Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2025.413066.4101 Volume 31, Issue 10 October. 2025
Manuscript ID:ZUMJ-2508-4101
DOI:10.21608/zumj.2025.413066.4101

ORIGINAL ARTICLE

# Effectiveness of Platelet-Rich Plasma in the Management of Chronic Diabetic Foot Ulcers.

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**Submit Date** 11-08-2025
**Accept Date** 06-09-2025

## ABSTRACT

**Background:** Diabetic foot ulcers (DFUs) are a dangerous side effect of diabetes that often leads to infection and amputation. Platelet-rich plasma (PRP) therapy is one promising strategy to enhance wound healing. This study aimed to evaluate the effectiveness of platelet-rich plasma (PRP) in treating chronic diabetic foot ulcers. **Methods:** This randomized controlled clinical trial was conducted at the Vascular Surgery Department, Zagazig University Hospitals, and included eighty patients with chronic DFUs who were randomly assigned into two groups: PRP treatment group (n=40) and conventional dressing group (n=40). Patients were followed for 12 weeks, and ulcer healing parameters, including healing area, rate of complete healing, and laboratory values, were assessed. **Results:** The PRP group demonstrated significantly larger healing areas at all follow-up points (p=0.01) and faster complete healing rates, with 70% achieving full healing by week 12 compared to 47.5% in the conventional group (p=0.01). Laboratory parameters, including Hb, PLT, albumin, and HbA1c, were comparable between groups. No adverse effects were reported. **Conclusion:** In addition to its defensive function, which lowers amputation rates, platelet-rich plasma (PRP) is a popular defense for healing chronic ulcers and reducing infection rates. For this reason, PRP is regarded as a very effective method for treating chronic ulcers, particularly diabetic foot wounds.

**Keywords:** Platelet-rich plasma, diabetic foot ulcers, healing wounds, and chronic ulcers

## INTRODUCTION

Diabetes mellitus is a growing global health concern with a rapidly increasing prevalence, posing significant burdens on individuals and healthcare systems alike. Diabetic foot ulcers (DFUs), which account for a significant amount of diabetes-related morbidity and death, are one of its most dangerous side effects. DFUs are the leading cause of lower limb amputations, accounting for up to 88% of non-traumatic lower leg amputations [1,2].

Between 4% and 10% of people are thought to have diabetic foot ulcers. with an annual incidence of approximately 1–4%. Alarmingly, People with diabetes have a 15% to 25% lifetime chance of getting a foot ulcer **[3].** Given these statistics, the primary goal in DFU management is to achieve rapid and complete wound healing, as delays significantly increase the risk of complications, including infections, gangrene, and eventual amputation.

Standard therapeutic approaches to DFU management typically include wound debridement, offloading of pressure, moist wound care, infection control, ischemia correction, and management of underlying comorbidities [4]. However, healing is often slow, and recurrence is common, prompting the search for more effective and advanced wound care options.

In recent years, platelet-rich plasma (PRP) has emerged as a promising adjuvant treatment for wounds. PRP is created by centrifuging a patient's own blood. an autologous concentration of platelets. It contains a rich mix of growth factors and fibrin, which are critical in promoting tissue regeneration and wound healing [5]. PRP was initially introduced in the 1980s and has since seen expanding use in specialties such oral-maxillofacial surgery, plastic surgery, and

orthopedic surgery. Its application in chronic wound healing, including DFUs, began gaining attention in the early 1990s [6].

By releasing locally active growth factors that promote neovascularization, platelets start the wound healing cascade, fibroblast proliferation, collagen synthesis, and epithelial regeneration. Additionally, by regulating cytokine activity, PRP has been demonstrated to lessen inflammation [7]. Additionally, PRP has antibacterial qualities against a variety of infections, such as Cryptococcus neoformans, MRSA, Candida albicans, and Escherichia coli [8].

As an autologous product, PRP carries a minimal risk of immune rejection and has a favorable safety profile, with only rare adverse effects such as mild local pain or infection at the injection site [9]. These characteristics make PRP a potentially valuable tool in enhancing the healing of chronic diabetic foot ulcers.

## AIM OF THE WORK

This study's objective is to assess how platelet-rich plasma (PRP) can be used to treat chronic diabetic foot ulcers, with particular focus on treatment outcomes, efficacy, incidence of postoperative complications, return to work, and its impact on patients' quality of life.

