



Clinical Case Report Book

A compendium
of wound care
clinical case studies
utilizing innovative
allograft solutions



AmnioBand®

AlloPatch® Pliable

Leneva™

SomaGen™ Meshed

About MTF Biologics Wound Care

Our legacy has helped define an industry and inspire change.

The largest tissue bank in the world, MTF Biologics is nonprofit and physician-led. Headquartered in Edison, New Jersey, MTF Biologics has spent more than 30 years honoring donated gifts by developing innovative, effective allograft solutions to help people heal. From orthopedics to wound care to plastic and reconstructive surgery, we have become a force in scientific progress and patient advocacy.

We are comprised of a national consortium of academic medical institutions, organ procurement organizations and tissue recovery organizations. MTF Biologics also has two subsidiaries, Statline and IIAM.

Our goal is simple—do what’s right for our patients, surgeons, tissue donors and their families through our three guiding principles:

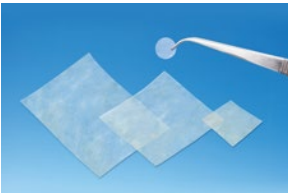
- Make an increased amount of safe tissue available to patients by building strong relationships with leading organ, eye and tissue recovery organizations.
- Provide the highest quality tissue by having the most stringent standards in the industry.
- Advance the science of tissue transplantation through our commitment to research and development.



Our Tissue Forms

We invest in research—awarding more than \$55 million to date in grants alone. The rigors of clinically testing new tissue advancements to aid toward healing, guides our path to innovation. That kind of thinking—and our drive to consistently improve and find better ways to do things—has led to the development of advanced techniques, setting new industry benchmarks. From helping people with diabetic foot ulcers find a solution that works, to giving patients with post-osteomyelitis closure, we are the difference makers with viable, research-proven solutions toward natural healing.

AmnioBand® ALLOGRAFT PLACENTAL MATRIX MEMBRANE



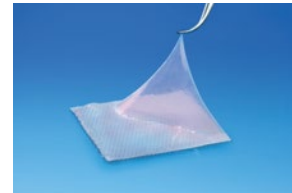
AmnioBand® Membrane is a bi-layer amnion and chorion membrane that helps in native tissue restoration and remodeling, providing optimal coverage in a wide variety of sizes for all types of acute and chronic wounds.

AmnioBand® ALLOGRAFT PLACENTAL MATRIX PARTICULATE



AmnioBand® Particulate is a dehydrated human placental membrane derived from amnion and chorion layers, and is optimal for contouring to wounds of various complex & unique topographies.

AmnioBand® ALLOGRAFT PLACENTAL MATRIX VIABLE MEMBRANE



AmnioBand® Viable Membrane is comprised of amnion membrane which provides a strong foundation of inherent biological properties which have been shown to help facilitate cell attachment and support the overall wound environment.

AlloPatch® ALLOGRAFT DERMAL MATRIX PLIABLE



AlloPatch® Pliable is derived from a deeper layer in the dermal tissue and has an open, uniform, collagen matrix for faster graft incorporation.

SomaGen™ ALLOGRAFT DERMAL MATRIX MESHED



SomaGen™ Meshed is a reticular dermal allograft designed to aid in the treatment of a variety of complex wounds.

leneva™ ALLOGRAFT ADIPOSE MATRIX

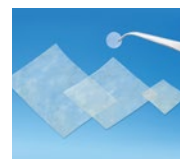


leneva™ is a human derived adipose allograft matrix designed to support the cellular repopulation and vascularization at the surgical site.

AmnioBand® Membrane

Table of Contents

AmnioBand® Membrane, Allograft Placental Matrix



| | |
|--|-----|
| Case 1 — Diabetic Toe Ulcer | A-2 |
| Case 2 — Diabetic Ankle Ulcer | A-3 |
| Case 3 — Diabetic Foot Ulcer | A-5 |
| Case 4 — Plantar Reconstruction Post-gangrene Excision | A-7 |

AmnioBand® Particulate, Allograft Placental Matrix



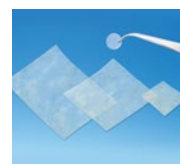
| | |
|--|------|
| Case 1 — Post-Mohs Surgery..... | A-9 |
| Case 2 — Parotid Tumor Radiation Therapy Wound | A-10 |
| Case 3 — Sacral Ulcer | A-12 |
| Case 4 — Post-Toe Amputation with Infection | A-13 |
| Case 5 — Post-Operative Osteomyelitis | A-14 |
| Case 6 — Venous Leg Ulcer | A-16 |

AmnioBand® Viable Membrane, Allograft Placental Matrix



| | |
|---|------|
| Case 1 — Chronic/Tramatic Wound | A-18 |
| Case 2 — Chronic/Tramatic Wound | A-20 |
| Case 3 — Venous Ulcer | A-22 |
| Case 4 — Venous Leg Ulcer | A-24 |
| Case 5 — DFU with Exposed Tendon | A-26 |
| Case 6 — Plantar Reconstruction Post-gangrene Excision..... | A-28 |





Case 1 — Diabetic Toe Ulcer

Patient Information

- 68 year old female with Type 2 diabetes, hypertension, congestive heart failure, peripheral vascular disease, and chronic kidney disease Stage 3.
- Previous right third toe amputation.

Initial Examination / Wound History

- Diabetic foot ulcer on second toe on right foot greater than 30 days duration.
- Previously treated with offloading, topical and systemic antibiotics. Diagnostic work-up showed no osteomyelitis and adequate transcutaneous oxygen measurements for healing.
- Initial wound size on right second toe 0.8cm x 1.0cm x 0.4cm (length x width x depth).

Treatment

- Underwent curette debridement. AmnioBand® Membrane was applied and secured with silicone fenestrated sheet (Mepitel® dressing) and foam dressing (AQUACEL®).
- Patient was using offloading shoe while awaiting her custom molded shoe.

Outcome

- Full wound closure at 12 days, with one application of AmnioBand® Membrane.



Initial wound



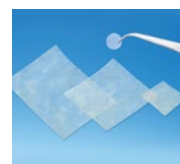
After application of AmnioBand® and Mepitel®



12 days - Wound Closure

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Case 2 — Diabetic Ankle Ulcer



Patient Information

- 57 year old male patient with long standing Type 2 diabetes, lymphedema, venous insufficiency, recurrent lower extremity ulcers of greater than 30 days duration.

Initial Examination / Wound History

- Eight month right medial malleolus wound.
- Previous treatment consisted of standard of care (SOC) including debridement, exudate management, off-loading. Failing SOC after 30 days, a split thickness skin graft (STSG) was used on the ulcer which also failed. Vascular studies showed adequate perfusion for healing and diagnostics showed no evidence of osteomyelitis.
- After failing SOC and STSG, right medial malleolus wound treated with compression, curette debridement, and antimicrobial dressing for wound bed prep for three consecutive weeks.

Treatment

- Initial wound after third week was 2.4cm x 3.0cm x 0.2cm, and was debrided to healthy bleeding tissue.
- AmnioBand® Membrane was applied and secured with silicone fenestrated sheet (Mepitel® dressing), and foam dressing (AQUACEL®).



Wound prior to initial application



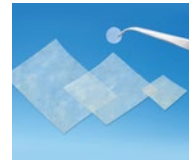
After applying AmnioBand® Membrane and Mepitel®



Day 12

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Case 2 — Diabetic Ankle Ulcer



Outcome

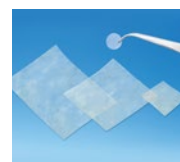
- Post one application of AmnioBand® Membrane, wound improved dramatically and demonstrated granulation and decrease in size including depth after 12 days: 2.1cm x 2.4cm x 0.1cm.
- Best practices for wound care were followed until full wound closure three weeks after initial application.
- Healthy plantar skin was noted at this location.



Week 3 - Wound Closure

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Case 3 — Diabetic Foot Ulcer



Patient Information

- 61 year old morbidly obese male, Type 2 diabetes mellitus with peripheral neuropathy, coronary artery disease, hypertension, hyperlipidemia, and prior ray amputation.

Initial Examination / Wound History

- 36 week ulcer on right plantar forefoot.
- Resistant to a variety of conservative wound care modalities including alginates, silvadine, and offloading.
- Initial wound was 1.50cm x 2.00cm x 0.10cm (length x width x depth) and was debrided to healthy bleeding tissue.

Treatment

- A standard diabetic foot exam was performed that revealed Semmes Weinstein monofilament wire testing, 0/10 points confirming severe peripheral neuropathy. Pulses were 2/4 and a doppler exam was done which revealed biphasic waveforms for both the dorsalis pedis and posterior tibial arteries.
- Initial HAlc level was 10.5% and serum creatinine was 1.0mg/dL.

Outcome

- Patient received weekly applications of AmnioBand® Membrane, and reached successful wound closure at week 6.
- Final HAlc was 8.9% and progressed to diabetic shoes with insoles and a toe filler.



Randomization



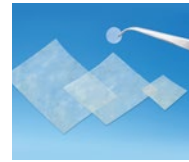
Week 1



Week 2

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Case 3 — Diabetic Foot Ulcer



Week 3



Week 4



Week 5



Week 6 - Wound Closure



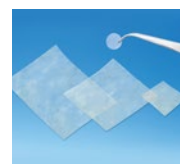
Week 7 - Validation

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AmnioBand® Membrane, Allograft Placental Matrix

Case 4 — Plantar Reconstruction Post-gangrene Excision

AmnioBand®
ALLOGRAFT PLACENTAL MATRIX
MEMBRANE



Patient Information

- 53 year old male Insulin-Dependent Diabetes Mellitus, Hypertension, Hyperlipidemia and Hba1c of 9.1 and no other pertinent medical problems.

Initial Examination / Wound History

- Patient present with low grade fever and grossly infected wound on the left foot 3rd metatarsal head. The wound has been present for 1.5 years and he had a previous 5th toe and metatarsal head resection. The fever started 5 days prior to the hospital admission.
- Diabetic foot ulcer 1cm x 0.8cm x 1cm with positive probe to bone. Base was fibronecrotic with active purulence and malodor. The wound tracks and undermines toward the medial arch.
- Initial consultation and surgery date was 3/4/19. Initial surgery was incision and drainage left foot into the plantar arch and extending from the 3rd toe to the 1st metatarsal phalangeal joint. Deep wound cultures were obtained and a second procedure on 3/8/19 was performed with resection of the 3rd metatarsal head and amputation of the 3rd toe. Following debridement application of SomaGen Meshed graft with application of negative pressure wound VAC therapy commenced.
- The decision to use a graft on the second procedure was to facilitate bone coverage and expedite growth of granulation tissue once we had cleared the infection. The wound VAC was changed Tuesday and Friday.



