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Clinical Efficacy and Safety of Theruptor 3-D Composite Microbicidal Dressing in Comparison with Bactigras and Allevyn Dressings on Wound Healing in Participants with Chronic Infected Wounds: A Randomized, Multi-Centric, Comparative, Parallel-Group, Prospective Study

Mayank Badkur, MS[1], Vinoth Sundaresan, MS[2], Tharun Ganapathy, MS[3], Tushar Mishra, MS[4], Keshavamurthy Vinay, MD[5], Michael Rodrigues, PhD[6], Ashok Kumar Moharana, MD[6], Deepak TS, MD[6], Sakthibalan Murugesan, MD[7], Mahalakshmi Durai, MTech[7], and Shoban Babu Varthya, MD[1]

Abstract

Background: Advanced wound care dressings are vital in managing the complexities of chronic wound treatment. For instance, Theruptor 3-D composite microbicidal dressing is designed with antimicrobial properties to promote wound healing. Despite the availability of several antimicrobial products in the market such as Bactigras, Allevyn, and Aquacel, their comparative efficacy remains unexplored. This study evaluated the clinical efficacy and safety of Theruptor versus Bactigras and Allevyn dressings for chronic wound healing.

Methods: A randomized, parallel-group study was conducted from May 2022 to July 2024 across five centres in India. Patients with chronic wounds were randomized to allocate Theruptor, Bactigras, and Allevyn dressings (diabetic and non-diabetic etiology; n = 35 each). Wound area, bacterial load, clinical signs and symptoms, exudate management, and product performance were assessed.

Results: A total of 210 patients with chronic wound in the age range of 19–87 years, were recruited and followed up for 8 weeks. The mean wound area was significantly reduced from Day 0 to Day 56 in in diabetic Theruptor (17.35 ± 15.08 cm^2 vs 4.13 ± 10.56 cm^2), Bactigras (12.93 ± 12.02 cm^2 vs 3.6 ± 7.75 cm^2), and Allevyn (14.36 ± 9.97 cm^2 vs 0.74 ± 1.65 cm^2) and non-diabetic Theruptor (20.45 ± 16.8 vs 3.01 ± 7.52 cm^2), Bactigras (18.16 ± 14.81 vs 2.52 ± 5.48 cm^2), and Allevyn (28.41 ± 19.97 vs 5.31 ± 9.94 cm^2) groups ($p < .0001$). Further, bacterial load, exudate scores, and clinical signs and symptoms non-significantly improved with time in all three groups ($p > .05$). In product performance analysis, Theruptor dressing (n = 33/33) was rated more comfortable to wear than Bactigras (n = 24/28, $p = .004$) and Allevyn (n = 25/30, $p = .02$) in diabetic patients. Among non-diabetics, more patients reported "no pain" during application and removal of dressing in

[1]Department of General Surgery, AIIMS Jodhpur, Rajasthan, India
[2]Department of General Surgery, Mahatma Gandhi Medical College and Research Institute, Pondicherry, India
[3]Department of General Surgery, SRM Medical College Hospital & Research Centre, Chennai, Tamil Nadu, India
[4]Department of General Surgery, AIIMS, Bhubaneswar, Odisha, India
[5]Department of Dermatology, Venereology and Leprology, Postgraduate Institute of Medical Education and Research, Chandigarh, India
[6]Research & Development (CareNow Medical Private Limited), Healthium Medtech Limited, Bengaluru, Karnataka, India
[7]Clinical Affairs, Healthium Medtech Limited, Bengaluru, Karnataka, India8Ki3 Private Limited, Chennai, Tamil Nadu, India9Department of Pharmacology, AIIMS Jodhpur, Rajasthan, India

Corresponding Author:
Deepak TS, Clinical Affairs, Healthium Medtech Limited, 8th Floor, Incubex Workspace, Brigade Triumph, Dasarahalli Main Road, Sector – B, Hebbal, Bengaluru 560092, India.
Email: deepak.ts@healthiummedtech.com

Theruptor group (n = 26/29 and 28/29) than in Bactigras (n = 18/31; $p = .04$ and n = 20/31; $p = .02$) and Allevyn groups (n = 12/29; $p = .001$ and n = 16/29; $p = .003$).

Conclusion: Theruptor provides a safe and effective alternative for chronic wound management with comparable healing outcomes to Bactigras and Allevyn dressings.

Keywords

chronic wounds, theruptor, bactigras, allevyn, wound healing

Introduction

Chronic wounds pose a major global health challenge to patients and physicians due to their prolonged healing times, high recurrence rates, and susceptibility to infections.[1–3] The global prevalence of chronic wounds ranges from 1.51 to 2.21 per 1000 individuals.[4] These wounds are more prevalent among women than men, with the average age of affected individuals ranging from 70 to 80 years.[5] Chronic wounds are categorized as diabetic foot ulcers (DFU), wounds associated with peripheral arterial disease, venous leg ulcers, and pressure ulcers.[6] Of the estimated 537 million diabetic people, 19% to 34% are expected to develop a DFU in their lifetime.[7] The complex aetiology of chronic wounds involves impaired angiogenesis, abnormal collagen accumulation, fibrosis, and prolonged inflammation.[8] Thus, effective management of chronic wounds necessitates early detection, debridement of necrotic tissue, and the application of advanced wound dressings that promote healing.[9]

Modern wound care solutions such as polymeric hydrogels and moist wound dressings are designed to address the multifaceted needs of chronic wound healing process.[10] These dressings provide a combination of benefits including moisture retention, microbial protection, exudate management, and promotion of granulation tissue.[7] Despite their effectiveness, consistent healing outcomes remain challenging for complex wounds that require prolonged care.[2]

Theruptor 3-D composite microbicidal wound dressing, developed by Healthium Medtech Limited, India, is an innovative wound care system with anti-microbial properties. It is a 3D hydrocellular dressing made of Polyethylene terephthalate (PET) and polyurethane, permanently bound and cross polymerized-cross-linked with "Dimethyl tetradecyl [3- (trimethoxy silyl) propyl] ammonium chloride" (DTAC). Its mechanism of action involves cationic sites to attract and disrupt negatively charged pathogens, leading to their lysis and elimination.[11] Evidence in the literature states that Theruptor is a broad range microbicidal dressing effective against Gram-positive and Gram-negative bacteria, fungi, yeast, and resistant strains and in reducing surgical site infections.[11,12]

Several antimicrobial wound care products are currently available in the market for instance, Bactigras wound dressing of Smith and Nephew is an antimicrobial dressing containing chlorhexidine as an active agent to combat bacterial infections.[13] Another product from Smith and Nephew is Allevyn wound dressing which incorporates silver as a potent antimicrobial agent. The ability of Allevyn to combat infections and promoting wound healing makes it a comparator in clinical evaluations of wound care products.[14] Bactigras and Allevyn are highly referenced and endorsed dressings in clinical practice guidelines as standard treatment options for chronic wounds. Their established safety, efficacy, and distinct mechanisms make them suitable and relevant comparators in clinical evaluations of wound care technologies.[15] The antimicrobial components in all the three dressings target bacteria, offering reliable options for infection management. However, despite the wide availability of these products, there is a notable lack of comparative evidence in the literature evaluating their relative performance to other advanced wound care technologies.

Based on this background, this randomized, multi-center, comparative, parallel-group, prospective study aims to assess the clinical efficacy and safety of Theruptor Wound Dressing in comparison with Bactigras and Allevyn dressings for the treatment of chronic wounds.

