3D Nanofabricated Polymer Scaffold Used to Treat Diabetic Foot Ulcers: A Case Series of Four Patients

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INTRODUCTION

In the United States there are an estimated 30.3 million people diagnosed with diabetes mellitus (DM) [1]. Non healing lower extremity ulcers remain one of the most challenging complications of diabetes (2). Treatment of these wounds contribute a burden to the health system of $25B (3).

The advancement of wound healing technology, and, specifically the study of the skin microbiome, have led to the development of a new 3-dimensional nanofabricated synthetic polymer (3DNSP*) product composed of naturally inherent structures known to encourage homeostasis and the body's natural wound healing process.

3DNPS* provides a critical prerequisite for successful tissue regeneration, a structure designed to mimic the scaffolding of the extracellular matrix.

A case series of four patients with 5 wounds is presented here, showing the efficacy of 3DNPS in treating difficult diabetic foot wounds.

METHODS

Four patients with five wounds who failed previous standard of care methods were treated with 3DNPS. All were diabetic patients with neuropathic wounds. Average age was 56 (range 51-68). Average wound size was 3.83cm (range 1.08cm-6.75cm).

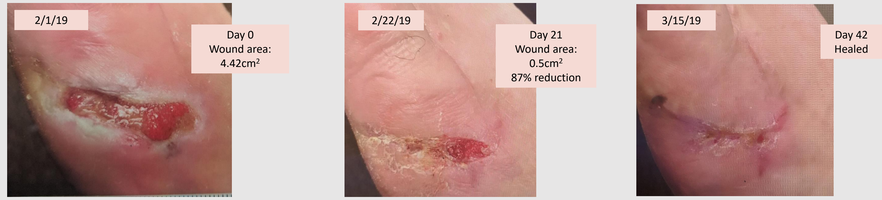
All wounds were treated with 3DNSP with weekly dressing changes, compression and off loading. 3DNSP is a USFDA regulated 361 Human Cellular Tissue (HCT/Ps) product under 21 CFR part 1271 part 361.

It is a synthetic scaffold containing no human or animal tissue/cells, and is designed to harness the innate inflammatory response, promote progression to the proliferative phase, and enable the regeneration of functional, native skin. It may also decrease scar formation by optimizing in situ tissue regeneration and by mitigating the inflammatory response.

3DNSP a novel electrospun nanofiber polymer that is available at room temperature. It is applied directly to a clean, debrided wound and secured with a compressive dressing and offloading as needed. In this series, weekly application of 3DNSP was performed.

PATIENT 1

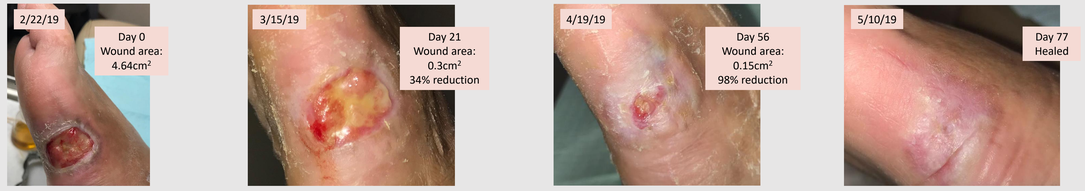
- 51 year old male with chronic diabetic foot ulcer/traumatic puncture wound plantar lateral left foot
- History of neuropathy, osteomyelitis, hypertension
- BMI 40
- s/p resection of 5th metatarsal head followed by 6 weeks IV antibiotics
- Treatment with PWM began 8 weeks later
- Wound healed in 6 weeks with 3 applications of 3DNPS



87% Wound Area Reduction at week 3

PATIENT 2

- 53 year old female with diabetic foot ulcer left lateral 5th metatarsal
- History of DM
- BMI 31
- Wound healed in 11 weeks with 9 applications of 3DNPS

