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A comparative study between the efficacy of simple collagen dressing and antimicrobial-based collagen dressing in the treatment of diabetic and non-diabetic ulcers

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ABSTRACT

Background: Chronic ulcers, especially diabetic foot ulcers, pose significant clinical challenges due to prolonged healing time, high infection rates, and increased health-care costs. **Aims and Objectives**: This study evaluates and compares the efficacy of simple collagen sheet dressing and antimicrobial-based collagen ointment dressing in treating diabetic and nondiabetic ulcers. **Materials and Methods**: The study employs a prospective, comparative research design. A total of 100 patients with chronic ulcers were included in this study. They were randomly (simple randomization by random number generator software, Statistical Package for the Social Sciences version 22) assigned to two groups: one group received antimicrobial-based collagen ointment dressings (n = 50), and the other received simple collagen sheet dressings (n = 50). The primary outcomes measured included wound size reduction, granulation tissue formation, infection rates (pus discharge), and epithelialization. Follow-up assessments were made at 7, 14, 21, 28, 35, and 42 days. **Results:** The simple collagen sheet group showed faster wound healing, greater granulation tissue formation, reduced infection, and significantly lower Bates–Jensen wound assessment tool scores over time ($P < 0.0001$). Differences were notable in both diabetic and non-diabetic cohorts. **Conclusion:** Simple collagen sheet dressings provide superior outcomes versus antimicrobial-based collagen ointment dressings, especially in non-diabetic ulcers. Wider adoption in clinical practice is recommended.

Key words: Collagen dressing; Chronic ulcers; Diabetic ulcers; Wound healing; Infection control; Bates–Jensen; Antimicrobial collagen ointment; Collagen sheet dressing

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INTRODUCTION

Chronic ulcers, particularly in diabetic and non-diabetic patients, pose significant challenges in wound management due to delayed healing, high infection rates, and extended hospital stays. Effective wound care is essential to promote healing, prevent complications, and reduce health-care costs.[1] Among the various advanced wound care options, collagen-based dressings have gained attention for their biological compatibility and ability to support tissue regeneration.[2-4]

Collagen dressings facilitate cellular migration, enhance fibroblast proliferation, and modulate local inflammation, factors critical for efficient wound healing.[5-7] They are derived from natural sources such as bovine, porcine, or equine collagen and act as scaffolds to promote granulation tissue formation.[8] Antimicrobial-based collagen dressings, which incorporate agents such as silver, gentamicin, mupirocin, or polyhexamethylene biguanide (PHMB), offer additional protection by preventing or controlling wound infections.[9]

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Despite their theoretical and clinical promise, there is limited standardized guidance regarding the comparative effectiveness, cost-efficiency, and long-term outcomes of collagen-based dressings versus conventional or other advanced dressings. Furthermore, evidence regarding the relative benefits of simple collagen dressings versus antimicrobial-impregnated collagen dressings remains unclear.

This study aims to evaluate and compare the efficacy of simple collagen sheet dressing and antimicrobial-based collagen ointment dressing in managing chronic ulcers. Using objective parameters such as the Bates–Jensen wound assessment tool (BWAT), this research intends to provide evidence-based recommendations to guide clinical practice, improve wound healing protocols, and enhance patient quality of life.

Aims and objectives

Aims

This study aims to compare the efficacy of simple collagen sheet dressing versus antimicrobial-based collagen ointment dressing in the management of diabetic and non-diabetic ulcers. The comparison focuses on wound healing outcomes, infection control, and overall clinical improvement. Key parameters such as granulation tissue formation, epithelialization, and wound contraction were evaluated. The BWAT was used as the standard measure, where lower scores indicate better healing.

Objectives

1. To compare wound healing outcomes between simple collagen sheet dressing and antimicrobial-based collagen ointment dressing in diabetic and non-diabetic ulcers
2. To assess the rate of granulation tissue formation and epithelialization in both treatment groups
3. To evaluate infection control efficacy by monitoring signs of bacterial colonization and pus discharge
4. To analyze wound size reduction and healing progress over time using the BWAT.

