

Fully-Synthetic Nanofiber Wound Matrix Facilitates Successful Closure of Chronic Lower Extremity Wounds of Various Etiologies

Matthew Regulski, DPM¹; Matthew R. MacEwan, PhD²

¹Ocean County Foot & Ankle Surgical Associates, Toms River, NJ, 08753. ²Acera Surgical, Inc., St. Louis, MO, USA, 63132.

PRIMARY AIM: Evaluate the efficacy and utility of nanofiber wound matrix in the treatment of chronic non-healing lower extremity wounds of various etiologies in patients with multiple comorbidities.

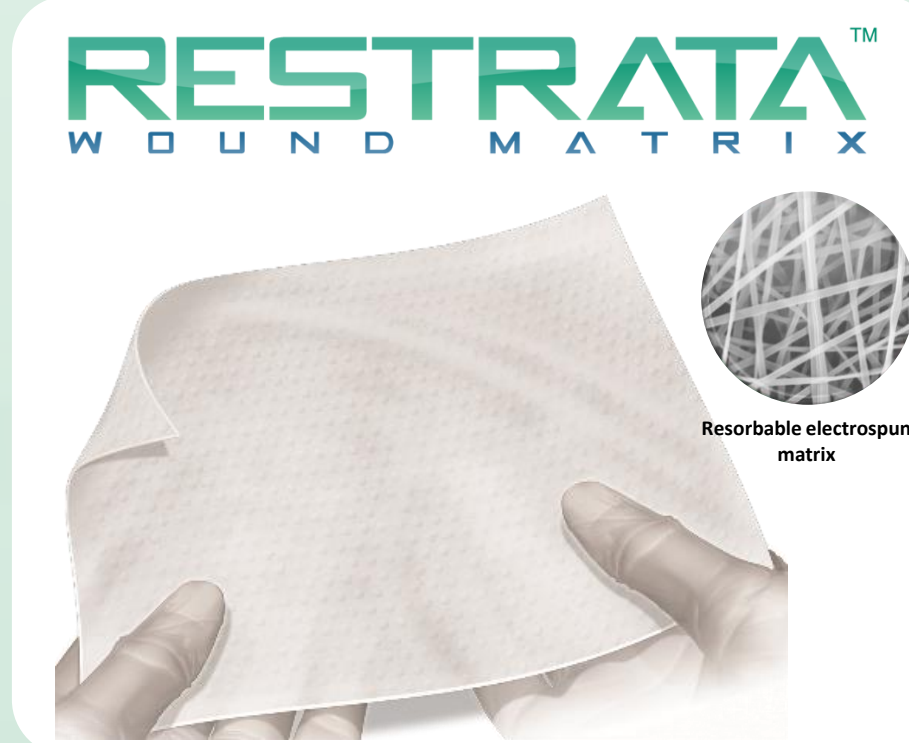
Introduction: Chronic non-healing wounds are a growing healthcare problem in the United States affecting over 6.5 million patients annually. In particular, diseases that compromise skin integrity and impair normal wound healing processes, such as diabetes and peripheral vascular diseases, are becoming more common and leading to an increasing number of chronic non-healing wounds. A fully-synthetic resorbable nanofiber material (Restrata™ Wound Matrix, Acera Surgical, St. Louis, MO) that exhibits structural similarities to the native extracellular matrix offers a new approach to the treatment of chronic wounds. This novel matrix is the first product to combine the advantages of synthetic construction (e.g. resistance to enzymatic degradation, excellent biocompatibility, strength/durability and controlled degradation) with the positive attributes of biologic materials (e.g. architecture similar to human extracellular matrix, fibrous architecture optimized to support cellular migration and proliferation, engineered porosity to encourage tissue ingrowth and vascularization). These features have been shown to allow the nanofiber material to achieve rapid and complete healing of wounds in preclinical large animal studies, superior to gold standard biologic material with diverse clinical indications in the wound care. The present study was designed to evaluate the efficacy and utility of the nanofiber wound matrix in the treatment of chronic non-healing lower extremity wounds of various etiologies in patients with multiple comorbidities.