Patient and Methods

Study Design

This randomized, multi-center, parallel-group, prospective clinical study was conducted between May 4, 2022 and July 8, 2024 across five centres in India: All India Institute of Medical Sciences (AIIMS, Jodhpur - Rajasthan), All India Institute of Medical Sciences (AIIMS, Bhubaneswar - Odisha), Mahatma Gandhi Medical College and Research Institute (MGMCRI, Puducherry), SRM Medical College Hospital and Research Centre (SRM, Tamil Nadu), and Postgraduate Institute of Medical Education and Research (PGIMER, Chandigarh). The study protocol and informed consent documents were reviewed and approved by the respective Institutional Review Boards of the centres. Written consent was obtained from all patients before initiating any study-related procedures. The study was pre-registered in Clinical Trials Registry-India and conducted in compliance with the Declaration of Helsinki, Good Clinical Practice (ICH-GCP), and ISO 14155 standards.[16,17]

Patients

The inclusion and exclusion criteria are detailed in Table 1. Adult patients aged ≥18 years, both males and females, with

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria	Exclusion Criteria
• Male or female patients of age 18 years or older. • Patients who had chronic wounds (either diabetic or non-diabetic) in origin and larger than 1 cm^2 up to 25 cm^2 for diabetic wounds, and 1 cm^2 up to 50 cm^2 for non-diabetic wounds. (Wound measurements were taken after debridement using rulers). • Patients presented with 2 or more signs of infection (pain, swelling, discharge, warmth, erythema, and malodour), but with reduced bacterial bioburden. • Class 1, 2, and 3 wounds of CDC Classification (Risk assessment & Infection control) • For diabetic wounds, up to grade 2 of the University of Texas Diabetic Foot Ulcer Classification System (Assessment and Diagnosis). • The age of the wound was between 3 months and one-year duration, with documented failure of earlier treatment to heal the wound. • Patients who provided informed consent and were willing to participate in all procedures and follow-up evaluations necessary to complete the study. • The patient who had adequate circulation to the affected extremity, as demonstrated by one of the following in case of diabetic and non-diabetic ulcers, within the past 60 Days before enrolment: (For all patients) • Doppler- ABIs with results of $\geq$0.7 and $\leq$1.2 to ensure adequate peripheral perfusion and arterial sufficiency to support wound healing, OR • Doppler arterial waveforms, which are triphasic or biphasic at the ankle of the affected leg	• Wound probing to bone (UT Grade III A- D). A positive probe-to-bone was confirmed when bone or joint can be felt with a sterile probe. • Index foot ulcers greater than 25 cm^2 for diabetic wounds and greater than 50 cm^2 for non-diabetic wounds to ensure uniformity in wound severity and to minimize variability in healing potential across treatment groups. Larger wounds often present with complex pathophysiology, which may require surgical interventions. • Known history of poor compliance with medical treatments. • Previously randomized or participated in another clinical trial. • Under radiation therapy or chemotherapy at the time of enrolment. • Known or suspected local skin malignancy to the index ulcer. • Serum Creatinine more than 2 mg/dl and HbA1c more than 10% • Non-revascularizable surgical sites. • Pregnant or lactating female. • Under immune system modulator medications. • Allergy to the test or comparator products employed in the study.

chronic infected ulcers of diabetic or non-diabetic etiology were screened for eligibility. Those patients who exhibited at least two clinical signs of infection alongside evidence of reduced bacterial bioburden and had chronic wounds with a post-debridement area ranging from 1–25 cm^2 for diabetic wounds or 1–50 cm^2 for non-diabetic wounds were eligible for the recruitment in the study. Any patients with a wound that was exceeding the specified size thresholds of 25 cm^2 for diabetic wounds or 50 cm^2 for non-diabetic wounds and/or probed to bone, classified as University of Texas (UT) Grade III A-D were excluded from the study.

Randomization and Intervention

Randomization was done using a Permuted Block technique, and allocation was concealed using serially numbered opaque sealed envelope technique. Both investigators and patients were not aware of the dressing allocation at the time of recruitment in the study. Patients were assigned randomly to the study groups with equal probability within groups for both diabetic and non-diabetic patients. Patients were allocated into three groups, which were sub-categorized as:

- **Group 1:** Patients with chronic wounds of diabetic and non-diabetic etiology received Theruptor 3-D Composite Microbicidal Wound Dressing (n = 35 each)
- **Group 2:** Patients with chronic wounds of diabetic and non-diabetic etiology received Bactigras Wound Dressing (n = 35 each)
- **Group 3:** Patients with chronic wounds of diabetic and non-diabetic etiology received Allevyn Wound Dressing (n = 35 each)

Patients received their assigned dressing and were followed for 8 weeks or 56 Days, with assessments conducted on Days 0, 3, 7, 14, 21, 28, 42, and 56. The patients had a window period of $\pm$ 7 Days between the visits.

Study Outcomes and Assessments

Physical examination, demographics, and medical history of the patients were documented at the time of recruitment. At baseline and during the follow-up, wound debridement was performed using saline irrigation and surgical removal of necrotic tissue. Saline irrigation was done with a normal saline solution to clean and remove loose debris. Surgical debridement was conducted using sterile instruments to excise adherent necrotic tissue until healthy tissue was exposed. Post debridement the wound measurements were taken.

The primary endpoints were to compare wound area, reduction in bacterial load (colony counts), and improvement in clinical signs and symptoms on Days 0, 3, 7, 14, 21, 28, 42, and 56 between the groups. For the same, the wound surface area was measured using a ruler to determine length, width, and depth. Digital photographs were captured at a distance of at least 30 cm, with a paper ruler at the wound site. The microbiological assessment of bacterial colony count at the wound site was done using a swab during each follow-up visit. Any improvement in signs and symptoms such as pain, swelling, discharge, warmth, erythema, and malodor were assessed at each visit.

The secondary endpoints included proportion of completely healed wounds, exudate management and wound bleeding during dressing changes (graded as None, Minimal, Moderate, or Heavy), maceration scores (0 = No maceration, 1 = minimal maceration, 2 = moderate maceration, and 3 = excessive maceration), erythema grading scale (redness: 0 = absent, 1 = mild, 2 = moderate, or 3 = severe), wound pain assessment using the Visual Analog Scale (VAS), Red-Yellow-Black (RYB) wound assessment scale (color of the wound bed), condition of the surrounding skin (healthy, inflamed, macerated, dry and flaky), percentage of tissue type (pink epithelial, beefy red granulation, dull red, friable granulation, yellow, black necrotic, and devitalized tissue), Wound-Quality of life (QoL) questionnaire,[18] and Cardiff wound impact questionnaire.[19] Also, visible fibres from the dressing material and adverse events were assessed for their presence or absence during each visit.

At the end of the study, the product performance on the basis of ease of application, comfort, discoloration of the surrounding skin, pain during application and removal, satisfaction with exudate and leakage handling, number of dressing changes required and the mean wear time of dressing was assessed.

All the measurements (length, width, and depth), wound assessment parameters, symptom scoring, and digital photographic documentation were conducted by trained site investigators from the wound care team according to a standardized protocol, to ensure consistency and minimize biasness. Although investigators were blinded to the dressing allocation at the time of patient recruitment and randomization, they were involved in the follow-up assessments.

Sample Size Calculation

The sample size was calculated using n-master, with the following formula:

$$n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1 - p_1) + p_2(1 - p_2)) / (p_1 - p_2)^2$$

where $Z_{\alpha/2}$ = critical value of the normal distribution at $\alpha/2$; Z_{β} = critical value of the normal distribution at β; p_1 and p_2 = expected sample proportions of the two groups.

Assuming a 5% level of significance ($\alpha = 0.05$) and a randomization ratio of 1:1:1 across the three arms, the required sample size was calculated based on the percentage of wound healing: 80% in the test arm and 96% in the comparator arm. At 80% power ($\beta = 20\%$), the estimated sample size for each arm was determined to be 61 patients. Considering 10% dropout rate, the sample size per arm was rounded up to 70 patients.[20] Thus, the total sample size for the study was set at 210 patients.

Statistical Methods

In the study, both intention-to-treat (ITT) population and per-protocol (PP) population analysis were planned however, the clinical efficacy of the dressings were evaluated using PP population. The ITT population included all randomized participants, regardless of protocol adherence or completion of the study. The PP population consisted of participants who completed the study without major protocol deviations, such as non-compliance with dressing application or missed follow-up assessments.

