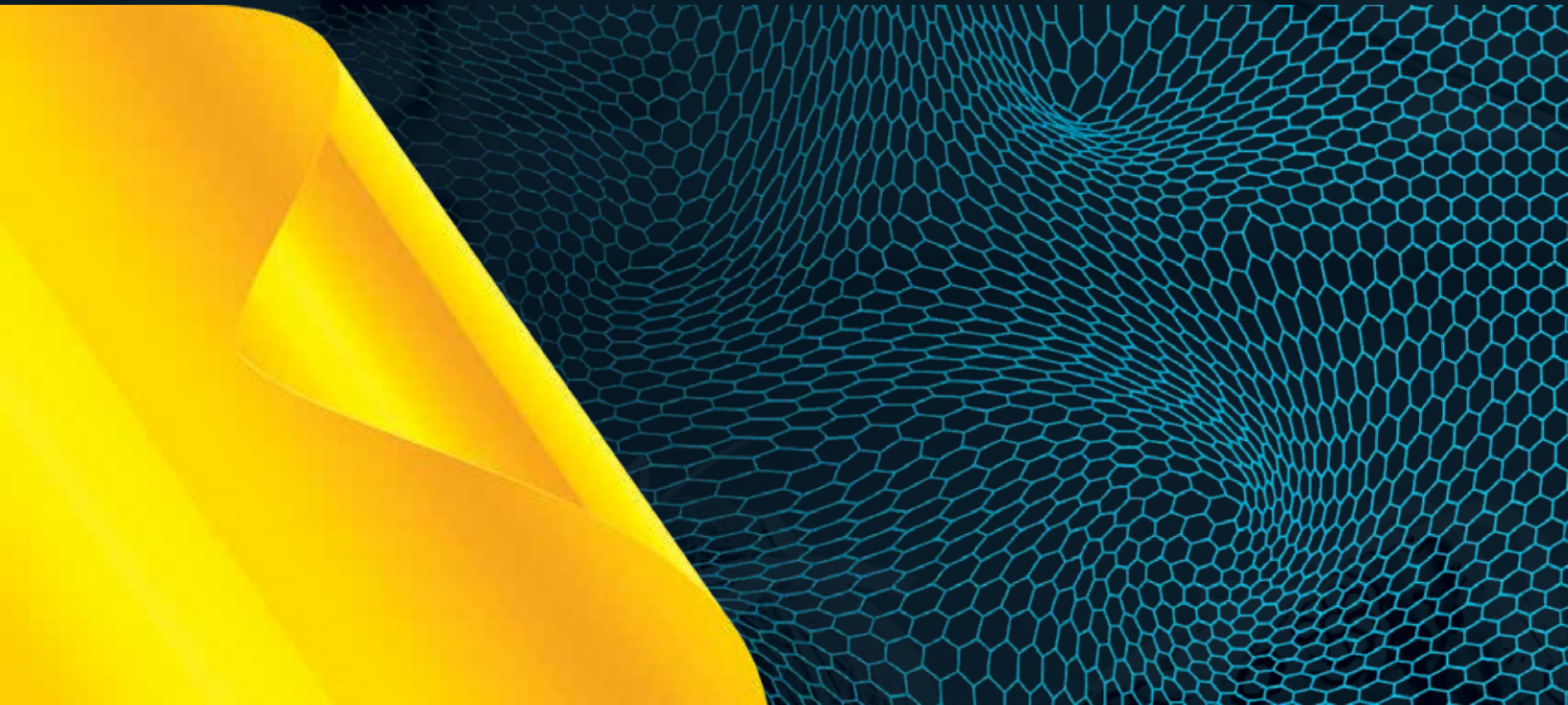


Microlyte[®]

BIORESORBABLE MATRIX



Provider Education White Papers and Case Reports

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Overview

Microllyte[®] Matrix is a synthetic resorbable wound matrix that comprises a polyelectrolyte multilayer (PEM) nanofilm of cationic polyallylamine hydrochloride and anionic polyacrylic acid, which together act as a functional molecular template to facilitate the granulation in the wound bed. The nanofilm matrix is coated with a 20-micron layer of polyvinyl alcohol (PVA) to provide moisture management and product handleability. The nanofilm matrix contains a low level of ionic and metallic silver (<25µg/sqcm) to prevent microbial contamination and colonization of the matrix. This report summarizes the efficacy of silver-loaded PEMs on wound closure and provides a brief description of why Microllyte[®] Matrix works so well in assisting wound healing.

The Polyelectrolyte Multilayer Matrix

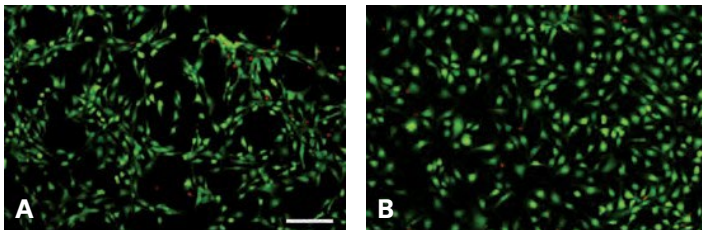


Figure 1. The PEMs which comprise Microllyte[®] Matrix act as a scaffold to support mammalian cell growth. A) As expected, cells grow on a glass surface (not treated with silver-loaded PEMs). B) Interestingly, the same cells spread more easily on silver-loaded PEMs. This suggests that skin cells may grow more evenly on silver-loaded PEMs leading to re-epithelialization of a wound.

The PEMs Matrix and Wound Healing

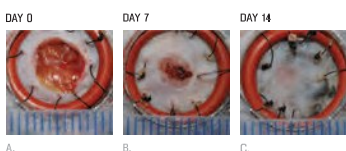
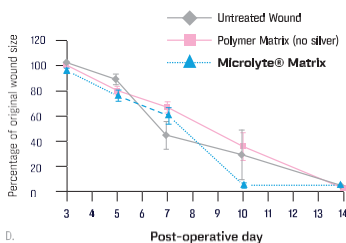


Figure 2. Mouse skin cells grow on silver-treated PEMs leading to re-epithelialization of a full-thickness wound. (A-C) Mouse wounds treated with Microllyte[®] Matrix close faster and more completely compared to control PEMs without silver or untreated wounds. (D) Quantification of wound closure over time.



Why are silver loaded PEMs so effective?

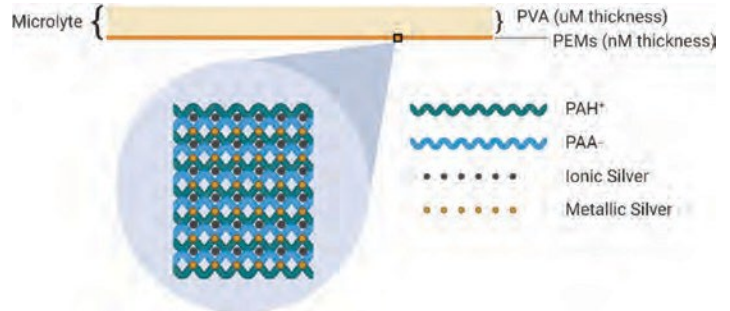


Figure 3.

- ▶ The PEM component of Microllyte[®] Matrix contains both anionic and cationic charged polymeric components which serve to shield approaching granulation cells from the generally disorganized surface chemistry common to wound beds.
- ▶ This masking provides a functional molecular matrix or template to facilitate the granulation process in the healing wound.
- ▶ The structure and charge of the PEMs allows for a low, but precise level of silver to be incorporated into the multilayer to provide gentle, but effective antimicrobial activity in the wound.
- ▶ The hydrophilic and biocompatible polyvinyl alcohol (PVA) in Microllyte[®] Matrix maintains a physiologically moist microenvironment in the wound, which further facilitates wound healing.

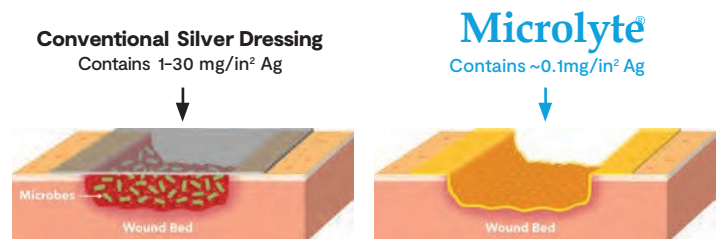
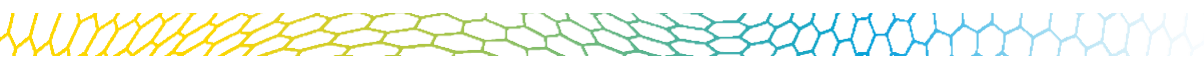
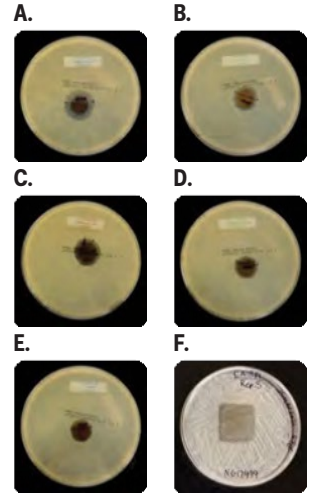
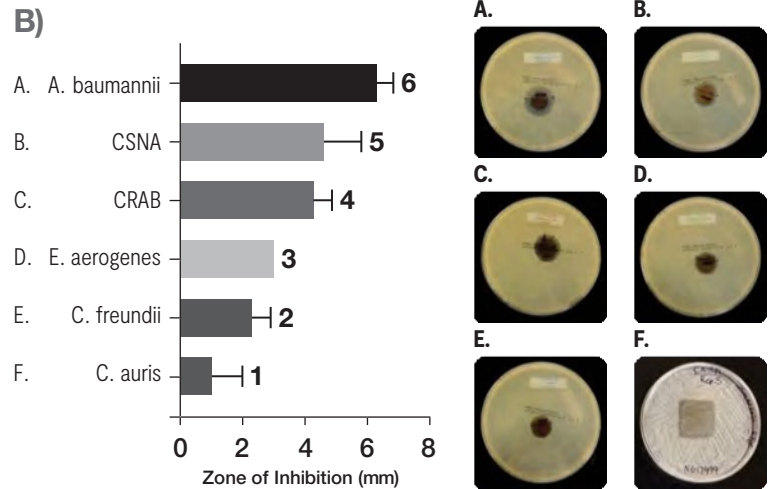
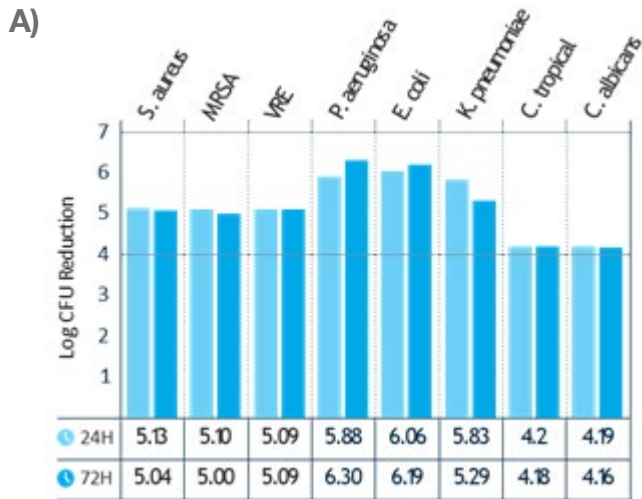