Methods: Six patients with six chronic wounds of varying etiologies and sizes (three diabetic foot ulcers, two venous leg ulcers, one pressure ulcer) that had persisted for at least 4 weeks and failed previous treatment with standard of care were included in this study. Comorbidities included diabetes mellitus, obesity, polymyalgia rheumatic, lymphedema, peripheral vascular disease, steroid use, and neuropathy. All patients received application of the nanofiber wound matrix material weekly or as deemed appropriate. Wound area measurements and observation of wound quality were assessed weekly.

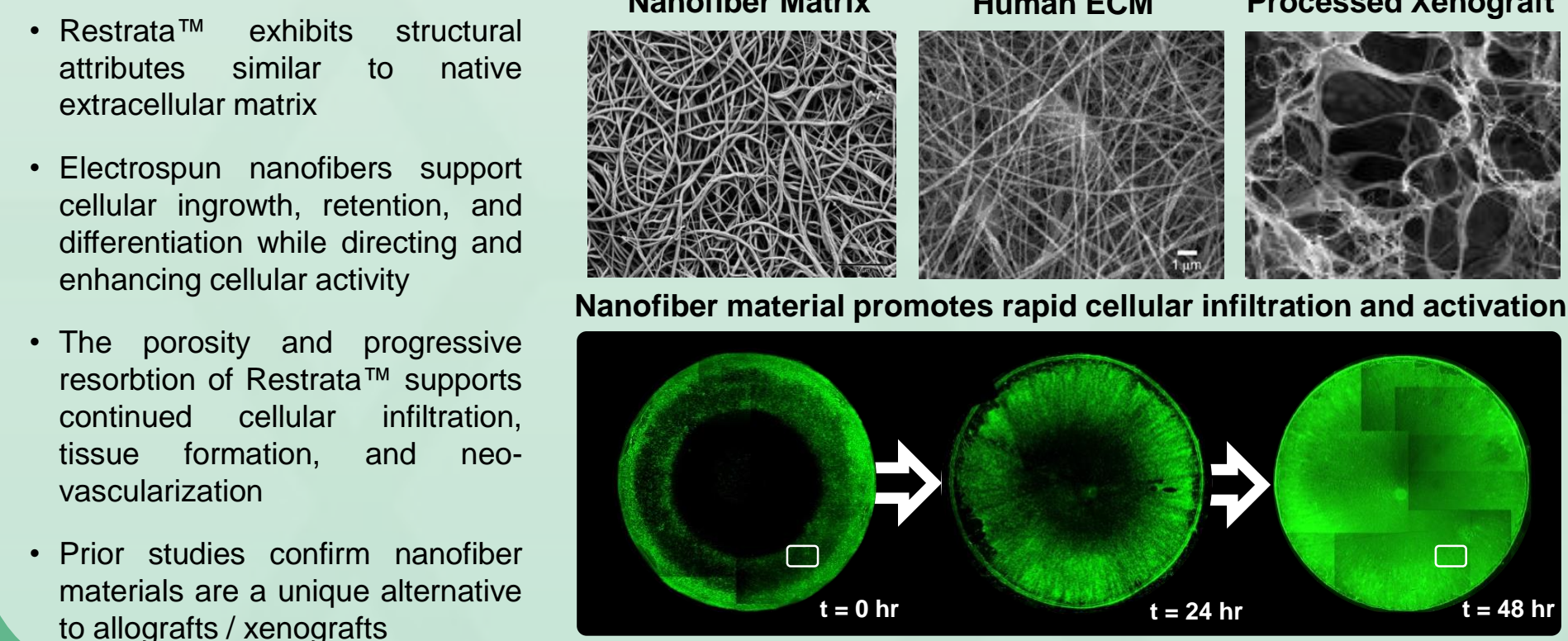
Results: All patients reached complete wound closure with no complications or adverse events. All wounds demonstrated sustained and progressive wound area reduction across multiple applications of the nanofiber wound matrix material. All wounds demonstrated marked improvement in wound quality and significant reduction in local inflammation.

Conclusions: The fully-synthetic nanofiber wound matrix represents a unique and beneficial treatment for a variety of chronic wounds (diabetic foot ulcers, venous leg ulcers, and pressure ulcers) in the lower extremity. The electrospun material possesses a nanoscale architecture that enables unique material and biologic properties ideally suited to wound healing scenarios. These unique attributes allow the nanofiber wound matrix to support wound healing, tissue regeneration, neovascularization, and epithelialization in challenging chronic wounds complicated by significant co-morbidities.