Initial Consultation - 3/4/19



Initial Surgery - 3/4/19



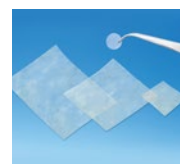
Week 0 - 3/8/19

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AmnioBand® Membrane, Allograft Placental Matrix

Case 4 — Plantar Reconstruction Post-gangrene Excision



Treatment

- 3/4/19: Incision and drainage left foot. Started IV vancomycin and methicillin sensitive staphylococcus aureus isolated. Wound packed with 0.25 sodium hypochlorite twice daily until second operating room debridement. Patient was switched to IV UNASYN.
- 3/8/19: 3rd rays resection with application of 6cm x 8cm SomaGen Meshed graft applied with sutures and negative pressure wound VAC therapy at 125mmHg continuous changed biweekly for three weeks after SomaGen Meshed application.
- 4/23/19: Application of AmnioBand Viable 3cm x 4cm graft with negative pressure wound therapy with changes Tuesday and Friday.
- 5/7/19: Application of AmnioBand Viable 3cm x 4cm graft wound VAC discontinued and WBAT in total contact cast.
- 5/14/19: Application of AmnioBand Membrane 3cm x 4cm graft WBAT in total contact cast.
- 5/24/19: Application of AmnioBand Membrane 18mm disk graft WBAT in total contact cast.
- 6/11/19: Application of 18mm AmnioBand Membrane disk with injection 5ml of Leneva allograft adipose matrix to 4th metatarsal head.
- 6/24/19: Wound closed.



Week 1 - 3/12/19



Week 10



Week 15 - Wound Closure - 6/24/19

Outcome

- Complete wound closure 6/24/19.
- Time to Closure = 15 weeks.
- Total number of grafts = 1 SomaGen Meshed, 2 AmnioBand Viable, 3 AmnioBand Membrane, 1 Leneva injection.





Case 1 — Post-Mohs Surgery

Patient Information

- 47 year old female with basal cell carcinoma on the left upper forehead.

Initial Examination / Wound History

- Post Mohs surgery wound, previously treated with Integra sheet (5/5/16) and Promogran™ Prisma (6/2/16).

Treatment

- The wound was superficially debrided and 40mg of AmnioBand® Particulate was sprinkled over the wound surface.
- Saline was dripped over the tissue to rehydrate and an applicator was used to spread for completed wound coverage.
- Adaptic® was applied as a non-adherent primary dressing followed by gauze and tape. The patient returned one week later for follow-up.

Outcome

- Full wound closure one week after application.



Initial - 6/10/16



Initial - 6/10/16



Week 1 - Wound Closure

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Case 2 — Parotid Tumor Radiation Therapy Wound



Patient Information

- 67 year old male. Parotid tumor removed surgically requiring total parotidectomy, partial auriculectomy, and radical neck dissection with local skin flap closure. Chemoradiation therapy was used to treat salivary gland cancer. In addition patient was participating in chemotherapy clinical trial.
- The patient had undergone a redo modified radical neck dissection and subsequently had chronic wounds of his neck and behind his ear since March 2015.

Initial Examination / Wound History

- Ulcerated lesion self-treated by serial daily applications of silver nitrate at the direction of his surgeon.
- Wound size was 1cm x 2cm, immediately posterior to the right ear with extensive daily bleeding.
- The wound area had undergone the maximal lifetime dose of radiation. Hyperbaric oxygen was discussed as an option for treatment, but ruled out due to concerns over chemotherapy clinical trial eligibility.
- AmnioBand® Particulate chosen as it can be applied to irregularly shaped surface areas. This site would not allow for suturing or placement of topical skin glues due to the compromised nature of the surrounding peri-wound tissue.



Initial - 5/25/16



Initial - 5/25/16



Week 1 - 6/1/16



Week 1 - 6/1/16

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Case 2 — Parotid Tumor Radiation Therapy Wound



Treatment

- Silver nitrate was used to cauterize wound. The wound was debrided and AmnioBand® Particulate was sprinkled on three separate occasions: 40mg on 5/25/16, 160mg on 6/1/16, 80mg on 6/8/16.
- Saline was dripped onto the tissue to rehydrate and the tissue was spread to fully cover the wound.
- Adaptic® and Hypafix® were applied as the primary and secondary dressings, respectively.
- After the third application, the patient was instructed to leave the dressings for 48hrs and then remove and apply Aquaphor® daily until the next one week follow-up.

Outcome

- The wound was fully closed at follow-up after the third application of AmnioBand Particulate.
- Total time to wound closure was three weeks.



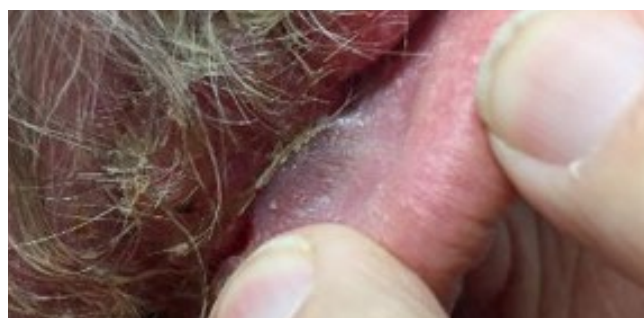
Week 2 - 6/8/16



Week 2 - 6/8/16



Week 3 - Wound Closure - 6/17/16



Post-Closure Follow-Up

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Case 3 — Sacral Ulcer

Patient Information

- 28 year old morbidly obese female. Other comorbidities include ASD, GERD, Biliary dyskinesia, and history of infected pilonidal cyst status post operative resection with post operative wound separation.

Initial Examination / Wound History

- Sacral wound that had recurred on two separate occasions.
- Wound size was 0.2cm x 0.1cm with no significant depth.
- Due to irregular location and difficulty with wound friction and traditional graft placement and fixation, AmnioBand® Particulate was chosen.

Treatment

- A single application of 40mg of AmnioBand® Particulate was used. Saline was dripped onto the tissue to rehydrate and the tissue was spread to fully cover the wound.
- Adaptic® and Hypafix® were applied as the primary and secondary dressings, respectively.
- After the application, the patient was instructed to leave the dressings for 48hrs and then remove and apply Aquaphor® daily until the next one week follow-up.

Outcome

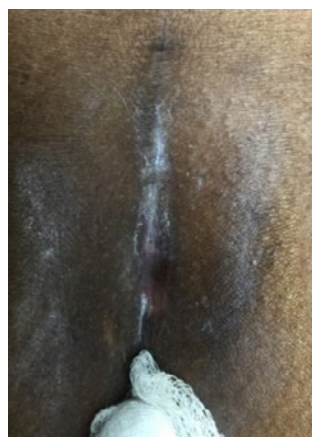
- Patient obtained full wound closure at one week after the first application of AmnioBand Particulate. Wound remained closed at follow-up on 9/16/16 (after four months).



Initial - 4/25/15



Initial - 4/25/15



Week 1 - Wound Closure
- 5/4/16



Post-Closure Follow-Up

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AmnioBand® Particulate, Allograft Placental Matrix

Case 4 — Post-Toe Amputation with Infection

AmnioBand®
ALLOGRAFT PLACENTAL MATRIX
PARTICULATE



Patient Information

- 59 year old female with Type 2 diabetes; hypertension, hyponatremia, BMI 38; history of MRSA infection, angina, multiple diabetic ulcerations.

Initial Examination / Wound History

- Osteomyelitis with actinobacteria and cellulitis on second toe of left foot and osteomyelitis of right hallux and cellulitis with ESBL *E. coli*. Previous treatments included IV cefepime, oral ciprofloxacin, oral metronidazole, and IV vancomycin. The actinobacteria was sensitive only to gentamycin and tobramycin.
- The cellulitis continued and the ID doctor advised that additional antibiotics would do no good.

Treatment

- Amputation of second toe of left foot. Post-amputation, AmnioBand® Particulate was rehydrated with tobramycin and applied over the metatarsal head to treat any residual infection that had progressed proximally. After application the wound was sutured closed.
- Dressings consisted of Adaptic® and gauze. Upon post-ops, no additional particulate was required and no further tobramycin was required as a culture taken of drainage demonstrated no evidence of actinobacteria.

Outcome

- Full wound closure and resolution of infection after 25 days post-treatment.



Initial - 5/6/16



Initial - 5/6/16



Week 1 (post-op) - 5/11/16



Full Closure - 6/1/16

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Case 5 — Post-Operative Osteomyelitis



Patient Information

- 74 year old male with history of Distal Polyneuropathy of unknown origin.

Initial Examination / Wound History

- Endocarditis & Hypercholesterolemia. Hammertoe surgery on 3/24/16 with incisional dehiscence. MRI positive osteomyelitis with destruction of distal and medial phalanx of right second toe. Failed short courses of oral cephalexin and clindamycin, plus a ten week course of IV daptomycin.

Treatment

- Removal of distal and middle phalanx, with head of the proximal phalanx second toe of right foot. AmnioBand® Particulate (80mg) was rehydrated with cephalexin (0.5-1cc) and applied over the proximal phalanx stump with the Freer elevator to treat any infection that had progressed proximally.
- The patient received the balance of the dose IV during the procedure. After application the wound was sutured closed.

Outcome

- Full wound closure and resolution of infection after 34 days post-treatment.



Initial - 10/12/16



Initial - 10/12/16



Initial - 10/12/16

Case 5 — Post-Operative Osteomyelitis



Day 13



Day 21



Day 34 - Wound Closure

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Case 6 — Venous Leg Ulcer

Patient Information

- 66 year old female with a history of hypertension, diabetes, and arterial fibrillation. The patient had two autoimmune diseases: hemolytic anemia and hepatitis, which were being treated with steroids and Lasix®.

Initial Examination / Wound History

- The patient had a history of multiple ulcers that had healed. Previously, she was prescribed compression socks and developed a blister upon use. At first diagnosis, the blister was opened up and wrapped with Unna boot.
- At follow up, the wound showed no progress with treatment using Unna boot alone. Based on the patient's history of multiple ulcerations, it was decided to proceed with treatment using advanced modalities.

Treatment

- The wound was debrided and 160mg of AmnioBand® Particulate was sprinkled over the wound surface. Saline was dripped over the tissue to rehydrate and an applicator was used to spread for complete wound coverage.
- Adaptic® was applied as the non-adherent primary dressing, followed by an Unna boot as the secondary dressing. At the first weekly follow-up, the dressings were changed and AmnioBand® Membrane discs were applied in a similar fashion. For the following three weekly follow-ups the dressings were changed and AmnioBand® Particulate was applied.



Initial Treatment - 5/18/16



Initial Treatment - 5/18/16



Week 1



Week 2



Week 2



Week 3

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Case 6 — Venous Leg Ulcer

- At the fifth follow-up the dressings were changed and a collagen-based product was applied. At the sixth follow up the wound had not closed further, so the dressings were changed and AmnioBand® Particulate was again applied on a weekly basis. At week eight, the initial wound was closed. At follow-up the next week a blister had developed in the area near the initial wound. Conservative treatment was used (no advanced wound care treatments) in combination with Unna boot the following three weeks, and the wound was again fully closed at week 12.

