Treatment of Diabetic Foot Ulcer with Placental Allograft Therapy

BioStem LIFE SCIENCES

CASE STUDY

Patient History

The patient is a 52-year-old male, who presented with a 38-month history of ulceration on the lateral aspect of his right foot at the cuboid level consistent with a long history of poorly controlled type II diabetes. The patient was also experiencing profound Stocking Distribution Neuropathy bilaterally to the midcalf, minimal to no sensation with hot, cold, and vibratory stimuli, and difficulties with 2-point discrimination. Patient's cuboid ulcer continued to be unresponsive to therapies and treatment such as KCI Vac Therapy, contact cast off-loading, weekly debridement, antibiotic therapy, and hyperbaric therapy.

The patient also presented with amputation of his right toes 1-4 at the PIP joint level secondary to a variety of ulceration. Within the last 12 months, prior to Perinatal Tissue Allograft Therapy, the patient underwent his final amputation of the 5th digit and 5th metatarsal.

The patient's next option was to consider a lower leg amputation or Perinatal Tissue Allograft Therapy.

The patient was given appropriate information and consented to attempt Perinatal Tissue Allograft Therapy.

Treatment Plan

The patient underwent the following protocol to initiate and continue treatment:

1. Diagnosis - The patient had a biopsy performed to rule out skin cancer, osteomyelitis (infection of the bone), and abscess.
2. Culture - Deep into sinus or tunnel.
3. Control - Glucose, nutritional levels of protein. Maintaining glucose within normal limits and nutritional values at their best capacity for the patient's healing process is the main goal.
4. Signaling - weekly debridement of the wound and coverage with Tegaderm or Opsite.
5. Inject around the wound approximately 8-10 mm from the wound edge, and if necessary through the Tegaderm or Opsite.
    a. Imagining the wound as the face of a clock:
        1. Inject in both sides of 12 and 6 (to the left and to the right of each)
        2. Inject above and below both 3 and 9 (above and below each)
6. Place non-stick gauze over the wound post injection.
7. Remove Tegaderm within 24 hours. Wash the wound and change the nonstick dressing once a day at minimum pending drainage volume.

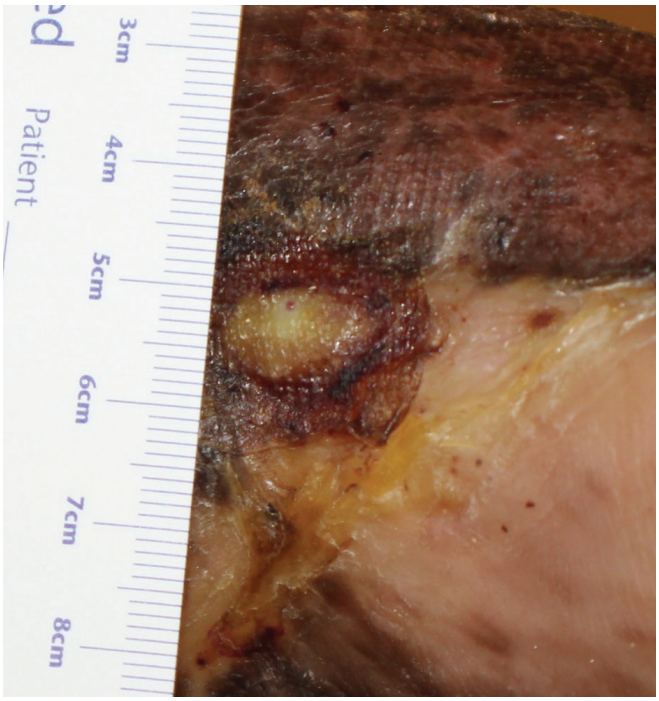
Patient Results/Outcomes

The patient started to respond within 5 days:

Patient LM Comparative

Day 0 - 4.7cm

Day 63 - Closed Margin



Patient LM (Day 90)

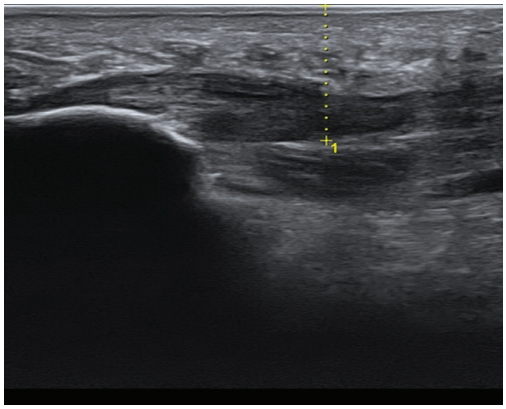
- Fully resolved
- On kidney transplant list
- Back to work
- Wearing diabetic shoe

Within 63 days, the wound fully closed. At 90 days, the patient was able to wear a wide diabetic shoe, was accepted onto a transplant list, and subsequently underwent kidney transplant without any secondary wounds developing. Over the follow-up period of 48 months, there was an improvement in 2-point discrimination and hot/cold discrimination with marginal improvement in vibratory sensation ability.

