

# A Comparative Study between Collagen Sheet Dressing and Collagen Granules Dressing in Management of Chronic Non-Healing Ulcer

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## Abstract

**Introduction:** A collagen granule dressing has advantage over conventional dressing, as it is non-immunogenic, non-pyrogenic, natural, and hypo allergic. There are various collagen preparations available and multiple studies have compared collagen preparations with other dressing techniques and materials. Most common forms of collagen used are collagen sheet and collagen granules. The present study was conducted to compare rate of healing of ulcer with collagen sheet dressing versus collagen granule dressing.

**Materials and Methods:** A total of 100 patients were included for a prospective comparative study and collagen granule and sheet dressings were applied. The variables that were analyzed are mean number of dressings required per week, mean number of days required for complete healing, and mean number of dressings required for complete healing.

**Results:** Distribution of number of dressing required for complete healing showed that the mean dressing required was more in sheet dressing (10.57) than granule dressing (7.26). Mean duration of weeks required for complete healing was noted and found that sheet dressing (7.04) required more weeks for complete healing than granule dressing (5.64).

**Conclusion:** The use of collagen granules dressing improved the rate of wound healing in chronic ulcers. Collagen granules are effective in decreasing the discharge and thus requiring fewer dressings per week as compared to collagen sheets.

**Key words:** Chronic, Collagen, Granules, Sheets, Ulcers

## INTRODUCTION

Ulcer is a break in the continuity of covering epithelium, skin or mucosa either following molecular death or traumatic removal.<sup>[1]</sup> A chronic wound may be a wound that does not heal during an orderly set of stages and in a predictable amount of duration, the way most wounds do; wounds that do not heal within 3 months are often considered chronic.<sup>[2]</sup> Inflammation, proliferation, and maturation with remodeling are well documented phases

of normal wound healing. An ulcer becomes chronic and non-healing if it gets arrested in any of these three phases. Several treatment strategies are available to stimulate wound healing.

Biological dressings like collagen form a better physiological barrier between the wound and the environment. They are also impermeable to bacteria. A collagen dressing also has other advantage over conventional dressing in terms of being natural, easy application, non-immunogenic, hypo allergic, non-pyrogenic, and pain free.<sup>[3]</sup>

There are various collagen preparations available such as gels, foams, granules, sheets, and colloids. Multiple studies have compared collagen preparations with other dressing techniques and materials. Most common forms of collagen

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used are collagen sheet and collagen granules. The present study was conducted to compare rate of healing of a chronic non healing ulcer when treated with two most common forms of collagen, that is, the collagen sheet dressing or collagen granule dressing.

## MATERIALS AND METHODS

The study is a prospective, comparative clinical study, which was conducted on 100 patients (sample size) with chronic non-healing ulcer attending the outpatient department (OPD) in the Department of Surgery at M.Y.H Hospitals and M.G.M Medical College, Indore (M.P).

### Inclusion Criteria

The following criteria were included in the study:

- Patients providing written consent
- Patients with chronic non healing ulcers
- Ulcers of >12 weeks duration
- All adults attending MYH OPD or admitted in M Y Hospital.

### Exclusion Criteria

The following criteria were excluded from the study:

- Patients not willing to give written consent
- Patients with diabetic foot ulcers
- Allergy to collagen
- Age <12 years
- Malignant ulcers.

After getting permission from ethical review committee, the study was initiated. Informed written consent was taken from every participant. Routine blood investigations were done. Wedge biopsy from the wound was taken. Radiological examinations were done using X-Ray and Color Doppler study. Fine-needle aspiration cytology of lymph nodes draining the site the site of ulcer was taken. Ulcer examination was done in all these patients and wound was assessed of its characteristics and photographed at the beginning of the study and at each subsequent follow-up. Size of the wound was assessed by placing a meter scale from the edges of the wound in its longest dimensions.

### Dressing Technique

After allotting the groups with the help of random number table, the procedure was properly informed to the patients. All the wounds were cleaned using 0.9% saline. After this, the collagen material was applied over the wound (granule/sheet) and it was covered with dry gauze followed by roller bandage application. Data were analyzed using SPSS statistics 25 and statistical method used was Chi-square test.

## RESULTS

A total of 100 patients were included in the study, out of them; granule dressing was done in 50 patients, while other 50 patients had sheet dressing. It was observed that maximum number (29) of patients was lying between age group of 41 and 50 years. Highest number of patients that had granule dressing was between the age group of 41 and 50 years, while in sheet dressing group, highest number of patients was having age group between 51 and 60 years [Table 1].

