

## Collagen versus Conventional Dressing in Management of Chronic Non-Healing Ulcers in a Tertiary Care Hospital

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### Abstract

**Introduction:** Wound dressing plays an important part in the healing of chronic ulcers. The decision to use newer dressing materials like collagen or conventional methods like povidone iodine depends on previous experience, cost, clinical and available resources.

**Objective/Aim:** To compare the effectiveness of collagen dressings with conventional dressing materials like povidone iodine in the treatment of chronic non healing ulcers in patients who are admitted in General surgery wards of a tertiary care medical college hospital.

**Materials and Methods:** This prospective, parallel group comparative trial done in patients admitted with chronic ulcers during the period from August 2021 to October 2022 compares the effectiveness of collagen granule dressing with conventional dressing material povidone iodine in the treatment of chronic non healing ulcers. The parameters age, sex, duration of ulcer, pain, rate of healing, duration of hospital stay, infection, need for split skin graft and patient compliance were studied. There were 60 patients during this study period who were randomized by lottery method into collagen dressing and conventional dressing groups.

The observations were entered into Microsoft excel and SPSS version 22 was used for analysis. Datas were analysed statistically by unpaired t test for numeric variables, chi square and Mann whitney u test for categorical variables. P value less than 0.05 was considered significant.

**Results:** Significant advantages of collagen dressing over conventional dressing in terms namely pain, rate of healing, duration of hospital stay, infection, need for split skin graft, and patient compliance were observed. No significant difference found in terms of age distribution, sex preponderance and duration of ulcer.

**Conclusion:** Collagen dressing had statistically significant less pain, faster healing rate, less duration of hospital stays, low infection rate, less need for skin grafting, better patient compliance and can be used as a suitable alternative to conventional dressing like povidone iodine in patients with chronic non-healing ulcers.

**Keywords:** Collagen, Dressing, Povidone Iodine, Ulcer.

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## Introduction

Ulcers not healing for three months are called chronic ulcers. Chronic non healing ulcers are complicated as they do not follow an orderly and timely process to produce complete healing. [1] Their proper management require good understanding of immunology, psychological, nutritional issues. They are commonly seen in diabetic, venous, trophic, pressure ulcers and necrotising fasciitis. These ulcers can cause painful lengthy hospital stay, multiple stages of surgeries, permanent disability, prolonged rehabilitation, loss of income and enormous financial burden. Wound dressing plays an important part in the healing of ulcer. To solve the above issues, it is vital to identify and use an ideal wound repair material. In the past, various forms of dressing substances like fine mesh gauze, calcium alginate, and hydrocolloid membranes were used but these were all penetrative to bacteria. Biological dressings have the most physiological boundary among the ulcer surface and environment and are resistant to bacteria. Collagen is a major protein of extracellular matrix and reconstituted collagen granule dressing is a biological dressing material which reduces inflammatory cells resulting in reduced healing time. 'Collagen' is derived from Greek word kola (glue) plus gene. They are the most ubiquitous protein in the human body comprising 30% of total body protein and 75% to 85% of skin. The Proteins are essential polymers and weigh nearly 15% of human body and are essential for the process of wound healing. Collagen attracts fibroblasts and encourages deposition of new collagen to the wound bed. It also helps to stimulate the growth of new tissue by encouraging angiogenesis, autolytic debridement and re-epithelization. [2]

## Methods

This prospective, parallel group comparative trial done in patients admitted with chronic ulcers in General Surgery wards at a Tertiary

care Medical College Hospital during the period from August'2021 to October'2022 compares the effectiveness of collagen granule dressing with conventional dressing material povidone iodine in the treatment of chronic non healing ulcers. The parameters age, sex, duration of ulcer at the time of hospitalization, duration of hospital stay in surgical ward, pain as graded per the numerical rating scale on a visual analogue score, rate of healing, infection, need for split skin graft, and patient compliance were studied.