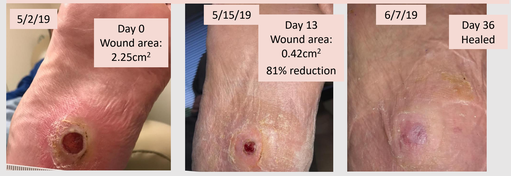


82% Wound Area Reduction at week 3

PATIENT 3

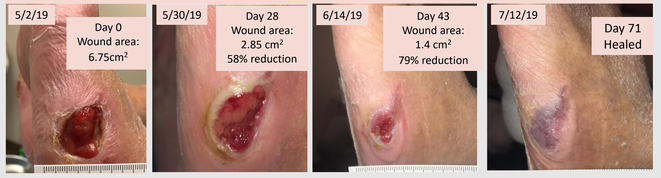
- 53 year old male with diabetic foot ulcers bilaterally
- History of Charcot neuropathy
- BMI 33.4
- Failed 8 weeks of antibiotics, silver alginate and offloading with Crowe Walker® (R foot)
- Right foot Wound healed in 5 weeks with 3 applications of 3DNPS
- Left foot Wound healed in 10 weeks with 6 applications of 3DNPS

RIGHT FOOT



Right: 81% Wound Area Reduction at week 2

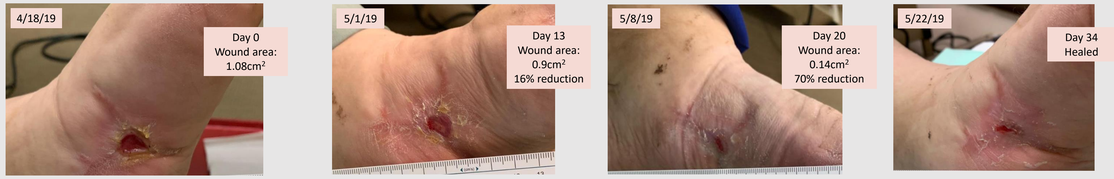
LEFT FOOT



Left: 58% Wound Area Reduction at week 4; 79% Wound Area Reduction at week 6

PATIENT 4

- 68 year old female with diabetic foot ulcer left medial arch
- BMI 42.5
- History of hypertension, depression, DM
- 6 weeks IV antibiotics, VAC, silver, collagen, offloading
- Treatment with 3DNPS began 8 weeks later
- Wound healed in 5 weeks with 4 applications of 3DNPS



70% Wound Area Reduction at week 3

Average Wound Area Reduction of 76% at 3 weeks

Average of 5 applications

Wounds healed in 7.4 weeks

RESULTS

All four diabetic patients who failed previous standard of care were treated with PWM. Infections were treated with antibiotics and all infected bone and soft tissue was surgically removed prior to treatment. Affected limbs were offloaded.

All wounds healed with an average number of 5 applications (range 3-9), in an average of 7.4 weeks (5-11). The average wound area reduction was 76% at 3 weeks. Average wound size was 3.83cm (range 1.08cm-6.75cm). No wound recurrence, nor adverse events or complications were reported.

CONCLUSIONS

Clinical outcomes in this preliminary series show safety and efficacy of a novel 3D nanofabricated polymer scaffold designed to mimic the scaffolding of extracellular matrix, with no reported wound or product related complications in treatment of DFUs in patients failing multiple previous treatment methods.

REFERENCES

[1] Centers for Disease Control and Prevention. *National Diabetes Statistics Report, 2017*. Atlanta, GA: Centers for Disease Control and Prevention; 2017.
[2] Most RS, Sinnock P. The epidemiology of lower extremity amputations in diabetic individuals. *Diabetes Care*. 1983;6(1):87–91.
[3] Lim HW, Collins SAB, Resneck JS Jr, et al. 2017. The burden of skin disease in the United States. J.Am.Acad.Dermatology.76:958-972.e2.

*3 Dimensional Nanofabricated Polymer Scaffold, Phoenix Wound Matrix®, Renovoderm, Nanofiber Solutions, Columbus, OH