

## Efficacy of total contact cast application versus conventional dressings in the management of plantar diabetic ulcers

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### Abstract

**Introduction:** Neuropathic ulcers are the prime precipitant of diabetes-related amputations of the lower extremity. Traditionally, diabetic foot ulcers are treated with regular dressings with frequent debridements with minimal weight bearing on the affected foot. The key element of any treatment programme designed to heal these wounds is effective reduction in pressure (offloading). **Materials and Methods:** This study was carried out in the Department of General Surgery, JSS Academy of Higher Education and Research, Mysuru, India from January 2020 to December 2020. This is an observational study and the data was collected prospectively. All diabetic patients with foot ulcers, who were admitted as in-patients, who gave consent, meeting the inclusion criteria were enrolled in the study. Patient's history, clinical, biochemical and radiological data were collected. **Results:** A total of 50 patients were included in the study. In that, the average age of patients in Group P was 55.6 years and in Group C was 57.8 years. Group P had 17 males and 8 females and Group C had 18 males and 7 females. Average duration of diabetes in Group P was 6.7 years and in Group C was 5.6 years. Mean HbA1c values of patients in Group C was 8.4% and in Group P was 8.3%; 73% of patients presented with ulcer secondary to trauma and in 27% of the patients the cause was unknown or had spontaneously occurred. **Conclusion:** Surgical debridement is the cornerstone of management of diabetic foot ulcers. Purified placental extract dressings showed faster and better healing rates when compared with conventional dressings.

**Key words:** Neuropathic ulcers, diabetic foot ulcers, Surgical debridement, HbA1c.

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### Introduction

Neuropathic ulcers are the prime precipitant of diabetes-related amputations of the lower extremity[1]. Traditionally, diabetic foot ulcers are treated with regular dressings with frequent debridements with minimal weight bearing on the affected foot. The key element of any treatment programme designed to heal these wounds is effective reduction in pressure (offloading)[2]. Approximately, 9% of the Indian urban population and 3% of the rural population is estimated to have diabetes. Foot ulceration is thought to affect 15% of people with diabetes at some time in their lives[3].

Several offloading devices are available, such as walkers, half shoes, orthoses, felted foam and the total contact casting (TCC)[4]. Total contact casts are anatomically conforming below knee cast with minimal padding.

TCC acts by providing protection from further trauma and deformity, reducing oedema, immobilization to help bone and soft tissue healing, offloading or redistribution of pressure and by providing protected weight bearing[5].

### Aims and Objectives

1. To compare the merits of topical placental extract over conventional dressing in diabetic foot ulcers.
2. To study the rate of wound healing in the two groups

### Materials and methods

This study was carried out in the Department of General Surgery, JSS Academy of Higher Education and Research, Mysuru, India from January 2020 to December 2020. This is an observational study and the data was collected prospectively. All diabetic patients with foot ulcers, who were admitted as in-patients, who gave consent, meeting the inclusion criteria were enrolled in the study. Patient's history, clinical, biochemical and radiological data were collected.

### Inclusion Criteria

- Type 1 and 2 diabetes mellitus.
- Diabetics between 18 - 75 years of age.
- Size of the ulcer less than 15 × 15 cm.
- Grade 1, 2 and 3 (according to Wagner classification - Table 1).

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**Exclusion Criteria**

- Patients treated on OPD basis.
- Tissue hypoxia (ischaemia, venous insufficiency), absent - dorsalis pedis, anterior and posterior tibial, and popliteal artery pulse.
- Grade 4 and 5 wounds (According to Wagner classification - Table 1).
- Patients with diabetic ketoacidosis.

The patients selected had ulcers in their foot secondary to trauma or had spontaneously developed the ulcer. Recruited patients were randomised to receive either topical application of human placental purified extract (PPE/placentrex) on the debrided wounds (Group P) or were debrided and dressed with dilute povidone iodine initially till the infection cleared and then with simple saline (Group C).

Grade Lesion 0 No open lesions: may have deformity or cellulitis 1 Superficial ulcer 2 Deep ulcer to tendon or joint capsule 3 Deep ulcer with abscess, osteomyelitis or joint sepsis 4 Local gangrene-forefoot or heel 5 Gangrene of entire foot Table 1. Wagner Classification System All patients were started on prophylactic antibiotics initially followed by targeted antibiotics according to culture sensitivity reports, long/short acting insulin for DM and analgesics/anti-inflammatory drugs. In the present study, all patient's glycaemic status was evaluated and were started on insulin according to sliding scale, initially followed by fixed doses when there was a good glycaemic control (long/short acting). Continuous variables were assessed with Wilcoxon Signed Rank Test and Student t-test. An intention to treat analysis was done and the value of significance was considered as  $< 0.05$ .

