

HELIOGEN™
FIBRILLAR COLLAGEN MATRIX



Case Studies



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Partial Second Ray Amputation in Comorbid Patient

- **Patient Background:** 56-yo male patient presented with acute osteomyelitis of the right second toe and underwent amputation.
- **Comorbidities:** Type 2 diabetes, heart failure, polysubstance use disorder, and bilateral extremity neuropathy.
- **Goal:** Avoid transmetatarsal amputation and close by secondary intention. HELIOGEN was applied as an ECM scaffold to support granulation tissue formation and epithelialization.



Presentation: Acute osteomyelitis of the right second toe.

ECM = Extracellular Matrix. NPWT: Negative Pressure Wound Therapy. S/P = Status Post.



Day 0 (S/P 2 days from amputation): Partial second ray amputation with exposed bone. Wound size: 4.0 cm x 2.5 cm x 1.5 cm.



Day 0 (cont.): 500 mg of dry HELIOGEN applied with NPWT, non-adherent dressing, 4 cm x 4 cm gauze, and Kerlix® gauze wrap. Wound size: 4.0 cm x 2.5 cm x 1.5 cm.

Partial Second Ray Amputation in Comorbid Patient (cont.)

VIDEO

Day 0 (cont.):
Application of
500 mg of dry
HELIOGEN.



Partial Second Ray Amputation in Comorbid Patient (cont.)



Day 4: No longer exposed 2nd metatarsal bone shaft and no exposed muscle or tendon. Wound size was reduced 83% to 3.5 cm x 1.5 cm x 0.5 cm.



Day 14: Continued granulation tissue formation with no probe or exposed bone. Surrounding inflammatory changes to the skin secondary to the NPWT. Treated with triamcinolone periwound. Wound size was reduced 91% from Day 0 to 3.3 cm x 1.0 cm x 0.4 cm.



Day 18: Pre-debridement.



Day 18 (cont.): Post-debridement. Wound size: 3.0 cm x 1.2 cm x 0.5 cm.



Day 18 (cont.): Dry HELIOGEN 500 mg was applied, then hydrated with few drops of saline. Non-adherent dressing, 4 cm x 4 cm gauze, and Kerlix® gauze wrap applied.

Partial Second Ray Amputation in Comorbid Patient (cont.)



Day 25: Wound progressed towards closure.



Day 28: Wound size: 2.3 cm x 0.6 cm x 0.3 cm.



Day 32: Wound size: 1.9 cm x 0.6 cm x 0.3 cm.

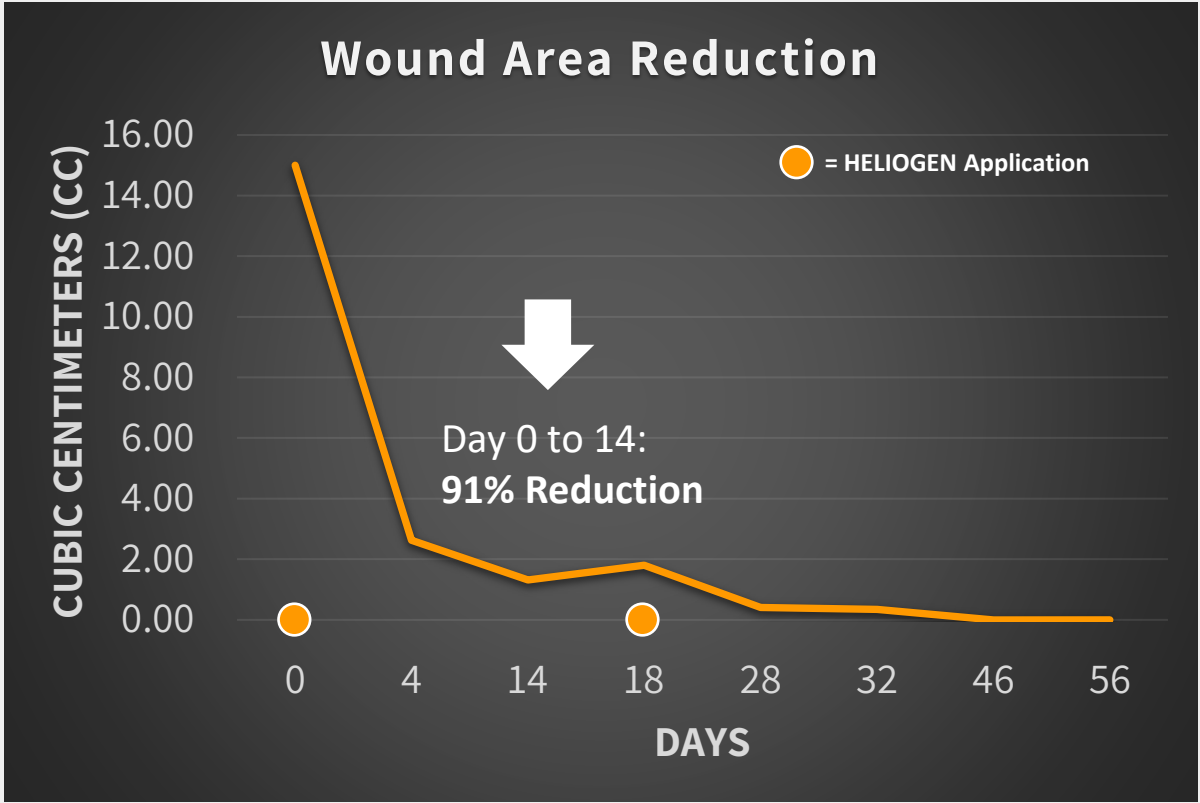


Day 46: Wound nearly closed measuring 0.2 cm x 0.1 cm x 0.1 cm.



Day 56: Wound closed.

Partial Second Ray Amputation in Comorbid Patient (cont.)



Results:

- Wound area was reduced 91% from Day 0 to Day 14.
- Wound closed on Day 56 after only two HELIOGEN applications.
- Surgeon and patient were both very satisfied with the observed results.

