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# A COMPARATIVE STUDY OF COLLAGEN GRANULE Vs CONVENTIONAL DRESSING IN CASE OF CHRONIC NON HEALING ULCERS

General Surgery

**KEYWORDS:** Non healing ulcer, dressing, infection, hospital stay.

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## ABSTRACT

**Background :** In a normal setting wounds have a well orderly and timely healing process that ends in proper restoration of anatomical and functional intergrity. Biological dressing material adhere well to the wound, helps to reduce the pain, limits infection and optimize the rate of healing. **Materials and methods:** Prospective study, comparative trial among patients admitted with chronic ulcers in general surgery wards at a tertiary referral hospital from January to December 2012. 60 patients were randomized into collagen or conventional group of 30 each. **Results:** In conventional dressing group the duration of hospital stay was on an average of 60.3 days whereas in collagen dressing it took 36.11 days P<0.001 significant. Infection was present in 70% of patients in the conventional group and in only 20% of patients in collagen group P<0.021 significant. 76% of patients in conventional group undergone split skin graft and 26% of patients in the collagen group has undergone split skin graft.Patient compliance was good in collagen group than conventional group. **Conclusion.** Collagen dressing reduces the duration of hospital stay and decrease the need of analgesics. Because of the simple application and good tolerance of the collagen granule, collagen granule can be advocated as a temporary biological dressing material in chronic non healing ulcer.

## INTRODUCTION

Chronic non healing ulcers are complicated and proper management involves an understanding of immunology, psychological ,nutritional issues the pathophysiology and metabolic interface including all the major organ systems. Chronic ulcers that are difficult to treat, include diabetic ulcers, venous ulcers, trophic ulcers, pressure sores and necrotizing Fascitis. These wounds can cause painful lengthy hospital stay, multiple stages of surgeries, permanent disability, prolonged rehabilitation, loss of income and enormous financial burden. In the past, various forms of dressing substances found, like fine mesh gauze, calcium alginate and hydrocolloid membranes. There major drawback is being they are penetrable to bacteria. On the other hand Biological dressings like collagen, have the most physiological boundary among ulcer surface and environment, and it is resistant to bacteria The major advantage of Collagen dressings when compared to conventional dressings; being comfort of applicability , being natural, non-pyrogenic, , hypoallergenic, non-immunogenic and pain-free. Collagen is a major protein of extracellular substance, and which is the most easily available and abundant protein in the animal kingdom. "Collagen" is derived from Greek word kola(glue) plus gene.They are the most ubiquitus protein in the human body comprising 30% of total body protein and 75% to 85% of skin . The following study has been deviced to compare the effectiveness of conventional dressing materials like saline, povidone iodine in the treatment of chronic non healing ulcers, with collagen dressings in patients who are admitted in general surgery ward at govt.Mohan kumaramangalam medical college hospital,salem.

## MATERIALS AND METHODS:

The study was a prospective, parallel group ,comparative trial among patients admitted with chronic ulcers in general surgery wards at govt.mohan kumaramangalam medical college hospital Salem. Sixty patients with chronic non healing ucers were studied.patients were randomized into collagen or conventional group of 30 each.study duration was 1 year between January to December 2012.

## ELIGIBILITY CRITERIA:

### INCLUSION CRITERIA:

1.Patients with chronic non healing ulcers
a. Diabetic ulcers
b. Venous ulcers
c. Pressure sores
d. Trophic ulcers
e. Post operative ulcers
f. Post traumatic ulcers
g. Post infectious ulcers
2. Patients willing to give informed consent

### EXCLUSION CRITERIA:

1.Clinically morbid patients
2.Patients refused to give consent
3.Chronic ulcer with evidence of underlying osteomyelitis, exposed bone, tendon or joint.
4.Malignancy
5.Arterial ulcer

## STUDY MATERIALS:

### FOR COLLAGEN DRESSING:

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 native state.Purified collagen is collagen which has been reassembled into separate triple helical moleculeswith or without telopeptide expansion,make into solution and regrouped into desired form.This reconstituted collagen is then cross-linked with tanning agents like gluteraldehyde or chromium sulphate to improve its tensile strength,to make it insoluble and to lower its antigenicity.

### FOR CONVENTIONAL DRESSSING:

Managed by saline and povidone-iodine (PVPI) Betadine containing 10% povidone-iodine in water was used for dressing chronic wounds.

