

Preliminary Results of a Pilot Study Evaluating the Use of a **Novel Stabilized Collagen Wound Dressing** for the Management of Plantar Neuropathic Foot Ulcers

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BACKGROUND

The Unite™ Biomatrix is a Type 1 collagen wound dressings manufactured and distributed by Pegasus Biologics. Derived from equine pericardium, the collagen is inherently strong and undergoes novel processing methods. After decellularization, the collagen is stabilized to resist premature enzymatic degradation and then sterilized without the use of ethylene oxide or gamma irradiation. The result is a safe, biocompatible, off-the-shelf collagen dressing that has shown promise in difficult to heal chronic wounds. The product has received FDA clearance.



Pre-Fenestrated Stabilized Collagen Dressing

INTRODUCTION

- Diabetes mellitus remains a common medical problem in today's society. There are an estimated 20.8 million diabetics in the United States (7% of the population).¹
- It has been reported that more than 60% of non-traumatic lower extremity amputations occur in people with diabetes.¹
- The treatment of plantar neuropathic foot wounds remains a challenge for the clinician, with recent advances in bioequivalent skin grafts offering an additional treatment option.
- As part of a pilot study, the authors evaluated a new stabilized collagen wound dressing for the treatment of neuropathic foot ulcerations. This represents two cases of the successful use of the **Unite™ Biomatrix** collagen wound dressing in healing of recalcitrant neuropathic foot wounds.

METHODS

- Once the wound has been adequately debrided of all non-viable tissue, the collagen dressings is applied using sterile instrumentation.
- The product is pre-fenestrated to manage wound exudate.
- The collagen dressing is cut to the size of the ulcer allowing a 4-5 mm overlap of the wound for suture placement.
- The collagen dressing is sutured to surrounding viable host tissue making certain to maintain intimate contact with the wound bed.
- To maintain a moist environment, a petroleum based triple antibiotic ointment is applied.
- The outer dressing is changed every 3 days to maintain a moist wound environment and to avoid dehydration of the collagen dressing.

RESULTS

- This represents the first two successful outcomes of recalcitrant diabetic foot ulcerations using the UNITE™ Biomatrix collagen wound dressing.
- UNITE™ Biomatrix offers the physician a new option for the treatment of neuropathic foot wounds.
- The authors are currently enrolling subjects for a larger evaluation.

REFERENCES

1. Prevention CfDCa. National Diabetes Fact Sheet: United States 2005: U. S. Department of Health and Human Services; 2005.

CASE 1

A 55 year old white female presented with a greater than two year history of a plantar diabetic neurotrophic foot ulceration at a transmetatarsal amputation sight on her right foot. The patient's wound had failed to heal after seven attempts at closure with other bioengineered skin grafts. After application of the Unite™ Biomatrix Wound Dressing, the wound healed completely in four weeks with no recurrent ulceration at that site.



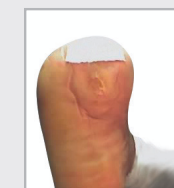
Pre-Application



Post-Application



2 Weeks



4 Weeks

CASE 2

A 52 year old white male with long standing plantar diabetic neurotrophic foot ulcer had history of wound failure after applications of bioequivalent skin graft and surgical removal of metatarsal head. After one application of Unite™ Biomatrix, the wound was completely healed at 13 days.



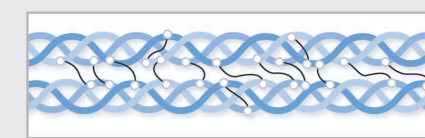
Pre-Application



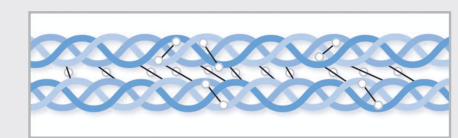
Post-Application



13 Days



Pegasus Biologics Flexible Collagen Crosslinking Technology



Conventional Rigid Crosslinking

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