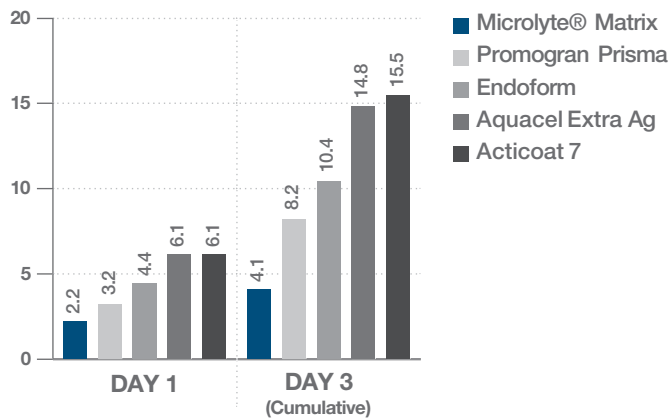
Figure 4. Microllyte[®] Matrix absorbs into the wound, changing the terrain within the wound bed. Microllyte[®] Matrix adheres to the wound bed, right where its matrix function is needed, while conventional matrices sit above the wound bed leaving space for microbes to hide and potentially flourish. Microllyte[®] Matrix creates a keratinocyte- and fibroblast-friendly environment that allows for faster and more complete wound closure.



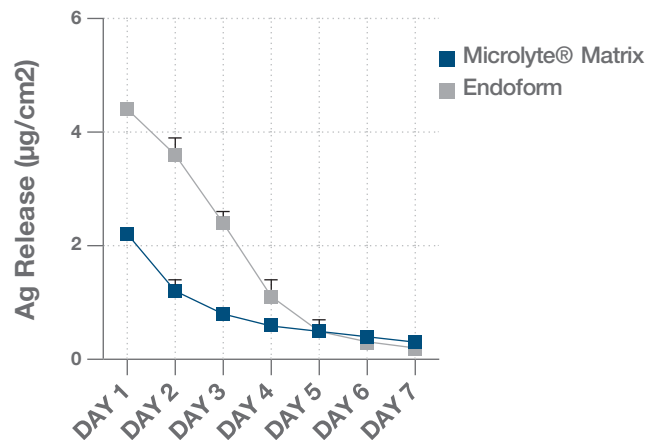


MicrolYTE® Matrix is 99.99% effective against a broad spectrum of wound-related microbes (A), and suspends low levels of ionic and metallic silver, at the interface between the burn and the matrix providing the burn wound with a powerful antimicrobial^{1,2}. Zone of inhibition studies show that MicrolYTE® Matrix has antimicrobial activity against microbes emerging as drug resistant (B).

3-Day Silver Release Profiles



7-Day Silver Release Profiles



MicrolYTE® Matrix maintains full strength for at least three days (C), and the addition of ionic and metallic silver provides rapid, effective, and sustained antimicrobial activity¹. In vitro tests show that MicrolYTE® Matrix releases a low, but effective amount of Ag⁺ daily over a 7-day period which is approximately half as much Ag⁺ as Endoform® (D).

References: ¹A Agarwal, et al., Biomaterials, 2010. 31(4): p. 680-690. ²M Herron, et al., Advanced healthcare materials, 2014. 3(6): p. 916-928.



Treatment for Stalled Radiation Head Wound

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Patient Presentation

- ▶ In January 2020, a 77-year-old male presented with a large (11cm x 14cm) radiation wound at top of his head after finishing radiation therapy in December 2019.
- ▶ Wound had been open for 1 month, and patient was in constant and severe pain.
- ▶ Wound was especially sensitive to touch, and no pain treatment was effective.
- ▶ Dressing changes took 45 minutes to an hour and involved multiple clinicians taking turns to slowly remove the dressing.
- ▶ Patient had difficulty sleeping.

Failed Therapy

- ▶ ADAPTIC TOUCH^a
- ▶ Mepitel[®]
- ▶ Xeroform^a

Procedure & Treatment

- ▶ Scalp was irradiated and debrided for second intention healing.
- ▶ Microlyte[®] Matrix was then tiled over the entire surface of wound, then covered with ADAPTIC TOUCH^a
- ▶ Microlyte and ADAPTIC TOUCH^a were reapplied on day 3.
- ▶ Patient was then assessed on day 4, day 14, then weekly until week 16.

Clinical Outcome

- ▶ After just **4 days of Microlyte[®]** treatment, the patient's wound decreased from 11cm x 14cm to 8.5cm x 10.5cm, a **42% reduction**.
- ▶ Patient reported slight pain at dressing removal, and no pain at all during and after Microlyte[®] application.
- ▶ Patient was able to sleep for the first time in months.
- ▶ Importantly, the wound did not become infected.
- ▶ On day 14, wound tissue showed increased granulation and decreased exudate.
- ▶ At 16 weeks, the wound decreased to 3.5 cm x 4 cm, a **91% reduction** from day 1.

Conclusion

- ▶ Post-irradiated tissue over a large surface area is notoriously difficult to treat and is prone to infection.
- ▶ Radiation wounds often turn into chronic ulcers, because of difficulty containing radiation treatment to malignant cells without damaging surrounding healthy cells.
- ▶ In this case study, we demonstrate that Microlyte[®] was able to close a large radiation wound by 42% in 4 days after previous treatment failed to close patient's wound.
- ▶ In addition to efficacy, Microlyte[®] use was painless and allowed the patient to sleep, thereby increasing his quality of life.
- ▶ **Microlyte[®] and ADAPTIC TOUCH^a worked together to jump-start patient's wound-healing process and shows promise in treating difficult-to-treat radiation chronic ulcers.**

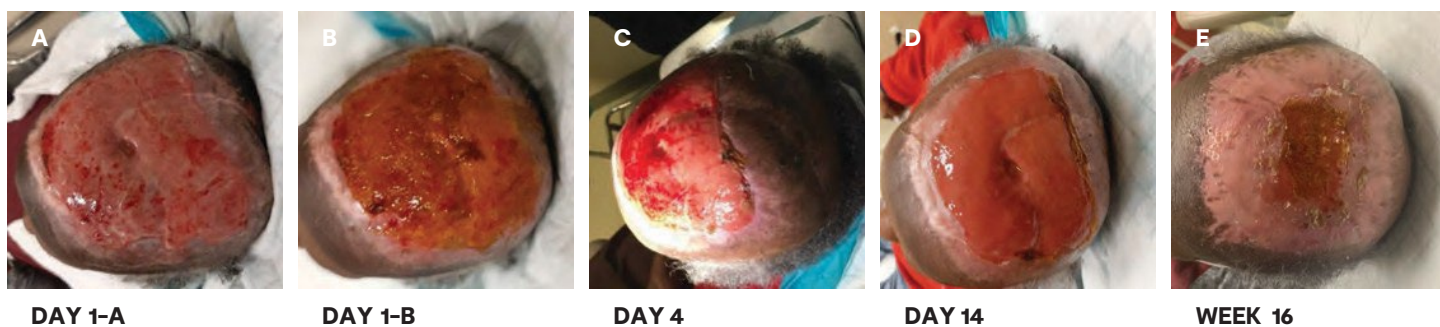


Figure 1: Patient presented with an excised scalp wound that was irradiated and debrided for second intention (A). Microlyte[®] was applied over the entire surface of wound (B), and then reapplied on the 3rd day (figure not shown). Wound closed 42% over 4 days (C) and demonstrated new granulation tissue and decreased exudate on day 14 (D). At 16 weeks, the wound decreased to 3.5 cm x 4 cm, A 91% reduction from day 1 (E).

Patient Presentation

▶ An 18-month-old female patient presented with first- and second-degree scalds to the left face, ear, neck, and shoulder covering 8% TBSA after an accident with a cup of hot coffee. On hospital admission, she was treated with a topical antibiotic ointment.

Adjunct Therapy

- ▶ Collagenase
- ▶ Antibiotic ointment
- ▶ AmnioBurn[®]
- ▶ Adaptic[®]
- ▶ VersaJet[®]

Procedure & Treatment

- ▶ On post-burn day 2, Microlyte[®] Matrix was used as the contact layer on the facial burn and left ear, and her shoulder wound was treated with collagenase and antibiotic ointment.
- ▶ All wounds were covered with Adaptic[®], and the head wound was also covered with a head wrap.
- ▶ On post-burn day 5, her shoulder burn and a 1 cm x 1 cm area on her neck were debrided in the OR, treated with AmnioBurn[®], covered with Adaptic[®], and then wrapped.

Clinical Outcome

- ▶ On post-burn day 5, and 3 days after Microlyte[®] Matrix application, both facial and ear wounds were 98% healed.
- ▶ The patient was seen on post burn day 10 and the face and ear were fully healed with improved re-pigmentation.
- ▶ On face and ear: Microlyte[®] Matrix was almost fully bioresorbed with a few areas with intact Microlyte[®] Matrix present, which easily flaked off without any trauma to healed wound.
- ▶ Patient was 100% healed with near-normal pigmentation on post-burn day 22.

Conclusion

- ▶ On face and ear: Microlyte[®] Matrix was almost fully bioresorbed with a few areas of intact Microlyte[®] Matrix present, which easily flaked off without any trauma to healed wound.
- ▶ The ear is a difficult area to dress and Microlyte[®] Matrix performed well, conforming to the intricate three-dimensional anatomy in this area.
- ▶ Secondary dressings were unnecessary although applied due to the age of the patient and the need to dress other areas.
- ▶ On neck and shoulder, due to the depth of the burn, Microlyte[®] Matrix was not used. Collagenase was used to debride and then amnion-chorion was applied.



Figure 1: Three days after Microlyte[®] Matrix application, both facial and ear wounds were 98% healed. The patient was seen on post burn day 10 and the face and ear were fully healed with improved re-pigmentation. Patient was 100% healed on post-burn day 22. Microlyte[®] Matrix was not used on shoulder and neck.

Treatment for Chronic Contaminated Wound After Total Thyroidectomy

Thea Price, MD

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Microlyte[®]
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Patient Presentation

A 59-year-old woman presented in May 2018 with delayed tracheal injury and perforation with abscess after total thyroidectomy for cancer. She returned to the OR for drainage and muscle flap complicated by dehisced surgical site infection. Comorbidities included: **papillary thyroid adenocarcinoma**

Failed Therapy

- ▶ Failed surgical repair with muscle flap

Procedure & Treatment

- ▶ Tracheal perforation closed with muscle flap
- ▶ Cultures: Group A Streptococcus Pyogenes
- ▶ Initial Thyroidectomy 5/21/2018
- ▶ Debridement and muscle flap 5/29/2018
- ▶ Microlyte applied at weekly evaluations
- ▶ Non-excisional debridement during weekly evaluations
- ▶ Secondary dressing with PICO vacuum
- ▶ No additional dressing changes at home
- ▶ No oral or topical antibiotics were administered

Clinical Outcome

By the first follow-up at Day 7, the wound had closed by ~90% based on wound volume (Figure 1B). Nine days later, the wound had closed by 98% (Figure 1C) and Microlyte was applied. At the 4-week follow-up, the wound was fully closed. The wound remained healed and patient retains only a small scar in the site of the original wound.

