

Autologous Homologous Skin Graft Regenerates Functionally Normal Skin within a Chronic Nonhealing Leg Wound Refractory to Skin Grafting

Mark S. Granick MD¹ & Stephen Milner, MB.BS, BDS, FRCSE²

¹Rutgers New Jersey Medical School, Department of Surgery, Division of Plastic Surgery, Newark, NJ, USA

²Chief of Clinical Operations, PolarityTE, Inc., Salt Lake City, UT, USA

mgranickmd@Rutgers.edu

INTRODUCTION:

The prevalence of chronic nonhealing wounds is 1-2% of the general population, with Medicare expenditures estimated to range as high as \$96.8 billion. Advances in chronic wound treatments have the potential to expedite healing times and reduce the overall economic burden on the healthcare system. Minimally Polarized Functional Units (MPFU) is a new autologous homologous product which regenerates full-thickness, functional skin with all of its layers and appendages. The purpose of this study was to compare the results obtained with MPFU versus split-thickness skin graft in the treatment of a chronic nonhealing leg wound.

METHODS:

The study is an intraindividual analysis of outcomes achieved utilizing MPFU in the treatment of a chronic leg wound in comparison to native skin and to a healed split thickness skin graft on the contralateral leg. The study sample is composed of a single patient that suffered bilateral traumatic leg wounds initially treated with split-thickness skin grafts (STSG). The right leg wound failed two treatments with STSG and was ultimately treated with MPFU two years after injury; while the left leg wound healed uneventfully with the original split-thickness skin graft. Intra- and inter-wound outcomes were assessed, including graft take, time to wound coverage, donor site morbidity, hair regeneration, pigment regeneration, sensation, sweat and sebaceous gland production, and pliability.

RESULTS:

Length of follow-up was 30 months from the date of initial injury and six months following treatment with MPFU. Within the chronic nonhealing right leg wound, MPFU demonstrated complete graft take, complete epithelial wound coverage in 8 weeks, and complete wound coverage with full-thickness functional skin in 14 weeks. In comparison to native uninjured skin, MPFU demonstrated equivalent two-point discrimination, pliability, and sweat and oil gland production. MPFU regenerated hair follicles and pigment that were qualitatively and quantitatively equivalent to native uninjured skin.



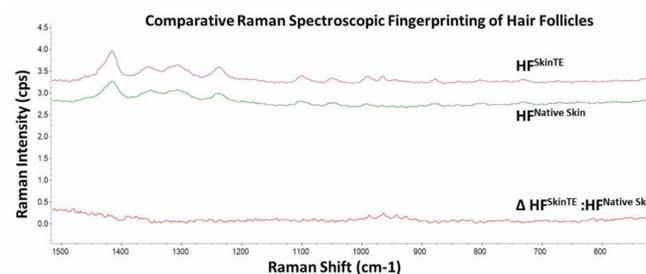
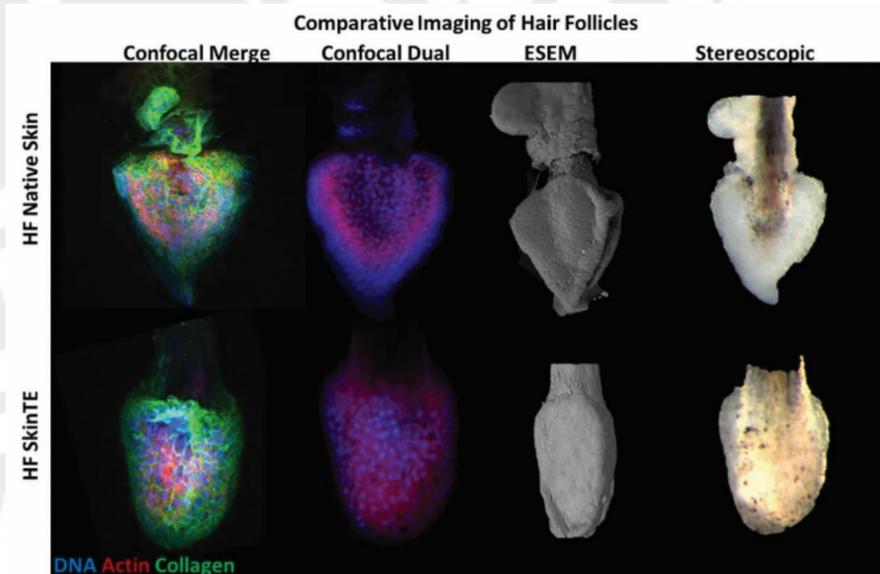
Figure 1. Chronic post traumatic wound right leg



Figure 2. Skin grafted fasciotomy wound left leg



Figure 3. Progression of healing after debridement and placement of MPFUs.



DISCUSSION:

These results demonstrate the ability of MPFU to regenerate full-thickness functional skin in a complex refractory wound. The patient had 2 unsuccessful STSGs after his injury. This wound became contaminated, chronic, and challenging to control. The wound was healed in 1 application of the MPFU. The failure of traditional STSG under ideal conditions and the success of MPFU under adverse conditions suggests that MPFU has the potential to avoid the downstream consequences of graft failure and the resulting chronic wound status if used in the acute setting. In addition, the ultimate results achieved with the skin regenerated by MPFU were equivalent to native uninjured skin throughout all testing performed, including digital single-lens reflex photography, microscopic imaging, sensory examination, and bioimpedance analysis; all of which were significantly different or absent in a healed STSG of the contralateral leg. Importantly, subjective patient-reported outcomes demonstrated a strong preference for treatment with MPFU compared to STSG, not only because MPFU was able to heal a chronic refractory wound, but also because the donor site consisted of a small linear incision for MPFU relative to that of a STSG. Beyond an analysis of the direct cost savings of healing a two and half year-old chronic wound, the case presented in this article also highlights the socioeconomic benefit, as the patient returned to work within 2 months of treatment of MPFU following a long period of disability.

CONCLUSIONS:

MPFU is capable of regenerating functionally normal skin within chronic nonhealing wounds refractory to all other treatment options, including split-thickness skin graft. The skin regenerated by MPFU is qualitatively and quantitatively equivalent to native skin across multiple functions and characteristics, including sensation, hair follicle morphology and composition, pigment regeneration, and gland production. MPFU has the potential to reduce the economic burden of chronic wounds if similar results can be achieved consistently.

REFERENCES:

Lough DM, et al. Transplantation of the LGR6+ Epithelial Stem Cell into Full-Thickness Cutaneous Wounds Results in Enhanced Healing, Nascent Hair Follicle Development, and Augmentation of Angiogenic Analytes. *Plastic and Reconstructive Surgery*; 3,2014; 133(3),pp 579–590.
Lough DM, et al. Transplantation of an LGR6+ Epithelial Stem Cell–Enriched Scaffold for Repair of Full-Thickness Soft-Tissue Defects: The In Vitro Development of Polarized Hair-Bearing Skin. *Plastic and Reconstructive Surgery*; 2,2016; 137(2),pp 495–507.