

THE USE OF AN AUTOLOGOUS MULTILAYERED LEUKOCYTE, PLATELET, AND FIBRIN PATCH IN WAGNER GRADE 2 AND 3 DIABETIC FOOT ULCERS

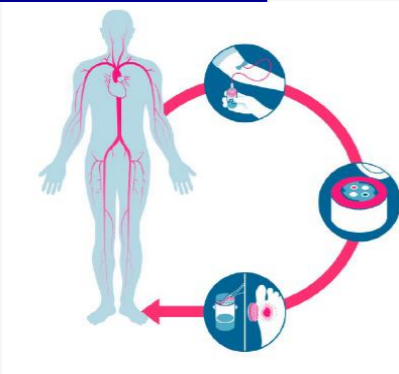
DR. FERIAL ABOOD, MD AND ABRAHAM BENITEZ, RN, GERALD CHAMPION REGIONAL MEDICAL CENTER, ALAMOGORDO, NM

PURPOSE AND BACKGROUND

In a recent study by Shah et al¹, Wagner Grade 2 diabetic foot ulcers (DFUs) proved to be the most prevalent DFU grade, accounting for 42% of the cases. Wagner Grade 3 DFU were the next most common at 34% whereas Grade 4 were only seen 12% of the time. As noted by Shah et al, "Elevated HbA1c levels, pre-existing peripheral arterial disease, and neuropathy strongly correlate to advanced Wagner's grade and need for amputation." While standard of care for DFUs is accepted as offloading, debridement, vascular intervention, glucose control and local wound management, Wagner Grade 2 DFUs and greater do not always respond to these standards and require advanced therapies. The use of an autologous multilayered leukocyte, platelet, and fibrin patch* in this population has proven to be effective in not only promoting granulation but also covering exposed bone, joint or tendon, often difficult to achieve in these complex patients.

WHAT IS THE MLPF PATCH?

The multilayered leukocyte, platelet, and fibrin (MLPF) patch* was developed in Denmark and is now available in the U.S. The 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 fully autologous, easily transferable to the patient, and displays a three-layered structure of leukocytes, platelets, and fibrin. This results in a sustained release of living cells and growth factors into the wound bed.

SUPPORT FOR MLPF PATCH

The MLPF patch has been investigated in a large randomized controlled trial. 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)². 17% (n=22) of the treatment group included wounds with depth to bone or tendon. Hard-to-heal DFUs were defined by less than 50% reduction in a 4-week run-in period. Weekly applications of MLPF patch resulted in significantly more ulcers healed and a shorter time-to-healing in the treatment group compared to best standard care alone². 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 heal³.

*3C Patch®, Reapplitx

METHODS

This case series presents patients with Wagner Grade 2 or 3 DFUs that responded exceptionally well to the MLPF patch. These DFUs failed to progress in a timely manner despite accepted standard of care measures. These wounds were measured and analyzed weekly. Patients ranged from 48-85 years old with a mix of Wagner Grade 2 and 3 DFUs. All had diabetic neuropathy, and several had recent vascular interventions. Patients were treated with standard of care and weekly applications of the MLPF patch.

RESULTS

Case 1

48-year-old Male. Type 2 DM and ESRD on hemodialysis. Patient with chronic Wagner grade 3 on posterior ankle that failed to heal with other conservative treatments. In 3 weeks and 3 applications, wound went from 1.08 cm² to fully closed after the second application.



5/10/23-2.0 x 2.2 x 0.4 cm;
Initial Visit; Exposed tendon



9/13/23-1.2 x 0.9 x 0.2 cm;
1st MLPF Patch application



9/20/23-1.1 x 1.0 x 0.2 cm;
2nd MLPF Patch application



10/4/23-Fully closed
After 2 applications

References

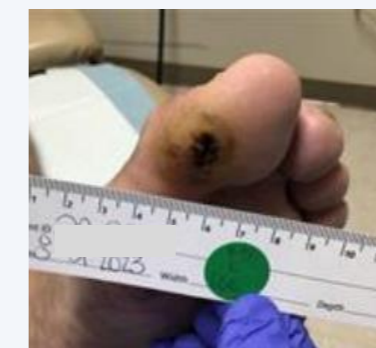
1. Shah P et al. (2022). Cureus. 14. 10.7759/cureus.21501.
2. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
3. Schaper N et al. on behalf of the International Working Group on the Diabetic Foot (IWGDF) 2023, www.iwgdguidelines.org.

