



# THE USE OF NEAR-INFRARED SPECTROSCOPY (NIRS) AND A MULTILAYERED LEUKOCYTE, PLATELET, AND FIBRIN PATCH FOR DIFFICULT TO HEAL DIABETIC FOOT ULCERS

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## PURPOSE AND BACKGROUND

Diabetic foot ulcers (DFUs) continue to be challenging to treat appropriately, and the costs associated with them continue to grow. One statistic is that one million dollars are spent on diabetic foot complications every 30 minutes in the US. A significant proportion of patients with DFUs also have peripheral vascular disease. Armstrong et al reported that the “current prevalence of [purely neuropathic, purely ischemic or a combination of the two] is 35%, 15%, and 50% respectively.”<sup>1</sup> As health care providers, it is imperative that the interventions chosen for DFUs are effective and evidence-based. The use of Near-Infrared Spectroscopy (NIRS) allows providers to determine if wounds are adequately perfused, which is essential to wound healing. In addition, the use of a multilayered leukocyte, platelet, and fibrin patch (MLPF) has been proven to accelerate wound healing via increased angiogenesis in DFU. This study sought to determine if the use of NIRS prior to placement of the MLPF patch would enhance healing in difficult to heal DFUs and improve perfusion.

## 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 fully autologous, easily transferable to the patient, and displays a three-layered structure of leukocytes, platelets and fibrin. This facilitates a sustained release of living cells and growth factors into the wound bed, including VEGF which stimulates angiogenesis.



## SUPPORT FOR MLPF PATCH

Game et al. evaluated the clinical effect of the MLPF patch on hard-to-heal DFUs in a large randomized clinical trial (RCT, n=269)<sup>2</sup>. Included were patients with ABIs as low as 0.5, a population typically excluded from clinical research. Despite including patients with low ABIs, this RCT still found a 58% relative increase in wound healing over the standard of care group. Similarly, Mendivil et al. published retrospective data showing that despite 78% of the patients having peripheral vascular disease and 56% having previous vascular interventions, 61% of wounds closed within 20 weeks of treatment, further supporting the use of the MLPF patch in ischemic patients<sup>3</sup>.

\*3C Patch®, Reaplix

## WHAT IS NEAR INFRARED SPECTROSCOPY?

The use of near infrared spectroscopy (NIRS) is rapidly becoming a reliable tool for vascular assessment as the ankle-brachial index (ABI) does not accurately reflect blood flow in diabetics due to calcification of vessels. The particular NIRS product utilized in our clinic, Mimosa®, allows detection of tissue oximetry and temperature in skin with the use of near infrared and infrared light. When assessing tissue oximetry, warmer colors such as red or yellow indicate adequate tissue oxygenation whereas cooler colors such as blue or purple indicate the need for close monitoring or vascular intervention. Likewise, warmer colors indicate normal tissue temperature whereas cooler colors indicate lack of perfusion.

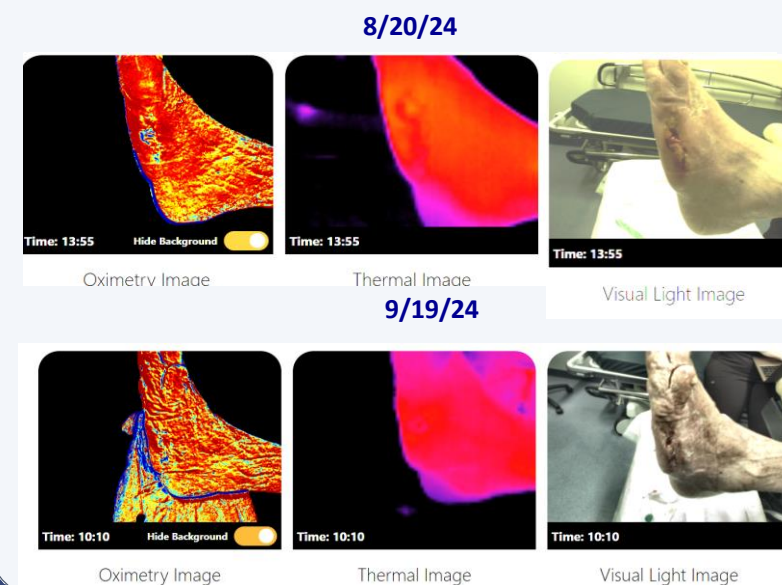
## METHODS

Our center uses NIRS before and after debridement to determine if sufficient debridement has been performed and if adequate perfusion is present. We have adopted this process when applying the MLPF to ensure proper wound bed preparation. This poster demonstrates how patients responded well to the MLPF patch, evidenced not only by wound closure but also by improvements in perfusion levels provided by NIRS imaging.

