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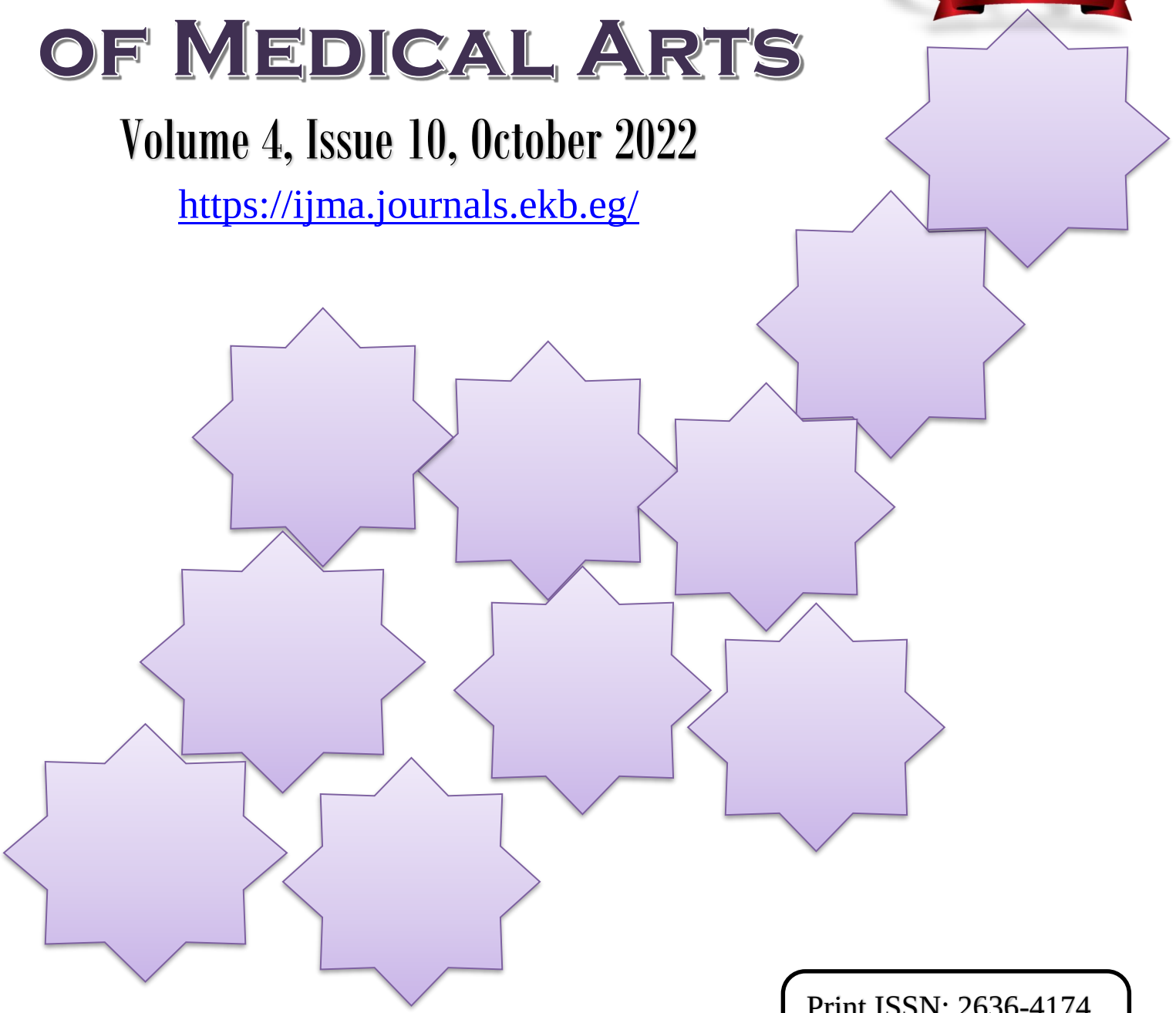

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Original Article

The Combination of Vacuum Assisted Closure Therapy and Platelet Rich Plasma for Management of Diabetic Foot Wound

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ABSTRACT

Background: Patients with diabetes foot wounds had a 2.5-fold higher risk of passing away than diabetic patients without foot wounds did**.** the development of a diabetic foot wounds is associated with a 5% mortality in the first 12 months and a 42% mortality within 5 years.

