

Original Research Article

Study of collagen dressing and conventional dressing in the treatment of diabetic foot ulcer

R. Saravanan, S. Ram Prakash*

Department of General Surgery, Govt Medical College Pudukkottai, Tamil Nadu, India

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***Correspondence:**

Dr. S. Ram Prakash,

E-mail: ram.kk369@gmail.com

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ABSTRACT

Background: Diabetic mellitus affects roughly 8.3% of the population in the United States, with more than 79 million people being pre-diabetic. Diabetic foot ulcers are one of the most serious and difficult consequences of diabetes mellitus to manage. Since the dawn of time, several therapy approaches have been tried. The treatment of diabetic foot ulcers has changed dramatically as technology and research have progressed, and the use of collagen dressings in diabetic foot ulcers remains one of them. In diabetic foot ulcers, a comparison of conventional and collagen dressings was made to determine the efficacy.

Methods: A prospective study was undertaken with 50 diabetic foot ulcer patients. Out of the 50 patients, 25 patients were subjected to collagen treatment and 25 patients to conventional treatment with normal saline.

Results: 80% granulation was observed in collagen treated group while there was no granulation was observed in the normal saline-treated group on day 7. The 62% epithelial tissue was present in the collagen treated group whereas 10% epithelial tissue was present in the normal saline-treated group on day 7.

Conclusions: Collagen dressing speeds wound healing in diabetic foot ulcer patients, lowering hospital stay and the necessity for split-thickness skin transplantation. Our research has led us to the conclusion that collagen dressings are superior to conventional dressings.

Keywords: Diabetic foot ulcer, Collagen, Normal saline-treated group, Collagen treated group

INTRODUCTION

Diabetic foot ulcer is a severe and common consequence of diabetes mellitus that considerably increases treatment expenditures. Diabetes mellitus affects around 8.3% of the population in the United States, with more than 79 million people being pre-diabetic.^{1,2} Patients with diabetes have a 12% to 25% lifetime risk of having a foot ulcer.³⁻⁵ Diabetic foot ulcers are the major cause of lower leg amputation in patients with diabetes, and surgery is used to treat diabetic foot ulcer progression in 85% of amputation cases.^{6,7} The human foot is a wonderful reflection of the diseases that plague it. Growth factors, extracellular matrix materials, bioengineered human skin, hyperbaric oxygen, and collagen dressing have all been

developed in recent years to enhance wound healing in diabetic foot ulcers. Collagen-based biological dressings provide a proper physiological contact between the ulcer and the environment, as well as prevent bacterial infection of the ulcer. Collagen, as a key component of the extracellular matrix, is a vital component of the human body. It influences connective tissue tensile strength and gives muscle strength and flexibility. Collagen is a fibrous protein that is found in the skin, bones, tendons, cartilages, blood vessels, and teeth. Because of its simple form and manageability, it is commonly utilised as a medical device.⁸ Collagen, the body's most abundant protein, plays a crucial part in the complete completion of adult wound healing. Collagen is an endogenous substance that is found in connective

tissue and is particularly important for the skin. For some years, the importance of collagen in wound healing has been recognised for the simple reason that the scar generated during wound healing is made up of collagen fibres.⁹ Collagen produces molecular diversity as part of the body's protein scaffolding.¹⁰ In today's medical settings, numerous types of dressing materials containing collagen fibres, collagen membranes, collagen gels, or collagen sponges are employed.^{11,12} Implanted collagen survival rates in animal experiments range from 80 to 100 percent due to its hemostatic effect and low antigenicity, and the materials stay stable for several weeks following surgery with no inflammatory responses or foreign body reactions. Collagen has been effectively employed in biocompatible dressing materials for various wounds such as burns or ulcers, based on encouraging outcomes.¹³

The current study compares the efficacy of collagen dressing to routinely used dressing components such as normal saline in the treatment of diabetic foot ulcers.

METHODS

This Prospective comparative study was conducted in department of surgery at govt. medical college Pudukkottai, in diabetic foot ulcer patients from June 2021 to December 2021.

The research included 50 patients who had a clinical picture of a diabetic foot ulcer. Before enrolling in the trial, signed informed consent was obtained once the method of the study was explained. Ethical committee approval obtained before recruiting patients. Consecutive sampling method were followed.

Inclusion criteria

Patients with chronic foot ulcer were included in the study.

Exclusion criteria

Critically ill patients, any evidence of underlying bone osteomyelitis and patients with malignancy were excluded from the study.

The patients were separated into two groups 25 patients in each group for analysis: group A (Collagen treated group) and group B (Normal saline-treated group).

Age, gender, length of hospital stays, ulcer size decrease in follow-up, percent reduction, percent granulation present, and percent epithelial tissue present were all observed and analysed in both groups. Wound swabs were collected at the time of admission, then again on the 7th, 14th, and 28th days of therapy, and as needed. The damaged region was extensively cleansed to remove external contamination and infected wounds were appropriately debrided before putting the dressing. Based

on pus culture sensitivity reports, both groups received antibiotic therapy.