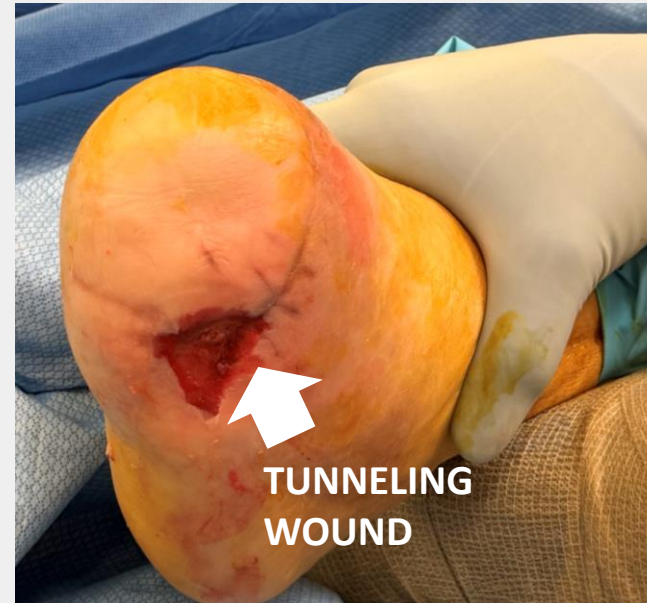
PU and Deep Tunneling Wound in Comorbid Patient

- **Patient Background:** 60-yo male patient with history of a left TMA returned with PU to the plantar lateral TMA stump.
- **Comorbidities:** Type 2 diabetes, peripheral neuropathy, dementia, and unable to take care of himself.
- **Goal:** Avoid proximal amputation since he would not be able to utilize prosthetic overnight. HELIOGEN was applied as an ECM scaffold to support granulation tissue formation and epithelialization.



Presentation: Pressure ulcer and deep tunneling wound.

PU = Pressure Ulcer. TMA = Transmetatarsal Amputation.



Day 0: Wound debrided and bled. 500 mg of dry HELIOGEN applied and achieved excellent hemostasis. Wound size: 4.5 cm x 4.5 cm x 1.0 cm.

PU and Deep Tunneling Wound in Comorbid Patient (cont.)



Day 6: Healthy granulation tissue formation. Deep tunneling wound filled up well. Wound size reduced 76% to 3.0 cm x 4.0 cm x 0.4 cm.



Day 13: Wound progressing towards closure.



Day 20: Wound size reduced 99% from Day 0 to 1.3 cm x 1.6 cm x 0.1 cm.

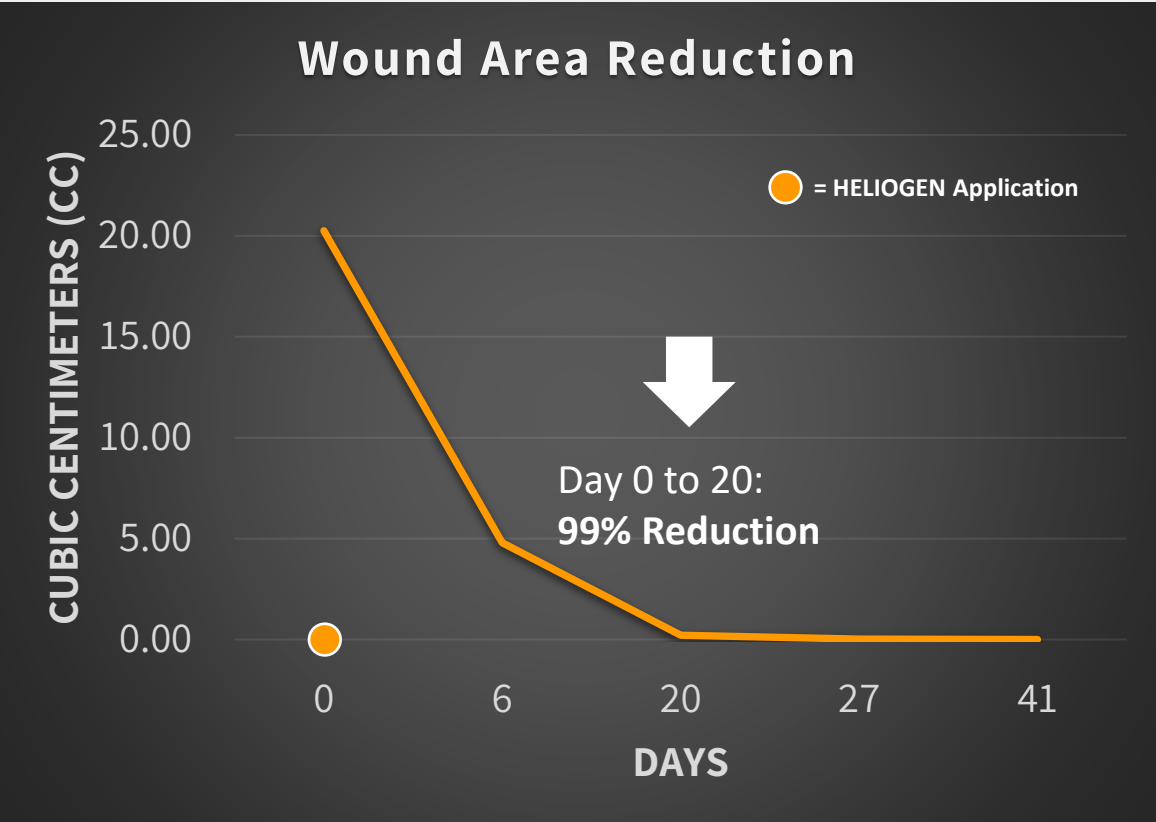


Day 27: Wound size reduced to near closure at 0.3 cm x 0.3 cm x 0.2 cm.



Day 41: Wound closed.

PU and Deep Tunneling Wound in Comorbid Patient (cont.)



Results:

- Wound area was reduced 99% from Day 0 to Day 20.
- Wound closed by Day 41.
- Surgeon and patient were both very satisfied with the observed results after only one application of HELIOGEN.

TMA Dehiscence in Comorbid Patient

- **Patient Background:** 65-yo male patient with a history of right lower extremity femoral to popliteal artery bypass, followed by a right foot transmetatarsal amputation with a dehisced stomp wound.
- **Comorbidities:** Type 2 diabetes, peripheral arterial disease, neuropathy, hepatitis C, HIV, and CAD.
- **Goal:** Close wounds by secondary intention. HELIOGEN was applied as an ECM scaffold to support granulation tissue formation and epithelialization.