Aim of the work: The purpose of our study was to evaluate the combination of vacuum assisted closure therapy and platelet rich plasma for management of diabetic foot wound.

Patients and methods: This prospective study was conducted at New Damietta University Hospital and National Institute of Diabetic and Endocrinology at Cairo. This study was conducted on 30 patients diagnosed as diabetic foot wound and aim to evaluate the combination of Vacuum assisted closure therapy for two sections par week for two weeks and many patients need three weeks for complete granulation phase and Platelet Rich Plasma injected into wound two sections par week for two weeks for epithelization the wound.

Results: Regarding size, depth and discharge of wound on VAC size at baseline was 106.58 cm^2, depth of 10.7 mm and no discharge was observed. After 7 days, size was 100.58, depth was 7.03 mm and discharge were 172. In day 14, size decreased to 91.52 cm^2, depth was 3.87 mm and discharge reached 128.67. At day 21 Size was 92.57 cm^2, depth was 2 mm and discharge were 80.

Conclusion: Negative pressure wound therapy is a promising technique gaining rapid popularity in DFU management all over the world. Faster wound healing and shorter hospital stays are observed, with few or no problems. Consequently, it is effective in treating diabetic foot ulcers. PRP therapy is a method for increase the epithelized area of Diabetic Foot Ulcers faster and comfortable for patient compered to standard treatment in this time.

Keywords: Vacuum Assisted Closure Therapy; Platelet Rich Plasma; Diabetic Foot Wound.

INTRODUCTION

A metabolic illness with numerous etiologies known as diabetes mellitus is defined by persistent hyperglycemia and changes in the metabolism of carbohydrates, fats, and proteins as a result of problems with insulin secretion, action, or both. Diabetes mellitus causes long-term harm to, dysfunction in, and failure of a number of organs [1]. Typical signs and symptoms of diabetes mellitus include thirst, polyuria, blurred eyesight, and weight loss. Ketoacidosis or a non-ketotic hyperosmolar state may occur in its most severe stages, which can cause stupor, coma, and, in the absence of adequate treatment, death [2]. Diabetes is a serious health issue in various societies. According to published data, the prevalence of diabetes among those over 20 years old in Egypt has increased from 9.9% in 1995 to 10.2% in 2000 and is predicted to reach 13.3% in 2025 [3].

Unfortunately, foot ulcers caused by diabetes can affect up to 15% of diabetics. This is a result of numerous risk factors for diabetes, including microangiopathy, neuropathy, and immunopathy [4]. These figures are concerning since there is a clinically significant risk that diabetic foot sores will develop. According to a population-based cohort research conducted in the United Kingdom, developing a diabetic foot wound is linked to mortality rates of 42% within five years and 5% during the first year after the wound develops. In addition, it was discovered that patients with diabetes foot wounds had a 2.5-fold higher risk of passing away than diabetic patients without foot wounds did [5].

Other local physical techniques were therefore applied to promote wound healing [6]. Examples include the use of single growth factors such epidermal growth factor [EGF], VEGF, granulocyte-colony stimulating factors, and nerve growth factor as well as vacuum-assisted closure, high-voltage pulsed current electrical stimulation, and hyperbaric oxygen therapy [7].

By draining fluid from open wounds, preparing the wound bed for closure, lowering oedema, and encouraging the creation and perfusion of granulation tissue, negative pressure wound therapy [NPWT], a more recent non-invasive adjunctive therapy approach, helps enhance wound healing [8]. After an infection has been removed or an amputation has been performed, Charcot neuroarthropathy wounds caused by neuropathy and deformity, as well as in reconstructive soft tissue and osseous surgeries, can all be treated with NPWT [9].

It has been demonstrated that using VAC devices, which are commercially accessible sub-atmospheric pressure devices, is an efficient technique to quicken the healing of a variety of wounds [10]. PRP is made from the patient own blood, there's no chance of rejecting the cells. PRP injections also only carry minimal risks, such as infection, tissue damage or pain at the injection site [11].

