



The D.I.C.E. Factor

Diabetes, Infection and Circulation
of the lower Extremities



GENESISTM

/// POWERING HEALTHCARE OPTIMIZATION

Non-Invasive Office Application





Patient will keep dressing on and dry.
Follow up weekly for 2-6 weeks until the
wound heals.

Stem Cell October 2011



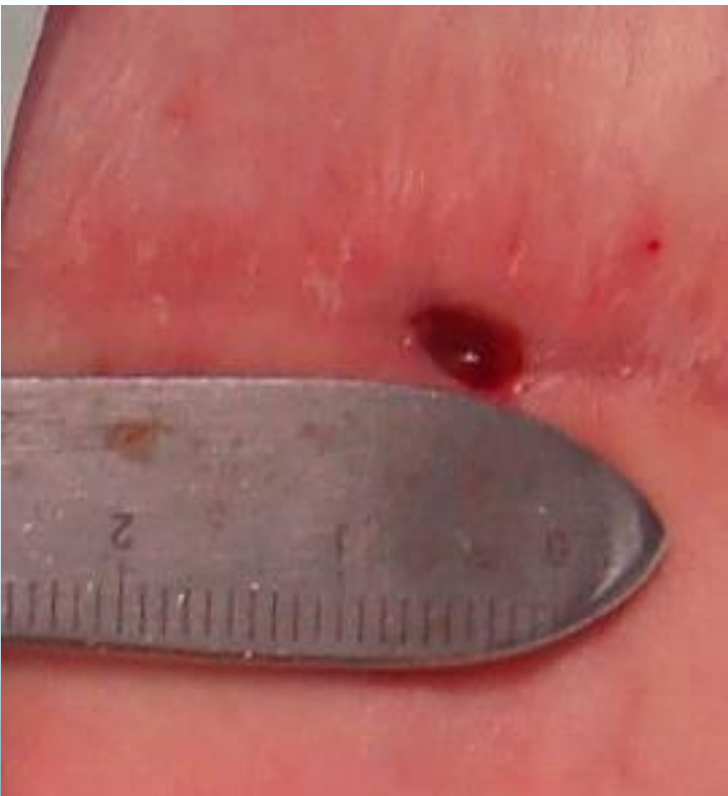
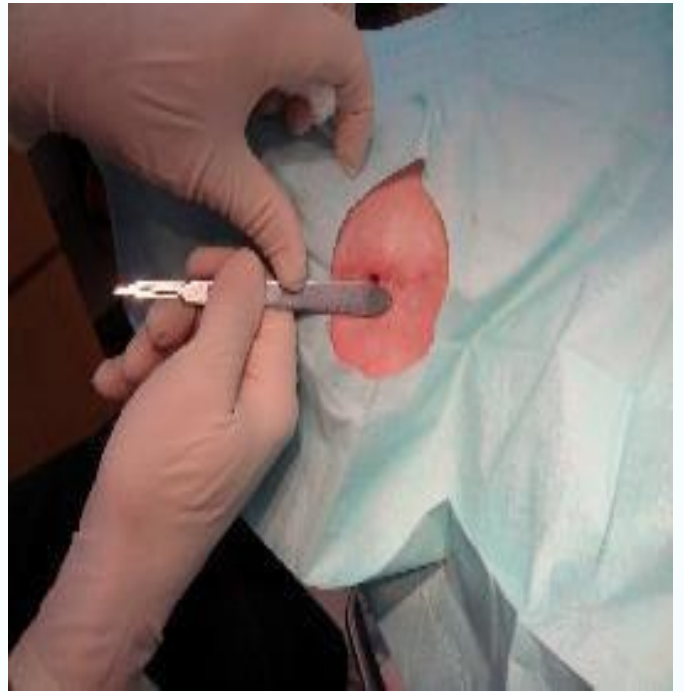
- Core blood
- Use biologic skin
 - Bone derived
 - Fat derived