Conclusion

Faster and more complete closure of a chronically infected wound was achieved by application of Microlyte than was achievable with other failed therapies. This patient had multiple risk factors for postoperative surgical site infection including poor glycemic control, polymicrobial infection, and ongoing tobacco abuse. Microlyte applied weekly was associated with a positive outcome and this patient was able to resume a normal lifestyle, including attending her own wedding without the need for a bandage on her neck.



Figure 1: Accelerated wound healing in infected, malignant, and radiated chronic plateaued wound after total thyroidectomy. Microlyte was applied to wound 9 days post-surgery (A). After one week (B), the wound had closed by 90% (volume). Nine days later Microlyte was applied again, at which point the wound was 98% closed (C). Complete wound closure was achieved with 28 days (D). Four months post operatively, only a small amount of scarring was visible (E). Microlyte was reapplied at each evaluation. All secondary dressings were standard per clinician preference and wound characteristics.

Patient Presentation

A 67-year-old diabetic male presented 10 weeks status post coronary artery bypass graft (CABG) surgery.

Adjunct Therapy

- ▶ NPWT
- ▶ ABD pad
- ▶ Medipore tape

Treatment

- ▶ Patient was treated with NPWT for 10 weeks after CABG procedure.
- ▶ Once wound edges were approximated, Microlyte[®] Matrix was applied as the contact layer, followed by an ABD pad which was then secured with Medipore tape.
- ▶ Microlyte[®] Matrix was changed twice per week for 6 weeks.
- ▶ At initial application of Microlyte[®] Matrix, hypergranulation with moderate bleeding was noted.

Clinical Outcome

There was no incidence of infection due to optimal bioburden management, and re-epithelialization was achieved in 6 weeks.

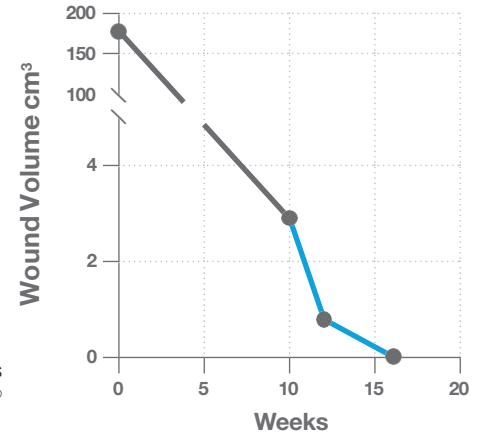


Figure 1. Bright blue lines indicate period of Microlyte[®] Matrix treatment.

Conclusions

- ▶ During the proliferation phase of wound healing; granulation and re-epithelialization process is often delayed or stalled due to bacterial contamination.
- ▶ Microlyte[®] Matrix successfully managed wound bioburden, and moisture control through optimal vapor transfer rate, and resulted in faster re-epithelialization and wound closure.

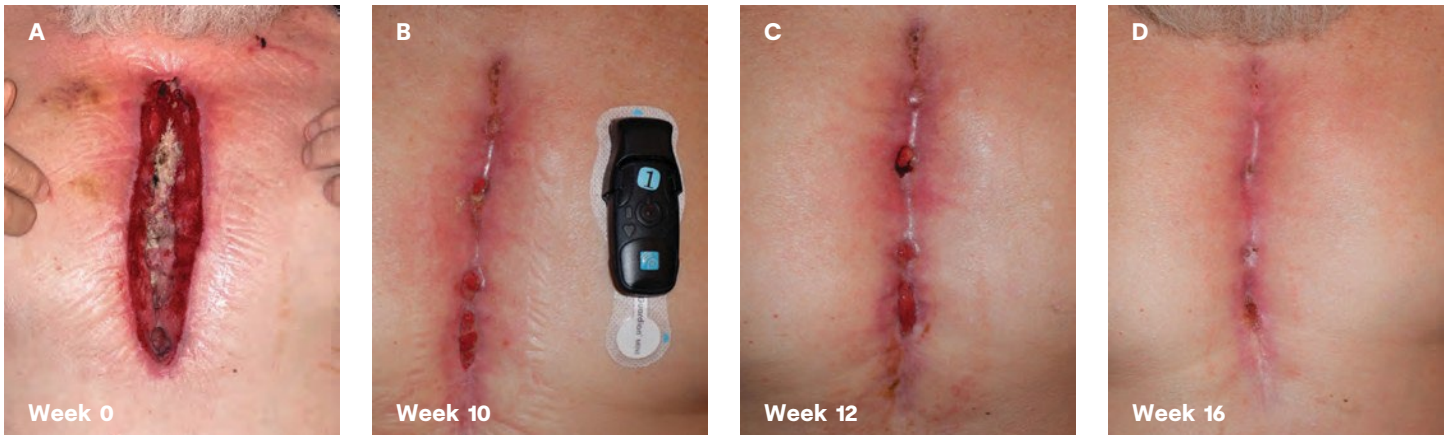


Figure 2: Wound healing progression of a post-CABG chest wound over 16 weeks. Microlyte[®] Matrix was applied from week 10 to week 16.



Radiation Breast Wound

Amanda Murray, NP-C, MSN, WCC
Great Falls Clinic Wound Care Center,
Great Falls, Montana

Patient Presentation

- ▶ A 65-year-old female patient presented with a 78 cm³ (17.2 x 11.4 x 0.4 cm) chronic ulcer that was open for 3 months after radiation treatment of the right breast.
- ▶ The patient was not a candidate for skin graft or rotational flap, so her wound was debrided after radiation to initiate wound healing.
- ▶ After debridement, conservative wound management with daily dressing changes were maintained for 1 month.

Adjunct Therapies

- ▶ Non-adherent silicone dressing
- ▶ ABD pad

Procedure & Treatment

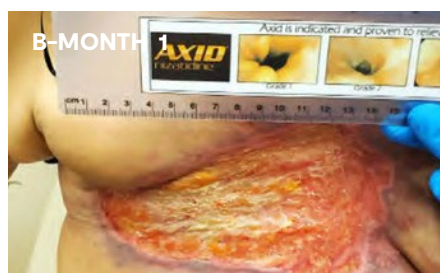
- ▶ One month after debridement, Microllyte[®] Matrix was applied weekly for 5 consecutive weeks.
- ▶ At week 6, the patient continued conservative wound management and daily dressing changes.
- ▶ At month 6, she returned to the clinic where she was again treated with Microllyte[®] Matrix.
- ▶ She was treated with Microllyte[®] Matrix monthly for 5 more months.

Clinical Outcome

- ▶ After 5 weeks of Microllyte[®] Matrix, the patient's wound became responsive to conservative wound therapy, leading to wound closure of 74% (11.4 x 8.8 x 0.2) approximately 5 months later.
- ▶ Five months later, with monthly application of Microllyte[®] Matrix the wound measured 4.2 x 3.4 x 0.1 (1.43 cm³) a 98% reduction in wound surface area.
- ▶ The patient reported less drainage and odor, and a subsequent reduced need for multiple dressing changes.
- ▶ Furthermore, application of Microllyte[®] Matrix on the wound was painless.
- ▶ Notably, Microllyte[®] Matrix allowed the patient to have fewer visits to clinic which was a 2-hour round trip.

Conclusion

- ▶ Post-irradiated tissue over a large surface area is notoriously difficult to treat and is prone to infection.
- ▶ Radiation wounds often turn into chronic ulcers, because of difficulty containing radiation treatment to malignant cells without damaging surrounding healthy cells.
- ▶ Microllyte[®] Matrix was well tolerated, effective, and improved the patient's quality of life.
- ▶ Microllyte[®] Matrix along with standard moisture management wound dressings show promise in treating difficult-to-treat radiation chronic ulcers.



A. The patient presented with a post-irradiated wound. **B.** Wound was prepped for microllyte, and Microllyte was applied for 5 consecutive weeks. **C.** At 6 months, the wound is reduced by 74%. **D-F.** Wound continues to close until it is 98% healed D-F.



Treatment of Epidermolysis Bullosa

Angela Gibson, MD

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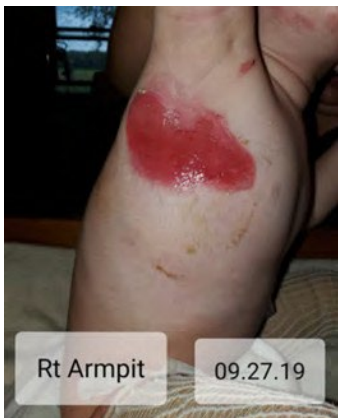
Patient Presentation

- ▶ In September 2019, a 2-year-old boy with epidermolysis bullosa (EB) presented with a partial-thickness armpit blister.
- ▶ After 2 days of standard-of-care treatment, his armpit turned into a full-thickness blister, resulting in a macerated wound.
- ▶ Microlyte[®] was suggested as an alternate therapy, and permission was granted 5 days later, during which time one more standard-of-care dressing change occurred.

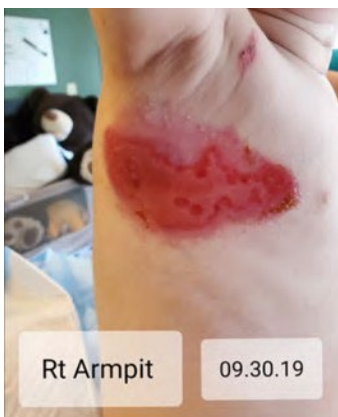
Procedure & Treatment

- ▶ Microlyte[®] was applied at days 1, 3, 4, 10 and 12 in combination with Kurlex gauze bandages

DAY 1



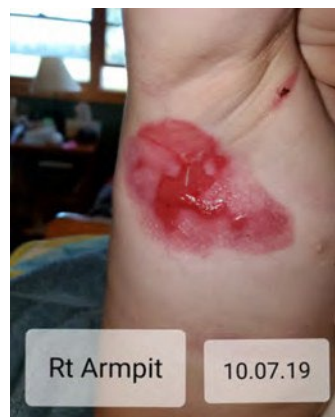
DAY 3



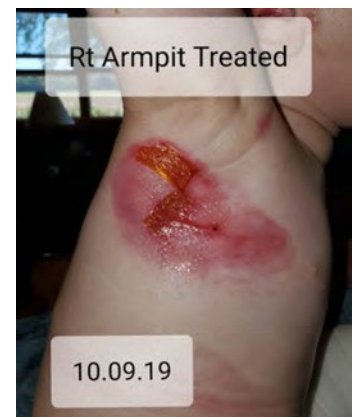
DAY 4



DAY 10



DAY 12



Clinical Outcome

- ▶ Treatment with Microlyte[®] appeared to contribute to significant closure of the EB blister wound.
- ▶ EB is a rare genetic disease of connective tissue that involves severe blistering of the skin from minor damage such as heat, rubbing, scratching or adhesive tape removal.
- ▶ In addition to enduring daily painful dressing changes, EB patients are at constant risk for infection and sepsis due to multiple open wounds.
- ▶ Because there is no cure, treatment focuses on caring for blisters, preventing new ones and protecting non-blistered skin.
- ▶ Microlyte[®] application to a severe full-thickness blister, lead to unprecedented improvement in patient's wounds.
- ▶ Importantly, because Microlyte[®] is completely bioresorbable, the matrix did not need to be removed, resulting in decreased pain and increased quality of life.
- ▶ Microlyte[®] shows promise as an adjunct therapy for patients with partial- and full-thickness wounds arising from epidermolysis bullosa.