Outcome

- Initial wound closed using AmnioBand® at week eight. Ancillary wound developed post-closure also healed at week 12.



Week 4



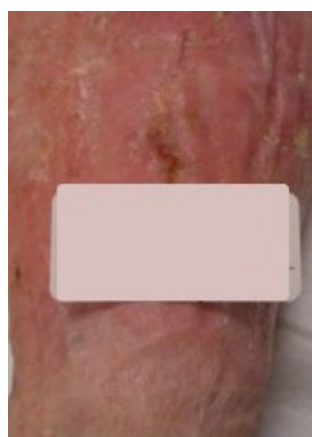
Week 4



Week 5



Week 6



Week 8 - Initial Closure



Week 12 - Fully Closed

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Case 1 — Chronic/Traumatic Wound



Patient Information

- 69 year old female, very obese with deep vein thrombosis in leg and pulmonary emboli. Has polymyalgia rheumatica.

Initial Examination / Wound History

- Trauma wound on left leg, ripped open skin. Complicated by lymphedema and steroid use.
- Open for eight weeks prior to graft application.
- Previous treatments included Drawtex®, Endoform®, Cutimed®Epiona, IODOSORB Gel, and Polymem® alongside multi-layer compression.
- Initial wound size is 10.24cm x 6.35cm x 0.40cm, total area 48.02cm².

Treatment

- First application of AmnioBand® Viable on 3/3/17, covered with Adaptic Touch and multi-layer compression wrap (Coban™ 2 Layer or multilayer with Unna boot).
- Noted no pain at second visit, continued with weekly applications of AmnioBand® Viable, covering with Adaptic Touch and multi-layer compression.
- No debridement after starting graft treatment.

Outcome

- Wound closure after seven weeks with six applications of AmnioBand® Viable.



Initial Wound - 3/2/17



Initial Treatment - 3/3/17

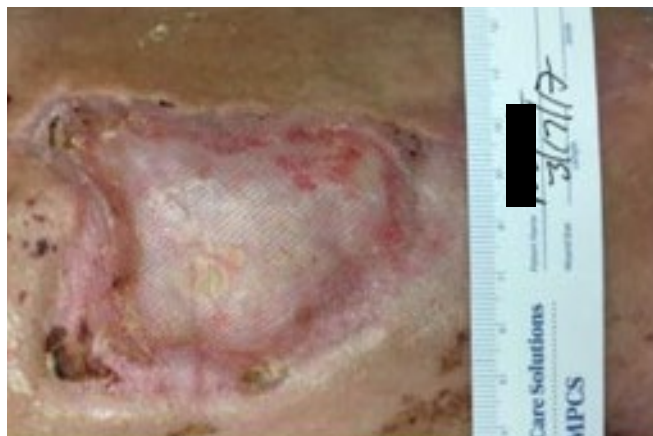
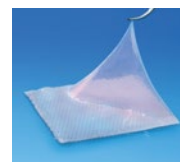


Week 1 - 3/10/17

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AmnioBand® Viable Membrane, Allograft Placental Matrix

Case 1 — Chronic/Traumatic Wound



Week 2 - 3/17/17



Week 3 - 3/24/17



Week 4 - 3/31/17



Week 6 - 4/14/17



Week 7 - Wound Closure - 4/21/17

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AmnioBand® Viable Membrane, Allograft Placental Matrix

Case 2 — Chronic/Traumatic Wound



Patient Information

- 69 year old female, very obese with deep vein thrombosis in leg and pulmonary emboli. Has polymyalgia rheumatica. Same patient as Case 1.

Initial Examination / Wound History

- Right leg ventral sagittal wound. Complicated by lymphedema and steroid use.
- Open for nine weeks prior to graft application.
- Previous treatments included biofilm-based wound care, Drawtex®, Cutimed®Epiona, Polymem®, and Collagenase SANTYL® alongside multi-layer compression.
- Initial wound size is 8.08cm x 2.63cm x 0.20cm, total area 18.47cm².



Initial Wound - 4/21/17



Week 1 - 4/28/17

Treatment

- First application of AmnioBand® Viable on 4/21/17, covered with ADAPTIC TOUCH® and multi-layer compression wrap.
- Continued weekly application of AmnioBand® Viable, covering with Adaptic and multi-layer compression.
- No debridement after starting graft treatments.



Week 2 - 5/5/17

Outcome

- Wound closure after eight weeks with eight applications of AmnioBand® Viable.
- Visit at nine weeks confirmed wound remained closed.



Week 3 - 5/12/17

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AmnioBand® Viable Membrane, Allograft Placental Matrix

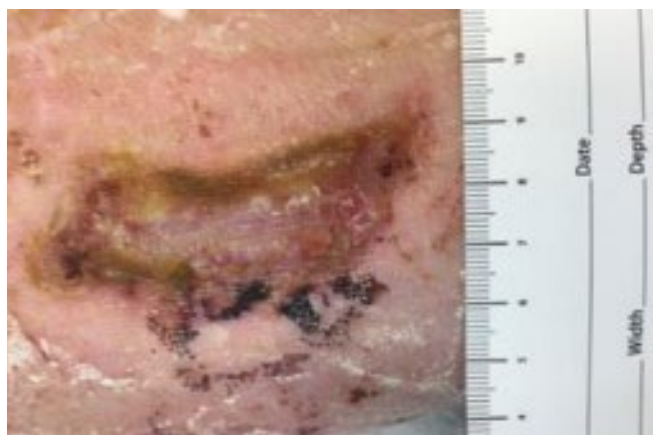
Case 2 — Chronic/Traumatic Wound



Week 4 - 5/19/17



Week 5 - 5/26/17



Week 6 - 6/2/17



Week 7 - 6/9/17



Week 8 - Wound Closure - 6/16/17

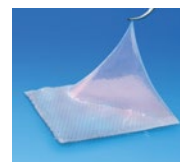


Week 9 - 6/23/17

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Case 3 — Venous Ulcer



Patient Information

- 70 year old diabetic male with long-standing history of recurrent venous leg ulcers.

Initial Examination / Wound History

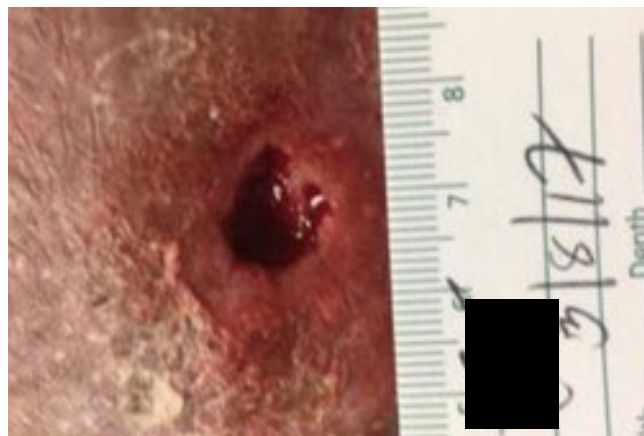
- Venous stasis ulceration on left inferomedial ankle.
- Had previous DVT and lymphedema in his leg.
- Open for nine weeks prior to graft application.
- Previous treatments included biofilm-based wound care, Drawtex®, Endoform®, Cutimed® Epiona, IODOSORB Gel, and Collagenase SANTYL® alongside multi-layer compression.
- Initial wound size 1.22cm x 0.97cm x 0.50cm, total area 0.80cm².

Treatment

- First application of AmnioBand® Viable on 3/8/17 and covered with ADAPTIC TOUCH® and multi-layer compression wrap.
- Continued weekly application of AmnioBand® Viable, covering with ADAPTIC TOUCH® and multi-layer compression.

Outcome

- Wound closure after five weeks, with four applications of AmnioBand® Viable.
- Visit at six weeks confirmed wound remained closed.
- Visit at 16 weeks confirmed wound remained closed.



Initial Wound - 3/8/17



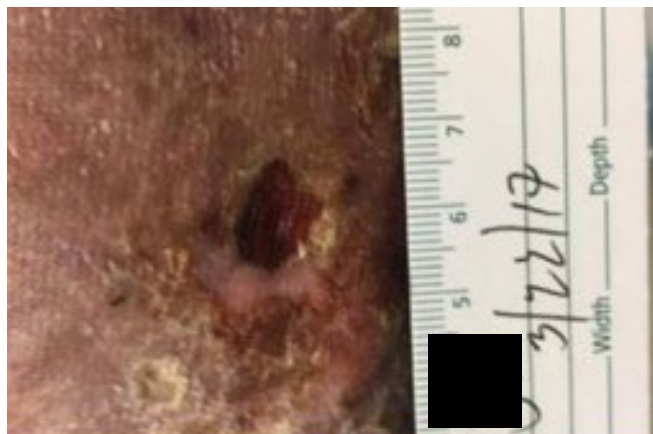
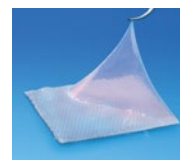
Initial Treatment



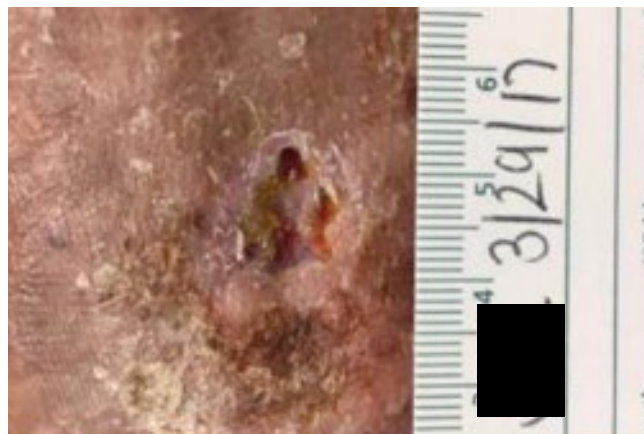
Week 1 - 3/15/17

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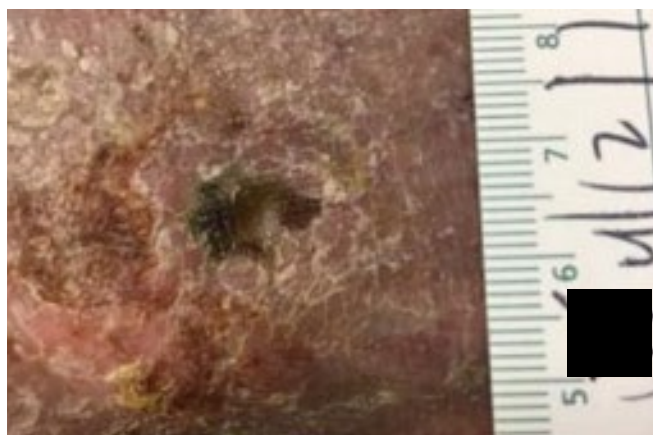
Case 3 — Venous Ulcer



