



A COMPARATIVE ANALYSIS OF TOPICAL PLACENTAL EXTRACT GEL OVER CONVENTIONAL METHODS OF DRESSINGS FOR DIABETIC FOOT HEALING ULCERS AT A TERTIARY CARE CENTRE

General Surgery

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are among the most serious complications of diabetes mellitus and are associated with delayed wound healing, increased risk of infection, prolonged hospitalization, and lower-limb amputations. Conventional dressing methods provide wound protection and infection control but do not promote tissue regeneration. Human placental extract contains biologically active substances such as growth factors, cytokines, nucleotides, and polydeoxyribonucleotides that enhance angiogenesis, collagen synthesis, granulation tissue formation, and epithelialization. **Methods:** This study was conducted in a tertiary care center among 58 patients with DFU belonging to age group of 30-75 years. Patients were divided into: Group A (topical placental extract gel dressing, n = 29) and Group B (conventional dressing, n = 29). Baseline demographics were comparable between the groups. Wound healing was assessed weekly for six weeks using ulcer size, percentage wound contraction, granulation tissue percentage, and slough percentage. The requirement for additional procedures was also noted. Student's t-test was used for comparison of continuous variables, while Chi-square test or Fisher's Exact test was used for categorical variables, with $p < 0.05$ considered statistically significant. **Results:** The mean reduction in ulcer area was significantly greater in Group A compared to Group B. Patients in Group A showed earlier granulation tissue formation, faster wound contraction, and more rapid epithelialization. The difference between the two groups was statistically significant. **Conclusion:** Baseline demographics, were comparable between the two groups. At the end of six weeks, mean ulcer area was significantly lower in Group A. Percentage wound contraction and granulation tissue formation were significantly higher in Group A, while slough percentage was significantly lower. A significantly higher number of patients in Group A required no additional surgical procedure, due to worsening of the wound.

KEYWORDS

Diabetic Foot Ulcer; Placental Extract Gel; Wound Healing; Conventional Dressing; Granulation Tissue; Ulcer Area Reduction

INTRODUCTION

Diabetes mellitus is a major global health problem and one of the leading causes of chronic non-healing wounds worldwide. The pathogenesis of DFU is multifactorial and involves peripheral neuropathy, peripheral vascular disease, infection, impaired angiogenesis, and defective collagen synthesis.^{1,2} Sensory neuropathy leads to repeated unnoticed trauma, while ischemia and impaired microcirculation delay tissue repair and predispose to chronic wound formation.¹ In addition, hyperglycemia impairs leukocyte function, fibroblast activity, and growth factor expression, resulting in delayed wound healing and increased susceptibility to infection.³

Conventional dressing methods such as saline and gauze dressings focus on maintaining wound cleanliness and controlling infection, but they do not stimulate tissue regeneration/ enhance wound healing.⁴ Frequent dressing changes, prolonged healing duration, and increased risk of complications remain major limitations of conventional wound care.³

Recent advances in wound management have focused on the use of bioactive and biologically derived dressings that can actively promote angiogenesis, granulation tissue formation, collagen deposition, and epithelialization.⁵ Human placental extract has emerged as a promising biological material as it possesses angiogenic, anti-inflammatory, immunomodulatory, and regenerative properties that accelerate wound healing in chronic diabetic ulcers.^{6,7}

Topical placental extract gel has been reported to enhance fibroblast proliferation, improve local vascularity, stimulate collagen synthesis, and promote epithelialization, thereby improving healing outcomes in DFU.⁸ It is relatively cost-effective, easy to apply, and feasible in resource-limited settings.⁹

Hence, the present study was undertaken to compare the efficacy of topical placental extract gel dressing with conventional dressing methods in the management of diabetic foot healing ulcers.

METHODS

Study Design & Location

This prospective comparative study was carried out on patients of Department of General Surgery at Akash Institute of Medical Sciences and Research Centre, Devanahalli, Bengaluru, Karnataka from March 2024 to September 2025.