Patient Presentation

- ▶ A 33-year old diabetic woman presented with a left arm MRSA-positive abscess in December 2017.
- ▶ Patient also had medical history of ongoing tobacco abuse and recurrent necrotizing soft-tissue infections.
- ▶ The abscess was drained and required multiple debridement procedures.
- ▶ As a result, patient was left with chronic wound with exposed bicep tendon.
- ▶ Attempted split-thickness skin-graft placement in January 2018 failed.

Failed Therapy

- ▶ Negative pressure wound therapy
- ▶ Intravenous antibiotics
- ▶ Surgery

Procedure & Treatment

- ▶ Exposed biceps tendon was covered with transparent Microllyte[®] Matrix .
- ▶ Microllyte[®] Matrix was used to manage the surgical wound, which was closed via Z-plasty.
- ▶ No oral or topical antibiotics were administered.
- ▶ Oral or topical antibiotics were not administered

Clinical Outcome

- ▶ By post-operative day 4, there was no sign of infection.
- ▶ By day 14, the wound was well-healed, and sutures were taken out.
- ▶ The wound remained healed and patient regained range of motion in her left elbow.

Conclusion

- ▶ Faster and more complete closure of a chronically infected wound was achieved by surgical wound management using Microllyte[®] Matrix compared to other failed therapies. This patient had multiple risk factors for postoperative surgical site infection including poor glycemic control, poly-microbial infection, and ongoing tobacco abuse.
- ▶ At the time of surgery Microllyte[®] Matrix was well tolerated and associated with a positive outcome.
- ▶ Microllyte[®] Matrix shows promise in the management of surgical wounds in at-risk patient populations.

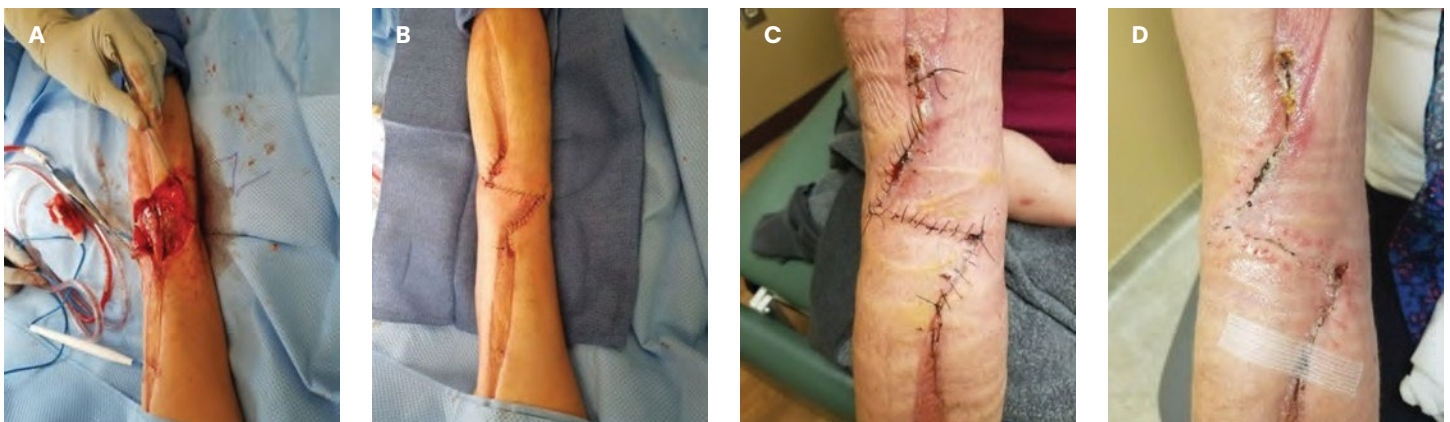
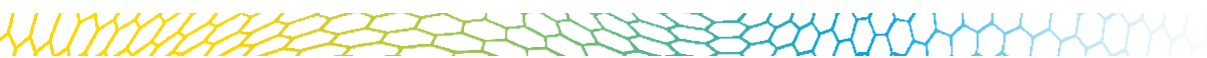


Figure 1: A. Microllyte[®] Matrix is applied to surgical wound. B. Surgical wound is closed via Z-plasty. C. Surgical wound is healing and free of infection. D. Healing has progressed over 14 days and sutures have been removed.



Patient Presentation

- ▶ In April of 2020, a 56-year-old female presented with an incarcerated ventral hernia which led to necrosis of the strangled intestinal tissue and abdominal wall.
- ▶ Consequently, she was in septic shock.
- ▶ Extensive intestinal and abdominal surgery was performed to remove necrotic tissue and fix hernia.
- ▶ Intestines were reattached using the stapled ileocolonic anastomosis method.
- ▶ Delayed wound closure and healing by secondary intention was chosen to monitor for infection before closing.

Adjunct Therapies

- ▶ NPWT
- ▶ Systemic antibiotics

Procedure & Treatment

- ▶ After extensive intestinal surgery, 14 pieces of Microlyte[®] Surgical 4"x 4" sheets were placed on the wound and left to heal by second intention for approximately 2 weeks.
- ▶ When wound was confirmed as infection free, then closed with sutures.
- ▶ A wound vac was placed to manage drainage and promote healing.
- ▶ Wound was checked approximately once a month, for 3 more months.

Clinical Outcome

- ▶ One month after abdominal closure, patient's incisional sutures were still in place and wound vac still secure. Some undermining was noted.
- ▶ One month later, patient continued to do well, and undermining was resolved. Exudate was minimal and free of purulence.
- ▶ At month three, she continued to improve with only lateral aspects of the wound open. NPWT was continued. No drainage or erythema was observed.
- ▶ Patient is free of infection and wound is greater than 90% healed with small lateral aspects remaining open which is being treated with Microlyte[®] Matrix .

Conclusions

- ▶ Ventral hernia repairs have an SSI rate of up to 23%, and incarcerated hernias are associated with a poor prognosis. Necrotizing infections are severe conditions with a high mortality rate due to sepsis and the subsequent multi-organ failure. And bowel resection, as this patient experienced, adds another layer of risk.
- ▶ The addition of Microlyte[®] Matrix to the surgical protocol may have been instrumental in controlling the bioburden of the wound, thereby allowing the wound to progress out of the inflammatory stage and onto healing.
- ▶ **Microlyte[®] Matrix shows promise as an adjunctive therapy when healing by second intention is indicated.**

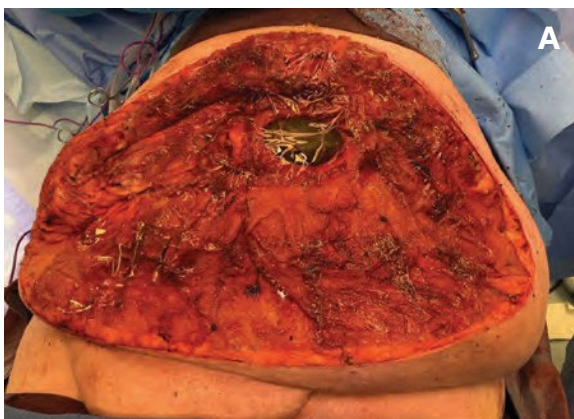
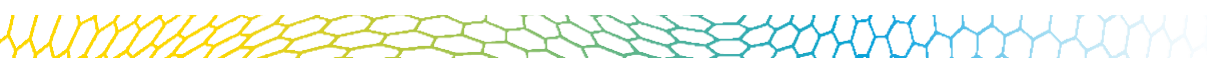


Figure 1.

A. 14 sheets of Microlyte[®] Matrix were used as the primary dressing after debridement.

B. Wound is greater than 90% healed and free of infection



Patient Presentation

- ▶ A 23-year-old male patient presented with an inflamed non-healing pilonidal cyst complicated by fistula that was re-occurring and/or open for approximately 4 years.
- ▶ Following his fourth and most recent wide excisional debridement, his full thickness wound measured 259 cm³.
- ▶ The patient reported pain at the surgical site and was given oral pain medication accordingly.
- ▶ Microllyte[®] Matrix was used to support growth of granulation tissue within his cavernous wound, promote re-epithelialization, and manage wound bioburden.

Previous Treatments

- ▶ Antibacterial foam dressing
- ▶ Betadine wet to dry
- ▶ Chemical cautery



Figure 1: A-H Healing progression of pilonidal cyst treated with Microllyte[®] Matrix and NPWT over 17 weeks.

Procedure & Treatment

- ▶ The patient's wound dressing was changed every 2 to 5 days over a 17-week period and was treated with the Matrix at each dressing change.
- ▶ Negative pressure wound therapy (NPWT) was placed at week 2 and reapplied every 2 to 5 days until week 4.
- ▶ The patient was also nutritionally supplemented with antioxidants and amino acids to further support wound healing.

Clinical Outcome

- ▶ After 1 week of Microllyte[®] Matrix treatment, the patient's wounds closed by 15%, and by week 2, his wound closed by 50%.
- ▶ One week after NPWT was added to his treatment plan; the patient's wound decreased by 80%, measuring 54 cm³.
- ▶ At week 17, the patient's wound measured 0.04 cm³, a 99% decrease in wound volume.
- ▶ Importantly, the patient reported decreased pain at the surgical site and his wound did not become infected, despite the heavy contamination of exit zones.