The data was statistically analyzed using SPSS software version 28.0.1. Continuous variables were analyzed using descriptive statistics and represented as mean, standard deviation (SD), and median. Categorical variables were expressed as counts and percentages. Inter- and intra-group comparisons were performed throughout the study. For intra-group comparisons, wound area reduction, colony count, exudate management, wound bleeding, maceration, erythema grading scale, wound pain assessment, and QOL questionnaire were analyzed using Wilcoxon matched-pairs signed rank test. For inter-group comparisons, colony count, wound bleeding, maceration, erythema grading scale, wound pain assessment, and QOL questionnaire were assessed by Kruskal-Wallis test, and wound area reduction and exudate management by Mann-Whitney test. For both intra- and inter-group comparisons, clinical signs and symptoms, bacterial load reduction, RYB wound assessment scale, condition of the surrounding skin, tissue types in wound bed, Cardiff wound impact questionnaire, and product performance parameters were evaluated using Fisher's exact test.

Results

A total of 241 patients were screened for the trial of which 210 patients were found eligible and enrolled. Recruited patients were then randomized and allocated into three treatment arms: Theruptor, Bactrigras, and Allevyn, further subcategorized as diabetic and non-diabetic patients (n = 35 each). Among the recruited patients, 180 completed the study, while 27 were lost to follow-up, and 3 were withdrawn. The disposition of patients across the study sites: AIIMS Rajasthan (n = 105), AIIMS Odisha (n = 24),

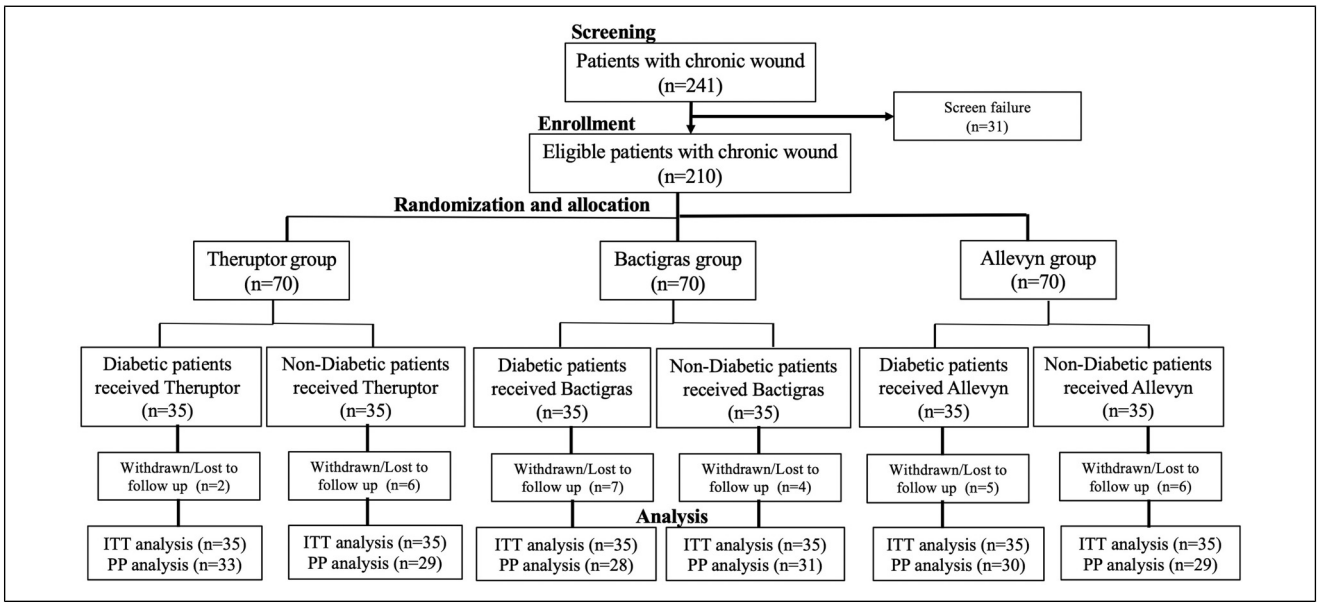

Figure 1. Flow Chart of the Patients.

MGMCRI (n = 51), SRM (n = 21), and PGIMER (n = 9). The consort flow chart of patients through the study is presented in Figure 1.

At baseline, the age of recruited patients ranged from 19 to 87 years. When the diabetic groups of Theruptor (55.14 ± 12.92 years), Bactigras (57.63 ± 13.34 years), and Allevyn (53.6 ± 11.7 years) were compared, no statistically significant differences in the age were observed among the treatment groups ($p > .05$). Similar results were observed for non-diabetic treatment groups (Theruptor: 45.43 ± 15.62 years, Bactigras: 50.57 ± 12.33 years, and Allevyn: 50.97 ± 16.09 years; $p > .05$). While the percentage of female patients (n = 163, 77.6%) was higher than male patients (n = 47, 22.4%) in the study, this trend was consistent across all the groups. Patient characteristics, including height, weight, and male-to-female ratio, were comparable across the study groups ($p > .05$). The details of patient characteristics for each treatment group are summarized in Table 2.

Reduction in Wound Area

Across all the three treatment arms, wound area in both diabetic and non-diabetic patients decreased significantly at all follow-up visits until week 8 or Day 56 when compared to baseline (Day 0) ($p < .0001$). The mean wound area was reduced significantly from 17.35 ± 15.08 cm^2, 12.93 ± 12.02 cm^2, and 14.36 ± 9.97 cm^2 at Day 0 to 4.13 ± 10.56 cm^2, 3.6 ± 7.75 cm^2, and 0.74 ± 1.65 cm^2 at Day 56 in diabetic Theruptor, Bactigras, and Allevyn groups, respectively ($p < .0001$). Similar results were observed for non-diabetic groups at Day 56 versus Day 0 (Theruptor: 3.01 ± 7.52 vs 20.45 ± 16.8 cm^2, Bactigras: 2.52 ± 5.48 vs 18.16 ± 14.81 cm^2, and Allevyn: 5.31 ± 9.94 vs 28.41 ± 19.97 cm^2; $p < .0001$). However, no statistically significant differences were observed in wound area reduction between the three groups in both diabetic and non-diabetic patients ($p > .05$) at any time period of the study. The median time for complete wound healing ranged from 6 to 8 weeks and was comparable across all three treatment groups for both diabetic and non-diabetic patients. The reduction in wound area during the visits in all the treatment arms is shown in Figure 2(a). The representative pictures of healed wounds from each treatment group is shown in Supplementary Figures 1 to 6.

Bacterial Load

Regarding bacterial infection in patients, a gradual but non-significant decrease in the number of patients were observed from Day 0 to Day 56 across all the treatment groups in both diabetic (Theruptor: 17 vs 4, Bactigras: 16 vs 5, and Allevyn: 17 vs 3) and non-diabetic patients (Theruptor: 17 vs 3, Bactigras: 18 vs 3, and Allevyn: 17 vs 6) except diabetic Theruptor group on Day 21 (n = 6; $p = .04$). When all the treatment arms were compared with diabetic and non-diabetic patients, no significant differences in the number of patients with bacterial infection were observed at any time point ($p > .05$) (Figure 2(b)). The detected microorganisms were: *Methicillin Resistant Staphylococcus aureus (MRSA), Proteus mirabilis, Escherichia coli, GNB Providencia stuartii, Acinetobacter baumannii, Klebsiella pneumoniae, Methicillin Sensitive Staphylococcus aureus (MSSA), Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Methicillin-Resistant Coagulase-*

Table 2. Patient Characteristics for Study Group.