## TECHNIQUE OF APPLICATION:

### 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.After collagen granule application,removal of dressing should be done on following days 0,3,5,10,12,15.

### 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 intra muscular analgesics.

**RESULTS OBTAINED WILL BE CALCULATED ACCORDING TO THE FOLLOWING CRITERIA**

1. Pain was subjective based on patients words on a visual analogue score of 0 to 10. 0 being no pain and 10 the maximum pain tolerable by the patient after 24 hrs of applying the dressing.

2.Infection as being present or absent by checking for any pus under the dressing visually and when infection is present pus is sent for the culture and sensitivity.

3.Rate of healing will be measured by number of days required for complete epithelialisation.

4.SSG need for ulcer is compared between the collagen and conventional dressing group.

5.Patient compliance is determined by feedback given by the patients about the comfortability of the dressing during followup.

**OBSERVATION AND RESULTS**

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

**TABLE 1**

| AGE GROUP | TEST | CONTROL |
|---|---|---|
| <20 | 1 | 0 |
| 21-40 | 10 | 9 |
| 41-60 | 15 | 15 |
| 61-80 | 4 | 6 |
| Mean | 46.17 | 47.7 |
| SD | 14.7 | 14.8 |
| P value | 0.690 Not significant | |

**SEX DISTRIBUTION:** The male and female ratio of the test group is 63.3%: 36.7% and the control group is 70%: 30%. Hence sex distribution is statistically similar between the two groups with P > 0.05.

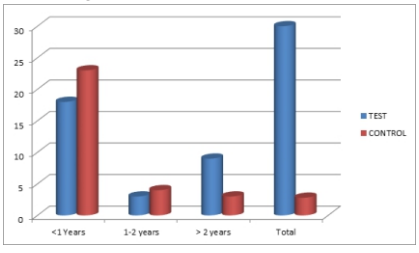
**TABLE 2**

| GENDER | TEST | CONTROL |
|---|---|---|
| MALE | 19 | 20 |
| FEMALE | 11 | 10 |
| TOTAL | 30 | 30 |

P value – 0.935 Not significant

**DURATION:** It is observed in our study most of the patients duration of ulcer,in both groups

p value > 0.05 – Not significant




P value >0.689 not significant

**TABLE 3:**

| Duration | Test | Control |
|---|---|---|
| <1 yr | 18 | 23 |
| 1-2 yrs | 3 | 4 |
| >2 yrs | 9 | 3 |
| Total | 30 | 30 |

**ONSET:** In this study mode of onset of ulcer is not significant in both control and test group; p value > 0.05.

| Onset | Test | Control |
|---|---|---|
| S | 14 | 16 |
| T | 16 | 14 |
| Total | 30 | 30 |

**DURATION OF HOSPITAL STAY:** In conventional dressing group duration of hospital stay was achieved on an average of 60.3 days where as in collagen dressing it took 36.11 days. P < 0.001 significant. This shows that collagen dressing helps in decreasing the length of hospital stay when compared to conventional dressing.

**TABLE 4:**

| DOHS | Test | Control |
|---|---|---|
| <40 | 22 | 4 |
| 41-60 | 7 | 11 |
| 60-80 | 1 | 12 |
| >80 | 0 | 3 |
| Total | 30 | 30 |
| Mean | 36.1 | 60.3 |
| SD | 12.9 | 17.6 |

**PAIN SCORING:** The average pain score in the range of 0 to 10 was 6.53 in conventional dressing whereas it was 2.7 in the collagen group. P<0.001 which is a significant reduction in pain score

**TABLE 5:**

| PAIN | TEST | CONTROL |
|---|---|---|
| MEAN | 2.7 | 6.53 |
| SD | 2.04 | 1.93 |
| P VALUE | <0.001 NOT SIGNIFICANT | |

**RATE OF HEALING:**

In conventional dressing group healing was achieved on an average of 54.37 days whereas in collagen dressing it took 30.27 days .P<0.001 significant shows that helps in decreasing healing time when compared to conventional dressing.

**TABLE 6:**

| ROH | TEST | CONTROL |
|---|---|---|
| MEAN | 30.27 | 54.37 |
| SD | 11.2 | 17.27 |
| P VALUE | <0.001 NOT SIGNIFICANT | |

**INFECTION:**Infection was present in 70% 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 collegen group and in only 27% of patients in conventional group which indicates lower rate of infection with collagen dressing.

