The use of a 3D Electrospun Synthetic Polymer Matrix (3DESPM) on challenging chronic ulcers

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3DESPM

INTRODUCTION

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 $4.3B 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]

Figure A. Course of the pH milieu in acute wounds.

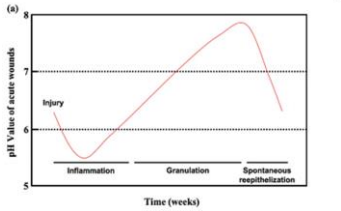
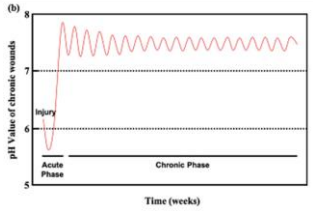
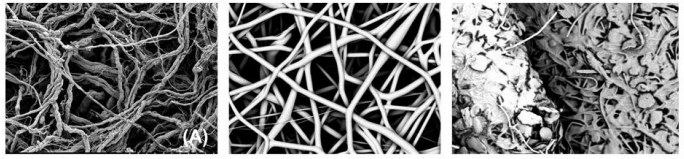


Figure B. Course of the pH milieu in chronic wounds[5]



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 regenerative 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)



Native Dermal ECM | PHOENIX Wound Matrix | PHOENIX cellular adhesion, infiltration & proliferation

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 3 complex, non-healing wounds. 3DESPM was applied to three wounds, on 2 patients, that were considered for amputation.

RESULTS:

Case # 1 - Recurrent Heel Wound x 1 year

44 year old female with a chronic left non-healing wound, history of neuropathy, hypertension, recurrent heel wound x 1 year, smoker, left heel abscess & osteomyelitis. Initial treatment plan included HBOT, NPWT. 3DESPM selected into treatment strategy to address the wound chronicity. Accelerated wound healing trajectory noted after 2nd application. Wound closure achieved with 5 applications of 3DESPM. **Resulted in avoiding amputation.**

Day 1 Initial image | Day 85

85 days with standard of care (SOC)

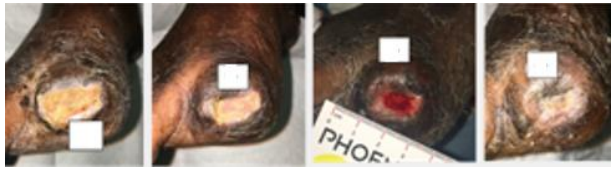
Day 113 | Day 148 | Day 231

Wound progression within 35 days after application of 3DESPM

Case # 2 Limb salvage

69 year old female with 2 non-healing wounds on right lower extremity. Hx of anemia, DMII, hypertension, prior L BKA, CVA, heavy smoker, wheelchair dependent, arterial occlusive disease with prior stents, R toe amputations. Resolved inflammation and healthy granulation tissue was observed after 1 application of 3DESPM. Wound closure achieved with 2 applications of 3DESPM within 7 and 8 weeks respectively. Treatment plan also included HBOT, NPWT, & growth factors avoiding amputation.

Wound 1



Day 1 | Day 28 1st application 3DESPM | Day 49 | Day 79

Wound closure within 7 weeks

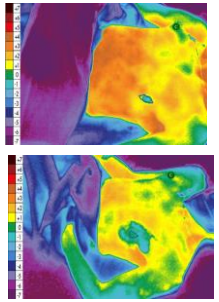
Wound 2

Day 1 | Day 71 1st application 3DESPM | Day 84 | Day 124

Wound closure within 8 weeks

Study Highlights:

- ***Resolved chronic inflammation after 1st application of 3DESPM***
- ***Accelerated healing was observed after 2nd application of 3DESPM***
- ***All 3 non-healing wounds achieved closure, avoiding amputation.***



The utilization of thermographic images on a challenging wound pre- 3DESPM and 1 week post application. Open wound bed is highlighted in blue.

RENOVODERM

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