Characteristics	Theruptor dressing		Bactigras dressing		Allevyn dressing	
	Diabetic (n = 35)	Non-Diabetic (n = 35)	Diabetic (n = 35)	Non-Diabetic (n = 35)	Diabetic (n = 35)	Non-Diabetic (n = 35)
Age (years)	55.14 ± 12.92 —	45.43 ± 15.62 —	57.63 ± 13.34 $p = .43$	50.57 ± 12.33 $p = .13$	53.6 ± 11.7 $p = .60$	50.97 ± 16.09 $p = .15$
Height (cm)	163.7 ± 7.57 —	164.9 ± 10.41 —	162.1 ± 8.45 $p = .43$	166.4 ± 8.29 $p = .13$	162.7 ± 9.61 $p = .60$	163.9 ± 8.77 $p = .14$
Weight (kg)	71.25 ± 12.68 —	69.38 ± 14.72 —	67.71 ± 9.61 $p = .19$	70.73 ± 10.65 $p = .5$	69.98 ± 11.34 $p = .66$	70.41 ± 11.84 $p = .46$
BMI (kg/m^2)	26.63 ± 4.69 —	25.45 ± 4.84 —	25.92 ± 4.30 $p = .50$	25.6 ± 3.97 $p = .57$	26.58 ± 4.66 $p = .96$	26.17 ± 3.60 $p = .19$
Gender (F/M)	27/8 —	27/8 —	25/10 $p = .79$	28/7 $p > .99$	26/9 $p > .99$	30/5 $p = .54$

Cm = centimetre, kg = kilograms, m = metre, F/M = Female/Male ratio, (Inter-group comparison with respective diabetic and non-diabetic etiology: p vs Theruptor using Student 't' test and Fisher's exact test for gender comparison).

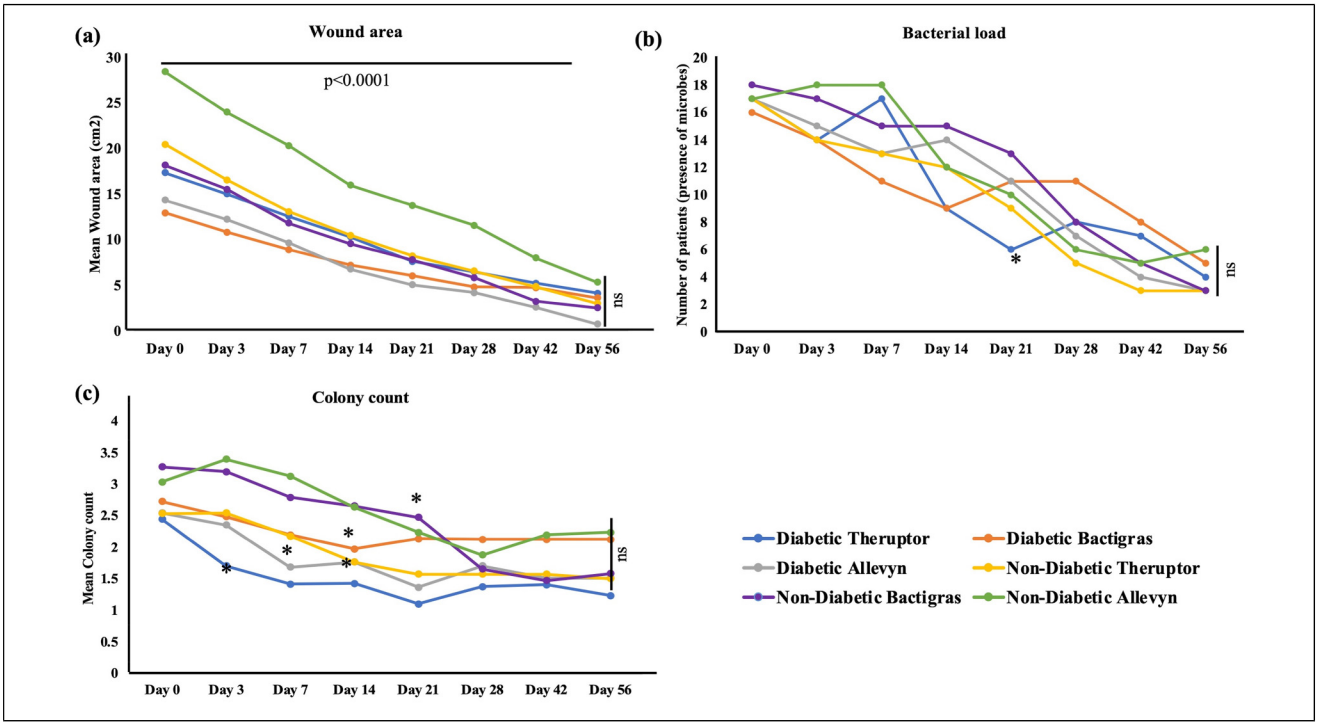

Figure 2. Primary Endpoints. The Graphs Depict (a) Mean Wound Area, (b) Proportion of Patients Showing Bacterial Load, and (c) Mean Colony Count. P-value was Calculated using Wilcoxon Matched Pairs Signed Rank Test for Intra-treatment (Subsequent Follow-up vs Day 0) Comparisons for Wound Area and Mean Colony Count, Mann-Whitney Test and Two-sided Kruskal-Wallis Test for Inter-treatment Comparisons (Theruptor vs Bactigras or Allevyn) for Wound Area and Mean Colony Count Respectively, and Fisher's Exact Test for Bacteria Load in Patients. ns = Non-significant; *$p < .05$ versus Day 0.

Negative Staphylococcus (MR-CoNS), Pseudomonas aeruginosa, Enterococcus faecalis, Methicillin sensitive Staphylococcus epidermis, Beta hemolytic streptococcus, Enterobacter cloacae, Citrobacter freundii, Citrobacter koseri, Enterobacter aerogenes, and Citrobacter diversus.

Further, the mean colony counts were highest in non-diabetic Bactigras group (3.29 ± 2.39) followed by Allevyn (3.05 ± 2.38) and Theruptor (2.55 ± 2.42) at Day 0 (Figure 2(c)) but non-significant ($p > .05$). In case of diabetic treatment groups, the mean colony counts were

comparable (Theruptor: 2.46 ± 2.41, Bactigras: 2.74 ± 2.37, and Allevyn: 2.56 ± 2.4, $p > .05$). The diabetic Theruptor group demonstrated a significant reduction in mean colony counts on Day 3 (1.72 ± 2.33; $p = .008$) and subsequent visits ($p < .05$) except Day 28 (1.39 ± 2.2; $p = .07$), compared to Day 0 (2.46 ± 2.41). Among non-diabetic patients, Theruptor demonstrated an early and sustained reduction in microbial load, with the first decrease observed on Day 7 (2.19 ± 2.22; $p = .03$) and maintained through subsequent visits ($p < .05$). In contrast, the reduction in microbial load was delayed in diabetic and non-diabetic Bactigras group and observed on Day 28 (diabetic: 2.14 ± 2.41 and non-diabetic: 1.67 ± 2.28, $p < .05$). However, no consistent reduction trend was observed in diabetic and non-diabetic Allevyn group. In the diabetic Allevyn group, a significant reduction was observed on Day 7 (1.7 ± 2.3; $p = .02$), followed by a non-significant reduction on Day 14 (1.78 ± 2.31; $p = .12$). In contrast, the non-diabetic Allevyn group showed a significant reduction only on Day 28 (1.89 ± 2.41; $p = .02$).

Clinical Signs and Symptoms

The clinical signs and symptoms include pain, swelling, discharge, warmth, erythema, and malodour, which showed no statistically significant differences across the three groups for both diabetic and non-diabetic patients throughout the study ($p > .05$) except diabetic Bactigras versus Theruptor on Day 21 (n = 19 vs 12, $p = .02$) and Day 28 (n = 22 vs 17, $p = .04$) for "no pain", non-diabetic Bactigras versus Theruptor on Day 42 for "discharge" (n = 0 vs 4, $p = .05$), and on Day 0 (n = 10 vs 2, $p = .02$) and Day 21 (n = 30 vs 23, $p = .05$) for "no swelling".

