

PriMatrix™ Dermal Repair Scaffold Utilization in Lower Extremity Ulcers

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Abstract

PriMatrix (TEI Biosciences, Boston, MA) dermal repair scaffold offers clear advantages over other dermal substitutes for ulcer/wound management. Intrinsicly strong, yet soft and supple when rehydrated, PriMatrix handles like natural tissue: it readily conforms to the surgical site and is easily sutured. The product's biochemistry and microporosity assure rapid cell penetration and revascularization. Ultimately, PriMatrix acts as a scaffold that can be naturally and progressively integrated, remodeled, and eventually replaced by functional host tissue. PriMatrix is intended for use in patients requiring management of skin ulcers, second-degree burns, surgical wounds, and trauma wounds. PriMatrix has FDA indications for partial and full thickness wounds, for diabetic, pressure and venous stasis ulcers, for surgical wounds, and for tunneling, draining, and traumatic wounds. It is available in a variety of sizes as large as 20 x 25 cm. This study investigates the potential use of this dermal repair scaffold in the management of lower extremity ulcerations. PriMatrix was utilized in seventeen lower extremity ulcers on eleven patients and was extremely successful in healing these ulcerations. The results suggest that PriMatrix is beneficial in lower extremity ulcers.

Methods

PriMatrix (TEI Biosciences, Boston, MA) grafts were applied to the ulcerations of the lower leg, ankle, and foot under clean technique after debridement or wound excision of the ulcer. For the patients that received more than one graft, the minimum time between grafts was three to four weeks. Pressure off-loading, when necessary, was strictly adhered to. The pressure off-loading was accomplished with a surgical shoe, crutches, or a wheel chair. Vascular status was evaluated in all patients and was deemed adequate if the pedal, popliteal, and superficial femoral pulses were palpable. Patients that did not meet this criterion had a non-invasive arterial vascular study completed and intervention if required. Patients were diagnosed with osteomyelitis by positive radiographs and/or MRI findings. Based on the location, extent, and co-morbidities, the osteomyelitis was surgically or medically managed.

Conclusions

This study suggests that lower extremity ulcers would benefit from management with PriMatrix dermal repair grafts (TEI Biosciences, Boston, MA). Additionally, PriMatrix dermal repair scaffolds may assist healing ulcerations in patients who smoke, where delays in ulcer healing are common.

Results

Patient	Age	Gender	Days Open	Days to Closure	# Apps.	Location	Size (cm)	Diabetes	ATC	Osteomyelitis	Bone	Surgery	Tobacco	Peripheral Artery Disease	Revasc.
1	54	m	23	67	1	foot	7 x 8 x 0.4	yes	10	yes	yes	no	no	no	n/a
2	66	f	243	34	2	heel	1.2 x 0.8	yes	8	no	no	no	no	no	n/a
3a	68	m	71	59	1	foot	12 x 6 x 1	yes	11	no	no	yes	yes	arthrectomy	n/a
3b	68	m	71	159	1	foot	0.5 x 0.5 x 0.5	yes	11	no	no	yes	yes	arthrectomy	n/a
4	43	m	180	28	1	ankle	2 x 2 x 0.4	no	n/a	no	no	no	no	no	n/a
5	29	m	18	7	1	great toe	1.5 x 1.5 x 0.5	no	n/a	no	no	no	no	no	no
6	50	m	45	62	2	leg	0.8 x 0.8 x 1.5	yes	11	yes	no	yes	yes	arthrectomy	n/a
7a	65	m	32	57	2	foot	3.5 x 4.3 x 0.4	yes	8	no	no	no	no	no	n/a
7b	65	m	32	34	1	great toe	2.5 x 1.7 x 0.3	yes	8	no	no	no	no	no	n/a
7c	65	m	32	57	2	foot	3.5 x 4.3 x 0.4	yes	8	no	no	no	no	no	n/a
7d	65	m	32	69	2	foot	2.5 x 2.6 x 0.4	yes	8	no	no	no	no	no	n/a
7e	65	m	32	34	1	foot	0.4 x 0.9 x 0.3	yes	8	no	no	no	no	no	n/a
7f	65	m	95	57	2	foot	1.7 x 0.6 x 0.3	yes	8	no	no	no	no	no	n/a
8	63	m	93	74	3	heel	2.8 x 5.5	yes	7	no	no	no	no	no	n/a
9	73	m	186	14	1	heel	0.5 x 0.5 x 0.5	yes	9	yes	no	yes	yes	arthrectomy	n/a
10	66	m	287	12	1	foot	1 x 1 x 0.4	yes	11	no	yes	no	yes	arthrectomy	n/a
11	59	m	40	62	2	foot	3 x 0 x 0.7	yes	12	yes	no	no	no	no	n/a
Avg.	58	89	52	2				10							

