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Efficacy of Collagen Particles in Non Healing Ulcers

Dr. Raghavendra, Y. H[1]*, Dr. Jyoti S. Karegoudar[2]

[1]Junior Resident, Department of General Surgery, Gadag Institute of Medical Sciences, Gadag, Karnataka, India
[2]Professor & Head of Department, Department of General Surgery, Gadag Institute of Medical Sciences, Gadag, Karnataka, India

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***Corresponding Author**
Dr. Raghavendra, Y. H

Junior Resident, Department of General Surgery, Gadag Institute of Medical Sciences, Gadag, Karnataka, India

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A B S T R A C T

An ulcer is defined as a break in continuity of covering epithelium, involving skin or mucous membrane and as a result of molecular death. Chronic ulcers of the foot are defined as a gradual breakdown of the epidermal and dermal tissue of the foot lasting for more than 6 weeks. Various factors have been implicated for an ulcer to develop in diabetic patients of which important is peripheral vascular disease which causes decrease in sensation as a result of peripheral neuropathy. This study was a prospective, comparative trial among patients diagnosed with non-healing ulcers in General surgery wards at Gadag Institute of Medical Sciences, Gadag. Duration of healing is significantly reduced in collagen dressing group, it has good compliance, reduced pain and infections, so collagen dressing is superior to routine conventional dressing.

Keywords: Collagen dressing, conventional dressing, non-healing ulcer, povidone iodine.

INTRODUCTION

An ulcer is defined as a break in continuity of covering epithelium, involving skin or mucous membrane and as a result of molecular death. Chronic ulcers of the foot are defined as a gradual breakdown of the epidermal and dermal tissue of the foot lasting for more than 6 weeks. Various factors have been implicated for an ulcer to develop in diabetic patients of which important is peripheral vascular disease which causes decrease in sensation as a result of peripheral neuropathy. Secondary infection in a chronic ulcer is very common that will have a copious amount of discharge that smells foul. Antibiotic treatment for infection, wound dressing, pressure relief (special foot wear, offloading, inserts and casting), debridement and desloughing are the traditional management approaches for diabetic ulcers. Embarrassing dressings, restricted mobility and disability are the other issues that are often a great concern to the patients. Collagens functions as structural proteins of extracellular matrix and are synthesized by the fibroblasts. In normal wound healing process special enzymes called matrix metalloproteinases (MMPs) breaks down the malformed and damaged collagen present at the site of wound. So when dressings containing collagen are used, the MMPS are kept busy breaking down that collagen and the healthy collagen that is innate of the body is thus protected, helping in hastening the healing process. There are other modalities of dressing other than conventional betadine dressing in ulcer management like sugar dressing, vacuum assisted closure method. Direct instillation of sugar on the wound will result in low osmolar effect, promoting early granulation tissue formation, reduction in oedema. Hence, bacteriostatic effect is enhanced and thereby hastens the wound healing.

Dressings containing sterile collagen particles were used in the study and compared with conventional (betadine) dressings. The aim of our study was to evaluate the efficacy of collagen particles, with an objective to compare the rate of healing process using collagen particles with those of conventional methods.

Aims and Objectives: To compare the efficacy of collagen particles vs conventional dressing in non-healing ulcers.

Materials and Method

The study was a prospective, comparative trial among patients diagnosed with non-healing ulcers in General surgery wards at Gadag Institute of Medical Sciences, Gadag. Total 40 patients with non-healing ulcers were studied and were randomized into collagen or conventional group of 20 each. Study duration was 6 months.

Inclusion Criteria:

1) Non healing ulcers including (diabetic foot, post operative ulcers, trophic ulcer, venous ulcer, post infectious ulcers, pressure sores)
2) Ulcers of size 5cm to 20cm in its largest dimension.
3) Patients willing to give consent.

Exclusion Criteria:

1) Chronic ulcers with evidence of osteomyelitis, malignancy.
2) Ulcers with exposed bones and tendons.
3) Ulcers of size more than 20cm in its largest dimension.
4) Patients not giving consent.

