



Clinical Experience with Human Keratin Matrix* in the Treatment of Venous Ulcers

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INTRODUCTION

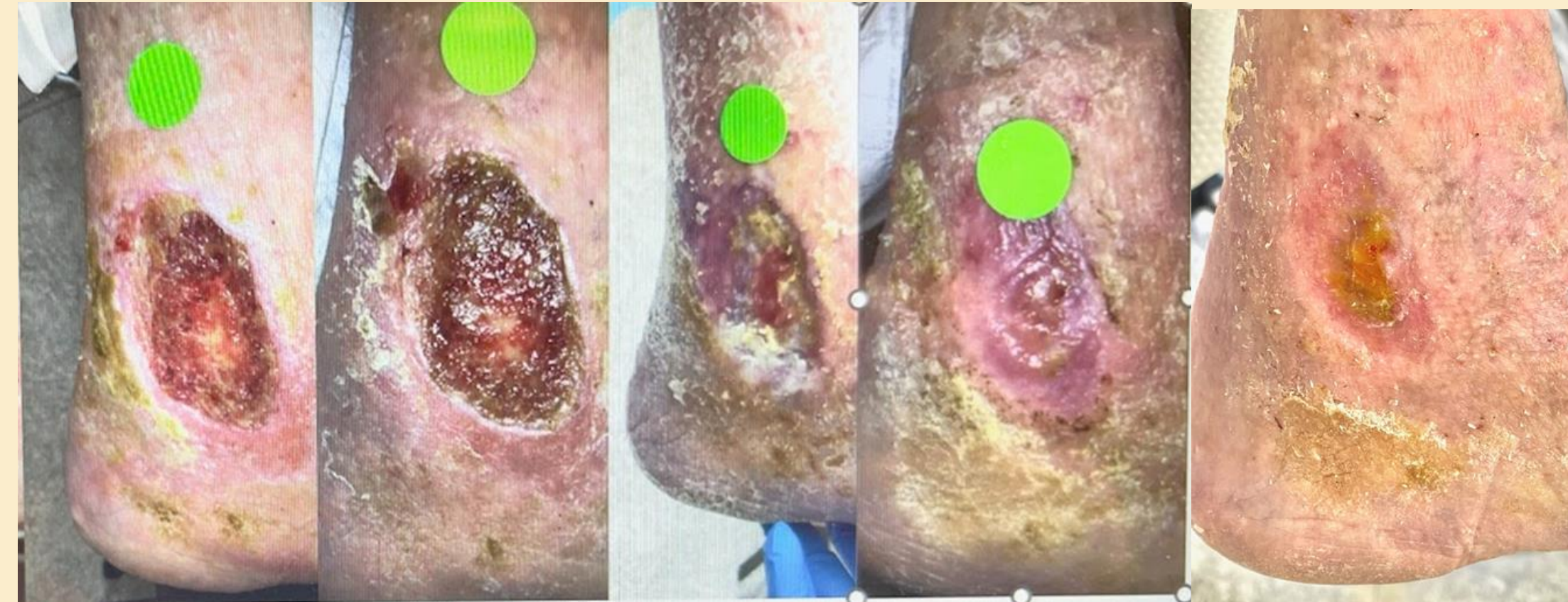
Venous Leg Ulcers (VLUs) are the most common type of lower extremity ulcer, accounting for 70–80% of ulcers that individuals seek medical evaluation and treatment for¹. These ulcers are typically the consequence of prolonged untreated ambulatory venous hypertension, characterized by persistent elevation in venous pressure while standing or walking, leading to chronic inflammation and compromised skin integrity. In the United States alone, it is estimated that approximately 6 million individuals are afflicted with Venous Leg Ulcers. This prevalence is particularly noteworthy as it accounts for up to 2% of the overall population, and 5% among individuals aged 65 and above¹.

These statistics underscore the significant burden that VLUs pose on both individual health and healthcare resources. The chronic and recurrent nature of VLUs emphasizes the need for effective management strategies and continued medical attention to mitigate their impact on affected individuals' quality of life and healthcare systems. In this study, we evaluated the effectiveness utilizing a human keratin matrix (HKM) in addition to standard of care treatments for healing VLUs.