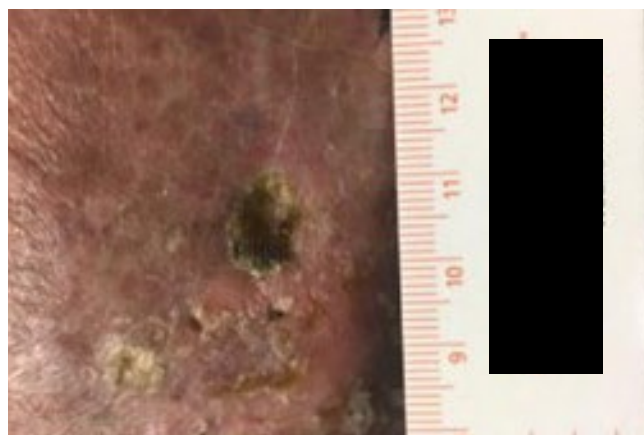
Week 2 - 3/22/17



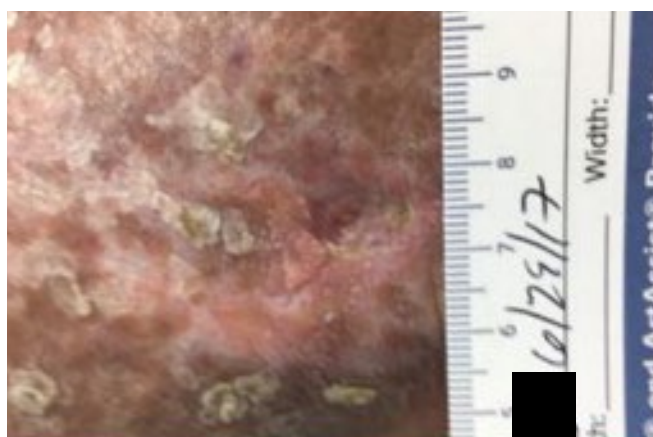
Week 3 - 3/29/17



Week 5 - Wound Closure - 4/12/17



Week 6 - 4/19/17



Week 16 - 6/29/17

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Case 4 — Venous Leg Ulcer

Patient Information

- 78 year old female, history of pulmonary fibrosis, PVD, bilateral pulmonary emboli, bilateral knee replacements.
- Originally presented to WC center approx. three years ago with venous ulcers of the lower leg.

Initial Examination / Wound History

- Wound on the left pre-tibial area.
- Biopsy performed on non-healing ulcer in 2016, basal cell carcinoma.
- Wide excision of basal cell with split thickness skin graft on 1/24/18 - Failed.
- Starting wound size 4/18/18 was 5cm x 4.5cm x 0.2cm (17.671cm²).
- Wound VAC (NPWT) in use, patient has large amount of drainage.
- History of issues with drainage from leg wounds. Drainage is pure lymphatic fluid, using up to three wound VAC canisters a week.

Treatment

- Debrided weekly prior to AmnioBand Viable application.
- First AmnioBand Viable treatment used on 4/18/18 - size 3cm x 4cm. Wound 5cm x 4.5cm x 0.2cm (17.671cm²). Covered with ADAPTIC™ and Steri-Strip™ prior to the NPWT foam placement. Wound VAC applied, but skin is extremely sensitive, she reacts to the drape that is sent with the KCI NPWT. Used Tegaderm™ to drape the area around the wound. Not changed for one week.



Pre-ABV - 4/18/18



Week 1 - 4/25/18



Week 2 - 5/2/18



Week 3 - 5/9/18



Week 4 - 5/16/18



Week 5 - 5/23/18

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Case 4 — Venous Leg Ulcer



- Continued weekly application of AmnioBand® Viable and NPWT.
- No AmnioBand® Viable applied 6/20/18 (small enough to close on its own), Wound size 0.4cm x 0.4cm x 0.1cm (0.126cm²). Wound VAC removed and Fibracol™ applied to separate pressure injuries from wound VAC; Unna boot placed to help control excessive leg edema.

Outcome

- Wound closure on 6/27/18 after ten weeks with nine applications of AmnioBand® Viable.



Week 6 - 5/30/18



Week 7 - 6/6/18



Week 8 - 6/13/18



Week 9 - 6/20/18



Week 10 - Wound Closure
- 6/27/18

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Case 5 — DFU with Exposed Tendon



Patient Information

- 59 year old diabetic male on dialysis.

Initial Examination / Wound History

- Diabetic foot ulceration on right first metatarsophalangeal joint incision with exposed tendon.
- Had hallux ulceration on the bottom of the foot that was fixed but at three weeks the incision started to split open and tendon was exposed.
- Open for six weeks prior to graft application.
- Previous treatments included biofilm-based wound care, Drawtex®, Endoform®, Cutimed® Epiona, and PolyMed® alongside use of a cam walker.
- Initial wound size is 1.31cm x 0.83cm x 0.20cm, total area 0.85cm².



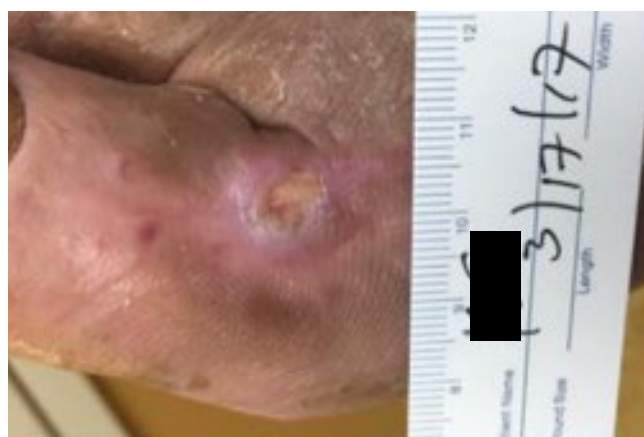
Initial Wound - 3/3/17

Treatment

- First application of AmnioBand® Viable on 3/3/17, covered with ADAPTIC TOUCH™ then soft cast (soft mild compression wrap) using cam walker to allow motion because wound is on driving foot.
- Second application of AmnioBand® Viable on 3/10/17, 0.91cm x 0.59cm x 0.20cm, total area 0.35cm² (41% of original), still a small area of exposed tendon with no sign of cellulitis or odors, continued to cover with ADAPTIC TOUCH™ and soft cast/cam walker.
- Third application used Endoform® on 3/17/17, 0.96cm x 0.66cm x 0.20cm, total area 0.48cm² (56% of original).



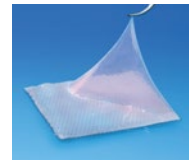
Week 1 - 3/10/17



Week 2 - 3/17/17

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Case 5 — DFU with Exposed Tendon



Outcome

- Wound closure after three weeks, with two applications of AmnioBand® Viable.
- Visit at four weeks confirmed wound remained closed.



Week 3 - Wound Closure - 3/24/17



Week 4 - Wound Remained Closed - 3/31/17

Case 6 — Plantar Reconstruction Post-gangrene Excision



Patient Information

- 53 year old male Insulin-Dependent Diabetes Mellitus, Hypertension, Hyperlipidemia and Hba1c of 9.1 and no other pertinent medical problems.

Initial Examination / Wound History

- Patient present with low grade fever and grossly infected wound on the left foot 3rd metatarsal head. The wound has been present for 1.5 years and he had a previous 5th toe and metatarsal head resection. The fever started 5 days prior to the hospital admission.
- Diabetic foot ulcer 1cm x 0.8cm x 1cm with positive probe to bone. Base was fibronectrotic with active purulence and malodor. The wound tracks and undermines toward the medial arch.
- Initial consultation and surgery date was 3/4/19. Initial surgery was incision and drainage left foot into the plantar arch and extending from the 3rd toe to the 1st metatarsal phalangeal joint. Deep wound cultures were obtained and a second procedure on 3/8/19 was performed with resection of the 3rd metatarsal head and amputation of the 3rd toe. Following debridement application of SomaGen Meshed graft with application of negative pressure wound VAC therapy commenced.
- The decision to use a graft on the second procedure was to facilitate bone coverage and expedite growth of granulation tissue once we had cleared the infection. The wound VAC was changed Tuesday and Friday.



Initial Consultation - 3/4/19



Initial Surgery - 3/4/19



Week 0 - 3/8/19

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Case 6 — Plantar Reconstruction Post-gangrene Excision



Treatment

- 3/4/19: Incision and drainage left foot. Started IV vancomycin and methicillin sensitive staphylococcus aureus isolated. Wound packed with 0.25 sodium hypochlorite twice daily until second operating room debridement. Patient was switched to IV UNASYN.
- 3/8/19: 3rd rays resection with application of 6cm x 8cm SomaGen Meshed graft applied with sutures and negative pressure wound VAC therapy at 125mmHg continuous changed biweekly for three weeks after SomaGen Meshed application.
- 4/23/19: Application of AmnioBand Viable 3cm x 4cm graft with negative pressure wound therapy with changes Tuesday and Friday.
- 5/7/19: Application of AmnioBand Viable 3cm x 4cm graft wound VAC discontinued and WBAT in total contact cast.
- 5/14/19: Application of AmnioBand Membrane 3cm x 4cm graft WBAT in total contact cast.
- 5/24/19: Application of AmnioBand Membrane 18mm disk graft WBAT in total contact cast.
- 6/11/19: Application of 18mm AmnioBand Membrane disk with injection 5ml of Leneva allograft adipose matrix to 4th metatarsal head.
- 6/24/19: Wound closed.



Week 1 - 3/12/19



Week 10



Week 15 - Wound Closure - 6/24/19

Outcome

- Complete wound closure 6/24/19.
- Time to Closure = 15 weeks.
- Total number of grafts = 1 SomaGen Meshed, 2 AmnioBand Viable, 3 AmnioBand Membrane, 1 Leneva injection.

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AlloPatch® Pliable

Table of Contents

AlloPatch® Pliable,
Allograft Dermal Matrix



| | |
|------------------------------------|-----|
| Case 1 — Diabetic Foot Ulcer | B-2 |
| Case 2 — Diabetic Foot Ulcer | B-4 |
| Case 3 — Diabetic Foot Ulcer | B-6 |



Case 1 — Diabetic Foot Ulcer

Patient Information

- 72 year old male, Type 2 diabetes mellitus with peripheral neuropathy, hypertension, high cholesterol, anxiety, depression, asthma, atrial fibrillation, and kidney stones.
- Prior history of healed neuropathic fractures to his feet.

Initial Examination / Wound History

- Patient presents with a non-healing left foot ulceration over his lateral column.
- Initial wound was 1.20cm x 1.20cm x 0.10cm and debrided to healthy bleeding tissues.

