

Original Research Article

Clinical study of sterile collagen (Biofil) particles in the management of chronic non healing ulcers and their comparison with saline dressings

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ABSTRACT

Background: Chronic non healing ulcers are a challenge to the patient and health care professional. They require special care and intensive treatment often for prolonged periods. These ulcers do not generally heal with conventional types of treatment within a reasonable time period and need special types of treatment like collagen particles, vacuum dressing, chemical debridement etc. The aim of the study was to compare the effect of sterile collagen particles with saline dressings in treatment of chronic non healing ulcers.

Methods: 30 test subjects were dressed using sterile collagen particles and 30 controls using saline gauze on day 2 and every 3rd day. The condition of the ulcer was followed up using the Bates-Jensen wound assessment score (BJWA score).

Results: BJWA score was significantly lesser at 4th week in test group. The p value was 0.00021. Test group mean score was 17.23 and for control group it was 21.467. BJWA score was significantly lesser even at 8th week in Test group. The p value was 0.00026. Test group mean score was 12.47 and control group it was 17.43. This signifies that healing rate is better in test group compared to control group.

Conclusions: Comparing the components in BJWA score we can conclude from our study that; collagen dressings are superior to saline dressing in all type of ulcers and irrespective of gender and age of a person. The best response was seen in non diabetic ulcer without Saphenofemoral incompetence who are non smokers.

Keywords: Collagen particles, Chronic ulcers, Bates-Jensen wound assessment score

INTRODUCTION

Ulcer is a break in the continuity of covering epithelium, skin or mucosa either following molecular death or traumatic removal¹. Chronic non healing ulcers are the ulcers which persist more than 6 months without any tendency towards healing.² Collagen (Biofil) particles with human growth hormone are used in the dressings of these wounds and their effects on wound healing have been evaluated.³ In this study we evaluate the effects of sterile heterologous collagen particles in the treatment of

chronic non healing ulcers and compare them to saline dressings.

METHODS

Study design

Prospective randomized control study with total 60 subjects 30 patients test subjects and 30 patients control subjects.

Study period

Study was conducted for the period of one year i.e. September 2018 to September 2019 at Dr. D. Y. Patil Hospital.

Inclusion criteria

This study includes venous, post traumatic, burns, decubitus and diabetic ulcers of duration more than two months, age group >18 yrs, single ulcers of size less than 8x6 cm, Hba1c levels <10 with normal arterial color doppler.

Exclusion criteria

Infected ulcers not taking any treatment/malignant ulcers/ulcers in patients having other malignancies, non consenting patients, uncontrolled diabetes, arterial insufficiency, poor nourishment, haemoglobin <9 g/dl,

with osteomyelitis, HIV and all hepatitis viruses were excluded.

Sampling technique and procedure

All subjects meeting the above criteria were considered and divided into tests and controls alternately. The test subjects were dressed using sterile collagen particles and controls using saline gauze. The dressings changed on day 2 and 3. Bilateral lower limb arterial and venous doppler was done. Compression stockings were given for those with venous insufficiency. All infected cases were debrided and irrigation done before including in the criteria. The progression of the ulcer was assessed at 4th week and 8th week and the necessary statistics were analysed using SPSS version 20.0. Informed and written consent of all patients was taken. Biofil particles were sprinkled sufficiently to cover the surface of the wound. The condition of the ulcer was followed up using BJWA score.⁴ Ethical approval was obtained for the study.

Table 1: Bates-Jensen wound assessment score to assess the condition of ulcer and follow its progression.

Item	Assessment	Day 0	4 th week	8 th week
Size	0=Healed 1=Length x width <4 sq cm 2=Length x width 4-<16 sq cm 3=Length x width 16.1-<36 sq cm 4=Length x width 36.1-<80 sq cm 5=Length x width >80 sq cm	-	-	-
Depth	0=Healed ulcer 1=Non-blanchable erythema on intact skin 2=Partial thickness skin loss involving epidermis &/or dermis 3=Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/or mixed partial and full thickness &/or tissue layers obscured by granulation tissue 4=Obscured by necrosis 5=Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures	-	-	-
Edges	1=Indistinct, diffuse, none clearly visible 2=Distinct, outline clearly visible, attached, even with wound base 3=Well-defined, not attached to wound base 4=Well-defined, not attached to base, rolled under, thickened 5=Well-defined, fibrotic, scarred or hyperkeratotic	-	-	-
Undermining	1=None present 2=Undermining <2 cm in any area 3=Undermining 2-4 cm involving <50% wound margins 4=Undermining 2-4 cm involving >50% wound margins 5=Undermining >4 cm or tunnelling in any area	-	-	-
Necrotic tissue type	1=None visible 2=White/grey non-viable tissue &/or non-adherent yellow slough 3=Loosely adherent yellow slough 4=Adherent, soft, black eschar 5=Firmly adherent, hard, black eschar	-	-	-
Necrotic tissue amount	1=None visible 2=<25% of wound bed covered 3=25% to 50% of wound covered 4=>50% and <75% of wound covered 5=75% to 100% of wound covered	-	-	-

Continued.