## METHODS

The Vascular Surgery Department at Zagazig University Hospitals carried out this randomized controlled clinical study from August 2023 to August 2024. All patients were monitored for a maximum of six months. All patients provided their informed permission before enrolling. The study protocol was approved by Zagazig University's Faculty of Medicine's Institutional Review Board (IRB# 10008-13/8-2023). The trial was conducted in accordance with the Declaration of Helsinki and the Code of Ethics for Human Research of the World Medical Association.

**Sample size:**

Based on previous data indicating using a power of 80% with a 95% confidence interval, the estimated sample size was 80 patients, with the PRP group showing a recovery rate of 84% compared to 52% in the conventional group.

Participants were randomly assigned into two equal groups (40 patients each) using a computer-generated randomization schedule. Group 1 received autologous PRP treatment, while Group 2 received conventional wound dressing.

Eligible patients included those diagnosed with type 1 or type 2 diabetes, with blood glucose adequately controlled by insulin or oral hypoglycemic agents. Only patients presenting with a chronic foot ulcer (present for at least 4 weeks) were incorporated. Ulcers that met the criteria for inclusion were given grades 1A or 1C by the University of Texas Treatment-Based Diabetic Foot Classification System. Furthermore, ischemic ulcer patients were considered if their ankle-brachial index (ABI) was 0.6 or higher.

Exclusion criteria were comprehensive and designed to eliminate confounding factors. Patients were excluded if they had ABI < 0.6, evidence of gangrene, or history of peripheral vascular repair within 30 days prior to enrollment. Additional exclusions included radiographic evidence of acute Charcot foot, suspected or confirmed osteomyelitis, ulcers smaller than 2 $cm^2$, clinically infected ulcers, or systemic signs of infection such as fever, pain, or erythema around the ulcer. Ulcers with exposed tendons, ligaments, or bone were also excluded. Patients were not eligible if they had received chemotherapy or radiotherapy in the preceding three months, had a platelet count of less than $100 \times 10^9$/L, hemoglobin less than 10.5 g/dL, and serum albumin less than 2.5 g/dL, or had any condition associated with immunodeficiency, liver disease, renal dialysis, malignancy, bleeding problems, collagen vascular disease, or hematologic disease. Failure to finish follow-up or inadequate venous access for blood collection were also regarded as exclusion grounds.

All participants underwent a standardized baseline assessment. A detailed medical history was obtained, including the duration of the current ulcer, symptoms suggestive of infection, and any relevant comorbidities. A thorough physical examination was performed, focusing on the characteristics of the ulcer and the general condition of the affected limb. Laboratory investigations included complete blood count (with emphasis on hemoglobin and platelet count), liver function tests, serum albumin levels, and glycated hemoglobin (HbA1c). Radiological assessment included plain X-rays of the foot to rule out osteomyelitis and arterial duplex ultrasonography to evaluate arterial patency and exclude significant occlusive disease.

**Management of patients**

All patients in both groups underwent standard initial wound management, including surgical debridement to remove necrotic tissue and debris, and to prepare the wound bed for optimal healing. The purpose of this phase was to provide consistent conditions for both groups and encourage the development of healthy granulation tissue. The University of Texas Classification System was used to record each ulcer's size (length, width, and depth) and grade at baseline.

Autologous venous blood was used to create platelet-rich plasma in the PRP group under sterile circumstances. Depending on the extent of the lesion, up to 20 mL of blood might be extracted. To prevent the platelets from activating and degranulating too quickly, the blood was drawn in tubes that contained an anticoagulant. Following a 7–10 minute soft spin centrifugation at 1000 rpm, the blood was separated into three layers: red blood cells (approximately 55% of the volume), platelet-poor plasma (PPP) at the top (approximately 40%), and a thin intermediate layer (approximately 5%) known as the "buffy coat." This layer contains concentrated platelets and leukocytes and is referred to as PRP.

The top two layers (PRP and PRP) plus a little, inevitable amount of RBCs were aspirated using a sterile syringe and moved into a second sterile tube devoid of anticoagulant. After that, a second centrifugation (hard spin) was carried out for ten minutes at 3000 rpm. Due to this process, the majority of the acellular PPP stayed at the top of the tube, while the platelets and a tiny quantity of RBCs settled at the bottom. After carefully removing around 80% of the PPP, the remaining PRP, now concentrated, was left at the tube's bottom.

In a sterile Petri dish, the PRP was gently combined with 0.1 mL of a 10% calcium chloride solution just prior to administration. The mixture was left to stand for 10–15 minutes, during which it formed a gel-like consistency suitable for topical application. The PRP gel was then applied directly to the debrided ulcer bed under sterile conditions.

