

TITLE PAGE

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**Title: Reduction Of Wound Surface Area And Healing Time In Diabetic Leg Ulcers: A Comparative Study Of Dressings At Tertiary Hospital**

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**ABSTRACT**

**Background:** Diabetic ulcers are chronic wounds that have failed to proceed through an orderly and timely reparative process. These ulcers pose a significant challenge to health care professionals and an immense burden on the economy. **Objective:** To assess wound healing with respect to reduction in slough and exudate, reduction in wound surface area and time taken to heal. **Materials and Methods:** This prospective study was conducted among patients admitted in the Department of Surgery at ESICMC & PGIMSR, Rajajinagar, Bengaluru, between January 2019 and June 2020. All these patients were allotted either groups, with 53 patients each in foam dressing group and 53 patients in saline dressing group using computer based randomization and study was carried out. **Results:** There was increased proportion of complete closure 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). **Conclusions:** 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. As majority of our patients belong to low socio-economic group this reduces their economic burden.

**Keywords:** wound healing, reduction in slough, exudate, wound surface area, time taken to heal

## Introduction

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>1</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>2</sup> Hence the need for the study.

**Materials and Methods:**

This prospective study was conducted among patients admitted in the Department of Surgery at ESICMC & PGIMSR, Rajajinagar, Bengaluru, between January 2019 and June 2020. Ethical clearance was taken from institutional ethical committee. The cases were taken up for study on admission and after obtaining Informed written consent. Duration of study was January 2019 to June 2020

**Inclusion criteria:**

1. Diabetics between age 18 and 60 years
2. Diabetic footulcers
3. Wagner's grade 1 or 2
4. Wound surface area more than 4cm<sup>2</sup> but less than 20 cm<sup>2</sup>
5. Palpable Dorsalis pedisartery/ Anterior tibialartery/ Posterior tibial artery

**Exclusion criteria:**

1. Wagner's grade 3 or 4
2. Osteomyelitis of underlying bone
3. Exposed underlying bone
4. HbA1c more than 7.5

Patients satisfying the above criteria were enrolled in the study after taking informed written consent. All the patients were evaluated with thorough history, clinical examination and investigations.

**Methodology:**

Data was collected using a pro-forma meeting the objectives of the study. Detailed history, clinical examination and necessary investigations were undertaken. The purpose of the study was explained to the patient and informed written consent was obtained.

Two groups were divided and current standard of practice were followed including serial debridement, control of infection using appropriate antibiotics as per wound swab & pus culture and sensitivity report, glycemic control with insulin, and adequate pain relief in both groups as per IWGDF (International Working Group on Diabetic Foot) Guidelines 2019.<sup>3</sup>

In saline dressing group, saline soaked gauze dressing was applied over ulcer and dressing was changed on daily basis, sometimes twice daily, depending on soakage, for 2 weeks and alternate day dressing was done thereafter.

In foam dressing group, polyurethane foam dressing was applied over the ulcer and dressing was changed once in 2 days for 2 weeks and biweekly dressing was done thereafter.

Wound size was assessed using serial photographs and sterile paper scales. Granulation tissue formation, reduction in slough and exudate, and pain, reduction in wound surface area, time taken to heal were assessed.

Dressings were done till the patients were discharged. Patients were discharged from the hospital after significant reduction in ulcer size and formation of healthy granulation tissue. Later patients were instructed to follow upon OPD basis. Patients were followed up for 12 weeks, weekly till 8 weeks and fortnightly till 12 weeks and data was collected.

### **Sample size estimation:**

Sample size was calculated using G\*power software, version 3.1.9.2 as: power of study = 80%, relative precision of +/- 5%, CI = 95% and attrition of 5%, the sample size calculated was 106, 53 in polyurethane foam dressing and 53 in saline dressing.

106 patients were included in this study after taking informed written consent.

All these patients were allotted either groups, with 53 patients each in foam dressing group and 53 patients in saline dressing group using computer based randomization and study was carried out.

### **Statistical analysis:**

The data was analysed using Statistical Package for Social Science (SPSS) software version 21. The data was analysed for descriptive statistics like frequency, percentage, mean and standard deviation. Chi Square Test was used to assess the statistical significant difference. A p-value was taken as significant when  $<0.05$ .