MATERIALS AND METHODS

Research design

This prospective, comparative study was conducted at Maharani Laxmi Bai Medical College, Jhansi, from November 2023 to March 2025. A total of 100 patients with diabetic and non-diabetic ulcers were equally divided into two groups:

- Group A: Simple collagen sheet dressing.
- Group B: Antimicrobial-based collagen ointment dressing.

Patients were monitored at regular intervals to evaluate wound healing, infection control, and clinical outcomes using the BWAT.

Sample selection

Inclusion criteria

- Patients with non-healing ulcers (e.g., diabetic, traumatic, venous ulcers, and pressure sores) of at least 6 weeks' duration
- Stage II and III ulcers as per the National Pressure Ulcer Advisory Panel (NPUAP) classification
- Stage II: Partial-thickness skin loss involving epidermis/dermis
- Stage III: Full-thickness skin loss extending to subcutaneous tissue, not beyond fascia.

Exclusion criteria

- Stage I and IV ulcers per NPUAP
- Malignant ulcers, or ulcers with poor vascularity
- Patients with connective tissue or immune system disorders
- Patients on immunosuppressants, steroids, chemotherapy, or radiotherapy
- Known allergy to dressing materials.

Sampling, including sample size calculation

$n=2^* ((Z\alpha/^2+Z\beta)/(E/S))^2$

Where:
n=Sample size per group
$Z\alpha/^2$=Z-score for desired confidence level (1.96 for 95%)
$Z\beta$=Z-score for desired power (0.84 for 80% power)
E=Expected difference (effect size) between groups
S=Standard deviation.

Example calculation

Assumptions:

- Effect size (E)=20% (0.20)
- Standard deviation (S)=30% (0.30)
- Confidence level=95%→$Z\alpha/^2$=1.96
- Power=80%→$Z\beta$=0.84

Step-by-step calculation:
$n=2^* ((1.96+0.84)/(0.20/0.30))^2$
$n=2^* (2.8/0.6667)^2$
$n=2^* (4.2)^2$
$n=2^* 17.64$
$n\approx35.28$

So, each group requires approximately 36 participants. Total=36x2=72.

To account for a 10% dropout: 72+10%=~80 total participants.

Methodology

The present study employed a prospective comparative observational design conducted at Maharani Laxmi Bai Medical College, Jhansi, between November 2023 and March 2025, involving 100 patients with chronic non-healing ulcers of at least 6 weeks' duration. Participants were randomly divided into two equal groups: one received antimicrobial-based collagen ointment dressings, and the other received simple collagen sheet dressings. The study included patients with diabetic, venous, traumatic, or pressure ulcers graded as stage II or III per the NPUAP classification.

Exclusion criteria encompassed stage I and IV ulcers, malignant wounds, ischemic ulcers, and patients with immunosuppressive conditions or known allergies to the dressing materials. Wound healing progress was systematically assessed using the BWAT at fixed intervals – on days 7, 14, 21, 28, 35, and 42 – tracking parameters such as granulation tissue formation, epithelialization, infection control, and wound contraction. Data were collected using a predesigned performa, analyzed using the Statistical Package for the Social Sciences version 22, and statistical significance was determined with $P<0.05$ using Student's t-test and Chi-square test, ensuring validity and reliability through standardized dressing protocols, trained observers, and consistent wound evaluation measures.

Ethical considerations

The study was approved by the Institutional Ethical and Research Committee (Certificate No.7349/IEC/I/2024–2025). Written Informed consent was obtained from each of the patients fulfilling the inclusion criteria before their enrolment in the study.

RESULTS

In our study, we showed that the majority of participants were in the 31–40 years age group (22%), followed by the 51–60 years (20%) and >60 years (24%) age groups (Table 1). There was a gradual decline in the number of patients as the age decreased, with only 6% of patients in the 10–20 years age group. This indicated that chronic ulcers, particularly those requiring collagen-based dressing treatment, were more prevalent in middle-aged and older individuals, likely due to the higher incidence of underlying conditions such as diabetes and venous insufficiency that contribute to wound development.

In our study, the sex distribution of patients indicated that the majority of the participants were male (82%), whereas only 18% were female (Table 2). This suggests that chronic ulcers, which often require advanced wound care such as collagen-based dressings, may be more common in males, potentially due to factors such as higher incidence of diabetes, trauma, and other comorbidities that lead to chronic ulceration. The disproportionate number of male patients could reflect demographic trends or social factors influencing health-care access and management in the studied population.