Presentation: Lateral dehiscent stomp wound and dorsal foot eschar.

CAD = Coronary Artery Disease. HIV = Human Immunodeficiency Virus. TMA = Transmetatarsal Amputation.



Day 0: Lateral deep wound as well as dorsal foot eschar debrided revealing a full thickness underlying wound.



Day 0 (cont.): Surgical debridement and dry HELIOGEN 500 mg applied and packed into both wounds.

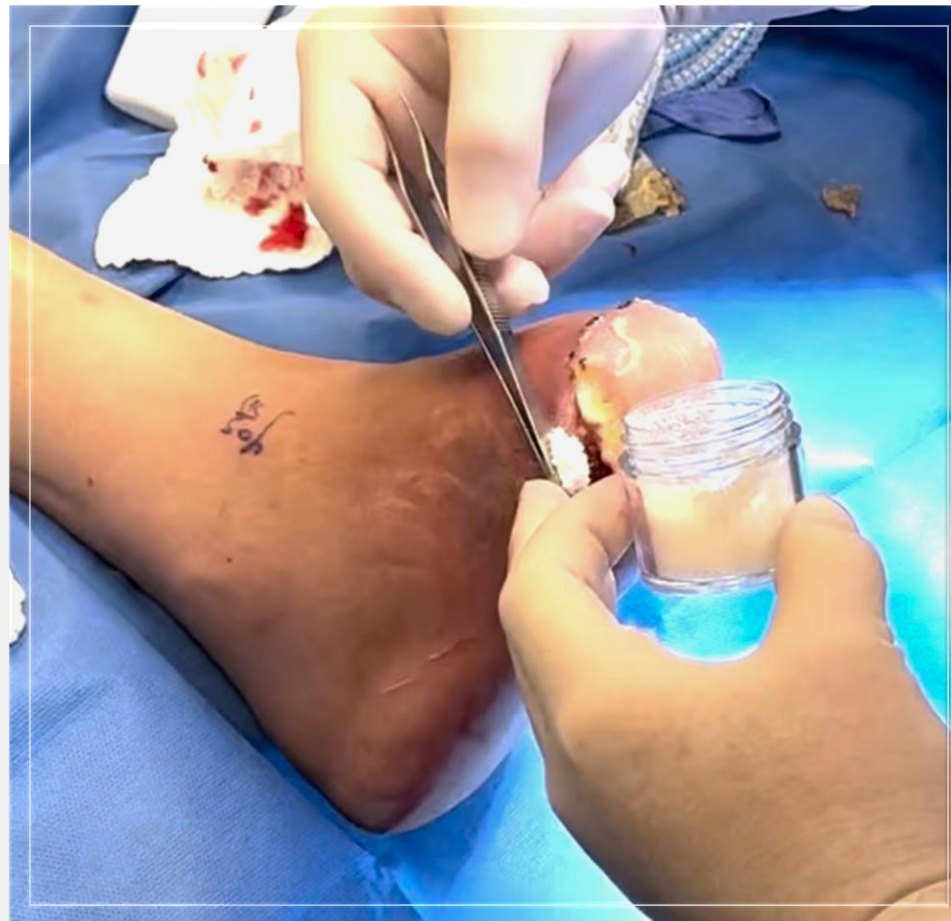


Day 5: Both wounds progressed towards closure.

TMA Dehiscence in Comorbid Patient (cont.)

VIDEO

Day 0 (cont.):
500 mg of dry
HELIOGEN applied.



TMA Dehiscence in Comorbid Patient (cont.)



Day 12: Lateral wound continued to progress towards closure. Wound size: 1.0 cm x 0.6 cm x 0.2 cm.



Day 12 (cont.): Second wound on top of the foot closed.



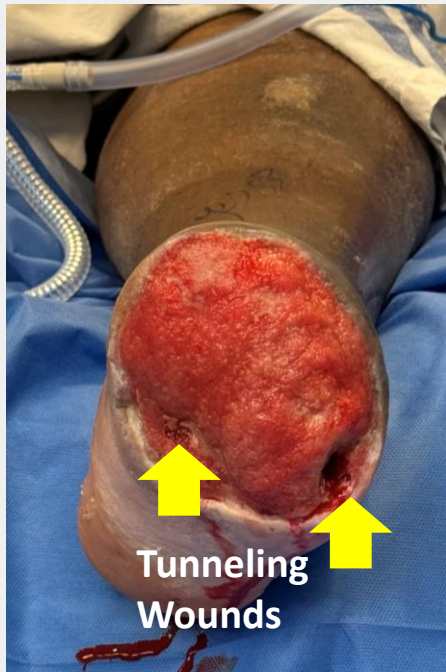
Day 19: Follow-up visit. Lateral wound almost closed. Wound size reduced by 90% to 0.4 cm x 0.3 cm x 0.1 cm.

Results:

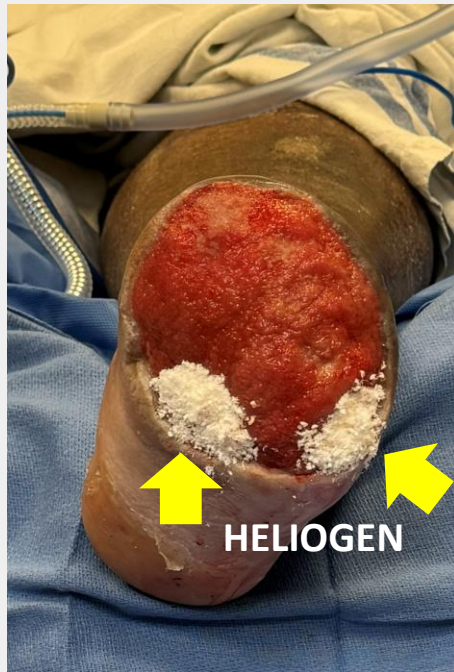
- Day 12: Wound on top of foot closed.
- Day 19: Lateral wound was nearly closed.
- Surgeon and patient were both very satisfied with the observed results after only application of HELIOGEN.

