

## Original Research Article

# A comprehensive study on effect of collagen dressing in diabetic foot ulcer

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## Abstract

**Introduction:** Wounds can cause painful lengthy hospital stay, multiple stages of surgeries, and enormous financial burden. Biological dressing's collagen granule dressing has advantage over conventional dressing in terms of non-immunogenic, non-pyrogenic, being natural, easy application and decreased days of healing.

**Objectives:** To compare the efficacy and safety of collagen granule dressings and conventional dressing in diabetic wounds in terms of reduced healing time, number of dressing, healing quality and complications

**Materials and methods:** A prospective study was done in which 30 patients who presented with diabetic wounds were chosen by random sampling technique, and were grouped into 2 groups consisting of 15 patients. Thirty patients with foot ulcer were evaluated. A collagen or conventional dressings were applied, and the patients were followed as per standard post-application treatment protocol. Patients underwent dressing changes every day until wound healing or for maximum period of 12 weeks. Changes in wound size were recorded when the dressing was removed; and at 4 and 12 weeks.

**Conclusions:** Our study is a hospital based case control prospective study done in 30 patients of chronic diabetic foot ulcers. There was statistically significant difference between the results of collagen and saline dressings as collagen dressings had better healing response rate as compared to placebo when given along with standard treatment of diabetic foot ulcer.

## Key words

Collagen dressing, Diabetic, Foot ulcer, Effect.

## **Introduction**

Ulcer healing in the diabetic patients is challenging due to a prolonged inflammatory response, extracellular matrix degradation irregularities, and increased bacteria presence. Collagen components are fundamental to the process of wound healing and skin formation. Recently, collagen-containing wound dressings, which create a biological scaffold matrix, have been used in the treatment of diabetic foot ulcer (DFU). However, there is not enough evidence to support that 100% collagen dressing can replace the diabetic wound management. In this study, we examined the effectiveness and safety of a new collagen dressing material in the treatment of DFU.

During the last decade, various new dressing materials developed, like calcium alginate, hydro-colloid membranes and fine mesh gauze. These have a disadvantage in that they become permeable to bacteria. Biological dressings like collagen on the other hand, create the most physiological interface between the wound surface and environment, and are impermeable to bacteria. Collagen dressings have other advantages over conventional dressings in terms of ease of application and being natural, non-immunogenic, non-pyrogenic, hypo-allergenic, and pain-free. The present study has been conducted to compare the efficacy of collagen dressing with that of conventional dressing materials like silver sulfadiazine, nadifloxacin, povidone iodine.

## **Aim**

To compare the efficacy and safety of collagen granule dressings and conventional dressing in deep wounds in terms of reduced healing time, number of dressing, healing quality and complications

## **Materials and methods**

Thirty patients with foot ulcer were evaluated. A collagen or conventional dressings were applied, and the patients were followed as per standard post-application treatment protocol. Patients

underwent dressing changes every day until wound healing or for maximum period of 12 weeks. Changes in wound size were recorded when the dressing was removed; and at 4 and 12 weeks.

### **Primary Endpoints:**

**1. Ulcer healing time:** Time required to completely heal ulcer after the initiation of the therapy with Collagen/Conventional dressings in patients with chronic foot ulcer.

### **Secondary Endpoints:**

**2. Duration of antibiotic therapy:** Duration for which antibiotic therapy was continued to completely heal ulcer after the initiation of the therapy with Collagen/ Conventional dressings in patients with chronic foot ulcer. Follow up period: Duration of follow up after the initiation of the therapy with Collagen/ Conventional dressings in patients with chronic foot ulcer. Adverse events reported with Collagen/ Conventional dressings in patients with chronic foot ulcer.

### **Eligibility criteria**

The following eligibility (inclusion/ exclusion) criteria were used for recruitment of patients in the study.

### **Inclusion criteria**

- Patients with chronic foot ulcer (diabetic/ burn patients).
- Patient willing to give informed consent
- In case of diabetic patients- diabetes mellitus is defined as per World Health Organization (WHO) criteria of age and duration of therapy
- Age  $\geq 35$  years
- Absence of insulin requirement in the first 5 years after diagnosis.