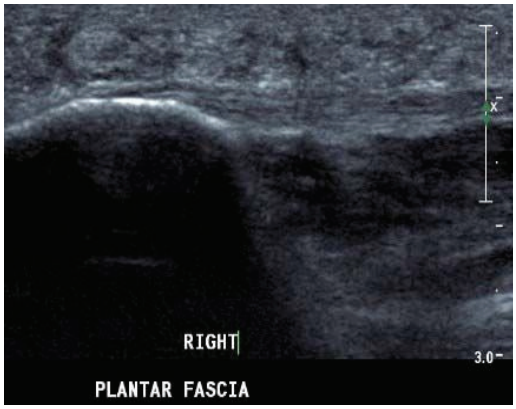
Used as a first line therapy vs standard of care, one application of placental allograft prevented development into a non-healing wound, as noted in this series of ulcerated fissure heel of a diabetic patient.

Plantar Fasciosis Resolved

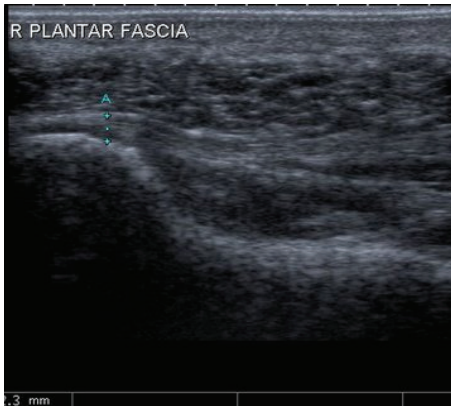
Another example of success using the BioStem Perinatal Tissue Allograft Therapy is seen in treating heel pain from either Achilles enthesopathy or plantar fasciosis, as seen in this ultrasound series.



Day zero



Week 6 - 45 Days



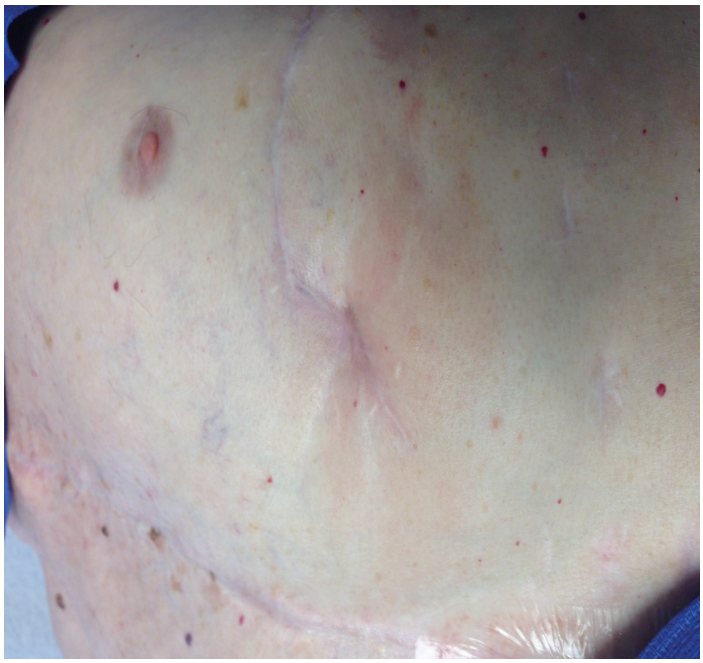
Week 24 - 168 Days

This patient had failed traditional heel pain therapy including night splints, stretching, corticosteroid injection, and change in shoe gear for over 12 weeks. The patient was offered implantation of BioStem Perinatal Tissue Allograft, and within 6 weeks pain was resolved, and by ultrasound examination, the thickness of fascia decreased, and continued to decrease to normal at 24 weeks.

Scar Revision

Scar revision without surgery, as reported in the International Journal of Cardiology 2016, multiple articles are now reporting that Perinatal Tissue Allograft implanted into and under keloid scar. The involuted scar is expected to remodel over the course of 6-12 weeks

- Pre-injection
- Painful scar
- Bedridden



- 14 days post injection
- No pain
- Normal turgor
- Walking without pain

First in Man: Amniotic Stem Cell Injection Promotes Scar Remodeling and Healing Processes in Late-Stage Fibrosis
Courtney Hemphill, Katherine Stavoe, Zain Khalpey
International Journal of Cardiology

BioStem Life Sciences is an FDA-registered, cGMP/cGTP compliant tissue processing facility, located in Pompano Beach, Fl. Our robust Quality Management System (QMS) was developed by pharmaceutical industry veterans, and certified tissue bank specialists in conjunction with in-house quality and regulatory professionals. BioStem's laboratory staff is fully trained in sterile and aseptic technique, ensuring the safety and compliance of every product leaving the facility.

Physicians have reported that these Perinatal Tissue Allografts can support soft tissue repair, reduce inflammation, and minimize scar tissue formation.