COMPLETE CLOSURE OF CHRONIC DIABETIC FOOT ULCERS FOLLOWING WEEKLY APPLICATION OF A SELF SUPPORTING AUTOLOGOUS BLOOD CLOT (FASTSKIN® PATCH)

Author: Martin Johnson, MD; Robert Thompson, MD; Marcus Gitterle, MD
Woundcentrics, LLC, San Antonio, TX

Background

Chronic diabetic foot ulcers (DFUs) that fail to demonstrate meaningful progression under standard of care (SOC) remain a significant contributor to infection, hospitalization, and lower extremity amputation.

Therapies that enhance granulation and epithelialization may improve healing trajectories in difficult-to-heal wounds.

FastSkin® Patch is a novel autologous blood-derived therapy The system produces a self-supporting autologous clot that is transferred directly to the wound followed by standard of care.

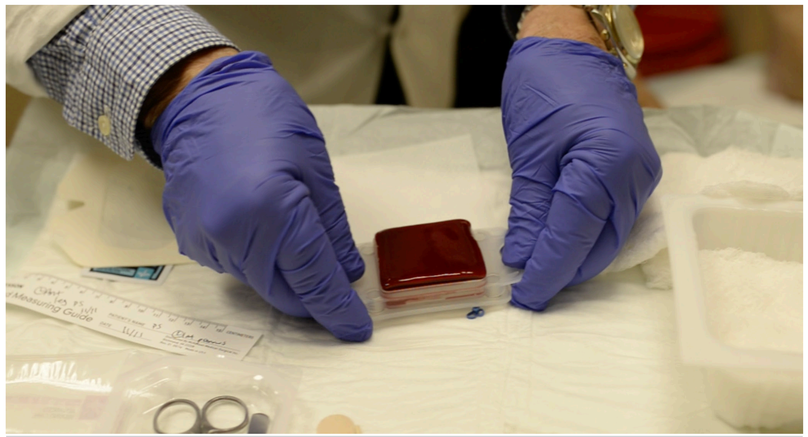


Figure 1. Fully autologous whole blood clot

Objective

To highlight specific case examples from a prospective multicenter open-label DFU clinical study conducted over a 12 week period. (See Gitterle et al poster for full study details).

Methods

Three patients with chronic DFUs present ≥4 weeks and demonstrating delayed healing under SOC were treated with weekly FastSkin® Patch, a fully autologous whole blood clot application in conjunction with sharp debridement and standardized offloading.

Patient examples are from a prospective multicenter open-label DFU clinical study conducted over a 12 week period.

At the time of treatment, a small volume of autologous blood was collected and processed to form a structurally stable clot The clot was applied directly to the wound surface providing immediate coverage of the wound surface which was then covered with a conventional secondary dressing within the existing wound care protocol.

Healing was defined as complete epithelialization without drainage.

Primary assessment included time to closure.

Safety was monitored throughout treatment.

Results

All three patients achieved complete wound closure (100%) within 12 weeks.

Time to healing occurred at TV 8 (n=2) and TV12 (n=1)

Early granulation tissue formation was observed during initial treatment visits, followed by progressive wound reduction leading to full epithelialization.

No device-related adverse events were reported.

Conclusion

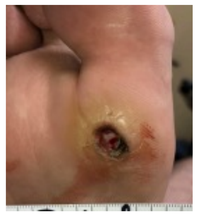
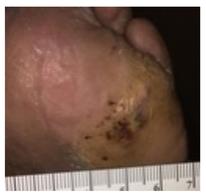
The autologous blood clot was simple to prepare and use. Because it maintained structural integrity, it was easy to adapt and position it to match the size, shape, and contours of the wound bed.

The FastSkin® Patch application was associated with complete closure of these DFU wounds, and findings support further studies to evaluate comparative effectiveness in additional wound types.

Patient Overview & Clinical Progression

Patient	Age	Sex	Ulcer duration	Ulcer location	Baseline size (cm2)	Mld-treatment	Healed at TV
004_004	46	M	5 months	Right Leg, Plantar, Forefoot	TV1 - 1.56 cm^2	TV6 - 0.72 cm^2	TV12 - closed
004_006	56	F	5 months	Medial, Right forefoot, 1st Toe	TV1 - 4.37 cm^2	TV4 - 0.77 cm^2	TV8 - closed
004_008	49	M	2 months	Left Leg, Plantar, Forefoot	TV1 - 1.5 cm^2	TV4 - 0.04 cm^2	TV8 - closed

Wound Progression Panel

Patient	Baseline	Mid-treatment	Healed
004_004	 TV1- 1.56 cm^2	TV6 - 0.72 cm^2	TV12 - closed
004_006	TV1 - 4.37 cm^2	TV4 - 0.77 cm^2	TV8 - closed
004_008	TV1 - 1.5 cm^2	TV4 - 0.04 cm^2	 TV8 - closed