



# BACKGROUND

Diabetic lower extremity wounds are notoriously difficult to heal.<sup>1</sup> Reported healing rates vary but can average as little as 24.2% in 12 weeks necessitating the development of advanced therapies aimed at shortening time to heal. Keratin has been recognized for centuries for its medicinal properties used to treat skin and hair related pathology. Recently, keratin has been evaluated for its potential to heal chronic wounds. Research shows that in chronic wounds keratinocyte activation is suppressed.<sup>4</sup> When keratinocytes are activated, they cause direct epithelialization of a wound bed via cellular migration and up regulation of basement membrane protein.<sup>2,3,4</sup> Further, activation promotes progression past the stalled inflammatory phase of wound healing allowing a wound to move expeditiously towards closure.<sup>3,5,6</sup> This study evaluates the efficacy of an applied keratin protein product that activates keratinocytes in chronic diabetic lower extremity ulcers.

#### METHOD

Ten patients with diabetic lower extremity ulcers were evaluated for healing rate with use of applied keratin. All patients were high risk for delayed healing. At risk subjects included those with: neuropathy, infection (treated), or peripheral vascular disease (treated) well more general comorbidities including renal disease and/or heart disease. Patients were educated on potential risks, benefits and complications of topical use of the applied keratin product.

Inclusion criteria included Diabetes Mellitus, exclusion criteria included untreated infection or untreated ischemia.

Once informed consent was obtained, the wound was appropriately debrided, preparing the site for application of the keratin. The keratin product was cross-hatched (to allow for passage of wound drainage as needed) then applied to the wound bed, fixed to site with gauze overlying. Patient followed up within 1 week of application.

### ACKNOWLEDGEMENT

Ryan Chatelain is a paid consultant for ProgenaCare Global, LLC, maker of ProgenaMatrix Human Keratin Matrix.

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# Accelerated Healing Rate in Difficult to Heal Wounds Utilizing a Novel Keratin-based Skin Substitute Ryan Chatelain, DPM

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#### **Clinical Case Patient 1**

63 y/o type I diabetic female with history of neuropathy, PVD s/p angioplasty, kidney transplant and previous midfoot level amputation presented with large lateral ankle and lower leg abscess including lateral compartment necrosis. She underwent I&D extensive debridement with hypochlorous acid, silver and collagen dressings then keratin application until closure.





First Appliction



2 weeks/ 2 Applications

#### **Clinical Case Patient 3**

66 y/o type II diabetic female with neuropathy, PAD and acute thrombosis s/p arterial thrombectomy and subsequent extensive debridement with 4th, 5th ray amputation.









First Appliction

7 Weeks

#### **Clinical Case Patient 10**

cigarette use, CAD.





First Appliction









6 Weeks/ 5 Applications

Green zones correspond to keratin

59 y/o type II diabetic neuropathic male, PVD s/p PTA with residual disease, right BKA, current

Red Zone indicates no keratin use- admitted for heart failure

# RESULTS

Patient #	Wound reduction <u>before</u> Keratin (cm sq)	Time w/o Keratin (weeks)	Healing Rate (cm sq/ week)	Wound reduction <u>with</u> Keratin (cm sq)	Time w/ Keratin (weeks)	Healing Rate (cm sq/ week)	% Healing Rate Increase
1	32 - 21.6	8	1.30	21.6 - 0	6	3.60	176.92%
2	26 - 8.64	14	1.24	8.64 - 0	4	2.16	74.19%
3	55 - 40	4	3.75	40 - 0*	7	5.71	52.38%
4	n/a	n/a	n/a	31.2 - 0	7	4.46	n/a
5	19 - 6.4	14.5	0.87	6.4 - 0	4.5	1.42	63.67%
7	4.95 - 1.82	20	0.16	1.82 - 0	8	0.23	45.37%
8	2.85 - 1.2	12	0.14	1.2 - 0	3	0.40	190.91%
9	n/a	n/a	n/a	11.25 - 0	6	1.88	n/a

Patient	Treatment Interval (w/ or w/o Keratin)	Wound Reduction (cm sq)	Weeks	Rate (cm sq/week)	Patient	Treatment Interval (w/ or w/o Keratin)	Wound Reduction (cm sq)	Weeks	Rate (cm sq/week)
6	1 (Without)	13.6 - 7	13	0.58	10	1 (Without)	4.2 - 5.1	14	-0.04
	2 (With)	7 - 0.35	5	1.13		2 (With)	5.1 - 3.9	1	1.20
	3 (Without)	0.35 - 0.66	4	-0.08		3 (Without)	3.9 - 4.05	4	-0.04
	4 (With)	0.66 - 0	9	0.07		4 (With)	4.05 - 0	8	0.51

#### DISCUSSION

Our study consisted of a small sample size and was meant as an initial evaluation of applied keratin efficacy in difficult to heal diabetic wounds. Initial results are promising as keratin consistently showed significantly increased healing rates compared to standard and advanced dressings commonly used today. Further, patients in clinical case 2 and 3 both experienced decreased healing rate when keratin discontinued for a period then increased healing rate once reapplied. Wound selection was important with appropriately debrided, viable granular wound bed as well as moisture control lending to success of the product.

# CONCLUSION

difficult to heal wounds.



#### Patients consistently experienced an accelerated healing rate with keratin use versus standard of care. Eight of the ten patients originally were treated with standard of care including silver and collagen dressings then switched to applied keratin. All 8 patients demonstrated increased healing rate with keratin use ranging from a 4.6% up to 190% increase in healing rate compared to previous care.

Further, 90% of patients healed in 8 weeks or less with diabetic wounds ranging in initial size from 6 cm<sup>2</sup> to 55 cm<sup>2</sup>. The single patient that did not was healing at a considerably increased rate but unfortunately passed away from cardiac complications prior to experiencing complete healing

Use of applied keratin protein seems to consistently accelerate epithelialization rates in chronic and