

UNITE™ Biomatrix Advanced Collagen Wound Dressing In the Treatment of the Neuropathic Wound

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INTRODUCTION

- Over 800,000 new neuropathic foot ulcerations are reported yearly.¹
- Neuropathic ulcerations remain the most common cause of non-traumatic lower extremity amputations.²
- The mortality rate following diabetic limb amputations remains between 40-70% within 5 years following surgery.³
- Neuropathic wounds require aggressive treatment to speed healing and avoid associated morbidity and amputation. The treatments should include control of infection and adequate offloading of the wound.⁴
- Many advances in the area of wound care are helping to heal these wounds. These include the use of collagen based dressings.⁵⁻⁷
- A multitude of collagen dressings are available. The literature is unclear regarding the optimal collagen dressing for the diabetic neuropathic wound.⁵⁻⁷
- As part of a pilot study we evaluated a new stabilized advanced collagen wound dressing: UNITE™ Biomatrix Wound Dressing (UBWD) manufactured and distributed by Pegasus Biologics.



Pre-Fenestrated Stabilized Collagen Dressing



Patient presents with 2 year history of neurotrophic foot ulceration. After application of UBWD, the wound healed in 4 weeks.

METHODS

19 neuropathic wounds were enrolled as part of a pilot study using the UBWD.

- All subjects were diabetic with neuropathic foot wounds
- All subjects feet had at least one palpable pulse (save one)
- All subjects signed a consent form and agreed to participate in the study
- All ulcerations were off-loaded

The UBWD was applied in standard fashion.

- All wounds were debrided of hyperkeratotic or non-viable tissue
- All wounds demonstrated a granular base with no sign of infection
- The UBWD was fenestrated to allow for normal wound drainage
- The UBWD was cut to the size of the wound with several millimeters of overlap for suture placement
- The dressing was sutured to the wound edges with non-absorbable nylon suture
- Care was taken to maintain a moist wound environment
 - Dressings were placed over the wound with triple antibiotic ointment and sterile dressing materials
 - Dressings were changed every 48-72 hours until the UBWD was determined to be non-viable (dried out or fell off)

The wounds were evaluated for:

- Duration UBWD remaining viable
- Time to wound healing
- Percentage size change in the wound at four weeks
- Complications

Results were analyzed:

- The median size of the ulceration at application of the UBWD and at completion was analyzed using the Sign Test
- The mean percent change in size of the wounds was analyzed using the Student's t-test
- In both, $p < 0.05$ was considered statically significant

RESULTS

Age: Mean 59.8 years (SD: 8.07; Min: 50.7 Max: 76.0)

Gender: 13 Male / 4 Female

ULCER SIZE DATA

Ulcer	Mean (Standard Deviation)	Median	Min - Max
Ulcer Duration Prior to Application (months)	11.5 (10.2)	8	0.75 - 30
Size Prior to UBWD Application (mm ²)	659.6 (1473.6)	224	28 - 6250
Size When Graft Fell Off (mm ²)*	411.7 (968.8)	110	0 - 4000
Size Change (mm ²)	247.9 (539.5)	75	-41 - 2250
Percent Change in size (%)**	48.1 (39.6)	36.2	-30.4 - 100

* p-value of 0.0003

**p-value = 0.0001

	Mean (Std Dev)	Median	Min - Max
Duration UBWD Remained Viable (weeks)	3.03 (0.74)	3	2 - 4

DISCUSSION

- Our results demonstrate a significant improvement in plantar neuropathic wounds treated with the UBWD.
- While the success of the product at a clinical level is exciting, the mechanism for this success at a basic science level remains under investigation. Derived from equine pericardium, the collagen dressing is inherently strong and undergoes novel processing methods. After decellularization, the tissue is stabilized (crosslinked) using non-toxic, water soluble chemicals which preserve the native collagen architecture. It has been demonstrated that the novel collagen crosslinking mechanism prevents the dressing from susceptibility to rapid enzymatic digestion. This stabilizing effect helps the dressing resist premature breakdown from high levels of matrix metalloproteases found in the chronic wound. It is this resistance to degradation which theoretically, gives the UBWD its advantage.
- These results demonstrate the first case series of neuropathic wounds using the UBWD and the potential benefit of a biocompatible, durable, and crosslinked Type I collagen wound dressing.
- The success of the novel UBWD in this early pilot series is encouraging. Larger randomized studies are planned, and will ultimately determine if this treatment will become more successful than other collagen based dressings.

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