This study was done after obtaining Institutional Human ethics committee clearance. Patients presenting with chronic non healing ulcers like diabetic ulcers, venous ulcers, pressure ulcers, trophic ulcers, post-operative ulcers, post traumatic ulcers, post infectious ulcers and patients willing to give consent were included in the study. There were 60 patients in this category during this study period.

Clinically moribund patients, chronic ulcers with underlying osteomyelitis, exposed bone, tendon or joint, malignant ulcers, arterial ulcers, and patients not willing to give consent for study were about 9 in number during this study period and were excluded from study.

The patients satisfying the inclusion criteria in the above study period were randomized by lottery method into collagen dressing and conventional dressing groups. Swab for pus culture from ulcer bed was taken at the time of admission in both groups.

The collagen used in this study for collagen dressing is a purified reconstituted collagen. Purified collagen refers to collagen, which is free from other components normally associated with it in its native state which has been reassembled into separate triple helical molecules with telopeptide expansion and regrouped into the desired form. This

reconstituted collagen is then cross - linked with tanning agents like chromium sulphate to improve its tensile strength, to make it insoluble, to decrease its rate of resorption and to lower its antigenicity. For conventional dressing Betadine containing 10% povidone-iodine in water was used. For collagen dressing, after thorough wash and debridement of the chronic ulcer with saline under aseptic precautions, the collagen granules were applied over the entire area of ulcer and once the granules get adhered to the ulcer area, dressing is done. Changing of dressing was done on days 0, 3, 5,10,12,15 with washing and collagen granule application done for each dressing. For conventional dressing, after thorough wash and debridement, dressing was done with gauze soaked in Povidone iodine solution. Both groups were given intravenous cephalosporins and antibiotics were changed after pus culture and sensitivity reports if warranted. The following parameters were studied between the two groups, namely age

distribution, sex distribution, duration of ulcer at the time of hospitalization, duration of hospital stay in surgical ward, pain as graded per the numerical rating scale on a visual analogue score from 0 to 10 with 0 being no pain and 10 the maximum pain tolerable by the patient after 24 hours of applying the dressing, rate of healing is assessed as evidenced by number of days required for complete epithelisation of wound, presence or absence of infection by checking for any pus under the dressing visually, need for split skin graft is identified by assessing the wound and patient compliance is determined by the feedback given by the patient about the comfortability of the dressing during follow up. The observations were entered into Microsoft excel and SPSS version 22 was used for analysis. Datas were analysed statistically by unpaired t test for numeric variables, chi square and Mann whitney u test for categorical variables. P value less than 0.05 was considered significant.



**Figure 1: Collagen Granule**



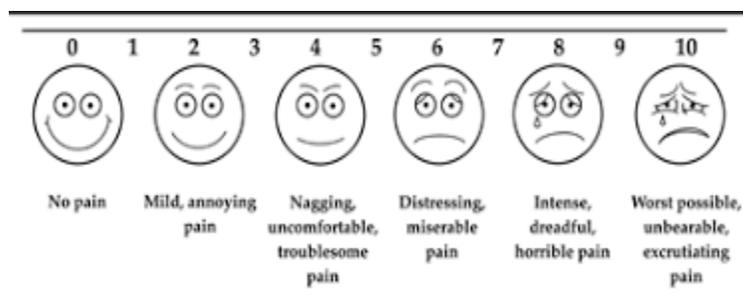
**Figure 2: Chronic Ulcer**



**Figure 3: Collagen Application**



**Figure 4: Chronic Ulcer 5 Days After Collagen Application**



**Figure 5: Visual Analogue Scale for Pain Assessment**

## Results

The results of the study are given below in the following tables

**Table 1: Age Distribution, Sex Distribution, Duration of Ulcer**

Parameter	Collagen Dressing	Conventional Dressing	P Value
<b>Age in Years - N (%)</b>			
<20	1(3.3)	0(0)	0.690
21 -40	10(33.3)	9(30)	
41 – 60	15(50)	15(50)	
61 – 80	4(13.3)	6(20)	
Mean	46.17	47.7	
SD	14.7	14.8	
<b>Sex Preponderance - N (%)</b>			
Male	19(63.3)	20(66.7)	0.935
Female	11(36.7)	10(33.3)	
<b>Duration of Ulcer - N (%)</b>			
< 1 year	18(60)	23(76.7)	0.689
1-2 years	3(10)	4(13.3)	
>2 years	9(30)	3(10)	

It was found that the above mentioned parameters in Table 1 namely age distribution, sex preponderance, duration of ulcer were statistically insignificant between collagen and conventional dressing groups.

