THE USE OF AN AUTOLOGOUS MULTILAYERED LEUKOCYTE, PLATELET AND FIBRIN FOR DIABETIC ULCERS: DOES IT MAKE A DIFFERENCE?

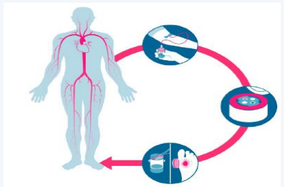
MICHAEL STEMPEL, DPM, FACFAS AND KARA COUCH, MS, CRNP, CWCN-AP, FAAWC, GEORGE WASHINGTON UNIVERSITY HOSPITAL, WASHINGTON, D.C.

PURPOSE AND BACKGROUND

33% of diabetic foot ulcers (DFUs) do not heal in a timely manner and ultimately become "chronic" wounds. Approximately 20% of moderate to severe DFUs lead to some form of amputation and patients with diabetes are up to 25 times more likely to have an amputation than non-diabetics. In a busy wound center located in a major metropolitan area, many products have been tried on these chronic wounds with varying degrees of success. When evaluating the adoption of the autologous multilayered leukocyte, platelet, and fibrin (MLPF) patch, providers were initially skeptical. The results however demonstrated the efficacy of the MLPF patch, facilitating wound healing in patients who had failed at least 10 applications of cellular tissue products (CTPs) and/or other advanced modalities.

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.

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 heal[2].

METHODS

24 patients with DFUs were included in this trial; all of whom had multiple comorbidities and had failed at least 10 applications of CTPs and/or other advanced modalities. All patients underwent weekly sharp debridement as well as adequate offloading and edema control. 6 of these patients are highlighted here.

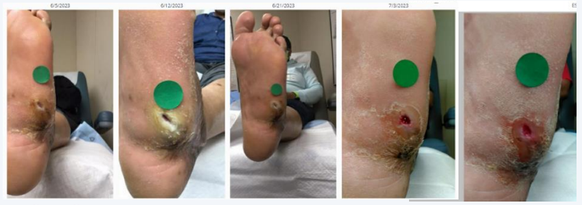
*3C Patch®, Reapplix

Case 1

44-year-old Male. Type 2 DM with neuropathy and HIV. Large Grade 3 ulcer extending from left posterior calf to plantar heel. Initial wound area was 67.2 cm^2 and within 13 weeks, area decreased to 9.1 cm^2 (86% reduction) with posterior wound almost healed. Due to several setbacks and development of new dorsal wound, wound is not yet completely closed.

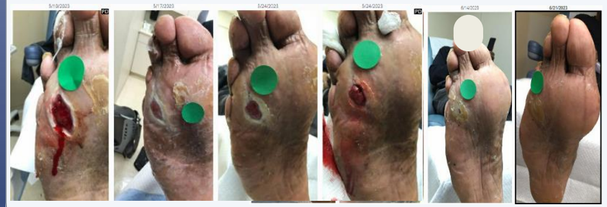
Case 2

56-year-old Female. Type 2 DM with neuropathy, anemia, and CKD. Patient with chronic Grade 1 on left plantar foot that was present 8 weeks with no improvement despite offloading and compression. Initial wound closed with 4 MLPF patches within 12 weeks but then recurred. After 6 more MLPF Patch applications, wound closed and remained closed.



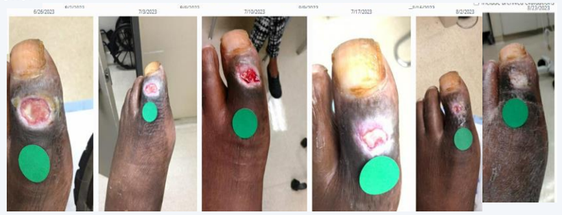
Case 3

65-year-old Male. Type 2 DM. History of surgical debridement on 3/21/23 of an infected plantar ulceration with application of collagen graft. Pt presented for follow-up evaluation after 1-month nursing facility stay for IV antibiotics of underlying osteomyelitis. Pt had protective weightbearing in a CAM boot. Pt achieved full closure after weekly debridements and 5 weekly applications of MLPF patch.