**Results:** 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.

TABLE 1: SITE OF THE ULCER

		Group			Chi square	P-value
		Normal Saline	Polyurethane Foam	Total		
<b>Dorsal</b>	Count	47	30	77	15.756	<0.001
	% of Total	43.5%	28.5%	72.9%		
<b>Plantar</b>	Count	6	23	29		
	% of Total	6.5%	21.5%	27.1%		
<b>Total</b>	Count	53	53	106		
	% of Total	50.0%	50.0%	100.0%		

TABLE 2: ULCER FLOOR

		Group			Chi Square	p-value
		Normal Saline	Polyurethane Foam	Total		
<b>Granulation with slough</b>	Count	44	41	85	0.854	0.623
	% of Total	41.1%	38.3%	79.4%		
<b>Slough</b>	Count	9	12	21		
	% of Total	8.9%	11.7%	19.6%		
<b>Total</b>	Count	53	53	106		
	% of Total	50.0%	50.0%	100.0%		

		Group			Chi square	p-value
		Polyurethane foam	Normal saline	Total		
<b>Dry</b>	Count	21	20	41	2.576	0.097
	% of Total	19.6%	18.7%	38.3%		
<b>Normal</b>	Count	23	21	44		
	% of Total	21.5%	19.6%	41.1%		
<b>Macerated</b>	Count	9	12	21		
	% of Total	8.9%	11.7%	19.6%		
<b>Total</b>	Count	53	53	106		
	% of Total	50.0%	50.0%	100.0%		

TABLE 3: SURROUNDING TISSUE

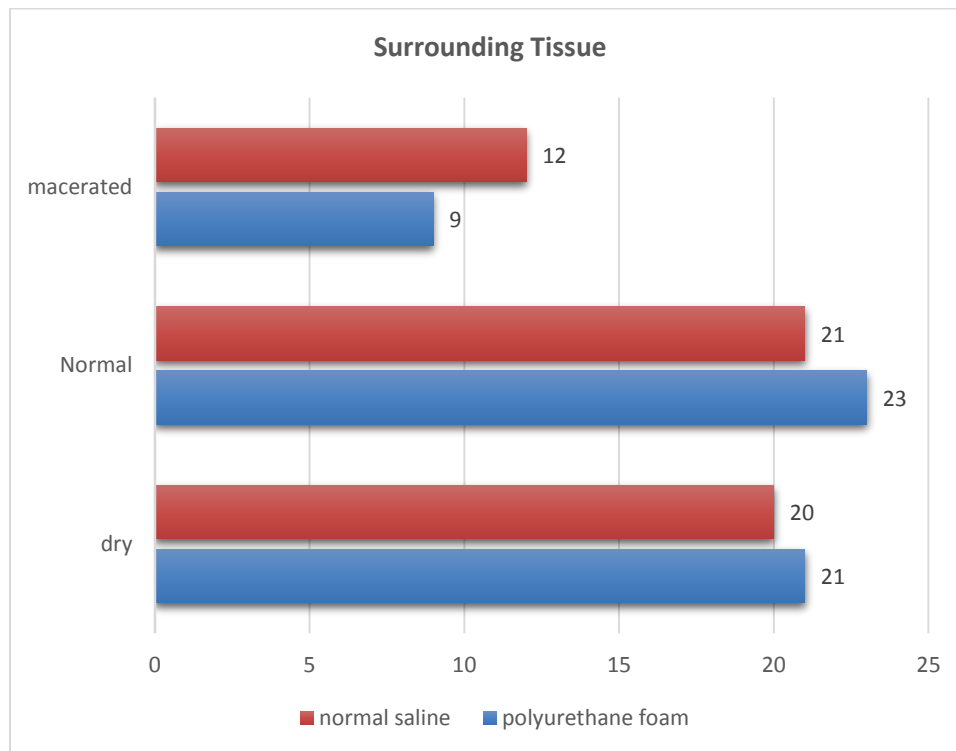
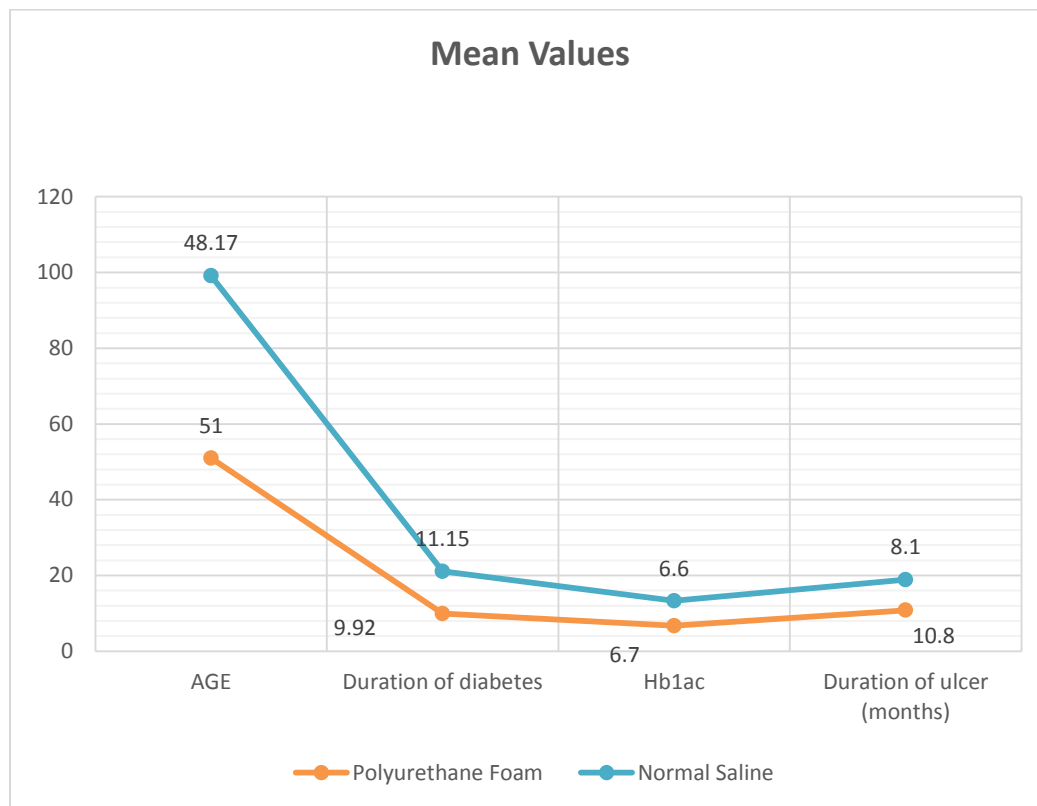