Item	Assessment	Day 0	4 th week	8 th week
Exudate type	1=None 2=Bloody 3=Serosanguineous: thin, watery, pale red/pink 4=Serous: thin, watery, clear 5=Purulent: thin or thick, opaque, tan/yellow, with or without odour	-	-	-
Exudate amount	1=None, dry wound 2=Scant, wound moist but no observable exudate 3=Small 4=Moderate 5=Large	-	-	-
Skin color surrounding wound	1=Pink or normal for ethnic group 2=Bright red &/or blanches to touch 3=White or grey pallor or hypopigmented 4=Dark red or purple &/or non-blanchable 5=Black or hyperpigmented	-	-	-
Peripheral tissue edema	1=No swelling or edema 2=Non-pitting edema extends <4 cm around wound 3=Non-pitting edema extends >4 cm around wound 4=Pitting edema extends <4 cm around wound 5=Crepitus and/or pitting edema extends >4 cm around wound	-	-	-
Peripheral tissue	1=None present 2=Induration <2 cm around wound induration 3=Induration 2-4 cm extending <50% around wound 4=Induration 2-4cm extending >50% around wound 5=Induration >4 cm in any area around wound	-	-	-
Granulation tissue	0=Skin intact or 1=partial thickness wound 2=Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth 3=Bright, beefy red; <75% & >25% of wound filled 4=Pink &/or dull, dusky red &/or fills <25% of wound - 5=No granulation tissue present	-	-	-
Epithelialization	1=100% wound covered, surface intact 2=75% to <100% wound covered &/or epithelial tissue extends >0.5 cm into wound bed 3=50% to <75% wound covered &/or epithelial tissue extends <0.5 cm into wound bed 4=25% to <50% wound covered 5=<25% wound covered	-	-	-

RESULTS

The peak incidence of ulcer is at the age of 51-60 years. However, there is gradual fall in such cases subsequently (Table 2).

Table 2: Age distribution of the patients in test vs. control.

Age distribution (in years)	Test group	Control group
	N (%)	N (%)
31-40	1 (2)	1(2)
41-50	6 (12)	6 (12)
51-60	13 (26)	10 (20)
61-70	6 (12)	10 (20)
71-80	4 (8)	3 (6)

Table 3: Gender distribution in test vs. control.

	Test group	Control group
	N (%)	N (%)
Male participants	23 (76.67)	23 (76.67)
Female participants	7 (23.33)	7 (23.33)
P value	1	
Inference	Equal gender distribution was seen in both the groups	

Equal number of patients with 23 male patients and 7 female patients in each group took part in the study. The p value was non significant at 1. The study is male predominant at 76.67% (Table 3).

Table 4: BJWA score in test versus control at week 4 and 8.

	Test	Control
BJWA score-4 weeks^a		
Mean	17.23	21.467
Std dev	4.03	4.265
P value	0.00021	
BJWA score at week 8^b		
Mean	12.47	17.43
Std dev	4.76	5.1
P value	0.00026	

a,b: inference: BJWA score was significantly lesser at 4th week in test group.

BJWA score was significantly lesser at 4th week in Test group. The p value was 0.00021. Test group mean score was 17.23 and control group it was 21.467. BJWA score was significantly lesser at 8th week in Test group. The p value was 0.00026. Test group mean score was 12.47 and control group it was 17.43 (Table 4).

Table 5: Ulcer healing in test versus control.

Ulcers healed	Test	Control	Difference
4th week	1	0	1
8th week	10	6	4
Percentage of healed ulcers at end of study (%)	33.30	20	13.20

There was a difference of 13.20% of healing ulcer in the test group when compared to control. 33.30% of the patients in test group had healed ulcer at 8th week follow up whereas it was 20% in control group who received saline dressings (Table 5).

Table 6: Type of ulcer etiology in test vs control.