Case 2

65-year-old male. Type 2 DM, COPD, RA, and hyperlipidemia. Wagner grade 2 on left 1st toe that was present over 8 months. After 4 weeks and 4 applications, wound went from 0.63 cm² to closed.



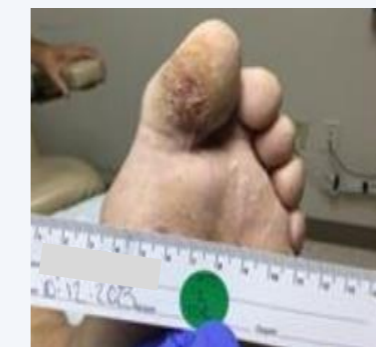
2/9/23-2.0 x 2.4 x 0.4 cm;
Initial visit



8/31/23- 0.9 x 0.7 x 0.5 cm
1st MLPF Patch application



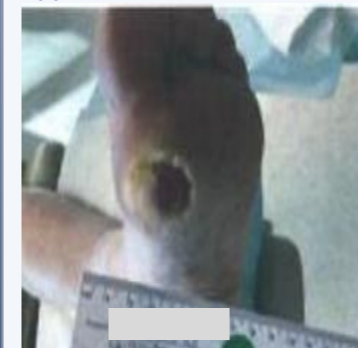
9/21/23- 0.3 x 0.3 x 0.2 cm
2nd MLPF Patch application



10/12/24; Fully closed
After 4 applications

Case 3

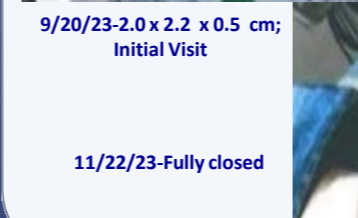
76-year-old Male. Type 2 DM. Patient had a chronic Wagner grade 3 ulcer over the first metatarsal head. After 10 weeks and 8 applications, wound went from 4.4 cm² to fully closed.



9/20/23-2.0 x 2.2 x 0.5 cm;
Initial Visit



10/11/23-2.0 x 2.2 x 0.5 cm;
After 3 applications



11/22/23-Fully closed

Case 4

71-year-old Male. Type 2 DM. Patient presents with Wagner grade 2 on great toe, 0.7 cm². The patient failed to respond to conservative treatment. Within 7 weeks and 6 applications, the chronic ulcer fully closed.



9/27/23: 1.0 x 0.7 x 0.4 cm;
Initial visit



10/25/23-0.7 x 0.6 x 0.3 cm;
After 3 applications



11/22/23-Fully closed
After 6 applications

Case 5

85-year-old Male. Type 2 DM. Wound on left heel that started out as pressure injury complicated by diabetic neuropathy. Wagner grade 2, 7.0 cm², with moderate purulent drainage. Wound closed after 6 weeks and 6 applications.



10/18/23-2.5 x 3.0 x 0.4 cm;
Initial Visit



2/7/24-Fully closed
After 6 applications

CONCLUSIONS

During this clinical evaluation, the MLPF patch proved to be a viable option with positive outcomes for hard-to-heal Wagner Grade 2 and 3 DFUs. In a complex patient population where treatment options are limited, the MLPF patch helped prevent further infections and potential loss of limb, even when other advanced therapies had failed. Patients achieved wound closure quickly, demonstrating improved outcomes. The MLPF patch should be considered in conjunction with standard of care when treating chronic DFUs.