

THE USE OF AN AUTOLOGOUS MULTILAYERED LEUKOCYTE, PLATELET AND FIBRIN PATCH AS A FIRST-LINE DEFENSE: WHY WAIT?



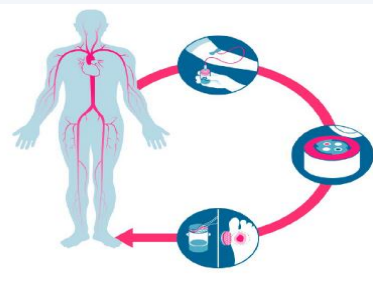
MICHAEL STEMPEL, DPM, FACFAS AND KARA COUCH, MS, CRNP, CWCN-AP, FAAWC, WASHINGTON, D.C.

PURPOSE AND BACKGROUND

In an outpatient wound center, conservative treatments, such as debridement, moist wound healing, and offloading, are often the first options for managing diabetic wounds. Advanced therapies are often only introduced when these methods fail. However, with the autologous multilayered leukocyte, platelet, and fibrin (MLPF) patch offers a paradigm shift. The MLPF patch can be started as a first-line defense, leveraging the patient's own cells to accelerate healing, eliminate risk of rejection, optimizing clinical outcomes, reduce loss of limbs, while saving valuable dollars and time spent on the wrong treatment.

WHAT IS THE MLPF PATCH?

The multilayered leukocyte, platelet, and fibrin (MLPF) patch* is produced from the patient's own blood by a unique procedure consisting of a fully automated centrifugation, coagulation, and compaction process.



The resulting patch is 100% autologous, easily transferable to the patient, and consists of a three-layered structure of leukocytes, platelets, and fibrin resulting in the sustained release of living cells and growth factors.

METHODS

In our wound care center, the MLPF patch is considered as soon as a patient presents with a chronic diabetic wound. This allows faster wound healing and dramatically decreases the potential for the development of complications, such as infection or subsequent surgical procedures. We evaluated the healing progression in complex diabetic patients utilizing MLPF patch as a first-line treatment. This case series builds on our previous SAWC poster presented in the spring of 2024.

*3C Patch®, Reaplix

Case 1

34-year-old male with type 2 DM with neuropathy, and right TMA. Patient presented with an acute Wagner Grade 3 diabetic ulcer on plantar aspect of his right foot. After 4 MLPF patch applications, the wound decreased from 3.36 cm² to 0.15 cm², a decrease of 96% in 4 weeks.



2/10/25



2/24/25



3/10/25

Case 2

50-year-old male with type 2 DM, PAD, status post distal bypass, left AKA, hypertension, and morbid obesity. Patient presented with a Wagner Grade 3 on the dorsal aspect of his right foot that had been surgically debrided. After 4 MLPF applications, wound decreased from 4.64 cm² to 2.74 cm², a decrease of 41%. Treatment is ongoing.



1/13/25



2/19/25



3/10/25

Case 3

56-year-old female with type 2 DM, hypertension, CKD, Charcot foot, and history of CVA. Patient with Wagner Grade 2 on the plantar aspect of her right foot. MLPF patches were used adjunctively with negative pressure wound therapy. After 5 MLPF applications, wound decreased from 3.19 cm² to 1.28 cm², a decrease of 60% and treatment is ongoing.



1/15/25



2/5/25



3/12/25

Case 4

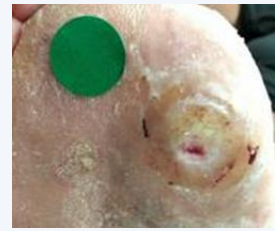
56-year-old Male with type 2 DM, neuropathy, CVA, and MRSA. Patient also s/p amputation of 1st and 2nd toe. Patient presented with a Wagner Grade 1 on the right plantar foot. Initial wound area was 0.52 cm² and with 4 MLPF patch applications, decreased to 0.07 cm², a decrease of 73%.



1/22/25



2/19/25



3/12/25

Case 5

82-year-old female with type 2 DM, neuropathy, CVA, and hypertension. Patient presented with a Wagner Grade 2 wound on the right medial ankle that was exacerbated by pressure due to patient's contracture. Wound area started at 12.31 cm² and decreased to 9.08 cm² after 10 MLPF applications. Treatment is ongoing.



12/18/24



1/15/25



3/10/25

Case 6

66-year-old male with type 2 DM, neuropathy, and a history of amputation of several toes. Patient presented with a Wagner Grade 1 wound on the plantar aspect of his right foot which measured 0.78 cm². While not a large wound, given the patient's history of prior amputations, it was imperative to heal the wound quickly. The wound decreased by 65% after 4 MLPF patch applications and went on to heal after the 6th application.



1/22/25



2/19/25



3/3/25

SUPPORT FOR MLPF PATCH

Game et al. evaluated the clinical effect of the MLPF patch on hard-to-heal DFUs in a multi-centered (32 clinics), observer masked, randomized clinical trial (RCT, n=269)¹. Weekly applications of MLPF patch resulted in significantly more ulcers healed and a shorter time-to-healing compared to best standard of care alone. As a result, the International Working Group on the Diabetic Foot (IWGDF) has twice recommended MLPF Patch as an adjunctive treatment for non-infected DFUs that are difficult to heal²

RESULTS

Of the patients we have treated with the MLPF patch, we have seen the greatest improvement in those patients who start MLPF patch therapy as soon as they present with a chronic wound. Four out of the 6 patients presented in this case series had a history of prior amputations, which made it an even greater priority to heal these new wounds quickly before a need for further amputation arose. With good standard of care and the addition of the MLPF patch as a first-line defense, patients are healing faster without further risk of infection or amputation.

CONCLUSIONS

A recent study by Musuuza, et. al. documented that "nearly 2 million Americans develop a diabetic foot ulcer each year; within 5 years of ulceration, 5% will undergo major amputation." A promising therapy is available that can achieve wound closure and therefore decrease the risk of major amputation and morbidity in patients with chronic diabetic wounds. It should be considered as a first-line defense in the efforts to save diabetic limbs. The IWGDF has recommended the use of the MLPF patch as it shows potential to be an efficacious treatment option for providers when treating these chronic diabetic wounds. These results are encouraging and we will continue to monitor these healing trends as these patients complete therapy.

References

1. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
2. Game F, et al. International Working Group of the Diabetic Foot guidance on use of interventions to enhance the healing of chronic foot ulcers in diabetes. (IWGDF 2023 update).
3. Musuuza et al. A systematic review of multidisciplinary teams to reduce major amputations for patients with DFUs. J of Vasc Surg: April 2020.