Human Keratin Matrix Graft Speeds the Healing of Refractory Venous Leg Ulcers

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Background

Venous leg ulcers (VLUs) account for 70-80% of leg ulcers worldwide. VLUs are associated with significant morbidity, significant healthcare cost, and negative socioeconomic impact[1,2]. These chronic wounds also increase the risk for amputation, causing further cost, reduced quality of life, and high 5-year mortality rate. As such, a multi-modal approach to care must be taken to treat these often-refractory wounds.

The use of keratin in wound healing promotes cell growth, migration, and differentiation. Keratin based products are shown to assist with epithelialization, a more ordered healing process, and faster healing[3,4]. Here, we report our success with ProgenaMatrix™, the first human keratin hydrogel matrix, in the treatment of VLUs.

[1]. Ren, S-Y., et al. *World J Clin Cases.* 2020; 8(21): 5070-5085. [2]. Raffetto, J.D., et al. *J Clin Med.* 2021; 10(29): 1-34. [3]. Batzer, A.T., et al. *Int Wound J.* 2016; 13: 110-115. [4]. Konop, M., et al. *Pharmaceutics.* 2021; 13(2029): 1-20.

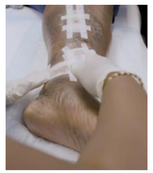
Methods

All patients had venous and arterial evaluations, and revascularization procedures were completed as indicated. Patients underwent a 4-week run-in period of standard local wound care, compression therapy, infection control, and exudate management. Wounds that saw no improvement with this conservative treatment then received ProgenaMatrix™ treatment weekly.

Treatment

Fenestrate ProgenaMatrix™ with an 11-blade.

Cut product to size.



Apply to the wound and secure. Change weekly with dressings.

Patients

We present a case series of nine patients aged 45-85 years with a total of 13 VLUs (four patients had bilateral leg ulceration). Wound age ranged from 12 wks to 15 years prior to ProgenaMatrix™ application. These patients all had complicated medical comorbidities including diabetes, poor nutrition, poor perfusion, and/or venous insuffiency.

Type 2 diabetics, 4 uncontrolled	HTN, 5 severely uncontrolled	Hyper-cholesterolemia	End stage renal disease, 1 hemodialysis
Chronic venous insufficiency	*The Patient Population*		Previous DVT
PAD w/ revascularization procedures	5 venous stenting, iliac vein compression	4 previous limb injury/trauma	Sickle Cell Anemia

Results

Overall, 100% of the wounds were responsive to the human keratin graft by visual evaluation. Notably, there was increased epithelialization, and granulation in the wound base. During the trial, one patient passed away from cardiac complications.

Eight wounds healed with no recurrence after an average of 8 product applications over 9.25 weeks.

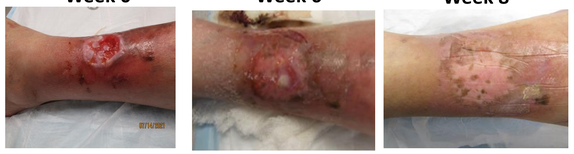
Among the unhealed wounds were the largest wounds, the oldest wound ages, and the bilateral wounds, as well as those complicated by recurrent infection and extensive exudate/lymphedema. These complications were exacerbated by non-compliance with compression wrapping and wound and dressing care, contributing to reduced healing and removal from the trial. However, 2 of these 4 wounds still showed marked decrease in wound volume.

#	Initial Vol. (cm^3)	Final Vol. (cm^3)	% Reduction	Endpoint
1	0.254	0.000	100.0	8 wks
2	4.781	0.000	100.0	15 wks
3	0.601	0.000	100.0	9 wks
4	42.312	82.661	-95.4	8 wks; NC
5	5.888	13.730	-133.2	8 wks; NC
6	15.111	4.660	69.2	10wks; NC
7	3.022	0.728	75.9	8 wks; NC
8	0.528	0.000	100.0	12 wks
9	0.141	0.000	100.0	12 wks
10	0.929	0.000	100.0	7 wks
11	0.066	0.000	100.0	7 wks
12	0.188	0.000	100.0	4 wks
13	1.130	0.236	79.2	Deceased

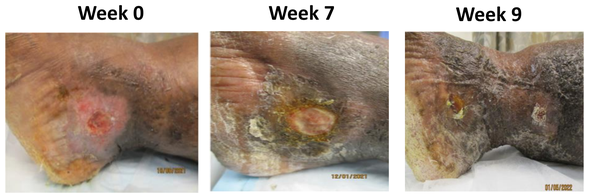
Red lines were patients removed from the study due to death or non-compliance (NC) with the standard of care.

Representative Cases

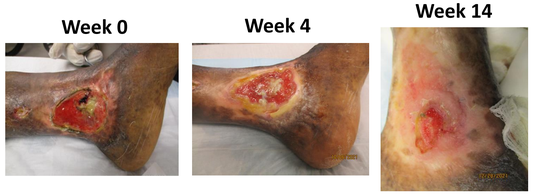
Patient JW, 85yrs M
Venous stasis
Initial size 1.2 x 2.7x x .1cm
Final size : Resolved 8 wks



Patient FB, 59yrs F
Venous stasis
Initial size 1.7 x 1.5x x.3cm
Final size Resolved 9wks



Patient KL, 81 yrs F
Mixed: venous stasis/ arterial
Initial size 5.8 x 3.5x x .3cm
Final size: Resolved 15 wks



Patient KB, 44 yrs F
Venous stasis/lymphedema
Initial size
Medial : 9.8 x 11x x.5cm
Lateral : 6 x 2.5 x .5 cm
Final size : Not resolved, 8wks
TRIAL ABORTED: Compliance
Medial : 9 x 11.7 x 1cm
Lateral : 6.6 x 5.3 x .5cm