Study Population

A total 58 adult subjects of either gender, aged ≥ 18 years

Inclusion criteria:

1. Patients giving written and informed consent
2. Type 2 diabetic patients
3. Patients in General Surgery OPD and IP with ulcer size of the healing ulcer less than 8×8 cm.
4. Serologically negative patients
5. Wagner's classification of diabetic foot ulcers (Grade 1, 2 and 3)

Exclusion criteria:

1. Wagner classification of diabetic foot ulcers (Grade 4 and 5 wounds)
2. Patients with diabetic ketoacidosis
3. Immunocompromised patients
4. Type 1 Diabetes mellitus
5. Loss of follow up
6. Non-healing ulcer -diabetic foot ulcers.

Procedure

After obtaining clearance from the institutional ethics committee, the patients were enrolled as per the inclusion criteria after obtaining written informed consent. A short clinical history was obtained. A standardized dressing protocol was followed in all cases.

Dressing protocol- The patients selected had ulcers in their feet secondary to trauma or spontaneously developed ulcer. Patients were randomized into two groups, as

Group A (Placentrex gel)

Group B (Conventional dressing with dilute povidone-iodine and saline.) with 29 patients each. Randomization of subjects done by coin toss method where head - Group A and tails - Group B.

The healing of the ulcer was analyzed based on

1. the decrease in size of the ulcer from the first dressing to weekly size monitoring for 6 weeks.
2. Healthy granulation tissue formation
3. Slough reduction

Statistical analysis

Data entered into Microsoft excel data sheet and analyzed using SPSS 22 version software. Categorical data represented as Frequencies & proportions, and Continuous data as mean $\pm$ SD. Bar diagrams used for graphical representation. Chi-square test/ Fischer's exact test used as test of significance for Categorical data. Students t test as the test of significance for Quantitative data. Independent t test to compare mean between two groups or Mann Whitney U test for skewed distribution. p value <0.05 considered as statistically significant.

RESULTS

Demographic Profile.

The study included 58 patients with DFU, aged 30–75 years. Group A and Group B had similar average ages (53.4 vs. 51.8 years) as in Fig 1. Gender distribution (Group A: 55.2% male & 44.8% female, Group B: 62.1% male & 37.9% female), with no statistically significant differences. Therefore, age and gender were comparable between the groups and did not influence treatment outcomes.

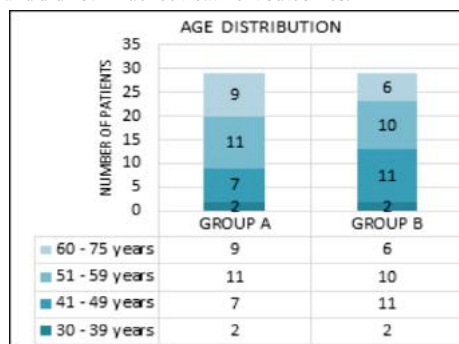


Fig 1: Age Distribution.

Comparison of Weekly Mean Ulcer Area.

It was done till 6 weeks, and the findings were noted as in the table given below (Fig 2). The comparison was done between the baseline and at the end of 6th week (Fig 3). The difference between 2 groups were statistically significant.

Time Interval	Placental Extract Group A (cm ²)		Conventional Dressing Group B (cm ²)		p value
	MEAN	SD	MEAN	SD	
Baseline	58.48	2.69	58.21	2.68	0.697
1st week	52.48	2.69	55.21	2.68	0.0003*
2nd week	44.48	2.69	51.21	2.68	<0.001 *
3rd week	36.48	2.69	46.21	2.68	<0.001 *
4th week	26.48	2.69	38.21	2.68	<0.001 *
5th week	16.48	2.69	30.21	2.68	<0.001 *
6th week	9.17	1.65	23.24	2.60	<0.001 *

Fig 2: Comparison of weekly mean ulcer area.

