

USING A MULTILAYERED LEUKOCYTE PLATELET FIBRIN PATCH OVER EXPOSED BONE AND TENDON: A CASE SERIES OF WAGNER GRADE 3 DIABETIC FOOT ULCERS

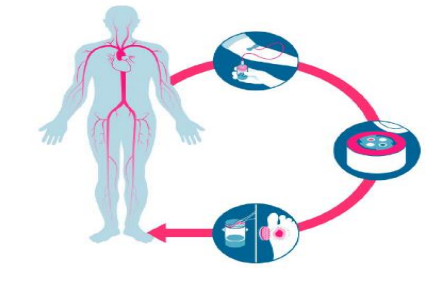
Tiffany Keith, PA-C , Jada Lowe, BSN, RN

PURPOSE AND BACKGROUND

Healing chronic wounds is particularly challenging when an exposed structure such as bone or tendon is present due to poor vascularization surrounding these structures. Poor perfusion impairs the ability to deliver essential nutrients required for wound repair. When comorbidities and limited compliance are also a factor, the wound becomes at a greater risk of infection, which further impairs the healing process. Approximately 20% of patients with diabetic foot ulcers (DFUs) develop osteomyelitis. Early and aggressive advanced modalities combined with good standard of care can greatly improve the time to heal these complex wounds. The use of an autologous multilayered leukocyte, platelet, fibrin (MLPF) patch is one such therapy that shows promise in this patient population, where few options are available.

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

In a probe-to-bone study, Fagher, et al.¹ found that by applying the MLPF patch to Wagner grade 3 DFUs, bone was covered in 18/26 ulcers (69%). 15 of those 18 ulcers achieved closure (83%) with complete epithelialization. The authors found that the MLPF patch was safe to apply to bone surfaces. Correspondingly, in the Game RCT², 12% of ulcers in the MLPF treatment group had exposed tendon, and 5% were down to bone. While the authors did not report outcomes on this subgroup, the study found clinically statistically significant healing outcomes in the MLPF patch group with no adverse effects.

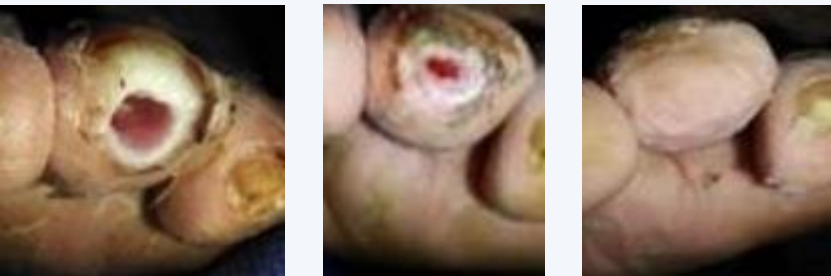
*3C Patch®, Reaplix

METHODS

We examined the use of the MLPF patch therapy in conjunction with standard of care (wound hygiene, offloading, sharp debridement, edema control, and appropriate dressing selection) in ten patients. We looked at the number of patches placed, weeks of therapy, wound age prior to beginning therapy, and previous modalities that were tried and failed. Our measure of a positive outcome was granulation over the exposed structures, as there are limited products indicated for this use with success.

Case 1

53-year-old diabetic female with traumatic injury to her third toe on her left foot. Conservative standard of care did not produce results, and it was deemed at 6 weeks to begin treating her with the MLPF patch. This patient has comorbid conditions of CHF, neuropathy, lymphedema, hypertension, sleep apnea, and confinement anxiety. She had been moderately compliant with therapy. Her wound healed using the MLPF patch after 3 applications.



Case 2

84-year-old male with diabetes with a Wagner Grade 2 DFU was treated beginning 5/6/24 with a measurement of 1.9 x 1.8 x 0.7cm. Aquacel AG Advantage, Sorbact with Orthofelt to offload, and total contact casting with Sorbact was tried, but the wound deteriorated to a Wagner Grade 3. He received his first MLPF patch on 8/29/24 (wound was 2.0 x 1.6 x 0.4cm) and received 8 subsequent MLPF patches. His wound healed on November 1st, 2024 after a total of 9 patch applications.



Case 3

69-year-old African American female presented to the clinic in May 2024 with a Wagner Grade 2 DFU to the right 4th toe measuring 1.5 cm². She was referred to vascular surgery for revascularization. Clinicians were concerned that a toe amputation would be required. The patient was treated with IV antibiotics. Santyl and Sorbact were also tried with minimal improvement. A cellular tissue product was considered but denied by insurance. Her wound regressed to 31.5 cm² in July. Bone was exposed in July, and a bone biopsy was performed. A decision was made to try the MLPF Patch to save the toe. On 8/22/24, the MLPF Patch was initiated with a wound measurement of 5.25 cm². The patient was completely healed on 11/13/2024.



Case 4-Ongoing

69-year-old diabetic female presented to the clinic with a circumferential wound to her second toe secondary to trauma. The wound was 100% black eschar. Debridement and bone biopsy was performed. The MLPF patch was initiated with beginning measurements of 1.4 x 2.4 cm. Wound age was 5 weeks at start of MLPF patch. Immediately the wound has responded positively.



RESULTS

Ten patients with Wagner 3 DFUs were chosen for their exposed bone or tendon to evaluate the effectiveness of the MLPF patch to cover the structures. Not only did the product deliver this positive outcome, but it went on to heal all but one patient who is currently still in treatment. This is promising data that should be replicated with a larger number of consecutive patients with Wagner 3 or exposed structures to determine the full efficacy of the product. Considering the complexity and acuity of all ten patients, this product's efficacy is notable.

CATEGORY	DATA
HEALING RATE	9/10 (90%)
SEX	MALE (5) FEMALE (5)
MEAN WOUND AGE	21 WEEKS
MEAN PATIENT AGE	63 YEARS
MEAN WOUND AREA AT START	1.4 cm ²
WAGNER GRADE 3	10
PREVIOUS TRIED THERAPIES	NPWT (2) CTP (2) TCC (2)
HISTORY OF COMPLIANCE	HIGH (4) MOD (4) LOW (2)

CONCLUSIONS

Medicare spends over \$32 billion annually on wound related treatments. The cost for wounds with exposed structures is significant, as it takes much longer to granulate over these structures, particularly in complex patients. More studies should be conducted on the financial benefit of using autologous MLPF patches on patients with exposed structures as a first option of therapy. The amount of money that could have been saved on these cases if 3C Patch was used first would be of interest to the authors and their clinic.

References

- Fagher, K., Katzman, P., Asmundsson, A., Ley, M. R., Larsson, G., Ahlberg, M., ... Löndahl, M. (2015). Treatment with a leukocytes and platelet rich fibrin patch on hard-to-heal diabetic foot ulcers probing to bone. POSTER ISOF, 58. Den Haag, 2015.
- 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.