The challenges face the patient with diabetic foot wound are coast of treatment of diabetes, coast of dressing for the wound, transport of patient from home to hospital and coast of this transport, bad habits to many patients that not accept bed ridding. The purpose of our study was to evaluate the combination of vacuum assisted closure therapy and platelet rich plasma for management of diabetic foot wound.

AIM OF THE WORK

Study question: Are Vacuum-Assisted Closure in combination of Platelet-Rich Plasma effective in healing wounds in patients with Diabetes Mellitus?

Research hypothesis: Vacuum-Assisted Closure is effective in healing wounds in patients with Diabetes Mellitus at granulation phase in addition to Platelet-Rich Plasma is effective in epithelization phase in healing of diabetic foot wound.

PATIENTS AND METHODS

This prospective study was conducted at New Damietta University Hospital and National Institute of Diabetic and Endocrinology at Cairo. This study was conducted on 30 patients diagnosed as diabetic foot wound and aim to evaluate the combination of Vacuum assisted closure therapy and Platelet Rich Plasma for management.

Inclusion criteria: Age 18 – 50 years and diabetic foot patients.

Exclusion criteria: osteomyelitis, ischemia, peripheral vascular diseases and malignancy.

Study tools: From each patient the following data had been collected upon admission:

complete history taking and clinical examination focusing on vital signs [blood pressure, temperature, heart rate, respiratory rate], resting oxygen saturation measured by a pulse oximeter, and enlarged lymph nodes, as well as a palpation of the arteries in the lower limbs.

Investigations included laboratory analysis of complete blood count [CBC], renal function test, liver test profile, ESR and blood glucose level [At each visit, glycemic control was evaluated]. Random blood sugar levels were maintained between 100 and 160 mg/dL. Radiological evaluation included plain X-ray of the foot and lower limb vascular duplex. ECG and Echocardiography were also done.

Procedure technique: The VAC therapy was preceded by extensive debridement. After cleaning the wounds, the foam was cut to fit the cavity of the wounds. In order to hide the foam around the wound tissue, plastic drapes were used to wrap the drain in a curl-like pattern. A vacuum unit with a standard negative pressure of 100–125 mmHg was attached to the drain. Every 72 hours, the dressing was changed, and it was carefully examined to see whether any slough had emerged, allowing for more debridement to be carried out before the new dressing. 14 days of the treatment process were spent at a typical sub atmospheric pressure and many patients need 21 days to complete granulation of wound bed. PRP preparation and activation were handled by the clinical pathology team. PRP treatment was applied after two weeks of VAC treatment. The wound washed with 0.9% normal saline solution then the PRP was injected to wound edges and floor and covered with sterile non absorbing dressing every 72 hours for 14 days.

Administrative and Ethical Design: Official approval was received from the college of medicine's ethical committee, New Damietta University Hospital, and the National Institute of Diabetes and Endocrinology in Cairo [Institutional Research Board, IRB]. An informed written consent was obtained from all patients after full explanation of the procedures.

Data management: All data were acquired, tabulated, and analysed using the statistical programme of special science SPSS version 22 [SPSS Inc. Chicago, IL, U.S.A.]: editing and coding. data entry on a computer. For both parametric and non-parametric data. In terms of quantitative information, mean, SD [standard deviation], median, and range were used. Frequencies and relative percentages were used to express the qualitative data.

RESULTS

Patients basal characteristics are presented in table [1]. We included 30 diabetic patients underwent wound care after operation by VAC and PRP. The mean age was 42±7.2. Males were 13 [43.33%] and females were 17 [56.67%].

Wound characteristics are presented in table [2]. Regarding side, left leg was affected in 19 [63.33%] cases and right leg was affected in 11 [36.67%] of cases. Regarding site of wound, Dorsum and fore foot were the most affected part in 23.33% of cases then Forefoot and sole and also sole only in 4 [13.33%] of cases.

Size and depth of wound on VAC presented in table [3]. Regarding size, depth and discharge of wound on VAC size at baseline was 106.58 cm^2, depth of 10.7 mm and no discharge was observed. After 7 days size was 100.58, depth was 7.03 mm and discharge were 172. In day 14 size decreased to 91.52 cm^2, depth was 3.87 mm and discharge reached 128.67. At day 21 Size was 92.57 cm^2, depth was 2 mm and discharge were 80. 16 patient complete management with complete absence of wound at day 21.