Treatment

- Standard diabetic foot exam was performed that revealed Semmes Weinstein monofilament wire testing 0/10 points confirming severe peripheral neuropathy. Pedal pulses were 2/4 and Doppler exam revealed biphasic waveforms for both the dorsalis pedis and posterior tibial arteries.
- Initial two week screening period, standard of care (alginate dressing, offloading with camboot) without any significant improvement.
- One application of AlloPatch® Pliable (size specific to minimize waste).



Initial screening visit



Week 2 - post-screening period



Randomization visit (received AlloPatch® Pliable)

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Case 1 — Diabetic Foot Ulcer

Outcome

- Wound closed after one week treatment with AlloPatch® Pliable.
- Final HgA1c noted to be 8.2% and progressed to a diabetic shoe with insoles.



Week 1 - Wound Closure (100% epithelial tissue present)



Week 2 - Validation (ulcer remains closed)

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Case 2 — Diabetic Foot Ulcer



Patient Information

- 44 year old male, Type 2 diabetes mellitus with periphery neuropathy, hypertension, asthma, hyperlipidemia, herniated disc and morbid obesity.

Initial Examination / Wound History

- Non-healing right foot ulceration for four weeks.
- History of recurring forefoot ulcers, gauze and antibiotic cream daily with offloading shoe.
- Initial wound size 1.50cm x 1.30cm x 0.10cm.

Treatment

- Standard diabetic foot exam was performed that revealed Semmes Weinstein monofilament wire testing, 0/10 points, confirming severe peripheral neuropathy. Pedal pulses were 2/4 and Doppler exam revealed biphasic wavelengths for both dorsalis pedis and posterior tibial arteries.
- Initial two week screening period with standard of care (alginate dressing, offloading with camboot) without any improvement.
- Wound debrided to healthy bleeding tissue. AlloPatch® Pliable applied weekly in the clinic. The wound was dressed with primary/secondary dressings and offloaded.



Initial screening period



Week 2 - post screening period



Randomization visit (received AlloPatch® Pliable)

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Case 2 — Diabetic Foot Ulcer

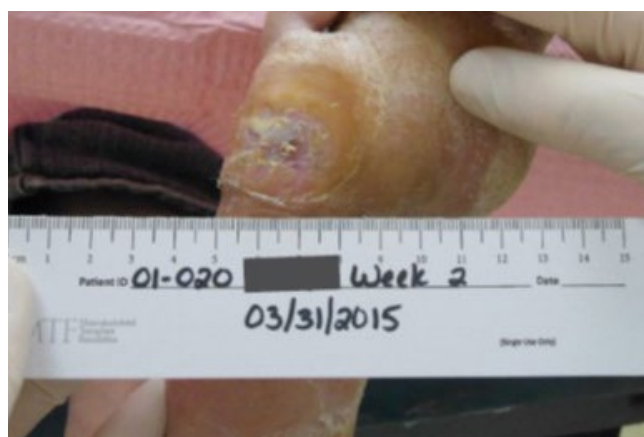


Outcome

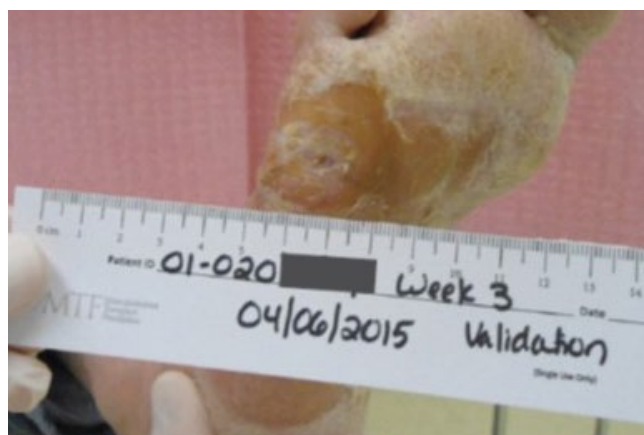
- Wound closed with only two week treatment with AlloPatch® Pliable.
- Final HgA1c was 9.9% and progressed to a diabetic shoe with insoles.



Week 1



Week 2 - Wound Closure



Validation visit (ulcer remains closed with epithelial tissue present)

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Case 3 — Diabetic Foot Ulcer



Patient Information

- 61 year old male, morbidly obese, Type 2 diabetes mellitus with periphery neuropathy, cardiac disease (previous myocardial infarction and placement of four cardiac stents), depression, hypertension, hyperlipidemia.
- Previous right partial first ray amputation.

Initial Examination /Wound History

- Non-healing left hallux ulceration for 36 weeks.
- Resistant to a variety of conservative wound care modalities (antibiotic creams, alginates as well as different offloading devices).
- Initial wound size 1.50cm x 1.50cm x 0.20cm.

Treatment

- Standard diabetic foot exam was performed that revealed Semmes Weinstein monofilament wire testing, 0/10 points, confirming severe peripheral neuropathy. Pedal pulses were 2/4 and Doppler exam revealed biphasic wavelengths for both dorsalis pedis and posterior tibial arteries.
- Initial two week screening period with standard of care (alginate dressing, offloading with camboot) without any improvement.
- Wound debrided to healthy bleeding tissue. AlloPatch® Pliable applied weekly in the clinic. The wound was dressed with primary/secondary dressings and offloaded.



Initial screening period



Week 2 - post screening period



Randomization visit (received AlloPatch® Pliable)



Week 1 (epithelial tissue has started to form)

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Case 3 — Diabetic Foot Ulcer



Outcome

- Wound closed with after five week treatment with AlloPatch® Pliable.
- Final HgA1c was 10.2% and progressed to a diabetic shoe with insoles.



Week 2



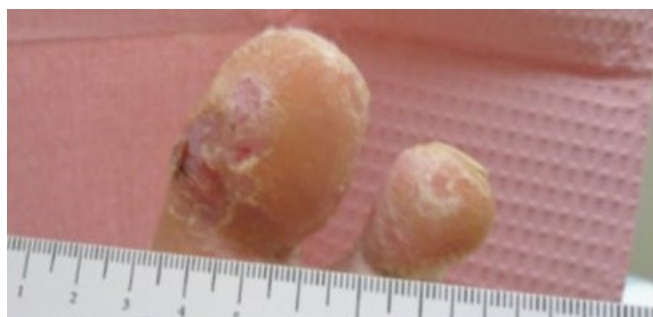
Week 3



Week 4



Week 5 - Wound Closure



Validation visit (ulcer remains closed with 100% epithelial tissue present)

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Leneva™

Table of Contents

Leneva™,
Injectible Allograft Regenerative Matrix



| | |
|---|------|
| Case 1 — DFU Reoccurrence Prevention: Fat Pad Augmentation | C-2 |
| Case 2 — Scar Minimization Via Subcutaneous Injection in Plantar Foot | C-4 |
| Case 3 — Ischial Pressure Ulcer Treatment | C-6 |
| Case 4 — Metatarsal Fat Pad Atrophy Treatment | C-8 |
| Case 5 — Plantar Reconstruction Post-gangrene Excision..... | C-10 |
| Case 6 — Post-Ulcer Fat Pad Augmentation Under 5th Metatarsal..... | C-12 |
| Case 7 — Treatment of Pre-Ulcerative Callous Under 3rd Metatarsal | C-14 |
| Case 8 — Subcutaneous Peri-wound Injection..... | C-15 |
| Case 9 — Heel Fat Pad Augmentation..... | C-16 |
| Case 10 — Treatment of Pre-Ulcerative Callous Under 1st Metatarsal | C-17 |
| Case 11 — Treatment of Pre-Ulcerative Callous in the Plantar Midfoot..... | C-18 |



Leneva™, Injectable Allograft Regenerative Matrix

Case 1 — DFU Reoccurrence Prevention: Fat Pad Augmentation



Patient Information

- 71 year old male with a 40-year history of type 2 diabetes, first ray amputation and a healed but frequently recurring diabetic foot ulcer.

Initial Examination / Wound History

- Patient presented for care of a recently healed but frequently recurring diabetic foot ulcer.
- He had been treated with custom shoes and molded multilaminar multidurometer insoles, frequent return visits (every 2-3 months) with callus debridement and instructions for home monitoring.
- Previous treatment included sharp debridement, biofilm gel, & bordered foam.
- Patient was scheduled for F-scan and Leneva allograft adipose matrix injection.

Treatment

- The F-Scan in shoe system (Tekscan Inc. Boston, Mass.) was used to determine the location of peak pressure.
- The patient was prepped and local anesthesia was infiltrated.
- A small puncture incision was made and 7.5cc of Leneva allograft adipose matrix were injected in the subcutaneous tissue with a blunt tip 20G cannula to provide protective padding and release of pressure.
- Patient was off-loaded for 4 weeks with total contact cast.



Initial Injection



Week 4



Month 4

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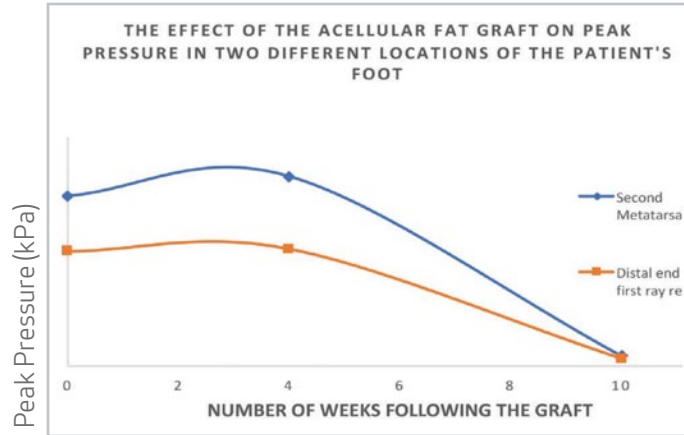


Case 1 — DFU Reoccurrence Prevention: Fat Pad Augmentation



Outcome

- One injection of Leneva allograft adipose matrix was used.
- There was a 76.8% decrease in mean peak pressure under the second metatarsal region, and a 70.1% decrease in mean peak pressure for the distal end of the first ray resection at the site of the postulcerative callus.
- By 2 months postoperatively, there was no evidence of residual callus. This extended out to the end of clinical follow-up at 4 months.



Reduction in mean peak pressure

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Case 2 — Scar Minimization Via Subcutaneous Injection In Plantar Foot



Patient Information

- 64 year old male with DM, COPD, and obesity with chronic foot ulcer.

Initial Examination / Wound History

- Plantar foot ulcer (1.5cm x 2.5cm x 0.2cm).
- Underwent OWR (Outpatient Wound Reconstruction) with STSG for definitive coverage.
- Wound closed at 6 weeks.
- Scarring and callous noted at site.

