

TheraSkin[®]

Real Skin Wound Therapy

Use of a Biologically Active Human Skin Allograft for Closure of Chronic Wounds

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Objective

To determine if a new-to-market biologically active human skin allograft, with both epidermis and dermis layers, can be used as a cost effective alternative to bioengineered skin substitutes for the treatment of DFUs, VSUs and other chronic wounds.

Introduction

The use of bio-engineered skin substitutes or xenografts has become the standard of care for treating non-responsive chronic diabetic and vascular ulcers. Yet each of these products has many restrictions that must be addressed before use. Many chronic wounds do not meet indicated use criteria or reimbursement criteria for these products. For the two most widely used bioengineered skin substitutes, usage is limited to one or two types of chronic wounds.

The Mary Immaculate Hospital Wound Care Center has a population of chronic wound care patients that may have had their wounds for years. These include surgical and oncologic wounds. Advanced wound care including debridement, skin substitutes and any required healthcare interventions are performed regularly. Yet in spite of utilizing advanced wound care treatments, patients return with new wounds or the previous wounds reopened. The Wound Care Center noted limitations of bioengineered skin substitutes as a scaffold for patients full thickness growth. Use of a biologic with all the key growth factors but with more collagen, may result in closed wounds that are stronger and less likely to reopen.

Hypothesis

We hypothesized that:

1. A new-to-market biologically active human skin allograft, with both epidermis and dermis layers, (TheraSkin®) can be used on a broader range of chronic wounds.
2. Use of TheraSkin to treat chronic wounds will yield similar or better clinical results than the use of bioengineered skin substitutes or xenografts.
3. TheraSkin, because it contains all the key growth factors but has substantially more collagen than bioengineered skin substitutes, will result in stronger closed wounds that are less likely to reopen.

Materials & Methods

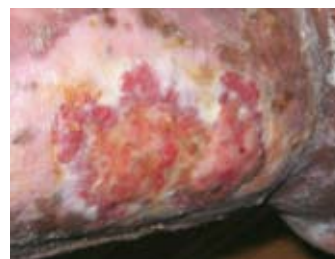
Patients with chronic wounds of varying times of duration were eligible to participate in this study. Three (3) patients were selected for review: a paraplegic male with heel pressure injuries and two elderly women with venous stasis. All in this study had persisted wounds for more than one year and each patient had been advised amputation would be needed as the next course of treatment.

Case Study 1



Patient A, an 83 year old female, has a history of venous stasis ulcers on the left medial malleolus and calf that have been persistent for several years. The patient is

wheelchair bound and her PCP suggested performing a Below Knee Amputation (BKA) rather than conservative treatment. Patient A refused the PCP suggested treatment and sought a second opinion from the Mary Immaculate Wound Care Center. Since her first visit in 2008 she had these ulcers close with the use of bio-engineered skin substitutes and xenografts; however, these wounds have never stayed closed.



The medial calf wound reopened in June of 2009. The primary wound in the wound bed was assessed at 3.5 x 3.8 x 0.1 with the patient in significant pain. After the wound bed was prepped, six (6) applications of TheraSkin were placed between 6/17/2009 and 9/2/2009. By 9/23/2009 the wound closed and compression was changed from



Unna boots to compression hose. All of the patient's wounds have remained closed.

Case Study 2



Patient B is a 43 year old long term paraplegic resulting from a spinal cord astrocytoma. He was referred to the Mary Immaculate Wound Care Center from home health care with

a stage 4 pressure ulcer of the right heel. The ulcer resulted from resting the heel on the foot pedals of his electronic wheelchair. The patient had been advised that his only option for treatment was a BK amputation by several non-wound care physicians.

Unhappy with the diagnosis, the patient sought a second opinion. His first assessment noted a slough covered wound of 2 cm x 6 cm. To further assess the wound, sharp debridement was done and diagnostics were scheduled to identify for the potential of osteomyelitis. Calcaneal osteomyelitis was diagnosed and IV antibiotics were ordered.



The wound bed was prepped 5/20/2009 and a KCI V.A.C. was placed to encourage development of granulation tissue prior to the first TheraSkin application. TheraSkin was placed 5/27/2009 to a wound bed measuring 2.4 x 8.4 x 0.2 with TheraGauze+FN as cover dressing and the V.A.C. to assist in graft incorporation. Four (4) applications of



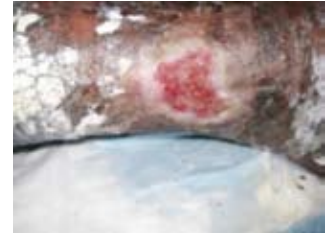
TheraSkin were placed between 5/27 and 7/8/2009. The wound was closed by 8/5/2009 with the patient remaining in a protective dressing to decrease the potential for new trauma.

Case Study 3

Patient C, an 85 year old female, with long standing venous stasis ulcers. Patient C is wheelchair bound except for ADLs. Patient C presented wearing an Unna boots due to her inability to tolerate static 4 layer compression wraps or put on compression stockings. Amputations of bilateral lower legs had been suggested due to ongoing ulcers.

On 8/12/09 after the largest of the wounds (4.5cm x 4.7 cm x 0.2cm) in the right medial malleolus wound bed was prepared, the first of six (6) applications of TheraSkin were placed.

The last application of TheraSkin was completed on 11/18/09 with only a 0.5 x 0.5 patch of hypergranulation tissue remaining. This area was treated with silver nitrate and a xenograft. As of 2/23/09 Patient C continued to remain in bilateral compression and amputation has been avoided at this time.



Conclusions

Hypothesis #1, 2 and 3 are supported by the results of the three case studies.

By September 2009, after four (4) to six (6) applications of TheraSkin, all three (3) patients' wounds were closed. No amputations were required and all wounds have remained closed. At the Mary Immaculate Hospital Wound Care Center, TheraSkin, which is 100% human skin, has become the therapy of choice for patients in need of advanced wound care. This is the case, not only because of the clinical efficacy of TheraSkin, but also because TheraSkin is 50-70% less expensive than alternative bioengineered skin substitutes. The Mary Immaculate Wound Care Center is applying TheraSkin on venous, diabetic, pressure ulcers, and dehisced surgical and oncologic wounds and anticipates using TheraSkin on an even wider variety of chronic wounds.



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