

## A Comparative Study Of Wound Healing With Polyurethane Foam Dressing And Saline Dressing In Diabetic Leg Ulcers

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**How to citation this article:** Dr. Nutan. B. V, Dr. M. Shridhar, “A Comparative Study Of Wound Healing With Polyurethane Foam Dressing And Saline Dressing In Diabetic Leg Ulcers”, IJMACR- January - February - 2021, Vol – 4, Issue -1, P. No. 218 – 226.

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**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

### Abstract

Diabetic ulcers are chronic wounds that pose a significant challenge to health care professionals and an immense burden on the economy. They also result in reduced quality of life and social isolation among patients. DFUs represent a current and important challenge in the development of novel and efficient wound dressings.

Patients admitted in the Department of Surgery at ESICMC & PGIMSR, Bengaluru, between Jan 2019 and June 2020 were source of data. 106 patients were included in this study, with 53 each in foam and saline dressing groups. Current standard of practice were followed including debridement, control of infection, glycemic control in both groups as per IWGDF guidelines. Mean age of the patients in foam group was 51 years and saline group was 48.1 years. Majority were males. Mean surface area of ulcer was 10.37 cm<sup>2</sup> and 9.72cm<sup>2</sup> in foam and saline dressing group respectively. Wounds were assessed for 12 weeks. The data was analysed using SPSS software

version 21. A p-value was taken as significant when <0.05.

There was no significant statistical differences in the reduction of slough and exudate (p-value 0.864), and appearance of granulation tissue (p-value 0.623). The mean surface area reduction in polyurethane foam group was 0.49cm<sup>2</sup>/week, whereas in saline group was 0.35cm<sup>2</sup>/week. 66 out of 106 ulcers showed complete closure at 12<sup>th</sup> week. There was increased proportion of complete closure of ulcers in 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 8<sup>th</sup> and 10<sup>th</sup> week in Polyurethane Foam group as compared to the normal saline group. The mean time taken for complete closure was longer in the saline group (11.2 weeks) as compared to the Polyurethane Foam group (10.7 weeks). Wound closure is the ultimate aim in diabetic ulcers. This study showed improved healing rates with foam dressings. Hence their implementation in the management of diabetic ulcers is recommended.

**Keywords:** Diabetic Ulcers, Polyurethane Foam Dressing, Saline Dressing

## Introduction

Ulcers and their management are fundamental in the practice of surgery. The prevalence of leg ulceration is approximately 3% to 5% in the older population aged 65 years and more.<sup>1</sup>

The words quoted by Luodon and published in 1805<sup>2</sup> very much summarize leg ulcer management, - "ulcers on the leg form a very extensive and important class of disease, the treatment of such cases is generally looked upon as an inferior branch of practice, an unpleasant and inglorious task where much labour must be bestowed and little honour gained."<sup>2</sup>

By definition, chronic wounds are wounds that have failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity over a period of three months.<sup>3</sup>

In the United States, it is estimated that 2 to 3 million patients per year are at a risk of developing diabetic ulcers.<sup>3</sup> These ulcers pose a significant challenge to health care professionals and an immense burden on the health care system and the economy. They also result in reduced quality of life and social isolation among patients.

Their origin is multifactorial and hence proper diagnosis of arterial, venous and neuropathic ulcers is essential if further compromise of the lower limb is to be avoided. Ulcers may appear similar, but upon closer inspection it becomes apparent that they are completely different entities.

Not only are lower limb ulcers of different etiologies but also ulcers have specific anatomic locations which by itself gives rise to special problems in their management. The presence of

diabetes mellitus impairs wound healing. In diabetic ulcers, there will be tissue ischemia and infection due to large vessel occlusion and end organ angiopathy. Also sensory neuropathy leads to repeated trauma and unrelieved wound pressure. The thickened capillary basement membrane decreases perfusion in the microenvironment, and elevated perivascular localization of albumin suggests increased capillary leak.<sup>3</sup>

VEGF upregulation in patients with diabetes is also impaired. Hypoxia is normally a potent upregulator of VEGF, but in diabetic patients VEGF expression is not upregulated in response to hypoxia.

Diabetics are susceptible to infection because of an attenuated inflammatory response, impaired chemotaxis and inefficient bacterial killing. Collagen degradation is increased, with impaired collagen deposition. Also collagen is brittle secondary to glycation. Collagen glycation diminishes focal adhesion formation between fibroblast and matrix resulting in decreased fibroblast migration.

