

**Effect of Topical Phenytoin with Normal Saline Dressing in Patients of Diabetic Foot Ulcers**Ekanta Apon Antarikshwa Sarma<sup>1</sup>, Jon Bordalai<sup>2</sup>, Damayanti Das<sup>3</sup><sup>1</sup>PGT 3<sup>rd</sup> Year, MBBS, Tezpur Medical College and Hospital, Tezpur, Assam, India<sup>2</sup>Associate Professor, Department of Surgery, Tezpur Medical College and Hospital, Tezpur, Assam, India<sup>3</sup>PGT 3<sup>rd</sup> Year MBBS, Tezpur Medical College and Hospital, Tezpur, Assam, India

Received: 01-11-2025 / Revised: 16-12-2025 / Accepted: 03-01-2026

Corresponding Author: Dr. Jon Bordalai

Conflict of interest: Nil

**Abstract**

**Introduction:** Chronic wounds, especially non healing types are one of the most common surgical conditions a surgeon comes across. One of the most feared complication of long term diabetes is loss of leg or foot. It has been estimated that one in five of all diabetic admissions to hospitals are for foot ulcers. The diabetic foot ulcers arrest in inflammatory stage of healing due to neuropathy, angiopathy and infections.

**Aims:** The aim of this study was to compare the effectiveness of topical phenytoin dressing with normal saline dressing in promoting healing of diabetic foot ulcers. It also aimed to evaluate associated outcomes such as infection rates and need for surgical intervention.

**Materials & Methods:** This hospital-based prospective randomized comparative study was conducted at Tezpur Medical College and Hospital from January 2024 to June 2025 and included 100 patients with diabetic foot ulcers.

**Result:** In our study secondary infection was significantly lower in the phenytoin group (6 patients, 12%) compared to the saline group (14 patients, 28%) ( $p = 0.04$ ). The need for surgical intervention was also less in the phenytoin group (4 patients, 8%) than in the saline group (11 patients, 22%) ( $p = 0.04$ ).

**Conclusion:** We concluded that topical phenytoin dressing is markedly more efficacious than regular saline dressing in the treatment of diabetic foot ulcers. Due to similar baseline characteristics across the two groups, the enhanced outcomes may be reliably ascribed to the intervention.

**Keywords:** Diabetic foot ulcer, Topical phenytoin, Granulation tissue, Surgical intervention.

**DOI:** 10.25258/ijcpr.18.1.106

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

**Introduction**

Chronic wounds, particularly non-healing varieties, are among the most prevalent surgical conditions seen by surgeons. One of the most dreaded complications of long-term diabetes is the loss of a leg or foot. It is estimated that one in five hospital admissions for diabetes are due to foot ulcers.[1] Historically, physicians have employed many treatments to heal these types of wounds. Diabetic foot ulcers stagnate in the inflammatory phase of healing due to neuropathy, angiopathy, and infections. The risk of lower extremity amputation is fifteen times greater in individuals with diabetes compared to those without. Fifteen percent of all diabetics get diabetic ulcers, with the most prevalent location being the foot.[2] The management of diabetic foot conditions presents a significant challenge. The pursuit of enhanced wound healing is one of the oldest challenges in medical practice. The management of wounds and wound dressings is a crucial component of diabetic

ulcer care, often overlooked. Wound care entails ulcer control, exudate management, and informed and judicious application of various dressing materials. The fundamental criteria for an optimal ulcer dressing include the maintenance of elevated humidity between the wound and the dressing; absorbency to eliminate excess exudate; non-adherence for painless removal during dressing changes; safety and acceptability to the patient (non-allergenic); facilitation of gaseous exchange while being impermeable to microorganisms; and cost-effectiveness.[3] In recent decades, numerous new dressings have been introduced. A cost-effective treatment plan for diabetic foot entails surgical debridement of the wound, enhancement of circulation via surgery or therapy, specialized dressings, and antibiotics. A variety of topical medications and gels are marketed for ulcers and wound healing. Few alternatives have demonstrated greater efficacy than saline wet to dry dressings.

Topical antiseptics, such as povidone-iodine, are generally seen as detrimental to the healing of wounds. Diabetic ulcers account for 50% of non-traumatic amputations. An examination of a novel strategy for treating these ulcers is necessary, focusing on cost-effectiveness and enhanced healing rates while reducing amputation rates. Certain trials using topical phenytoin have demonstrated a higher healing rate in chronic foot ulcers compared to standard bandages.[4] Patients with diabetic ulcers frequently experience impaired wound healing and infections, ultimately resulting in lower limb amputation. This study aimed to compare the efficacy of topical phenytoin dressings with regular saline dressings in facilitating the healing of diabetic foot ulcers. The objective was to assess related outcomes, including infection rates and the necessity for surgical intervention.