However, a significant improvement was observed in the proportions of patients reporting absence of clinical signs and symptoms during subsequent visits as compared to Day 0 ($p < .05$), which are:

Pain: A significant improvement in pain relief was observed across all diabetic treatment groups from Day 0 to Day 21 (Theruptor: 3 vs 12, $p = .02$ and Allevyn: 4 vs 16, $p = .002$) except diabetic Bactigras group which showed significant improvement on Day 14 (3 vs 12, $p = .01$). A significant increase in the proportion of patients reporting no pain was observed in non-diabetic group from Day 14 as compared to Day 0 (Theruptor: 1 vs 10, Bactigras: 2 vs 9, and Allevyn: 1 vs 8) ($p < .05$) (Figure 3(a)). The mean pain score was reduced significantly from 5.97 ± 2.71, 5.54 ± 1.99, and 5.87 ± 2.53 at Day 0 to 1.49 ± 1.91, 1.07 ± 1.09, and 0.83 ± 1.18 at Day 56 in diabetic Theruptor, Bactigras, and Allevyn groups, respectively ($p < .05$). Similarly, for non-diabetic Theruptor, Bactigras, and Allevyn groups, the mean pain scores were decreased from 7.55 ± 1.48, 6.81 ± 1.91, and 7.24 ± 2.15 at Day 0 to 1.48 ± 2.28, 1.1 ± 1.74, and 1.21 ± 1.99 at Day 56 ($p < .05$).

Swelling, discharge, and warmth: On Day 3, non-diabetic Theruptor groups (n = 9 vs 2, $p = .04$) showed a significant increase in the proportion of patients reporting "no swelling" and non-diabetic Bactigras (n = 10 vs 2, $p = .02$) and non-diabetic Allevyn groups (n = 9 vs 2, $p = .04$) in "no discharge" as compared to Day 0. From Day 7 to subsequent follow-ups, a significant increase in the proportion of patients reporting no swelling, no discharge, and no warmth across all the diabetic and non-diabetic treatment groups as compared to Day 0 ($p < .05$) (Figure 3(b–d)).

Erythema: On Day 14 and subsequent follow-ups, a significant increase in the proportion of patients reporting no erythema across all the diabetic and non-diabetic treatment groups as compared to Day 0 ($p < .05$). Both diabetic (n = 16 vs 7, $p = .04$) and non-diabetic (n = 7 vs 1, $p = .05$) Theruptor group and diabetic Bactigras group (n = 15 vs 5, $p = .01$) showed significant improvement on Day 7 versus Day 0. (Figure 3(e)). Similar results were obtained for mean erythema scores calculated using erythema grading scale ($p < .05$).

Malodor: On Day 3, the number of patients reporting no malodor significantly increased across all treatment groups compared to Day 0, in both diabetic (Bactigras: 13 vs 5, Allevyn: 12 vs 4) and non-diabetic (Theruptor: 15 vs 6, Bactigras: 13 vs 3, Allevyn: 15 vs 6) patients ($p < .05$) except for diabetic Theruptor group (n = 10 vs 3, $p = .06$). During subsequent visits, a significant increase in the proportion of patients was observed across all the treatment groups ($p < .05$) (Figure 3(f)).

Wound Assessment

RYB wound assessment data is given in Supplementary Table 1. On Day 7, only non-diabetic Allevyn group showed significant reduction in patients with black tissue (n = 7 vs 0, $p = .01$) while number of patients with red tissue significantly increased in diabetic Allevyn (n = 16 vs 25, $p = .03$). From Day 28 and subsequent visits, a significant improvement in tissue type was observed, with healthy red tissue progressively replacing yellow and black tissues across all treatment groups ($p < .05$). On comparing diabetic and non-diabetic Theruptor with Bactigras and Allevyn groups, no significant differences were observed across all time points or wound tissue color categories ($p > .05$).

Next, the tissue types in the wound bed were assessed in terms of pink (epithelial), beefy red granulation, dull red, friable granulation, yellow, black necrotic, and devitalized. Notably, no patient had black necrotic or devitalized type of tissue from any of the groups. Only diabetic Theruptor group ($p = .006$) showed significant improvement in the condition of tissue type in wound bed on Day 7 while non-

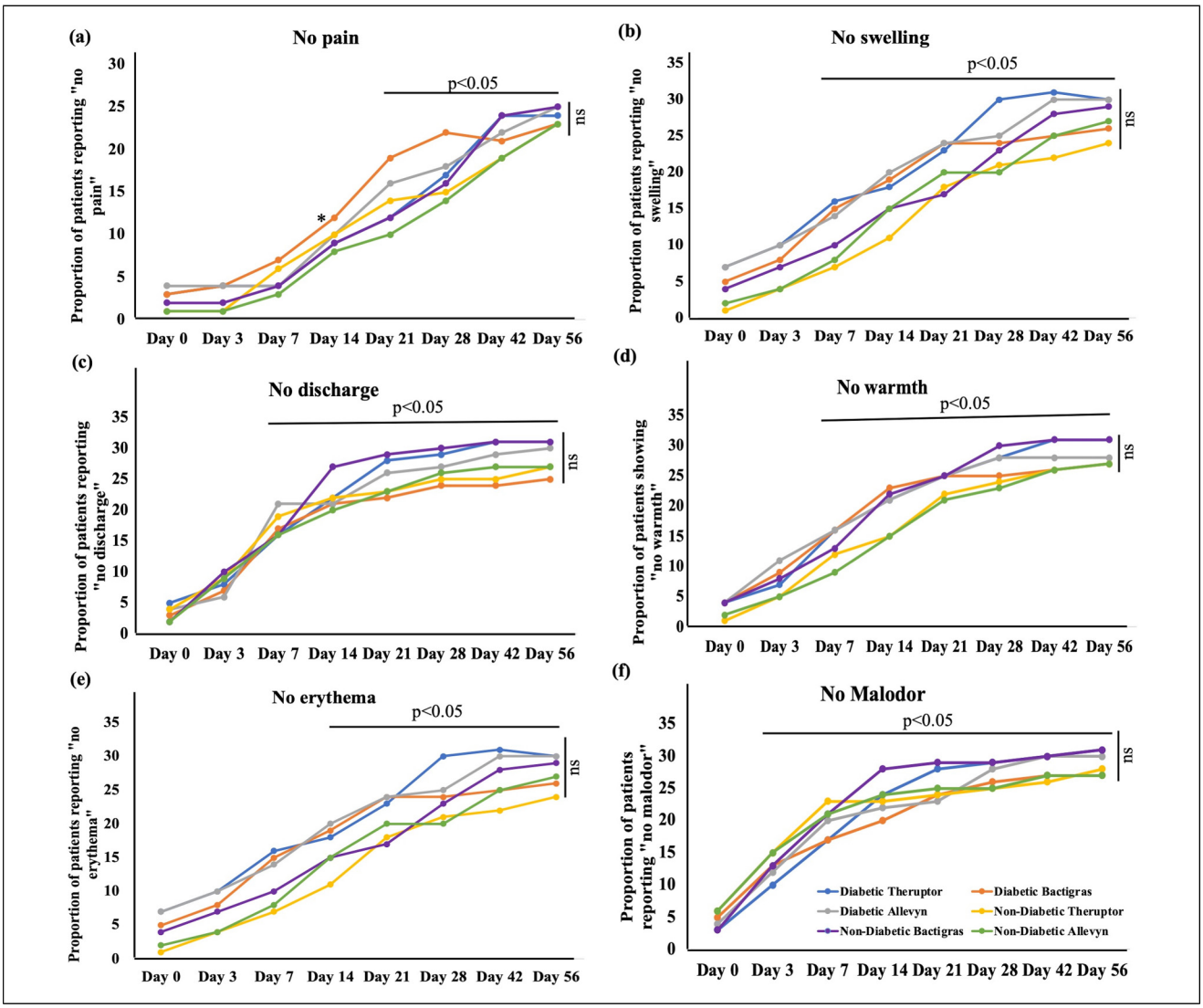

Figure 3. Improvement in Clinical Signs and Symptoms. the Graphs Depict the Proportion of Patients Reporting (a) no Pain (b) no Swelling (c) no Discharge (d) no Warmth (e) no Erythema and (f) no Malodor. P-Value was Calculated Using Fisher's Exact Test (two-Sided) for Comparisons. Ns: non-Significant; *$p < .05$ Versus Day 0.

diabetic Theruptor ($p = .007$) and Allevyn ($p = .01$) groups on Day 14 as compared to Day 0. From Day 21 and subsequent visits, significant improvement in the condition of tissue type in wound bed was observed in all other diabetic and non-diabetic groups ($p < .05$).