RESULTS

Out of the 50 patients in the study, 32 were male and 18 were female. The 68% males and 32% females were present in the normal saline-treated group and 60% males and 40% females were present in collagen treated group. In the above study, most of the patients (48%) were found to be in the age group of 51 to 60 years followed by 36% of patients in the age group of 41 to 50 years and 8% of patients being from the age group 40 years and >61 years in normal saline-treated group. In collagen treated group, most of the patients (60%) were found to be in the age group of 51 to 60 years followed by 28% of patients in the age group of 41 to 50 years, 8% of patients in the age group >61 years and 4% patients in the age group. The mean duration of stay in the hospital was found to be 36.24 days and 26.11 days in the normal saline-treated group and collagen treated group respectively (Table 1).

Reduction in ulcer size was recorded on the day of admission, on the 7th day, 14th day and 28th day. In the normal saline-treated group, on the day of admission ulcer size reduction was found to be 18.21 ± 7.06 , on the 7th day was found to be 17.11 ± 8.14 , on the 14th day was found to be 15.27 ± 8.73 and at 28th day was found to be 13.84 ± 6.28 . In collagen treated group, on the day of admission ulcer size reduction was found to be 15.99 ± 7.37 , on the 7th day was found to be 14.31 ± 9.21 , on the 14th day was found to be 12.31 ± 7.16 and on 28th day was found to be 10.14 ± 5.61 (Figure 1).

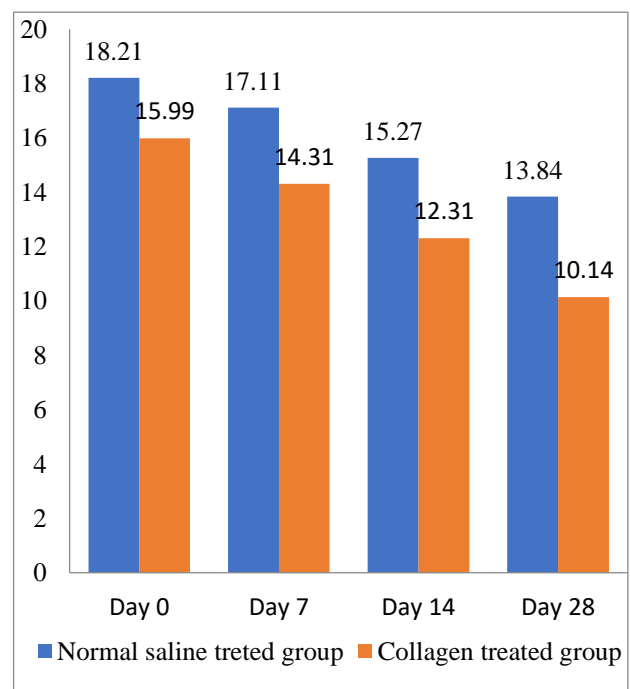
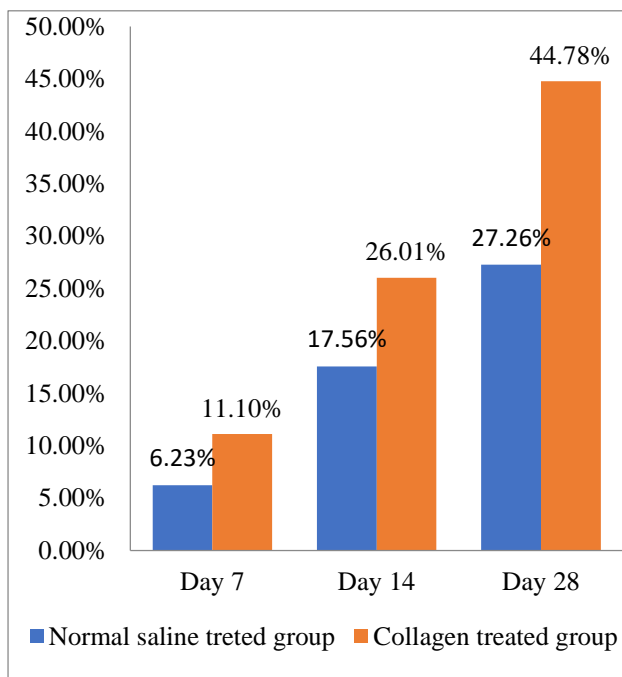


Figure 1: Ulcer size reduction in normal saline-treated group and collagen treated group.

Table 1: Demographic data.

Variables	Normal saline group (%)	Collagen group (%)
Gender		
Males	68	60
Females	32	40
Age group (Years)		
<40	8	4
41-50	36	28
51-60	48	60
>61	8	8
Duration of hospital stay	36.24 days	26.11 days

On the 7th day, % reduction was found to be 6.23% in the normal saline-treated group and 11.10% in collagen treated group. On the 14th day, it was found to be 17.56% and 26.01% in the normal saline-treated group and collagen treated group respectively. On the 28th day, 27.26% reduction was observed in the normal saline-treated group while 44.78% reduction was observed in collagen treated group (Figure 2).

