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Collagen Granule Dressing Versus Conventional Dressing in the Management of Early Diabetic Foot Ulcer

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Abstract

Background: Diabetic foot ulcers (DFUs) are a significant and debilitating complication of diabetes mellitus, often leading to lower extremity amputation. Conventional dressings, while widely used, may not adequately address the biological complexities of chronic wounds. This study evaluates the efficacy of collagen granule dressings compared to conventional saline dressings in accelerating the healing of early-stage DFUs.

Methods: This was a prospective, analytical, hospital-based study conducted from March 2023 to February 2024 at the Department of General Surgery, Silchar Medical College and Hospital. A total of 100 patients

with early diabetic foot ulcers (Wagner-Meggitt grades 1, 2, and 3) were randomly assigned to two groups. Group A (n=50) received conventional normal saline dressings, while Group B (n=50) was treated with collagen granule dressings (BIO Collaz). The primary endpoints were the time to complete wound healing, rate of ulcer size reduction, and duration of hospital stay. Secondary endpoints included healthy granulation tissue formation and microbial load.

Results: The collagen granule group (Group B) demonstrated a statistically significant reduction in both ulcer size and healing time compared to the conventional dressing group (Group A). Granulation tissue formation was markedly higher in Group B, with 75.60% at Day 14 compared to 59.00% in Group A (p=0.001). Furthermore, Group B showed significantly better microbial control, with 76% of patients having no growth on wound culture at Day 14 compared to 34% in Group A. Patients in the collagen group also experienced a shorter mean hospital stay (p=0.036) and required fewer total dressing changes (p=0.002).

Conclusion: Collagen granule dressings appear to be a superior treatment modality for the management of early diabetic foot ulcers. Their use significantly accelerates the healing process, promotes granulation tissue formation, and reduces microbial load. The clinical benefits, combined with a reduction in hospital stay and fewer dressing changes, make collagen granule dressings a cost-effective and highly effective option for DFU care.

Keywords: Diabetic foot ulcer, Collagen, Wound healing, Granulation tissue, Wound dressing.

Introduction

The global prevalence of diabetes mellitus is a growing public health crisis. The International Diabetes Federation estimates that the number of individuals with diabetes will rise from 382 million in 2013 to 592 million by 2035[1]. One of the most devastating and common complications of diabetes is the diabetic foot ulcer (DFU), a condition that affects up to 10% of diabetic patients annually and precedes over 85% of non-traumatic lower extremity amputations [2].

The pathophysiology of DFUs is complex, involving a combination of peripheral neuropathy, peripheral artery disease, and biomechanical deformities. Chronic hyperglycemia leads to a dysregulated wound healing response, characterized by a persistent inflammatory state. In a healthy wound, matrix metalloproteinases (MMPs) are crucial for breaking down damaged tissue[3,4]. However, in chronic wounds like DFUs, MMPs are overexpressed, leading to the degradation of healthy collagen and an arrest in the proliferative phase of healing.

Conventional wound care, primarily involving debridement and moist dressings (such as saline), is often insufficient to address this underlying biological dysfunction. There is a critical need for advanced wound care technologies that are both clinically effective and accessible, particularly in resource-limited settings.

Collagen is a fundamental protein in wound healing, providing the structural scaffold for new tissue growth. The application of a collagen-based dressing is theorized to act as a "sacrificial substrate" for excess MMPs [5], thereby protecting the body's natural collagen and promoting granulation tissue formation. This study aims to compare the efficacy of a collagen granule dressing with a conventional dressing in the management of early DFUs.

Materials and Methods

Study Design and Setting: This prospective, analytical, hospital-based study was conducted in the Department of General Surgery at Silchar Medical College and Hospital, Assam, India, over a one-year period from March 2023 to February 2024.

Participants: The study included 100 adult patients with chronic diabetic foot ulcers who were admitted to the surgical department. Patients were included if they had a Wagner-Meggitt classification of grade 1, 2, or 3. Exclusion criteria included patients with peripheral vascular disease, osteomyelitis, or ulcers with underlying gangrene.