Treatment

- 1.5cc of Leneva allograft adipose matrix placed to soften scar (See placement on “adipose matrix placement” image).
- Steri strips used to minimize adipose matrix migration.
- Offloading shoe continued.

Outcome

- After 2 weeks post-injection, the wound remained healed.
- The scar was “softer and more mobile.”
- No additional adipose was added.



Initial Wound



STSG



Week 6

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Leneva™, Injectable Allograft Regenerative Matrix

Case 2 — Scar Minimization Via Subcutaneous Injection In Plantar Foot



Adipose Matrix Placement



Week 8



Closeup of scar at Week 8

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Leneva™, Injectable Allograft Regenerative Matrix

Case 3 — Ischial Pressure Ulcer Treatment

leneva™
ALLOGRAFT ADIPOSE MATRIX



Patient Information

- 64 year old male with paraplegia. Developed a right ischial pressure ulcer, stage 4.

Initial Examination / Wound History

- Right Ischial ulcer (6cm x 3cm x 4cm).
- Underwent surgical excision ulcer with partial osteotomy and flap for definitive closure.
- At 6 weeks surgical site remained healed.
- Deep soft tissue deficit noted overlying remaining bone.



Initial Wound

Treatment

- 5cc of Leneva allograft adipose matrix placement in subcutaneous tissue in order to bulk soft tissue over bone.
- Steri-strips used over the injection sites.
- No additional offloading prescribed.

Outcome

- At 8 weeks the surgical site remained closed.
- The area overlying the bone had more volume with soft, pliable padding.
- No additional adipose was added.



Surgical Flap



Week 6

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Leneva™, Injectable Allograft Regenerative Matrix
Case 3 — Ischial Pressure Ulcer
Treatment



Adipose Matrix Placement



Week 8



Soft tissue volume increased

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Case 4 — Metatarsal Fat Pad Atrophy Treatment



Patient Information

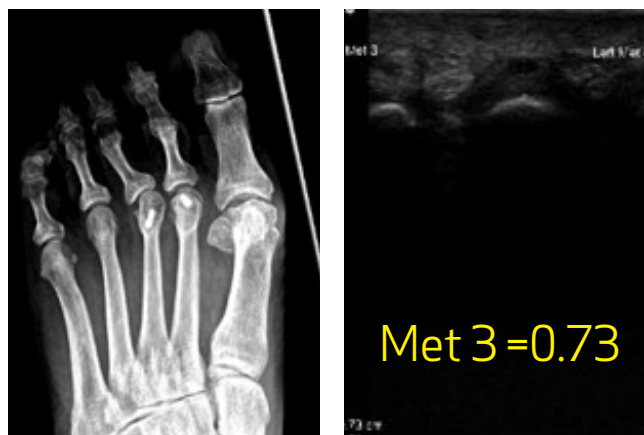
- 76 year old, Female, Raynaud's, Anxiety Arthritis, Depression, GERD, Dyslipidemia, Migraine, osteoporosis, No Tobacco use, No alcohol, L1-5 Spine fusion.

Initial Examination

- Fat Pad Atrophy, large painful callouses on forefoot, present for 25 years.
- Failed callus pads, shoe gear changes, multiple custom orthotics, routine debridement.
- 2002 bunion repair with residual deformity and metatarsal 2,3 osteotomy - no callus improvement.
- Xray: Abnormal metatarsal parabola.
- Fat pad atrophy with prominent metatarsal head. Highly questionable outcome from any more bone surgery, therefore offered a low risk, non invasive option of hydrated adipose injection to cushion prominent bone.



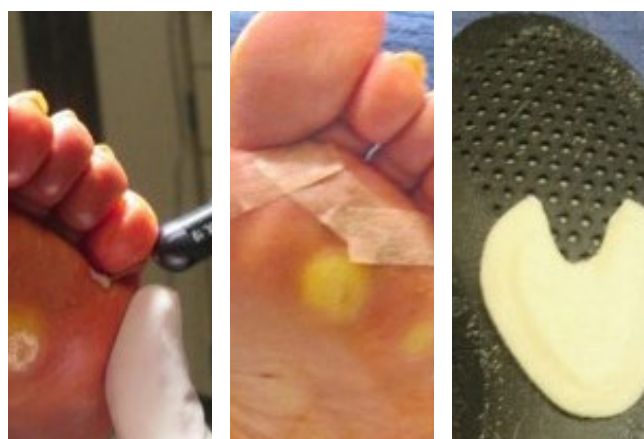
Initial Wound - 4/2/19



Xray and ultrasound image of fat pad under 3rd metatarsal at 0.73 cm thickness

Treatment

- Ultrasound on the patient's foot to evaluate fat pad.
- Local numbing agent injected into the patient's foot (5 total injections).
- Shaved existing calluses off and pin pointed zones needing more padding.
- 12cc of hydrated adipose were injected into the forefoot in a cross hatch pattern.
- Dressed with steristrips, no post operative ice permitted, elevation.



Initial Treatment

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Case 4 — Metatarsal Fat Pad Atrophy Treatment



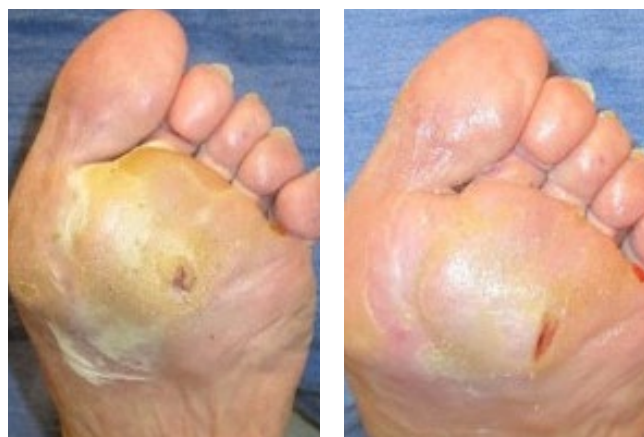
- Limit weight bearing to 10 minutes/hour, OTC Tylenol or ibuprofen for pain.
- Advised to wear supportive sneaker-like shoes, encourage to do NWB range of motion.
- Follow-up schedule: 2 weeks, 1 month, 2 months, 6 months, 12 months.

Outcome

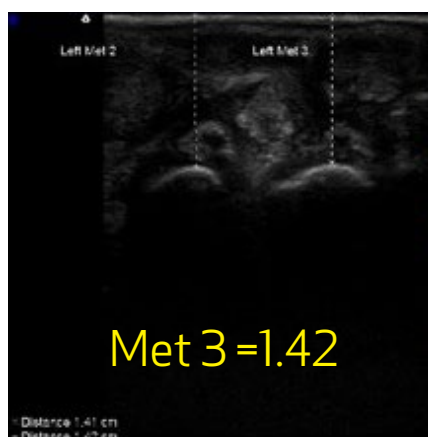
- Two weeks post-op
 - Patient noted some discomfort but tolerable.
 - No use of any OTC pain medications.
 - Limited weight bearing.
 - Stayed in closed supportive shoe majority of the day.
 - Used water proof pad in shower to cushion foot.
- 1 month post-op
 - Patient reported no pain.
 - Debridement of the peeling top layer of skin, debridement of lesion, ultrasound.
 - No deep IPK - Intractable Plantar Keratoma (deep callus) noted, skin supple underneath, advised on moisturizer, continue limited weightbearing with shoe gear, may increase to 15 min/hour, continue range of motion.



Week 2 - 4/16/19



Week 4 - Pre and Post-Debridement of callus - 4/30/19



Ultrasound showing fat pad thickness under 3rd metatarsal at 1.42cm

Case images and information courtesy of Jeffrey A. Gusenoff, M.D. & Beth Gusenoff, D.P.M. Used by permission. As with any case study, the results & outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Leneva™, Injectable Allograft Regenerative Matrix

Case 5 — Plantar Reconstruction Post-gangrene Excision

leneva™
ALLOGRAFT ADIPOSE MATRIX



Patient Information

- 53 year old male Insulin-Dependent Diabetes Mellitus, Hypertension, Hyperlipidemia and Hba1c of 9.1 and no other pertinent medical problems.

Initial Examination / Wound History

- Patient present with low grade fever and grossly infected wound on the left foot 3rd metatarsal head. The wound has been present for 1.5 years and he had a previous 5th toe and metatarsal head resection. The fever started 5 days prior to the hospital admission.
- Diabetic foot ulcer 1cm x 0.8cm x 1cm with positive probe to bone. Base was fibronectic with active purulence and malodor. The wound tracks and undermines toward the medial arch.
- Initial consultation and surgery date was 3/4/19. Initial surgery was incision and drainage left foot into the plantar arch and extending from the 3rd toe to the 1st metatarsal phalangeal joint. Deep wound cultures were obtained and a second procedure on 3/8/19 was performed with resection of the 3rd metatarsal head and amputation of the 3rd toe. Following debridement application of SomaGen Meshed graft with application of negative pressure wound VAC therapy commenced.
- The decision to use a graft on the second procedure was to facilitate bone coverage and expedite growth of granulation tissue once we had cleared the infection. The wound VAC was changed Tuesday and Friday.



Initial Consultation - 3/4/19



Initial Surgery - 3/4/19



Week 0 - 3/8/19

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Leneva™, Injectable Allograft Regenerative Matrix

Case 5 — Plantar Reconstruction Post-gangrene Excision



Treatment

- 3/4/19: Incision and drainage left foot. Started IV vancomycin and methicillin sensitive staphylococcus aureus isolated. Wound packed with 0.25 sodium hypochlorite twice daily until second operating room debridement. Patient was switched to IV UNASYN.
- 3/8/19: 3rd rays resection with application of 6cm x 8cm SomaGen Meshed graft applied with sutures and negative pressure wound VAC therapy at 125mmHg continuous changed biweekly for three weeks after SomaGen Meshed application.
- 4/23/19: Application of AmnioBand Viable 3cm x 4cm graft with negative pressure wound therapy with changes Tuesday and Friday.
- 5/7/19: Application of AmnioBand Viable 3cm x 4cm graft wound VAC discontinued and WBAT in total contact cast.
- 5/14/19: Application of AmnioBand Membrane 3cm x 4cm graft WBAT in total contact cast.
- 5/24/19: Application of AmnioBand Membrane 18mm disk graft WBAT in total contact cast.
- 6/11/19: Application of 18mm AmnioBand Membrane disk with injection 5ml of Leneva allograft adipose matrix to 4th metatarsal head.
- 6/24/19: Wound closed.



Week 1 - 3/12/19



Week 10



Week 15 - Wound Closure - 6/24/19

Outcome

- Complete wound closure 6/24/19.
- Time to Closure = 15 weeks.
- Total number of grafts = 1 SomaGen Meshed, 2 AmnioBand Viable, 3 AmnioBand Membrane, 1 Leneva injection.