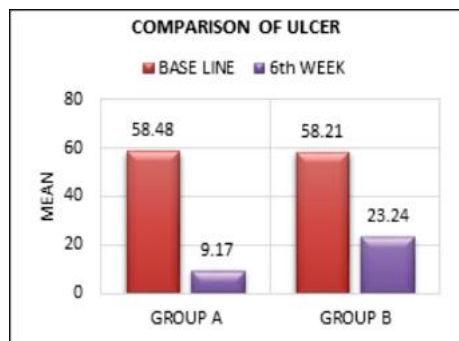


Fig 3: Comparison between baseline & 6th week.

Follow up after 6 weeks.

The Percentage wound contraction & Granulation tissue formation at the end of 6 weeks was significantly higher in Group A compared to the Group B ($p < 0.001$). The Mean slough percentage after 6 weeks was significantly lower in Group A compared to Group B. The difference was highly statistically significant ($p < 0.001$), using Independent t Test. (Fig 4)



Fig 4: Wound Healing

Requirement of Surgical Procedures.

As shown in Fig 5, the comparison for nil surgical procedure Group A was statistically significant ($p = 0.03$) than Group B. For wound debridement, there was no statistically significant difference between the 2 groups. For Disarticulation Group B had higher requirement that Group A with a statistically significant difference ($p = 0.04$).

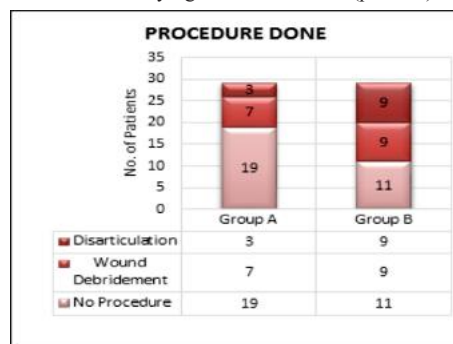


Fig 5: Procedure Done

DISCUSSION

This Prospective study demonstrates, comparable age distribution and gender distribution between Group A and Group B ensuring that it did not act as a confounding factor influencing wound healing outcomes. Since advancing age is known to impair wound healing due to reduced cellular regeneration and vascularity, the absence of a statistically significant age difference strengthens the validity of the observed treatment effects.

In the present study, Group A demonstrated significantly better wound healing outcomes compared to Group B. Patients treated with placental extract gel showed greater reduction in ulcer area, earlier granulation tissue formation, faster wound contraction, and improved epithelialization. These findings support the biological role of placental extract in enhancing tissue repair and accelerating wound healing.^{6,7}

The findings of the present study are comparable with those reported by Navadiya SK et al., who observed earlier granulation tissue formation and shorter duration of healing in patients treated with placental extract dressings compared to conventional dressings.⁷ Similarly, Vivek VJ et al. demonstrated significantly greater wound contraction and faster granulation tissue formation in the placental extract group.⁸ Chandanwale A et al. also reported improved wound healing outcomes and reduced wound induration with placental extract-based dressings.⁹

Another important finding of the present study was the reduced requirement for additional surgical procedures in Group A. Fewer patients required disarticulation or extensive debridement compared to Group B. Similar observations were reported by Navadiya SK et al.

and Vivek VJ et al., who noted improved wound bed preparation and reduced progression of diabetic foot ulcers with placental extract dressings.^{7,8}

No major adverse effects were observed in patients treated with topical placental extract gel, indicating that it is a safe and well-tolerated treatment modality. Its ease of application, cost-effectiveness, and biological activity make it a practical option for diabetic foot ulcer management, particularly in resource-limited settings.^{6,9}

Thus, the present study supports the growing evidence that topical placental extract gel dressing is superior to conventional dressing methods in promoting wound healing in diabetic foot ulcers.

CONCLUSION

1. Topical placental extract gel dressing was found to be more effective than conventional dressing methods in promoting healing of diabetic foot ulcers.

2. Patients treated with placental extract gel demonstrated a significantly greater and earlier reduction in ulcer area compared to those treated with conventional dressings.

3. The placental extract gel group showed faster granulation tissue formation, improved wound contracture, reduced slough, and better epithelialization than the conventional dressing group.

4. The use of placental extract gel was associated with a shorter duration of wound healing, fewer surgical interventions, and a lower incidence of disarticulation compared to conventional dressing methods.

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