Intervention: Patients were randomly allocated into two groups of 50 each.

- **Group A (Control):** Patients in this group were treated with conventional normal saline dressings.
- **Group B (Experimental):** Patients in this group received a collagen granule dressing (BIO Collaz) as the primary dressing.

Treatment Protocol: All patients underwent standardized wound care, which included daily wound debridement as necessary, meticulous foot hygiene, and strict control of blood sugar levels. Systemic antibiotics were administered based on wound culture sensitivity. Dressings were changed on alternate days for both groups.

Data Collection and Outcomes:

- **Primary Outcomes:**
  - **Ulcer Size:** The size of the ulcer was measured daily using a transparent sheet and a ruler, and the surface area was calculated to track the rate of reduction.
  - **Healing Time:** The number of days from the initial dressing application to development of healthy granulation tissue or the readiness for Split-Thickness Skin Grafting (SSG) was recorded.
- **Secondary Outcomes:**
  - **Granulation Tissue:** The growing granulation tissue in the wound bed was visually assessed and recorded on Day 0, Day 7, and Day 14.
  - **Microbial Growth:** Wound swabs for bacterial culture were taken on Day 3 and Day 14 to assess microbial load.
  - **Hospital Stay:** The total number of days the patient was hospitalized was recorded.
  - **Dressing Frequency:** The total number of dressings required for complete healing was noted.

Statistical Analysis: Data were analyzed using appropriate statistical software. Continuous variables were compared using the Student's t-test, and categorical variables were compared using the Chi-Square test. A p-value of <0.05 was considered statistically significant.

Results

Patient Demographics and Clinical Characteristics: The study cohort had a mean age of 54.4 years, with a male-to-female ratio of 1.77:1. The majority of patients (62%) had a history of diabetes for more than 10 years, and a significant proportion (42%) had poor glycemic control (HbA1c > 10%).

Ulcer Healing and Size Reduction: The mean ulcer size at baseline was comparable between Group A (10.65 cm^2) and Group B (10.38 cm^2). At the end of the study period, the collagen granule group demonstrated a significantly faster rate of wound size reduction and a shorter overall healing time compared to the normal saline group ($p < 0.05$).

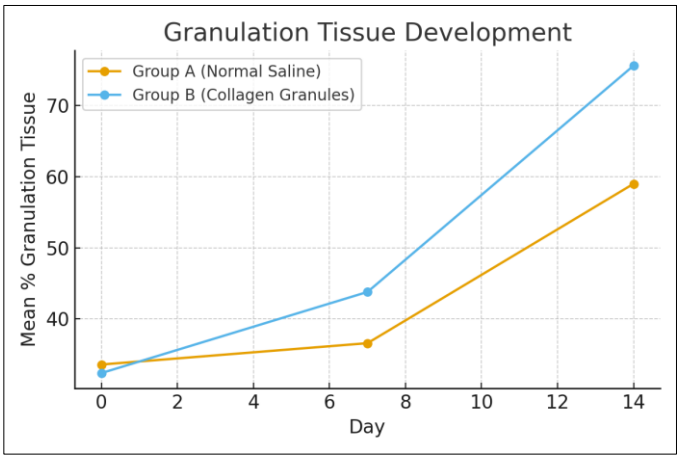
Figure 1: Before and after images of wound healing

Granulation Tissue Formation: The rate of granulation tissue formation was significantly higher in the collagen group, as detailed in Table 1 and visualized in Figure 2.

