



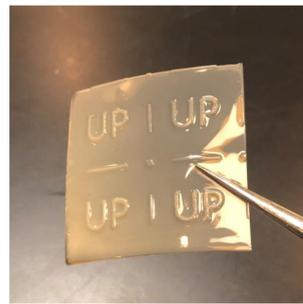
# Real-World Treatment Scenarios of Complex Lower Extremity Wounds with a Human Keratin Hydrogel Matrix

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## INTRODUCTION

Many chronic wound etiologies are based in severe comorbidities (e.g. diabetes, infections, or vascular insufficiencies) that greatly impact their ability to heal. As such, trials of novel therapeutics have narrow inclusion criteria and treatment instructions that provide ideal results which may not be replicated in the clinic. Because of this, there has been a recent push for real-world results and risk-adjusted data to better define wound healing outcomes<sup>1</sup>.

Research has shown keratin may mitigate some aspect of chronic wound pathology, such as inflammation<sup>2</sup>, and promote closure of chronic wounds<sup>3</sup>. Here, we used a human keratin hydrogel matrix (HKHM) on multiple patients with complicated wounds to collect real-world evidence on its wound healing efficacy.



Human Keratin Hydrogel Matrix (HKHM)

## METHODS

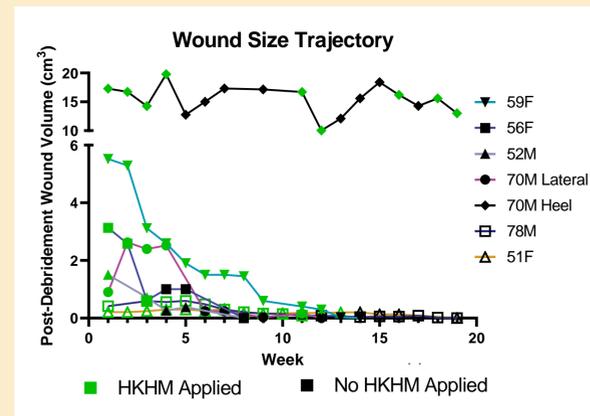
Six patients (3 female, 3 male, >50 y.o.) with a total of 7 wounds were seen weekly for debridement, wound volume measurement, and treatment with HKHM at the provider's discretion. Other secondary treatments were prescribed as indicated.

Patient	Wound Type	Comorbidities	Run-In
56F	Necrotizing Fasciitis	Cancer (+Chemotherapy), COPD	3 mo.
52M	DFU	Type 1 Diabetes, Anemia	2 wk.
59F	Dehiscence	Type 2 Diabetes	4 mo.
70M			
78M	DFU	Type 2 Diabetes, Leukemia, PAD	2 wk.
51F	Venous Stasis	Venous Insufficiency	1 mo.

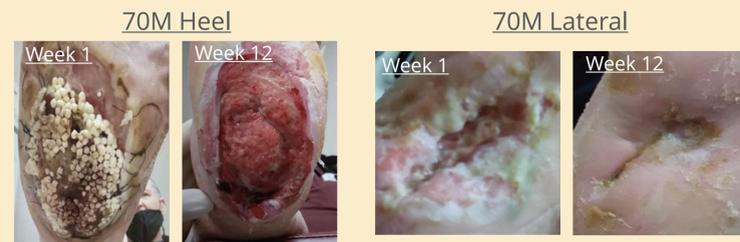
## SIGNIFICANCE

Providers often see patients with very large wounds, infections, unmanaged comorbidities, etc. Additionally, healthcare coverage may limit the number of applications of advanced wound care products for a single patient. By presenting our results treating complicated wounds and limited treatments with HKHM, it can be better determined in which wound care scenarios this product will be effective.

## RESULTS



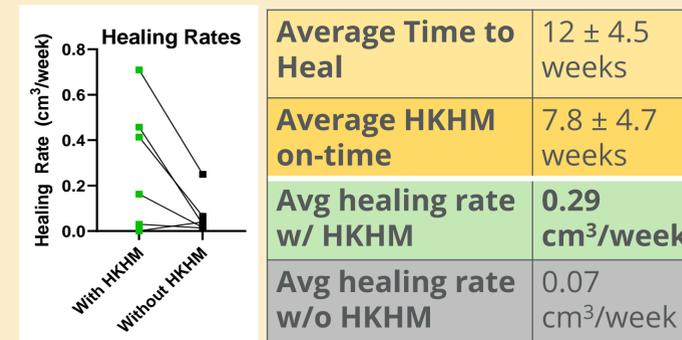
Graph of wound size progression during the treatment period. Six wounds closed during the study period in an average of 12 weeks. In all cases, HKHM treatment was applied for at least the first three weeks of treatment. Use was discontinued in this study due to suspected infection or sufficient healing.



One wound remained open and is under treatment due to recurrent infection. Another wound on the same foot of the patient healed completely in 12 weeks.



Examples of wounds closed in this study. Green regions represent usage of HKHM.



Analysis of healing rates in the 6 wounds that healed during the study period.

## DISCUSSION

Wound care is a diverse field spanning numerous medical specialties, and wound care providers encounter many different types of patients each with a different medical history beyond their wound. Because of these intricacies, "real-world data" has become increasingly important in wound care. Indeed, many conditions contribute to wound etiology and chronicity<sup>4</sup> and providers need access to real-world data to understand how these underlying pathologies will affect their wound treatment plan.

In this work, we show HKHM is an effective product to promote closure of chronic lower extremity wounds in a variety of patients with complicated wounds. In these cases, HKHM was applied for at least the first 3 weeks of treatment, then discontinued when the wound no longer warranted use of an advanced wound care product. Interestingly, these wounds that previously had not closed with standard of care did so after HKHM treatment.

Keratin has previously been demonstrated to positively impact factors of wound chronicity, including protease activity<sup>5</sup> and chronic inflammation<sup>2</sup>, suggesting it may help move the wound to a pro-healing state. Our results show HKHM is effective in complex wound healing scenarios and when weekly application is unavailable.

## REFERENCES

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