The collagen used in this study is a purified reconstituted collagen. Purified collagen refers to collagen which is free from other components normally associated with it in its native state. Purified collagen is collagen which has been reassembled into separate triple helical molecules with or without telopeptide expansion, made into solution and then regrouped into the desired form. This reconstituted collagen is then cross-linked with tanning agents like glutaraldehyde or chromium sulphate to improve tensile strength, to make it insoluble to decrease its rate of resorption andto lower its antigenicity.

For Conventional Dressing- Managed by saline and povidone-iodine (PVPI) Betadine containing 10% povidone-iodine in water was used for dressing chronic wounds. Collagen Dressing -Thorough wash of the chronic ulcer is done using normal saline. Dead skin and necrotic tissue removed from the ulcer. Under aseptic precautions after thorough wash with normal saline to wash off preservative agents collagen dressing is applied over the wound trimming it with scissors so as to cover the entire area. The collagen granule adherent to the wound within an hour. Collagen dressing was repeated every 3 days for 15 days.

Conventional dressing -Thorough wash of the chronic wound is done using normal saline. Dead skin, necrotic tissue removed from the chronic ulcer and dressing was done using gauze soaked with Betadine solution. Patients of both the groups were also given intra venous broad spectrum anti-biotics and analgesics.

Figure 1: Collagen application to ulcers

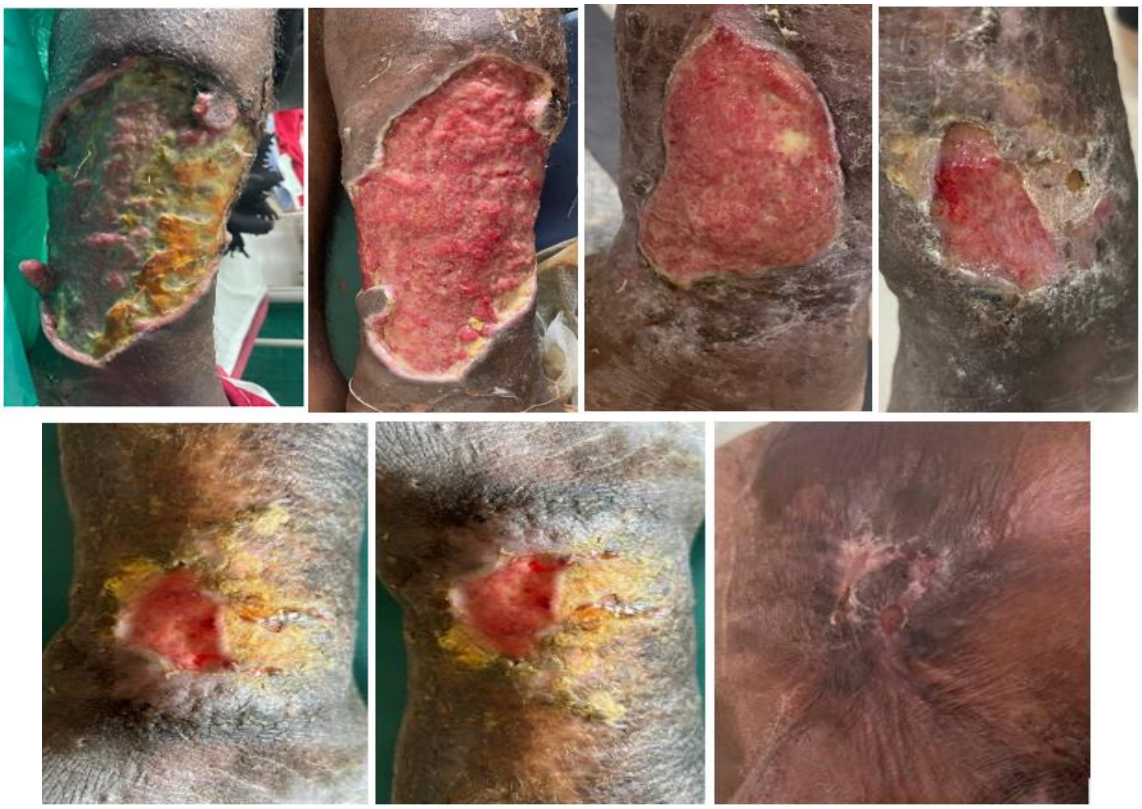

Figure 2: Healing of ulcer after collagen dressing

RESULTS

In the present study 40 patients were randomised into two groups, in Group A for 20 patients collagen dressing and Group B for 20 patients conventional dressing was done.