Diabetic Ulcer

Biologic Skin Graft



Ulcer non-healing



ACHILLES TENDON RUPTURE

Biologic Skin Graph



Achilles Rupture
Pictures 14 days post op

Minimal to no pain – went to
movies 2 days post op

Out of cast boot 30 days post
op



Diabetic Foot Ulcer:

Case 1

34 year old male patient with a history of poorly controlled insulin independent diabetes mellitus

Initial Examination:

Patient was admitted through the emergency department for an infected diabetic foot wound that encompassed his entire midfoot. The wound extended from just proximal to the 1st metatarsophalangeal joint to the talar navicular joint of the right foot. The total surface area of the wound was 18.76 cm². The wound was extended to the muscles but no bone was exposed. The wound revealed a foul odor and approximately 8cc of pus were expressed from the wound, collected in a syringe and sent out for microbiological analysis for culture and sensitivity studies. The patient had intact vascular supply to the foot with biphasic dorsalis pedis, posterior tibial, perforating peroneal waveforms via Doppler examination. His wound was graded as Grade IIB according to the University of Texas Classification System.



Treatment:

The patient was taken to the operating room for an incision and debridement. After the initial debridement, a negative pressure wound closure system was applied to serve as an active drainage system to the wound. The patient was placed on gentamicin IV for 14 days. Ten days later the wound was debrided once again, and no nidus or active infection could be found. Two days later, the Graft allograft was placed on the wound. The graft was not secured with sutures or staples, and non-adherent dressing and wet gauze were applied to the wound with a bolster suture.



Outcome:

The graft was left intact for 7 days then the dressings were removed. The wound appeared to have reduced in size by 30%. The wound was redressed with sterile wet to moist gauze dressings. At day 14, the wound had reduced by another 15%. A second graft was applied. At day 28 the wound was extremely superficial and essentially healed with two pin point areas that went on to heal successfully. At 3 months, patient remains fully healed walking in a custom molded shoe.



Mohs Surgery Patient: Case 2

69 year old female with previous history of skin cancer, arthritis and hypertension.

Patient History:

The patient is a moderate drinker and smokes one pack per day.

Initial Examination:

Patient presented with a subcutaneous nodule inferior to her right eye. A 2.0 mm punch biopsy was performed. The path report showed an invasive carcinoma, favoring Basal cell carcinoma.

Treatment:

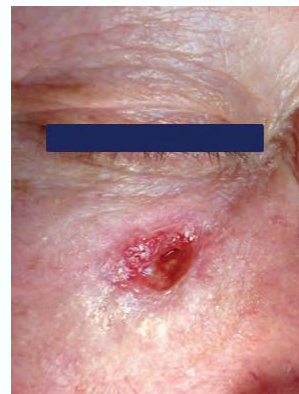
Mohs surgery was scheduled to remove the lesion and it was elected to apply an Graft 2 cm x 3 cm allograft. The patient was instructed not to remove the cover dressing for 48 hours and then to remove the dressing on a daily basis and reapply a sterile saline soaked gauze and redress. The patient continued with moisture retentive dressings and healed with no complications and very little scarring. Follow up at 10 months shows virtually zero scarring.



Application of Graft



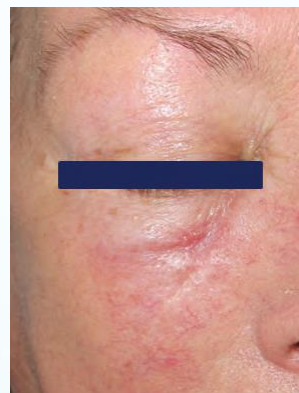
Day 1



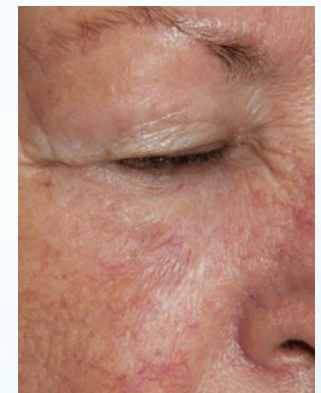
Week 2



Week 3



Week 4



Ten Months



Day 1



Ten Months

Keloid Scar Revision: Case 3

Patient History:

Patient presented with keloid scar after Caesarean section procedure.

