WHEN CONSERVATIVE TREATMENTS FAIL, WHAT'S NEXT? THE USE OF AN AUTOLOGOUS MULTILAYERED LEUKOCYTE, PLATELET, AND FIBRIN PATCH FOR DIABETIC FOOT ULCERS

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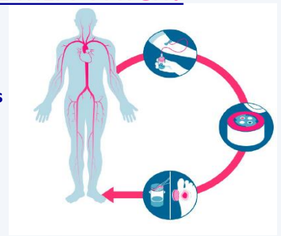
PURPOSE AND BACKGROUND

Standard of care for diabetic foot ulcers (DFUs) is widely recognized as proper offloading, regular debridement, moist wound healing, infection control, glycemic control, and vascular interventions as necessary. However, what happens when these interventions aren't enough? Providers have commonly had to rely on the use of cellular, acellular, matrix-like tissue products (CAMPs) and other advanced treatment options to treat these ulcers. However, research shows only 23% of appropriate DFUs are treated with CAMPs with varying degrees of success. Also, these products frequently do not have evidence to support their use and typically are not recommended by the International Working Group of the Diabetic Foot (IWGDF). A recent development in treating DFUs is the use of autologous products to use the body's own natural defense and regenerative properties. In this case series, an autologous multilayered, leukocyte, platelet, and fibrin (MLPF) patch was trialed in patients previously treated with proper offloading and vascular intervention without success. The decision to try this product was based on the holistic nature of using the body's own cells to regenerate and heal.

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 facilitates 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)[1]. 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 alone[2]. As a result, the International Working Group on the Diabetic Foot (IWGDF) continues to recommend MLPF Patch as an adjunctive treatment for non-infected diabetic foot ulcers that are difficult to heal[2].

*3C Patch®, Reapplix

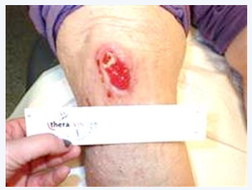
METHODS

This case series looks at the progress of 5 patients with previous vascular interventions without successful wound closure. Some had poor glycemic control despite appropriate medical interventions. Weekly applications of the MLPF patch were administered and proper standard of care was followed.

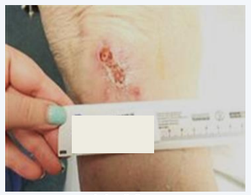
RESULTS

Case 1

93-year-old Female. Type 2 DM. Calcified vessels in bilateral lower extremities. On Aspirin and Plavix. Patient with nonhealing ulcer referred to wound center after five weeks of conservative treatment.



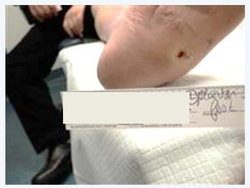
5.5 x 3.4 cm;
2 weeks prior to initial application



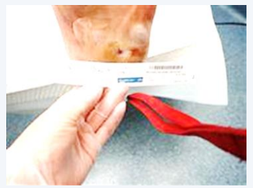
1.1 x 0.9 cm;
After 4 applications

Case 2

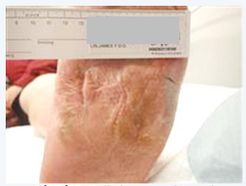
65-year-old Male. Uncontrolled Type 2 DM. Presented with recurring wound to plantar heel and Charcot Foot, despite continuous use of CROW walker therefore MLPF Patch was initiated. After 7.5 weeks, the wound achieved full closure.



5/5/23: 1.0 x 0.7 x 0.3 cm
Initial application



6/6/23: 0.5 x 0.5 cm;
After 4 applications

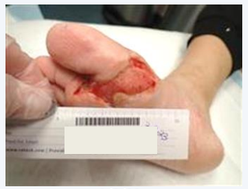


6/27/23: Full closure achieved.
Total Contact Casted for 1 more week, then discharged

Case 3

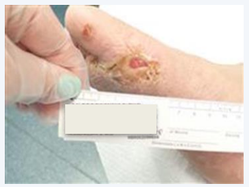
54-year-old Female with uncontrolled Type 2 DM. Podiatry surgically debrided Wagner Grade 3 DFU and recommended amputation. Patient refused and requested limb salvage. Weekly debridements, HBO for more than 30 days, and total contact casting were performed. After 1 month of this treatment, due to slow progress, the MLPF Patch was added. In one month, the patient achieved full closure and amputation was no longer necessary. The patient was discharged from wound care.

Initial visit 2/3/23



3/2/23

3/21/23: 5.0 x 5.0 cm
1st Patch application

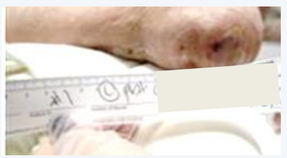


4/11/23: 1.2 x 0.6 cm
4th Patch application

Case 4

66-year-old Female. PMH of Type 2 DM, anemia, COPD, pulmonary HTN, CHF, and ESRD with a complex nonhealing DFU on the left heel. Patient had vascular intervention to improve wound healing. Patient treated in WCC 30 weeks prior to using MLPF Patch. Within eight weeks and eight applications, patient achieved full closure.

6/13/23: 12.0 x 4.0 cm, Initial visit



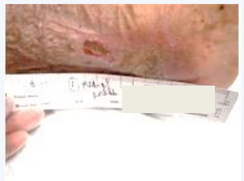
10/3/23: 4.0 x 4.0 cm
Initial application

11/28/23: After 7th application,
1.0 x 1.0 cm; 76% volume reduction

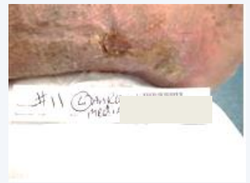
12/26/23: Full closure achieved

Case 5

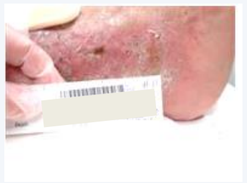
61-year-old Male. Type 2 DM, DVT LLE and hypertension. LLE ABI 1.2. Presented with left medial ankle wound. MLPF Patch initiated as well as venous ablation completed to promote healing and prevent recurrence. Wound achieved closure after 8 weeks.



10/3/23: 2.0 x 2.0 cm
Week before 1st application



11/7/23: After 4th application
1.0 x 0.5 cm, 71% volume reduction



12/7/23: Full closure achieved

CONCLUSIONS AND WHAT'S NEXT

In this case series, the use of an autologous patch adjunctive with diabetes management, sharp debridement, and appropriate offloading brought these complex DFUs to full closure. When advanced treatment modalities failed, it made sense to use the MLPF patch to attempt closure for these wounds. Treatment options for chronic wounds in diabetic patients when advanced therapy doesn't work are limited. The ability to use the patient's cells to produce their own growth factors and other nutrients required with minimal effort and low risk is an attractive option with the MLPF patch.

The evidence supports the utilization of the autologous MLPF patch in DFUs and should be considered more frequently in this challenging patient population. Further analytics from this series and additional patients are ongoing with regard to improved workflow. More data is being collected and will be analyzed and presented at a later date, should it prove significant.

References

1. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
2. Schaper N et al. on behalf of the International Working Group on the Diabetic Foot (IWGDF) 2023, www.iwgdfguidelines.org.