TMA, Application of HELIOGEN™ and AMNIOEFFECT®, and Bridge to STSG

- **Patient Background:** 46-yo male patient with a history of a previous right contralateral BKA underwent an ipsilateral left TMA followed by surgical debridement and NPWT four days later. He is non-weight bearing.
- **Comorbidities:** Type 2 diabetes and peripheral neuropathy.
- **Goal:** Avoid an ipsilateral BKA. HELIOGEN was applied as an ECM scaffold to support granulation tissue formation and to bridge to a STSG.



Day 0: S/P 30 days after NPWT treatment, deeper tunneling wounds debrided.



Day 0 (cont.): 500 mg of dry HELIOGEN packed and applied to tunneling wounds.



Day 0 (cont.): AMNIOEFFECT applied and stapled* in place.



Day 19: Tunneling wounds nearly closed. Granulation tissue observed.



Day 33: Tunneling wounds closed. Scheduled for STSG. Surgeon and patient were both very satisfied with the observed results.

TMA, Application of HELIOGEN™ and AMNIOEFFECT®, and Bridge to STSG (cont.)

VIDEO

Day 0 (cont.):
AMNIOEFFECT
application with
staples.*



Deep Sub-Fifth Metatarsal Pressure Ulcer

- **Patient Background:** 54-yo female patient suffering from right sub-fifth metatarsal head Pressure Ulcer (PU) on the right foot for 3 months. She previously initiated care at the wound clinic with multiple other treatments that failed to progress.
- **Comorbidities:** Multiple sclerosis.
- **Goal:** Obtain secondary intention closure in a chronic challenging wound. Provide HELIOGEN as an ECM scaffold to support granulation tissue formation and epithelialization.



Presentation: Deep pressure ulcer.

Day 0: 5th metatarsal head resection and surgical debridement (not pictured). 500 mg dry HELIOGEN applied with non-adherent dressing, 4 cm x 4 cm gauze, and Kerlix® gauze wrap. Wound size: 2.0 cm x 1.5 cm x 0.5 cm.

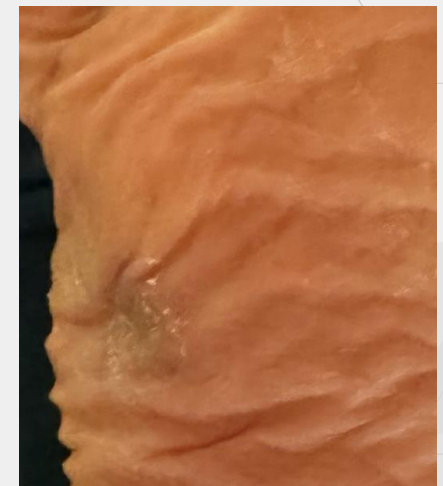


Day 14: 98% reduction in wound size to 0.6 cm x 0.3 cm x 0.2 cm.

Sutures from previous 5th metatarsal head resection.

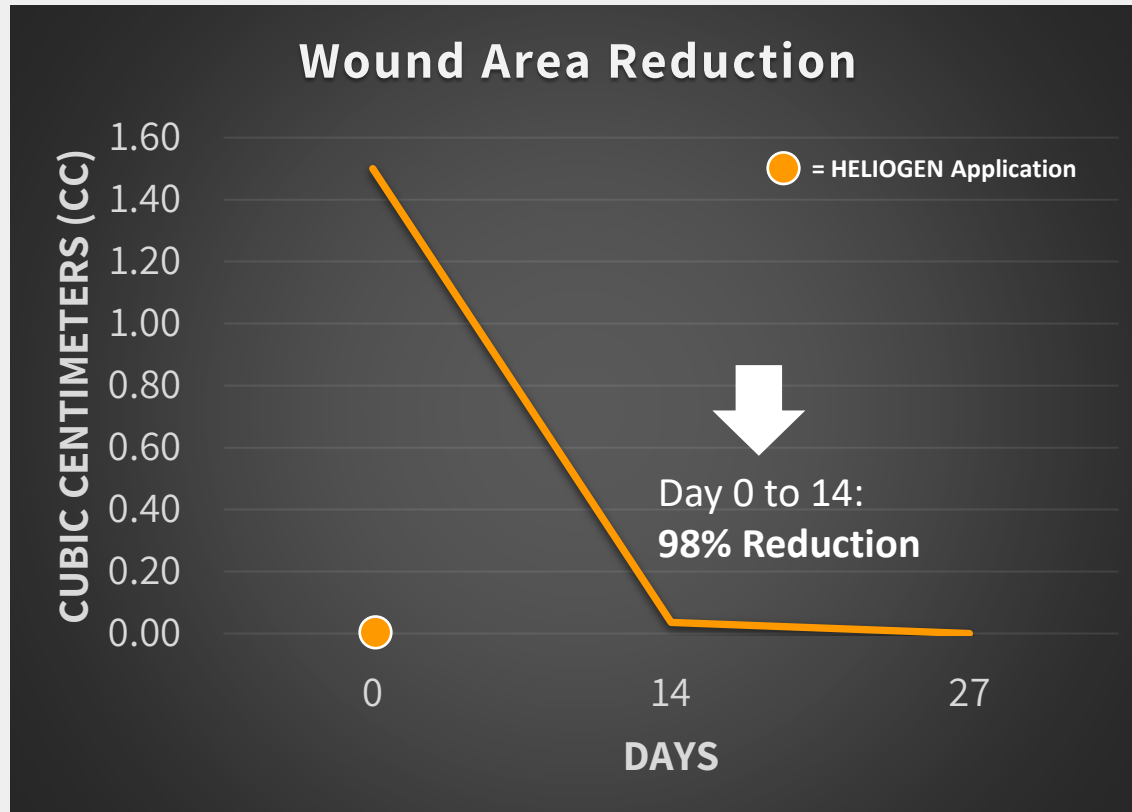


Day 27: Wound closed.



Day 69: Wound remained closed.

Deep Sub-Fifth Metatarsal Pressure Ulcer (cont.)



Results:

- Wound area was reduced 98% from Day 0 to Day 14, and wound closure achieved by Day 27.
- Patient returned to normal life activities.
- Surgeon and patient both were very satisfied with the observed results.