In the control group, conventional dressing was applied after surgical debridement, following standard wound care protocols including moist wound healing principles, regular dressing changes, and offloading techniques as appropriate

**Post-Procedural Care**

Following debridement and initial management, patients in both groups received standardized wound care protocols tailored to the intervention received. Two complementary types of platelet-rich plasma were administered to the PRP group. To encourage local tissue regeneration and angiogenesis, activated PRP was first injected directly into the ulcer's base and margins. Second, PRP in gel foam form was applied topically to the ulcer surface to maintain a sustained release of growth factors and support wound healing. Dressings were changed twice weekly under sterile conditions. This procedure was followed for a maximum of 12 weeks or until the incision healed completely, whichever came first (Figure 1).

In the conventional dressing group, wound care consisted of irrigation of the ulcer using sterile normal saline, then applying a sterile dressing and petrolatum gauze. Additionally, dressing changes were done twice a week (Figure 2). Standard offloading strategies were applied in both groups to reduce plantar pressure and facilitate ulcer healing, particularly for ulcers located on weight-bearing areas of the foot. These measures included the use of appropriate footwear and walking aids when necessary, in accordance with established diabetic foot care guidelines.

Both groups were monitored regularly for signs of infection, healing progress, and any complications during the follow-up period. Either the ulcer's full epithelialization or the completion of the 12-week follow-up period served as the treatment protocol's endpoint.

**Follow-up and outcome assessment:**

All patients were followed up twice weekly for a total duration of 12 weeks or until the ulcer had fully healed, whichever came first. Every follow-up appointment included a clinical evaluation of the ulcer, including its length, width, and depth were measured using a sterile metric tape to evaluate the rate of healing over time. Baseline measurements were recorded at the initial visit, and subsequent measurements were documented consistently at each follow-up to monitor wound progression. The study endpoint was complete epithelialization of the ulcer or completion of the 12-week follow-up.

**Statistical analysis**

IBM SPSS Statistics for Windows, Version 27.0, was used to examine, code, and statistically analyze the gathered data (IBM Corp., Armonk, NY, USA). Statistical testing and data presentation were carried out according to each variable's distribution and type. The data

distribution's normality was evaluated using the Shapiro-Wilk test. The mean ± standard deviation (SD) or, when applicable, the median and range were used to express numerical variables. Frequencies and percentages were used to summarize categorical variables. Continuous variables between the two research groups were compared using the independent samples t-test for normally distributed data. Using the Chi-square test ($\chi^2$), associations between categorical variables were assessed. A p-value < 0.05 was considered statistically significant with a 95% confidence range.

## RESULTS.

Table 1 showed that the age of patients ranged from 50 to 65 years, with the conventional group's mean being 56.9 ± 5.7 years and the PRP group's being 58.6 ± 6.4 years (p = 0.2). The bulk of participants in both groups were male (62.5% in PRP vs. 70% in conventional), and there was no significant difference between the two groups (p = 0.8). Hypertension was the most common comorbidity, affecting 70% of the PRP group and 65% of the conventional group. About half of the patients in both groups were smokers. There were no appreciable differences between the groups in terms of ulcer characteristics (foot site and side) or risk factors.

The Hb level ranges from 9 to 13.5 mg/dl with a mean of 11.6 mg/dl in the PRP group and 12 mg/dl in the conventional group. PLT ranging from 230 to 280 with a mean of 250 in the PRP group and 266 in the conventional group. The mean Hb A1c was 8.7 in the PRP group and 8.4 in the traditional group, indicating no appreciable change between the groups. (Table 2).

Anthropometric data related to the ulcer on every parameter; there were no statistically significant differences between the two groups. The ulcer volume was 2 ± 0.3 $cm^3$ and 1.9 ± 0.5 $cm^3$, respectively (p = 0.5), and the mean ulcer area for the PRP group was 7.4 ± 1.5 $cm^2$, compared to 7.1 ± 1.3 $cm^2$ for the conventional group (p = 0.6). Additionally, the mean ABPI was comparable (Table 3).

Both groups demonstrated progressive healing over the 12-week follow-up period. However, the PRP group showed significantly greater healing areas compared to the conventional group at all time points, starting from week 1 through week 12. At week 12, according to the PRP group's mean healing area, it was 7.6 cm, while the conventional group's was 5.5 cm (p = 0.01) (Table 4).