In our study, the ulcer type distribution among patients showed that diabetic ulcers were the most common, affecting 50% of the patients (Table 3). This was followed by traumatic ulcers (27%), venous ulcers (13%), and bed sores (10%). The high prevalence of diabetic ulcers aligns with the well-known complications of diabetes, such as poor circulation and neuropathy, which significantly contribute to chronic wound formation. The considerable presence of traumatic ulcers also emphasizes the importance of addressing injuries, which, when compounded by other conditions, may lead to long-term ulceration, particularly in individuals with inadequate wound care access or adherence.

In our study, loss of protective sensation was present in 41% of patients, whereas 59% did not (Table 4). Peripheral neuropathy, commonly seen in diabetic patients, significantly contributes to the development of ulcers, especially in the lower extremities, due to reduced sensation and delayed detection of wounds. The relatively high percentage of patients without neuropathy indicates

Table 1: Age-wise distribution of patients

Age (in years)	Number of patients	Percentage
10–20 years	06	6.00
21–30 years	09	9.00
31–40 years	22	22.00
41–50 years	19	19.00
51–60 years	20	20.00
>60 years	24	24.00
Total	100	100

Table 2: Sex distribution of patients

Sex	Number of patients	Percentage
Male	82	82.00
Female	18	18.00
Total	100	100.00

Table 3: Ulcer type distribution

Ulcer type	Number of patients	Percentage
Bed sore	10	10.00
Diabetic	50	50.00
Traumatic	27	27.00
Venous	13	13.00
Total	100	100.00

that ulcers in these individuals may result from other factors such as trauma, venous insufficiency, or circulatory issues, highlighting the need for a comprehensive approach to wound care and management across different ulcer types.

In our study, the distribution of ulcer dressing types among the patients showed that 50% of the patients received antimicrobial-based collagen ointment dressings, whereas the remaining 50% were treated with simple collagen sheet dressings (Table 5).

On day 1, diabetic patients had higher wound scores compared to non-diabetic patients. Over time, significant reductions in wound scores were observed in all groups, but the rate of improvement was more pronounced in the simple collagen sheet dressing group, particularly in non-diabetic patients, where the score declined sharply (Table 6). The P-values indicate statistically significant differences between dressing types, especially from day 7 onward, with the simple collagen dressing group consistently achieving lower wound scores, implying better wound healing efficacy over the study period. The results suggest that while both dressing types aid healing, simple collagen dressing appears to be more effective, particularly in non-diabetic patients, in reducing wound burden (Graph 1).

On day 1, we can see a large ulcer with exposed subcutaneous tissues and irregular margins, minimal-to-moderate granulation tissue present, moderate serosanguinous discharge visible around margins, and irregular undermined necrotic zones at the periphery (Figure 1). On day 42 after weekly dressing with a simple collagen sheet, we can see significant size reduction with clear demarcation and shrinkage of the wound area, healthy granulation tissue covering most of the wound bed, with minimal or no wound discharge, epithelialization at margins visible, and well-progressed healing phase with signs of wound closure (Figure 2).

Table 4: Peripheral neuropathy distribution

Ulcer type	Number of patients	Percentage
Present	41	41.00
Absent	59	59.00
Total	100	100.00

Table 5: Distribution of dressing type among diabetic and non-diabetic patients

Dressing type	Group A (diabetic patients) (n=50)		Group B (non-diabetic patients) (n=50)	
	n	Percentage	n	Percentage
Antimicrobial-based collagen ointment dressing	25	50.00	25	50.00
Simple collagen sheet dressing	25	50.00	25	50.00
Total	50	100	50	100

