DISPROVING MISCONCEPTIONS SURROUNDING WORKFLOW EFFICIENCY IN A HOSPITAL-BASED WOUND CENTER WITH THE AUTOLOGOUS MULTILAYERED LEUKOCYTE, PLATELET, AND FIBRIN PATCH

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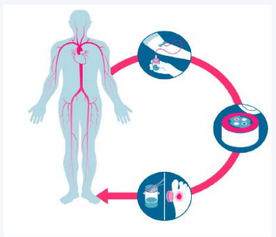
PURPOSE AND BACKGROUND

A novel therapy for treating diabetic foot ulcers (DFUs) is the use of the autologous multilayered leukocyte, platelet, and fibrin (MLPF) patch. While a robust randomized controlled trial[1] was conducted to prove its efficacy, many providers and program directors are reluctant to incorporate this treatment into their practice. Misconceptions exist that this therapy is too timely for a busy wound care center and that its use will negatively impact the workflow of a hospital-based wound center. When reviewing our own center's efficiency, we were curious to determine if the use of the MLPF Patch did in fact alter our workflow and how it differed from other treatment interventions.

WHAT IS THE MLPF PATCH?

The multilayered leukocyte, platelet, and fibrin (MLPF) patch* was developed in Denmark and is now available in the U.S. 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, 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.

*3C Patch®, Reapplix

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)[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. As a result, the International Working Group on the Diabetic Foot (IWGDF) continues to recommend MLPF Patch as an adjunctive treatment for non-infected diabetic foot ulcers that are difficult to heal[2].

METHODS

In this study, we analyzed thirty patients over four months in each of these categories:

- Debridement without special procedure
- Debridement with application of a cellular tissue product
- Debridement with application of the MLPF patch.

We looked at the cumulative time of a visit, excluding any abnormal offset variables that would prolong the visit time. This includes registration, intake, procedure, the application of a secondary dressing, and discharge. We determined average registration/intake time and discharge time to be 15 minutes each.

When considering the time needed to apply a cellular tissue product, we included the time required to log in the cellular tissue product and any subsequent tracking.

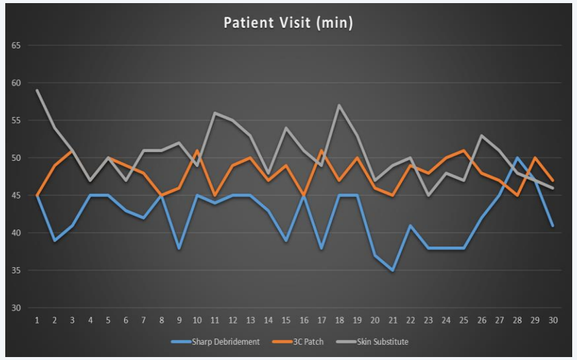
RESULTS

What we found initially was not unexpected; the debridement visit without separate procedure was obviously the quickest, with an average of 42.3 minutes per visit. Interestingly, the MLPF patch only extended the visits an average of 5 minutes, with an average of 48.0 minutes per visit. This was less than the cellular tissue product visit, by an average of 4 minutes. We found our average visit when applying a cellular tissue product was 50.6 minutes; this time includes time spent logging and tracking the cellular tissue product.

Procedure	Average Time(minutes)
Sharp debridement only	42.3
Sharp debridement + 3C Patch	48.0
Sharp debridement + Cellular Tissue Product	50.6

After analyzing the data statistics (Students' T-test), we found a statistically significant difference between the pairs:

95% CI
Debridement vs. 3C Patch 3.32914E-10
3CP vs. CTP 0.000872253
Debridement vs. CTP 7.44016E-13



CONCLUSIONS

Even though the MLPF patch requires additional time for venipuncture and the automated proprietary centrifugation process, the time spent in the hospital-based wound center was approximately 4 minutes less than when a cellular tissue product was used. In addition to saving the time of logging and tracking needed for CTPs (not necessary for autologous therapy), other benefits of the MLPF patch include no special storage requirements and zero risk of rejection. This data disproves the common misconceptions of slowing the clinic workflow and negatively impacting a wound center's efficiency. Therefore, the MLPF patch should be considered as a first line advanced wound care treatment option without hesitation. One limitation of our study is that it was conducted only in a hospital-based wound center. These results do not represent the complexity and workflow in a physician-office setting where human resources and space may be limited. Further replication of this protocol in other centers that use the MLPF patch is needed to affirm these findings.

References

1. Game F et al. The Lancet. 2018 Nov; 6(11): 870-878.
2. Schaper N et al. on behalf of the International Working Group on the Diabetic Foot (IWGDF) 2023, www.iwgdfguidelines.org.