Type of ulcer	Test	Control
	N (%)	N (%)
Venous	7 (23.33)	9 (30)
Traumatic	3 (10)	2 (6.67)
Diabetic	20 (66.67)	19 (63.33)
Total	30 (100)	30 (100)

Diabetic ulcers were predominant type of ulcers in both the groups at 66.67% in test and 63.33% in controls. Venous ulcers were seen in 23.33% of test group patients whereas it was 30% in the control group. Traumatic ulcers were less predominately seen at 10% and 6.67% respectively in test and control groups. Diabetic foot ulcers require more number of debridements per ulcer compared to other types of ulcers. More number of debridements are required in control group compared to test group (Table 6).

DISCUSSION

Table 2 highlights the age distribution of patients in the study. It is to be noted that the peak incidence of ulcer is at the age of 51 to 60 years. However, there is gradual fall in such cases subsequently. Diabetes mellitus can set commonly in fourth to fifth decade of life. The rate of complications gradually increases and can peak in 6th decade of life.⁵

Alzahrani et al noted a high incidence of diabetic foot ulcers with a mean age of 56.9 years.⁶ Saraf et al conducted a study in India in patients with chronic non healing wounds and noted that majority of subjects were aged 30 to 59 years of age.⁷ They also observed that patients aged 50 and above had significantly delayed healing. This closely correlates with our study.

Table 7: Mean ages of chronic ulcers in various studies.

Study	Result - age of incidence of chronic ulcer
Alzahrani et al⁶	30-50
Saraf et al⁷	>40
Sethia et al⁸	52
Rao et al⁹	50.58
Our study	51-59

A study by Saraf et al noted epidemiology of non healing wounds in Indian subjects.⁷ They evaluated 100 patients of these 85 (85%) were male and 15 (15%) female (male to female ratio: 5.7:1). Sethia et al studied chronic venous ulcers and found that most of the patients were over 40 years of age.⁸ Rao et al evaluated 100 patients with foot ulcer and compared collagen and saline dressings and found the mean age of incidence of ulcers was 50.8 and that 75% of chronic ulcers were in males.⁹ In our study the male to female ratio was (3.29:1). It is to be noted that incidences of non healing ulcers is higher in males. Equal number of patients with 23 male patients and 7 female patients in each group took part in the study. The p value was non significant at 1. The study is male predominant at 76.67%.

Table 8: Studies comparing healing rates using collagen dressings versus saline dressings.

Study	Collagen dressings (%)	Saline dressings (%)
Datta et al¹⁰	75	60
Veves et al¹²	37	28
Singh et al¹³	87	80
Our study	33	20

Datta et al noted that collagen based dressing showed better results like faster wound healing, less usage of antibiotics and less symptoms such as pain and discomfort at site of ulcer.¹⁰ Chalimidi et al noted that dressing with collagen particles was effective in early

healing of chronic ulcer by formation of early granulation tissue and also by wound contraction.¹¹

There was difference of 13.20% of healing ulcer in the test group when compared to controls. 33.30% of the patients in test group had healed ulcer at 8th week follow up whereas it was 20% in control group who received saline dressings. This was corroborated by Datta et al, Veves et al noted a healing of 37% when dressing was done using collagen whereas it was 28.3% in those patients where moist gauze was used for dressing at 12 weeks of follow up.¹² Singh et al compared collagen dressings with conventional dressings and concluded collagen-treated wounds were rendered more sterile and healed better as compared to those treated with conventional dressings.¹³

BJWA score was significantly lesser at 4th week in Test group. The p value was 0.00021. Test group mean score was 17.23 and control group it was 21.467. BJWA score was significantly lesser at 8th week in test group. The p value was 0.00026. Test group mean score was 12.47 and control group it was 17.43.

CONCLUSION

The peak incidence of foot ulcer is between the ages of 51-60 years after which there is a decline. Ulcers are more common in males. BJWA scoring can be used as a useful adjunct in determining the condition of an ulcer and to follow up its progression. Venous ulcers are the most common ulcers followed by diabetic ulcers and diabetic foot ulcers required more number of debridements per ulcer compared to other types of ulcers. Finally comparing all the components in BJWA score we can conclude from our study that, collagen dressings are superior to saline dressing in all type of ulcers and irrespective of gender and age of a person. The best response is seen in non diabetic ulcer without SFJ incompetence who are non smokers and the worst response was seen in diabetic ulcers with SFJ incompetence who are smoker and with higher HbA1c levels.

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