DFU in Uncontrolled Diabetic Patient

Patient Background: 55-yo male patient with uncontrolled diabetes, multiple comorbidities, and history of lower extremity neuropathic burns, ulcers, and osteomyelitis.

Comorbidities: Type 2 diabetes with polyneuropathy, hypercholesterolemia, HTN, CVA, OSA, left foot traumatic second-degree burns, anxiety & depression.

Goal: Obtain wound closure in uncontrolled diabetic with comorbidities and previous history of neurotrophic wounds. Provide HELIOGEN as an ECM scaffold to support granulation tissue formation and epithelialization.



Presentation: Wound debrided and measured 1.6 cm x 1.1 cm x 0.2 cm.



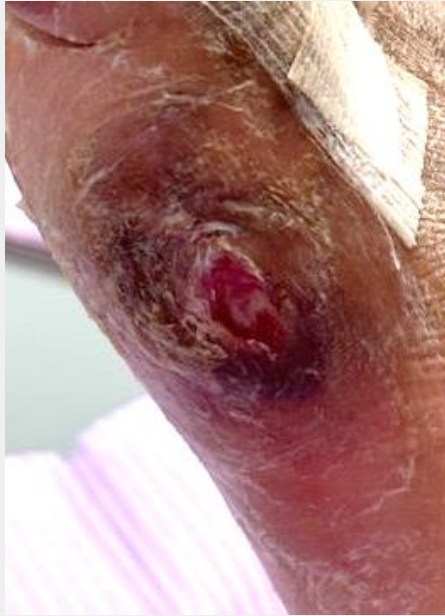
Day 0: 1st HELIOGEN 500 mg paste application. Non-adherent & bordered dressing applied w/ forefoot wedge shoe for offloading.



Day 14: Pre (left) and post (right) debridement. Wound size: 1.0 cm x 0.5 cm x 0.1 cm, an 86% wound reduction. 2nd HELIOGEN 500 mg paste application (not pictured).

CVA = Cerebral Vascular Accident. ECM = Extracellular Matrix.
HTN = Hypertension. OSA = Obstructive Sleep Apnea.

DFU in Uncontrolled Diabetic Patient (cont.)



Day 21: Debridement and 3rd HELIOGEN 500 mg paste application (not pictured). Wound size: 0.6 cm x 0.5 cm x 0.1 cm, a 40% wound reduction.

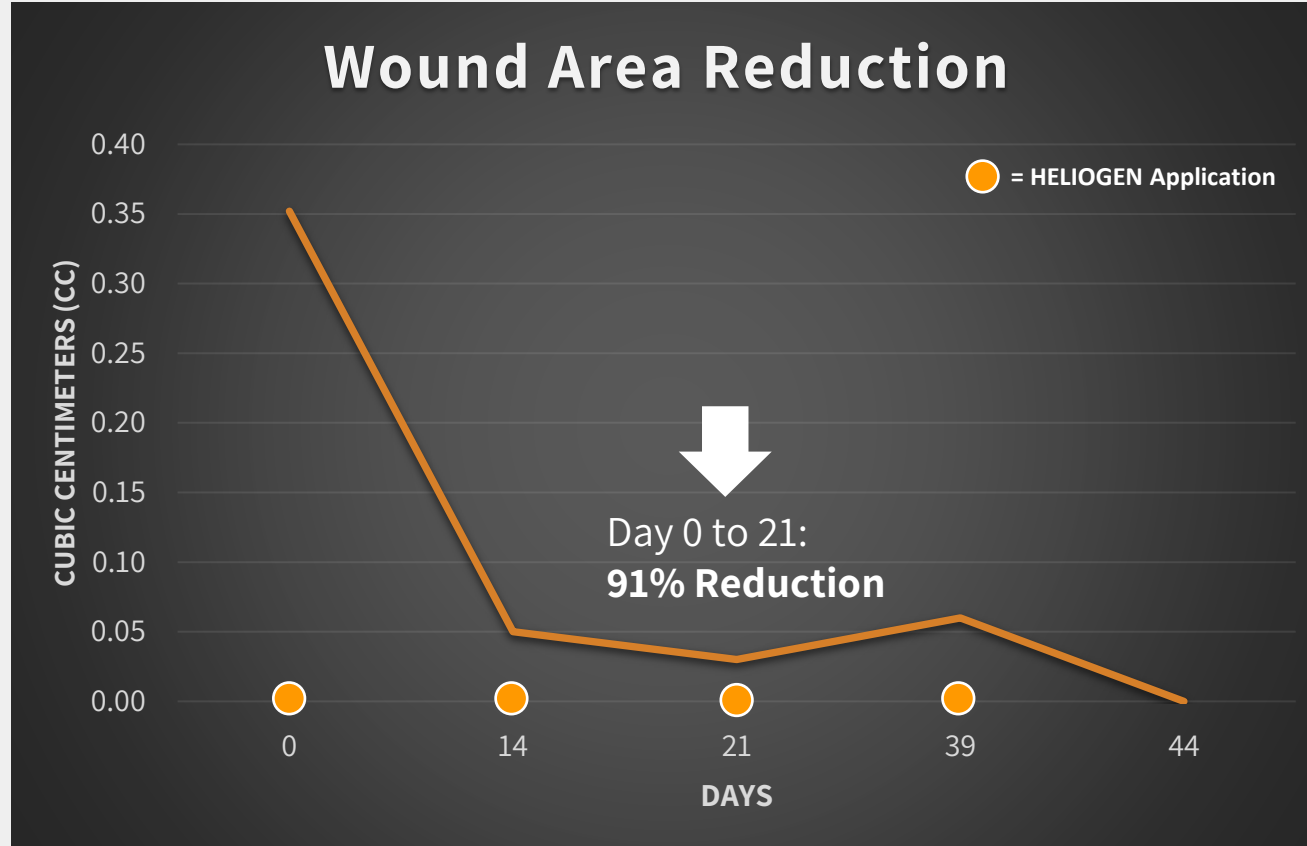


Day 39: Delay in treatment due to patient's vacation. Debridement and 4th HELIOGEN 500 mg paste application (not pictured). Wound size: 0.6 cm x 1.0 cm x 0.1 cm.