Treatment:

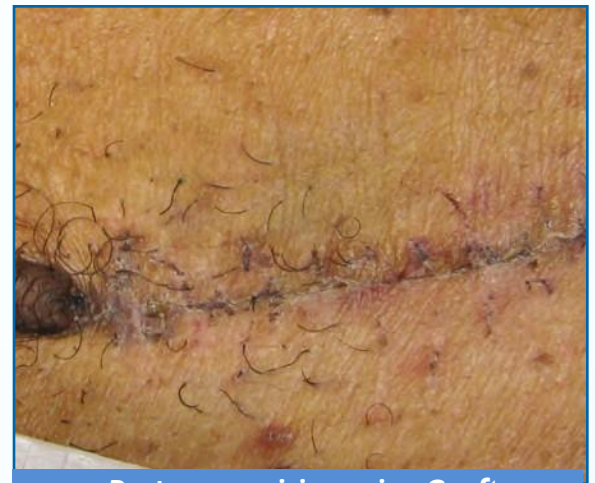
In order to evaluate the effectiveness of Graft in keloid scar reduction, one-third of the scar was treated with Graft in revision surgery. Graft was placed within the incision site before suturing.

Outcome:

Scarring was greatly reduced in height and color. Subsequent revision surgery treated remainder of keloid scar with Graft.



Pre-Op



Post-scar revision using Graft
on 1/3 portion of original scar



Scar after Graft use

Diabetic Foot Ulcer:

Case 4

74 year old non-insulin-dependent diabetic male with non-healing neuropathic ulcer of the right great toe.

Patient History:

Previous medical treatment included over-the-counter topical medications and oral antibiotics.

Initial Examination:

On presentation, the wound was a Wagner Grade 2 full thickness plantar right hallux wound that had been present for four months. The size of the wound was 0.7 cm x 0.6 cm x 0.2 cm on initial presentation.

Treatment:

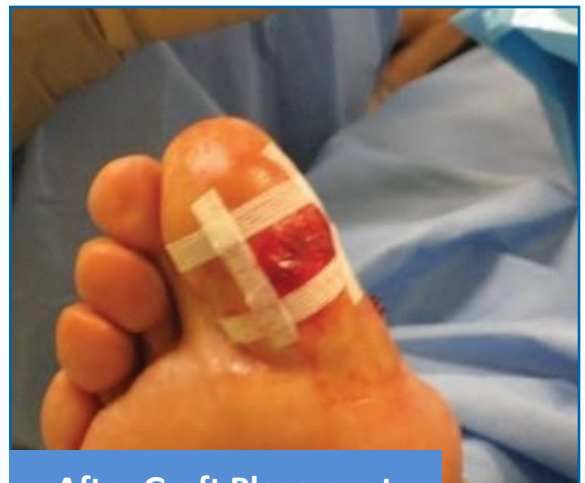
The patient underwent the standard protocol with initial debridement and application of the Graft allograft.

Outcome:

After 4 weeks post-op, the patient showed gradual healing with eventual complete resolution of the wound. Hematoxylin and eosin (H&E) stain showed initial inflammatory cells moving to subsequent deposition of dense collagen and graft incorporation with minimal inflammatory response at the site.



Prior to Treatment



After Graft Placement



Result at 4 weeks

Diabetic Foot Ulcer:

Case 5

*70 year old insulin-dependent diabetic female
with non-healing neuropathic ulcer of the plantar left heel.*

Patient History:

Previous treatment included over-the-counter topical medication and oral antibiotics. The patient presented with a past medical history of insulin- dependent diabetes, hypertension and peripheral vascular disease. Ulcer present for 7-8 months secondary to callus formation.

Initial Examination:

Objective findings included no signs of infection, pain or drainage. Weak palpable pulses were present but audible on Doppler with a biphasic sound. The wound presented as a Wagner Grade 2 full thickness left heel wound and had been present for seven to eight months. Size of the wound was 1.9 cm x 1.8 cm x 0.3 cm on initial presentation.