There were 78 male patients and 22 female patients. Number of male and female patients in granule dressing was 38 and 12, respectively. In sheet dressing group, male and female patients were 40 and 20, respectively.

On the basis of etiology, traumatic ulcers were the most common and accounted for 42 cases, while vasculitic ulcers were least common in our study (seven cases). Most number of granule dressings was done in traumatic ulcer etiology, while maximum number of sheet dressings was done in venous ulcers [Table 2].

We found that lower limb (81 patients) was the most common site of the ulcer followed by torso (11 patients) and upper limb (8 patients). The mean ulcer size at the start of the study in collagen granule dressing group was 15.56 cm<sup>2</sup> with a standard deviation of 4.27 cm<sup>2</sup> while in collagen sheet dressing group it was 14.78 cm<sup>2</sup> with a standard deviation of 4.31 cm.

It was observed that majority of the patients had the ulcer for around 16–19 weeks of duration, followed by 20–

**Table 1: Age distribution**

Age group	Granule dressing		Sheet dressing		Total	%
	Count	%	Count	%		
20–30	8	16.00	10	20.00	18	36
31–40	12	24.00	8	16.00	20	40
41–50	15	30.00	14	28.00	29	58
51–60	13	26.00	15	30.00	28	6
Above 60	3	6.00	2	4.00	5	5
Total	50	100	50	100	100	100

**Table 2: Etiology of ulcer**

Etiology	Granule dressing		Sheet dressing		Total
	Count	%	Count	%	
Venous	16	32	22	44	38
Traumatic	24	48	6	12	42
Trophic	6	12	6	12	8
Vasculitic	2	4	2	4	7
Others	2	4	2	4	8
Total	50	100	50	100	100

23 weeks of duration [Table 3]. Out of 100, 92 patients had serous or serosanguinous discharge from the wounds of which 48 were in collagen granule group and 44 in collagen sheet group. Only eight patients had non-discharging wounds. Of these, two were in collagen granule group and six were in collagen sheet group.

The mean number of dressings required for complete healing was noted in both the groups and compared and it was observed that collagen granules needed lesser time for complete healing than collagen sheets. The result was also statistically significant [Table 4]. On comparing the number of weeks needed for complete healing, it was noted and found that sheet dressing required more weeks ( $7.04 \pm 0.97$  weeks) for complete healing than granule dressing ( $5.64 \pm 0.96$  weeks). This difference was not statistically significant having *P*-value of 0.15 [Figure 3].

Mostly there were no complications after the collagen dressing. However, those who developed complications had pain as the most common one followed by fever, infection, and lastly bleeding from the ulcer [Table 5]. The complications were less in collagen granules dressing and  $P = 0.032$ . Mean reduction in wound size was compared at 3<sup>rd</sup>, 5<sup>th</sup>, and 8<sup>th</sup> weeks and higher reduction was found in granule dressing group than sheet dressing group at 3<sup>rd</sup>, 5<sup>th</sup>, and 8<sup>th</sup> week [Table 6].

Mean number of required dressing required per week in our study was noted from 1<sup>st</sup> to 8<sup>th</sup> week. It showed that during 1<sup>st</sup> week, mean number of dressing required of granule dressing and sheet dressing was the same. In the granule-dressing group, mean number of dressings required at 3–6<sup>th</sup> week was lower in collagen granules group than collagen sheet group. At week 7<sup>th</sup> and 8<sup>th</sup>, the mean number of dressings required was the same [Figure 4].

## DISCUSSION

Wound healing involves a timely expression of varied growth factors that promotes cellular proliferation and migration, collagen deposition and formation of latest animal tissue matrix. A common feature of all chronic wounds is elevated levels of matrix metalloproteinases, resulting in increased proteolytic activity and decreased activity of growth factors that are integral part of wound healing process. Collagen has a role during this phase as it specifically inhibits the function of proteases without any influence on activity of growth factors. Thus collagen is more effective as compared to regular moistened gauze dressing.

In the present study, male patients (78) were more than female patients (22). Number of male and female patients

**Table 3: Distribution as per duration of ulcer**

Duration of wound (Weeks)	Granule dressing		Sheet dressing		Total
	Count	%	Count	%	
12–15	8	16	12	24	20
16–19	20	40	18	36	38
20–23	18	36	16	32	34
>24	4	8	4	8	8
Total	50	100	50	100	100

**Table 4: Mean number of dressings required for complete healing**

Group	Mean no. of dressings for complete healing					T-statistic	P-value
	Count	Min.	Max.	Mean	SD		
Granule dressing	50	5	10	7.26	1.34	-6.11	0.007
Sheet dressing	50	4	15	10.57	3.77		

