# Application of a Bioengineered Electrospun Synthetic Polymer Matrix (3DESPM) for Limb Salvage: A Case Series.

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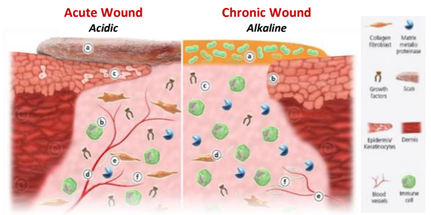
## INTRODUCTION

Over 150,000 people undergo amputations of the lower extremity in the United States each year.[1] This incidence is directly proportional to rates of peripheral arterial occlusive disease, neuropathy, and soft tissue sepsis.[2] This correlation is due to the increased incidence of diabetes mellitus, which is present in eighty-two percent of all vascular-related lower extremity amputations in the United States. Patients with diabetes mellitus have an astounding 30 times greater lifetime risk of undergoing an amputation when compared to patients without diabetes mellitus, which translates to an economic strain in healthcare systems of over $4.3billion in annual costs in the USA alone.[3] Trauma to the lower extremity can lead to amputation in over 20% of patients when associated with severe wound contamination and significant soft tissue loss.[4]

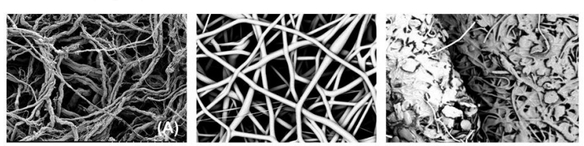
Many healing processes are affected by changes in pH including angiogenesis, collagen formation, and macrophage activity. [5-9] A change in pH has also been shown to influence the toxicity of bacterial end products and affect enzyme activity. [6] In particular, the matrix metalloproteinases (MMPs), which are important for wound healing and extracellular matrix remodeling. [9-13] Studies have also reported that variations in pH may affect wound closure, graft take, microbial infection rates, bacterial virulence, and biofilm formation.[14-15]




## A NOVEL 3D ELECTROSPUN SYNTHETIC POLYMER MATRIX (3DESPM)

A novel 3-D electrospun synthetic polymer matrix (3DESPM, PHOENIX™ Wound Matrix, RenovoDerm®, Dublin, OH) is scientifically engineered to mimic native ECM to provide a multidimensional solution to wound healing. The 3DESPM microporous scaffold has fibers ranging 600–1,000 nm in diameter and acts as a stimulus to facilitate pro-regenerative cellular adhesion, infiltration, and proliferation for the tissue regeneration and repair of acute/chronic wounds and burns. (Fig. 1)

Comprised of two bioresorbable synthetic polymers, **Polyglycolide** or poly(glycolic acid (PGA) and **poly(L-lactide-co-caprolactone)** (PLCL), 3DESPM naturally degrades into α-hydroxy acids and fatty acids, which stimulate pro-regenerative cellular activity for wound healing. 3DESPM acts as a protective barrier, supporting a pro-healing wound environment, by enacting low pH and lactate mediated effects that address chronicity and sustained inflammation, helping to restore the healing process. 3DESPM demonstrated a reduction in pH from 7.4 to 4.75 within a 1-week period during an in vitro degradation test in isotonic PBS solution (unpublished).




## PURPOSE

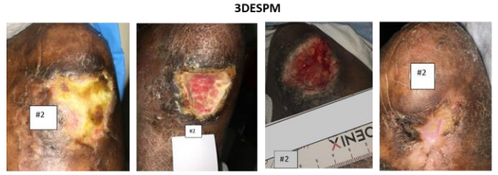
These case studies, focused on the potential of a new bioengineered electrospun synthetic polymer matrix (3DESPM), with its acidic degradant contributions, to improve the healing trajectory of 7 complex non-healing wounds. 3DESPM was applied to seven wounds, on 2 patients, that were considered for amputation.

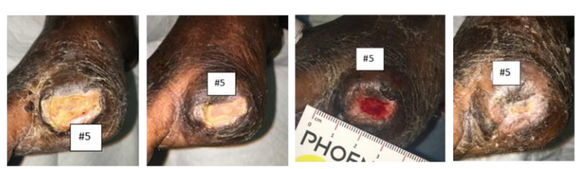
## RESULTS:

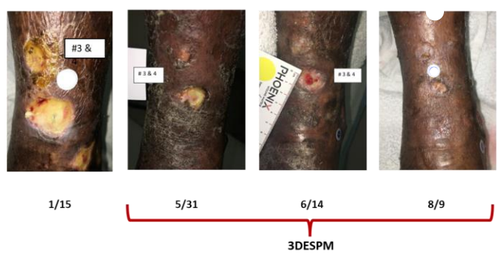


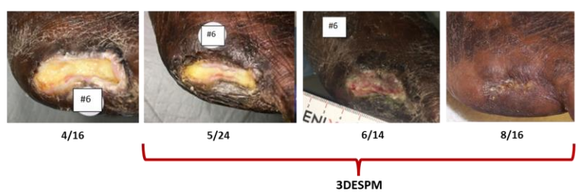

**Case #1 – Limb salvage treatment strategy on 6 complex wounds**
69-year-old female with 6 right lower extremity non-healing wounds. History of anemia, hypertension, DMII, L BKA (12 years prior), CVA, heavy smoker, wheelchair dependent, non operable right lower extremity arterial occlusive disease with prior stents, right 1st & 5th toe amputations, and was to have a right lower extremity amputation. **Introduction of 3DESPM into treatment strategy in May accelerated the wound healing trajectory**.

Complete wound closure was achieved after 2 applications of 3DESPM. Her treatment plan of care also consisted of HBOT, NPWT, & growth factors avoiding amputation.







**Case #2 – Limb salvage on chronic non-healing wound**

44-year-old female with a chronic left heel non-healing wound. History of neuropathy, hypertension, recurrent heel wound x 1 year, smoker, left heel abscess and osteomyelitis. **Introduction of 3DESPM into treatment strategy in June accelerated the wound healing trajectory**.

Complete wound closure was achieved, utilizing 5 applications of 3DESPM. Her treatment plan also consisted of HBOT & NPWT avoiding amputation.


***Study Highlights:*** This real-world case series demonstrated an acceleration in the healing trajectory after introduction of 3DESPM into the treatment of these complex, non-healing wounds to avoid amputation.

- ***All 7 wounds achieved closure, avoiding amputation.***
- ***Accelerated healing was noted after introduction of 3DESPM into treatment strategy***
- ***Average time to wound closure ~5.6 weeks*** ***(after introduction of 3DESPM)***

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*Frank Aviles, Jr. is a paid consultant of RenovoDerm LLC.

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