Hyperglycemia also induces increased production of inflammatory molecules- TNF- $\alpha$ , IL-1, and interfere in collagen synthesis. High glucose exposure also results in changes in the cellular morphology, decreased proliferation, and abnormal differentiation of keratinocytes. Altered leucocyte infiltration and wound fluid IL-6 characterize the late inflammatory phases of wound healing.

There is abnormal expression of growth factors and rapid degradation in wound fluids, as a result of increased insulin degrading enzyme activity. Insulin degrading enzyme activity is positively correlated with HbA1c levels. There is increasing evidence that the resident cells in chronic wounds undergo phenotypic

changes that render them senescent and impair their capacity for proliferation and movement

Two critical points while selecting an appropriate wound dressing are absorption and occlusion. Studies have demonstrated that the rate of epithelialization under a moist occlusive dressing is twice as that of wound left uncovered and dry

Characteristics of an ideal dressing include- providing a moist environment, removal of excess exudate, prevention of desiccation, allowing gaseous exchange, impermeability to microorganisms, thermal insulation, prevention of particulate contamination, non-toxicity to beneficial host cells, mechanical protection, non-traumatic, easy to use and cost effectiveness.<sup>3</sup>

Clinical studies demonstrate that the exudate produced from wound in moist conditions stimulate keratinocyte proliferation and fibroblast growth with subsequent preservation of growth factors for wound repair. In the final stages of healing, epithelial cells divide and migrate at an increased rate in a moist environment to optimize the formation of new tissue in the wound. Epithelial cells need moisture to move across the surface of the wound and are inhibited in a dry environment. The optimum condition to promote wound healing is created in an isolated moist environment by application of moisture- occlusive or semi-occlusive dressings.

Occlusive dressings effectively seal the wound isolating it from the external environment to produce a hypoxic environment in the wound which stimulates wound bed revascularization and quicker healing.

In this study we compare saline soaked gauze dressing with polyurethane foam dressing. Mesh gauze dressing, the oldest type of dressing, loses its effectiveness when saturated, whereas the newer materials such as foam dressings, provide absorbent

quality for removing exudate and have a non-adherent quality which prevents disruption of newly formed granulation tissue on removal.

Also Saline dressings are cheap but traumatic and need frequent change of dressing. Polyurethane foam dressings are highly absorbent, decrease the wound maceration and reduce the frequency of dressing.

Diabetic complications have become a serious issue in India and the dramatic rise in the number of patients with diabetes has exacerbated this problem. However, awareness on serious health condition, namely, diabetic foot disease is inadequate among patients and healthcare providers .

Advances in the treatment modalities are likely to improve healing rates of diabetic ulcers and further implementation of moist wound healing will support this.<sup>4,5</sup> Hence the need for the study

### Results

Out of 106 patients, 49 patients were aged less than 50 years, and 57 patients were aged more than 50 years. The incidence of diabetic foot ulcers is more in elderly patients, with significant p-value 0.009. Out of 106 patients, 34 were females and 72 were males. Incidence is more in males. With statistically significant p-value <0.001.

Out of 106 patients, 28 patients had IDDM, and 78 patients had NIDDM, with no statistically significant difference i.e, p- value 0.475. Out of 106 patients, 23 patients had Grade 1 ulcers and 83 patients had Grade 2 ulcers, with no statistically significant difference. P-value 0.574. Out of 106 patients, 85 patients had dry to low exudate, 21 patients had moderate to high exudate, with no statistically significant difference with p-value 0.864.

Out of 106 patients, 77 patients had ulcer over the dorsum of the foot and 29 patients had ulcer over plantar aspect of foot. Out of 106 patients, 85 patients had granulation

tissue with slough and 21 patients had slough. The p-value was 0.623, with no statistical significant difference. The mean time to complete closure was higher in the Normal saline (11.2 weeks) as compared to the Polyurethane Foam group (10.7 weeks). There was no complete closure till 2<sup>nd</sup> week in both the Polyurethane Foam and Normal Saline group. There was increased proportion of complete closure in 3<sup>rd</sup> week, 4<sup>th</sup> week, 6<sup>th</sup> week, 8<sup>th</sup> week and 10<sup>th</sup> week in Polyurethane Foam group as compared to the normal saline group.