FIGURE 1: SURROUNDING TISSUE DISTRUBUTION

TABLE 4: MEAN DIFFERENCES BETWEEN GROUPS

	Group	Mean	Std. Deviation	Std. Error Mean	t-test	p-value
<b>AGE</b>	Polyurethane Foam	51.00	8.481	1.165	1.754	0.0845
	Normal Saline	48.17	8.187	1.125		
<b>Duration of diabetes</b>	Polyurethane Foam	9.92	5.477	.752	1.125	0.340
	Normal Saline	11.15	5.746	.789		
<b>Hb1ac</b>	Polyurethane Foam	6.724	.3111	.0427	1.074	0.711
	Normal Saline	6.665	.3189	.0438		

<b>Duration of ulcer (months)</b>	Polyurethane Foam	10.858	7.6989	1.0575	1.746	0.069
	Normal Saline	8.113	8.3082	1.1412		



**FIGURE 2: MEAN DIFFERENCES BETWEEN GROUPS**

**TABLE 5: MEAN SIZE OF ULCERS AT EACH FOLLOWUP**

	Group	Mean	Std. Deviation	N
<b>Baseline</b>	Polyurethane Foam	10.370	5.2496	53
	Normal Saline	9.713	5.2362	53
	Total	10.042	5.2283	106
<b>1st week</b>	Polyurethane Foam	9.357	4.7902	53
	Normal Saline	7.834	3.9828	53