Additionally, the PRP group experienced a much higher rate of full ulcer healing. By the eighth week, 10% (n=4) of PRP patients achieved full healing, while in conventional group complete healing was at 10th week, and at the end of the follow-up period 28 cases (70%) in PRP were healed completely while in conventional group 19 cases (47.5%) were healed completely, with a statistically significant difference (p = 0.01) (Table 5).

**Table 1:** Baseline demographic, clinical Risk factors, and ulcer-related characteristics of the studied groups:

| | | PRP | | Conventional | | P value |
|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | |
| **Age (years)** | | 58.6 | 6.4 | 56.9 | 5.7 | 0.2 |
| | | N | % | N | % | |
| **Sex** | **Male** | 25 | 62.5 | 28 | 70 | 0.8 |
| | **female** | 15 | 37.5 | 12 | 30 | |
| **Risk factors** | **HTN** | 28 | 70 | 26 | 65 | 0.7 |
| | **Smoking** | 22 | 55 | 20 | 50 | 0.5 |
| **Ulcer-related data** | | | | | | |
| **Foot** | **Rt** | 25 | 62.5 | 22 | 55 | 0.5 |
| | **Lt** | 15 | 37.5 | 18 | 45 | |
| **Site** | **Sole of the foot** | 28 | 70 | 26 | 65 | 0.7 |
| | **Dorsum of the foot** | 3 | 7.5 | 5 | 12.5 | |
| | **Toe amputation site** | 9 | 22.5 | 9 | 22.5 | |

Independent t-test; chi square test

**Table 2:** Laboratory data of studied groups:

| | PRP | | Conventional | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| HB (mg/dl) | 11.6 | 2.2 | 12 | 1.7 | 0.6 |
| PLT (×10 $^{9}$ /l.) | 250 | 18.6 | 266 | 15.3 | 0.8 |
| Albumin (g/dl) | 3.6 | 1.2 | 3.7 | 1.1 | 0.3 |
| HB A1c | 8.7 | 1.3 | 8.4 | 1.3 | 0.3 |

Independent T-test

**Table 3:** Ulcer Anthropometric data of studied groups:

| | PRP | | Conventional | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| ABPI | 0.81 | 0.12 | 0.82 | 0.11 | 0.8 |
| Area | 7.4 | 1.5 | 7.1 | 1.3 | 0.6 |
| Volume | 2 | 0.3 | 1.9 | 0.5 | 0.5 |
| Length | 3.9 | 1.3 | 3.8 | 0.7 | 0.9 |
| Width | 1.9 | 0.4 | 1.8 | 0.3 | 0.9 |

**Table 4:** Healing area of studied groups

| | PRP | | Conventional | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| 1$^{st}$ week (cm) | 0.5 | 0.01 | 0.3 | 0.01 | 0.01* |
| 4$^{th}$ week (cm) | 2.4 | 0.01 | 2 | 0.01 | 0.01* |
| 6$^{th}$ week (cm) | 3.5 | 0.1 | 3.1 | 0.1 | 0.01* |
| 8$^{th}$ week (cm) | 5 | 0.1 | 4.2 | 0.1 | 0.01* |
| 10$^{th}$ week (cm) | 6.4 | 0.1 | 4.9 | 0.1 | 0.01* |
| 12$^{th}$ week (cm) | 7.6 | 0.01 | 5.5 | 0.1 | 0.01* |
| P value | 0.01* | | 0.01* | | |

Independent t-test; * for significant

**Table 5:** Rate of complete healing of studied groups:

| | PRP | | Conventional | | P value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| 1$^{st}$ week | 0 | 0 | 0 | 0 | - |
| 4$^{th}$ week | 0 | 0 | 0 | 0 | - |
| 6$^{th}$ week | 0 | 0 | 0 | 0 | - |
| 8$^{th}$ week | 4 | 10 | 0 | 0 | 0.2 |
| 10$^{th}$ week | 15 | 37.5 | 6 | 15 | 0.01* |
| 12$^{th}$ week | 28 | 70 | 19 | 47.5 | 0.01* |