BACKGROUND: Fully-Synthetic Nanofiber Wound Matrix Mimics Human ECM and Supports Cell Ingrowth, Retention, and Differentiation



- Restrata™ Wound Matrix is the only persistent, flexible, fully-synthetic, bioengineered skin substitute for use in wound closure
- Restrata™ is composed of non-woven, resorbable synthetic nanofibers whose structure and architecture mimics that of native ECM
- Due to Restrata™'s fully synthetic design, the matrix resists enzymatic degradation, persists in the wound bed, reduces inflammatory response, and supports cellular/tissue ingrowth
- The unique properties of Restrata™ also offers improved ease-of-use, flexibility, and clinical versatility with significant logistical advantages over existing amniotic / allogenic products

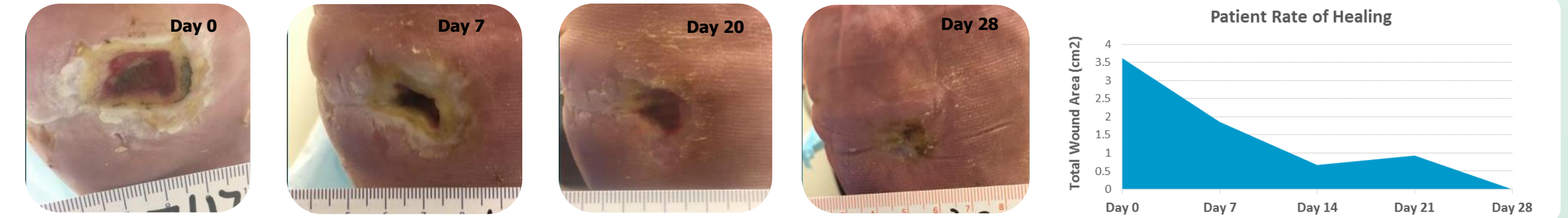


METHODS: Nanofiber Wound Matrix Applied Weekly In Conjunction with Non-Adherent Dressing

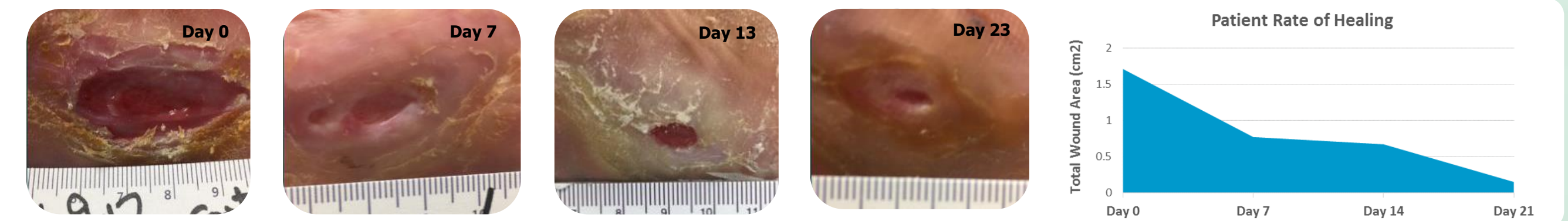


RESULTS: All Wounds Demonstrated Sustained Healing, Marked Improvement in Wound Quality, Reduction in Inflammation, and Complete and Persistent Closure

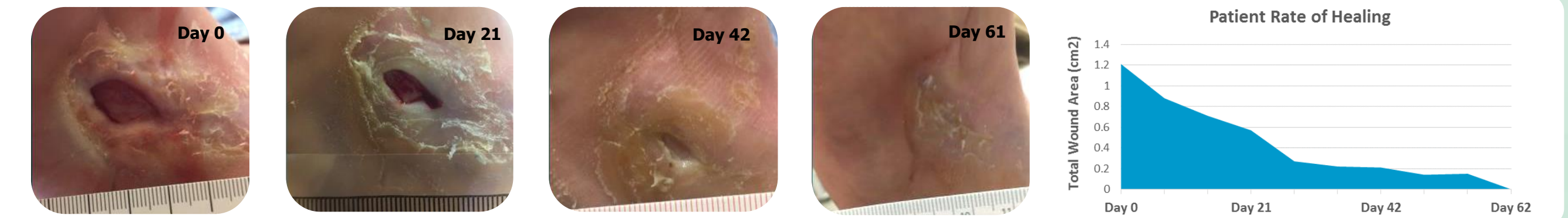
CASE #1: Diabetic Foot Ulcer
 • 80yo M, +Hx non-healing wounds
 • Wound open for >18 mos
 • Failed Grafix™, Provant™ therapy
 • Treated with Restrata™, BlastX™
 • Healed in 4 wks with 3 applications



