THE USE OF AN AUTOLOGOUS MULTILAYERED LEUKOCYTE, PLATELET AND FIBRIN PATCH FOR DIABETIC ULCERS: SHIFTING THE MINDSET

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PURPOSE

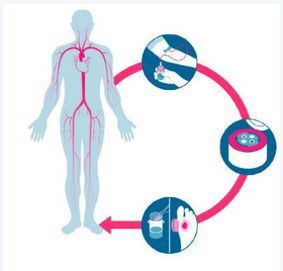
Diabetic foot ulcers continues to have a profound impact on the economics of the United States. In 2017, it was reported that $78 billion was spent to treat diabetic foot ulcers. Unfortunately, the funding into research into this devastating disease process has not improved since 2017 and is much lower than other diseases, with only $1.1 billion spent on diabetes research compared to $6.2 billion spent on cancer research. It is imperative that the mindset starts to shift towards better education and treatment of people with diabetes. In this case series, several patients with recalcitrant chronic diabetic wounds were treated with a novel therapy that demonstrated phenomenal results.

BACKGROUND

In most wound care centers, a large number of patients living with DFUs are treated. Our center is no different. In addition to following standards of practice for diabetic wound care, including glycemic control, proper offloading and wound bed preparation, we are constantly thriving to offer cutting edge treatments that are not only cost-effective but are unique from the status quo. This is where the MLPF patch came in to play.

WHAT IS THE MLPF PATCH?

The multilayered leukocyte, platelet and fibrin (MLPF) patch* was developed in Denmark and is now available to U.S. patients. 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 resulting in living cell and growth factor release into the wound bed.

*3C Patch®, Reapplix

SUPPORT FOR MLPF PATCH

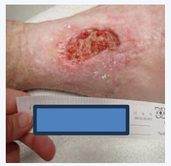
The MLPF patch has been investigated in a large randomized controlled trial. Game et al evaluated the clinical effect of the MLPF patch on hard-to-heal DFUs in a multi-centered (32 clinics), observer masked, randomized clinical trial (RCT, n=269)[2]. Hard-to-heal DFUs were defined by less than 50% reduction 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) recently recommended MLPF Patch as an adjunctive treatment for non-infected diabetic foot ulcers that are difficult to heal[3].

METHODS

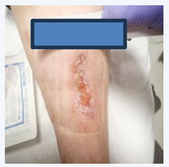
This case series presents several patients who failed to progress in a timely repair sequence during conventional wound care despite weekly sharp debridement, local wound care, and offloading as indicated. All patients presented with type 2 diabetes. Investigators measured and analyzed wounds weekly.

RESULTS

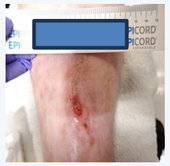
Case 1



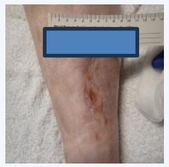
5.2 x2.1 x 0.4 cm;
Initial Visit



4.5 x 1.5 x 0.3 cm;
After 1 application



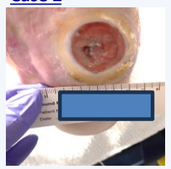
1.3 x 0.8 x 0.2 cm;
After 2nd application



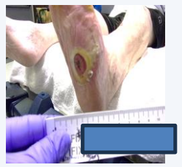
0.5 x 0.3 x 0.2 cm;
After 3rd application

68-year-old Female. Type 2 DM, ESRD and PVD. Patient with wound to anterior tibia that had been present for 8 months after scraping it on an end table. Seen weekly by home health for the previous 3 months with Unna boot dressings applied. After 3 applications of patch, wound closed.

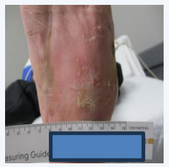
Case 2



4.3 x 3.9 x 0.9 cm;
Initial visit



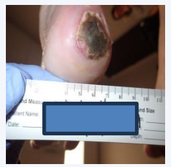
8-week follow-up;
After 3 applications



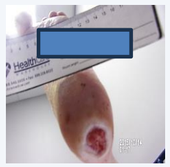
0.5 x 0.3 x 0.2 cm; 10-week follow-up
After 4 applications

73-year-old male. Type 2 DM, ESRD, RA, with Charcot foot. Wound on plantar foot had been present for "years." Wound was made worse after patient was stranded in his wheelchair with wound submerged for over 12 hours in hurricane flooding while awaiting rescue. After 10 weeks and 4 applications, in conjunction, with total contact casting, wound closed.

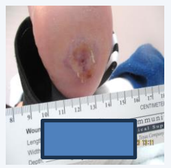
Case 3



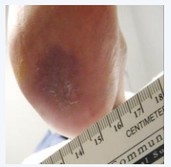
4.8 x 2.9 x 0.1 cm;
Initial Visit



2.8 x 2.5 x 0.5 cm.
2-week follow-up;
After 1 application



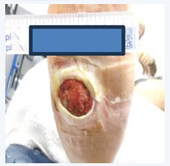
0.6 x 0.5 x 0.2 cm;
6-week follow-up
After 3 applications



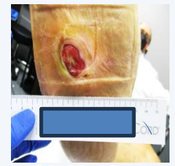
Fully Closed

86-year-old female. Type 2 DM, ESRD, and PVD. Patient with pressure injury to heel that she developed after a hip fracture. The patient was seen at another facility previously and the wound remained the same size and severity for 18 months. After 8 weeks and 4 applications, wound closed.

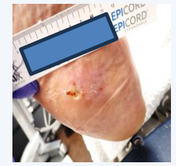
Case 4



3.5 x 4.2 x 0.8 cm;
Initial visit



3.0 x 2.6 x 0.7 cm;
2-week follow-up; After 1 application

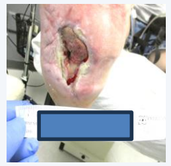


1.0 x 0.8 x 0.3 cm;
6-week follow-up; After 3 applications

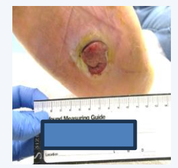
0.4 x 0.3 x 0.1 cm;
10-week follow-up;
After 4 applications

62-year-old male. Type 2 DM, PVD, with Charcot foot. Wound on plantar foot had been present for "years." Gets worse after every duck hunting season despite custom-made waders.

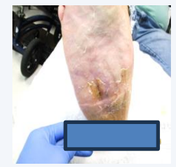
Case 5



6.1 x 4.2 x 1.5 cm;
Initial Visit



4.2 x 2.8 x 1.0 cm;
3-week follow-up;
After 2 applications



0.2 x 0.1 x 0.1 cm;
8-week follow-up;
After 6 applications

64-year-old male. Type 2 DM, PVD, with Charcot foot. Wound on plantar foot had been present for 6 years. Had healed several times but after recent osteomyelitis, had gotten worse again.

CONCLUSIONS

This case series demonstrates the effectiveness of a multilayered leukocyte, platelet and fibrin patch. This therapy is innovative, involves the patient in their own healing, and ultimately helps prevent future infections and amputations. Now is the time to shift the mindset in the war against diabetic foot ulcers and MLPF patch should be a first-line defense tactic in that fight.

References

1. Armstrong DG, Boulton AHM, Bus, SA (2017). Diabetic foot ulcers and their recurrence. New England Journal of Medicine, 376: 2367-2375.
2. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
3. Rayman G et al. on behalf of the International Working Group on the Diabetic Foot (IWGDF) 2019, www.iwgdfguidelines.org.