When the condition of the surrounding skin was assessed by healthy, inflamed skin, macerated, dry and flaky skin, we observed a significant difference in the number of patients with dry and flaky skin in diabetic Bactigras versus Theruptor group (n = 5 vs 0, $p = .01$) on Day 0. On Day 7 versus Day 0, a significant increase in the number of patients with healthy skin was observed in diabetic (n = 10 vs 2, $p = .02$) and non-diabetic (n = 9 vs 5, $p = .02$) Allevyn groups and a decrease in patients with macerated skin in diabetic Allevyn group (n = 4 vs 12, $p = .04$). When maceration was scored independently, a significant reduction in the mean maceration score was observed in the diabetic Bactigras group only on Day 3 versus Day 0 (0.64 ± 0.95 versus 0.86 ± 1.01, $p = .03$). From Day 21 and subsequent visits, a significant increase in number of patients with healthy skin and a reduction in mean maceration score in diabetics and non-diabetics treatment groups was observed ($p < .05$).

Overall, diabetic and non-diabetic Theruptor, Bactigras and Allevyn groups showed comparable results in terms of condition of the surrounding skin, types of tissue in wound bed, and RYB wound assessment at all time points during the follow up visits ($p > .05$).

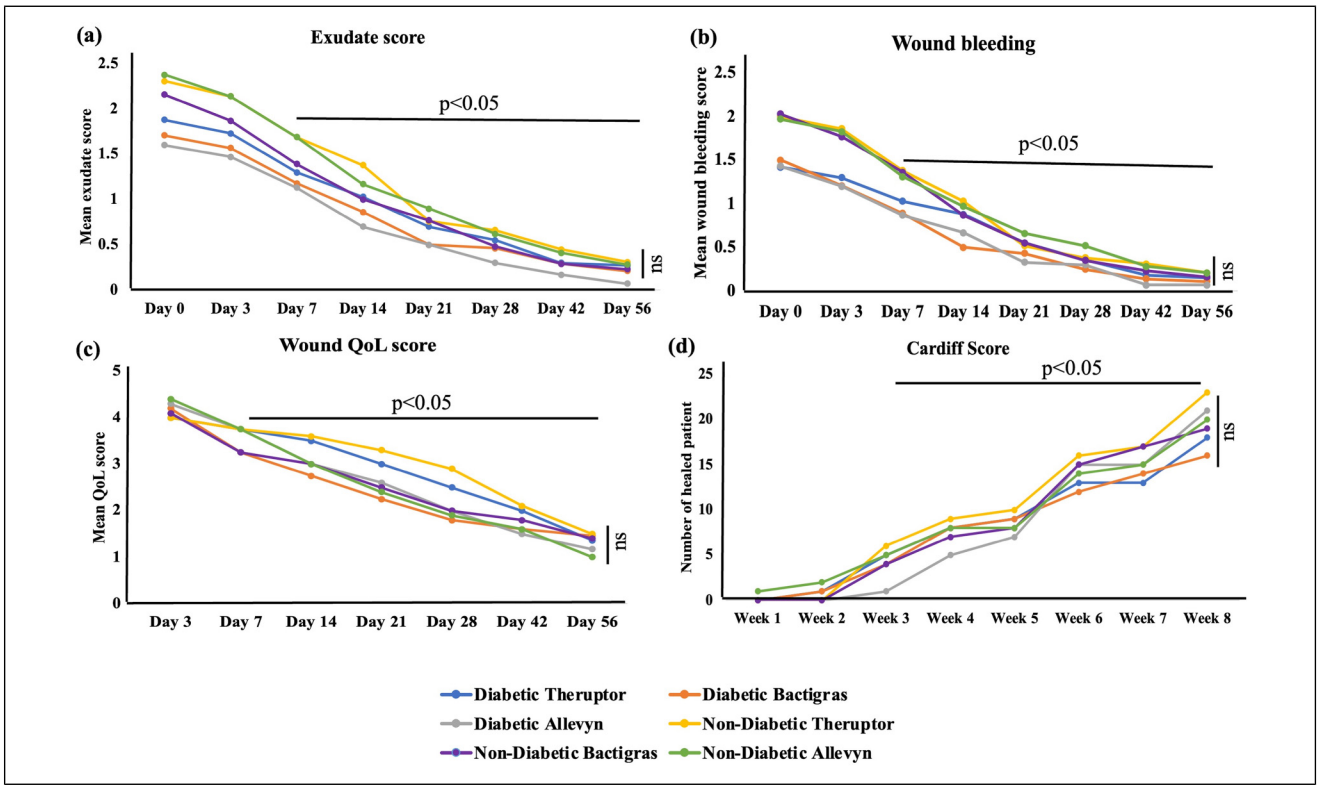

Figure 4. Secondary Endpoints. The Graphs Depict (a) Mean Exudate Management Score (b) Mean Wound Bleeding Score (c) Mean Wound QoL Score, and (d) Proportion of Patients with Completely Healed Wound (Cardiff score). The Data were Analyzed Using Wilcoxon Matched Pairs Signed Rank Test for Intra-treatment (Subsequent follow-up vs Day 0) Comparisons for Exudate Management, Wound Bleeding, and Wound QoL Score.

For Inter-treatment Comparisons Mann-Whitney Test (Theruptor vs Bactigras or Allevyn) for Exudate Management, and Two-sided Kruskal-Wallis Test for Wound Bleeding and Wound QoL Score, and for Both Intra and Inter-treatment Comparisons of Cardiff Score, Fisher's Exact Test (two-sided) was Used. $p < .05$ versus Day 0; ns: Non-significant.

Exudate Management and Wound Bleeding

On Day 3, the mean exudate management scores were significantly reduced in non-diabetic Bactigras (1.87 ± 0.92 vs 2.16 ± 0.93, $p = .004$) and Allevyn (2.14 ± 0.99 vs 2.38 ± 0.9, $p = .03$) groups and bleeding scores in diabetic (1.21 ± 0.83 vs 1.5 ± 1.04, $p = .04$) and non-diabetic (1.77 ± 0.96 vs 2.03 ± 1.05, $p = .008$) Bactigras, and non-diabetic Theruptor (1.86 ± 1.03 vs 2 ± 1.04, $p = .04$) groups as compared to Day 0. At subsequent visits (Days 7, 14, 21, 28, 42, and 56), exudate and wound bleeding scores were significantly decreased in both diabetic and non-diabetic patients across all treatment groups ($p < .001$), as shown in Figure 4(a and b). However, the mean exudate and wound bleeding scores were comparable among diabetic and non-diabetic treatment groups at any time period ($p > .05$).

Wound QoL Score

Wound QoL score comprises of 17 questions related to body, psyche, everyday life, and overall quality of life that are rated from 0 (not at all) to 4 (very much). A significant improvement in the mean QoL score was observed on Day 7 and subsequent visit as compared to Day 3 in all the diabetic and non-diabetic treatment groups. However, no significant difference was observed when all three treatment groups were compared ($p > .05$) (Figure 4(c)).

Cardiff Wound Impact Questionnaire/ Completely Healed Wounds

When the data was compared using the Cardiff wound impact questionnaire, two patients were healed on Day 7 in diabetic Theruptor and non-diabetic Allevyn groups (n = 1 patient each). On Day 21 or Week 3, both diabetic (n = 5 vs 0, $p = .05$) and non-diabetic (n = 5 vs 0, $p = .05$) Theruptor, diabetic Bactigras (n = 5 vs 0, $p = .05$), and non-diabetic Allevyn (n = 5 vs 0, $p = .05$) groups showed significant increase in patients with healed wounds as compared to Day 3. In total, 55 patients in diabetic (Theruptor: 18, Bactigras: 16, and Allevyn: 21) and 62 patients in non-diabetic (Theruptor: 23, Bactigras: 19, and Allevyn: 20)

groups had completely healed wounds (Figure 4(d)). However, no significant difference was observed when all three treatment groups were compared ($p > .05$).

