The Use of a Novel Autologous Multilayered Leukocyte, Platelet and Fibrin Patch in Healing Chronic Diabetic Foot Ulcers

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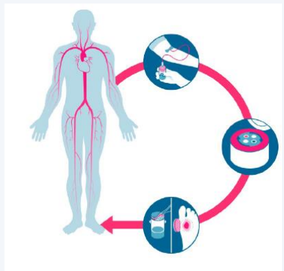
PURPOSE

The use of a novel autologous multilayered leukocyte, platelet, and fibrin patch has seen an increase in utilization in the United States. While platelet-rich plasma therapy has been around for decades and is used frequently in orthopedic and podiatric cases, this new approach to an autologous blood product uses a proprietary centrifugation process to harvest the leukocytes, platelets and fibrin from the patient's own blood. The compaction process allows these cells to become a sturdy patch to be applied directly to the wound, thus bypassing the diabetic patient's own vasculature to deliver the cells needed for wound healing.

BACKGROUND

Diabetes is a huge epidemic in the United States and unfortunately, many patients do not even realize they have diabetes until it has already affected many systems in the body, including the renal, vision and sensory systems. While earlier estimates supported that 25% of people with diabetes will develop a foot ulcer in their lifetime, new data shows is it more likely to be 34%. Current data also shows that every 1.2 seconds, someone in the world will develop a DFU and non-traumatic amputations are performed every 20 seconds in this same group.[1] It is very important that people with diabetic foot ulcers seek the appropriate care, and sometimes this involves the use of advanced wound products. In this study, we look at several patients treated with the multilayered leukocyte, platelet, and fibrin (MLPF) patch and see how, despite past infections or impaired vascular status, this therapy helped improve the wound.

An autologous multilayered leukocyte, platelet and fibrin (MLPF) patch* has been developed 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.



*3C Patch®, Reapplix

WHAT IT LOOKS LIKE

The resulting patch is fully autologous, readily transferable to the patient and displays a three-layered structure of leukocytes, platelets and fibrin resulting in cell and growth factor release 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]. 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].

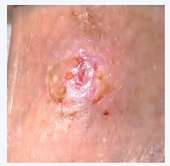
METHODS

This case series presents three patients who failed to progress in a timely repair sequence using conventional wound care, despite weekly sharp debridement, local wound care and offloading as indicated. Other advanced wound products have been tried and failed. All patients presented with type 2 diabetes with one being of advanced age and having extensive cardiac disease, one patient having Charcot arthropathy and one patient having compromised vascular status. Patient age range was 69-95 years old. Investigators measured and analyzed wounds weekly.

RESULTS

Case 1

0.84 cm^2; 100% necrotic



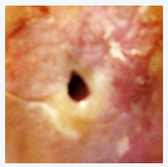
0.12 cm^2; still with slough present

0.25 cm^2; 100% granulated

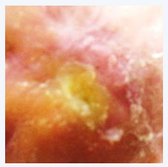
95-year-old Female, retired LPN. Type 2 DM, history of myocardial infection, coronary artery disease and congestive heart failure. Patient above had a right medial ankle wound; 4 total MLPF applications from 100% necrotic to wound almost closed.

Case 2

1.197 cm^3; significant callus and maceration



0.75 cm^3; maceration and callus improved. Significantly less depth.



0.63 cm^3; less depth noted.

69-year-old male, type 2 DM with polyneuropathy, hyperlipidemia, hypertension and gout. Charcot foot with lengthy surgical history included foot surgery with tendon/ligament repair, I&D with bone biopsy to right foot in Oct. 2019, and subsequent I&Ds in January 2022 and June 2022. 6 applications of MLPF were used and wound decreased by over 50% in volume.

Case 3

0.03 cm^3; pale wound base, callus noted.

After 2 applications, 0.006 cm^3; notable decrease in wound size

0.004 cm^3; almost fully closed.

76-year-old female, type 2 DM with polyneuropathy, congestive heart failure, and peripheral vascular disease. Revascularization performed and stents placed in lower extremity. Wound center had been treating the patient for over 2 months with no real improvement noted. At time of 1st MLPF application, wound was 0.6x0.5x0.1 cm. In 1 week, the wound decreased by over 50%. After 4 applications and 4 weeks, wound decreased by 75% to 0.2x0.2x0.1 cm.

DISCUSSION

In this case series, the use of the autologous patch, in conjunction with local sharp debridement and standard of care dressings proved effective in improving wound depth and quality of the wound bed and promoted wound healing even in patients with advanced age and extensive cardiac history, Charcot arthropathy, and peripheral vascular disease with questionable blood supply. For both case 2 and case 3, the standard of care included offloading with a total contact cast.

CONCLUSIONS

This case series represents the effectiveness of using a novel multilayered leukocyte, platelet and fibrin patch in hard-to-heal diabetic foot ulcers. It is important to keep in mind that even small wounds, like these presented in this case series, still can become infected and ultimately lead to amputation and possibly death and therefore must be effectively treated with adjunctive therapies when standard of care treatments fail to work.

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.