Limb Preservation and Functionality Utilizing a Human Keratin Hydrogel Matrix Wound Covering for Chronic Diabetic Ulcerations

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INTRODUCTION

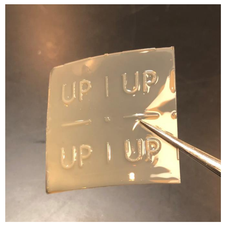
Diabetic ulcerations are one of the primary factors in lower extremity amputation[1]. Because of the high 5-year mortality rate of limb amputations[2], wound care providers may attempt to surgically close chronically open wounds with a split-thickness skin graft (STSG) taken from healthy skin of the same patient.

While these can be highly effective, they create another wound on the patient that must heal. This recovery period does not address the impact chronic lower extremity wounds have on patient quality of life, such as impaired ambulation and the time take for constant wound care.

Providers may also attempt to achieve wound closure using advanced wound care products, such as a human keratin hydrogel matrix (HKHM). Keratin products have been demonstrated to assist in healing chronic wounds[3], but improvement of quality of life has not yet been directly investigated. Here, we study a limited series of chronic diabetic wound patients treated with HKHM for wound closure and restored ambulation.

METHODS

Four patients (42-70 years old) with wounds that had not healed after at least 5 weeks of standard of care were seen weekly for wound care: debridement, HKHM application, appropriate secondary dressing, and offloading where indicated. Wound size was measured weekly until closure. Function restoration was assessed as return to normal ambulation after wound closure.



Human Keratin Hydrogel Matrix (HKHM)

SIGNIFICANCE

Chronic lower extremity wounds can often inhibit the ability to walk normally or at all, and these disrupted biomechanics may even result in additional wounds in the foot and ankle. It is important to know that the healed skin of a wound after closure with HKHM will support normal ambulation without pain or damage to the new tissue.

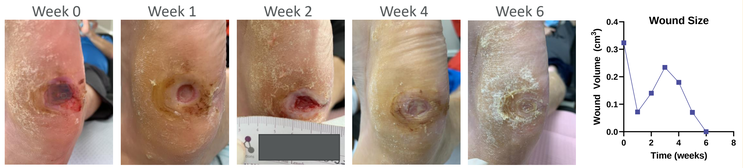
RESULTS

Case 1: 63-Year-Old Male

Plantar, right great toe
- Diabetes Mellitus (HgA1c 8.0)
- Peripheral Artery Disease
- 6 weeks unresponsive to standard of care

Case 2: 65-Year-Old Male

Plantar, left foot infection
- Diabetes Mellitus (HgA1c 6.6)
- Psoriasis
- Thrombocytopenia
- IV antibiotics
- 16 weeks since 1st presentation

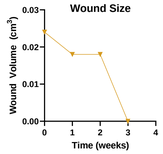


Case 3: 51-Year-Old Male

Plantar, left foot abcess
- Diabetes Mellitus (HgA1c 9.0)
- Previous adenoidectomy
- 5 weeks wound vac and IV antibiotics

Case 4: 42-Year-Old Female

Plantar, right great toe
- Diabetes Mellitus (HgA1c 8.0)
- Past infection and antibiotic injection
- 8 weeks unresponsive to standard of care



DISCUSSION

Non-healing lower extremity wounds are common in diabetic patients, affecting around 13% of diabetics[4]. Previous research showed keratin may mitigate some of the proposed causes of chronicity in diabetic wounds, such as dysregulated inflammation[5]. However, wound closure is only one aspect of treating the wound patient.

In this first investigation into restored quality of life in diabetic chronic wound patients, all wounds closed 100% with HKHM treatment without the need for surgical closure via STSG. These patients were able to return to normal ambulation on the treated foot, and have not shown any recurrence in the 3 months since the study conclusion.

Creating a functional and persistent positive outcome for the patient is essential to maintain their quality of life. Our data suggest HKHM, in conjunction with good standard wound care practices, promotes functional healing in chronic diabetic ulcers without surgical intervention. Future investigation will continue to monitor for wound recurrence, and quantitative quality-of-life assessments will give more insight into the efficacy of HKHM.

REFERENCES

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