USE OF APPLIED KERATIN MATRIX OVER AN OPERATIVE SITE TO ACCELERATE INCISIONAL HEALING RATE IN DIABETIC PATIENTS

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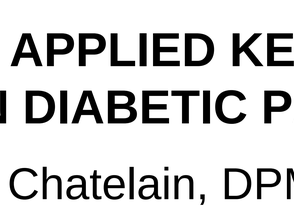
BACKGROUND

Keratin has recently been studied for its potential to accelerate healing in wounds due to its effect on fibroblasts and keratinocytes. Fibroblasts play a key role in early wound healing and human keratin has been associated with increased fibroblast attachment and proliferation both vital to coaptation of a surgical incision. Keratinocytes are active in later stages of wound healing with applied keratin demonstrating an increase in keratinocyte activation leading to increased epithelialization of a wound.
Incision healing times vary depending on type and location of surgery but there are generally accepted rates reported. Patients with comorbid conditions such as diabetes, peripheral vascular disease, auto-immune disease, renal disease and heart disease have been documented to potentially demonstrate slow or complicated healing. Delayed healing of post-operative incisions is purported to lead to increase potential for post-operative infection, increased scarring, and potential decrease in wound strength.
The purpose of this study is to evaluate the effect of keratin matrix applied topically over an incision to potentially increase healing rate and reduce scarring of a surgical incision in difficult to heal diabetic patients.



METHOD

Ten patients undergoing foot or ankle surgery with primary closure of surgical wounds were selected for this study. After surgery was performed following uniform aseptic technique a keratin protein matrix was applied directly over the primarily closed incision, then a layered gauze dressing. All patients were high risk for delayed wound healing with history of diabetes and many with multiple comorbidities including peripheral vascular disease, renal disease and/or heart disease. Inclusion criteria included diabetes, exclusion criteria included untreated infected or ischemic wounds.

Inclusion criteria included Diabetes Mellitus and we limited patient pool to those undergoing a toe amputation within the last six months, exclusion criteria included untreated infection or untreated ischemia.

Once informed consent was obtained, after primary closure of a surgical procedure, the keratin product was cross-hatched (to allow for passage of wound drainage as needed) then applied directly over the incision, affixed to site with adhesive strips and nonadherent applied over the site with gauze overlying. Patient followed up within 1 week of application.

ACKNOWLEDGEMENT:

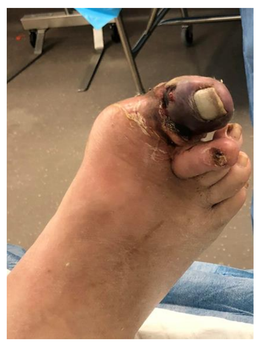
RESULTS

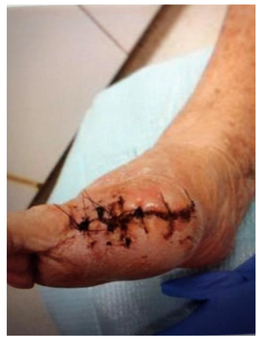
All ten patients healed without dehiscence. Average healing time was 4 days faster than comparable surgeries without the keratin matrix. Further, there were no incidences of post-operative infection and was an absence of hypertrophic/prominent scarring.
In both groups, the significantly attenuated healing rates were in patients with significant peripheral vascular disease with suboptimal revascularization.

Clinical Case 1

Patient 5

62 y/o diabetic neuropathic male, current cigarette smoker, gangrene great toe s/p amputation x 5 days

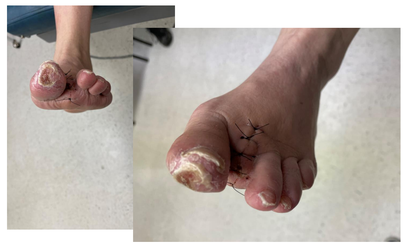




Clinical Case 2

Patient 8

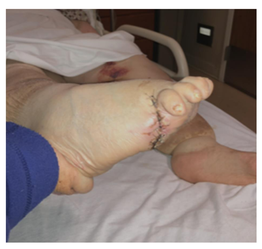
52 y/o type II diabetic female with neuropathy, osteomyelitis left 2nd digit s/p amputation x 5 days showing no inflammation

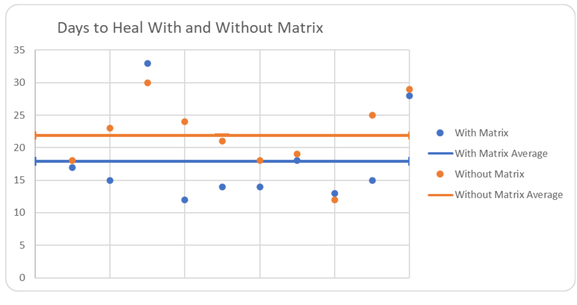


Clinical Case 3

Patient 6

33 y/o type I diabetic neuropathic male, current cigarette use, CAD. 5th digit osteomyelitis s/p amputation x 6 days





RESULTS DATA

	With Matrix			Without Matrix	
Patient #	Procedure	Comorbidities	Days to Heal	Procedure	Days to Heal
1	R 1st toe amp	PVD	17	2nd toe amp	18
2	L 2nd digit amp		15	1st toe amp	23
3	L 1st toe amp	PVD	33	5th tow amp	30
4	R 3rd toe amp		12	2nd toe amp	24
5	R 1st toe amp		14	1st toe amp	21
6	R 5th toe amp		14	partial 1st toe amp	18
7	R 1st toe amp	PVD	18	3rd toe amp	19
8	L 2nd digit amp		13	5th toe amp	12
9	R 5th toe amp	PVD	15	1st toe amp	25
10	L 4th toe amp	PVD	28	1st toe amp	29
			Average 17.9		Average 21.9

DISCUSSION

This is a preliminary proof of concept study with a small sample size meant as an initial evaluation of applied keratin efficacy in healing surgical incisions. Results showed, on average, a 4-day increased healing rate compared to similar cases performed on patients with similar comorbidities. Reduced inflammation with minimal scarring was noted in a majority of patients.
While direct keratinocyte activation and migration is thought to potentially directly contribute to increased incisional healing, the proposed mechanism of action for clinically evident reduced inflammation may be linked to macrophage polarization to M2 anti-inflammatory phenotype. Further, research shows that specific cytokines released by keratinocytes and fibroblasts may promote inflammation modulation.

CONCLUSION

Use of applied keratin protein seems to potentially accelerate epithelialization rates in primary incisional healing in surgical procedures of at-risk patients.

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