CASE #2: Diabetic Foot Ulcer
 • 77yo F, +Hx non-healing wounds
 • Wound open for >10 mos
 • Failed Promagran Prisma™
 • Treated with Restrata™, BlastX™
 • Healed in 3 wks with 3 applications



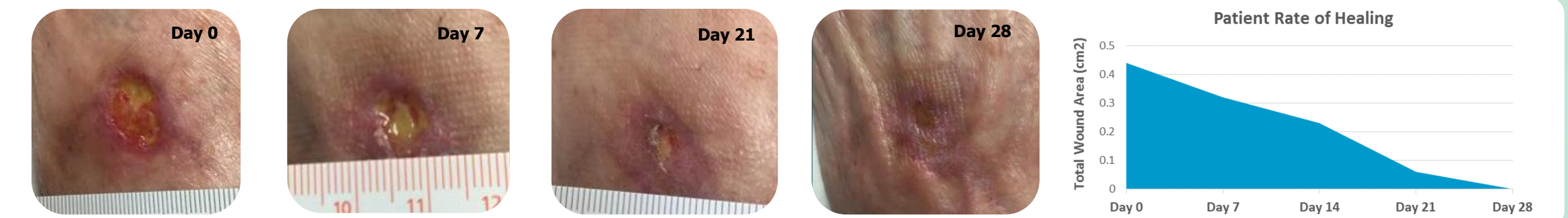
CASE #3: Diabetic Foot Ulcer
 • 64yo M, +Hx non-healing wounds
 • Wound open for >23 mos
 • Failed Grafix™, AmnioBand™
 • Treated with Restrata™, BlastX™
 • Healed in 9 wks w/8 applications



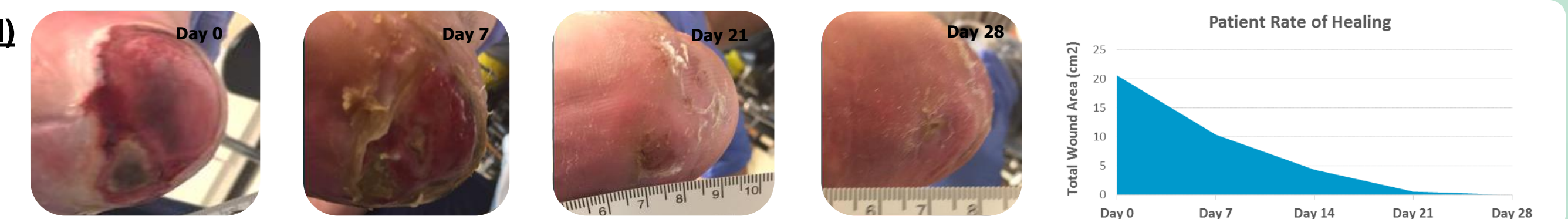
CASE #4: Venous Leg Ulcer
 • 75yo M, +Hx non-healing wounds
 • Wound open for >6 mos
 • Failed SOC + compression wrap
 • Treated with Restrata™
 • Healed in 2 wks with 2 applications



CASE #5: Venous Leg Ulcer
 • 70yo F, +Hx non-healing wounds
 • Wound open for >4 mos
 • Failed Grafix™
 • Treated with Restrata™
 • Healed in 4 wks with 3 applications



CASE #6: Pressure Ulcer (Heel)
 • 45yo M, +Hx non-healing wounds
 • Wound open for >8 mos
 • Failed TRITEC™ Silver
 • Treated with Restrata™
 • Healed in 4 wks with 3 applications



CONCLUSIONS: Nanofiber Wound Matrix Supports Wound Healing in Challenging Wounds