The Use of an Autologous Multilayered Leukocyte, Platelet and Fibrin Patch in Diabetic Limb Salvage

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PURPOSE

Diabetic foot ulcers (DFUs) are common wounds frequently seen in wound centers and podiatry offices. These wounds can lead to infection, amputation, and ultimately death if not treated appropriately. 70% of DFUs remain unhealed after 20 weeks of treatment, 60% of them become infected and 20% end in different levels of amputation[1]. Additional recent research demonstrated that patients with diabetic foot ulcers, Charcot neuropathy or neuropathic fractures and dislocations have a higher fear of amputations and infections than those without these complications and even more than fear of death[2]. Interventions to assist in healing these wounds before they become infected and lead to amputation are constantly being developed. This case series looked at multiple patients at risk of amputation and the use of a multilayered leukocyte, platelet and fibrin (MLPF) patch.

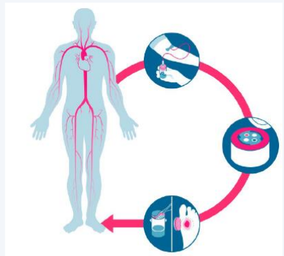
BACKGROUND

Diabetic foot ulcers (DFUs) remain a clinical challenge and the affected patients bear a high risk of increased mortality and amputation. The underlying pathogenesis arises from compromised peripheral blood flow due to the onset of ischemia or neuropathy leading to the risk of lower limb loss. The incidence of amputation is 20 times higher in diabetic patients than in those without diabetes. In other words, more than 1 million people with diabetes will lose a foot or leg every year due to complications from diabetes. Not only is the lower limb at risk but the patient's life is as well; since 2021 there have been approximately 6.7 million adults between the age of 20-79 who have died either from diabetes alone or complications that followed it. In one study, patients treated according to protocols based on the International Consensus on the Diabetic Foot were followed for 1 year and 23% did not heal. DFU recurrence is also common; within 1 year after healing from an ulcer, 40% of patients have a recurrence. Therefore, an effective solution to these wounds is necessary to prevent these complications and the MLPF patch is one such solution.

*3C Patch®, Reapplix

HOW IT WORKS

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.



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.

EVIDENCE FOR MLPF PATCH

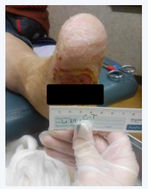
The MLPF patch has been investigated in a large randomized controlled trial. Game et al evaluated the clinical effect of the MLPF patch on hard-to-heal DFUs in a multi-centered (32 clinics), observer masked, randomized clinical trial (RCT, n=269)[1]. Hard-to-heal DFUs were defined by less than 50% reduction 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) recently recommended the MLPF patch as an adjunctive treatment for non-infected diabetic foot ulcers that are difficult to heal[3].

METHODS

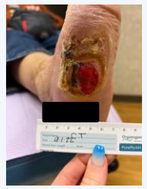
This case series presents several patients who were at risk of amputation and failed to progress in a timely repair sequence during conventional wound care despite weekly sharp debridement local wound care and offloading as indicated. Other advanced wound products had also been tried and failed. The investigator measured and analyzed the wounds weekly.

RESULTS

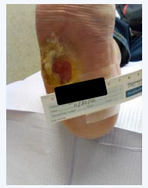
Case 1



Jun. 22-21.6 cm²



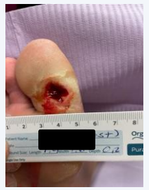
Sept. 1-9.2 cm²



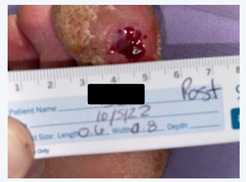
Nov. 30-6.44 cm²

74-year-old female, type 2 DM, severe peripheral arterial disease. Wound had been present over 8 months and the patient was scheduled for a below knee amputation due to infection, location and duration of the plantar foot wound and inadequate blood flow despite several revascularizations,. However, she sustained a myocardial infarction prior to the amputation and subsequently sought a second opinion in hopes of healing her wound. Several MLPF patch applications were performed and her wound dramatically decreased in size from 21.6 cm² to 6.44 cm² which ultimately prevented a major amputation.

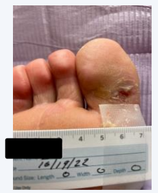
Case 2



Sept. 14-2.24 cm²



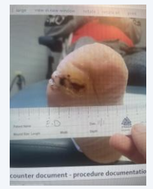
Oct. 5-0.48 cm²



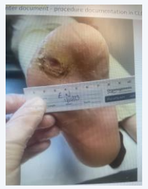
Oct. 19-0.0 cm²

54-year-old male, type 2 DM. Wound had been present for over 18 months. A topical growth factor gel as well as collagen dressings had been tried and were unsuccessful. The patient was at risk of amputation of the great toe, which can contribute to major issues with balance and the biomechanics of the foot. In 6 weeks and just 4 applications of MLPF patch, the wound went from 2.24 cm² to 100% closed.

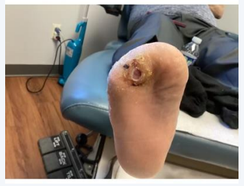
Case 3



Nov. 1-1.44 cm²



Jan. 10-2.25 cm²



Mar 28.-1.17 cm²

56-year-old male with type 2 DM and peripheral arterial disease. History of right transmetatarsal amputation and therefore at increased risk of further amputation. Wound had been present for 4 months with deterioration of wound noted from Nov. 1 to Jan. 10 with standard of care. MLPF patch therapy initiated on Jan. 10 and wound continues to decrease in size, with over 50% reduction after subsequent applications.

DISCUSSION

In this case series, the use of the autologous MLPF patch, in conjunction with local sharp debridement and appropriate offloading, not only contributed to significant improvement in the size of the wounds but more importantly, prevented amputations. These significant improvements enabled the patients to continue to heal their wounds and improve their quality of life.

CONCLUSIONS

The outcomes found in this case series support the applicability of this well proven technology in patients at risk of lower leg amputation. As research has proven, mortality risk greatly increases after amputation and any treatment that can prevent amputations from occurring should be considered.

References

1. Lipsky B.A., Peters E.J., Senneville E., Berendt A.R., Embil J.M., Lavery L.A., Urbancic-Rovan V., Jeffcoate W.J. Expert opinion on the management of infections in the diabetic foot. Diabetes Metab. Res. Rev. 2012; 28 (Suppl. 1): 163-178. doi: 10.1002/dmrr.2248.
2. Wukich DK, Raspovic KM, Suder NC. Patients with Diabetic Foot Disease Fear Major Lower-Extremity Amputation More Than Death. *Foot & Ankle Specialist. 2019; 11(1): 17-21.* Downloaded March 29, 2023 from People With Diabetic Foot Disease Fear Amputation More Than Death – DE Blog (diabeticfootonline.com).
3. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
4. Rayman G et al. on behalf of the International Working Group on the Diabetic Foot (IWGDF) 2019, www.iwgdfguidelines.org.