Outcome:

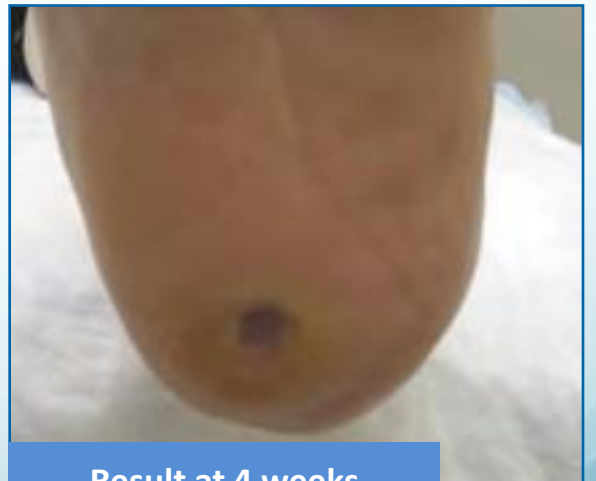
At the first postoperative week, observation showed evidence of full graft uptake with healthy granulation tissue within the wound bed. Decrease of the wound margins was noted as well. At the fourth postoperative week, wound measurements were taken to be 1.0 cm x 0.8 cm x 0.1 cm with a resulting 50% reduction in overall wound volume and marked wound healing progression.



After Initial Debridement



After Graft Placement



Result at 4 weeks

Diabetic Foot Ulcer:

Case 6

54 year old female patient with insulin independent diabetes mellitus, controlled with an A1c of 8.1.

Initial Examination:

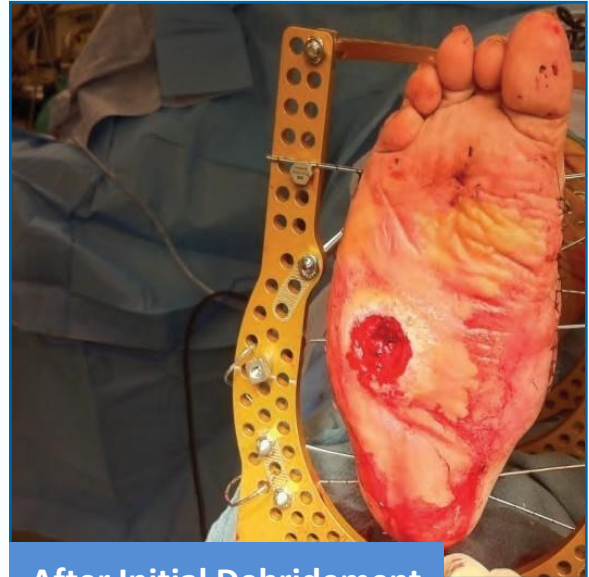
Patient had chronic Charcot disease of the right foot with a plantar lateral ulcer, non-infected, non-ischemic graded as a IB according to Texas Classification. Patient had the wound for approximately 1 year. The wound was being treated with felted foam dressings for off-loading and weekly debridement.

Treatment:

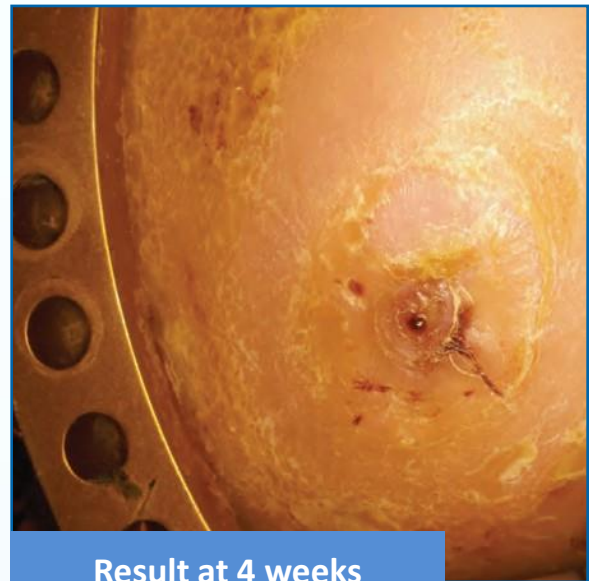
Patient was taken to the operating room for Charcot reconstruction with external fixation. The wound was debrided radically at time of reconstruction and Graft was applied.