Product Performance Analysis

The product performance analysis results are shown in Table 3. In the diabetic Theruptor group (n = 33), the number of patients reporting the dressing as comfortable to wear was significantly higher as compared to those in the Bactigras (n = 24, $p = .004$) and Allevyn groups (n = 25, $p = .02$) while non-significant in non-diabetic groups. The number of diabetic patients reporting "no pain" during dressing application was statistically similar between the Theruptor (n = 22), Allevyn (n = 15), and Bactigras (n = 16) group ($p > .05$) while significantly higher for dressing removal in Theruptor versus Bactigras (n = 30 vs 20, $p = .02$). In non-diabetic patients, the number of patients reporting "no pain" during application and removal was significantly higher in the Theruptor group (n = 26 and 28) than in the Bactigras (n = 18 and 20, $p = .04$) and Allevyn groups (n = 12, $p = .001$ and n = 16, $p = .005$).

However, the number of diabetic and non-diabetic patients reporting dressings were easy to apply, no discoloration in the surrounding skin of the wound, patient satisfaction with the exudate and leakage handling of the dressings, mean number of dressing changes, and mean wear time of dressing was statistically similar across the three groups ($p > .05$).

Macroscopic Fibres

No macroscopic fibers were visible on wound bed after removal of the dressing on any of the patients during their study visits.

Adverse Events

No adverse events were reported in any of the treatment groups throughout the study period.

Discussion

Chronic wounds are commonly associated with high morbidity and negative impact on patients' quality of life.[21] Modern advanced dressings with adapted properties are employed as part of the standard of care to provide protection and optimal healing environment.[15] The findings of the study provide important insights into the comparative safety and effectiveness of these dressings in terms of wound healing, microbial load reduction, and clinical symptom management.

The present study included a diverse patient population with no significant differences in baseline characteristics, including age, height, weight, and gender distribution between the treatment groups. In our study, we observed that the number of females recruited exceeded that of males in each group. Popescu et al (2023) mentioned that chronic wounds are more prevalent among women than men,[5] aligning with our data.

Further, our results demonstrated that all three Theruptor, Bactigras and Allevyn dressings were equally effective in reducing wound area in chronic wounds, suggesting their potential to promote healing. The median healing time ranged between 6 to 8 weeks. In a study, Rodrigues et al (2024) assessed the efficacy of Healthium Theruptor, 3 M Tegaderm and Plain Gauze dressings in wound healing in abdominal and joint surgeries and suggested seven weeks of median healing time,[12] similar to our findings. In another study, Liang et al (2024) showed a good therapeutic effect of silver-based dressings on chronic wound healing.[22] Both studies are in concordance with our findings that emphasized the role of modern dressings in chronic wound healing.

Bacterial load reduction was another key outcome, with all treatment groups showing a gradual decrease in bacterial presence and colony counts from Day 0 to Day 56. The DTAC antimicrobial technology of Theruptor, silver-impregnated Allevyn, and chlorhexidine-incorporated Bactigras dressing actively exhibited antimicrobial properties and effectively reduce bacterial infection. Szweda et al (2018) compared the antimicrobial activity of commercially available wound dressing materials such as silver, chlorhexidine acetate, povidone-iodine, and manuka honey against *Escherichia coli* and *Staphylococcus epidermidis* and found it effective in eliminating them.[23] In another study, Palvik et al (2019) assessed the antimicrobial and antiprotease ability of chlorhexidine, silver, and octenidine against *Staphylococcus aureus, Pseudomonas aeruginosa, Serratia liquefaciens*, and *Serratia marcescens* and found them effective as antimicrobial dressings.[24] In accordance with these studies, we observed a reduction in these targeted microorganisms in our study.

Further, wound assessment using the RYB classification system, tissue type on wound bed site, and condition of the surrounding skin showed a progressive shift towards healthy tissue types with all the three dressings i.e, Theruptor, Bactigras, and Allevyn groups. These dressings demonstrated significant tissue regeneration from yellow and black necrotic tissue to healthy red tissue from Day 14 onwards, inferring the importance of selecting appropriate dressings that promote granulation tissue formation and prevent further tissue necrosis. In a study, Wang et al (2022) studied the repairing effects of silver-containing dressings on chronic refractory wounds and concluded that silver-containing dressings effectively promote wound healing

Table 3. Product Performance Analysis.

Characteristics N (%)/ Mean ± SD	Diabetic Theruptor	Diabetic Bactigras	Diabetic Allevyn	Non-Diabetic Theruptor	Non-Diabetic Bactigras	Non-Diabetic Allevyn
N	33	28	30	29	31	29
Dressing easy to apply	33 (100)	27 (96.4)	28 (93.3)	29 (100)	31 (100)	28 (96.5)
Dressing comfortable to wear	33 (100)	**24 (85.7)***	**25 (83.3)***	28 (96.5)	28 (90.3)	27 (93.1)
No discoloration in surrounding skin	27 (81.8)	22 (78.5)	24 (80)	24 (82.7)	28 (90.3)	27 (93.1)
Pain on dressing application	11 (33.3)	12 (42.8)	15 (50)	3 (10.3)	**13 (41.9)***	**17 (58.6)***
Pain on dressing removal	3 (9)	**8 (28.5)***	6 (20)	1 (3.4)	**11 (35.4)***	**13 (44.8)***
Satisfaction with exudate and leakage handling of dressing	33 (100)	26 (92.8)	30 (100)	29 (100)	31 (100)	29 (100)
Number of dressing changes required	7.82 ± 3.89	7.71 ± 4.47	9.07 ± 4.53	7.00 ± 3.49	7.07 ± 2.66	7.93 ± 4.42
Mean wear time of the dressing (days)	0.91 ± 0.29	1 ± 0	1 ± 0	1 ± 0	1 ± 0	0.97 ± 0.19

*$p < .05$ versus respective diabetic or non-diabetic Theruptor group. (Fisher's exact test). The bold values denote statistical significant differences between the groups.

process by generating epithelial tissue and granulation tissue, and inhibiting bacterial growth on the wound,[25] which favours our data.

Significant reductions in exudate scores and wound bleeding were observed across all treatment groups. All three dressings, Theruptor, Bactigras, and Allevyn have proven efficacy in effective exudate management for wound healing. Shrestha et al (2024) examined the effect of commercial silver-based dressing in the treatment of chronic and burn wounds and suggested these dressings were effective in heavy exudate management.[26] This study supports our findings.

In the case of product performance, Theruptor was found better than Bactigras and Allevyn in terms of comfort to wear, and patients reporting no pain while applying and removing the dressings. In accordance with our findings, Shankar et al (2024) found better performance of Theruptor as compared to standard of care in terms of ease of application, ease of removal, comfort to wear and exudate management in oncological surgeries wound management.[27] Another study by Rodrigues et al (2024) also found the better performance of Theruptor and Tegaderm as compared to plain gauze dressing.[12]

Strengths and Limitations: The strength of the study lies in the distribution of patients across the participating centers (AIIMS Jodhpur, AIIMS Bhubaneshwar, MGMCRI, SRM, and PGIMER), providing a broad representation of the study cohort from different regions that enhances the generalizability of the results.

However, there are several limitations also. First, the observational design of the study which relies on subjective assessments for clinical symptoms and pain relief, may introduce potential bias. Additionally, no independent assessors separate from patient care team were involved in the assessment of study outcomes, which may raise the risk of measurement bias. Next, the follow-up period of 56 Days or 8 weeks may be relatively short for chronic wound studies and could not provide insights into long-term outcomes such as healing benefits, recurrence rates, or complications associated with wound healing. Further, the inclusion of both diabetic and non-diabetic patients could act as confounding factors, influencing healing trajectories and infection risks. Microbiological evaluation was performed using swab sampling, a non-invasive method chosen for patient comfort and practicality during repeated follow-ups. However, this approach may not accurately capture the microbial load, detect pathogens in deep tissues, or provide quantitative colony counts. While tissue biopsy remains the gold standard for such assessments, its invasive nature made it unsuitable for routine follow-up in this study. Therefore, the bacterial load data from swab samples was carefully interpreted, acknowledging the possibility of underestimation or incomplete detection of deeper infections.