**TABLE 7:**

| INFECT30ION | TEST | CONTROL | P VALUE |
|---|---|---|---|
| P | 6 | 22 | 0.021 SIGNIFICANT |
| A | 24 | 8 | 0.036 SIGNIFICANT |
| TOTAL | 30 | 30 | |

P value <0.05 significant

**SSG:** 76% of patients in conventional group was undergone SSG and 26% of patients in collagen group wsa undergone SSG, P < 0.046 significant. 23% of patients in conventional group was treated primarily with saline and povidone iodine dressing and 73% of patients in collagen group was treated primarily with collagen dressing, P < 0.037 significant.

**TABLE 8:**

| SSG | TEST | CONTROL | P VALUE |
|---|---|---|---|
| D | 8 | 23 | 0.046 SIG |
| ND | 22 | 7 | 0.037 SIG |

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| | | | |
|---|---|---|---|
| TOTAL | 30 | 30 | |

P VALUE <0.05 SIGNIFICANT

**PATIENT COMPLIANCE:** : Patient compliance in the conventional group was good in 33% of cases whereas in collagen group it was 87%, P < 0.043 and bad in 67% of cases in conventional group whereas in collagen group it was 13%. hence there was better compliance rate observed with collagen dressing

**TABLE 9:**

| PC | TEST | CONTROL | P VALUE |
|---|---|---|---|
| B | 4 | 20 | 0.037 SIG |
| G | 26 | 10 | 0.043 SIG |
| TOTAL | 30 | 30 | |

**DISCUSSION**

Chronic 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. 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..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. Saline or povidone iodine dressing is being used as standard dressing in many centers for chronic ulcers. The denuded areas of skin pose a real challenge to Surgeons who treat traumatic wounds, abrasions and burns. The keratin layer of skin is a very active anti-microbial 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 of collagen to act as the platform on which it grows and arranges itself. The intact epithelium responsible for a protective layer over cutaneous nerves. It is for these resolution that chronic ulcers need a temporary cover with collagen granule till such time the body is able to manufacture a cover of its own or till such time the surgeon is able to cover it by a skin graft. In the present study collagen was used as an alternative to povidine iodine or saline dressing to cover the non healing ulcers during the initial phase of healing in 30 out of 60 patients included in the study. It was experimented that xenogenous collagen granules had good conformability in lining mucosa and skin. The main use of collagen granules is to prevent the action of metalloproteinases. Collagen granule is a biological resources 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. Collagen granules, when applied over the ulcer surface,it encourages neovascularisation, and increases body's healing mechanisms. Moreover, it is comfortable ,well tolerated by subjects,way of application is simple and easy and has the additional advantage of reducing pain. The number of patients studied was 60 and randomly divided into test group (30) and control group (30). Both the test and control groups were matched regarding their age, sex, onset, duration of ulcer .In addition, there was no significant difference between the two groups with respect to age ,sex , baseline of ulcer size ,duration and onset. Infection was present in 70 % of patients in conventional group and 20% in collagen group. None of the cases showed any adverse reaction to collagen proving its safety as a biological dressing. Collagen dressing helps in decreasing healing time when compared to conventional dressing. Collagen helps in tissue remodeling and gives a better wound healing when compared to conventional dressing. Duration of hospital stay reduced in collagen group patients thereby decreasing economical and social burden of patients. Better compliance rate was observed with collagen dressing.

**CONCLUSION:**

In the present study, 60 patients were taken up for the comparison of collagen dressing v/s conventional dressing.

The following observation was made:

a. The material was readily available and easily reconstituted for simple and easy application.

b. The collagen granule dry, moist, supple and intact when applying over ulcer.

c. It was effective in promoting haemostasis.

d. It acted as a temporary covering material on the sensitive nerve endings of raw wounds, which reduced pain.

e. It acted as a mechanical barrier preventing wound contami nation hence reduced infection

f. It appeared to be sufficiently robust to withstand trauma.

g. The collagen granule did not evoke any antigenic reactions.

h. It was useful in inducing granulation and epithelisation and in preventing infection and abscess formation.

i. Good patient compliance was noted as it significantly reduce pain and its added value of giving a cosmetically better scar .

By considering the above points in this study collagen granule was found to be suitable alternative to conventional dressing methods and when used judiciously in controlled clinical situations ,collagen granule is biologically acceptable and excellent in wound healing and early granulation tissue formation.

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