Independent t-test; * for significant

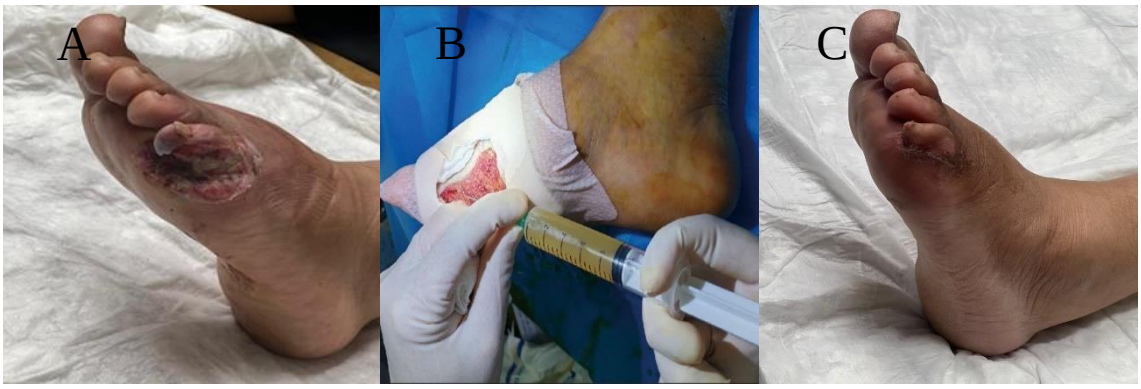


**Figure 1:** (A) chronic ulcer after debridement. (B) Platelet-rich plasma gel foam was applied on the surface of the ulcer. (C) complete healing with the ulcer.

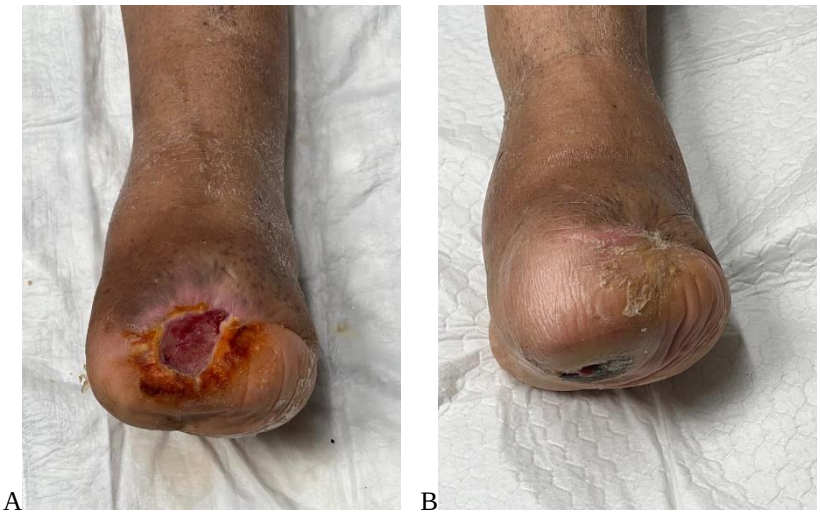


**Figure 2:** (A) chronic ulcer after debridement. (B) complete healing of the ulcer after conventional dressing.

## DISCUSSION

The current study showed that platelet-rich plasma (PRP) can effectively aid in the healing of diabetic foot ulcers (DFUs), alongside its preventive role in reducing infection rates and amputation risk. These findings are consistent with the systematic review and meta-analysis by de Leon et al. [10], study found that PRP had a positive impact on chronic wound healing and associated variables like pain and infection.

Eighty patients with chronic ulcers, ages 50 to 65, were enrolled in the study. The mean age of the conventional group was 56.9 years, while the PRP group was 58.6 years.

The majority of patients were males (62 vs 70%) and we found that age and gender had no effect on rate of healing in agreement with [11] .

40 patients in this research received subcutaneous injections of autologous PRP in and around the periphery of their wounds, whereas the remaining 40 patients received normal bandages made of antibiotics, saline, and local antiseptics.

According to a study by Saad Setta et al. [12], PRP patients demonstrated wound healing with a reduction in healing time when compared to standard dressing. The PRP group's healing was noticeably faster.

Kakudo et al. [13] Autologous PRP was used to treat five cases of intractable skin ulcers; three of these ulcers healed fully in 4 weeks, and the lesion epithelialized on average in 6.6 weeks.

In this study, the PRP group's weekly healing rate was higher for the first eight weeks and then began to decrease. After the first eight weeks, Ahmed et al. [14] demonstrated the similar idea of healing rate.

There were no discernible variations between the groups in laboratory parameters or ulcer anthropometric data at baseline, suggesting that the treatment method rather than confounding

variables is most likely responsible for the observed outcomes.

According to a recent meta-analysis, PRP therapy significantly healed ulcers in small, difficult-to-heal acute and chronic wounds and facilitated wound healing when compared to control wound care [15].