Moreover, the study involved multiple follow-up assessments over time, we did not apply repeated measures statistical techniques such as generalized estimating equations (GEE) or mixed-effects models. Instead, non-parametric tests were used for comparisons at individual time points due to the non-normal distribution and ordinal nature of several outcome variables. This approach does not fully account for intra-subject correlations or time-dependent effects. Lastly, this study did not include multivariate analyses (eg, logistic regression or multiple linear regression) to control for potential confounding factors such as age, sex, comorbidities, or baseline wound size. Such analysis would have shifted our focus from comparative clinical performance of the dressings to determining predictive factors in wound healing process. The absence of such analysis may limit the overall statistical robustness.

Conclusion

Conclusively, Theruptor, Bactigras, and Allevyn wound dressings are safe and effective treatment options for chronic wound management in both diabetic and non-diabetic patients. Theruptor demonstrated better product performance in terms of the application and removal of the dressing compared to Bactigras, and Allevyn. Overall, all three dressings show comparable safety and efficacy in promoting wound healing and are suitable alternatives depending on patient-specific needs.

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Author Contributions

Mayank Badkur, Vinoth Sundaresan, Tharun Ganapathy, Tushar Mishra, Keshavamurthy Vinay, and Shoban Babu Varthya carried out data acquisition, analysis, and approved the final manuscript. Michael Rodrigues, Ashok Kumar Moharana, Deepak TS, Sakthibalan Murugesan, and Mahalakshmi Durai designed research, carried out analysis and interpretation of data, and revised the manuscript.

Data Availability Statement

The data supporting the findings of this study are available within the article, further inquiries can be directed to the corresponding author.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The authors Michael Rodrigues, Ashok Kumar Moharana, and Deepak TS are employees of Healthium Medtech, manufacturers of Theruptor dressing. Other author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical Approval and Informed Consent Statements

The study protocol and informed consent documents were reviewed and approved by the respective Institutional Review Boards of the centres ie, All India Institute of Medical Sciences (AIIMS, Jodhpur - Rajasthan), All India Institute of Medical Sciences (AIIMS, Bhubaneswar - Odisha), Mahatma Gandhi Medical College and Research Institute (MGMCRI, Puducherry), SRM Medical College Hospital and Research Centre (SRM, Tamil Nadu), and Postgraduate Institute of Medical Education and Research (PGIMER, Chandigarh). Written consent was obtained from all patients before initiating any study-related procedures. The study was pre-registered in Clinical Trials Registry-India (CTRI/2022/03/041044).

ORCID iD

Deepak TS https://orcid.org/0000-0002-2858-8198

Supplemental material

Supplemental material for this article is available online.

References

1. Cai M, Liu Z, Sun X, et al. Advances in the development of medical dressings for the treatment of diabetic foot wounds. *Chem Eng J*. 2024;498(3):155575.
2. Challenges in the treatment of chronic wounds - PMC [Internet]. [cited 2025 Jan 17]. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC4528992/
3. Robles-Tenorio A, Lev-Tov H, Ocampo-Candiani J. Venous leg ulcer. In: *StatPearls [Internet]*. StatPearls Publishing; 2025 [cited 2025 Jan 17]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK567802/
4. Martinengo L, Olsson M, Bajpai R, et al. Prevalence of chronic wounds in the general population: Systematic review and meta-analysis of observational studies. *Ann Epidemiol*. 2019;29:8-15.
5. Popescu V, Cauni V, Petrutescu MS, et al. Chronic wound management: From gauze to homologous cellular matrix. *Biomedicines*. 2023;11(9):2457.
6. Zhu X, Olsson MM, Bajpai R, Järbrink K, Tang WE, Car J. Health-related quality of life and chronic wound characteristics among patients with chronic wounds treated in primary care: A cross-sectional study in Singapore. *Int Wound J*. 2021;19(5):1121-1132.
7. McDermott K, Fang M, Boulton AJM, Selvin E, Hicks CW. Etiology, epidemiology, and disparities in the burden of diabetic foot ulcers. *Diabetes Care*. 2023;46(1):209-221.

8. Alhajj M, Goyal A. Physiology, granulation tissue. In: *StatPearls [Internet]*. StatPearls Publishing; 2025 [cited 2025 Jan 17]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK554402/
9. Nuutila K, Eriksson E. Moist wound healing with commonly available dressings. *Adv Wound Care (New Rochelle)*. 2021;10(12):685-698.
10. Britto EJ, Nezwek TA, Popowicz P, Robins M. Wound dressings. In: *StatPearls [Internet]*. StatPearls Publishing; 2025 [cited 2025 Jan 17]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK470199/
11. Gupta R, Murthy KS, Bhagavan KR, Moharana AK, Rodrigues M, Ts D. Antimicrobial properties of theruptor 3D-hydrocellular wound dressing: An *in vitro* study. *Int J Surg Open*. 2022;46(2):100528.
12. Rodrigues M, Varthya S, Sunderasan V, et al. Efficacy, safety, and cost-effectiveness of healthium theruptor versus 3 M tegaderm versus plain gauze dressing for wound dressings used in abdominal and joint surgeries: A prospective, multicentric, randomized study. *Cureus*. 2024;16(2):e53947.
13. Muangman P, Nitimonton S, Aramwit P. Comparative clinical study of bactigras and telfa AMD for skin graft donor-site dressing. *Int J Mol Sci*. 2011;12(8):5031-5038.
14. Amione P, Ricci E, Topo F, et al. Comparison of allevyn adhesive and biatain adhesive in the management of pressure ulcers. *J Wound Care*. 2005;14(8):365-370.
15. Shi S, Wang L, Song C, Yao L, Xiao J. Recent progresses of collagen dressings for chronic skin wound healing. *Collagen Leather*. 2023;5(1):31.
16. GUIDELINE FOR GOOD CLINICAL PRACTICE.
17. ISO [Internet]. [cited 2025 Jan 14]. ISO 14155:2011. Available from: https://www.iso.org/standard/45557.html
18. Wound-QoL [Internet]. [cited 2025 Jan 14]. Wound-QoL. Available from: https://www.wound-qol.com/
19. CardiffTool.pdf [Internet]. [cited 2025 Jan 14]. Available from: https://swrwoundcareprogram.ca/Uploads/ContentDocuments/CardiffTool.pdf
20. Bagul A, Narwade N, Bhupatkar A, Murali S, Shah Y. Is vacuum assisted closure dressing better than conventional management of diabetic wounds? *Int Surg J*. 2018;5(6):2199.
21. Li X, Xue X, Xie P. Smart dressings and their applications in chronic wound management. *Cell Biochem Biophys*. 2024;82(3):1965-1977.
22. Liang K, Liu Y, Jiang F. Analysis of therapeutic effect of silver-based dressings on chronic wound healing. *Int Wound J*. 2024;21(8):e70006.
23. Szweda P, Gorczyca G, Tylingo R. Comparison of antimicrobial activity of selected, commercially available wound dressing materials. *J Wound Care*. 2018;27(5):320-326.
24. Pavlík V, Sojka M, Mazúrová M, Velebný V. Dual role of iodine, silver, chlorhexidine and octenidine as antimicrobial and antiprotease agents. *PLoS One*. 2019;14(1):e0211055.
25. Wang R, Guo Y, Li B, Zheng J, Tang Z, Shu M. Application effect of silver-containing dressings in the repair of chronic refractory wounds. *Evid Based Complement Alternat Med*. 2022;2022:3616923.
26. Shrestha S, Wang B, Dutta PK. Commercial silver-based dressings: In vitro and clinical studies in treatment of chronic and burn wounds. *Antibiotics*. 2024;13(9):910.
27. Prabha Shankar A, Br KK, Shankar B, et al. Oncological surgical wound care: A comparison of theruptor NXT non-adherent dressing and the current standard of care. *Cureus*. 2024;16(3):e56593.