Table 1: Comparison of Mean Percentage of Granulation Tissue

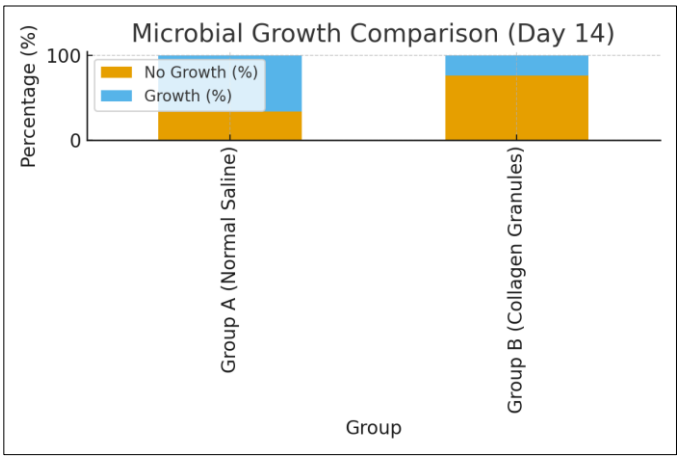
Assessment Time point	Group A (Normal Saline) Mean (%)	Group B (Collagen Granules) Mean (%)	p-value
Day 0	33.60	32.40	>0.05
Day 7	36.60	43.80	0.006
Day 14	59.00	75.60	0.001

Figure 2: Granulation Tissue Development



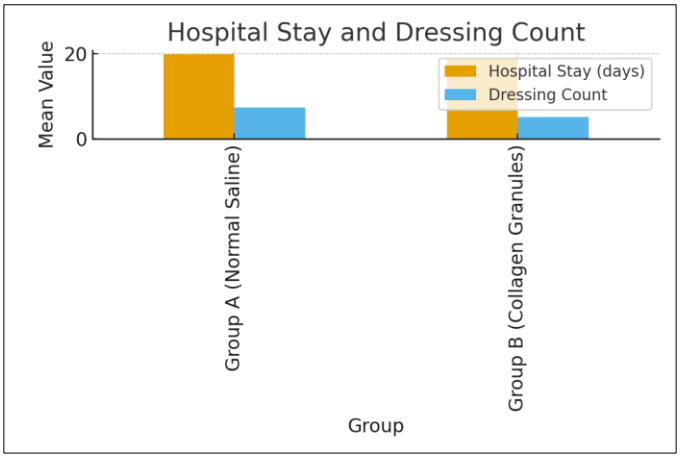
Microbial Load: At Day 14, wound cultures from Group B showed "No growth" in 76% of patients, compared to Group A, where only 34% of patients showed no growth. This indicates the superior microbial control provided by the collagen granules.

Figure 3: Microbial Growth Comparison



Hospital Stay and Dressing Frequency: The mean hospital stay for Group B was 18.74 days, which was significantly shorter than Group A's 19.78 days (p=0.036). Additionally, the mean number of dressings required for healing was 5.06 in the collagen group, significantly lower than the 7.30 dressings required for the normal saline group (p=0.002).

Figure 4: Hospital Stay and Dressing Count



Discussion

This study demonstrates that collagen granule dressings are significantly more effective than conventional normal saline dressings in managing early diabetic foot ulcers (Wagner grades 1-3). Patients treated with collagen granules showed faster wound healing, higher granulation tissue formation (75.60% vs. 59.00% at Day 14, p=0.001), better microbial control (76% vs. 34% no growth at Day 14), shorter hospital stay (18.74 vs. 19.78 days, p=0.036), and fewer dressing changes (5.06 vs. 7.30, p=0.002).

The superior outcomes with collagen are attributed to its role as a "sacrificial substrate" for excess matrix metalloproteinases (MMPs) in chronic wounds [3,4]. By diverting MMP activity away from native collagen, it creates a favorable environment for granulation tissue formation [5,6]. The reduced microbial load is likely an indirect effect of accelerated healing and improved tissue vascularity rather than direct antimicrobial action [7].

These clinical findings suggest potential economic advantages through reduced hospital stay and lower resource utilization [8-10]. Although collagen dressings have higher upfront costs, downstream savings make them cost-effective.

This study has limitations including single-center design, modest sample size, subjective granulation assessment, and short follow-up. Future multicenter trials with longer follow-up and molecular studies are recommended.

Conclusion

Collagen granule dressings are superior to conventional saline dressings for early diabetic foot ulcers (Wagner grades 1-3). They significantly accelerate wound healing, promote granulation tissue formation, and reduce microbial load. These benefits translate into shorter hospital stay and fewer dressing changes, offering both clinical and economic advantages. Collagen granule dressings may be considered for integration into standard clinical practice for diabetic foot ulcer management.

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