Granulation type are presented in figure [1]. With VAC, granulation was partial in 14 [46.67%] cases and total in 16 [53.33%] cases.

Epithelization type with PRP were presented in figure [2]. With PRP, epithelization was partial in 25 [83.33%] cases and total in 5 [16.67%] cases.

Total granulation at the end of the study was done in all cases. Regarding epithelialization, five [16.67%] cases were totally epithelialized and 25 [83.33%] of cases were partially epithelialized. Complete healing was achieved in 5 [16.67%] cases [table 3].

Mean decrease in size with VAC was 15.07 Cm^2 with percentage of 16.62 %. Mean decrease in size with PRP was 31.12 Cm^2 with percentage of 51.96 %. Mean total decrease in size at the end of the study after combination between VAC and PRP was 60.32 Cm^2 with percentage of 64.7 [figure 3].

Table [1]: Patients basal characteristics

	Mean ± SD	Range
Age	42±7.2	27-50
Gender	Number	Percentage
Male	13	43.33
Female	17	56.67

Table [2]: Wound characteristics

	Number	Percentage
Lateralization		
Left	19	63.33
Right	11	36.67
Site of wound		
Dorsum	3	10
Dorsum and forefoot	7	23.33
Dorsum and sole	1	3.33
Dorsum, forefoot and leg	1	3.33
Forefoot and sole	4	13.33
Forefoot, sole and dorsum	2	6.67
Heel	3	10
Heel and Leg	1	3.33
Heel and sole	3	10
Sole	4	13.33
Sole and Forefoot	1	3.33

Table [3]: Size and depth of wound on VAC

	Mean ± SD	Range
Size		
Size 0 on vac cm²	106.58±58.86	15-252
Size 7 on vac cm²	100.58±56.83	15-252
Size 14 on vac cm²	91.52±55.26	10-241.5
Depth		
Depth 0 mm	10.7±3.1	7-20
Depth 7 mm	7.03±2.68	4-17
Depth 14 mm	3.87±2.24	1-10
Discharge		
Discharge 7 cm	172±92.94	60-550
Discharge 14 Cm	128.67±68.27	40-400
Size, Depth and Discharge at 21		
Size 21 on Vac cm²	92.57±53.63	7-207
Depth 21 mm	2±1.24	1-6
Discharge 21	80±24.81	50-120
	Number	**Percentage**
Absence 21 on VAC	16	53.33