Outcome:

Total wound closure achieved at 4 weeks.



After Initial Debridement



Result at 4 weeks

Diabetic Foot Ulcer:

Case 7

61 year old male patient with insulin independent diabetes, well controlled with a A1c of 7.3, no other comorbidities.

Initial Examination:

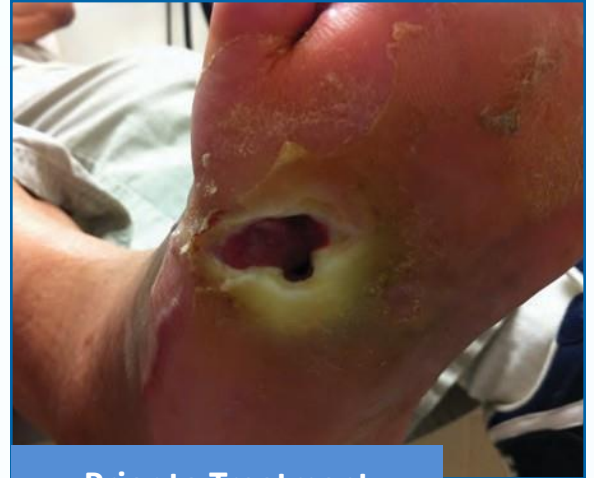
Patient presented with a right foot, Grade IIA ulcer to the distal plantar aspect, below the 5th metatarsal head. After serial debridements, the patient developed a Grade IIIB ulcer. The patient was taken to the OR for debridement of osteomyelitis infected bone and soft tissue.

Treatment:

After IV antibiotics for treatment of MRSA, and negative cultures, an Graft amniotic membrane allograft was applied.

Outcome:

The patient was kept non-weightbearing during this time. Total wound closure was obtained in 6 weeks.



Prior to Treatment



Prior to Graft Placement



Result at 6 weeks

Diabetic Foot Ulcer:

Case 8

Diabetic ulcer had up to this point been open for approximately 1.5 years and resulted in the amputation of two toes.

Patient History:

Treated this wound with 8 wound V.A.C. applications, 4 Apligraf, 1 Oasis, and 1 GraftJacket.

Treatment:

Applied two Graft amniotic membrane allografts and an aggressive treatment plan.

Outcome:

Achieved closure in 35 days.



After Initial Treatment



Result at 35 days

Post-Traumatic Wounds:

Case 9

59 year old female

Patient History:

Motor vehicle accident with open left ankle fracture treated with Open Reduction Internal Fixation (ORIF) with exposed bone.

Initial Examination:

Treated with subsequent intravenous antibiotics, hardware removal, negative pressure therapy, Oasis® application, bone stimulator, and hyperbaric oxygen treatment.

Treatment:

With worsening measurements, Graft amniotic membrane was applied at three and half months

Outcome:

Due to unavailable product, only one application was utilized. Subsequent Medihoney® dressing changes and office debridements were associated with a gradual decrease in wound size to closure at ten months.