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Leneva™, Injectable Allograft Regenerative Matrix

Case 6 — Post-Ulcer Fat Pad Augmentation Under 5th Metatarsal



Patient Information

- 66 year old male, diabetic with neuropathy and fifth met cuboid dislocation.

Initial Examination / Wound History

- Patient was seen with a fifth met base abscess. He was placed on IV antibiotics and underwent surgical incision and drainage. The ulceration with weekly debridements and a CROW boot.
- Currently Post ulceration fifth metatarsal base.

Treatment

- 3 cc of Leneva allograft adipose matrix was injected subcutaneously per wound and any high pressure area.
- Post injection offloading pad, continue with CROW boot.
- Instructions to remain in the CROW boot.
- Follow-up one week
 - Pre MRI and Pre Ultrasound images.
 - Immediately Post Ultrasound images.
 - MRI and Ultrasound images at 12 weeks.

Outcome

- Continued healing of the skin with clinical improvement.



Pre-injection



Pre-injection



Week 1- Post-injection

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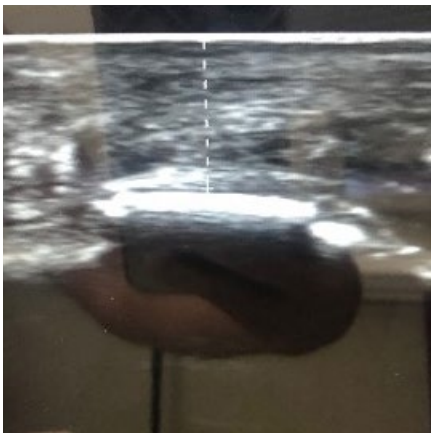
Leneva™, Injectable Allograft Regenerative Matrix
 Case 6 — Post-Ulcer Fat Pad
 Augmentation Under 5th Metatarsal



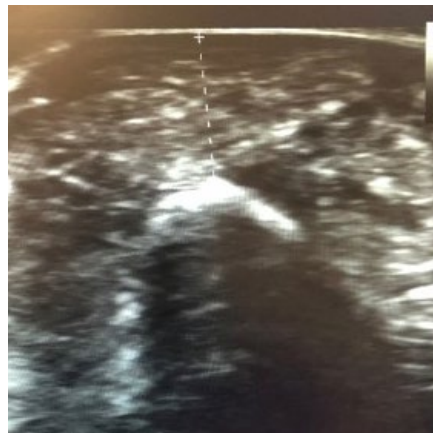
Week 5



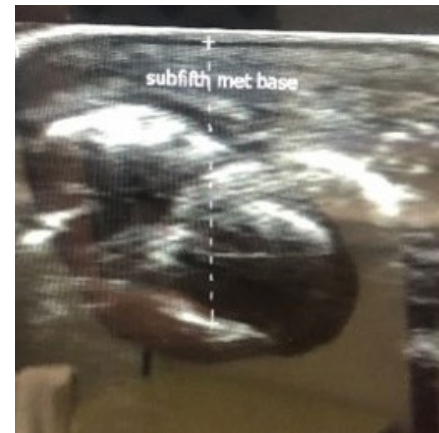
Week 12



Pre-injection - No Allograft



Immediate post-injection



Week 10 - post-injection



Ultrasound imaging of allograft at 10 weeks in subcutaneous tissue

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Case 7 — Treatment Of Pre-Ulcerative Callous Under 3rd Metatarsal



Patient Information

- 66 year old male with a history of Type II DM with neuropathy.

Initial Examination / Wound History

- Previous Charcot breakdown of the first metatarsal phalangeal joint with altered mechanics leading to lesser MPJ dislocation.
- Preulceration site with submetatarsal three prominence.
- Hyperkeratotic lesion with pinpoint dermal bleeding indicative of future ulceration and skin breakdown.
- Goal is to offload the high pressure area with adipose matrix to prevent further breakdown of tissue and heal the damaged dermis.



Pre-injection



Week 4

Treatment

- Debridement of hyperkeratotic lesion and preparation with alcohol.
- 5cc injection of Leneva allograft adipose matrix into subcutaneous tissue.
- Offloading pad with custom molded diabetic innersoles and shoes.
- Follow-up one week post injection, scheduled additional follow-up for 4 weeks.

Outcome

- Current findings at four weeks post injection show clinical improvement with less peak pressure on the skin at the site of injection of the dermal layers of skin as indicated by healed capillary dermal bleeding, decreased keratin build up of the callus.

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Case 8 — Subcutaneous Peri-wound Injection



Patient Information

- 52 year old diabetic male with history of cardiovascular disease, myocardial infarction, long history of recurrent diabetic foot ulcers & left foot TMA.

Initial Examination / Wound History

- Patient presented with Wagner grade 1 right 5th ray ulcer that had been open for 4 weeks from rubbing in his shoe.
- Wound measured 1cm x 1cm x 0.2cm.
- Previous treatment included sharp debridement, biofilm gel, & bordered foam.
- Patient was scheduled for surgery for wound excision and surgical reconstruction of digital deformity.

Treatment

- 3cc injection of Leneva allograft adipose matrix to peri-wound subcutaneous tissue to fill in soft tissue defect and provide protective padding.
- Wound was covered with biofilm gel and a bordered foam.
- Patient was fitted for a custom molded diabetic shoe.

Outcome

- One injection of Leneva allograft adipose matrix matrix was used.
- Wound healed in 6 weeks and remained healed at 3.5 months post treatment.
- Patient didn't require surgery and was able to return to work as a construction worker.



Initial treatment - 5/3/19



Week 6 - Wound Closure - 6/13/19



Month 3.5 - 8/8/19

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Leneva™, Injectable Allograft Regenerative Matrix

Case 9 — Heel Fat Pad Augmentation

leneva™
ALLOGRAFT ADIPOSE MATRIX



Patient Information

- 77 year old diabetic female with a past medical history of PVD, kidney disease requiring dialysis, neuropathy, and recurrent diabetic foot ulcers.

Initial Examination / Wound History

- Patient had a past history of a gangrenous plantar diabetic foot ulcer with necrotizing fasciitis & osteomyelitis.
- Patient required extensive surgical reconstruction with excision of the calcaneus bone.
- Patient had fibrotic scar tissue as a result of the extensive surgery with recurrent heel pre-ulcerative Wagner grade 0 lesions and open ulcers.

Treatment

- 5/24/19: 5cc injection of Leneva allograft adipose matrix to the subcutaneous tissue surrounding calloused fibrotic tissue.
- 6/21/19: Calloused tissue debrided to expose healthy granular tissue.
- Biofilm gel and bordered foam applied.
- Molded ankle foot orthosis and custom molded shoe for off-loading.

Outcome

- One injection of Leneva allograft adipose matrix was used.
- In 6 weeks pre-ulcerative lesion healed and quality of tissue improved.
- Diabetic Foot Ulcer prevented.



Initial treatment - 5/24/19



Week 4 - 6/21/19



Week 6 - Wound Closure - 7/5/19

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Case 10 — Treatment of Pre-ulcerative Callous Under 1st Metatarsal



Patient Information

- 60 year old male with history of progressive neuropathy of unknown etiology.

Initial Examination / Wound History

- Previous history included multiple open wounds as a result of progressive neuropathy.
- Patient has undergone past wound excision with surgical reconstruction and a rotational flap for wound closure.
- The patient presented with pre-ulcerative callous formation and because of operative history is at continual risk of tissue breakdown.

Treatment

- 6/18/19: Injection of 5cc Leneva allograft adipose matrix to fill in soft tissue defect and provided protective padding.
- CAM walker was used for off loading after the injection.
- Patient was fitted for a custom molded diabetic shoe.

Outcome

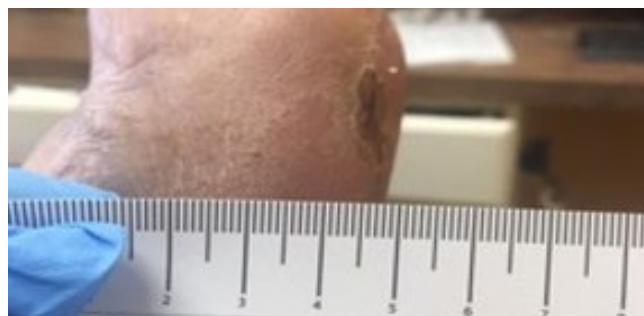
- One injection of Leneva allograft adipose matrix was used.
- The patients pre-ulcerative lesions and tissue was improved in 2 weeks.
- Patient remained closed at 6 weeks.



Initial treatment - 6/18/19



Week 2 - 7/2/19



Week 2 - 7/2/19



Week 6 - 7/30/19

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Case 11 — Treatment of Pre-ulcerative Callous in the Plantar Midfoot



Patient Information

- 79 year old Diabetic female with past medical history of peripheral vascular disease, hypertension, equines deformity, & recurrent diabetic foot ulcers.

Initial Examination / Wound History

- Patient has a History of a plantar gangrenous diabetic foot ulcer with necrotizing fasciitis that required extensive surgical reconstruction and two revascularizations.
- As a result of the surgery patient has fibrotic scar tissue on her plantar foot and is at high risk of ulcer reoccurrence.
- Patient presented with a pre-ulcerative Wagner grade 0 lesion on plantar foot.

Treatment

- 5/16/19: injection of 5cc Leneva allograft adipose matrix to fill in soft tissue defect and provide plantar padding.
- A Crow walker was used for off-loading.

Outcome

- One injection of Leneva allograft adipose matrix was used.
- Pre-Ulcerative lesion healed and quality of tissue improved in 6 weeks.
- Patient remained closed at 12 weeks.



Initial treatment - 5/16/19



Week 6 - 6/27/19



Week 12 - 8/8/19

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SomaGen™ Meshed

Table of Contents

SomaGen™ Meshed,
Allograft Dermal Matrix



| | |
|--|------|
| Case 1 — Wide Local Excision of Squamous Cell Carcinoma | D-2 |
| Case 2 — Hematoma Resection due to Motor Vehicle Accident..... | D-4 |
| Case 3 — 4 th & 5 th Ray Resection..... | D-6 |
| Case 4 — Plantar Reconstruction Post-gangrene Excision..... | D-8 |
| Case 5 — Reconstruction after 4th and 5th Ray Amputation | D-10 |



SomaGen™ Meshed, Allograft Dermal Matrix

Case 1 — Wide Local Excision of Squamous Cell Carcinoma



Patient Information

- 86 year old, male with chronic venous insufficiency and squamous cell carcinoma (SCC).

Initial Examination / Wound History

- Wide local excision of squamous cell carcinoma in minor room with immediate grafting.
- No prior treatments.
- Starting wound size is 4cm x 5cm.

Treatment

- Graft size used - 6cm x 8cm SomaGen™ Meshed, initial treatment date - 8/28/18. At week 4 - 10/3/18 - wound size reduced to 2cm x 2.5cm.
- Sutured in place with 4-0 monocryl. Dressings applied- Adaptic™, Steri-Strip™ 4x4, Kling roll bandage, Coban™.