**Table 5: Complications after dressings**

Complications	Granule dressing		Sheet dressing		Total	P-value
	Count	%	Count	%		
Pain	8	16	8	16	16	0.032
Fever	6	12	8	16	14	
Infection	4	8	10	20	14	
Bleeding	0	0	2	4	2	
None	32	64	22	44	54	
Total	50	100	50	100	116	

**Table 6: Mean reduction in wound size**

Week	Granule dressing (cm <sup>2</sup> )	Sheet dressing (cm <sup>2</sup> )	P-value
3	-4.68	-2.03	0.001
5	-3.56	-2.21	
8	-7.28	-7.34	

in granule dressing was 38 and 12, respectively. In sheet dressing group, male and female patients were 40 and 20, respectively. Kumar and Kartheek 2018 showed that males had increased number of ulcers (79%) as compared to females (21%) with male to female ratio 3.76.<sup>[4]</sup> A study done by Jaiswal *et al.* in 2006 in AFMC showed a similar male: female ratio. Males being more involved in physical work and labor.<sup>[5]</sup>

In this study, we have also analyzed patients according to etiology of wound. It suggested that traumatic ulcers were the most commonly found accounted for 42 cases, while vasculitic ulcers (7) were least commonly found in our study. Maximum number of granule dressing was done in traumatic ulcer etiology, while maximum number of sheet dressing was seen in venous ulcers. In trophic ulcers, equal number of patients had granule dressing and sheet dressing. Similarly, Choudhary *et al.* showed that highest number of

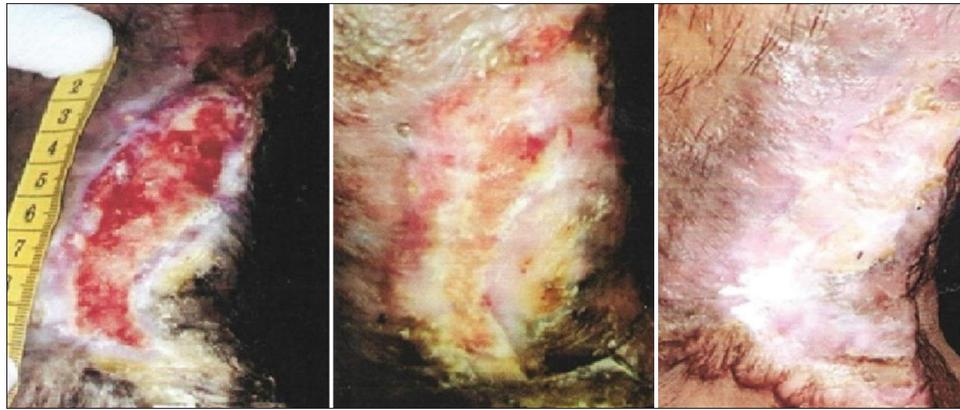


Figure 1: Collagen sheet dressings at day 0, after 9 collagen sheet dressings, and after 12 collagen sheet dressings, respectively



Figure 2: Collagen granule dressing at day 0, after 2 collagen granule dressings, and after 6 collagen granule dressings

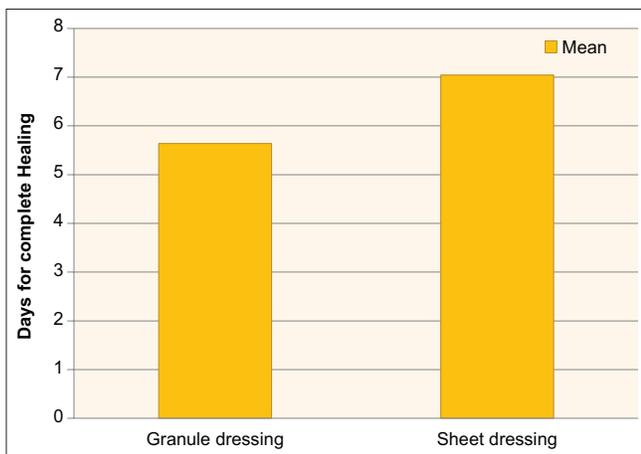


Figure 3: Mean number of weeks needed for complete healing

patients had traumatic ulcers, while venous and pressure ulcer was minimum in that study.<sup>[6]</sup>

In the present study, we found that lower limb (81) was the most common site of the ulcer followed by torso (11). Among the patients who were having leg ulcers, 42 had granule dressing while 39 had sheet dressing. Upper limb was the least common site of ulcers in our study and the number of patients having granule dressing and sheet

