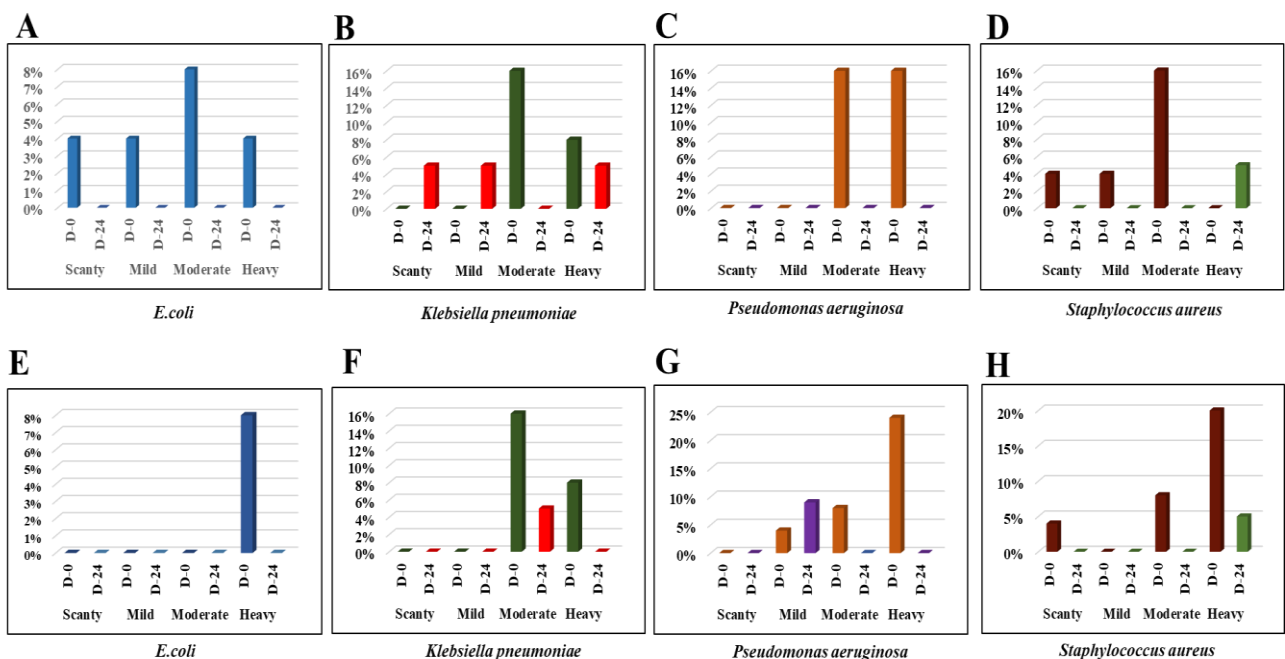


Figure 6: Micro-organism found in swab sample collected for culture from patients with infected wound: Framycetin group (A-D) and VELVERT (E-H). Percentage of patients showing changes in microorganism profile from baseline.

Table 1: Summarizes the criteria used to determine eligibility for participation in the study. Inclusion criteria specify the characteristics required for enrollment, while exclusion criteria indicate conditions or factors that disqualify potential participants

Inclusion criteria	
1.	Patients were required to have the ability to read and comprehend the informed consent document and sign it to provide data for the study.
2.	Patients had to consent to the collection of their data at predefined follow-up intervals.
3.	Female subjects were eligible if they were willing to use contraceptive pills for the study, were permanently sterilized, or met the criteria for post-menopause, defined as the cessation of menses for at least twelve (12) months prior to enrollment.
4.	Patients had a history of suffering from infected wounds with a size of more than 25 cm ² .
5.	Patients had traumatic infected wounds with a duration of less than 1 month.
Exclusion criteria	
1.	Patients who were unwilling or unable to comply with the necessary follow-up visits for data collection.
2.	Patients who tested positive for HIV, HBsAg, and HCV.
3.	Concurrent participation in another clinical trial.
4.	Pregnant females.
5.	Patients on immunosuppressive medication, corticosteroids, or undergoing chemotherapy.
6.	Patients with impaired decision-making capacity.
7.	Patients with a severe comorbid disorder, not expected to survive more than 12 months.
8.	Those with active diabetic foot infections.
9.	Patients with allergies to any materials contained in investigational devices.
10.	Patients with specific wound types, such as burn wounds, DFU, malignant ulcers, tubercular ulcers, leprotic ulcers, gangrenous ulcers, ischemic ulcers, or bed sores.
11.	Any other condition that, according to the investigator's judgment, could interfere with the study.