	Total	8.595	4.4503	106
<b>2nd week</b>	Polyurethane Foam	7.840	4.4996	53
	Normal Saline	6.636	3.3758	53
	Total	7.238	4.0045	106
<b>3rd week</b>	Polyurethane Foam	6.475	3.9064	53
	Normal Saline	5.425	3.0937	53
	Total	5.950	3.5463	106
<b>4th week</b>	Polyurethane Foam	5.287	3.2297	53
	Normal Saline	4.326	2.9328	53
	Total	4.807	3.1078	106
<b>6th week</b>	Polyurethane Foam	4.355	2.8571	53
	Normal Saline	3.413	2.8521	53
	Total	3.884	2.8801	106
<b>8th week</b>	Polyurethane Foam	3.045	2.6444	53
	Normal Saline	2.430	2.5077	53
	Total	2.738	2.5832	106
<b>10th week</b>	Polyurethane Foam	1.783	2.2784	53
	Normal Saline	1.738	2.3222	53
	Total	1.760	2.2895	106
<b>12th week</b>	Polyurethane Foam	.896	1.5981	53
	Normal Saline	1.236	2.0787	53
	Total	1.066	1.8530	106

**SURVIVAL ANALYSIS: Cox Regression Model**



TABLE 6: NUMBER OF COMPLETE CLOSURE

Case Processing Summary				
Group	Total N	Complete closure	Censored	
			N	Percent
<b>Polyurethane Foam</b>	477	94	383	80.3%
<b>Normal Saline</b>	477	75	402	84.3%
<b>Overall</b>	954	169	785	82.3%

Table shows number of complete closure, based on the total number of follow-ups and number of patients in each group. Hence, total 9 follow-ups leads to the 477 lesions in both Polyurethane Foam and Normal Saline group. About 94 lesions were completely closed among Polyurethane Foam which was higher than 75 completely closed lesions in Normal saline group.



**FIGURE 3: COMPLETE CLOSURE OF ULCER WITH FOAM DRESSING APPLICATION**

**TABLE 7: MEAN TIME TAKEN FOR COMPLETE CLOSURE**

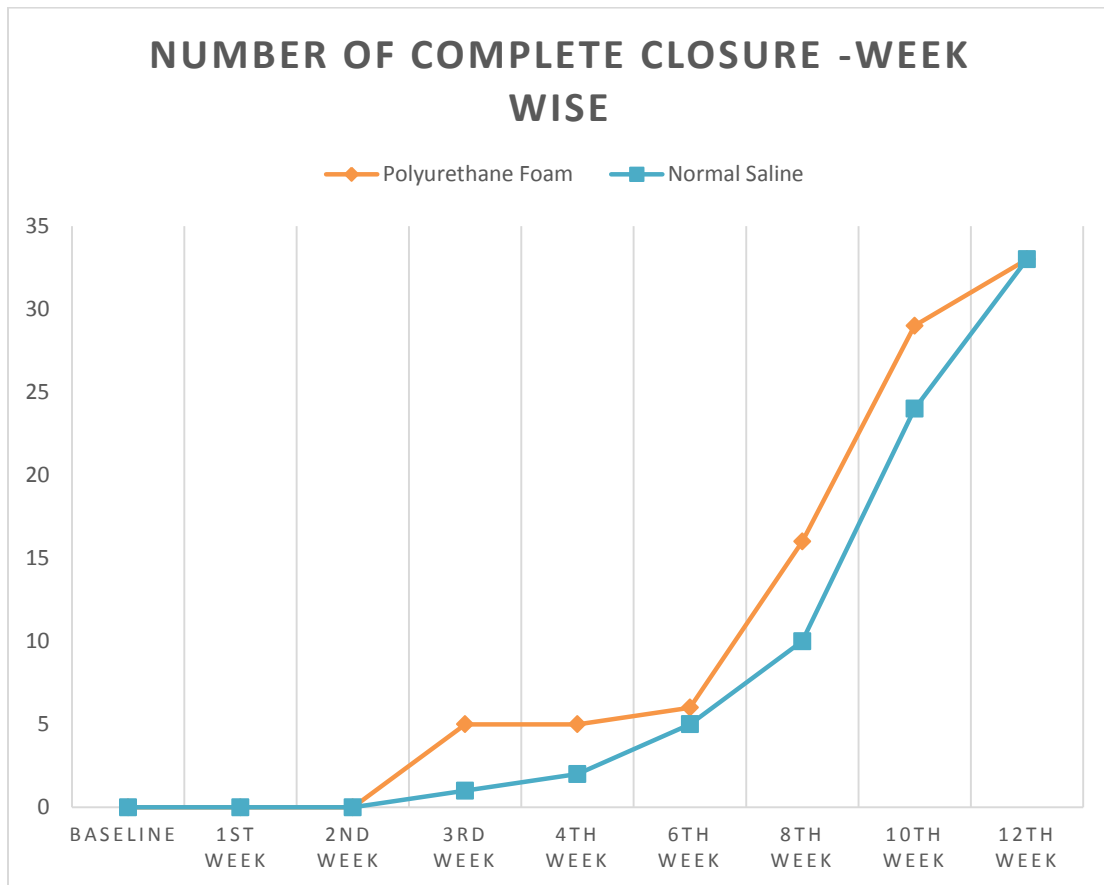
Group	Estimated Mean time to complete closure			
	Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
<b>Polyurethane Foam</b>	10.706	.145	10.423	10.990
<b>Normal Saline</b>	11.255	.112	11.036	11.474
<b>Overall</b>	10.978	.092	10.797	11.158