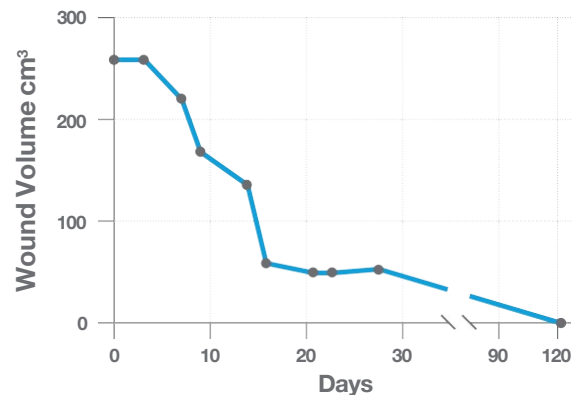
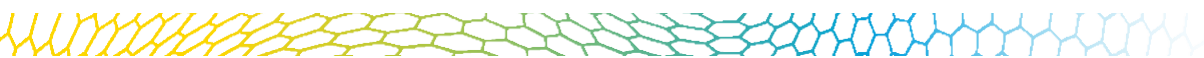


Figure 2. Graphical depiction of healing progression over 17 weeks. Bright blue lines indicate period of Microllyte[®] Matrix treatment.

Conclusions

- ▶ After 4 years of wound chronicity, Microllyte[®] Matrix was able to close this patient's wound by 99% in 17 weeks, and significantly reduced the patient's levels of pain.
- ▶ Microllyte[®] Matrix therefore shows promise as an adjunct therapy in treating chronic pilonidal cysts.



Patient Presentation

A 22-year-old woman presented in Feb 2017 with a pilonidal cyst. The cyst was removed surgically. The patient had no comorbidities.

Failed Therapy

- ▶ Failed surgical repair
- ▶ Dakin's antiseptic solution
- ▶ Compression
- ▶ Mupirocin
- ▶ Negative pressure wound therapy (NPWT)
- ▶ Wound remained non-healing for 31 days

Treatment

- ▶ Microllyte applied twice during the first week and at weekly evaluations, thereafter
- ▶ NPWT was administered in conjunction with Microllyte
- ▶ The wound did not require debridement during weekly evaluations
- ▶ Neither oral or topical antibiotics were administered

Clinical Outcome

The initial size of the stalled surgical wound was 6.9 cm². After only 1 week of treatment (two applications of Microllyte), the wound size decreased by 46%. Additional weekly treatments with Microllyte in conjunction with NPWT closed the wound by 94% in 3 weeks and 98% in 6 weeks.

Conclusion

Faster and more complete closure of a chronically wound resulting from surgery was achieved by application of Microllyte and NPWT than was achievable with other failed therapies. Microllyte, applied weekly, was associated with a positive outcome, however, it is likely that if Microllyte had been used in the post-surgical management of the wound the infection could have been avoided.



Figure 1: Accelerated wound healing in stalled wound after surgical removal of a pilonidal cyst. Microllyte was applied to wound 31 days post-surgery (A). After one week (B), the wound had closed by 46%. One week later Microllyte was applied again, at which point the wound was 65% closed (C). After 3 weeks treatment, 94% wound closure was achieved(D). An additional weekly treatment for 3 resulted in 98% closure of the wound (E). Microllyte was reapplied at each evaluation. Negative pressure wound therapy was used in conjunction with Microllyte at each application.



Patient Presentation

- ▶ A 20-year-old male presented with non-circumferential, 2nd degree burns on the posterior and anterior of his lower left leg.
- ▶ His burn was caused by a vape pen that exploded in his pocket, 30 minutes prior to hospital admission.
- ▶ Patient was in a significant amount of pain and was given Dilaudid for inpatient pain management.
- ▶ His wounds were sloughing, had copious amounts of soot, and covered approximately 4% of his total body surface area.
- ▶ Per hospital protocol, his wounds were treated with standard of care: his wounds were irrigated, treated with silver sulfadiazine, then covered with a non-occlusive dressing, followed by a final sterile dressing.
- ▶ Patient was prescribed ibuprofen and Percocet for outpatient pain management and was scheduled for burn debridement and Microllyte[®] Matrix treatment in 2 days.

Adjunct Therapies

- ▶ Silvadene Cream
- ▶ Saline
- ▶ Kerlix Gauze
- ▶ Ace Wrap

Procedure & Treatment

- ▶ On the day of burn debridement, the patient's wounds were scrubbed under general anesthesia.
- ▶ Microllyte[®] Matrix was then placed directly on top of the debrided wound.
- ▶ The Microllyte[®] Matrix-covered wounds were then covered with Kerlix gauze and finished with an Ace wrap.

Clinical Outcome

- ▶ Seven days after debridement and Microllyte[®] Matrix treatment, the patient reported that the wound felt much better.
- ▶ All wounds were dry, healing remarkably well, with epithelium fully intact.
- ▶ Patient was no longer in pain.

Conclusion

- ▶ Second-degree burns usually reepithelialize in 2 to 3 weeks¹, however, **after just 1 application of Microllyte[®] Matrix, the patient's wounds were fully reepithelialized in 7 days.**
- ▶ Microllyte[®] Matrix was well-tolerated and associated with a positive outcome.
- ▶ Microllyte[®] Matrix shows promise in the management of 2nd degree burns.

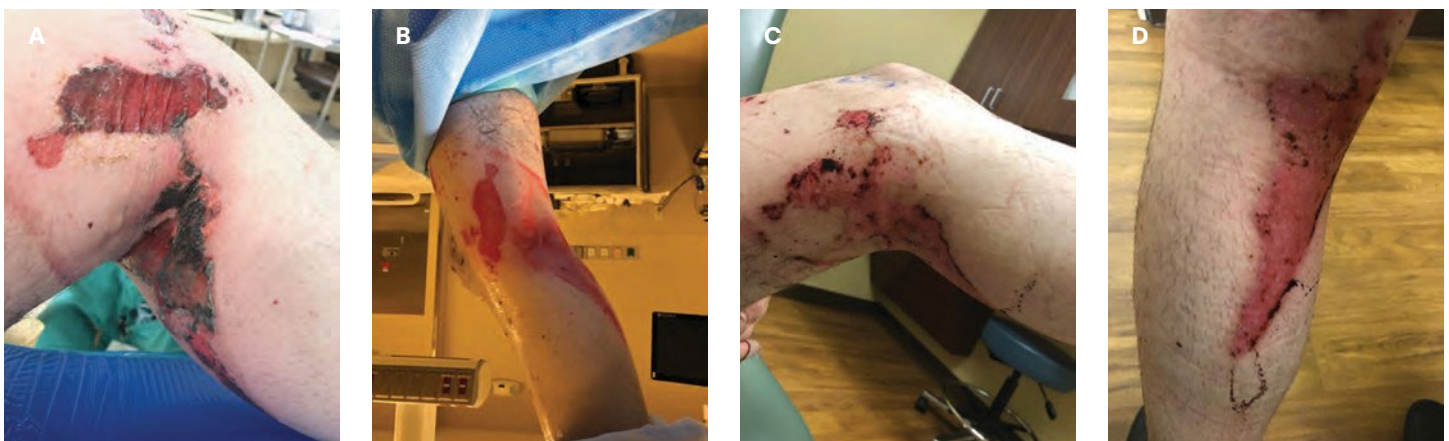


Figure 1: **A.** Patient presents with 2nd degree burn wounds covered in slough and soot. **B.** Patient's wounds are debrided prior to covering with Microllyte[®] Matrix. **C and D.** Patient's burn wound is remarkably improved, and he is no longer in pain.

Patient Presentation

A 43-year-old woman presented in Jan 2017 with a stalled full-thickness burn wound. The patient had no comorbidities.

Failed Therapy

- ▶ Silvadene[®]
- ▶ Antibiotics
- ▶ Iodoflex[®]
- ▶ Silver foam
- ▶ Compression
- ▶ Wound remained non-healing for 35 days

Treatment

- ▶ Microlyte was applied at weekly evaluations for 12 weeks
- ▶ The wound did not require debridement during weekly evaluations
- ▶ Microlyte was covered with gauze
- ▶ Neither oral or topical antibiotics were administered

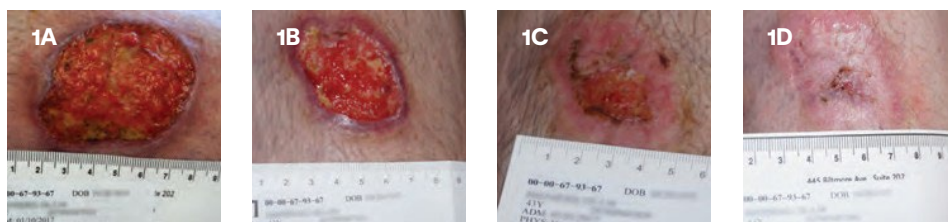


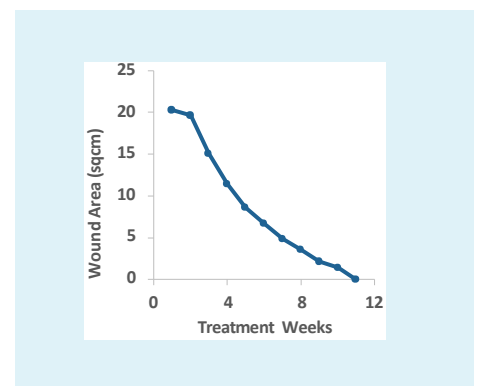
Figure 1: Accelerated wound healing in stalled burn wound. Microlyte was applied to wound after 35 days non-healing (A). After four weeks (B), the wound had closed by 53%. At eight weeks treatment, the wound was closed 85% (C). By 11 weeks treatment, complete (100%) wound closure was achieved (D). Upon application of Microlyte, the previously-stalled wound proceeded to complete closure at a steady pace (E).

Clinical Outcome

The initial size of the stalled full-thickness burn wound was 24.1 cm². After a single Microlyte treatment, the wound was reduced in size by 16%. Additional weekly treatments with Microlyte resulted in steady closure of the previously-stalled wound, until complete closure was achieved by the 11-week evaluation.

Conclusion

Faster and more complete closure of a chronic wound resulting from full-thickness burn trauma was achieved by application of Microlyte than was achievable with other failed therapies. Microlyte applied weekly was associated with a positive outcome. This patient avoided a costly skin-grafting procedure over a full-thickness burn wound, including an extended hospital stay and a potentially painful donor site.



Recalcitrant Shin Wound

Furqan Alex Khan, APRN ACNS-BC
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Patient Presentation

A 72-year-old diabetic female presented with a recalcitrant surgical wound that was stalled for 8 weeks on her left shin, which was associated with a fall.

Due to slow healing progression, the patient was referred to wound care.

Adjunct Therapy

- ▶ Non-Selective Debridement
- ▶ ABD pad
- ▶ Gauze roll

Procedure & Treatment

- ▶ Osteomyelitis was managed with IV Vancomycin for 8 weeks. Nonviable tissue was debrided utilizing sharp debridement with a 7mm dermal curette.
- ▶ Microllyte[®] Matrix was applied to the wound, followed by an ABD pad which was then secured with gauze roll and tape.
- ▶ Microllyte[®] Matrix was applied to the wound and the dressing was changed two (2) times each week for 3 weeks.

Clinical Outcome

- ▶ Microllyte[®] Matrix managed the bio layer effectively, maintained a protective layer over the wound margins, and thus facilitated epithelial cell migration and contraction.
- ▶ There was no incidence of infection, and wound closure was achieved in 3 weeks.

