

# The Use of An Autologous Multilayered Leukocyte, Platelet and Fibrin Patch in Healing Recalcitrant Chronic Ulcers

DR. DAVID KNIGHT, MD, DR. PETER FERRANTE, DPM, DR. PETER ZDANKIEWICZ, MD AND MICHAEL DORSO, LPN, PROGRAM DIRECTOR, RESTORIX HEALTH, WATERBURY, CT

## PURPOSE

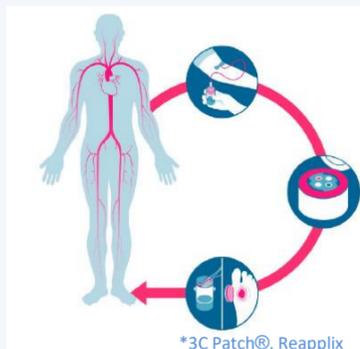
A chronic ulcer is described as an ulcer that doesn't follow the normal wound healing trajectory as expected but rather, due to various reasons, fails to progress as expected. These chronic ulcers take a huge toll on the patient as well as on the health care system, costing billions of dollars each year. Novel ways of treating chronic ulcers continue to be developed. One newer technology is the use of an autologous multilayered leukocyte, platelet and fibrin (MLPF) patch to heal patients with diabetes and chronic ulcers and improve their quality of life. This case series evaluated the effectiveness of this technology in healing these recalcitrant wounds.

## BACKGROUND

Currently, there are 415 million adults living with diabetes in the world, with a prediction of 640 million by 2040. One in 2 adults with diabetes are not aware they have it but are already experiencing complications from diabetes, such as retinopathy, cardiovascular disease, kidney disease, and neuropathy. Diabetes also increases one's risk of mobility impairment by 70%<sup>1</sup>. The symptoms of neuropathy are what leads to diabetic foot ulcers (DFUs). One in every 4 adults with diabetes will develop a foot ulcer and up to 56% of these ulcers will become infected. Additionally, a person with a diabetic foot ulcer is 30 times more likely to have an amputation than someone with a non-diabetic foot ulcer. Due to these statistics, it is imperative to treat DFUs early, before the ulcer becomes infected and ultimately leads to amputation and even death.

## 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 fully automated procedure consisting of a 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.

## 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)<sup>2</sup>. 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<sup>2</sup>. 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<sup>3</sup>.

## METHODS

This case series presents four patients who failed to progress in a timely repair sequence using conventional wound care, despite weekly sharp debridement, local wound care and offloading or compression as indicated. Other advanced wound products have been tried and failed. All patients presented with type 2 diabetes. Two patients presented with unique wounds, one in an area of radiation damage and the other in a total hip replacement that developed osteomyelitis. Weekly patches were applied with therapy ranging from one to 13 applications. Patient age range was 67-81 years old. Investigators measured and analyzed wounds weekly.

## RESULTS

### Case 1



67-year-old female, type 2 DM, history of radiation damage to anterior leg present for over 3 years. Wound area at start of MLPF therapy: 12.75 cm<sup>2</sup>. After 6 MLPF applications, wound decreased to 3.5 cm<sup>2</sup>. After 12 applications, wound decreased to 2.25 cm<sup>2</sup>. In addition to a decrease in wound size, patient's pain also dramatically decreased. The MLPF therapy gave her hope and ultimately led to her giving up alcohol which she had been using as coping mechanism.

### Case 2



77-year-old male, type 2 DM, PAD with prior revascularization. Wound on right medial foot. History of pseudomonas and osteomyelitis. Previously tried negative pressure wound therapy and extracellular matrix products. Wound decreased in size from 76.5 cm<sup>2</sup> to 1.5 cm<sup>2</sup> after 8 application of the MLPF patch.

### Case 3



81 y/o female, type 2 DM. On Xarelto. Demonstrated a reduction in wound size from 0.686 cm<sup>3</sup> to 0.096 cm<sup>3</sup> after 8 applications of the MLPF patch.

### Case 4



70-year-old male diner owner. Type 2 DM, venous insufficiency, and peripheral vascular disease with revascularization. Wound failed to progress so patient was started on hyperbaric oxygen treatments and MLPF patch therapy. Wound area at start of MLPF patch: 1.2 cm<sup>2</sup>. After 8 weeks, wound had decreased in area to 0.25 cm<sup>2</sup> a reduction of 80%. Prior to initiation of MLPF patch applications, patient's pain was so severe he was having difficulty sleeping. With this therapy his pain has dramatically decreased, so much so that he shares his experience with friends and patrons.

## DISCUSSION

In this case series, the use of the autologous patch, in conjunction with local sharp debridement and standard of care dressings demonstrated significant improvement in not only the size of the wound but also the quality and integrity of the healed tissue. Due to improvements in wound healing, not only have the patients' wounds improved but also the patients' quality of life, prompting one patient to give up alcohol because of the hope the patch has given her.

## CONCLUSIONS

The outcomes found in this case series, including a very challenging patient population, support the applicability of this multilayered leukocyte, platelet, and fibrin patch. In a patient population where recalcitrant chronic ulcers are frequently seen, providing therapy that supports wound healing is necessary to prevent infection, amputation and possibly death.

### References

1. Wong. Lancet D&E, 2013; 1: 106-14.
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.