Most number of patients were in the age group between 40-60 years. The mean $\pm$ SD for collagen group is (46.17 $\pm$ 14.7) and conventional group is (47.7 $\pm$ 14.8). Age

distribution was similar between the two group with P>0.05 not significant. The male and female ratio of the collagen group is 63.3%:36.7% and the conventional group is 70%:30%. Sex distribution was similar between the two groups with P>0.05 not significant. The duration of ulcer at the time of hospitalization was not statistically significant between collagen and conventional groups with P value>0.05.

**Table 2: Duration of Hospital Stay, Pain, Rate of Healing of Ulcer**

Parameter	Duration of Hospital Stay (No. of Days)		P Value	Pain (Scale From 0 To 10)		P Value	Rate Of Healing (No. Of Days)		P Value
	Collagen	Conventional		Collagen	Conventional		Collagen	Conventional	
Mean	36.1	60.3	<0.001	2.7	6.53	<0.001	30.27	54.37	<0.001
SD	12.9	17.6		2.04	1.93		11.2	17.27	

In collagen dressing group, duration of hospital stay was achieved on an average of 36.1 days whereas in conventional dressing group duration of hospital stay was achieved on an average of 60.3 days with  $P < 0.001$  significant. This shows that collagen dressing helps in decreasing the length of hospital stay when compared to conventional dressing.

The average pain score in the range of 0 to 10 was 2.7 in the collagen dressing group and was 6.53 in conventional dressing group with  $P < 0.001$  showing a significant reduction in pain score in collagen dressing group.

In collagen dressing group healing was achieved on an average of 30.27 days whereas in conventional dressing group healing was achieved on an average of 54-37 days with  $P < 0.001$  showing a significant decrease in rate of healing in collagen dressing when compared to conventional dressing.

**Table 3: Infection, Need for Split Skin Graft, Patient Compliance of Ulcer**

Parameter	Infection N (%)			Need For Split Skin Graft N (%)			Patient Compliance N (%)		
	Collagen	Conventional	P value	Collagen	Conventional	P value	Collagen	Conventional	P value
Yes	6(20)	22(73)	0.021	8(26)	23 (76)	0.046	26(87)	10 (33)	0.043
No	24(80)	8(27)		22(74)	7(24)		4(13)	20 (67)	

Infection was present in only 20% of the patients in collagen group and in 73% of patients in conventional group with a P value of 0.021 indicating a significant lower rate of infection with collagen dressing.

Need for split skin graft was observed in 26 % of patients in collagen group and in 76% of patients in conventional group with a P

value of 0.046 indicating a significantly lower need for split skin graft with collagen dressing.

Patient compliance was observed in 87% of patients in collagen group and in 33% of patients in conventional group with a P value of 0.043 indicating a significant patient compliance with collagen dressing.

## Discussion

Chronic non healing ulcer management is a real challenging task to the surgeon as the wound is devoid of keratin layer which makes it susceptible to infections. A meta-analysis was done by C.J.Walter *et al* of various studies studying the efficacy of various dressing materials, like hydro colloid, basic wound contact dressing and absorbent dressings. It was found that there were no significant advantages over any of the type of dressings over exposed wounds [2]. No single dressing is suitable for all types of wounds. Ideal dressings should perform one or more of the following functions like maintain a moist environment at the wound-dressing interface, absorb excess exudates without leakage to the surface of the dressing, provide thermal insulation, mechanical and bacterial protection, allow gaseous and fluid exchange, absorb wound exudates, maintain humidity and optimal pH, be non-adherent to the wound and easily removed without trauma and provide some debridement action, be non-toxic, non-allergenic, non-sensitizing and sterile [3,4]. It should provide optimum pH and thermal insulation, should be easy to apply and must be cost and resource effective [5].