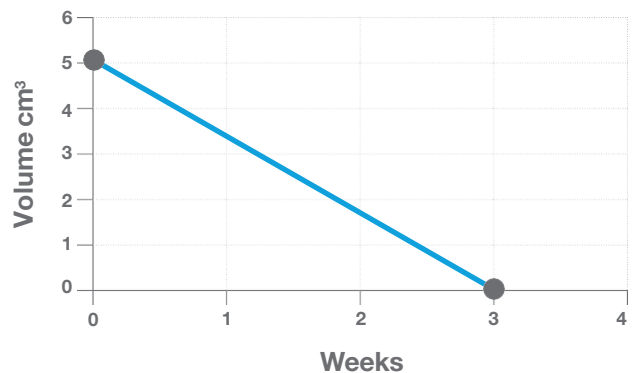


Figure 1. Bright blue lines indicate period of Microllyte[®] Matrix treatment.

Conclusions

Microllyte[®] Matrix has consistently proven to be an effective wound management dressing during the proliferation phase of wound healing from granulation to 100% re-epithelialization.



Figure 2: Healing progression of shin wound treated with Microllyte[®] Matrix after osteomyelitis was resolved.



Patient Presentation

- ▶ For some patients with venous leg ulcers, compression therapy is not enough; adjunctive therapy is necessary to aid in wound healing.
- ▶ Difficult to heal wounds can lead to decreased quality of life, increased healthcare costs, and other morbidity.
- ▶ Microllyte[®] Matrix has been shown to support cell growth and vascularization, thus improving wound healing, and a porcine derived 3-dimensional extracellular matrix allows for host cell migration.
- ▶ The simultaneous use of these products may lead to favorable healing results.
- ▶ Four patients with venous leg ulcers characterized as having bacterial impediment to healing were chosen to participate in this study.

Procedure & Treatment

- ▶ Patients had silver impregnated polymer film and porcine derived 3D extracellular matrix applied to their wounds weekly for 8 weeks followed by an additional 4 weeks of observation without product application to observe for synergistic effects on wound healing.
- ▶ Wound cultures were obtained at weeks 1,3, and 7.
- ▶ Primary endpoints were overall wound area reduction and treatment tolerance at 12 weeks.
- ▶ Secondary endpoints were percentage of wound closure at 12 weeks, change in wound characteristics, number of patients with closed wounds, and presence of bacteria.

Clinical Outcome

- ▶ Wound area reduction was observed in 4/4 patients.
- ▶ On average, there was a 44% decrease in wound area at 8 weeks.
- ▶ One patient achieved complete wound closure prior to receiving the 8th application of the product.
- ▶ There was also a decrease in bacteria present in the wound's of 2/4 patients, as reflected by wound culture data.
- ▶ Patients tolerated both products well without any adverse effects reported.
- ▶ Despite this patient group having wounds with a bacterial impediment to heal, patients experienced a reduction in wound size due to the use of the products.
- ▶ While many patients were not able to achieve complete wound closure, these products were effective in decreasing the bacterial burden of some of the wounds and improving overall wound healing.

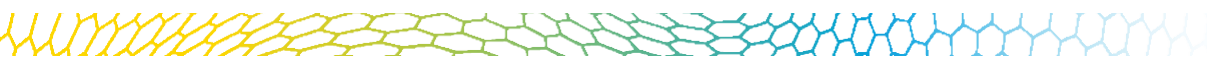
Conclusions

- ▶ The simultaneous use of both Microllyte[®] Matrix and collagen demonstrated favorable would healing results in the treatment of types of venous leg ulcers.
- ▶ Microllyte[®] Matrix, therefore, shows promise as an adjunctive therapy in the treatment of venous leg ulcers.



Figure 1: Healing progression of venous leg wound after 7 applications of Microllyte[®] Matrix and a porcine derived 3-dimensional extracellular matrix.

Case series reported at Mount Sinai Morningside-West, New York, NY, USA, 2021



Patient Presentation

A 80-year-old male presented July, 11 2018 with a venous stasis ulcer sized 11 x 9 x 0.3cm. Ulcer had been present for 36 months. Comorbidities included:

- ▶ Hypertension
- ▶ CVA with mild left hemiparesis
- ▶ Venous insufficiency/hypertension
- ▶ Cardiac disease
- ▶ CVI ulcer left LE x 7 years

Failed Therapy

- ▶ Debridement
- ▶ Compression therapies (Tubigrip[®], short stretch wraps, 2-layer compression hose, and Velcro closure devices)
- ▶ Vasopneumatic pump
- ▶ Multiple CTP applications

Procedure & Treatment

- ▶ Culture to confirm contamination conducted in wound clinic
- ▶ Initial Debridement of wound conducted weekly by provider
- ▶ Microllyte applied at evaluations 2-3x per week
- ▶ An absorptive pad was placed over Microllyte and was used in conjunction with a fuzzy wale compression stockinet (EdemaWear[®])
- ▶ Oral or topical antibiotics were not administered

Clinical Outcome

A 36-month old venous stasis ulcer (Fig. 1A) was treated with Microllyte and a novel compression garment. Using compression alone, the wound responded favorably (Fig. 1B). The addition of Microllyte, however, appeared to have a synergistic effect and the ulcer closed rapidly over a four-month period (Figs 1C-G). After 5 months of combined treatment with Microllyte and a compression stockinet, the venous stasis ulcer now .5 x .5 x .1 cm (99.9% reduction in wound volume) with islands of epithelium in the base. The margins are contracting and surrounding skin is remodeling scar tissue.

Conclusion

Faster and more complete closure of a venous stasis ulcer was achieved by application of Microllyte in conjunction with compression therapy using Edemawear[®] than was achievable with other failed therapies. This patient had significant comorbidities that had previously confounded healing of the venous stasis ulcer. The synergistic success of Microllyte and EdemaWear[®] suggest promise in the treatment of venous stasis ulcers.

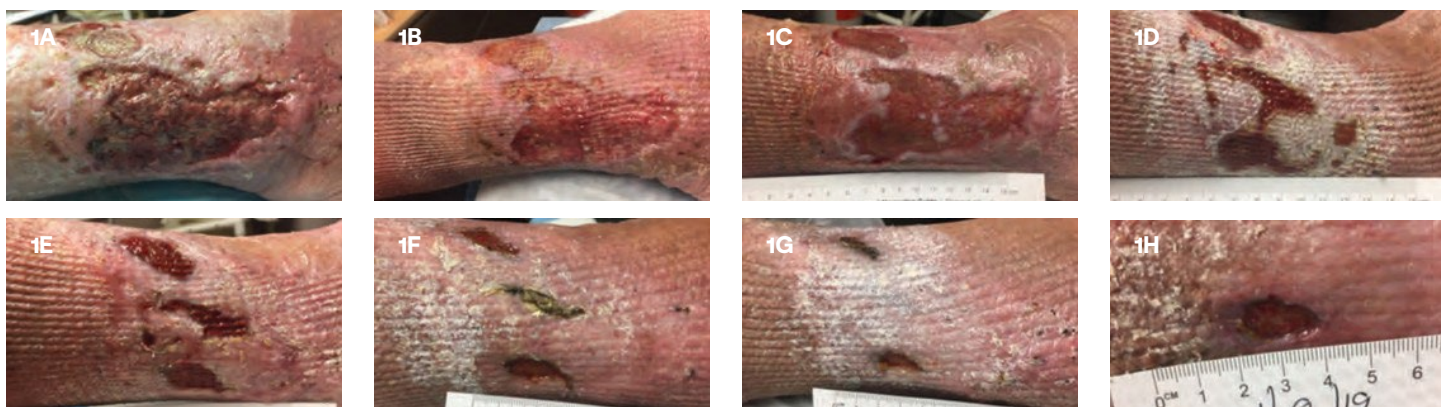


Figure 1: When wound presented, it had remains stalled for 36mo (Fig.1A). After initial compression treatment, some improvement was observed (Fig. 1B). After 5 months of combined treatment with Microllyte and a compression stockinet, significant and rapid reduction of wound volume was observed (Fig. 1C-H), suggesting a strong synergistic effect between Microllyte and EdemaWear[®].



Patient Presentation

- ▶ An 80-year-old female patient presented with an unhealing post-op Mohs surgical wound on her leg, which was open for 78 days.

Failed Therapies

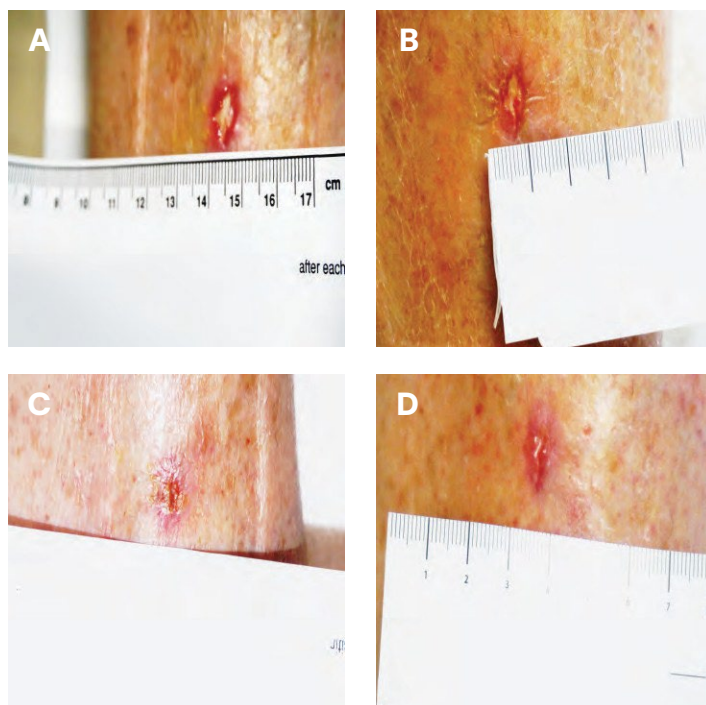
- ▶ Silver foam
- ▶ Compression
- ▶ Gentamycin
- ▶ Bactroban
- ▶ Systemic antibiotics

Procedure & Treatment

- ▶ MicrolYTE[®] Matrix was applied after debridement and followed by standard wound care protocol.

