

PriMatrix™*Dermal Repair Scaffold*

Healing of Chronic Plantar Heel Ulceration with PriMatrix™

Peter Sheehan, MD — Diabetes Foot and Ankle Center
Hospital for Joint Diseases
New York, New York

Ulceration
Developed

2 years

Conservative treatment failed to reduce the size and depth of the left heel ulceration

**Patient
Presentation**

Initial PriMatrix
Application

Weeks 1 - 20

Additional applications
of PriMatrix as needed

Week 21

Completely Healed

Patient Presentation

A 71 year old African American female with a history of Hansen's Disease, HTN, osteoporosis, and Charcot Deformity of the left foot, presented to the Diabetes Foot and Ankle Center at the Hospital For Joint Diseases for complaint of a chronic ulceration of her plantar left heel.

The ulceration had been present for more than two years. X-rays, previous MRI, soft tissue, and bone samples had shown that there was fusion of the tarsal bones and tarsal-metatarsal joints and collapse of the left calcaneus with diffuse sclerosis. No signs of osteomyelitis were observed.

The deformity was attributed to the patient's history of Hansen's Disease. Previous conservative treatment such as wet to dry dressing, Xeroform™ and dry sterile dressing, and Dermagraft® did not help in reducing the size and depth of the left heel ulceration.

Treatment Regimen

The left heel ulceration was treated using PriMatrix™ Dermal Repair Scaffold. At the initial visit, the ulcer was a "reversed L" in appearance, measuring 3.3 x 0.5 cm on the vertical arm of the "L" and 5.0 x 1.5 cm on the horizontal arm of the "L", with a depth of 1.2 cm at the deepest portion of the wound located on the hinge of the "L".

The base of the wound was granulated, except for the deepest portion of the wound, which contained several patchy areas of fibrin material. There was mild edema of the left heel and ankle, but no signs of erythema, calor, dolor or purulence. The wound bed was prepared first by cleansing the wound with saline, then the fibrin material was sharply debrided.

A 5 x 5 x 0.08 cm sheet of PriMatrix was divided into 0.5 cm strips (leaving the length and thickness unchanged) to conform to the base of the wound. The strips were then immersed into sterile saline until softened.



Figure 1. Chronic plantar heel ulceration upon initial patient presentation.



Figure 2. Ulceration immediately following the first application of PriMatrix™ Dermal Repair Scaffold

Treatment Regimen, Continued

There was no active bleeding of the wound before application of PriMatrix. The strips of PriMatrix were layered to conform to the wound bed, with no overlapping strips. Excess PriMatrix that extended over the wound edges was trimmed. A secondary dressing consisting of Adaptic™, 4 x 4 sterile gauze, 4" Kling®, and Coban™ was applied over the wound. A Darco surgical shoe with ¼" plastizote insert was applied.

The patient used a walker for ambulation. The patient was asked to keep the dressing dry, clean, and intact until the next visit in one week.



Figure 3. Ulceration one week after the initial PriMatrix application.



Figure 4. Ulceration six weeks after the initial PriMatrix application.



Figure 5. Ulceration 14 weeks after the initial PriMatrix application.



Figure 6. Ulceration 21 weeks after the initial PriMatrix application.

Clinical Outcome

On the next visit one week later, the patient returned to the clinic for follow-up. The patient denied any irritation from the dressing. The dressing was filled with emulsified PriMatrix and wound debris. The wound itself measured 2.5 x 0.3 cm on the vertical arm and 4.0 x 1.3 cm on the horizontal arm of the "reversed L". The deepest part of the wound measured 0.9 cm. The wound base was granulated with areas of patchy fibrinous material at the deepest part of the wound.

The wound was cleansed with saline and sharply debrided. PriMatrix was prepared and applied to the wound in the same manner as the initial application. The wound was dressed with Adaptic, dry sterile dressing, and Coban.

Over the next several visits, the aforementioned regimen was followed. There was continual decrease in the size of the ulceration. By week 5 there was complete closure of the vertical arm of the "reversed L" with the horizontal arm measuring 4.5 x 1.8 x 0.9 cm. The wound base remained to be granulated with mild fibrin coverage at the deepest part of the wound. There were no signs of infection in the affected limb.

At the 21 week visit, the wound had completely healed on presentation. There was some callous formation over the healed ulceration with no signs of infection. The patient denied any irritation or discomfort with usage of PriMatrix over the wound. With closure of the ulceration, a cast was taken of the patient's foot for fabrication of an ankle foot orthosis.

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

The product 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 instructions, warnings and precautions.

PriMatrix is a trademark of TEI Biosciences Inc.

Xeroform is a trademark of Kendall.

Dermagraft is a registered trademark of Advanced BioHealing, Inc.

Adaptic is a trademark of Johnson & Johnson.

Kling is a registered trademark of Johnson & Johnson.

Coban is a trademark of 3M.

© 2007—TEI Biosciences Inc.—All rights reserved.

PN 607-999-003 v01

TEI
BIOSCIENCES
Repair | Reinforce | Regenerate

7 Elkins Street

Boston, Massachusetts 02127 USA

866.524.0022 (toll-free)

617.268.1616

www.teibio.com