Day 44: Wound closed.

DFU in Uncontrolled Diabetic Patient (cont.)



Results:

- Wound area was reduced 91% from Day 0 to Day 21, and wound closure achieved by Day 44.
- No treatment between Days 21 and 39 due to patient's vacation.
- Patient functionality returned to baseline normal with no pain.
- Patient returned to work and normal life activities.
- There was good cosmesis at the wound closure site with no hypertrophic fibrosis.
- Surgeon and patient both were very satisfied with the observed results.

Surgical Incision Dehiscence With Exposed Tendon

Patient Background: 55 yo female patient S/P resection of posterior calcaneal Haglund's deformity with Achilles Tendon repair presented at Day 14 with distal surgical incision dehiscence and exposed tendon. Pain and drainage from incision. Patient reported getting dressing wet.

Comorbidities: Obesity with BMI >30 S/P bariatric surgery, HTN, and OSA.

Goal: Obtain closure of a complex wound in a patient with multiple comorbidities. Provide HELIOGEN as an ECM scaffold to support granulation tissue formation and epithelialization.



Presentation: Postop Day 14 surgical incision dehiscence with exposed tendon measuring 2.3 cm x 1.3 cm x 0.2 cm.



Day 0: Debridement and 1st HELIOGEN 500 mg paste application and covered with non-adherent dressing. Patient off-loaded with boot.



Day 10: Wound size: 1.5 cm x 0.7 cm x 0.1 cm, a 12% wound reduction. Granulation tissue observed. Debridement and 2nd HELIOGEN 500 mg paste application (not pictured).

ECM = Extracellular Matrix. HTN = Hypertension. OSA = Obstructive Sleep Apnea. S/P = Status Post.

Surgical Incision Dehiscence With Exposed Tendon (cont.)



Day 17: Wound size: 1.5 cm x 0.5 cm x 0.1 cm, an 86% wound reduction. Debridement (left) and 3rd HELIOGEN paste application (right).

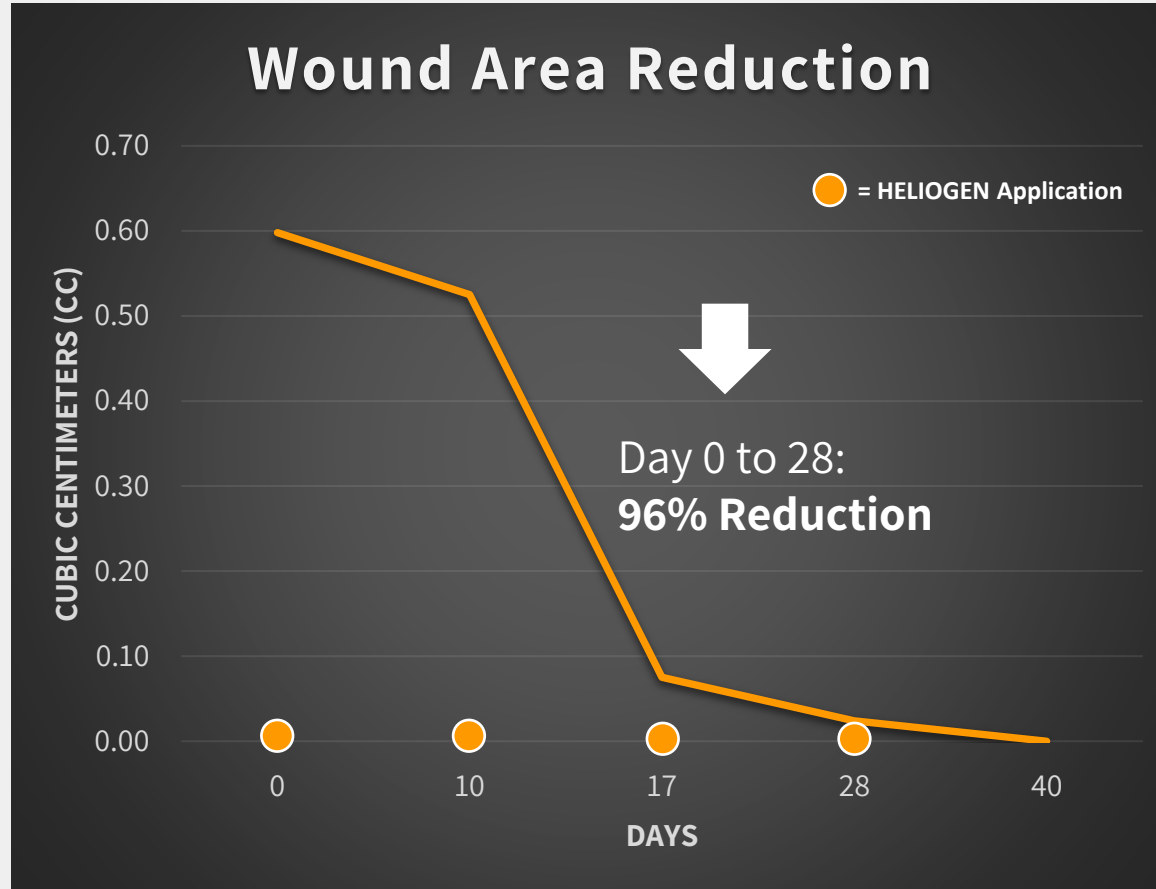


Day 28: Wound size: 0.8 cm x 0.3 cm x 0.1 cm. 4th HELIOGEN 500 mg paste application.



Day 40: Wound closed.

Surgical Incision Dehiscence with Exposed Tendon (cont.)



Results:

- Achieved closure of a complex wound in a patient with multiple comorbidities in 40 days with a 96% wound reduction by Day 28.
- HELIOGEN provided an ECM scaffold to support granulation tissue formation and epithelialization.
- Patient is back to normal ambulation, shoe gear, and life activities.
- Surgeon and patient were very satisfied with the results.

Surgical Wound Dehiscence Over Nerve

Patient Background: 56-year-old healthy male had elective surgery to excise a painful ganglion cyst causing neuritis on the dorsum of his right foot without complications. Two weeks postoperatively, the patient presented with a fully dehiscent surgical incision and hematoma in the wound base. Patient had not been compliant to using a postop shoe, being non-weight bearing to the treated foot, and keeping the foot dry.

