VOLUME 1 - CASE STUDY

# TREATMENT OF RECALCITRANT DIABETIC FOOT ULCERS WITH DERMAL ALLOGRAFT (ALLOSKIN™ RT) IN A CLINICAL OFFICE SETTING

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### Introduction

This case study is the first in the case series. The patient, a 58 year old male with a history of Type II Diabetes and lower extremity neuropathy, presented to the Emergency Department with pain in his right foot that had been going on for two weeks. The patient could not recall any trauma to the right foot however, he is neuropathic. The patient did report pus and drainage from his right second digit nail bed. Upon examination, the patient presented with a black, necrotic, right second digit and dusky-looking first digit. He also had an abscess on the lateral aspect of his right foot. His pulses were good, but the digits were not viable and were very infected without improvement on IV antibiotics. The patient initially underwent a second digit amputation as well as an incision and drainage (I&D) of the right lateral abscess the same night. The patient returned three days later for a delayed primary closure of the second digit amputation site and was again taken to the OR five days later for resection of the fifth digit, secondary to osteomyelitis (likely from the abscess site on the lateral aspect of the foot which tracked to the fifth digit). At this time, negative pressure wound therapy (NPWT) was applied over the lateral aspect of the right foot. The patient was discharged from the hospital and readmitted through the Emergency Department three weeks later with cellulitis of the right foot with dusky black/gray appearing first, third, fourth digits. The patient was taken to the OR for a transmetatarsal amputation (TMA). Two weeks following the TMA, the patient presented to the hospital with wound dehiscence at the amputation site. Two separate I&D procedures were done on the patient in the OR. During the second I&D procedure, NPWT was applied over the dehisced TMA site.

The patient was sent home on NPWT, using the V.A.C.° Therapy system (KCI, San Antonio, TX) and continued NPWT for twelve weeks post-TMA, with thrice-weekly, in-home V.A.C. Therapy dressing changes. We saw no decrease in wound size resulting from V.A.C. Therapy. However, the wound was not infected and it had a healthy granular base.

## AlloSkin RT Treatment

Upon cessation of V.A.C. Therapy (visit 1) skin graft treatment began in the clinic using AlloSkin™ RT (AlloSource®, Centennial, CO) and wound progression was monitored over a period of 10 office visits (from 3/22/2011 – 5/24/2011). Throughout the course of treatment, AlloSkin RT grafts were applied a total of three times (visits 1, 3, and 7). The product comes from the processor as a sterile packaged allograft, 1:1 meshed, which is applied to the wound in a sterile fashion with the reticular side of the cadaveric dermis down and in contact with the entire wound topography. Securing the graft corners with a single stitch, the wound was dressed with Adaptic® and Silvercel® (both from Systagenix, Gargrave, U.K.), Kling® flexible dressing (Johnson & Johnson, New Brunswick, NJ), Kerlix™ 4x4 gauze (Covidien, Mansfield, MA), and wrapped with an Ace™ Bandage (3M, St. Paul, MN).

Weekly, the dressings were removed, the wound inspected and measured, and the peri-wound area was debrided. Additional grafts were reapplied as needed to areas of healthy granulation tissue. The appropriate lower extremity was off-loaded with a post-operative shoe and crutches, and the patient was not allowed to get the foot wet during the entirety of the treatment period.

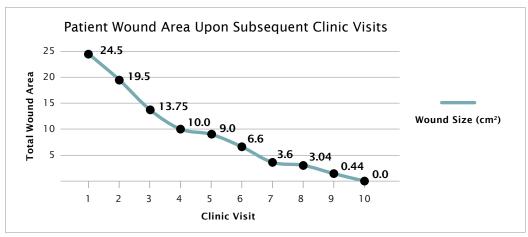
# Results

The wound area decreased consistently and was closed at the 10th clinic visit (at nine weeks), with an average healing rate of 2.72 cm<sup>2</sup> per week (*Figure 1*). The patient was neuropathic and had no pain before or during treatment, although he does now complain of pain at the TMA site, over which the wound has healed. The patient was seen in the clinic three times after the wound closed. The wound is still closed and the patient is doing well.

### Conclusion

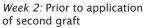
AlloSkin™ RT appears to be an efficacious treatment option in the outpatient wound clinic when treating diabetic foot ulcers. This diabetic foot ulcer required three 80 cm² AlloSkin RT grafts over the 10 week course of treatment.

Figure 1. Rate to wound healing with AlloSkin RT - Patient 1



# Case Study #1 Clinical Progression:





Week 6: Third graft applied

Week 9: Wound closure achieved



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