It was observed that in collagen group, the material was readily available and easily reconstituted for simple and easy for application. The collagen granule dry, moist, supple and intact when applying over ulcer. It was effective in promoting haemostasis. It acted as a temporary covering material on the sensitive nerve endings of raw wounds, which reduced pain which was more in conventional dressing group. Collagen granules acted as a mechanical barrier preventing wound contamination hence reduced infection. The collagen granule did not evoke any antigenic reactions and it was useful in inducing granulation and epithelisation and in preventing the infection and abscess formation. Usage of collagen has good patient compliance as a result of the comfortability of the dressing as it significantly reduced pain and its added value of giving a cosmetically better scar.

In this study collagen granule was found to be very suitable alternative to conventional dressing methods & when used judiciously incontrolled clinical situations, collagen granule is biologically acceptable and from the clinical point of view, an excellent in wound healing and early granulation tissue formation.

Table 1: Age Distribution

Age Group	Collagen group	Conventional dressing group	Total number
20-30	1	5	6
31-40	1	1	1
41-50	8	2	11
51-60	6	7	13
61-70	3	4	6
71-80	1	2	3
TOTAL	**20**	**20**	**40**

Most number of the subjects fell in the age group between 40 - 60 years. The mean± SD for collagen group is (46.17 ± 14.7) and conventional dressing group is (47.7 ± 14.8), so age distribution is statistically similar between the two group with P >0.05 insignificant.

The male and female ratio of the test group is 64.2%: 35.8% and the control group is 70%: 30%. Hence sex distribution is statistically similar between the two groups with P > 0.05.

Table 2: Number of Days for Healing (Conventional Dressing Group)

Number of Days	Number
30-35	0
36-40	3
41-45	9
46-50	7
51-55	1
TOTAL	**20**
Average	**46.95 days**

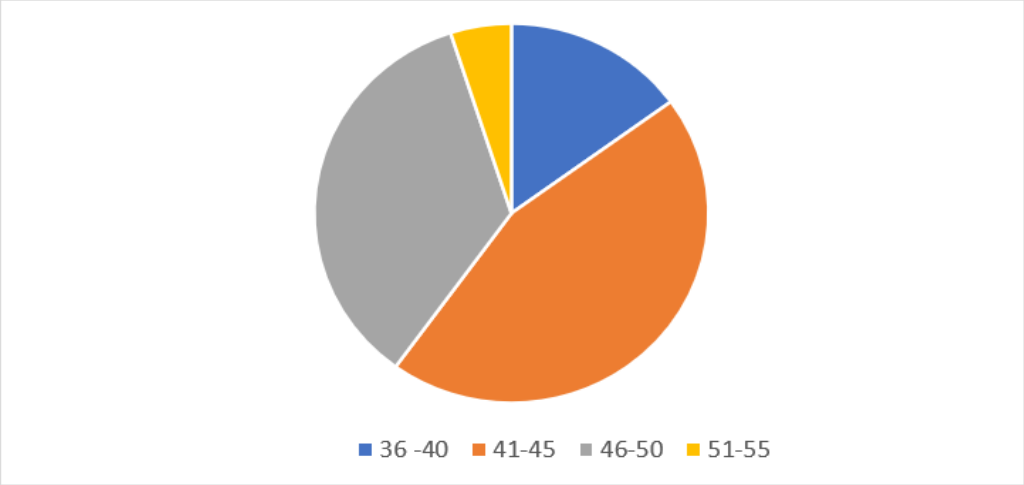

Figure 3: Duration of healing in conventional dressing group

Table 3: Number of Days for Healing (Collagen Dressing Group)

Number of Days	Number
21-25	3
26-30	9
31-35	7
36-40	1
TOTAL	**20**
Average	**29.5 days**