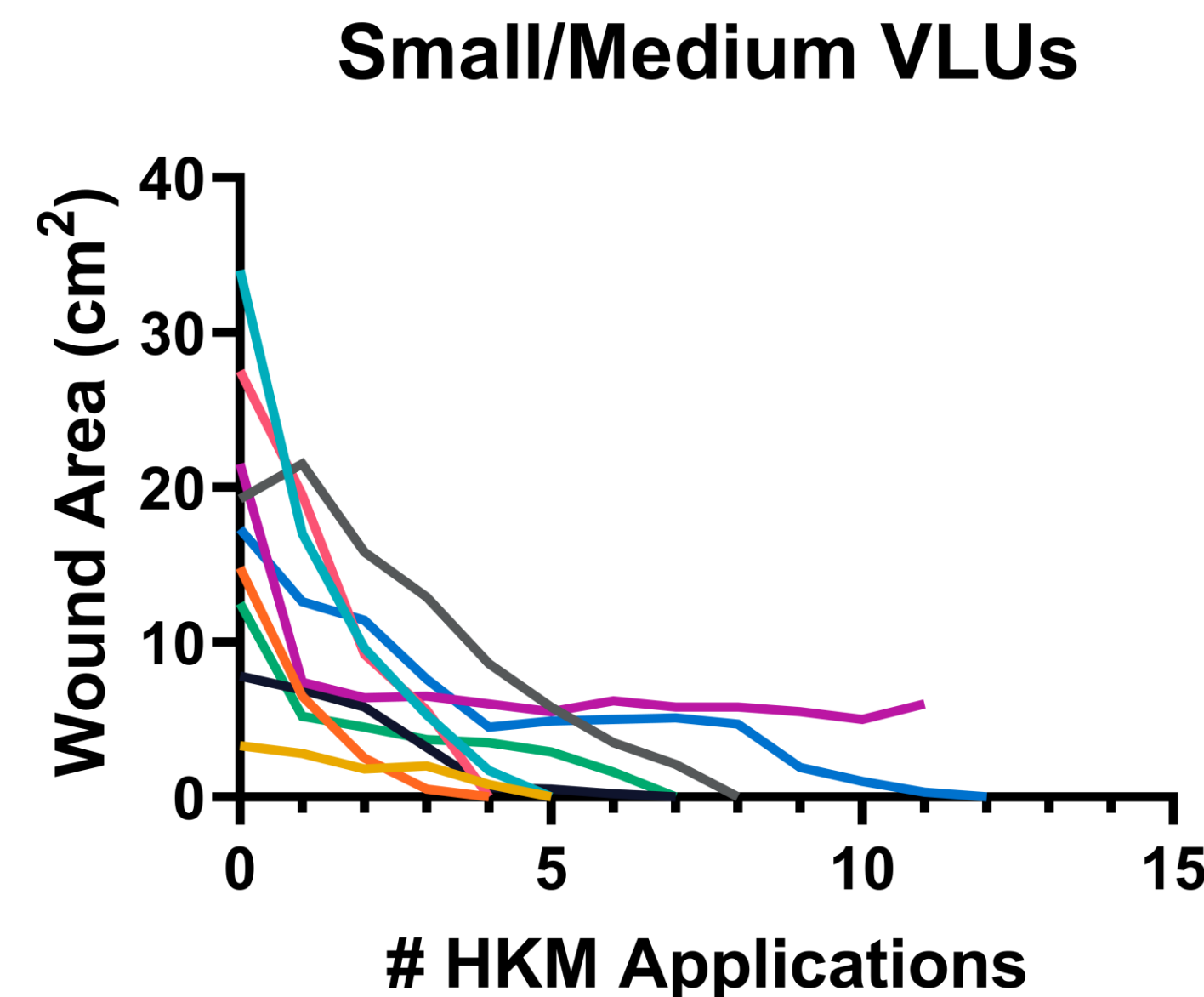
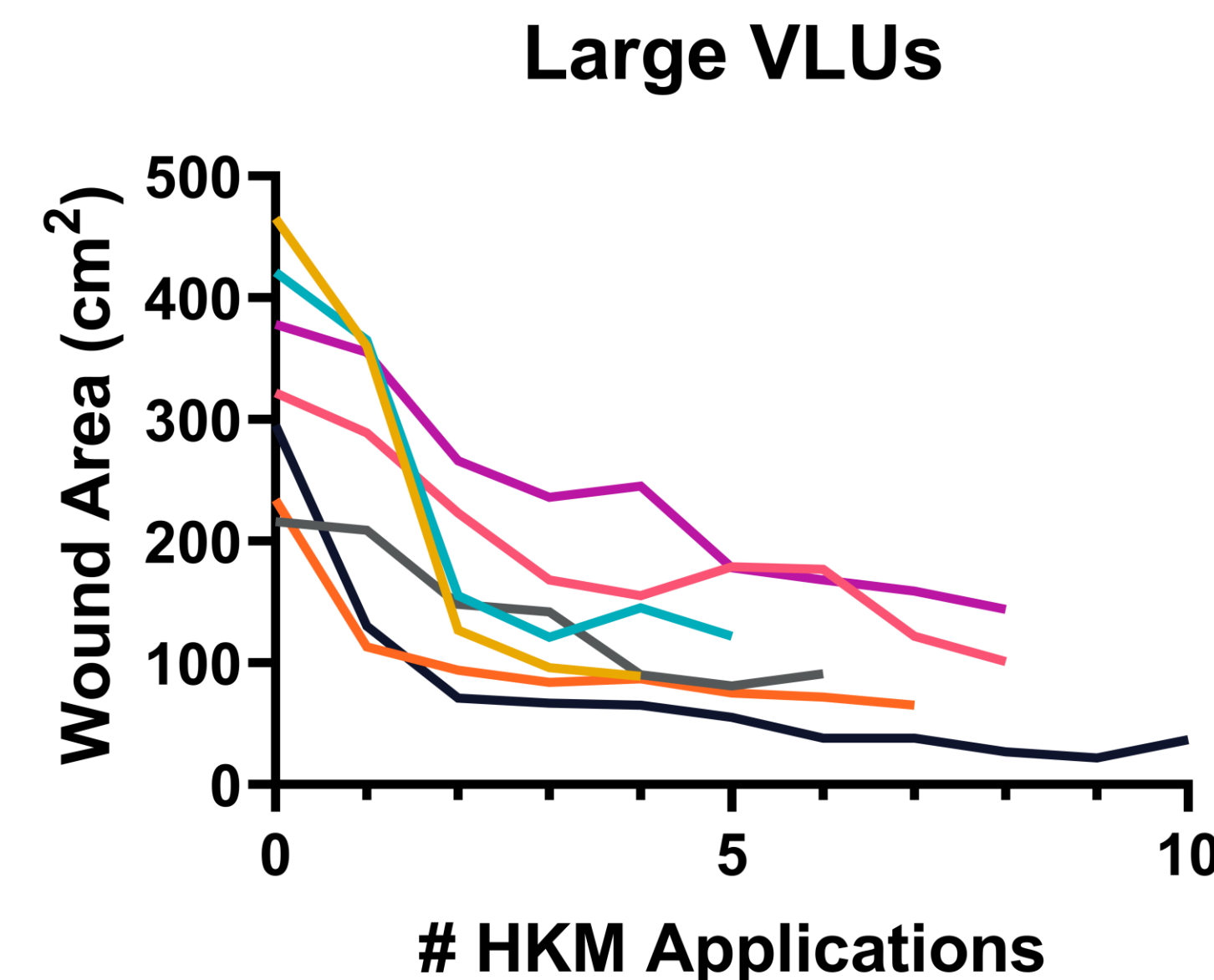
METHODS

