The Use of Bio-Engineered Human Skin Substitutes in the Office Setting

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**Introduction:**

Diabetic foot wounds can pose a formidable challenge for the clinician and patient, especially in the face of multiple comorbidities. There is a direct correlation between the duration of the wound and the incidence of infection. (1) Appropriate referral and the use of off-loading in conjunction with the use of bio-engineered human skin substitute is utilized in the office setting to achieve rapid, cost-effective wound closure. (2)

**Methods and Materials:**

This case presents a 79 year old female patient who suffers with multiple comorbidities including: Type II Diabetes, Obesity, Chronic Renal Failure controlled with Peritoneal Dialysis, Hyperlipidemia, and her mobility is limited to transfers. On presentation the patient has a wound that measures 4.5 x 7 cm, displaying a border of black eschar. The patient was transferred to me after conservative measures 4.5 x 7 cm, displaying a border of black eschar. The patient then underwent off-loading with a TCC, serial debridement and application of a bio-engineered human skin substitute over an 8 week period. (4)

**Discussion:**

The use of local wound care, off-loading with a TCC, and weekly applications of a bio-engineered human skin substitute was utilized to bring this heel wound to closure in the physician’s office. It has been shown, wounds exhibiting no significant reduction in size by the fourth week of treatment have an approximate rate of healing of 9% and require a treatment plan modification. (5)

**Documentation Pearls:**

Many carriers burden physicians in the private setting with pre and post payment audits to justify medical necessity for services that are provided to beneficiaries. As the landscape of health care provision changes, it is important for the clinician to accurately document his or her services to ensure appropriate reimbursement. Wound measurements, including length, width and depth need to be clearly documented in addition to the condition of the wound bed and edges. The wound bed should be free of necrotic tissue and infection prior to application of a bio-engineered human skin substitute. It is customary to document debridement performed, instruments used, amount of bleeding that occurred, and method of achieving hemostasis. Appropriate referral should be documented to satisfy third party payors that glucose control and vascular status has been optimized. Payors are also interested in documentation of product use and wastage. Appropriate ICD coding to indicate that the patient is diabetic, and the wound is on the foot is also required.

A bio-engineered human skin substitute utilizing human fibroblasts, was incorporated into the treatment plan to assist in rapid, cost-effective closure. Provision of an exogenous supply of fibroblasts results in accelerated wound closure. Fibroblasts are responsible for several functions in assisting with wound closure. (6) Fibroblasts produce growth factors including, but not limited to, vascular endothelial growth factor (VEGF), platelet derived growth factor (PDGF), and transforming growth factor – β (TGF-β). In addition, this cell line produces matrix proteins and glycosaminoglycans, which are the scaffold for neo-vascularization and epithelization of the wound surface. (7) A study reveals that patients treated with a bio-engineered human skin substitute containing fibroblasts showed a 30% healing rate at 12 weeks compared to those receiving conventional therapy displaying an 18.3% rate of closure at 12 weeks. (8)

**Conclusion:**

Diabetic foot wounds cost approximately $28,000 over a two year period. A patient diagnosed with diabetes has a 5.8% incidence of developing a foot ulcer over three years. (9) This diabetic patient was seen in the office setting with a chronic heel wound. There was no change in the wound size over a 4 week period prior to transfer to my care. An alternate plan was formulated to include multi-disciplinary intervention, off-loading and application of bio-engineered human skin substitute containing fibroblasts. Wound closure was achieved in 8 weeks. The patient was able to resume physical therapy, and within a few weeks, short periods of guarded ambulation became a reality for this patient.

**References:**