### Materials and Methods

**Type of Study:** A hospital-based prospective randomized comparative study.

**Place of Study:** Tezpur Medical College and Hospital.

**Study Duration:** January 2024 to June 2025.

**Sample Size:** 100 Diabetic foot ulcers patients.

### Inclusion Criteria

- Patients diagnosed with diabetes mellitus presenting with foot ulcers
- Age  $\geq$  18 years, of either gender
- Wagner grade I–III diabetic foot ulcers
- Ulcer duration of at least two weeks
- Patients willing to provide informed consent

### Exclusion Criteria

- Wagner grade IV and V ulcers
- Presence of osteomyelitis or malignancy in the ulcer
- Critical limb ischemia or severe peripheral vascular disease
- Known hypersensitivity to phenytoin
- Patients on immunosuppressive therapy or with severe systemic illness

### Study Variables

- Type of dressing used (topical phenytoin / normal saline)
- Ulcer size and duration
- Rate of wound healing
- Time to complete ulcer healing
- Presence of secondary infection
- Need for surgical intervention
- Duration of hospital stay

**Statistical Analysis:** Data were entered into Excel and subsequently analyzed using SPSS and GraphPad Prism. Continuous variables were summarized as means with standard deviations, while categorical variables were presented as counts and percentages. Comparisons between independent groups were performed using two-sample t-tests, and paired t-tests were applied for correlated (paired) data. Categorical data were compared using chi-square tests, with Fisher's exact test applied when expected cell counts were small. A p-value of  $\leq 0.05$  was considered statistically significant.

### Result

**Table 1: Baseline Demographic Characteristics**

Variable	Phenytoin Group	Normal Saline Group	p-value
Mean age (years)	56.4 $\pm$ 8.2	55.9 $\pm$ 7.9	0.74
Male (%)	34 (68%)	32 (64%)	0.67
Duration of diabetes (years)	9.6 $\pm$ 3.1	9.2 $\pm$ 3.4	0.58
HbA1c (%)	8.4 $\pm$ 1.1	8.5 $\pm$ 1.2	0.81

**Table 2: Baseline Ulcer Characteristics**

Parameter	Phenytoin Group	Saline Group	p-value
Mean ulcer area (cm <sup>2</sup> )	12.8 $\pm$ 3.6	13.1 $\pm$ 3.4	0.66
Ulcer duration (weeks)	6.2 $\pm$ 1.8	6.4 $\pm$ 1.9	0.61
Wagner Grade I–II (%)	38 (76%)	36 (72%)	0.64
Wagner Grade III (%)	12 (24%)	14 (28%)	0.64

**Table 3: Percentage Reduction in Ulcer Size over Time**

Time Interval	Phenytoin Group	Saline Group	p-value
2 weeks	32.5 $\pm$ 8.4	18.6 $\pm$ 7.9	<0.001
4 weeks	58.2 $\pm$ 10.3	36.4 $\pm$ 9.8	<0.001
6 weeks	78.9 $\pm$ 11.2	54.3 $\pm$ 10.6	<0.001

**Table 4: Mean Time to Appearance of Healthy Granulation Tissue**

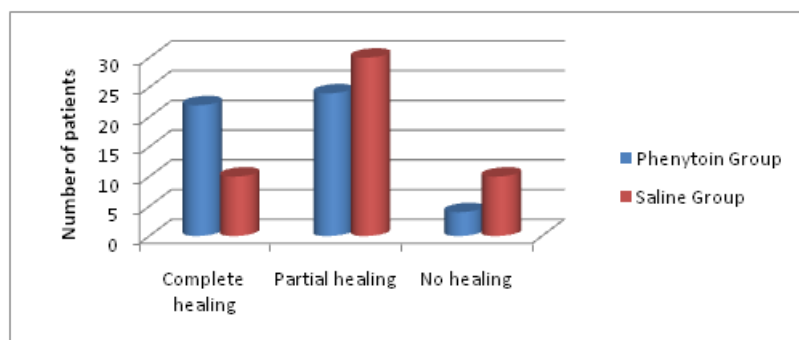
Group	Mean $\pm$ SD	p-value
Phenytoin dressing	9.4 $\pm$ 2.1	<0.001
Normal saline dressing	15.8 $\pm$ 3.2	