Patient four months after ankle ORIF

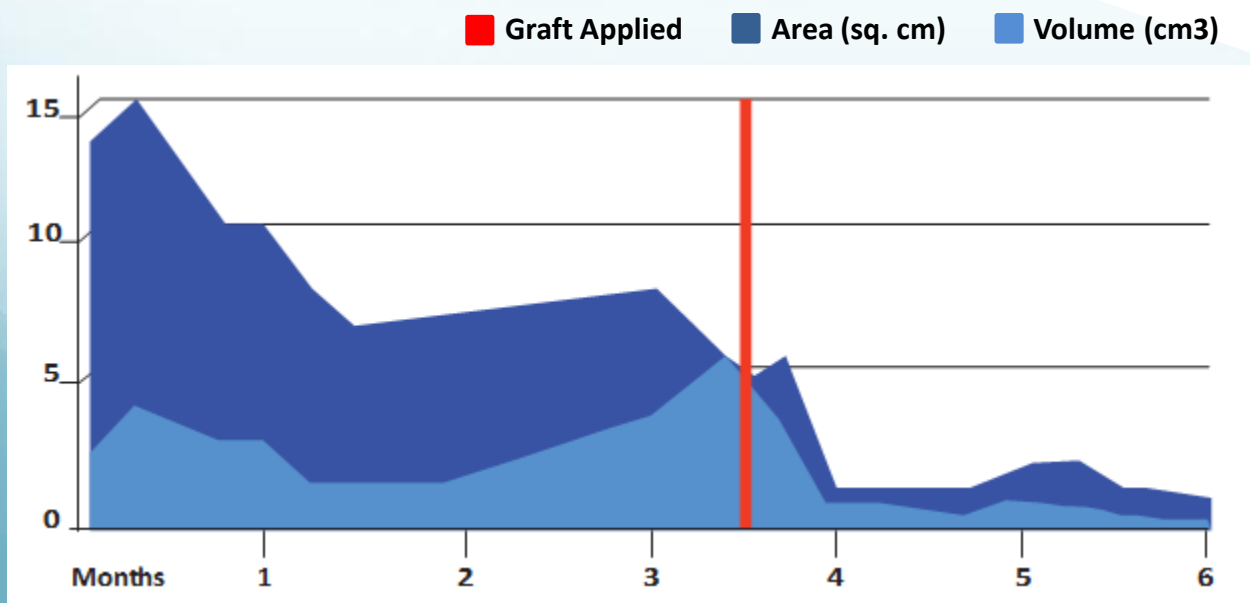


Patient at date of Graft application



Patient 8 weeks after Graft application

Healing rate of Patient



Post-Surgical Wounds:

Case 10

31 year old female

Patient History:

Crush injury to left calf

Initial Examination:

Patient developed seroma necrosis that required inpatient surgical debridement.

Treatment:

Graft applied after debridement surgery 4 weeks after admission.

Outcome:

Patient had significant epithelialization 4 weeks after Graft application.



On admission



4 weeks later: Debridement and Graft application



4 weeks post Graft application

Post-Surgical Wounds:

Case 11

Right-hand dominant 53 year old female smoker with polyarticular rheumatoid and osteoarthritis who was dependent upon forearm crutches for ambulation.

Patient History:

After undergoing left olecranon bursa excision, she developed post-operative wound dehiscence at three weeks. This was initially treated with in-office wound debridement, topical medicinal honey dressings and elbow splinting.

Initial Examination:

Initial wound measured 2.7 cm x 1.8 cm x 0.1 cm prior to initial debridement and 2.8 cm x 2.8 cm x 0.3 cm thereafter. No joint exposure was noted. At five weeks postoperatively, the wound had retracted but remained open and negative pressure therapy was begun to enhance secondary intention closure of the wound. The wound healing progressed, only to plateau again despite eight weeks of therapy.

Treatment:

The wound was then addressed with Graft application at five weeks post-op with concomitant termination of negative pressure application. A single application of Graft was used, resulting in wound closure at three weeks post application. A non-adherent dressing over the membrane was replaced after one week.

Outcome:

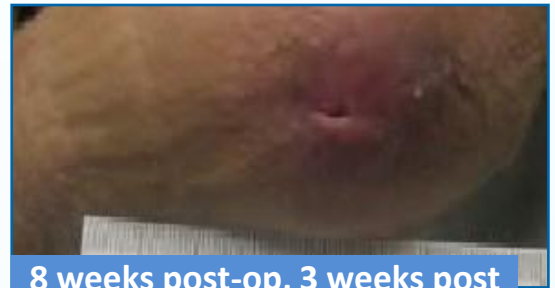
The patient missed a second-week follow-up appointment, but was noted upon the third-week time point post-Graft application to have the wound healed with re-epithelialization. The patient was discharged. No recurrence was reported at one month after follow-up inquiry by phone and there were no further follow-up visits. Wound measurement evaluation indicated a plateau in the effectiveness of more conservative therapies which was overcome by the subsequent application of Graft.