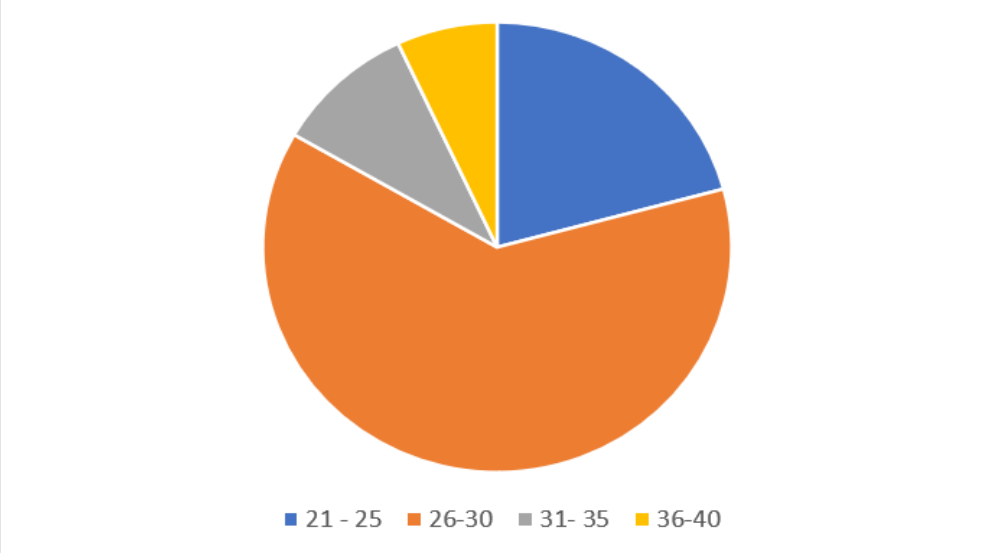

Figure 4: Duration of healing in collagen dressing group

In conventional dressing group duration of hospital stay (including visits for dressing / healing) was achieved on an average of 46.95 days where as in collagen dressing it took 29.5 days. P < 0.001 significant. This shows that collagen dressing helps in decreasing the length of hospital stay when compared to conventional dressing. This shows that collagen dressing helps in decreasing healing time when compared to conventional dressing.

Infection was present in 65% of patients in conventional group and in only 20% of the patients in collagen group. P < 0.021significant and infection was absent in 80% of collagen group and in only 35% of patients in conventional group which indicates lower rate of infection with collagen dressing. 74% of patients in conventional group was undergone SSG and 28% of patients in collagen group was undergone SSG, P < 0.046 significant. hence there was better compliance rate observed with collagen dressing

DISCUSSION

Non healing ulcer management is a real challenging task to the Surgeon. Wound is devoid of its keratin layer which makes it vulnerable to infections [1]. There is continuous infection, slough formation due to absence of the skin barrier. ulcer area lacks the scaffold of collagen which makes the wound difficult to epithelialize resulting in abscess and osteomyelitis. Exposed nerve endings are vulnerable to external stimuli causing pain [2]. All these features point towards need of a barrier over the burn wound to protect the underlying tissue, and that can act as a scaffold for epithelialization. Over the years the dressing for ulcer has evolved from the traditional exposure method to the biological dressings [3, 4]. Saline or povidone iodine dressing is being used as standard dressing in many centres for chronic ulcers. The denuded areas of skin pose a real challenge to Surgeons who treat traumatic wounds, abrasions and burns [5]. The keratin layer of skin is a very active antimicrobial barrier. Uncovered raw areas are lacking its protection; thereby deferring wound healing by exposing bared areas of subcutaneous tissues to infection. The organised growth of epithelium requires a layer which act as the platform [6-9]. The fact that grafted wound heals faster with less complication than an open wound has been realized for almost a century Povidone iodine dressing for chronic ulcers dressing as one of the standard dressing in many centres. The main use of collagen granules is prevent the action of metalloproteinases. Collagen granule is a biological resource, that induce the wound healing via organization of granulation tissue and fresh fibres formation in the wound surface there by make a better atmosphere for increased wound healing [10]. Collagen granules, when applied over the ulcer surface, it not only encourages neovascularisation, but also increase rate of healing mechanisms [11, 12]. Moreover, it is comfortable,well tolerated by subjects, way of application is simple and easy and has the additional advantage of reducing pain.

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