**Table 5: Wound Healing Outcome at 6 Weeks**

Outcome	Phenytoin Group	Saline Group	p-value
Complete healing	22 (44%)	10 (20%)	0.009
Partial healing	24 (48%)	30 (60%)	
No healing	4 (8%)	10 (20%)	

**Table 6: Complications and Secondary Outcomes**

Parameter	Phenytoin Group	Saline Group	p-value
Secondary infection	6 (12%)	14 (28%)	0.04
Need for surgical intervention	4 (8%)	11 (22%)	0.04
Average hospital stay (days)	14.2 $\pm$ 3.6	18.5 $\pm$ 4.1	<0.001

**Figure 1: Wound Healing Outcome at 6 Weeks**

In our study mean age of patients in the phenytoin group was  $56.4 \pm 8.2$  years compared to  $55.9 \pm 7.9$  years in the normal saline group ( $p = 0.74$ ). Males constituted 68% (34 patients) in the phenytoin group and 64% (32 patients) in the normal saline group ( $p = 0.67$ ). The mean duration of diabetes was  $9.6 \pm 3.1$  years in the phenytoin group and  $9.2 \pm 3.4$  years in the normal saline group ( $p = 0.58$ ). Mean HbA1c levels were  $8.4 \pm 1.1\%$  and  $8.5 \pm 1.2\%$  in the phenytoin and normal saline groups respectively ( $p = 0.81$ ). In our study the mean ulcer area in the phenytoin group was  $12.8 \pm 3.6$  cm<sup>2</sup>, which was comparable to  $13.1 \pm 3.4$  cm<sup>2</sup> in the saline group ( $p = 0.66$ ). The mean duration of ulcers was  $6.2 \pm 1.8$  weeks in the phenytoin group and  $6.4 \pm 1.9$  weeks in the saline group ( $p = 0.61$ ). Wagner grade I–II ulcers were observed in 76% (38 patients) of the phenytoin group and 72% (36 patients) of the saline group, while Wagner grade III ulcers were present in 24% (12 patients) and 28% (14 patients) respectively. The distribution of Wagner grades was similar between the two groups, with no statistically significant difference ( $p = 0.64$ ). At 2 weeks, the mean percentage reduction in ulcer size was significantly higher in the phenytoin group ( $32.5 \pm 8.4$ ) compared to the saline group ( $18.6 \pm 7.9$ ), with a highly significant difference ( $p < 0.001$ ). This difference became more pronounced at 4 weeks, where the phenytoin group showed a mean reduction of  $58.2 \pm 10.3$

versus  $36.4 \pm 9.8$  in the saline group ( $p < 0.001$ ). By 6 weeks, ulcer size reduction was  $78.9 \pm 11.2$  in the phenytoin group compared to  $54.3 \pm 10.6$  in the saline group, again demonstrating a statistically significant improvement with phenytoin treatment ( $p < 0.001$ ). The mean time to appearance of healthy granulation tissue was significantly shorter in the phenytoin dressing group ( $9.4 \pm 2.1$  days) compared to the normal saline dressing group ( $15.8 \pm 3.2$  days).

This difference was highly statistically significant ( $p < 0.001$ ). Complete healing was achieved in 44% (22 patients) of the phenytoin group compared to 20% (10 patients) in the saline group, and this difference was statistically significant ( $p = 0.009$ ). Partial healing was observed in 48% (24 patients) in the phenytoin group and 60% (30 patients) in the saline group. No healing occurred in only 8% (4 patients) of the phenytoin group, whereas a higher proportion of patients in the saline group, 20% (10 patients), showed no healing. Secondary infection was observed in 12% (6 patients) of the phenytoin group compared to 28% (14 patients) in the saline group, with this difference being statistically significant ( $p = 0.04$ ). The need for surgical intervention was significantly lower in the phenytoin group at 8% (4 patients) versus 22% (11 patients) in the saline group ( $p = 0.04$ ). Additionally, the average duration of

hospital stay was significantly shorter in patients treated with phenytoin dressing ( $14.2 \pm 3.6$  days) compared to those receiving normal saline dressing ( $18.5 \pm 4.1$  days), showing a highly significant difference ( $p < 0.001$ ).

