

Background

Current Standard of Care for DFU's represents a growing cost to healthcare and produces sub-optimal clinical outcomes resulting in avoidable complications including amputation and significant quality of life implications for people with diabetes.

Here we report on the treatment of five patients with non-healing DFU's using an Advanced Regenerative Tissue Matrix.* This product is a decellularized human skin that maintains the structural matrix through a unique cell extraction and non-gamma sterilization process.¹ This preserves the biochemistry of the skin's healing environment and provides one-and-done application aimed at improving healing outcomes, improving the patient and clinician experience and lowering health care costs.

Purpose

This case series was conducted at WestView Ambulatory Outpatient Wound clinic in Stony Plain, AB. The purpose of this case series was two-fold. First, was to determine the effect of an Advanced Regenerative Tissue Matrix* on wound healing trajectories. The second was to examine clinician and patient reported experiences related to application and outcomes.

Methods

Five patients with DFUs received a one-time application of the regenerative matrix. Wound duration ranged from three months (post-surgical) to more than two years. One patient had three wounds, and another had two for a total of eight wounds receiving matrix application. Each patient followed a strict plantar pressure off-loading plan, regularly attended West View Ambulatory Wound Clinic, and performed diabetes self-care.

Infection was ruled out or treated prior to matrix application. Each wound was sharply debrided, and the matrix applied according to protocol. An appropriate cover dressing was then applied, and a strict offloading plan was followed.

Patients attended at least weekly dressing changes with close monitoring. This included photo documentation. Diabetes management was assessed through review of HgA1C within 3 months of matrix application.

*- DermGEN™ - DeCell Technologies inc.

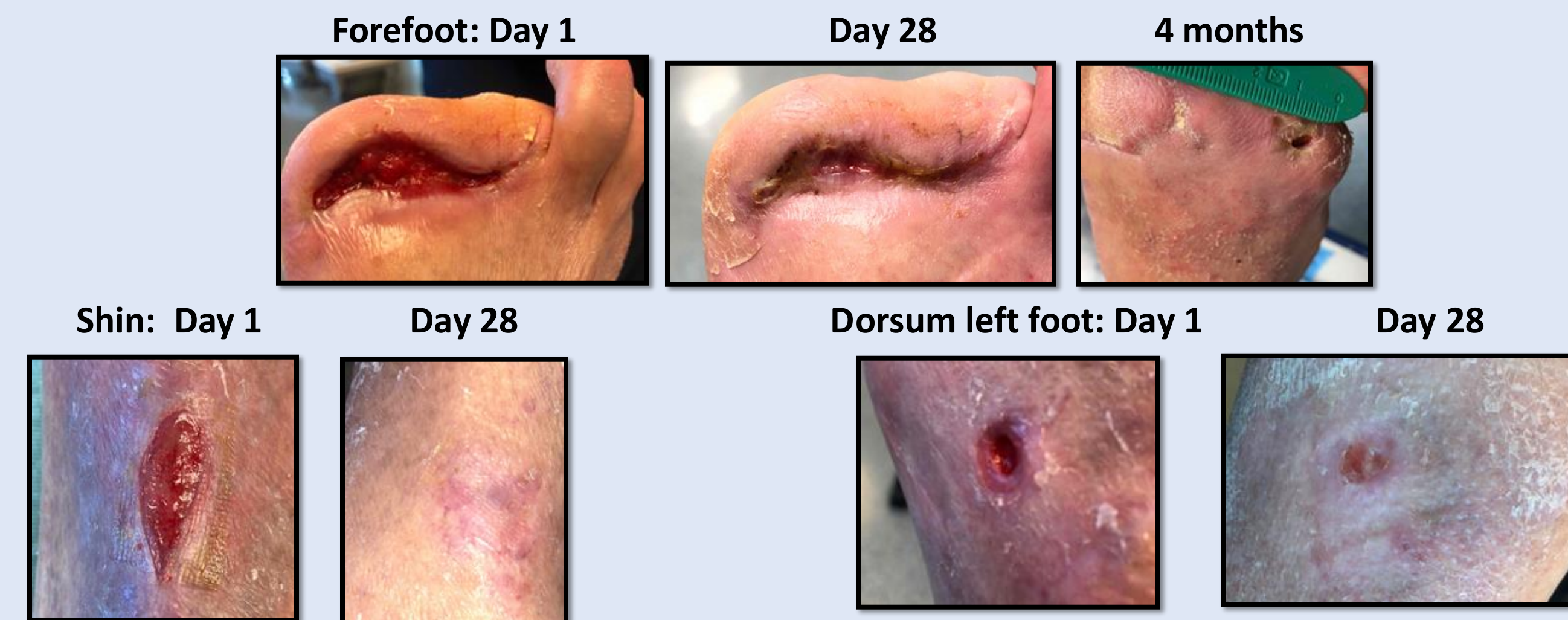
Findings

Case 1: 49-year-old male with Type 1 diabetes. Wound history of 2 plus years to left 4th MTH present. Treated for osteomyelitis 4 months prior to graft application. Recent traumatic wound present on left 2nd toe. HgA1C 8.2. Matrix applied to both wounds.



Case 2: 83-year-old male with Type 2 diabetes, CAD, PAD and amputation of right D1-3 toes. Non-healing wound to right forefoot amputation sites, and chronic trauma related wounds to left shin and dorsum of left foot. HgA1C 8.1

NOTE: further complication resulted in amputation of right D4-5 toes 3 months after graft application.



Case 3: 54-year-old female with Type 1 diabetes and chronic kidney disease. Long history of diabetic foot ulcerations including amputation of multiple toes. Ulcer to right 5th MTH for 6 months. 2mm wound at 6 weeks, when patient moved out of province. HgA1C 8.6.



Case 4: 73-year-old male with PAD and revascularization history. Recurrent osteomyelitis resulting in left forefoot amputation; non-healing for 3 months. HgA1C 6.6



Case 5: 70-year-old male with Type 2 diabetes, PAD and history of osteomyelitis to right 1st MTH resulting in ray amputation of right D1 toe. Non-healing for 4 months. Unable to bring to closure with negative wound pressure therapy.



Results

Wound outcomes were assessed by wound closure. Five of eight wounds closed in 27-29 days from application. The two most complex wounds involving forefoot amputation (Cases 2 & 4) closed in 84 and 119 days, respectively. One patient's wound (Case 3) progressed to a 2 mm superficial wound in 39 days before the patient moved out of province preventing further follow-up.

Wound closure was significantly expedited compared to current practice. Clinicians reported high satisfaction with application, management protocol, and wound outcomes. Patients reported a positive experience and were very satisfied with wound outcomes and its impact on their quality of life.

Implications

This Advanced Regenerative Tissue Matrix* has the potential to improve DFU healing outcomes. Findings here were consistent with previously reported results.² The product's one-and-done application saves health resources and clinician time. Ultimately, patients benefit the most, with a timely return to skin health and activities of normal life.

References

1) Ontario Health (June 2021) Skin Substitutes for Adults with Diabetic Foot Ulcers and Venous Leg Ulcers: A Health Technology Assessment. *Ontario Health Technology Assessment Series*. Vol. 21, no. 7, pp 1-165.

2) Costa, I.G., Glazebrook, M., Lu, S., McLaren, A and Gratzer, P.F.A.(2022) A feasibility and safety study of a novel human decellularized dermal matrix to accelerate healing of neuropathic diabetic foot ulcers in people with Type 1 and Type 2 diabetes. *Canadian Journal of Diabetes*. Vol. 46, no. 7, pp 671-677. DOI 10.1016/j.cjcd.2022.03.010.