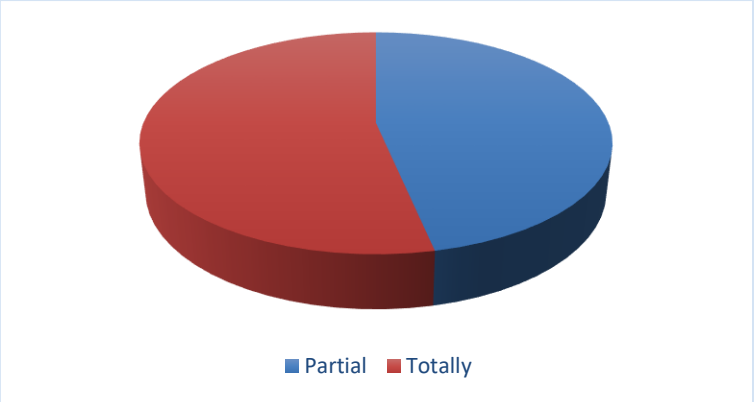

Figure [1]: Granulation type of included subjects after management

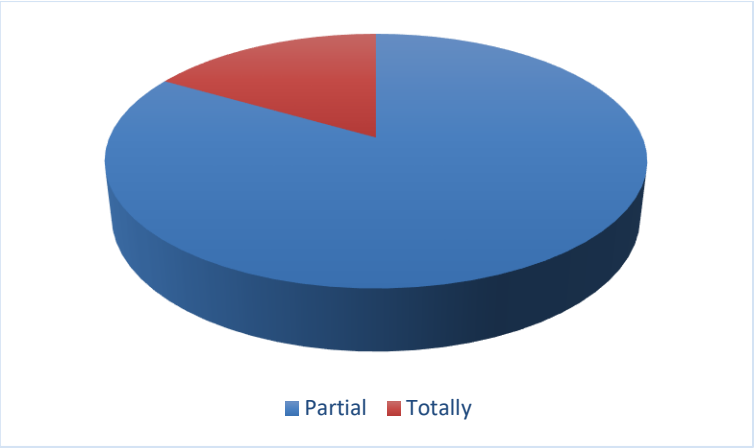

Figure [2]: Epithelization type of included subjects after management

Table [4]: Evaluation of the combination of vac and PRP on diabetic foot wound at the end of the study

Healing	Number [%]
Total Granulation	30 [100%]
Epithelialization	30 [100%]
• **Partial**	25 [83.33%]
• **Total**	5 [16.67%]
Complete Healing	5 [16.67%]

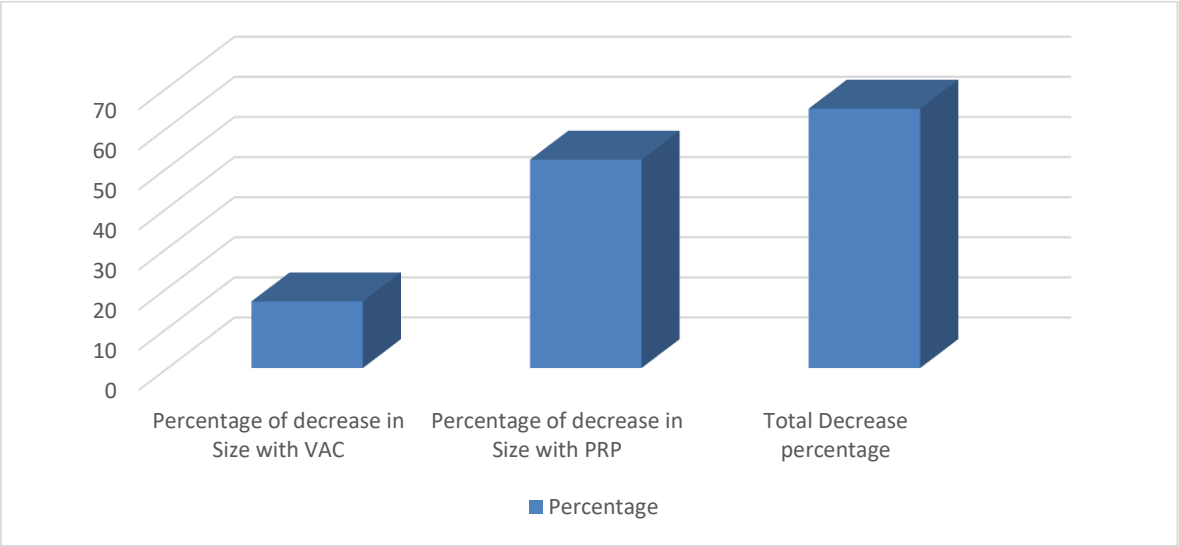

Figure [3]: Percentage of decrease in size through and at the end of the study

DISCUSSION

The risk of death is at least two times higher for those with diabetes than for those without it. In 2017, 12% of all healthcare costs worldwide were related to diabetes. In low- and middle-income countries, 79% of the population has diabetes [12].

Our study's objective is to assess the effectiveness of platelet-rich plasma and vacuum assisted closure therapy in treating diabetic foot wounds.

A sizable multi-centric RCT proved the efficacy of VAC therapy for diabetic foot ulcers. The previous study included patients with diabetic foot ulcers who had [1] a larger surface area than in other studies, and [2] a longer length of hospital stays [13].

Tran *et al.* [14] evaluated vacuum-aided wound closure [VAC] therapy for the management of diabetic foot ulcers. They studied 30 DFU patients between the ages of 38 and 70. 20 patients [66.66%] were between the ages of 40 and 60.