### Discussion

We found that baseline characteristics, including age, gender distribution, duration of diabetes, glycemic control (HbA1c), ulcer size, duration, and Wagner grades, were comparable between the phenytoin and normal saline groups, confirming effective randomization and minimizing potential confounding factors. This ensured that differences observed in clinical outcomes could be attributed to the intervention. Topical phenytoin dressing demonstrated superior efficacy in promoting wound healing, consistent with previous reports. In our study, the mean percentage reduction in ulcer size at 2, 4, and 6 weeks was significantly higher in the phenytoin group ( $32.5 \pm 8.4\%$ ,  $58.2 \pm 10.3\%$ , and  $78.9 \pm 11.2\%$ ) compared with the saline group ( $18.6 \pm 7.9\%$ ,  $36.4 \pm 9.8\%$ , and  $54.3 \pm 10.6\%$ ;  $p < 0.001$ ), reflecting accelerated ulcer contraction. Shaw et al. (2011) similarly reported faster healing with topical phenytoin in diabetic foot ulcers [5].

Tabana et al. (2024) observed earlier granulation tissue formation in the phenytoin group, which aligns with our finding of a shorter mean time to healthy granulation tissue ( $9.4 \pm 2.1$  vs.  $15.8 \pm 3.2$  days;  $p < 0.001$ ) [6]. Vardhan et al. (2016) reported reduced hospital stay and improved healing outcomes with phenytoin [7], while Kanakapur et al. (2024) noted superior ulcer contraction and bacterial load reduction with phenytoin compared to conventional antiseptic dressings [8]. Earlier studies, including Ahmed and Ahmed (2014) and a 1992 clinical trial, also demonstrated enhanced healing rates with phenytoin-treated ulcers [9].

In our study, complete healing was achieved in a higher proportion of patients receiving phenytoin (44% vs. 20%;  $p = 0.009$ ), and rates of secondary infection (12% vs. 28%;  $p = 0.04$ ) and surgical intervention (8% vs. 22%;  $p = 0.04$ ) were significantly lower. Additionally, phenytoin-treated patients experienced shorter hospital stays ( $14.2 \pm 3.6$  vs.  $18.5 \pm 4.1$  days;  $p < 0.001$ ), highlighting its clinical and economic advantages.

### Conclusion

We concluded that topical phenytoin dressing is markedly more efficacious than regular saline dressing in the treatment of diabetic foot ulcers.

Due to similar baseline characteristics across the two groups, the enhanced outcomes may be reliably ascribed to the intervention. Patients administered topical phenytoin exhibited expedited ulcer size reduction, early emergence of healthy granulation tissue, and an increased rate of full healing. Furthermore, phenytoin dressing was linked to markedly decreased risks of subsequent infection and diminished necessity for surgical intervention. The reduced length of hospital stay noted in the phenytoin group indicates both clinical and economic advantages. Topical phenytoin is a safe, effective, and cost-efficient alternative to traditional saline dressings for enhancing wound healing in diabetic foot ulcers.

### Reference

1. Boulton AJ. The diabetic foot. Medical Clinics of North America. 1988 Nov 1;72(6):1513-30.
2. Most RS, Sinnock P. The epidemiology of lower extremity amputations in diabetic individuals. Diabetes care. 1983 Jan 1;6(1):87-91.
3. Mann CV, Russell RC, Bailey H, Love RJ. Bailey and Love's short practice of surgery. (No Title). 1995 Sep 20.
4. Muthukumarasamy MG, Sivakumar G, Manoharan G. Topical phenytoin in diabetic foot ulcers. Diabetes care. 1991 Oct 1;14(10):909-11.
5. Shaw J, Hughes CM, Lagan KM, Stevenson MR, Irwin CR, Bell PM. The effect of topical phenytoin on healing in diabetic foot ulcers: a randomized controlled trial. Diabet Med. 2011;28:1154-7.
6. Tabana C, ShaheenBanu A, Ganesan S. Evaluating the efficacy of topical phenytoin in the healing of neuropathic diabetic foot ulcers: a comparative study. Cureus. 2024;16:e63282.
7. Vardhan A, Garg P, Sehgal VK, Naidu CD, Bankar M, Mittal S. Efficacy of topical phenytoin in healing diabetic foot ulcers. Int J Basic ClinPharmacol. 2016;5(6):2645-8.
8. Kanakapur S, Hoogar P, Kumar PKH. A comparative study on wound healing with topical phenytoin 50 mg/ml and Betadine 10% as dressing agents in diabetic foot ulcers. J Neonatal Surg. 2024;14:32-8.
9. Ahmed A, Ahmed MI. A comparison of efficacy of topical phenytoin and Vaseline gauze dressing with Vaseline alone in healing diabetic foot ulcers. J Postgrad Med Inst. 2014;28(3).