USING A MULTILAYERED LEUKOCYTE, PLATELET, FIBRIN PATCH TO COVER EXPOSED STRUCTURES IN CHRONIC WOUNDS

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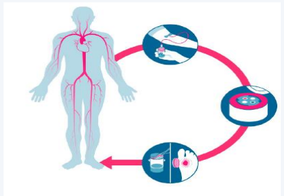
PURPOSE AND BACKGROUND

Healing chronic wounds can be incredibly challenging. It is not uncommon for patients to suffer with a chronic wound for months or even years. Healing wounds with exposed structures such as bone, tendon, or ligaments or deep into the hypodermis often demonstrates an even slower progression. The longer these structures remain exposed, the more at risk they become of infection, and non-viability. With few tools available to granulate tissue over bone, tendon, and ligaments, providers must turn to proven therapies to offer solutions to patients. A well-designed RCT, [1] using a 4-week run-in period to demonstrate wound chronicity, yielded a 58% relative increase in healing diabetic foot ulcers (some with bone, tendon, or ligament exposure) over standard of care when treated with an autologous multilayered leukocyte, platelet, fibrin (MLPF) patch. Within that study, the authors found that of the exposed structure wounds, 41% healed vs. the control of 14%. A second pilot study[2] looked at chronic wounds that probed to bone and found that 58% healed with complete epithelialization using the same autologous MLPF patch. As a result of this research, the International Working Group on the Diabetic Foot (IWGDF) has twice recommended MLPF Patch as an adjunctive treatment for non-infected diabetic foot ulcers (DFUs) that are difficult to heal[3]. With these studies in mind, we compared our outcomes in 13 patients with chronic wounds and wounds with exposed structures to those in the RCT[1] using a multilayered leukocyte, platelet, and fibrin patch.

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.

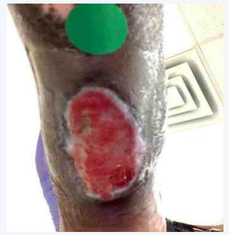
*3C Patch®, Reapplix

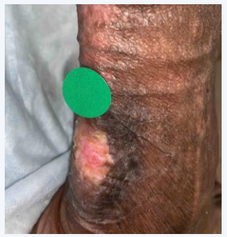
METHODS

We analyzed the results of 13 very challenging chronic wounds (defined as not improved or healed by greater than 50% in 4 weeks). 6 wounds had exposed tendon, 3 had exposed hypodermis, and 3 were chronic wounds that were hard to heal. Appropriate standard of care (sharp debridement, infection control, exudate management, offloading, edema control, and proper dressing selection) was provided with the addition of the MLPF Patch. We analyzed the closure rates of these wounds, as well as granulation rate over these exposed structures.

Case 1 Exposed Tendon

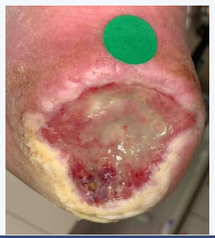
69 y/o female with diabetes, PVD, history of MRSA to the foot. Patient presented to the clinic with a diabetic ulcer to the posterior ankle. Wound was treated for 15 weeks in the wound center prior to starting MLPF Patch therapy and was 22 weeks old. This was a full-thickness wound with 25% tendon exposure. 12 patches were applied in conjunction with compression. Tendon completely covered after the 2nd application and wound ultimately closed.

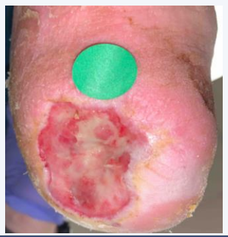




Case 2 Exposed Tendon

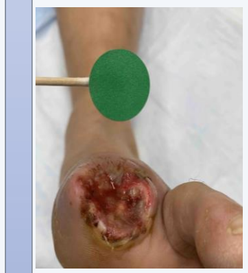
65 y/o female with hypoxia due to respiratory failure (on home oxygen), diabetes, obesity, and atrial fibrillation. Patient presented with Wagner 3 DFU to the posterior calcaneus with 25% tendon exposure. Combined with negative pressure wound therapy(NPWT), the patient received 11 MLPF patch applications. Tendon completely covered after 3rd application. Wound area was reduced by 50% before the patient was admitted to the hospital and expired due to congestive heart failure.