Wound age 10 weeks



5 weeks post-op, Graft Applied



8 weeks post-op, 3 weeks post Graft application

Post-Surgical Wounds:

Case 12

56 year old non-diabetic patient; neuropathic. Dehiscent surgical wound after removal of ganglion cyst.

Treatment:

Previously treated with negative pressure and Xeroform before initiating use of Graft dehydrated Human Amnion/Chorion Membrane allograft.

Outcome:

Closure achieved in 4 weeks with 4 applications of Graft.



Post-surgery



First application



2nd application



3rd application



4th application &
subsequent closure

Other Wounds:

Case 13

68 year old male with chronic arterial insufficiency of the right ankle

Patient History:

Patient’s wound showed no improvement after revascularization.

Treatment:

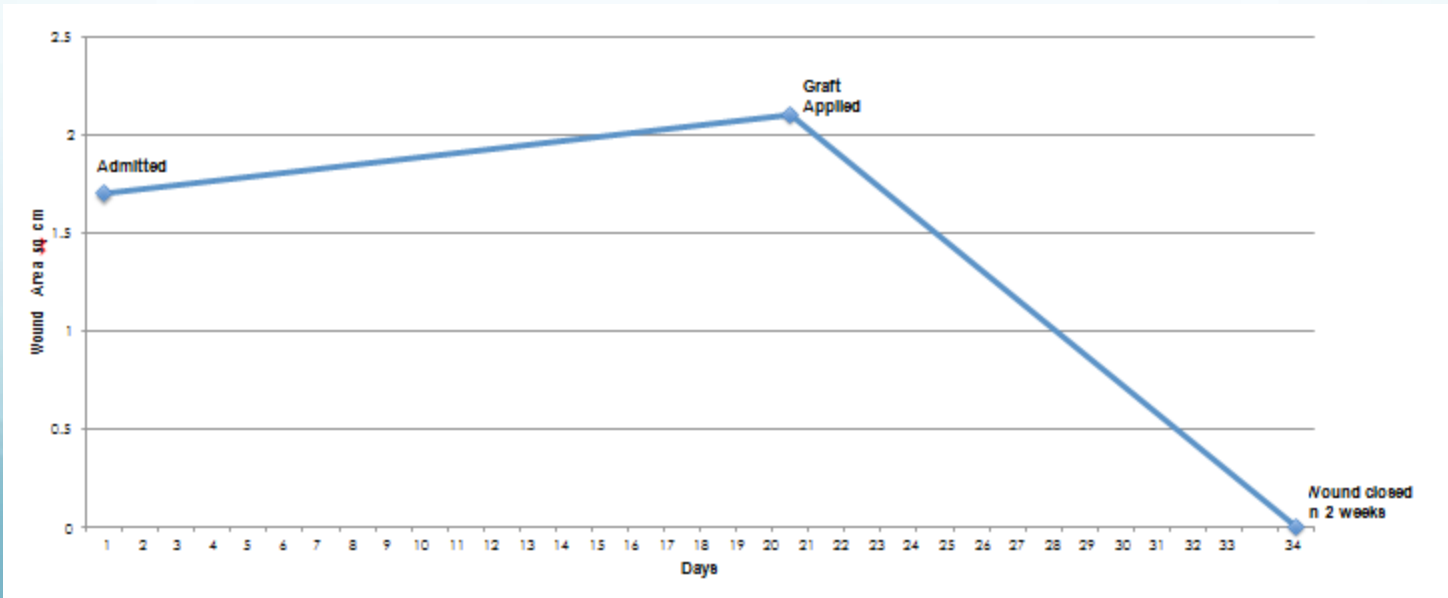
One application of Graft.

Outcome:

Patient’s wound was slow to heal until application of Graft. Wound healed in 2 weeks after Graft application.



Chronological improvement in wound size over time





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