

# Enhanced Healing in Hard to Heal Wounds Using a Novel Tissue Regenerative Matrix\*



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## Introduction

- ⊙ To date, hard-to-heal wounds (HHWs) represent a considerable source of morbidity due to the population aging and the increasing of comorbidities: hence, the management of HHWs generate considerable health costs.<sup>1</sup>
- ⊙ It is claimed that as much as half of chronic wounds fail to heal with current treatments.<sup>2</sup>
- ⊙ HHWs fail to progress through the orderly phases of healing but remain in a self-perpetuating inflammatory stage, despite adequate wound management.<sup>3</sup>
- ⊙ Many studies have proven that stem cells and “regenerative” (M2) macrophages promote wound healing since they can directly and indirectly stimulate residing cells, release biomolecules, modulate inflammation, and remodel the extracellular matrix (ECM).<sup>4</sup>
- ⊙ ECM-based scaffolds are decellularized tissues that can stimulate natural tissue regeneration capacity by providing native tissue-specific ECM signals, directing anti-inflammatory macrophages and activating constructive remodeling.<sup>4</sup>
- ⊙ In this case series, we report on the use of a novel tissue regenerative matrix\* made from decellularized human skin.

## Case History

- ⊙ We present three cases of difficult to heal wounds. Patient #1 is a 60-65 year old female with a necrotic toe-fusion surgical site.
- ⊙ Patient #2 is a 35-40 year old male with a charcot foot deformity and large DFU.
- ⊙ Patient #3 is an 85-90 year old male diabetic with a non-healing leg amputation site.
- ⊙ In each case, standard of care and the inclusion of advanced adjuvant treatment did not achieve wound closure

## Clinical Situation

- ⊙ Patient #1 had exposed hardware removed and persistent dried bone was exposed with a wound size of 5.2 cm x 2.0 cm. The wound remained open for 9 months.
- ⊙ Patient #2 had a deep infection present and required extensive surgical debridement with a wound size of 9.0 cm x 4.5 cm. The wound was open for 4 weeks.
- ⊙ Both Patients #1 and #2 received standard of care wound treatment but failed to close.
- ⊙ Patient #3 had a stump flap necrose that required debridement. The patient refused revision surgery. Instead, the patient received HBOT and NPWT treatments with slow healing. The wound remained open for 5 months.

## Actions Taken

- ⊙ A new tissue regenerative scaffold derived from human skin\* (Figure 1.) was used to treat each patient after debridement and the creation of a lightly bleeding base in each wound.
- ⊙ For Patients #1 and #2, pieces of the scaffold were sized to match the wound area.
- ⊙ For Patient #3, only two pieces of the scaffold measuring 5 cm x 5 cm and 3 cm x 3 cm were available and applied to a part of the open stump wound.
- ⊙ All patients had a secondary dressing applied on top of the scaffold (Tegaderm Silicone foam®) which was changed weekly.

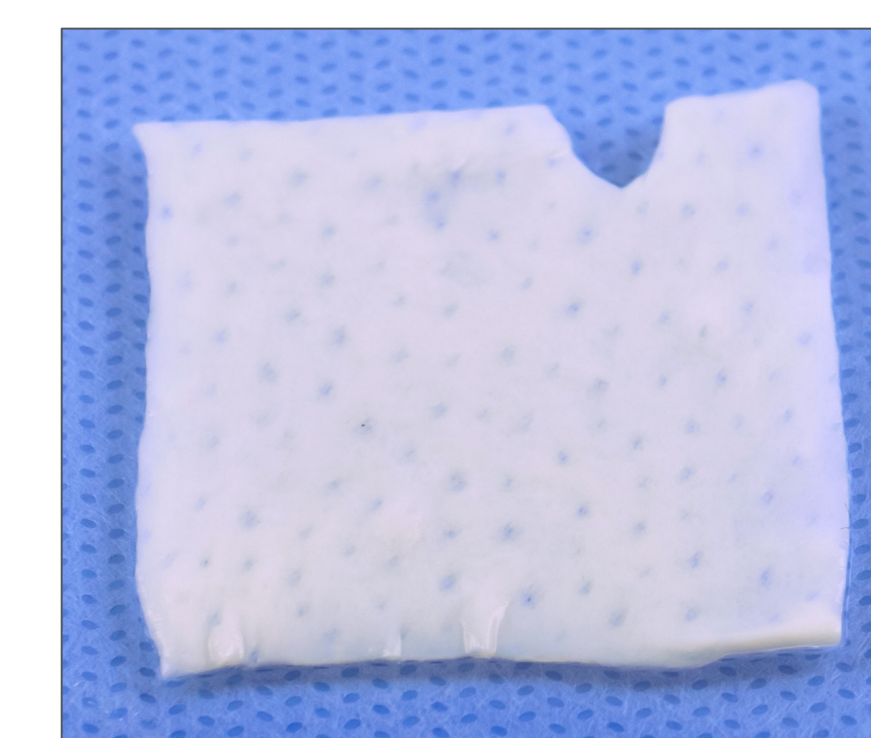


Figure 1. Tissue Regenerative Scaffold

## Results

- ⊙ Patients did not have any complications during treatment. Significant new tissue growth, both in area and depth, was observed. Refer to Figures 2-4.
- ⊙ All patients achieved closure after 10 weeks post treatment.

Figure 2. Patient #1 – Toe Fusion, Bone Exposure.



Figure 3. Patient #2 – Large DFU.

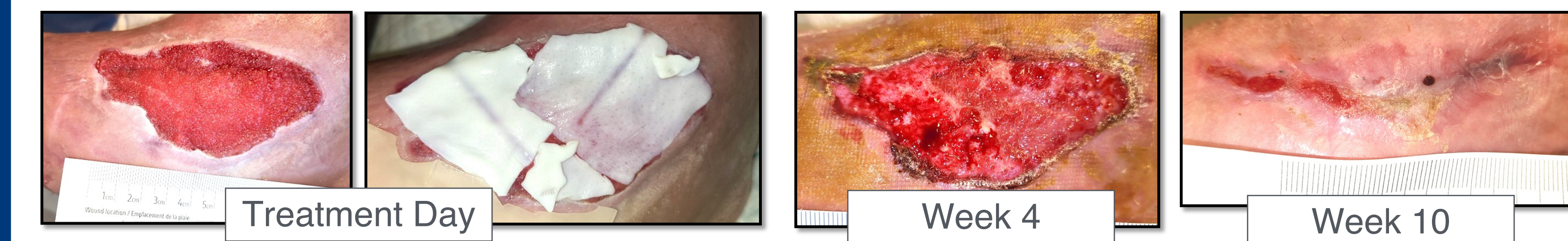


Figure 4. Patient #3 – Amputation Stump. Note partial coverage with tissue matrix.



## Implications for Practice

- ⊙ A new tissue regenerative scaffold\* used on these patients provided the needed environment and stimulation for cells to mount effective healing and regeneration lacking with other enlisted treatments. This approach may help to provide a more effective treatment for difficult to heal wounds.

## References

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## Acknowledgements

\*DermGEN™ for the study was supplied by RegenMed under license from DeCell Technologies Inc.