**Figures and Graphs**

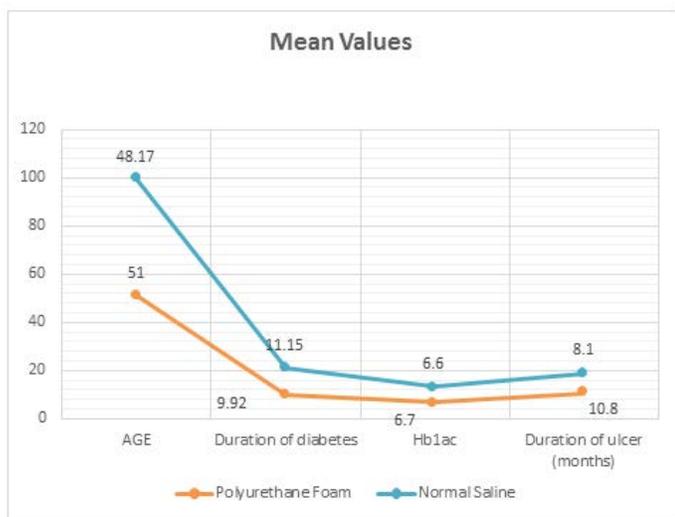


Figure 1 Complete Closure of Ulcer with Foam Dressing Application

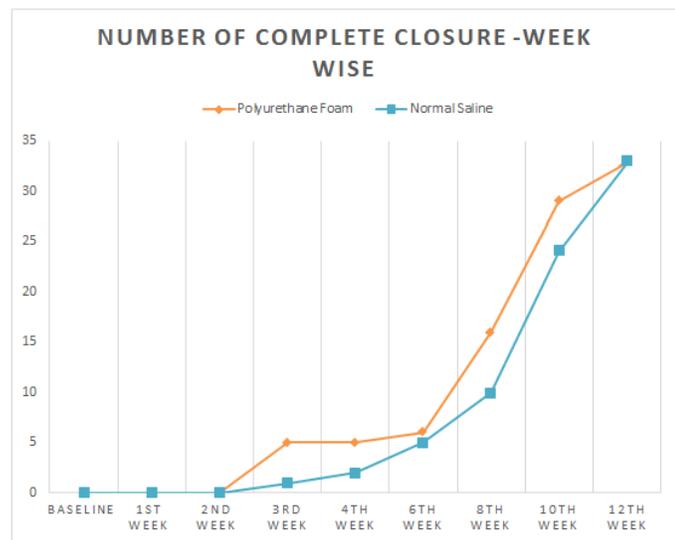
**Discussion**

The incidence of diabetes across the globe is high. There is also a rapid rise of diabetes across the world. 80% of the people with diabetes are from low and middle income nation.<sup>4</sup> This increase is believed to be due to increase in aging and growing populations, urbanization, family history, obesity, poor diet and sedentary lifestyles. In 2003, it is estimated that approximately 194 million people worldwide, or 5.1% in the age group 20-79, have diabetes.<sup>4</sup> This estimate is expected to increase to about 333 million or 6.3% in the adult population, by 2025.<sup>4</sup>

The prevalence of foot ulcers among people with diabetes is 4% to 10%, the annual population based incidence is 1% to 4.1%, and the lifetime incidence may be as high as 25%. These ulcers frequently get infected, cause great morbidity,



Graph 1



Graph 2

engender considerable financial costs, and are usually the first step leading to lower extremity amputation.<sup>5</sup> Those who develop a diabetic foot ulcer are at a greater risk of premature death, myocardial infarction and fatal stroke than those without a history of ulceration. Annual incidence of amputation ranges between 0.25% to 1.8%.<sup>6</sup> It is not only the financial costs to societies but equally as important are the costs to the patients that have a foot ulcer. Patients with diabetic foot ulcers are more likely to have depression.<sup>7</sup> Their quality of life is poorer.<sup>8</sup> People with a history of foot ulcers have a 40% greater mortality rate than those with diabetes alone.<sup>9</sup> Mortality following amputation is similar to the presence of a foot and is around 50% at 5 years.<sup>10</sup> It is a pivotal event in a person's life.

The risk factors for development of diabetic foot ulcers are neuropathy, peripheral vascular disease, foot deformity, present or previous diabetic foot ulcer, age, gender, social isolation, retinopathy and renal disease.<sup>11</sup>

In our study, out of 106 patients, 53 patients were included in foam dressing group and 53 patients in saline dressing group. The mean age of the patients was 51+/-8.481 years in foam dressing group, and 48.17+/- 8.187 years in saline dressing group. 46% of patients were aged less than 50 years, and 54% were aged more than 50 years overall (p-value 0.009). This is showing an increased incidence of diabetic ulcers with age. In foam dressing group 23 patients were females and 30 patients were males. Whereas in saline dressing group 11 were females and 42 were males. 31.8% of patients were females, and 68.2% were males overall (p-value <0.001). This male predominance is probably due to the reason that in our society males work outdoors

mostly and will be barefoot while working, thus are more prone to trauma. Besides, a lot of males smoke cigarette which impedes blood supply by increasing vasospasm, blood viscosity and hypercoagulability, thus predisposing to ischemic foot ulceration.