Table 2: Demographic characteristics of the study participants. Data is presented as mean $\pm$ S.D. or percentage.

Characteristics		Standard of care (N=25)	VELVERT Dressing (N=25)
Age (Years)		38.92 $\pm$ 14.93	37.80 $\pm$ 14.26
BMI (kg/m ²)		24.24 $\pm$ 1.67	24.56 $\pm$ 1.91
Height (cm)		166.96 $\pm$ 4.47	165.32 $\pm$ 5.71
Weight (kg)		67.56 $\pm$ 5.19	67.08 $\pm$ 5.50
Gender n (%)	Male	24 (96.0)	22 (88.0)
	Female	1 (4.0)	3 (12.0)
Smoker n (%)	Yes	0 (0.0)	0 (0.0)
	No	25(100.0)	25(100.0)

Table 3: Pain levels from the baseline of the VELVERT and standard of care.

Pain	Framycetin	VELVERT Dressing	<i>p</i> value
Day 4	-1.16 $\pm$ 0.83	-1.00 $\pm$ 0.69	0.081
Day 8	-2.32 $\pm$ 1.39	-2.26 $\pm$ 1.03	0.077
Day 12	-3.09 $\pm$ 1.28	-2.96 $\pm$ 1.12	0.747
Day 16	-3.71 $\pm$ 1.40	-3.65 $\pm$ 1.37	0.706
Day 20	-4.68 $\pm$ 1.77	-4.74 $\pm$ 1.54	0.413
Day 24	-5.64 $\pm$ 1.92	-5.77 $\pm$ 1.78	0.307

Table 4: Assessment of dressings based on surgeon's questionnaire regarding their experience with use of dressing for the treatment of infected wound. The data is analysed based on various parameters on a scale of 1 to 5, where 1 represents "Easy" and 5 represents "Difficult" related to experience during use of devices.

Characteristics	Levels	Standard of care		VELVERT Dressing	
		Day 0	Day 24	Day 0	Day 24
Ease of handling	1	22 (88%)	20	24 (96%)	22 (100%)
	2	1 (4%)	1	1 (4%)	0 (0%)
	3	1 (4%)	0 (0%)	0 (0%)	0 (0%)
	4	1 (4%)	0 (0%)	0 (0%)	0 (0%)

Appropriateness of instruction for use	1	21 (84%)	20 (95%)	24 (96%)	20 (91%)
	2	4 (16%)	0 (0%)	1 (4%)	2 (9%)
	3	0 (0%)	1 (5%)	0 (0%)	0 (0%)
Ease of application	1	20 (80%)	20 (95%)	23 (92%)	21 (95%)
	2	4 (16%)	0 (0%)	2 (8%)	1 (5%)
	3	1 (4%)	1 (5%)	0 (0%)	0 (0%)
Conformance to tissue surface	1	16 (64%)	14 (67%)	16 (64%)	18 (82%)
	2	8 (32%)	7 (33%)	9 (36%)	4 (18%)
	4	1 (4%)	0 (0%)	0 (0%)	0 (0%)
Overall performance of device response	1	16 (64%)	16 (76%)	21 (84%)	22 (100%)
	2	9 (36%)	5 (24%)	4 (16%)	0 (0%)

