



# Supportive Evidence of Enhanced Wound Healing with the Utilization of a Cryo-Preserved Human Cellular Repair Matrix



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## Overture

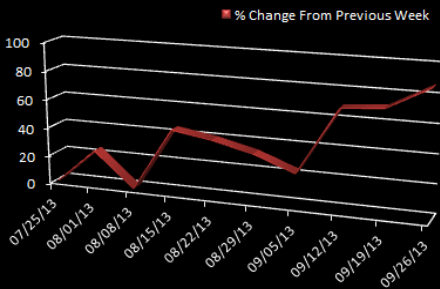
A novel human cellular repair matrix, which contains living epithelial cells, neonatal fibroblasts, mesenchymal stem cells, and growth factors has been proposed to offer contributions to all phases of wound healing. Subsequently, the possibility of improving a wound's response to treatment (and ultimately expediting wound closure) may be promoted with the application of these cryopreserved tissue products.

## CASE REVIEW ONE

A 47 y/o SCI veteran presented to clinic (7/17/13) as an outpatient consult concerning a traumatic injury to dorsum of right foot sustained during a cycling injury in Wisconsin. Patient was sent to local ED and was admitted to hospital for local wound care and IV antibiotics following the development of significant ascending cellulitis. Patient returned to VA following discharge with oral antibiotics and resolution of cellulitis with instruction for wet-to-dry daily dressing changes as local wound care orders. Initial measurements were taken 07/17/13 and revealed an 8.5 x 3.5cm ulceration with large central defect measuring 2.8 x 2.5 with exposed tendon.



07/25 – 7.7 x 3.4 x 0.1 (Grafix Core)  
08/01 (one week after initiation of advanced bioengineered tissue) 6.6 x 3.0 x 0.1 with NO exposed tendon (Grafix)  
08/08 – marked visual improvement (Grafix)  
08/15 – 5.0 x 2.2 x 0.1 (Ovation 1c)  
08/22 – 4.4 x 1.5 x 0.1 (Ovation 1c)  
08/29 – 4.0 x 1.1 x 0.1 (Ovation 1c)  
09/05 – 3.4 x 1.0 x 0.1 (Ovation and D/C Negative Pressure)  
09/12 – 2.1 x 0.5 x 0.1 (Grafix Prime)  
09/19 – 1.0 x 0.3 x 0.1 (Grafix and D/C Transcutaneous O2)  
09/26 – 0.2 x 0.2 x 0.1 (Zinc Oxide)



## MATERIALS & METHODS

Patient was initially converted to daily dressing changes consisting of Santyl/Collagenase with gentamicin. This plan was implemented for a period of one week (prior to consideration of advanced biologics) while labs were processed to assess patient's overall capacity towards wound healing, ascertain absence of any leukocytosis, and demonstrate reduced neutrophil counts as well as remove any microcellular denatured protein(s) and necrotic collagen remnants.

A cryo-preserved human cellular repair matrix (Grafix Core<sup>®</sup>) was chosen initially as the wound displayed progression through the subcutaneous tissue(s) and concomitantly beyond the indications for many other bioengineered products. This was later modified to a minced form of the repair matrix (Ovation<sup>®</sup>), and a final return to graft form (Grafix Prime<sup>®</sup>) to aid in epithelialization. Implementation of negative pressure and transcutaneous oxygen served as adjunct additions to the patient's care in the early course of treatment.

## Conclusion

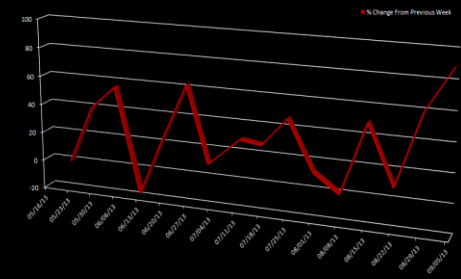
Failure to progress through all phases of wound healing in a timely manner leaves a patient susceptible to staggering, yet well-documented, rates of mortality/morbidity. As such, uncovering progressive treatment modalities to combat refractory and chronic wounds are paramount. These case studies serve to demonstrate the ability of a human cellular repair matrix to contribute to wound closure with *overwhelming efficacy*.

## CASE REVIEW TWO

A 43 y/o veteran presented to clinic (04/23/13) with an ulceration to plantar aspect of his left foot. Patient PMH included, but not limited to, hypertension and hyperlipidemia, uncontrolled DM, Charcot Arthropathy, and a long-standing history of recurrent ulcerations/abscesses and subsequent amputations secondary to marked noncompliance. Culture tissues revealed a large degree of polymicrobial burden, including MRSA. Radiographs were not definitive for any acute osseous destructive pathologies. Minocycline and Augmentin per Infectious Disease recommendations were started to control overlying infection.



04/23 Santyl/Gent  
05/09 – 4.5 x 4.5 x 0.5 (Grafix Core and SNaP)  
05/16 – 4.5 x 4.5 x 0.5 (Core & NP)  
05/23 – 3.7 x 4.1 x 0.4 (Ovation - d/c SNaP due to drainage; KCI consult)  
05/30 – 3.6 x 3.7 x 0.2 (Ovation)  
06/06 – 3.8 x 4.1 x 0.2 (Ovation)  
06/13 – 3.5 x 3.4 x 0.2 (Ovation & Grafix Prime)  
06/20 – 3.2 x 2.8 x 0.1 (Ovation & Grafix)  
06/27 – 3.0 x 2.7 x 0.1 (Ovation & Grafix)  
07/03 – 2.5 x 2.3 x 0.1 (Ovation)  
07/12 – 2.1 x 2.0 x 0.1 (Ovation)  
07/18 – 1.6 x 1.4 x 0.1 (Ovation - d/c KCI due to Home Health)  
07/25 – 1.4 x 1.4 x 0.1 (Grafix Prime)  
08/01 – 1.4 x 1.4 x 0.1 (Grafix)  
08/08 – 1.1 x 0.9 x 0.1 (Grafix)  
08/15 – 1.0 x 0.9 x 0.1 (Grafix)  
08/22 – 0.6 x 0.6 x 0.1 (Grafix)  
08/29 – 0.2 x 0.2 x 0.1 (Grafix)  
09/05 – CLOSURE



## MATERIALS & METHODS

Unlike the prior case, wound location dictated the need for additional considerations concerning off-loading of the ulcerative site. This was accomplished via TCC's during the period of the SNaP Negative Pressure System and later with a modified plastazote insert inside a CamWalker after changing to the KCI Vac System. It was the ease of removing the CamWalker that slowed the wound's progression during the first weeks of August, as patient admittedly "removed the dressing after one day" (08/01) and participated in "mowing lawns and moving furniture without the boot on." (08/15) Patient's treatment of aggressive wound-care and off-loading to affected limb served to prevent proximal amputation. Interestingly enough, patient was even desirous of a BKA on initial visit as he did not believe this wound could be healed. Patient was advised to seek employment that required him to be less ambulatory as condition would periodically reoccur with continued lifestyle.