Outcome

- Closed in 13 weeks.



Initial 8/28/18



After 3 days



Week 2 - 9/14/18

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SomaGen™ Meshed, Allograft Dermal Matrix

Case 1 — Wide Local Excision of Squamous Cell Carcinoma



Week 4 - 10/3/18



Week 6 - 10/17/18



Week 8 - 10/31/18



Week 13 - Wound Closure

Case images and information courtesy of Dr. Jarrod Kaufman, MD FACS. Used by permission. As with any case study, the results & outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.



Case 2 — Hematoma Resection due to Motor Vehicle Accident



Patient Information:

- 59 year old female with history of trauma to anterior shin secondary to Motor Vehicle Accident (MVA) with associated infected hematoma which was initially misdiagnosed as a fracture blister.
- Fracture of tibia in addition to hematoma which was in proper alignment with minimal displacement noted and no surgery required.
- Patient Medical History: Seizure disorder, hypertension, anxiety.

Initial Examination:

- Hematoma noted on anterior shin left with initial examination on 7/26/18, >1 week post MVA.
- Edema / erythema noted peri-wound with positive fluctuance with severe pain on left lower extremity.

Treatment:

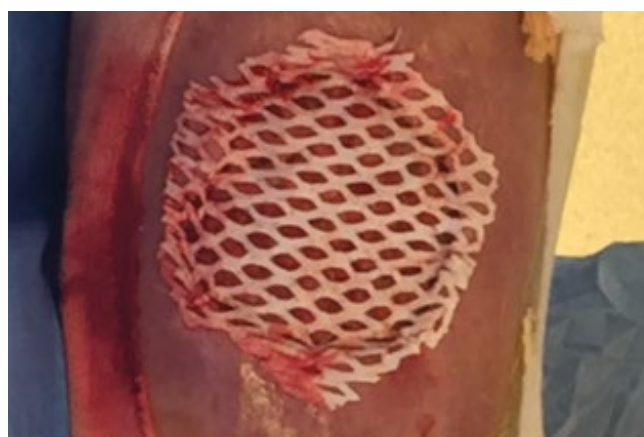
- Initial treatment was an Incision and Drainage (I&D) on anterior shin right leg on 7/27/18 in the Operating Room with wound measured to 6cm x 6cm x 0.3cm to fascia post I&D to below fascial plane in the Operating Room.
- Culture taken: + Methicillin Resistant Staph Aureus (MRSA).
- Started on Intravenous(IV) Vancomycin while in house, which was changed to Doxycycline 100mg oral twice a day x four weeks on discharge.
- KCI Negative pressure instillation wound therapy was started post I&D with instillation of saline every 3.5 hours for 10 minute dwell-time.



Initial - 7/26/18



Post-excision - 7/29/18



Application of SomaGen Meshed - 7/29/18

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Case 2 — Hematoma Resection due to Motor Vehicle Accident



- Excision of ulceration with application of 6cm x 8cm SomaGen Meshed was applied and sutured with 4-0 monocryl sutures, covered with Adaptic followed by KCI negative pressure dressing (medium black foam) at -125mmHg, 7/29/18.
- Wound VAC was discontinued on week 8—wound size was 4.8cm x 5cm x 0.2cm to subcutaneous tissue. Wound was covered with adaptic and alginate followed by multi-layer compression dressing at the wound center 2x per week.
- Patient was followed 2x per week and non-weight bearing for 12-14 weeks until healed.
- Patient required no other advanced tissue products and healed with local care which included application of Adaptic + calcium alginate followed by multi-layer compression of left lower extremity with no other OR debridements nor any hospital admissions.

Outcome:

- This patient went onto healing with no complications and with no advanced modalities utilized other than multi-layer compression wrap and non-weight bearing status for 12-14 weeks.



Week 4 - VAC removed



Week 8



Week 12 - 10/23/18

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Case 3 — 4th & 5th Ray Resection



Patient Information:

- 42 year old male with no past medical history on admission though was diagnosed with uncontrolled diabetes on admission with HbA1c of 10.0.
- Patient has long family history of diabetes.
- Patient was profoundly neuropathic, though unaware of loss of protective sensation.

Initial Examination / Wound History:

- Patient states that he stepped on a metal object two weeks prior to admission and self-treated with bacitracin, though was concerned when toe started to discolor and prompted Emergency Room (ER) visit.
- On initial examination, gas gangrene noted of lateral 5th metatarsophalangeal joint (MPJ) right foot with osteomyelitis of 4th and 5th metatarsals right foot.

Treatment:

- Partial 4th and 5th ray resection right foot with I&D Abscess right foot with application of Instill VAC at -125mmHg with 10 minutes dwell time with Dakins (0.25%) every 3.5 hours.
- Application of SomaGen Meshed 6cm x 8cm right foot with application of VAC at -125mmHg, with pre-debridement measurement: 5.5cm x 6.3cm x 0.2cm to subcutaneous tissue.
- VAC application 2x per week for four weeks with application of total contact cast (TCC) for immobilization.



Initial in ER, 9/11/18



Partial 4th/5th ray + I&D Abscess, 9/14/18



Application of SomaGen Meshed, 9/19/18

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Case 3 — 4th & 5th Ray Resection



- After VAC dressing removed and discontinued. Extracellular matrix (Endoform) application + Tissue-Engineered Skin Substitute was done weekly until healed.

Outcome:

- Patient currently healed and ambulating well with diabetic shoes with custom inserts with no complications noted.
- Following excision, only a single application of SomaGen Meshed was required to create a viable dermal layer to allow us to apply skin substitutes in order epithelialize and heal the complex wound.



Week 1 - 9/26/18



10/12/18 - VAC Discontinued



Wound Closure - 12/11/18

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Case 4 — Plantar Reconstruction Post-gangrene Excision



Patient Information

- 53 year old male Insulin-Dependent Diabetes Mellitus, Hypertension, Hyperlipidemia and Hba1c of 9.1 and no other pertinent medical problems.

Initial Examination / Wound History

- Patient present with low grade fever and grossly infected wound on the left foot 3rd metatarsal head. The wound has been present for 1.5 years and he had a previous 5th toe and metatarsal head resection. The fever started 5 days prior to the hospital admission.
- Diabetic foot ulcer 1cm x 0.8cm x 1cm with positive probe to bone. Base was fibronectic with active purulence and malodor. The wound tracks and undermines toward the medial arch.
- Initial consultation and surgery date was 3/4/19. Initial surgery was incision and drainage left foot into the plantar arch and extending from the 3rd toe to the 1st metatarsal phalangeal joint. Deep wound cultures were obtained and a second procedure on 3/8/19 was performed with resection of the 3rd metatarsal head and amputation of the 3rd toe. Following debridement application of SomaGen Meshed graft with application of negative pressure wound VAC therapy commenced.
- The decision to use a graft on the second procedure was to facilitate bone coverage and expedite growth of granulation tissue once we had cleared the infection. The wound VAC was changed Tuesday and Friday.



Initial Consultation - 3/4/19



Initial Surgery - 3/4/19



Week 0 - 3/8/19

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Case 4 — Plantar Reconstruction Post-gangrene Excision



Treatment

- 3/4/19: Incision and drainage left foot. Started IV vancomycin and methicillin sensitive staphylococcus aureus isolated. Wound packed with 0.25 sodium hypochlorite twice daily until second operating room debridement. Patient was switched to IV UNASYN.
- 3/8/19: 3rd rays resection with application of 6cm x 8cm SomaGen Meshed graft applied with sutures and negative pressure wound VAC therapy at 125mmHg continuous changed biweekly for three weeks after SomaGen Meshed application.
- 4/23/19: Application of AmnioBand Viable 3cm x 4cm graft with negative pressure wound therapy with changes Tuesday and Friday.
- 5/7/19: Application of AmnioBand Viable 3cm x 4cm graft wound VAC discontinued and WBAT in total contact cast.
- 5/14/19: Application of AmnioBand Membrane 3cm x 4cm graft WBAT in total contact cast.
- 5/24/19: Application of AmnioBand Membrane 18mm disk graft WBAT in total contact cast.
- 6/11/19: Application of 18mm AmnioBand Membrane disk with injection 5ml of Leneva allograft adipose matrix to 4th metatarsal head.
- 6/24/19: Wound closed.



Week 1 - 3/12/19



Week 10



Week 15 - Wound Closure - 6/24/19

Outcome

- Complete wound closure 6/24/19.
- Time to Closure = 15 weeks.
- Total number of grafts = 1 SomaGen Meshed, 2 AmnioBand Viable, 3 AmnioBand Membrane, 1 Leneva injection.

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Case 5 — Reconstruction after 4th and 5th Ray Amputation



Patient Information

- 46 year old male insulin-dependent diabetes mellitus and HbA1c of 9.6 and no other pertinent medical problems.

Initial Examination / Wound History

- Patient was febrile to 101.3°F with soft tissue emphysema and grossly infected wound right foot 4th metatarsal head. The wound was there for several weeks and the fever started 4 days prior to the hospital admission.
- Diabetic foot ulcer 2cm x 1cm x 1cm with positive probe to bone. Base was fibronectic with active purulence and malodor.
- Initial consultation and surgery date was 4/30/19. Initial surgery was incision and drainage right foot with amputation of 4th and 5th metatarsal heads and respective toes. Deep wound cultures were obtained of soft tissue and bone. Clean cut bone culture and biopsy were also obtained of the 4th and 5th metatarsal shafts.
- 2nd Procedure on 5/3/19 for repeat debridement application of SomaGen Meshed graft and application of negative pressure wound VAC therapy.
- The decision to use a graft on the second procedure was to facilitate bone coverage and expedite growth of granulation tissue once we had cleared the infection.



Initial Wound - 4/30/19



Initial Treatment



Application of SomaGen - 5/3/19

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Case 5 — Reconstruction after 4th and 5th Ray Amputation



Treatment

- 4/30/19: Incision and drainage with partial ray resections of 4 and 5. IV UNASYN started and methicillin sensitive staphylococcus aureus isolated. Wound packed with 0.25 sodium hypochlorite twice daily until second operating room debridement.
- 5/3/19: Debridement and application of 6cm x 8cm SomaGen Meshed graft applied with sutures and negative pressure wound vac therapy at -125mmHg continuous changed weekly for three weeks after SomaGen Meshed application. Then VAC changes performed Mon/Wed/Fri.
- Treatment regimen included strict non weight bearing for three weeks followed by heel weight bearing in surgical shoe.

Outcome

- Complete wound healing 7/17/19.
- Time to heal = 10 weeks 5 days.
- Total number of grafts = 1 SomaGen Meshed.



Week 1 - 5/9/19



Week 6



Week 10 - Wound Closure - 7/17/19

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