As regard lateralization we found that left leg was affected in 19 [63.33%] cases and right leg was affected in 11 [36.67%] of cases. Regarding site of wound, Dorsum and fore foot were the most affected part in 23.33% of cases then Forefoot and sole and also sole only in 4 [13.33%] of cases. **Abdelhafez *et al*. [15]** found that 36 individuals had the majority of their ulcers in the right lower limb; just 14 patients had ulcers in the left leg.

In our study, regarding size, depth and discharge of wound on VAC size at baseline was 106.58 cm^2, depth of 10.7 mm and no discharge was observed. After 7 days size was 100.58, depth was 7.03 mm and discharge were 172. In day 14 size decreased to 91.52 cm^2, depth was 3.87 mm and discharge reached 128.67. At day 21 Size was 92.57 cm^2, Depth was 2 mm and discharge were 80. 16 patient complete management with complete absence of wound at day 21. **Arora *et al*. [16]** showed that the size of the wound ranged from 5.1 to 8.7 cm [mean of 7.6 ± 0.8 cm].

In the study of **Tran *et al*. [14]**, the average initial wound surface area was 103.07 cm^2, and over the course of 31 days, this considerably decreased to 94.53 cm^2. This demonstrated successful wound healing following VAC treatment, with a mean reduction in size of 9.53 cm^2.

Swaminathan *et al*. [13] demonstrated that at the time of enrolment, all patients received DFUs of more than 5 weeks' duration from II-III grade without granulation tissue. **Lone *et al*. [6]** conducted a prospective case-control research comparing the use of conventional dressings and vacuum-assisted closure [VAC] for the management of DFU. He noted that by the end of week two, granulation tissue had developed in 26 [92.85%] of the patients in group A [vacuum-assisted closure], compared to 15 [53.57%] of the patients in group B. [conventional dressing]. By the conclusion of week 5, only 10 [40%] of the patients in group B had 100% granulation, compared to 21 [77.78%] patients in group A. When the wound was completely granulated, the hospital stay for the NPWT group was 14.87±7.62 days as opposed to 21.53±10.17 days in the traditional group. According to **Abdelhafez *et al*. [15]** Vacuum dressing has significantly lower average granulation in percentage of ulcer area than does average granulation. **Hussein *et al*. [17]** found similar results

In our study, PRP had a size of 77.39 cm^2 at day 2, 70.43 cm^2 at day 5, 62.43 cm^2 at day 8, 57.32 cm^2 at day 11, and 55.5 cm^2 at day 14. Complete epithelization was discovered in one case at day 11 and in four cases at day 14. According to **Swaminathan *et al*. [13]** findings, 100% [6/6] of patients successfully closed their DFUs after 12 weeks, including 2 cases involving whole toes. A full recovery took an average of 7.1 weeks. The earliest period was four weeks. After two weeks, granulation tissue appeared in all patients. And two weeks after receiving PRP and PPP treatment, the size of the wounds considerably shrank.

The safest way to treat DFUs is in this way. Over the course of 12 weeks, none of the patients experienced any negative effects. In our investigation, we discovered that PRP epithelization was complete in 5 [16.67%] cases and partial in 25 [83.33%] cases. Data for the wound area prior to and during wound care treatment were published in two trials by **Karimi *et al*. [18]** and **Saldalamacchia *et al*. [19]** [N = 64]. In comparison to conventional therapy alone, the addition of PRP did not result in a greater amount of epithelialized tissue [MD = 0.70 cm^2; 95% CI: 0.96, 2.35; p = 0.41; I2 = 70%].

Another approach for the treatment of wounds is platelet rich plasma. Almost all surgical disciplines are increasingly using autologous platelet-rich plasma [PRP] to treat a variety of soft-tissue and hard-tissue disorders, most notably to promote bone formation and cure chronic non-healing wounds.

Conclusion: NPWT is a promising technique gaining rapid popularity in DFU management all over the world. When treating diabetic individuals' foot ulcers, NPWT utilising VAC is successful. VAC therapy is a possible treatment for diabetic foot ulcers. There are signs of quicker wound healing and shorter hospital stays, with few or no problems. Consequently, it is effective in treating diabetic foot ulcers. PRP therapy is a method for increase the epithelized area of Diabetic Foot Ulcers faster and comfortable for patient compered to standard treatment in this time.

Conflict of Interest and Financial Disclosure: None

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