### **Exclusion criteria**

- Critically ill patients
- Patient refusal
- Any evidence of underlying bone osteomyelitis

- Malignancy

The study was conducted on total thirty patients with diabetic ulcer patients who reported at Stanley Medical College, Chennai. All diabetic ulcer patients attending the Surgery Department were invited to participate in the study and written informed consent was taken. All patients underwent a standard clinical and laboratory evaluation. Briefly, information about age, known DM duration, smoking habits, arterial blood pressure, and anthropometric measurements was collected. Patients with diabetic ulcer who were willing to give informed consent were considered. Critically ill patients and patients who refused were excluded. In case of Type II diabetic patients, WHO criteria of age and duration of therapy (Age  $\geq 35$  years & absence of insulin requirement in the first 5 years after diagnosis) were used.

In all patients, wound size was noted before treatment initiation. A collagen or conventional dressings were applied to wound, and all patients were followed as per standard post-application treatment protocol. Patients underwent dressing changes every day until wound healing or for maximum period of 12 weeks. Changes in wound size were recorded when the dressing was removed; and at 4 and 12 weeks.

Healing time, duration of antibiotic therapy, follow up period were noted. All patients were also followed up for adverse events

## Results

**Table - 1** documents the age distribution of the patients taken for the study. **Table - 2** shows effect of healing.

## Discussion

Foot problems are the most common indication for hospital admission in diabetes. They account for approximately 20% of all hospital admissions in diabetics [8]. Approximately 50% of all non-traumatic amputations are in diabetics. Most hospital beds are occupied with diabetic patients

with foot problems than all other causes associated with the disease.

**Table – 1:** Age distribution.

Age group (Years)	Case	Control
<20	0	0
21-30	0	0
31-40	3	2
41-50	4	6
51-60	6	5
61-70	1	1
>71	1	1

**Table – 2:** Effect of healing.

	Case	Control
Complete healing	12	5
Partial healing	3	10

Of the many complications of diabetes, those involving the foot lead not only to pain and suffering, but take months to heal. It leads to loss of working hours, hospitalization and great expense both to the patient and the community [1, 2].

Different modalities of treatment have been used time to time to treat the diabetic foot ulcers such as debridement, different anti- infective wound dressing, antibiotics according to culture sensitivity, skin grafting etc. [3].

Even after various modes of treatment, treatment failure rate is very high. Hence we planned to use the collagen dressing for the treatment of diabetic foot ulcer. There is a large body of evidence that suggest collagen is a common denominator in all stages of wound healing. Collagen serves as the key extracellular component for repair and remodelling of skin tissue.

The exogenous collagen functions as a substrate for hemostasis and is chemotactic to cellular elements of healing such as granulocytes, macrophages and fibroblasts. The materials promote wound maturation by providing a scaffold for more rapid transition [4]. Biomaterials are resistant to degradation and

provide a template for cellular attachment, migration and proliferation.

As a biomaterial, collagen offers several advantages over traditional dressings, growth hormones and biological coverings.

For this purpose, we selected 30 diabetic foot ulcer patients.

We included only chronic ulcers of at least 30 days duration. We excluded those patients who were having neoplastic disease, pre-existing cardiovascular, pulmonary or immunological disease.

We did collagen dressing in 15 patients; in remaining patients standard dressing was used. We also followed standard treatment of diabetic foot that includes good glycemic control, control of infection by appropriate antibiotics according to culture sensitivity and debridement if needed in all patients.

After 12 weeks of collagen treatment, there were 12 patients who achieved complete healing and 3 patients achieved partial healing, while in control group, only 5 patients achieved complete healing and 10 patients had partial healing.

In our study, complete response at 1st and 2nd weeks in both study as well as control groups were statistically at par but after 2 weeks complete response was significantly higher in study group.

Partial response was significantly higher in study group except at 3rd week as compared to control group.

Duration of ulcer also have effect on healing response, if ulcer was of prolonged duration, healing was delayed in both groups, but healing was better in study group as compared to control group.

Collagen dressings have very good results in our study. Collagen favors the outcome because of

increased defense mechanisms by stimulating and differentiation of early and late granulocytes, erythrocytes and megakaryocyte precursors cells [6]. Side effects of collagen are generally infrequent and mild and can be well tolerated by the patients [7].

## Conclusion

Our study is a hospital based case control prospective study done in 30 patients of chronic diabetic foot ulcers. There was statistically significant difference between the results of collagen and saline dressings as collagen dressings had better healing response rate as compared to placebo when given along with standard treatment of diabetic foot ulcer.

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