In our study, 28 patients had type 1 diabetes mellitus, and 78 patients had type 2 diabetes mellitus, corresponding to 26.4% and 73.4% respectively (p-value 0.475). Incidence of Type 2 diabetes mellitus is increasing rapidly, also it is the most common type of diabetes mellitus.<sup>4</sup> The mean duration of diabetes was 9.92+/-5.47 years in foam dressing group and 11.15+/-5.74 years in saline dressing group (p-value 0.34). The mean duration of ulcer was 10.85+/- 7.69 months in foam dressing group and 8.11+/-8.30 months in saline dressing group (p-value 0.069). The mean HbA1c levels were 6.72+/-0.32 in foam dressing group and 6.66+/-0.32 in saline dressing group (p-value 0.71).

In our study, Meggit Wagner's classification was used to assess the severity of diabetic ulcers. 23 patients had grade 1 ulcer and 83 patients had grade 2 ulcer (p-value 0.574). The limitations of this classification system is that it does not include PAD and infection, yet it is widely accepted classification system because of its simplicity and also it is well established. Other classification systems have come up over years such as University of Texas, SINBAD, PEDIS etc., University of Texas system includes infection and ischemia and is better classification than Wagner. SINBAD and PEDIS being other classification systems which are also being used.

In our study, 21 patients out of 106 had moderate to high exudative discharge from the ulcer and 85 patients had dry to low exudate (p-value 0.864). All ulcers required serial debridements under local

anaesthesia and IV antibiotics were administered as per culture sensitivity reports. 77 patients had ulcer over dorsal aspect of foot and 29 patients had ulcer over plantar aspect of foot (p-value <0.001). Diabetic foot ulcers are more common in the plantar aspect of foot. Dorsal aspect ulcers being the more predominant ulcers in our study.

The baseline mean size of ulcer was 10.37±5.24 cm<sup>2</sup> in foam dressing group and 9.72±5.23 cm<sup>2</sup> in saline dressing group. The ulcers were assessed weekly till 4<sup>th</sup> week and fortnightly thereafter till 12<sup>th</sup> week. The difference in Reduction in slough and exudate (p-value 0.864), formation of granulation tissue (p-value 0.623) between the two study groups were not found statistically significant in our study.

In our study, the mean surface area reduction was 0.49cm<sup>2</sup> per week in foam dressing group and 0.35cm<sup>2</sup> per week in saline dressing group. There was also increased proportion of complete closure of ulcers in 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 8<sup>th</sup> and 10<sup>th</sup> week in foam dressing group compared to saline dressing group. There was significant reduction in wound surface area in foam dressing group.

Our study showed longer healing time in saline dressing group compared to foam dressing group. The estimated mean time taken to heal was 10.4 to 10.9 weeks in foam dressing group and 11.03 to 11.47 weeks in saline dressing group.

Polyurethane Foam dressing provides a moist wound healing environment and thus aids in faster healing.

G Rayman et al, in their study “Sustained silver releasing foam dressing in the treatment of diabetic foot ulcers” investigated clinical performance and safety of a sustained silver releasing foam dressing, contreet foam in the treatment of diabetic foot ulcers. The relative ulcer area was reduced by a mean of 56% or by 56% in average in 4 weeks. Foam dressing showed good exudate management properties and was considered easy to use. Our study showed mean ulcer surface area reduction of 51% in average in 4 weeks.<sup>12</sup>

Lohmann. M et al, in their study “ Safety and performance of a new non-adhesive foam dressing for the treatment of diabetic foot ulcers ” studied the safety and performance of Biatain, non-adhesive foam dressing, and concluded that the dressing is safe and effective in the management of diabetic foot ulcers. Also showed results of considerable wound area reduction and prevented maceration, with 40% reduction in surface area by 6 weeks.<sup>13</sup>

J. L. Richard et al, in their study “Management of diabetic foot ulcers with a TLC-NOSF foam wound dressing” described that, at 12 week follow up, the mean surface area reduction was 62.7% and concluded that this foam dressing may help promote healing in diabetic ulcers.<sup>14</sup>

Similar studies conducted showed improved healing rates with moist wound healing environment.