Comorbidities: Cervical and lumbar radiculopathy (noncontributory).

Goal: Obtain wound closure in a patient with surgical wound dehiscence to prevent nerve damage. Provide HELIOGEN as an ECM scaffold to support granulation tissue formation and epithelialization over nerve.



Presentation: Before debridement.



Sutures removed and wound debrided.



Day 0: 500 mg of HELIOGEN paste application. Covered with Mepitel® and secured with Steri-Stips® and dry border dressing.



Surgical Wound Dehiscence Over Nerve (cont.)



Day 14: Wound progressed toward closure. 2nd application of HELIOGEN.



Day 21: Wound progressed further toward closure. 3rd application of HELIOGEN.



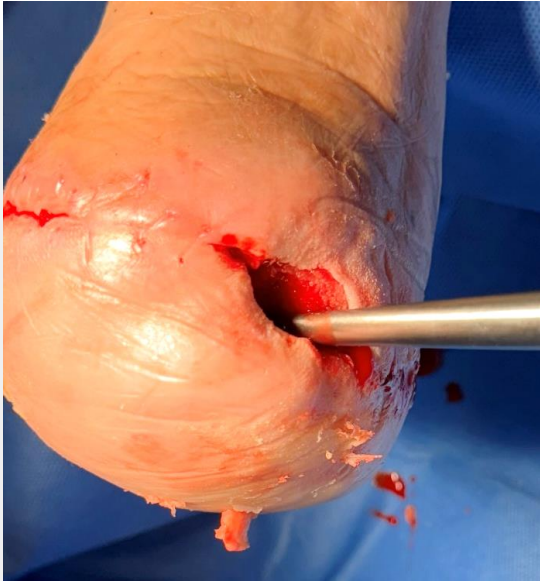
Day 28: Wound closed.

Results:

- Patient had 3 applications of HELIOGEN and went on to full closure at Day 28.
- Patient and surgeon both satisfied with results in the presence of dehiscence with potential nerve compromise.
- There was no evidence of nerve damage and minimal scarring at the site.

Dehisced Deep Tunneling Wound in Foot Amputation

- **Patient Background:** 57-yo male presented with a dehisced deep tunneling wound post Chopart left foot amputation that was not showing any progress towards closure despite SOC and NPWT treatment.
- **Comorbidities:** Type 2 diabetes, left Chopart amputation, and history of right BKA.
- **Goal:** Fill in the deep tunneling wound that failed to progress with previous treatments. Provide HELIOGEN as an ECM scaffold to support granulation tissue formation.



Day 0: Surgical debridement of dehisced deep tunneling wound.



VIDEO: Showing the depth of the tunneling wound.



VIDEO: 500 mg of HELIOGEN paste was applied.



Day 6: Depth of the wound was greatly reduced after a single HELIOGEN application. Wound size: 2.5 cm x 0.6 cm x 1.2 cm.

Dehisced Deep Tunneling Wound in Foot Amputation (cont.)



Day 20: Wound progressed toward closure. Wound size: 2 cm x 0.8 cm x 0.2 cm, an 82% wound area reduction.



Day 27: Wound completely granulated. Patient scheduled to come in for AMNIOFIX application with goal to obtain epithelialization.

Results:

- Patient's deep tunneling wound had mostly filled in and granulated by Day 27 after a single HELIOGEN application.
- Patient and surgeon both very satisfied with results in the presence of a wound that had previously failed to progress with other treatments.

TMA in a Diabetic Patient With PAD

Patient Background: 83-year-old male with type 2 diabetes seen for inpatient consult. He initially sustained a blister to the plantar left foot 8 months prior, which did not heal. Outpatient arterial studies had shown that he had adequate perfusion, but a repeat CTA showed occlusion to ATA bilaterally. Interventional Cardiology performed angiogram.

Comorbidities: Type 2 diabetes with polyneuropathy, hyperlipidemia, HTN, and PAD.

Goal: Obtain wound closure in diabetic with comorbidities and previous history of neurotrophic wounds. HELIOGEN provided an ECM scaffold to support healing and control of minor bleeding.



Presentation: Patient admitted with DFU that started as a plantar blister.



Day 0: Left foot S/P TMA with implantation of Stimulan® antibiotic beads and HELIOGEN in the wound bed and to the incision line.

TMA in a Diabetic Patient With PAD (cont.)



Day 12: S/P TMA primary closure stable.



Day 49: Wound closed.



Day 83: Wound remained closed.

Results:

- Patient and surgeon both very satisfied with wound closure at Day 49 after one HELIOGEN application and remained closed at Day 83.

Great Toe Amputation in Diabetic Patient

Patient Background: 88-year-old female with type 2 diabetes, CKD3, seen for inpatient consult for left great toe wound with distal infection and osteomyelitis.

Comorbidities: Type 2 diabetes with polyneuropathy, COPD, EF 50%, HTN, RA, hyperlipidemia, and PAD.

Goal: Obtain wound closure in diabetic with comorbidities and previous history of neurotrophic wounds and osteomyelitis following a partial hallux amputation. Provide HELIOGEN as an ECM scaffold to support healing and control of minor bleeding.



Presentation: Patient admitted with DFU, infection, and osteomyelitis.

CKD3 = Chronic Kidney Disease, Stage 3. COPD = Chronic Obstructive Pulmonary Disease. DFU = Diabetic Foot Ulcer. EF = Ejection Fraction. HTN = Hypertension. PAD = Peripheral Arterial Disease. RA = Rheumatoid Arthritis.

Great Toe Amputation in Diabetic Patient (cont.)



Day 0: Partial great toe amputation to remove infected bone and soft tissue. 500 mg HELIOGEN (0.5 g) hydrated with 2 mL normal saline (4:1 ratio fluid to HELIOGEN) and closed primarily. Non-adherent dressings applied.



Day 27: Wound closed.

Results:

- Patient had uneventful healing of great toe amputation stump without complications at Day 27.
- Patient and surgeon both very satisfied with results in the presence of multiple comorbidities, vascular compromise, and previous infection/osteomyelitis.

