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ABSTRACT

The 60 day healing outcomes for the Triple Helix Collagen Powder Dressing[®] was evaluated in treating a total of ten chronic lower extremity ulcers: seven diabetic foot and three venous stasis ulcers. This Triple Helix Collagen Powder Dressing[®] is a 100% Bovine Type 1 collagen used as a primary wound dressing. This Triple Helix Collagen Powder Dressing[®] is indicated for use on first- and second-degree burns, full- and partial-thickness wounds, pressure ulcer stages II-IV, diabetic vascular and venous insufficiency ulcers, light to heavily exuding wounds. The collagen powder dressing is supplied as a one-gram powder vial.

The 60 day healing outcomes for the Triple Helix Collagen Powder Dressing[®] was evaluated in seven chronic Diabetic foot ulcers and three venous stasis ulcers and was proven extremely useful in healing these wounds. All seven of the chronic Diabetic foot ulcers healed within the 60 day period. Two of the three venous stasis ulcers healed in the 60 day period and the third venous stasis ulcer healed 92% in the 60 day period. The results demonstrated that the use of the Triple Helix Collagen Powder Dressing[®] in treating chronic Diabetic foot and venous stasis ulcers offers an advantage for healing.

METHOD

Triple Helix Collagen Powder Dressing[®] was used to treat seven chronic Diabetic foot ulcers and three venous stasis ulcers. These chronic ulcers demonstrated no healing after a minimum of four weeks of weekly sharp excisional debridement, daily gentamicin sulphate ointment 0.1% USP with gauze dressing, and either pressure off-loading or compression lower leg dressing as appropriate. Once Triple Helix Collagen Powder Dressing[®] was initiated, weekly sharp excisional debridement with daily gauze dressing and either pressure off-loading or compression lower leg dressing as appropriate was continued and the daily gentamicin sulphate ointment 0.1% USP was discontinued. Pressure loading was accomplished with a surgical shoe, crutches, or a wheel chair. The compression dressing involved either a primer unna boot with calamine or the profore multilayer compression bandage system. Arterial vascular status was evaluated, considered adequate to heal, and included in this evaluation if the pedal, popliteal, and superficial femoral pulses were palpable.

CHART

Abbreviations: Sub-q – subcutaneous tissue, cm-centimeter, sq. cm.-square centimeter, m-male, f-female, vasc.-vascular, pyh-pack year history, n/a-not applicable.

Pt. #	Wound	Days wound open before treatment	wound size at start cm sq.	Days to closure post tretament	dfu days to closure	vsu days to closure	wound size at end cm sq	% closed in 60 days	Location	DM	A1c	Age	Male	Female
1	1	77		34	34				Right plantar foot	1	9.6	54	1	
2	2	74		54	54				Right plantar foot	1	10.2	51	1	
3	3	84		35	35				Right plantar foot	1	7.4	44	1	
4	4	47		49	49				Right plantar foot	1	9.8	72	1	
5	5	45		42	42				rt sub mth #1	1	6	74	1	
6	6	87		44		44			right ankle VSU	0	0	68	1	
7	7	147		63		63			right leg VSU ant	0	0	67		1
7	8	156	82				6.5	92	right leg VSU med	0	0	61		1
8	9	126		43	43				Left plantat foot	1	9.8	66	1	
9	10	111		44	44				Left plantat foot	1	10	57	1	
Total				408	301	107							8	2
Average		95.4		45.3	43	53.5					10.4	61.8888889		

RESULTS

10 ulcers from 10 patients were evaluated for the benefit of 60 day healing outcomes for Triple Helix Collagen Powder Dressing[®] was evaluated in treating these seven chronic diabetic foot and three venous stasis ulcers (Chart 1). Two venous stasis ulcers were from female patients and the remaining ulcers were from male patients. All seven foot ulcers occurred in Diabetic patients. There were no patients that used tobacco. All patients were deemed to have adequate arterial circulation by the presence of palpable pedal, popliteal, and superficial femoral artery pulses. The average age of the patients was 62 years old. The average hemoglobin A1c for the Diabetic patient's was 10.4. The average time that the ulcers was present before Triple Helix Collagen Powder Dressing[®] application was 95 days. The average time to complete healing for the all the patients except patient number eight was 45 days. Patient eight was treated for a venous stasis ulcer with lupus disease. Patient number eight's wound healed 92% in the 60 day period. These results are summarized in chart one.

CASE REVIEW OF SELECTED PATIENT

A 54-year-old male with type II diabetes presented with a chronic, non-healing right plantar Diabetic foot ulcer (DFU) (Figure 1). This DFU was open for 77 days and had not responded to weekly debridement, pressure off loading with DM shoes and crutches, and daily application of gentamicin sulphate ointment 0.1% USP with a dry sterile dressing. This patient's hemoglobin A1c was 9.6 and he did not use tobacco. No peripheral arterial disease of the lower extremity was present. Daily application of the Triple Helix Collagen Powder Dressing[®] was initiated with sterile gauze and pressure off-loading was continued (Figure 2). There was complete healing at 34 days with out reoccurrence (Figure 3).



DISCUSSION
Several important points were identified. Triple Helix[®] was beneficial in treating these Diabetic foot and heel ulcers. The ulcers were open an average of 87 days with healing at an average of 31 days. These results support that addition studies with larger enrollment would verify these initial findings.



CONCLUSION
This study suggests that Diabetic foot and heel ulcers would benefit from management with Triple Helix[®].

Product notation: *
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