Case 4

89-year-old Male. Type 2 DM and history of PAD. Pt presented with a left dorsal great toe wound for over 4 months. Initial wound volume was 4.9 cm^3 and within 6 weeks, volume decreased to 0.25 cm^3. Total area decreased by 89% with 5 weekly MLPF Patch applications and subsequent wound closure was achieved in 7 weeks.

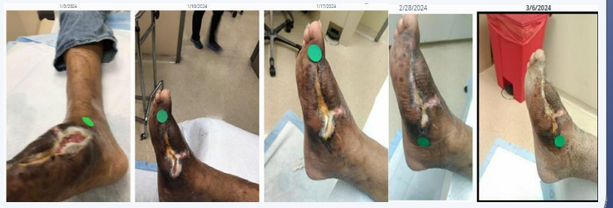


Case 5

58-year-old Male. Type 2 DM. Initially seen 10/16/23 with a wound on dorsal aspect of his foot for at least 1 month. Presented with eschar and colonized wound that was treated topically. Full closure achieved in 5 applications of MLPF patch over 2.5 months; wound healing complicated by a CVA and required hospitalization.

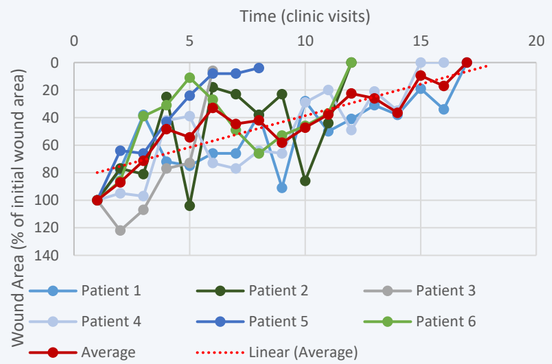
Case 6

46-year-old Male. Type 2 DM. History of partial 1st ray amputation due to osteomyelitis. After initial period of successful healing utilizing NPWT and antibiotics, osteomyelitis returned requiring further revision of the 1st metatarsal as well as 2nd metatarsal head. Continued NPWT and IV antibiotics. The tissue flaps remained viable and the underlying bone infection was resolved with granulation covering the bone. MLPF patch initiated on 1/3/24 and full closure achieved with 7 weekly applications.



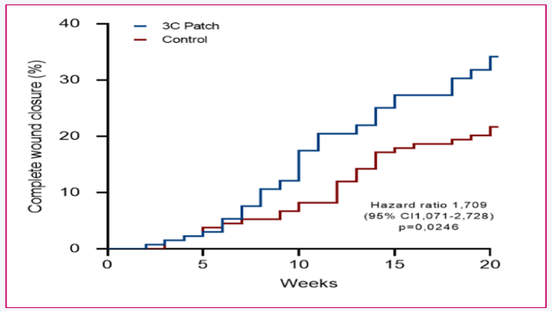
RESULTS

Our Data



Of the total 24 patients in this trial, 45.8% healed (11 total patients). This outperformed the Lancet data of 34% healed over a similar timeframe.

RCT Data



CONCLUSIONS

In this case series, the use of the MLPF Patch, in conjunction with diabetes management, sharp debridement, appropriate offloading and edema control, contributed to significant improvement in the wounds. No amputations or infections were seen in this trial group and wound healing was almost 46% with an average of 10 MLPF Patch applications. In a complex patient population that had failed at least 10 applications of cellular tissue products and/or other advanced modalities., the use of the MLPF patch is now considered a first line option in this clinic.

References

1. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
2. Rayman G et al. on behalf of the International Working Group on the Diabetic Foot (IWGDF) 2019, www.iwgdfguidelines.org.