**Results**

A total of 50 patients were included in the study. In that, the average age of patients in Group P was 55.6 years and in Group C was 57.8 years. Group P had 17 males and 8 females and Group C had 18 males and 7 females. Average duration of diabetes in Group P was 6.7 years and in Group C was 5.6 years. Mean HbA1c values of patients in Group C was 8.4% and in Group P was 8.3%; 73% of patients presented with ulcer secondary to trauma and in 27% of the patients the cause was unknown or had spontaneously occurred.

**Table 1: The average age of patients**

S.No	Group	Average age
1	Group P	55.6 years
2	Group C	57.8 years

**Table 2: Average duration of diabetes**

S.No	Group	Average duration of diabetes
1	Group P	6.7 years
2	Group C	5.6 years

**Table 3: Mean HbA1c values**

S.No	Group	Mean HbA1c values
1	Group P	8.3 years
2	Group C	8.4 years

After dressing the wound, average time for complete granulation was 14.98 days in Group P, while 20.14 days in Group C. P value of this comparison was  $< 0.05$  (0.003), which is statistically significant suggesting better efficacy of placental extract dressing in diabetic wounds as compared to Group C.

Average area of the wound in Group C at the time of admission was 79.16 cm<sup>2</sup> and at the time of discharge the wound had contracted on an average to an area of 65.43 cm<sup>2</sup>, in Group P average area of the wound at the time of admission was 72.78 cm<sup>2</sup> and at the time of discharge the wound had contracted on an average to an area of 52.55 cm<sup>2</sup> which is statistically significant.

In Group P - 88% of patients were treated conservatively and 12% had Split Skin Grafting (SSG); while in Group C 62% of patients were treated conservatively and 38% had SSG. Rate of Wound Contraction (% Reduction) in Group P was 27.7% and in Group C was 17.3% which is significant. The average hospital stay was  $20 \pm 1$  days in Group P and  $25 \pm 1$  days in Group C. Purified placental extract (Placentrex) group had lesser hospital stay, lesser overall treatment time and faster wound healing.

**Discussion**

Lower Extremity Amputation (LEA) rate is 15 to 40 times higher in the diabetic patients. In 2002, the age-adjusted LEA rate among men was 7.0 per 1,000 persons with diabetes compared with the rate among women reported as 3.3 per 1000 persons with diabetes. In this study, men constituted more than 70% of the study population, probably due to more exposure to trauma[6].

Metabolic polyneuropathy predominantly affects the lower extremities. It is found in approximately 30% of diabetics and increases in prevalence with increasing duration of disease. Sensory involvement causes loss of sensation of pain and temperature, and subsequently perception of vibration. Because of this, diabetics are unable to detect changes in temperature, excess pressure produced by tight-fitting shoes or any other continued trauma. In this study 73% of the ulcers were traumatic in origin, trauma being the triggering factor secondary to neuropathy, 27% were spontaneous in origin secondary to blister rupture or unnoticed trivial trauma[7].

The majority of wounds are caused by Staphylococcus aureus, beta-haemolytic streptococci and other gram-positive cocci.

In this study first line of empirical antibiotics used were metronidazole, cephalosporin (Preferably 3rd generation) and amikacin. Targeted antibiotics were administered based on culture and sensitivity report[8].

Many techniques are available for wound dressing. All reduce infection and improve granulation growth. Povidone Iodine is routinely used as antiseptic solution. It is used initially for discharging wound in presence of infection and then dressing done with normal saline. Normal saline covers up the wound and provides a moist environment for healing[9].

Surgical management of diabetic foot ulcers is often required and includes aggressive incision, drainage and debridement of non-viable soft tissue and bone. Multiple debridements were necessitated among 1/3rd of the study population for the management of the diabetic foot ulcer[10].

**Conclusion**

Surgical debridement is the cornerstone of management of diabetic foot ulcers, all patients underwent surgical debridement first followed by daily dressings with topical agents. Purified placental extract dressings showed faster and better healing rates when compared with conventional dressings. Wound granulated faster in the study group. The final area and percentage reduction of the wound was better in placentrex group. There were no adverse effects or reactions noted in any of the patients when Placentrex gel was applied over the ulcer.

Very few studies have been done to test the efficacy of purified placental extract on foot ulcers; needs studies with larger study groups to test efficacy of placentrex on various wounds.

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