A total of 17 ulcers from 11 patients were evaluated in this review of the benefit of PriMatrix grafts in treating ulcers of the lower leg, ankle, and foot (summarized in Chart 1, above). Of these ulcers, 9 were from the foot (patients 1,2,3,5,7,8,9,10,11) one from the ankle (patient 4) and one from the lower leg (patient 6). Ten patients were male (patients 1,3,4,5,6,7,8,9,10,11) and one patient was female (patient 2). Nine patients had diabetes (patients 1,2,3,6,7,8,9,10,11). Three of the patients were smokers (patients 3,6,9). Four of the patients had impaired arterial circulation with three managed by arthroectomy (patients 3,6,10). The remaining 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 58 years old. The average time that the open ulcer was present for all patients was 89 days. The average time to complete healing for the all the patients was 52 days. The average number of PriMatrix graft applications was 1.6.

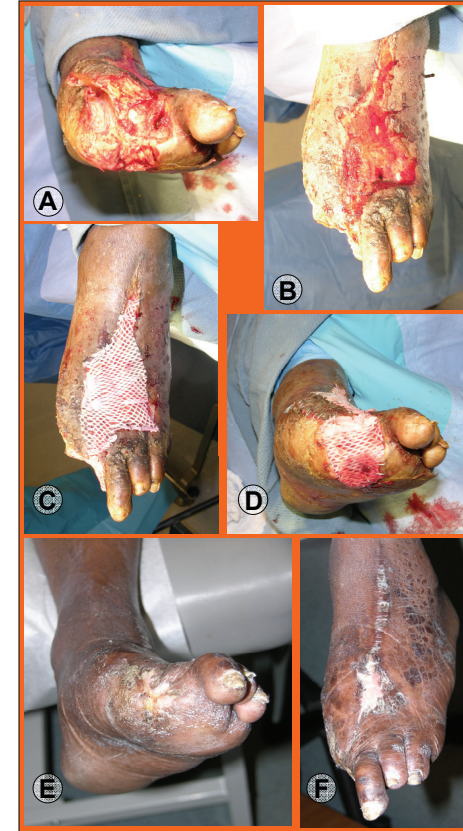
Discussion

Although the sample size of the patients evaluated for the benefits of PriMatrix grafts in treating lower extremity ulcers was not large enough to draw statistically significant conclusions, several important points were identified. The PriMatrix was beneficial in treating these lower extremity ulcers. The ulcers/wounds were open an average of 89 days with healing time averaging at 52 days. There was decent healing in the patients that smoked. This would suggest that although there is some delay in healing associated with tobacco use, PriMatrix was still beneficial in healing ulcers in smokers. These results support further investigation of PriMatrix in addition studies with larger enrollment that would verify these initial findings.

Selected Case Reviews

Case #1

A 68-year-old diabetic male who used tobacco (patient 3) presented with exacerbation of left foot gangrene progressing to necrotizing fasciitis, of seventy one days duration. The patient had a recent arteriogram with superficial femoral and tibial arthroectomy with good results. The great toe was amputated and remaining necrotic tissue excised (Fig. 1 A,B). The recipient site was managed with application of a meshed PriMatrix graft. The PriMatrix graft was meshed in a 2:1 ratio (Fig. 1 C,D). The dorsal foot ulcer was healed in 59 days and the distal/plantar foot ulcer was healed in 159 days without recurrence (Fig. 1 E,F). The ulcers received a total of one application of PriMatrix dermal repair scaffold graft.



Case #2

A 63-year-old male (patient 8) presented with a diabetic heel ulcer after excision of an eccrine syringofibroadenoma, a benign soft tissue mass. The excision did not allow primary closure and the intent was to allow the defect to heal by secondary intention. After 93 days of wound care there was no closure of the ulcer (Fig. 2A). The ulcer received a total of three applications of meshed PriMatrix graft (Fig. 2B). The PriMatrix graft was meshed in a 2:1 ratio. There was rapid healing by secondary intention with staged application of the PriMatrix (Fig. 2C). The diabetic ulcer healed in 74 days without recurrence (Fig. 2D).