Clinical Outcome

- ▶ After just 25 days of MicrolYTE[®] treatment, patient's wounds were closed 100%



Conclusions

- ▶ Mohs Micrographic Surgery is the sequential removal of layers of cancerous skin, until all cancer is removed, after each excised layer is inspected via microscopic visualization.
- ▶ As a result, Mohs can take place over several hours or even days.
- ▶ Though the SSI rate for Mohs is less than 5%, the increased morbidity of an open wound with advanced age is significant.
- ▶ Also, the SSI rate of clean surgical wounds such as Mohs doubles with each additional hour of surgery.¹
- ▶ Despite the challenge of advanced age and recalcitrant state of the wound, MicrolYTE[®] Matrix was able to jump-start the healing process and completely close the wound after just 24 days.
- ▶ **MicrolYTE[®] Matrix shows promise as a post-operative prophylactic antimicrobial wound matrix for Mohs Micrographic Surgery.**

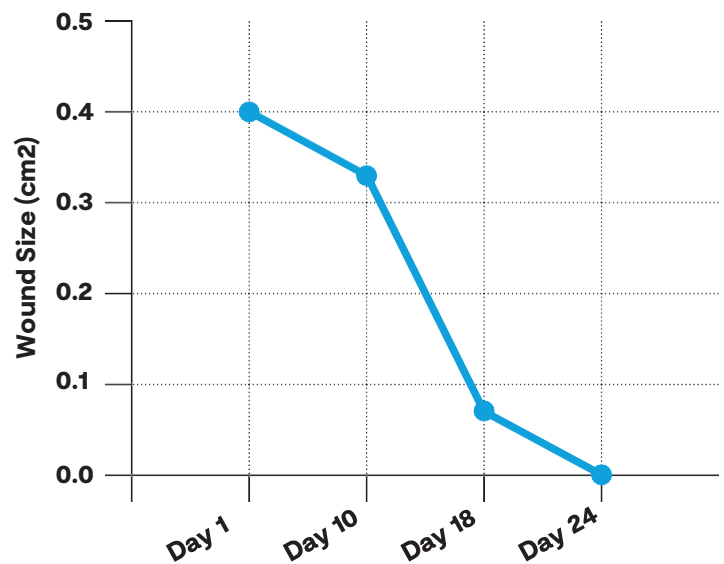
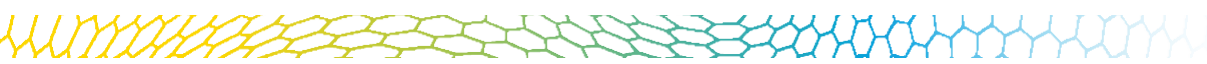


Figure 1:

A. Wound at day 1 after being open for 78 days. B. Wound is 18% closed C. wound is 83% closed D. wound is 100% closed.

Reference: (DelMauro, Kalberer et al. 2020)



Salvage of Limb with Necrotizing Fasciitis

Christopher Moore, DPM Moore Foot & Ankle Specialists

Microllyte®

BIORESORBABLE MATRIX

Patient Presentation

An elderly male patient presented with necrotizing fasciitis up the medial leg, with gas gangrene down to tendons, and osteomyelitis which caused partial amputation of the 1st ray. Patient also had a severe pes planus deformity. Overall prognosis of leg salvage was poor.

Adjunct Therapies

- ▶ Apligraf®
- ▶ External Fixator

Procedure & Treatment

- ▶ Microllyte® Matrix was applied weekly after debridement for 37 weeks.
- ▶ Four weeks after initial treatment, patient's leg was fitted with an external fixator for complete off-loading.
- ▶ After 4 additional weeks, Apligraf® was applied directly on top of Microllyte® Matrix ; and the wound was monitored weekly until complete reepithelialization.

Clinical Outcome

- ▶ After 4 weeks of Microllyte® Matrix treatment, the patient's wound showed no signs of infection which qualified him for an external fixator.
- ▶ One month later, his wound granulated sufficiently over both bone and tendon, which qualified him for Apligraf® treatment.
- ▶ Frank graft take was observed, and patient went on to heal completely at 37 weeks.

Conclusion

- ▶ Necrotizing fasciitis is a bacterial infection that, without prompt attention, can lead to limb loss, sepsis and death.
- ▶ In this case, we demonstrate that Microllyte® was able to 1) reduce bioburden of the wound, 2) promote granulation over bone and tendon, 3) prevent recurring infection, and 4) prepare wound bed for application of a skin substitute.
- ▶ Microllyte® Matrix and Apligraf® worked together to eradicate bioburden and promote wound healing, respectively, and shows promise in treating severe infections such as necrotizing fasciitis and osteomyelitis.

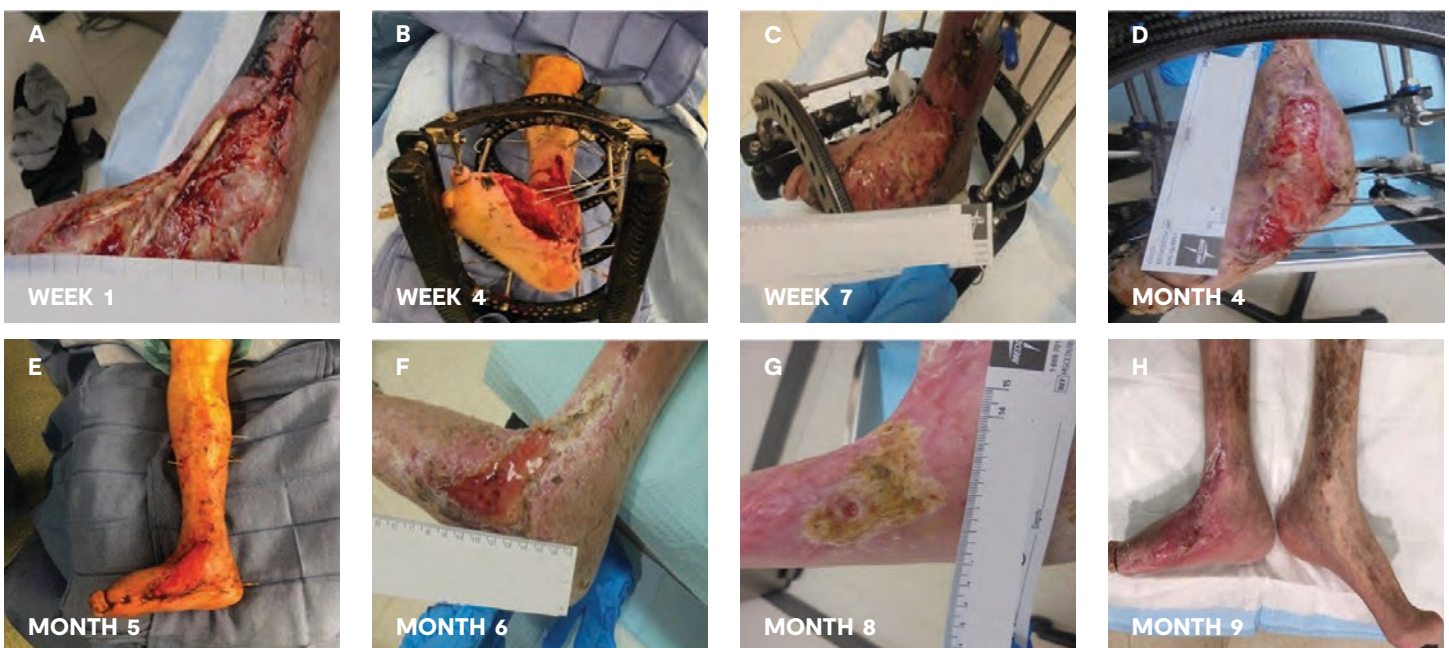


Figure 1: (a) Initial presentation with necrotizing fasciitis and osteomyelitis, (b) external fixator is attached after infection is cleared (c) Apligraf® is applied (d) re-epithelialization progresses (e) external fixator is removed (f,g) re-epithelialization continues to progress, (h) wound closure is complete.

Patient Presentation

A type-2 diabetic, HIV-positive male patient presented with Charcot neuroarthropathy midfoot collapse, neurotrophic foot ulcer, severe infection with abscess, osteomyelitis, and sepsis. Patient also had an unspecified autoimmune disease that was treated with methotrexate.

Adjunct Therapies

- ▶ NPWT
- ▶ Antimicrobial beads
- ▶ CROW boot
- ▶ External fixator

Procedure & Treatment

- ▶ After exhaustive conservative care and reconstructive surgery, Microllyte® Matrix was placed onto the deep wound bed, under flap, and primarily closed.
- ▶ Microllyte® Matrix was then reapplied once a week with standard wound care for 24 weeks.
- ▶ At the time of skin grafting, Microllyte® Matrix was applied directly onto the recipient site, below the skin graft, as well as on the donor site.
- ▶ Patient wore CROW boot or external fixator throughout this time.

Clinical Outcome

- ▶ Sixteen weeks after primary closure, skin flap necrosed and required debridement.
- ▶ The tissue revealed below was healthy, and bones were completely covered.
- ▶ Wound was debrided weekly for 7 weeks until there was enough granulation tissue.
- ▶ To promote re-epithelialization, an autologous skin graft was used, and 5 days later, the recipient site was almost healed, and the donor site was completely healed.

Conclusion

- ▶ Charcot neuropathic osteoarthropathy is a complication of diabetes that involves disorganization of bones, joints, and soft tissues of the foot, and can present with or without plantar ulceration.
- ▶ Acute localized inflammation triggers a bone resorption response which leads to mid-foot collapse.
- ▶ In this report, Microllyte® Matrix was able to accelerate wound closure in a patient with multiple comorbidities and high risk of infection.
- ▶ Additionally, his donor site wound was healed completely after just 5 days of Microllyte® Matrix application.

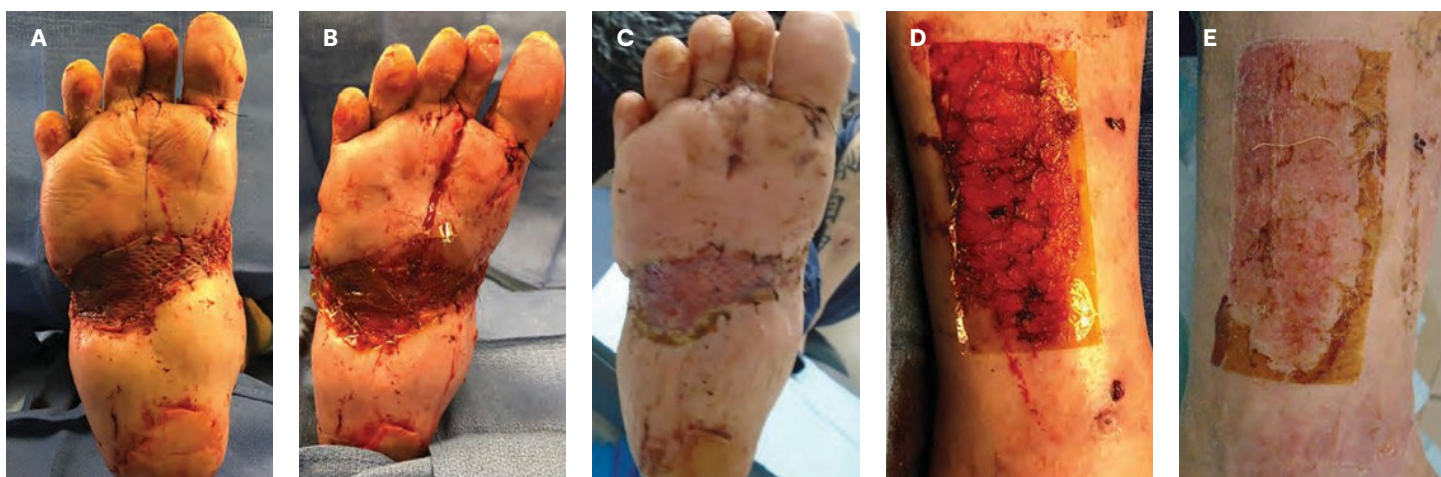


Figure 1: An autologous skin graft was used with Microllyte® Matrix to promote epithelialization of a plantar ulcer. A-B. Microllyte® Matrix was placed directly on the wound bed and under skin graft. C. Wound was almost completely healed after 5 days. D. Microllyte® Matrix was placed directly on top of donor site. E. Wound was completely healed after 5 days.