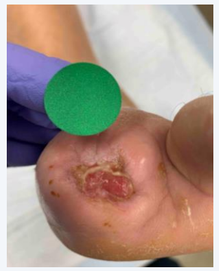


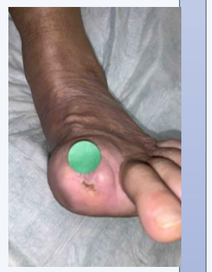


Case 3 Exposed Muscle and Fascia

68 y/o male with diabetes and neuropathy. He presented with a Wagner 3 DFU status post great toe amputation due to osteomyelitis. A full thickness wound with muscle and fascia exposed was noted at first assessment. MLPF patch treatment began 2 weeks after surgical amputation. The wound closed after 6 applications of MLPF patch at week 10 of treatment.

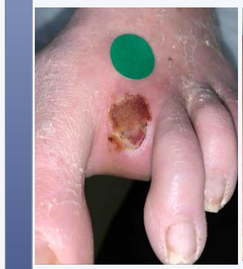


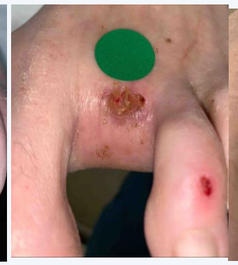


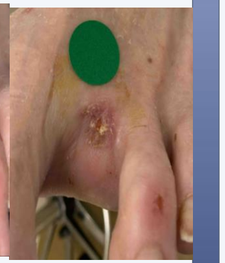


Case 4 Chronic wound

67 y/o male with diabetes, gout, prior amputations, and hypertension. He presented with a Wagner 3 DFU to the left foot status post amputation of the 2nd toe due to osteomyelitis. The wound was open for 9 weeks prior to MLPF patch treatment. The wound received 3 applications of MLPF patch and closed.





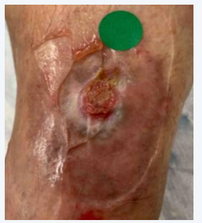


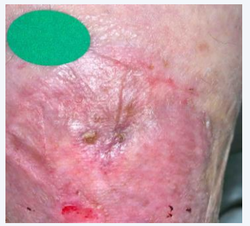
References

1. Game F et al. LeucoPatch system for the management of hard-to-heal diabetic foot ulcers in the UK, Denmark, and Sweden: an observer-masked randomized control trial. The Lancet. 2018.
2. Jergensen B, et al. (2011). A pilot study to evaluate the safety and clinical performance of Leucopatch, an autolougous, additive-free, platelet-rich fibrin for the treatment of recalcitrant chronic wounds. The International Journal of Lower Extremity Wounds, 10(4), 218-23.
3. Game F, et al. International Working Group of the Diabetic Foot guidance on use of interventions to enhance the healing of chronic foot ulcers in diabetes. (IWGDF 2023 update).

Case 5 Chronic wound

77 y/o female presented with a full thickness diabetic ulcer to the left lower extremity complicated with venous disease. The wound failed to heal with NPWT, hyperbaric oxygen, and compression. MLPF patch treatment began when the wound was 14 weeks old. This was a full thickness wound that received 5 applications of MLPF patch.





RESULTS

In the 6 patients with exposed tendons, 4 patients were able to get coverage over the tendon, 1 improved 25% before admission to hospice, and 1 required further extensive surgical debridement (clouding the ability to measure improvement). In the group of 3 patients with exposed hypodermis, 1 decreased wound size by 92% after 19 applications of the MLPF Patch, while the other 2 closed. Lastly, in the chronic wound group, 1 wound reduced volume by 43% and surface area by 13%, another healed with compression (mixed diabetic/venous ulcer to lower leg) and 5 applications of the MLPF Patch, and the last patient (VLU) received compression and 24 applications of the MLPF Patch. This patient is still undergoing therapy.

CONCLUSIONS

When good standard of care is not enough, the MLPF Patch could be a favorable option. This data shows the efficacy of an autologous MLPF Patch to be a viable treatment choice for chronic wounds, wounds deep into the hypodermis, as well as wounds with exposed structures. With zero risk of rejection, it is also a very cost-effective tool to drive down the financial impact of infection and rejection costs associated with those complications. This was a retrospective analysis, and more prospective studies may be beneficial to the wound care specialty to evaluate the cost factor in greater detail. With appropriate standard of care, the addition of this autologous MLPF patch could expedite the healing time of challenging wounds, such as those presented in this case series.