Additionally, platelets exhibit antibacterial action against some germs on the skin, and clinical data shows that the incidence of infection is reduced in wounds treated with PRP. As a result, PRP therapy offers a number of benefits that may offer a useful and successful therapeutic strategy for minor, difficult-to-heal ulcers [16].

Our sample's varied age distribution, particularly the fact that most of the participants are over 55, is consistent with the population's overall prevalence of diabetes and DFU. Our results are in line with research that indicates DFU primarily affects people in their fifth decade or older, even though studies report different mean ages [17].

The wide range of age groups that benefited from PRP was highlighted by the participants, whose mean age was 60.40 ± 9.72 years [18].

Positively, 70% of instances demonstrated successful ulcer repair, indicating that PRP treatment showed potential. This is consistent with research from Saudi Arabia and India, which reported 73.91% healing rates and 100% healing in all instances, respectively [19].

PRP's effectiveness in decreasing volume and weakening ulcers was supported by another trial that showed a good response in 63 out of 65 ulcers [16].

In a similar vein, research involving 24 patients who received a single PRP injection revealed that the wounds healed in 8.2 ± 1.9 weeks with a smaller size [20].

Due to its continuous success rates in multiple trials, PRP has been demonstrated to be a safe, simple, and cost-effective way to improve wound healing in a variety of non-healing ulcers.

Regarding the effectiveness rate of PRP in treating non-healing DFUs, many other researches have shown conflicting results [21]. Revealed an astounding 97.6% success rate in treating DFUs entirely with PRP injections.

Our results, however, were similar to those of Suthar et al., who showed that PRP injections had a 70.83% success rate in DFU patients who did not heal [20].

These varying success rates demonstrate the complexity of PRP therapy outcomes, suggesting that a number of variables may influence how well it suits specific patient groups. The significance of early PRP therapy treatment in predicting positive outcomes is highlighted by a noticeably faster response in patients with a shorter mean ulcer length [22].

According to studies, PRP is a useful and adaptable therapeutic approach for improving DFU healing, consistently working across a range of patient variables, including blood pressure, age, gender, and smoking status [22].

Our findings further support the potential efficacy of PRP in DFU repair, especially in an older population with diabetes and chronic obesity. Further study is necessary to evaluate and enhance targeted therapies in diabetic wound care.

Our research demonstrates that PRP therapy is a successful treatment for non-healing DFUs. The current study's findings provide credence to the use of PRP in DFU management plans. The goal of future research should be to improve the practical applicability and effectiveness of PRP in diabetic wound care by further validating these findings through bigger, standardized investigations.

While our findings support platelet-rich plasma (PRP) as an easy, affordable, and safe supplement to diabetic foot ulcer treatment (DFUs), several limitations must be acknowledged. First, although no major adverse effects were observed, the relatively small sample size and limited duration of follow-up may not have been sufficient to detect infrequent complications or rare adverse events. Second, the 12-week follow-up period was adequate for assessing short-term healing outcomes, but it was insufficient to evaluate long-term ulcer recurrence, durability of healing, or potential delayed complications. Third, despite efforts to standardize ulcer classification and treatment protocols, certain patient-related factors such as nutritional status, adherence to offloading strategies, and glycemic control may have influenced healing outcomes and introduced variability. Additionally, as with any clinical intervention, individual responses to PRP therapy may differ, and its effectiveness may not be uniform across all patient subgroups.

## CONCLUSION:

In addition to its defensive function, which lowers amputation rates, platelet-rich plasma (PRP) is a popular defense for healing chronic ulcers and reducing infection rates. For this reason, PRP is

regarded as a very effective method for treating chronic ulcers, particularly diabetic foot wounds.

**Conflict of Interest:** There are no conflicting interests, according to the authors.
**Financial Disclosures:** No specific grant from a public, private, or nonprofit funding organization was awarded for this study.
**Availability of the data:** On reasonable request, the corresponding author will provide the datasets created and/or examined during the current work.
**Author's contribution:** In addition to writing and getting the book ready for publication, the writers were in charge of gathering and analyzing the data. The final version was examined and approved by all authors.

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## Citation

**Salim, A., Tawfik, A., Mohammed Abdelghany, K., Ellithy Soliman, M. Effectiveness of Platelet-Rich Plasma in the Management of Chronic Diabetic Foot Ulcers.. *Zagazig University Medical Journal*, 2025; (4966-4973): -. doi: 10.21608/zumj.2025.413066.4101**