Table shows the estimated mean time to complete closure of the ulcer. 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).

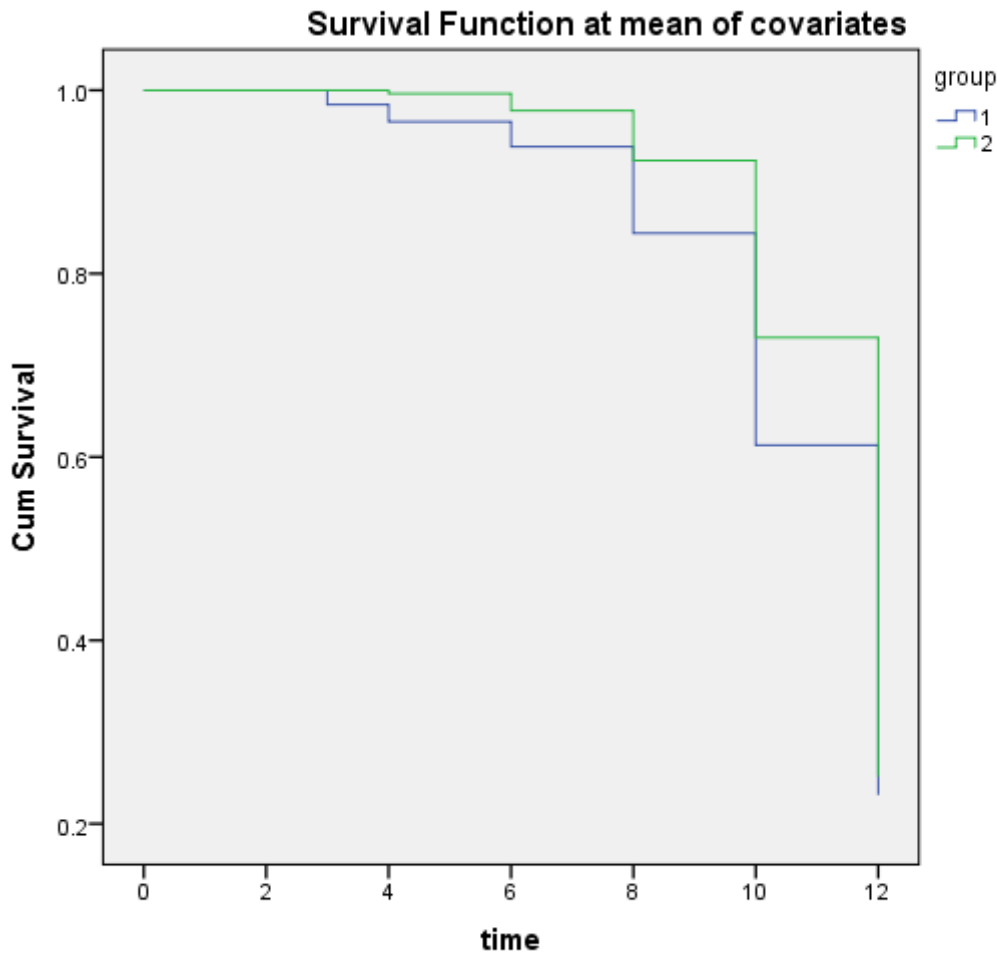
**TABLE 8: NO. OF COMPLETE CLOSURE OF ULCERS IN EACH GROUP WITH EACH FOLLOWUP**

	<b>Polyurethane Foam</b>	<b>Normal Saline</b>
<b>Baseline</b>	0	0
<b>1st week</b>	0	0
<b>2nd week</b>	0	0
<b>3rd week</b>	5	1
<b>4th week</b>	5	2
<b>6th week</b>	6	5
<b>8th week</b>	16	10
<b>10th week</b>	29	24
<b>12th week</b>	33	33

Table shows number of complete closure of ulcers in Polyurethane Foam and Normal Saline group with each follow up. 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. There was no significant difference between both the groups at 12<sup>th</sup> week.



**FIGURE 4: WEEK WISE COMPLETE CLOSURE OF ULCERS**



**FIGURE 5: SURVIVAL ANALYSIS- COX REGRESSION MODEL**

**Discussion:** The baseline mean size of ulcer was  $10.37 \pm 5.24 \text{ cm}^2$  in foam dressing group and  $9.72 \pm 5.23 \text{ cm}^2$  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  $0.49 \text{ cm}^2$  per week in foam dressing group and  $0.35 \text{ cm}^2$  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<sup>4</sup>, 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.

Lohmann. M et al<sup>5</sup>, 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.

J. L. Richard et al<sup>6</sup>, 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. Similar studies conducted showed improved healing rates with moist wound healing environment.

**TABLE 9: COMPARISION 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 <sup>4</sup>	0.50cm <sup>2</sup> / week	56%	80.6%
Lohmann. M et al <sup>5</sup>	0.51cm <sup>2</sup> / week	40%	81.8%
J. L. Richard et al <sup>6</sup>	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. Patients with diabetes and foot ulcer are suffering from a multiorgan disease with a complexity of factors related to outcome. PAD, infection of the foot and comorbidities are the most important factors predicting ulcer healing, major amputation and mortality.