Discussion

Wound healing can be impaired by the presence of infection; microorganisms from different sources are presented with an opportunity to colonize, notably in the case of chronic wounds. Bacteria are a common part of the skin microbiota and wounds, however reaching above a critical threshold of existing bacteria and the development of a biofilm may impede wound healing process (Bowler et al., 2001). The increase of antibiotic resistance in infected wounds has led to the need to develop further options which can be used to treat infected wounds effectively. The current clinical study was conducted to evaluate the safety and efficacy of an herbal antimicrobial dressing VELVERT against infected wounds in comparison to standard treatment with Framycetin cream. Healing progression was measured by observing the reduction in the wound area and scoring the condition of the wound by monitoring changes in 15 different parameters as a cumulative BWAT score. At the end of the study, 2 patients achieved complete closure of the wound and intact surface was observed. 7 patients achieved 75% to < 100% wound coverage with >0.5cm epithelial tissue extension into the wound bed. For remaining 13 patients, less than 75% wound closure was observed, whereas in previous studies they reported healing rate of 47.5% for Allevyn and 50.7% for Mepilex (Franks et al., 2007). Majority of wounds are polymicrobial, in that, they involving both aerobic and anaerobic microorganisms (Twum-Danso et al., 1992). An antimicrobial dressing, thus, should be effective against both aerobic and anaerobic microorganisms. *S. aureus* is considered one of the most problematic bacterium in wound infections (Bowler et al., 2001; Roy et al., 2020; Rutherford & Spence, 1980; Twum-Danso et al., 1992). In the present study, VELVERT was found to be effective in decreasing the *S. aureus* load from 32% (including 20% heavy load) to 5%, in addition to other microorganisms. VELVERT was able to effectively reduce the severity and prevalence of various microorganisms in infection wounds when compared to the standard of care. Another clinically important factor to consider is the level of exudate while evaluating an antimicrobial dressing. Infected wounds often produce excessive exudate (fluid) containing infectious material. VELVERT is designed for high exudate absorption. Adequate absorption of exudate decreases wound size and aids in healing process (Alihosseini et al., 2023). One of the parameter in BWAT score is the exudate amount which was evaluated using a scoring system ranging from 1-5, where 1 represents the dry tissue wound and 2-5 represents varying degree of exudate. By the end of the study mean score of VELVERT was found to be 1.27 ± 1.39 and for standard of care it was 1.23 ± 1.13 . However, the number of VELVERT dressing used was approximately half of that of standard of care, since, standard of care was changed every alternative day and VELVERT dressing was changed every 4th day. In our study, VELVERT's conformability was found to be effective along with standard of care, which expresses the proximity of dressing with the wound bed (Lustig & Gefen, 2021). A superior conformance to tissue reduces the potential exudate pooling between wound and dressing gaps, (Lustig & Gefen, 2021) as was observed with VELVERT. Dressing changes cause moderate to severe pain in 74% of patients and causes substantial stress for patients and clinicians (Gardner et al., 2014). Pain experienced during dressing changes is comparable to movement-evoked pain, as both involve mechanical stimulation at the wound site, which can trigger or intensify pain (Gardner et al., 2017). In addition to decreased number of dressing changed, the non-adherent property of this dressing is advantageous in the management of pain during wound care process. In the current study, the pain level was reduced from severe to moderate level following 4th visit in comparison to standard of care, where same level of pain decline was achieved after 7th visit. At the end of the study, a prominent decrease in the level of pain was observed with lesser visits in comparison to standard of care. Further studies and clinical trials focused on antimicrobial dressings can shed light on their respective benefits and guide medical professionals in making informed decisions regarding the management of infected wounds. Multi-modal approaches to wound management, involving physical debridement and antimicrobial therapy has been shown to enhance healing. Antimicrobial dressings that are able to interfere with biofilms existing in hard-to-heal wounds can potentially aid wound care process. In the current study, VELVERT Dressing was more effective in mitigating the presence of *Klebsiella pneumoniae* across all severity categories compared to the Standard of care. Additionally, initially two more patients had *S. aureus* infection that were included in the VELVERT group, however, one patient in each group was found to be infected with a heavy load of *Staphylococcus aureus* on the last day of the study.

Conclusion

In conclusion, VELVERT dressing demonstrates promising potential as an advanced wound care solution. Its ability to enhance protection against infections, promote faster wound closure, and improve patient comfort by reducing dressing changes and managing exudate effectively makes it a valuable option for treating infected wounds. Furthermore, the absence of adverse events in the VELVERT group highlights its safety profile. These findings suggest that VELVERT could significantly enhance the quality and convenience of wound care, offering a novel and effective alternative to standard of cares.

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