It has been shown that collagen has hemostatic activity, promotes the growth of endothelial cells, prevents the action of matrix metalloproteinases which are factors promoting wound healing. Hence, collagen as a dressing material has been evaluated by many studies, though lack of definitive guidelines on the role of collagen in wound management. Collagen granules promote hemostasis, aid in wound debridement, promote granulation and neovascularisation, have enhanced fibroblastic activity and aids in re-epithelization and wound remodelling [2-5]. The use of collagen over other conventional dressing materials has to be judged on the basis of previous experience, clinical and available resources and cost.

In this study, the following parameters, namely age distribution, sex distribution, duration of ulcer, pain, rate of healing, duration of hospital stay, infection, need for split skin graft, and patient compliance were studied between the collagen dressing and conventional dressing group.

### Age, sex preponderance and duration of ulcer

In this study age distribution, sex preponderance, duration of ulcer were statistically insignificant between collagen and conventional dressing groups and these factors were not analysed much in previous studies.

### Pain

In this study, pain scoring as graded per the numerical rating scale on a visual analogue score from 0 to 10 with 0 being no pain and 10 the maximum pain tolerable by the patient after 24 hours of applying the dressing was 2.7 in collagen dressing and 6.53 in conventional dressing with p-value less than 0.001. This finding that reduction in pain in collagen dressings is supported by studies conducted by B.Ponten *et al* [6]. Whitaker *et al* [7]. RH Demling *et al* [8]. RL Gerding [9]. which all showed that there was less pain experienced by those undergoing collagen dressing.

### Rate of healing

It was found that collagen dressing took an average of 30.27 days, whereas in conventional dressing it took 54.37 days; with p value less than 0.001 in our study. These findings are in accordance with the studies done by Whitaker *et al* [7]. RH Demling [8]. RL Gerding [9]. Kolenik *et al* [10]. MP Levin *et al* [11]. S Gupta RL [12]. which all suggest that collagen dressings are associated with faster re epithelization rates.

### Hospital stays

In this study the average hospital stay was 36.11 days in collagen dressing and 60.3 days in conventional dressing with p value less than 0.001. These findings are in accordance with the studies done by Kolenik *et al* [10], MP Levin *et al* [11] and Gupta RL [12]. which all suggest that collagen dressings are associated with lesser duration of hospital stay.

### Infection

In this study, 20% patients in collagen group developed wound infection as against of 70% patients in conventional group suggesting significantly lower infection rates among those receiving collagen dressing. This is supported by Gupta RL [11], A Mohan Kumar *et al* [13], and Prasath Pandharinath Ghule [14], which all suggest that incidence of infection in collagen dressing is significantly lesser.

### Need for split skin graft

In this study, it was seen that, 76% in conventional dressing group and 26% in collagen dressing group had undergone subsequent split skin grafting. It shows that percentage of patients requiring split skin grafting is significantly lower in those receiving collagen dressing which is supported by a study done by Onkar Singh *et al* [15].

### Patient compliance

Patient compliance was good in 87% of patients in collagen dressing group and in 33% of conventional dressing group suggesting a significantly better patient compliance with collagen dressing. This is supported by studies done by RL Gerding [9], Onkar Singh *et al* [15], and Babu TS [16] who showed 92% compliance rate with collagen dressing.

### Cost

Although collagen dressing materials are expensive than conventional dressings, the

lesser number of dressings needed, faster healing time, lesser need for skin grafting, lesser duration of hospital stay and better patient compliance lead to an overall cost effectiveness for collagen dressing when compared to conventional dressing [17].

### Conclusion

Collagen dressings had statistically significant lesser pain, faster healing rates, lesser duration of hospital stay, lower infection rate, lesser need for split skin grafting, better patient compliance when compared to conventional dressing in management of chronic non healing ulcers. Collagen dressing can be used as a suitable alternate to conventional povidone iodine dressing in suitable patients.

**Ethical approval:** The study was approved by the institutional human ethics committee

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