Chronic Pressure Ulcer in Diabetic Patient

- **Patient Background:** 68-yo male patient with chronic Pressure Ulcer (PU) of his left 5th metatarsal head. He previously underwent a left first metatarsal phalangeal joint fusion.
- **Comorbidities:** Type 2 diabetes and history of bilateral chronic foot ulcerations.
- **Goal:** Obtain closure in a chronic challenging wound and avoid dehiscence. Provide HELIOGEN as an ECM scaffold to support wound closure.



Day 0: Surgical wound debridement of PU.



Day 0 (cont.): Dry HELIOGEN 500 mg applied.



Day 0 (cont.): Skin edges re-approximated and closed primarily with non-adherent dressing, 4 cm x 4 cm gauze, and Kerlix® gauze wrap.



Day 3: Primary closure was stable.

Results:

- Primary closure was stable at follow up with no complications.
- Surgeon and patient both were very satisfied with the observed results after one HELIOGEN application.

Open Quadriceps Tendon Repair Revision

- **Patient Background:** 45-year-old male presented with retear of quadriceps tendon repair at patella insertion on the left knee. Initial left quad repair occurred ~10.5 weeks prior.
- **Radiograph results:** Patella baja from torn quad tendon confirmed by MRI.
- **Comorbidities:** Venous vascular disease, smoker, testosterone use. Aggressive PT (not compliant). Biobrace® Reinforced Implant used during first repair.
- **Goal:** HELIOGEN provided an ECM scaffold to support healing and control of minor bleeding.



Presentation: Retear of quadriceps tendon.

Patella baja = Condition where kneecap appears to be lower than normal, when quadriceps tendon ruptures.



Day 0: Repaired tendon. HELIOGEN hydrated into slurry and rubbed into the repair and primary closure site. HELIOGEN was easy to handle and helped control minor bleeding.



Day 35: Wound at primary closure site healed without complications. Closure site where HELIOGEN was applied had better cosmesis than prior surgery where HELIOGEN was not used.

➤ Breast Reduction Incisional Dehiscence

Patient Background: Female (22 yo) with 2 cm T-Junction defect on left breast 28 days post breast reduction surgery.

Method:

- HELIOGEN (0.5 g) hydrated with 2 mL normal saline (4:1 ratio fluid to HELIOGEN) applied with non-adherent bandage covering site 28 days post breast reduction.

Results:

Defect area on T-Junction demonstrated wound closure at Day 7 and healed well per treating surgeon's assessment.



Presentation: 2cm defect at T-Junction 28 days status post breast reduction surgery.



Day 0: Application of HELIOGEN dough consistency to wound.



Day 7: Wound closure.

Mastopexy Incisional Dehiscence

Patient Background: Female (46 yo) with 3 cm vertical mastopexy dehiscence and incisional defect on left breast following revisional reconstruction due to Grade 4 capsular contracture.

- Bilateral breast capsulectomy and implant exchange.
- Bilateral revision mastopexy.
- Right breast total capsulectomy.
- Ultrasound and power-assisted liposuction of bilateral axilla.
- Fat grafting to bilateral breasts.

Method:

- **Day 0:** Wound debrided and first HELIOGEN (1.0 g) w/ 1 cc saline applied with bolster dressing.
- **Day 7:** New granulation tissue and improvement. Wound debrided and 2nd application of HELIOGEN (1.0 g) w/ 1 cc saline applied with bolster dressing.



Presentation: 3 cm surgical incision dehiscence wound 83 days postop mastopexy procedure.



Day 7: Wound debrided prior to HELIOGEN paste application.

Mastopexy Incisional Dehiscence (cont.)

Results

- New granulation tissue 1 week after HELIOGEN application following stagnant wound healing for 83 days
- Wound healing progressed after the 2nd application of HELIOGEN
- Wound closure at Day 97.



Day 35: Wound reduced in size.



Day 56: Wound further reduced in size.



Day 97: Wound closed.

Chronic Wound Post-Squamous Cell Resection

Patient Background: Male (90 yo) underwent excision (4 cm diameter by 3 cm deep) of squamous cell tissue that had prevented wound healing for 50 days.

Method:

- **Day 0:** Wound packed with dry HELIOGEN (2.0 g) and covered with Xeroform gauze and occlusive dressing on day 50.
- **Day 2:** No bleeding, signs of infection, nor any post-op pain. Wound packed with dry HELIOGEN (2.0 g) and covered with Xeroform gauze, dry gauze, and an occlusive dressing.
- **Day 16:** Significant improvement, healthy granulation tissue. Diameter unchanged, **depth reduced ~90% from 3 cm to 3-4 mm**. Wound packed with HELIOGEN (2.0 g) and covered with Adaptic dressing and an occlusive dressing.



Day 2: Status post 1st HELIOGEN application.



Day 16: Depth of wound reduced ~90% with granulation tissue (top view).



Day 16: Lateral view of wound reduction.

Chronic Wound Post-Squamous Cell Resection (cont.)

Results

- By Day 37, defect filled in with new skin and a 1.5 – 2 cm diameter puckered area of granulation tissue formed.
- Day 49: Wound closed.



Day 37: Wound filled in and progressed toward closure with granulation tissue formation

Gregory Ripich, MD | General Surgery | Hamilton, NY



Day 49: Wound closed



Post-Mohs Facial Wound

Patient Background: Female (82 yo) with 3.5 cm left temple wound following Mohs excision for basal cell carcinoma.

Method:

- Wound area undermined, irrigated, hemostasis obtained, and wound edges advanced using 3-0 PDS in purse string fashion for advancement of fasciocutaneous flaps closing the wound to 2.5 cm.
- HELIOGEN (0.5 g) w/ 1 cc saline applied and covered with bolster dressing coated with bacitracin ointment.

Results

- Five days after HELIOGEN application, bolster dressing removed and no signs of infection.
- One month after HELIOGEN application wound completely healed.
- Treating surgeon noted that the aesthetic result, in his experience, was favorable when compared to a well-done skin graft or flap reconstruction.



Presentation: Left temple Mohs wound after purse string closure from 3.5 cm to 2.5 cm.



Day 30: Post-Mohs temporal wound completely healed post HELIOGEN application.

HELIOGEN™

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