Toe Amputation Site

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Patient Presentation

A 73-year-old female underwent amputation of the right 5th toe associated with a diabetic foot ulcer and osteomyelitis.

Adjunct Therapy

- ▶ Collagen dressing
- ▶ ABD Pad
- ▶ Gauze roll
- ▶ Cloth tape

Procedure & Treatment

- ▶ Moistened collagen foam dressing was utilized initially for optimal proteases management.
- ▶ MicrolYTE® Matrix was applied to the wound (2) times weekly.
- ▶ The amputation site was then covered with a single layer of ABD pad and foot was secured with gauze roll and tape.

Clinical Outcome

- ▶ After protease activity was controlled with a moistened collagen foam dressing, the bioresorbable polymeric matrix assisted with bioburden management, and increased re-epithelialization rate due to minimal dressing changes.
- ▶ Wound closure was achieved in 8 weeks.

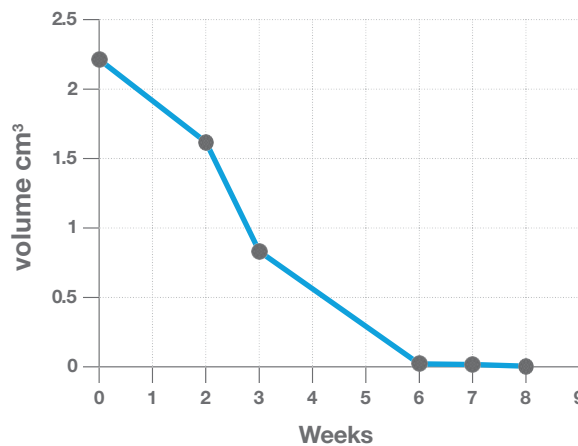


Figure 1. Bright blue lines indicate period of MicrolYTE® Matrix treatment.

Conclusions

MicrolYTE® Matrix has consistently proven to be an effective wound management dressing during the proliferation phase of wound healing from granulation to 100% re-epithelialization.



Figure 2: Wound healing progression of amputation site associated with a diabetic foot ulcer. MicrolYTE® Matrix was used from week 0 to week 8.



Patient Presentation

- ▶ An 81-year-old female diabetic patient presented with a gangrenous non-healing transmetatarsal amputation site that was open for 5 months.
- ▶ In the final two months, her wound grew from 10.7 cm³ to 31.7 cm³, a 196% increase in wound volume.
- ▶ She also had several co-morbidities including end-stage renal disease and peripheral vascular disease, hypertension, chronic heart failure, obesity, and had a history of osteomyelitis.
- ▶ Microllyte[®] Matrix, was added to her treatment plan to help manage any potential wound bioburden, support granulation tissue generation, and promote re-epithelialization of her amputation site.

Previous Treatments

- ▶ Debridement
- ▶ Negative pressure wound therapy NPWT
- ▶ Total contact casting (TCC)
- ▶ Antibiotics
- ▶ Adjuvant hyperbaric oxygen therapy.

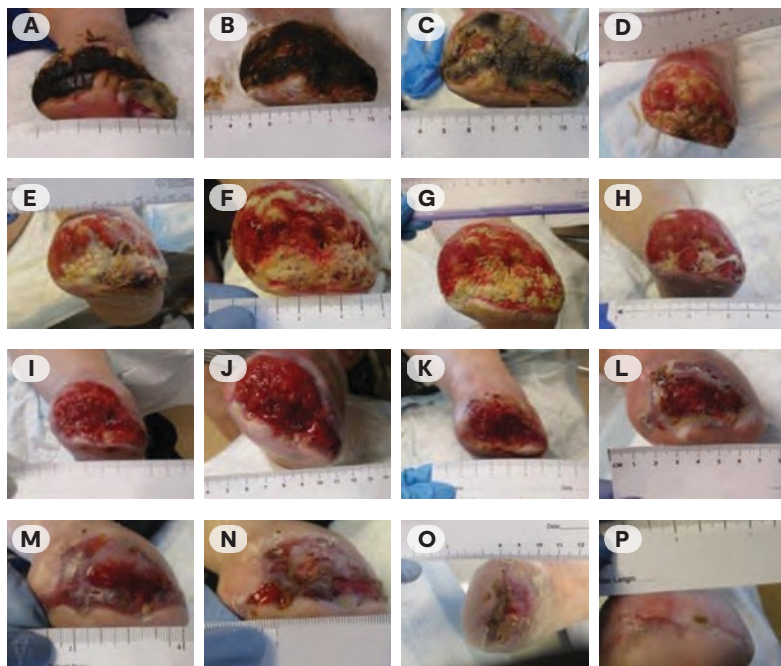


Figure 1: A-H Healing progression of TMA; wound is healed by 99% at month 5.

Procedure & Treatment

The Matrix was used as the contact layer starting at month 5 (presentation directly to escharotic plaque) and was continued for 4 months with application every 2 to 9 days (serial debridement along with silver matrix resulted in granulation tissue throughout to allow placement of CTP), and according to placement of dermal matrix substitute and or TCC placement.

Clinical Outcome

- ▶ One month after the matrix was added to her treatment plan, her wound decreased from 31.4 cm³ to 7.4 cm³, a 76% decrease in wound volume.
- ▶ At month 2, her wound measured 0.4 cm³ and at month 4, her wound measured 0.04 cm³, a 99% decrease in wound volume.



Figure 2. Graph depiction of healing progression over 5 months. Bright blue lines indicate period of Microllyte[®] Matrix treatment.

Conclusions

- ▶ After just one month of adding the Matrix to the patient's treatment plan, her wound decreased dramatically by 76%.
- ▶ This is especially remarkable given that her wound was actively increasing for the previous 5 months.
- ▶ The Matrix appeared to prepare the wound bed for successful graft take and shows promise as an adjunct therapy in treating non-healing TMAs in complex diabetic patients.



Treatment of Diabetic Foot Ulcers with Microlyte® Matrix

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[NCT 03204851]

Microlyte®

BIORESORBABLE MATRIX

Overview

- ▶ In a pilot study of Microlyte® Matrix in complex chronic wounds conducted at Mission Hospital (Asheville, NC), six patients with a total of 8 non-healing diabetic foot ulcers (DFUs) were evaluated.
- ▶ Over an average period of 53 weeks, an est. \$132,000 was spent to unsuccessfully treat these 8 DFUs.
- ▶ In this report, we discuss the clinical and economic advantages of Microlyte® Matrix treatment on 3 representative DFU cases.

Patient Presentation

- ▶ Patient 1: 68 y/o previously treated with a cast, Endoform®, Silvadene® Cream, and Silver Foam, non-healing for 48 weeks, costing approx. \$13,000
- ▶ Patient 2: 47 y/o male previously treated with Antibiotics, Mediporeã , non-healing for 41 weeks, costing approx. \$11,000
- ▶ Patient 3: 56 y/o previously treated with Promogran® Prisma, Iodoflex* , non-healing for 61 weeks, costing approx. \$17,000

Procedure & Treatment

Microlyte® Matrix was applied weekly after debridement and followed by standard wound care protocol.

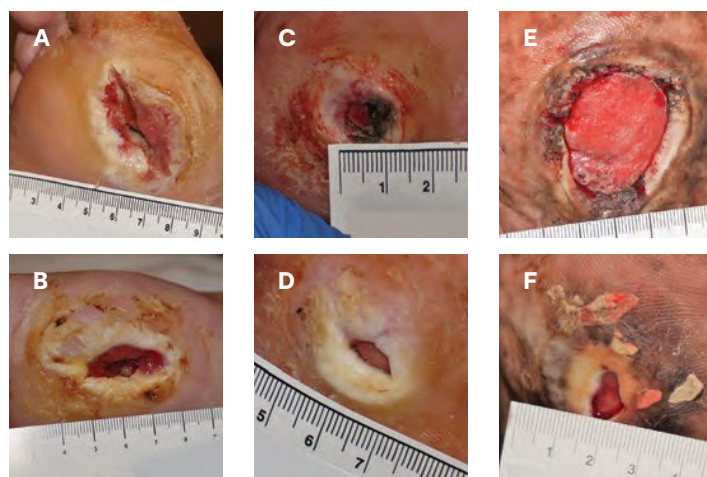


Figure 1: (A,C,E) before Microlyte® Matrix treatment, (B,D,F) after Microlyte® Matrix treatment.

Clinical Outcome

After Microlyte® Matrix treatment for an average of 5 weeks, approximately \$12,000 was spent to treat all 8 DFU and resulted in average closure of almost 80%. This reflects a 90% reduction in cost-of-care to accomplish varying, but substantial, degrees of closure in non-healing wounds. Treatment for patients 1, 2 and 3 cost \$2,400, \$705 and \$3,019, respectively. Furthermore, no pain during application or secondary dressing change was reported.

Conclusion

In addition to improving patient outcomes and quality of life, faster healing of DFUs will allow clinics to generate higher revenues through increased patient volume while decreasing the risk for nosocomial infections in the at-risk diabetic patient population. Furthermore, the Matrix is compatible with other adjunctive wound care therapies and traditional wound care regimens, which makes it easily adoptable by wound care clinics, thereby increasing overall treatment success of DFUs.

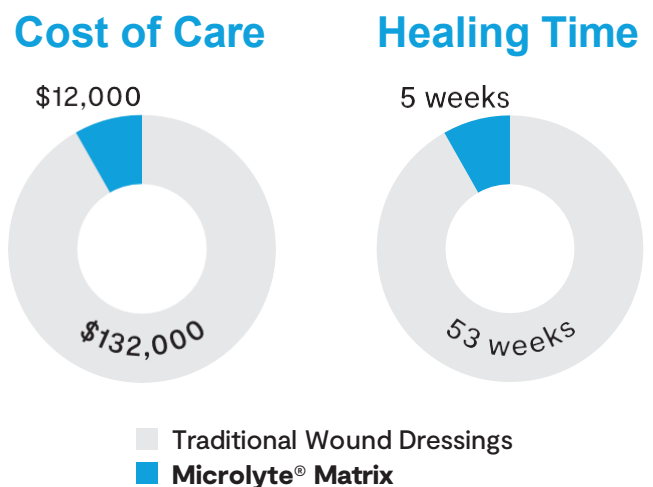


Figure 2: Microlyte® Matrix treatment significantly reduces the cost of care due to faster healing times.