Table 1: Comparison of Wound Healing With Other Studies

Studies	Median Ulcer Surface area reduction per week	Mean reduction in ulcer surface area at 6 <sup>th</sup> week	Mean reduction in ulcer surface area at 12 <sup>th</sup> week
G. Rayman et al	0.50cm <sup>2</sup> / week	56%	80.6%
Lohmann. M et al	0.51cm <sup>2</sup> / week	40%	81.8%
J. L. Richard et al	0.47cm <sup>2</sup> / week	38.2%	82.7%
Our study	0.49cm <sup>2</sup> / week	38.8%	80.3%

Foam dressing group showed better results compared to saline dressing group in our study.

**Conclusion**

Diabetic foot disease is a source of major patient suffering and societal costs. Patients presenting with diabetic ulcers must be assessed holistically to identify the underlying cause of ulceration.

The risk factors for the development of ulcers in foot and leg are **neuropathy, peripheral vascular disease, foot deformity**, history of present or previous diabetic foot ulcer.

Advancing age is also an important risk factor, incidence being more common in the **age group 40-60 years**.

Also higher prevalence is seen among **male gender**. Wound closure is the ultimate aim in diabetic ulcers and early intervention will promote this to occur. The two methodologies of dressings applied in this study thus help in assessing wound healing rates, with improved healing and **increased proportion of complete closure of ulcers seen in foam dressing group** compared to conventional saline dressings.

Polyurethane foam dressing are an excellent alternative to saline dressings because of the following reasons:

- Prevention of tissue dehydration and cell death
- Increased breakdown of dead tissue on the wound surface
- Interaction of growth factors on their target cells
- Accelerated angiogenesis
- Significant reduction in wound pain
- Less risk of infection
- Less scar tissue is formed resulting in better cosmetic appearance
- Removal of dressing is less traumatic and less painful
- Optimal wound healing environment
- Improved quality of life for the patient

This study has shown improved healing rates in diabetic ulcers with foam dressings. This also helps in reduced hospital stay and early return to work. Hence their implementation in the management of diabetic ulcers is recommended.

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#### Acknowledgements

I express my sincere thanks and profound gratitude to my guide, **Dr. M. SHRIDHAR**, Director Professor, Department of General Surgery, ESICMC & PGIMSR, Bengaluru, for his support, patience and guidance which helped me in completing this dissertation. I have been amazingly fortunate to have a teacher like him, who gave me the freedom to explore on my own and at the same time the guidance to recover when my steps faltered.

I am grateful to **Dr. JEETENDRA KUMAR. J. M**, Dean, ESICMC & PGIMSR, Bengaluru, and **Dr. LAKKANNA. S**, Director Professor & HOD, Department of General Surgery, ESICMC & PGIMSR, Bengaluru, for providing encouragement,

that made me more alert towards successful completion of this thesis.

I am also grateful for my teachers **Dr. LATHA. G. A,** **Dr.CHANDRAKANT KESARI,** **Dr. HEMANTH.S.GHALIGE,** **Dr.PREETHAM RAJ** for their constant criticism and support which helped me in improving my work.

I am also thankful to all my friends and colleagues, **Dr. Swaroop. C. P,** **Dr. SATISH. H. T,** **Dr.SHIVAKUMAR. M** , for the discussions, help and support which made me improve.

My earnest thanks to all those who helped me to carry out this work, especially my father Late Sri **VEERAPPA. B.S** , my mother, my elder brother, my seniors, my juniors, my patients, staff of ESIC Hospital, Medical Records Department and all those whom I failed to mention. **Dr. NUTAN. B.V.**

#### **Abbreviations**

- ATA - Anterior Tibial Arter
- C/S - Culture Sensitivity
- DFU - Diabetic Foot Ulcer
- DM - Diabetes Mellitus
- DPA - Dorsalis Pedis Arter
- FA - Femoral Arter
- IL-1,6 - Interleukin-1,
- IWGDF - International Working Group on Diabetic Foo
- PAD - Peripheral Artery Diseas
- PDGF - Platelet Derived Growth Facto
- PFD - Polyurethane Foam Dressin
- PTA - Posterior tibial Arter
- SD - Saline Dressin
- SSG - Split Skin Graftin
- TNF- $\alpha$  - Tumor Necrosis Factor alph
- VEGF - Vascular Endothelial Growth Factor