

PriMatrix™

Dermal Repair Scaffold

Healing of a Plantar Heel Traumatic Avulsion to Bone with PriMatrix™

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Patient Presentation

Patient Presentation

A 31-year-old Hispanic male presented to the wound care center on 11/09/06 for treatment of a wound resulting from a motorcycle accident that had taken place 18 days earlier. The patient had a right heel fat pad and plantar heel skin avulsion to the bone that had required debridement, irrigation and repair on 10/22/06. The patient was started on intravenous antibiotic therapy and discharged on 10/25/06 with oral antibiotics. The patient had no significant premorbid health history.



Figure 1. Right heel fat pad and plantar heel skin avulsion to bone.

Weeks 0 — 13

Hyperbaric treatments, silver dressing and living skin equivalent applications, and other treatment modalities

Treatment Regimen

Upon presentation to the wound care center on 11/09/06, an initial evaluation revealed a large black, necrotic area that extended from the right posterior heel to the instep area that measured 18 cm x 11 cm. Wound depth was not measurable due to eschar. Initial treatment involved a culture of wound exudate after a small incision and debridement (I&D), and MRI. The culture report was negative but the MRI revealed evidence suggestive of osteomyelitis of the right posterior heel area. Antibiotic therapy continued and hyperbarics was initiated on 11/10/06, daily. The patient underwent another I&D and debridement to bone on 11/11/06.

Week 14

1st PriMatrix Application

Week 17

2nd PriMatrix Application

Week 20

3rd PriMatrix Application

Week 22

4th PriMatrix Application

Week 23

5th PriMatrix Application

Week 24

Completely Healed

Figure 1 portrays the patient's right heel as of 11/17/06. The patient was unable to off-load due to the location and significant size of the wound. Over the course of the next three months, the patient underwent 26 hyperbaric treatments and other treatment modalities including silver dressing application and application of a living skin equivalent. While the wound did show improvement throughout this course of treatment (Figure 2), progress was slower than anticipated.



Figure 2. Wound following hyperbaric treatments, application of a living skin equivalent, and other treatment modalities.

Treatment Regimen, Continued

PriMatrix™ Dermal Repair Scaffold is an acellular collagen matrix derived from fetal bovine dermis. The treating physician chose to use this product in an effort to speed the patient's recovery time by closing the wound more rapidly. On 02/16/07, an 8 x 8 cm piece of PriMatrix was trimmed to the dimensions of the wound in a dry state. It was then applied to the debrided wound bed and hydrated in place by applying droplets of room temperature saline with a syringe. Complete hydration was achieved within approximately 30 seconds. The product was secured in place using Steri-Strip™ skin closures, covered with a silicone-based contact layer and non-stick dressing pads, and wrapped with gauze bandages.



Figure 3. Preparing PriMatrix Dermal Repair Scaffold for application.

This was the first of five staged applications spaced over nine weeks. When at least 75% of the PriMatrix had been incorporated into the wound bed, a new piece of product was applied over the portion of the PriMatrix that remained intact. Prior to each reapplication, the wound was debrided around the edges and irrigated with saline at 2 - 10 psi. The product was then cut to size and hydrated in place. In most cases, nearly the entire 8 x 8 cm piece of PriMatrix was applied, sometimes with smaller pieces stacked on top of one another to fill the depth of the wound. The final application took place on 04/19/07.

Clinical Outcome

From the first application, rapid reepithelialization was observed. No side effects were noted, such as the brownish slough observed earlier in the treatment process upon application of a living skin equivalent. With each subsequent application of PriMatrix, the dimensions of the wound progressively decreased (Figures 5-8). The wound measurements over the course of treatment are summarized in Table 1, shown to the right. One week after the fifth PriMatrix application, the wound had healed completely, as shown in Figure 9, and the patient was discharged.

Conclusions

The PriMatrix Dermal Repair Scaffold has been shown to effectively decrease wound depth and size for a wound resulting from a traumatic avulsion to the foot heel pad. Both the treating physician and the patient were impressed by the rapid healing response of the wound upon application of the collagen scaffold. Its broad indications allow for use of the product in multiple challenging wound healing applications.



Figure 4. One week prior to the initial application of PriMatrix.



Figure 5. One week after the 2nd PriMatrix application.



Figure 6. Two weeks after the 2nd PriMatrix application.

Table 1: Wound Dimensions Over Time

Date	Treatment Stage	Length (cm)	Width (cm)	Depth (cm)
11/09/06	Initial evaluation	18.0	11.0	(eschar)
11/27/06	Following surgical debridement	15.9	14.8	1.2
01/12/07	Following hyperbaric treatments	17.0	7.5	0.9
01/18/07	Prior to silver dressing applications	12.8	6.8	0.6
02/01/07	Following application of living skin equivalent	11.5	6.5	0.3
02/16/07	1st PriMatrix application	9.0	4.0	0.2
03/08/07	2nd PriMatrix application	6.5	2.5	0.2
03/30/07	3rd PriMatrix application	6.0	1.0	0.1
04/13/07	4th PriMatrix application	1.0	0.4	0.1
04/19/07	5th PriMatrix application	0.5	0.2	0.1
04/26/07	Wound healed; patient discharged	0	0	0



Figure 7. Three weeks after the 2nd PriMatrix application.



Figure 8. Two weeks after the 3rd PriMatrix application.



Figure 9. Completely healed wound after the 5th application of PriMatrix.

PriMatrix™ Dermal Repair Scaffold is part of a family of soft tissue repair products developed and manufactured by TEI Biosciences Inc.

PriMatrix is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic and venous ulcers
- Second-degree burns
- Surgical wounds — donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds — abrasions, lacerations and skin tears
- Tunneled/undermined wounds
- Draining wounds



Please refer to the PriMatrix Instructions for Use enclosed in each product package for complete indications, instructions, warnings and precautions.

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