DISCUSSION

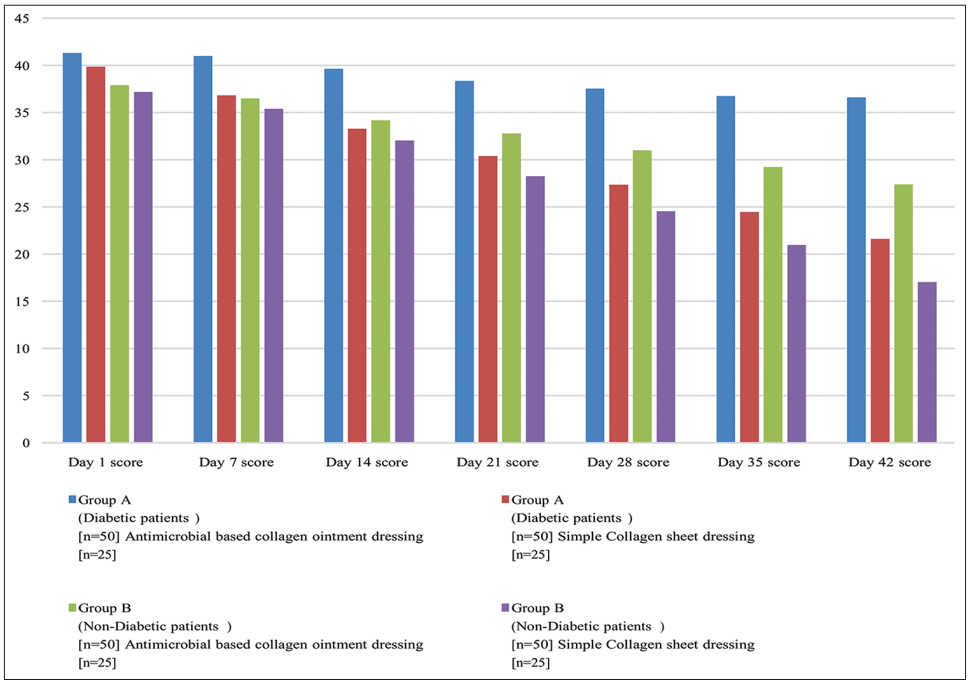
Chronic ulcers, especially in diabetic and non-diabetic patients, are a major challenge due to delayed healing and high infection risk. Collagen-based dressings have gained prominence for their regenerative properties, offering a biologically compatible scaffold that supports cellular migration and tissue repair. This study compared two commonly used collagen dressings: A simple collagen sheet and an antimicrobial-based collagen ointment.[5,10]

Simple collagen dressings, derived from bovine or porcine sources, create a moist wound environment, promote granulation tissue, and accelerate epithelialization. However, they lack antimicrobial properties, limiting their effectiveness in infected wounds. In contrast, antimicrobial-based collagen dressings incorporate agents such as silver, mupirocin, or PHMB to control infection while

Table 6: Bates–Jensen wound assessment tool scores (Mean±SD) over time

Bates–Jensen wound assessment tool (Mean±SD)	Group A (diabetic patients) (n=50)		P-value (t-test)	Group B (non-diabetic patients) (n=50)		P-value (t-test)
	Antimicrobial-based collagen ointment dressing (n=25)	Simple collagen sheet dressing (n=25)		Antimicrobial-based collagen ointment dressing (n=25)	Simple collagen sheet dressing (n=25)	
Day 1 score	41.32±3.637	39.88±3.528	0.16	37.88±4.419	37.20±3.617	0.55
Day 7 score	41.00±3.055	36.80±3.958	0.0001	36.52±3.331	35.40±3.629	0.26
Day 14 score	39.64±2.885	33.28±3.889	0.0001	34.20±3.149	32.04±3.588	0.02
Day 21 score	38.36±2.998	30.40±3.291	0.0001	32.80±2.661	28.24±3.126	0.0001
Day 28 score	37.56±2.399	27.36±2.447	0.0001	31.00±2.398	24.52±3.280	0.0001
Day 35 score	36.76±2.728	24.48±1.828	0.0001	29.24±2.454	20.96±2.685	0.0001
Day 42 score	36.60±2.693	21.60±1.258	0.0001	27.40±1.190	17.04±1.485	0.0001

SD: Standard deviation



Graph 1: Bates–Jensen wound assessment tool scores (Mean±Standard deviation) over time

Figure 1: Image shows a day 1 diabetic foot ulcer before collagen sheet dressing

Figure 2: Image shows day 42 after application of collagen sheet dressings

aiding healing, making them suitable for contaminated wounds.[5,10,11]

The study, conducted at Maharani Laxmi Bai Medical College, Jhansi, included 100 patients with Grade II and III ulcers, randomized into two groups. Healing was assessed using the BWAT over a 42-day period.