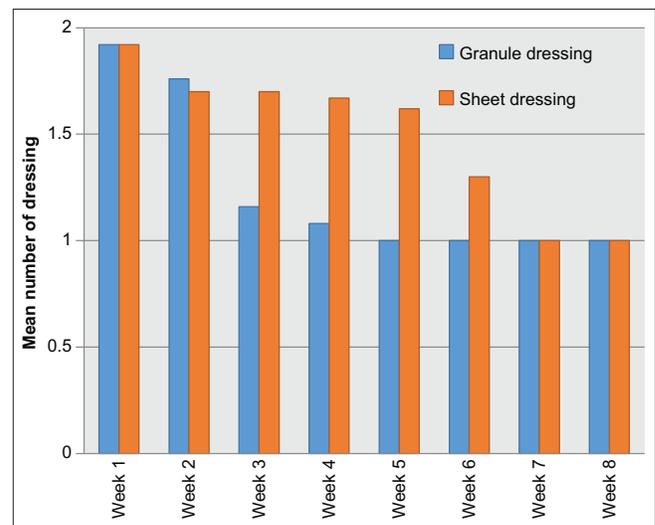


Figure 4: Mean number of dressing required per week

dressing was equal (4). Similar results were reported by the previous stud done by Kumar and Kartheek.<sup>[4]</sup>

We noted the duration of wound in our study and it showed that majority of the patients (38) had around 16–19 weeks of duration. Minimum duration noted in the study was 12–15 weeks in total 20 patients, among them 8 had granule

dressing, while 12 had sheet dressing. A total of eight patients in the study were having duration of wound for >24 weeks. A previous study done by Singh *et al.* in 2011 reported similar findings.<sup>[3]</sup>

Discharge among the all patients was noted. Out of total 100 patients, 92 patients had serous/serosanguinous discharge, while eight were not having any discharge. Proportion of no discharge was found more in patients who had sheet dressing (6) than granule dressing (2). Distribution of number of dressing required for complete healing showed that the mean dressing required was more in sheet dressing (10.57) than granule dressing (7.26). This difference was statistically significant having  $P = 0.007$ . In line with the present study previous studies done by Datta *et al.*<sup>[7]</sup> and Shankar *et al.*<sup>[8]</sup> also reported that discharge was the most common.

Mean duration of weeks required for complete healing was noted and found that sheet dressing (7.04) required more weeks for complete healing than granule dressing (5.64). This difference was not statistically significant having  $P = 0.15$ . Maximum complications found in our study were pain in 16 patients, which was equally distributed in granule dressing and sheet dressing group. Fever and infection were found to be second most common complications in 14 patients. The number of patients having fever and infection was higher in sheet dressing than granule dressing group. None of the patients reported bleeding in granule dressing group.

Mean reduction in wound size was noted on 3<sup>rd</sup>, 5<sup>th</sup>, and 8<sup>th</sup> weeks and higher reduction was found in sheet dressing group than granule dressing group at 8<sup>th</sup> week with  $P = 0.001$ . Datta *et al.* showed that after application of collagen sheet, at the day 0 the mean ulcer size is  $32.40 \pm 17.45$  cm. At the end of 8<sup>th</sup> week, the mean of ulcer size is  $11.73 \pm 10.69$  cm. There was significant decrease in ulcer size at a given point of time when compared to the previous week with  $P < 0.0001$ .<sup>[7]</sup>

Mean number of required dressing required per week in our study was noted from 1<sup>st</sup> to 8<sup>th</sup> weeks. It showed that during 1<sup>st</sup> week, mean number of dressing required of granule dressing and sheet dressing was the same. In the granule-dressing group, mean number of dressings required at 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> weeks were 1.76, 1.16, and 1.08,

respectively. In the sheet-dressing group, mean number of required dressing at 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> week was 1.7, 1.7, and 1.67, respectively. At weeks 7<sup>th</sup> and 8<sup>th</sup>, equal number of mean dressings was required.

## CONCLUSION

Wound healing is a composite process involving a numerous chemical and biological events. The present study was conducted to compare rate of healing of ulcer with collagen sheet dressing versus collagen granule dressing in management of chronic non-healing ulcers. Collagen available in various forms has different rates of healing. Collagen granules when compared to collagen sheets in dressing of chronic non-healing ulcers [Figures 1 and 2] required lesser time for healing, fewer dressing, and good control of discharge. To conclude, the use of collagen granules dressing accelerated the rate of wound healing in chronic ulcers. Collagen granules are effective in decreasing the discharge and thus requiring fewer dressings per week as compared to collagen sheets. This property of collagen granules can be attributed to collagen granules having larger surface area of contact as compared to sheet and also the pores between the granules allow for better infiltration of cells in between the collagen particles as compared to sheet.

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