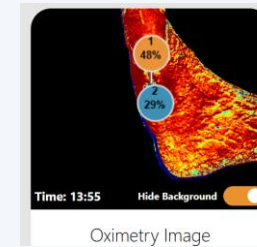
## RESULTS

### Case 1

81-year-old male treated in our clinic for over 9 months. He had a history of osteomyelitis and received hyperbaric oxygen therapy for 3 months. He failed several cellular tissue products as well as several attempts at surgical closure. After just 6 applications of the MLPF patch, using NIRS to assess tissue perfusion (and provide a baseline), his wound went from 3.1 cm<sup>2</sup> to closed with restored complete tissue oxygenation.

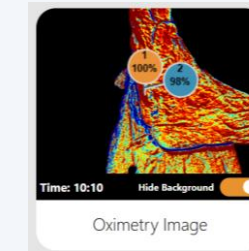


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Areas of decreased perfusion noted

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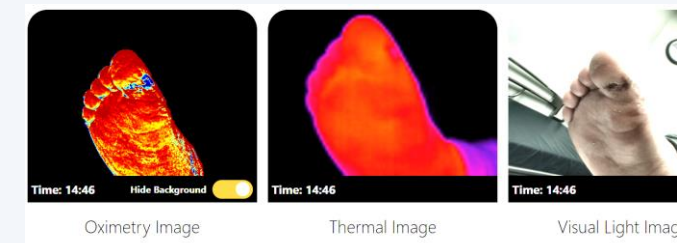


Improved perfusion noted with use of MLPF Patch

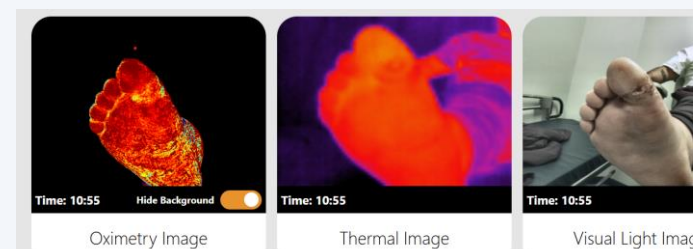
### Case 2

35-year-old male with type 2 diabetes presented with a wound to the plantar aspect of his right foot. In order to preserve this patient's limb, and accelerate healing, the MLPF patch was used as a first line of defense. Although his youth was likely helpful, the MLPF patch performed much the same way as the elderly patient. After 9 MLPF patch applications and using NIRS to assess tissue perfusion and oxygenation (and provide a baseline), the patient's wound went on to full healing.

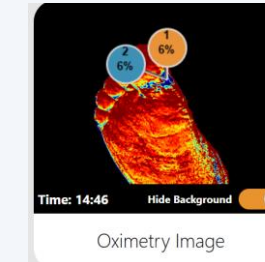
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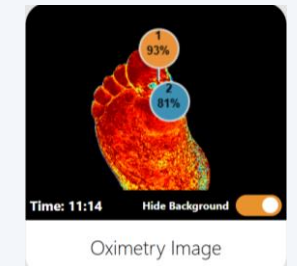


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Areas of decreased perfusion noted

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Improved perfusion noted with use of MLPF Patch

## CONCLUSION

The utilization of Near-Infrared Spectroscopy (NIRS) has demonstrated the significant angiogenic response induced by the MLPF patch—an important finding given that diabetic foot ulcers (DFUs) are frequently associated with ischemia. Further studies are needed to determine the effectiveness of the MLPF patch in all ischemic wounds. This author would be interested in continued research in the use of DFUs as well as further research hypothesizing reperfusion induced by the MLPF patch in other ischemic wounds such as pressure injuries and vascular ulcers.

## References

1. Armstrong et al. DFUs and vascular insufficiency: Our population has changed, but our methods have not. J Diabetes Sci Technology. 2011 Nov 1; 5(6): 1591-1595.
2. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
3. Mendivil et al. Retrospective Data Analysis of the Use of an Autologous Multilayered Leukocyte, Platelet, and Fibrin Patch for Diabetic Foot Ulcers Treatment in Daily Clinical Practice. Adv Skin & Wound Care, Nov 2023.