Both groups showed improvement, but simple collagen sheets demonstrated superior healing outcomes, especially in non-diabetic ulcers. By Day 42, mean BWAT scores in non-diabetic patients were significantly lower in the collagen sheet group (17.04±1.485) than in the antimicrobial group (27.40±1.190). Similarly, diabetic patients also fared better with collagen sheets.

Despite antimicrobial dressings being effective in infected wounds, the study found that simple collagen sheets provided faster and more consistent wound healing, highlighting their value in managing clean chronic ulcers.

Across multiple studies, collagen-based dressings consistently outperform standard, saline, or antimicrobial treatments in terms of healing speed, granulation tissue formation, and wound size reduction. Our study's results are in strong agreement with existing literature, especially in non-diabetic wound healing (Table 7).

Table 7: Comparative analysis of wound healing outcomes (Bates–Jensen/healing metrics)

Study	Type of dressing compared	Sample size	Follow-up duration	Healing outcome	Comparison to our study
Our Study (2025)	Simple collagen sheet versus Antimicrobial collagen ointment	100 (50 per group)	6 weeks (42 days)	Mean wound score at day 42: Diabetic group: 21.60 (simple) versus 36.60 (antimicrobial) Non-diabetic group: 17.04 versus 27.40 (P<0.0001)	Simple collagen sheet showed significantly faster healing, especially in non-diabetics
Shu et al., 2022[12]	Collagen dressing versus standard care	961 (metaanalysis)	Varies across RCTs	Risk ratio for healing: 1.53 Healing velocity is significantly higher in the collagen group Lower recurrence	Confirms collagen's superior healing effect and aligns with faster reduction in wound scores
Ramesh and Rajendran 2023[13]	Collagen dressing versus normal saline	100 (50 per group)	5 weeks	73.43% ulcer reduction (collagen) versus 54.5% (saline) 90% showed granulation tissue by week 1 in the collagen group	Supports our early improvement (Day 7 onward) in the collagen group, particularly granulation formation
Gondil et al., 2022[14]	Collagen dressing (monotherapy)	100 diabetic patients	2 weeks	Wound size reduced from 41.3 mm^2 to 18.9 mm^2 Statistically significant (P=0.001)	Mirrors our Day 14 trend, where collagen sheet patients showed a steep drop in wound scores
Park et al., 2019[15]	Collagen+foam versus foam alone	30 patients	6 weeks	82.4% complete healing in the collagen group versus 38.5% in the control Time to 50% wound reduction: 21 days versus 42 days	Correlates with a sharp score decline in our study after Day 21 in the collagen group
Haesler 2018[16]	ORC/Collagen versus gauze/foam	Multiple studies (systematic review)	Varies	Healing time: 4.63±1.18 weeks (collagen) versus 7.79±1.61 weeks (control), P=0.001	Confirms our healing timeline: Significant difference between groups observed by Week 5–6

RCTs: Randomized controlled trials

Limitations of the study

This single-center, prospective comparative study has limited generalizability due to its relatively small sample size and short follow-up period. The absence of blinding and microbiological profiling may introduce observer bias and restrict insights into infection control mechanisms. Additionally, the study did not include a cost-effectiveness analysis or long-term outcomes, which are crucial for guiding clinical decisions in diverse healthcare settings.

CONCLUSION

This study shows that simple collagen sheet dressings are more effective than antimicrobial-based collagen ointment dressings in promoting wound healing, reducing infection, and improving outcomes in chronic ulcers. Their simplicity, biocompatibility, and better wound modulation make them ideal, especially for diabetic foot ulcers. Although antimicrobial ointments aid infection control, they lag in wound contraction and epithelialization. Hence, collagen sheets are recommended for managing Grade II and III ulcers. Further large-scale studies are needed to assess their long-term efficacy and cost-effectiveness, particularly in resource-limited settings.

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VP- Concept, design, literature survey, data collection and analysis, and manuscript preparation; **RS**- Study design, guidance, and final review; **SK**- Wound protocol and technical guidance; **RV**- Statistical analysis, interpretation, and manuscript revision.

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