**Figure 2: Percentage reduction in normal saline-treated group and collagen treated group.**

Follow up on the 7th day, 14th day and 28th day was taken for percentages granulation present and percentages epithelial tissue present. The 0%, 100% and 100% granulation were observed on the 7th, 14th and 28th day in the normal saline-treated group while 80.0%, 100% and 100% granulation were observed on the 7th, 14th and 28th day in collagen treated group respectively. Similarly, 10%, 65% and 100% epithelial tissue were present on the 7th, 14th and 28th day in the normal saline-treated group while 62%, 100% and 100% granulation were observed

on 7th, 14th and 28th day in collagen treated group respectively (Table 2).

Table 2: Percentage granulation and percentage epithelial tissue present in normal saline-treated group and collagen treated group.

Variables	Normal saline group (%)	Collagen group (%)
Granulation present (%)		
Day 7	0	80
Day 14	100	100
Day 28	100	100
Epithelial tissue present (%)		
Day 7	10	62
Day 14	65	100
Day 28	100	100

DISCUSSION

Collagen has a crucial role in wound healing. Local tissue ischemia, bioburden, necrotic debris, recurrent trauma, and other variables cause wounds to stall in the inflammatory phase, increasing their chronicity. Collagen breakdown products are chemotactic agents for many cells that are required for the production of granulation tissue. Collagen-based dressings can also remove wound exudates while maintaining a moist wound environment. Collagen is a biological substance that aids wound healing by forming and arranging newly produced fibers and granulation tissue in the wound bed, creating an ideal wound healing environment.¹⁴ Collagen granules help angiogenesis and strengthen the body's healing processes when sprinkled over a wound.^{15,16} This provides mechanical assistance by lowering oedema and fluid loss from the ulcer site, stimulating fibroblast recruitment into the ulcer, and enhancing granulation tissue metabolic activity. Collagen dressings are simple to apply to wounds and have the added benefit of stopping bleeding.¹⁷

In a wound-healing study conducted by Veves et al 276 diabetic foot ulcer patients were divided into two comparable groups, of which 51 (37%) had full wound closure compared to 39 (28.3%) control (moistened gauze) patients after 12 weeks of care, but this difference was not statistically significant ($p=0.12$).¹⁸ In terms of wound healing rates, this study found that collagen dressings outperformed conventional dressings significantly. Compared to normal saline-treated groups, we also observed a significant percentage reduction in ulcer size in collagen treated group on the 7th day, 14th day and 28th day. Also, there was a significant increase in percent granulation was observed on the 7th day in collagen treated group when compared to the normal saline-treated group. Percent epithelial tissue was also significantly increased on day 7 in the collagen treated group when compared to the normal saline-treated group. When the duration of hospital stay was observed, it was found that the collagen treated group had shown a shorter

duration of stay when compared to the normal saline-treated group. Mishra et al discovered a statistically significant difference in the number of wounds that healed completely after six weeks in the collagen dressing group ($p=0.013$).¹⁹ In a comparable trial on 120 patients, Onkar et al gave collagen dressing to 60 patients with wounds of various aetiologies whereas the other 60 patients received traditional dressing treatments. The Onkar et al trial was conducted over 8 weeks, and percentages of wounds treated with collagen dressing had more than 75% wound closure compared to 80% with traditional dressing ($p=0.21$).²⁰ Rao et al compared collagen to traditional dressings in 100 patients with persistent foot ulcers caused by diabetes or burn injuries. The 75 of the 100 patients were treated with collagen dressing, while the others received standard dressing. The study found that collagen dressing had a significantly greater rate of wound healing than moistened gauze. The healing time for patients who received collagen dressing was 4.63 ± 1.18 weeks, which was significantly less than the healing period for patients who received conventional dressing (7.79 ± 1.61 weeks). The study indicated that collagen dressing is dependable and effective for the treatment of chronic foot ulcers, considerably reducing healing time, SSG demand, and follow-up time.²¹

Although collagen is widely established for its role in encouraging wound healing in chronic wounds, there has been little research on the use of collagen as a dressing material for diabetic foot ulcers. As a result, the current study's findings are encouraging, demonstrating that the use of collagen dressing has a significant benefit in diabetic foot ulcer healing when compared to traditional dressing. However, before using collagen dressing, the diabetic foot ulcers should be debrided and cleansed.

CONCLUSION

When compared to conventional dressing with normal saline, collagen dressing accelerates wound healing and thereby minimises hospital stay. Collagen dressings perform significantly better than standard dressings in terms of chronic ulcer recovery. We were able to show that collagen dressing is superior to standard dressings when considering the early development of granulation tissue and epithelial tissue through our research. As a result, we propose that collagen be used regularly in diabetic foot ulcers of small and medium-size. As a result, while the current study's findings suggest that collagen-based dressings can reduce the need for future skin grafting in a considerable proportion of cases of diabetic foot ulcers, more randomised controlled studies with a larger number of patients are needed to firmly establish this kind of therapy as a viable alternative in the treatment of diabetic foot ulcers.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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