This retrospective study investigates the efficacy of a HKM in promoting the healing of VLUs. Standard of care for this study included detailed noninvasive venous insufficiency identification, endovenous interventions, compression therapy, and wound care. Wound care for this study consisted of topical analgesia, debridement, hypochlorous acid-soaked gauze applications, and normal saline irrigations. The HKM was fenestrated and applied directly to the wound bed. The graft was secured by a one-sided silicone adhesive contact layer, and covered with hydrogel, a 4x4 gauze, and a foam dressing. Compression was achieved with a three-layer compression wrap.

RESULTS



97-year-old male patient with a wound age of 3 years treated with 4 applications human keratin matrix. Time to closure after starting applications was 40 days



These graphs represent the wound surface area reduction for two groups of patients: large and small/medium VLUs. The large VLU group consists of 7 patients with wound area sizes 113–365 cm². The small/medium VLU group consists of 9 patients with wound area sizes of 2.8–21.5 cm². Each colored line on the graph represents a different patient.

DEMOGRAPHICS

Large VLUs	Small to Medium VLUs
Mean age 62.5 years old	Mean age: 67 years old
7 patients: 5 male, 2 female	9 patients: 5 male, 4 female
History of deep vein thrombosis: 4/7	History deep vein thrombosis: 2/9
Popliteal vein reflux: 6/7	Popliteal vein reflux: 3/9
Below knee great saphenous vein reflux: 5/7	Below knee great saphenous vein reflux: 7/9
Great saphenous vein ablation: 6/7	

DISCUSSION

Our findings revealed a **49% average reduction** in the ulcer surface area in the larger VLU group and a **69% reduction** in the small to medium VLU group **after just three applications** of the human keratin matrix. In the larger VLUs, the average reduction in ulcer area at the conclusion of the application regimen was **62%**. These participants received **6 applications** of the product on average. In the small to medium VLU group, **8 out of 9 (88%) VLUs healed completely** during the study period. These participants averaged **4.5 applications** of the HKM.

There have been significant advances to our understanding of this type of Ulcer, and the development of endovenous interventions the last decade has been associated with improvements in healing times and reduction of recurrence rates. Simultaneously, several advances have been observed in the local management of VLUs. Despite the many options available for small VLUs, there is paucity of local products aiming to treat large VLUs. These outcomes indicate the significant potential of the human keratin matrix as a promising intervention for the treatment of VLUs of all sizes.

REFERENCES

1. Raffetto JD et al. *Journal of Clinical Medicine*. 2021; 10(1):29