Foot complications in patients with diabetes can be prevented and managed with an integrated, multidisciplinary approach. It requires the involvement of a chain extending from the chiropodist and general practitioner to the general surgeon, vascular surgeon and the rehabilitation specialists. Accurate diagnosis of the underlying cause is the first step towards a successful treatment plan. The most important intervention to prevent diabetic foot complications is early recognition of high risk patients and their referral to the multidisciplinary team. Prompt treatment decreases the risk of the fatal outcome i.e. amputation.

**Conclusion:**

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. As majority of our patients belong to low socio-economic group this reduces their economic burden. Hence their implementation in the management of diabetic ulcers is recommended.

**References**

1. Townsend CM, Beauchamp RD, Evers BM, Mattox KL. Sabiston textbook of surgery E-book. Elsevier Health Sciences; 2016 Apr 22.
2. Butcher M. Moist wound healing, exudate and management of the wound bed. *Journal of wound care*. 2010 May;19(Sup):10-3.
3. Lipsky BA, Senneville É, Abbas ZG, Aragón-Sánchez J, Diggle M, Embil JM, Kono S, Lavery LA, Malone M, van Asten SA, Urbančič-Rovan V. Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update). *Diabetes/Metabolism Research and Reviews*. 2020 Mar;36:e3280.
4. Rahman GA, Adigun JA, Fadeyi A. Epidemiology, etiology and treatment of chronic leg ulcer: experience with sixty patients. *Annals of African Medicine*. 2010;9(1).
5. Lohmann M, Thomsen JK, Edmonds ME, Harding KG, Apelqvist J, Gottrup F. Safety and performance of a new non-adhesive foam dressing for the treatment of diabetic foot ulcers. *Journal of Wound Care*. 2004 Mar;13(3):118-20.
6. Richard JL, Martini J, Farail MB, M'Bemba J, Lepeut M, Truchetet F, Ehrler S, Schuldiner S, Sauvadet A, Bohbot S. Management of diabetic foot ulcers with a TLC-NOSF wound dressing. *journal of wound care*. 2012 Mar;21(3):142-7