Enluxtra™
Self-Adaptive Wound Dressing

Case Studies

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Self-Adaptive Advanced Wound Dressing Study

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Abstract of presentation at The Symposium on Advanced Wound Care (SAWC) Spring 2012

The purpose of this study was to determine the effectiveness of a self-adaptive advanced wound dressing for achieving optimal moisture balance in multiple wound types. The subject dressing had the unique property of being able to sequester large amounts of exudate or conversely prevent desiccation of a dry wound. This allowed the dressing to be used throughout the healing of a wound. A total of 15 patients from a variety of settings (clinic and nursing homes) were selected. The types of wounds in the study included venous, diabetic, and decubitus ulcers as well as acute traumatic and chronic wounds. The dressing was applied one to three times per week either in clinic or in home settings, based on the wound and in conjunction with local best practices throughout the entire study. Our overall approach was to use this dressing on any wound regardless of etiology or the amount of exudate, and to decrease dressing changes to a minimum (once a week) until the wound was completely re-epithelialized.

Our conclusion was that this dressing was effective on all types of wounds with minimal to heavy exudate and with no need for dressing customization. We observed notable improvements of wound edge conditions. The dressing demonstrated excellent properties with regard to preservation of peri-wound skin. Dressing removal was painless and non-traumatic. It also seemed that this dressing minimized formation of biofilm, therefore reducing the need for debridement. We had promising results with extended use in patients with once a week dressing changes with moderate drainage. The utilization of one-fit-all dressing for multiple wound types, which exhibit minimal to severe exudate, simplified wound care. This dressing improved the quality consistency of practical moist wound healing and facilitated care continuum in the clinic, home and facility settings.

* Enluxtra™ Wound Dressing, OSNovation Systems, Inc., BASF, Inc.
Case study 1: Chronic lower extremity venous stasis ulcer

Enluxtra® Wound Dressing Clinical Results

Patient:
A 53-year-old male presented with a draining lateral venous stasis ulcer on his left lower leg that had been present for several months. Patient is a heavy smoker (1 pack a day) with a history of untreated hypertension, arterial compromise, and refused revascularization (ankle/brachial index: .82).

Wound Description:
Upon presentation to the clinic, the venous stasis ulcer appeared weepy and stalled in the inflammation phase of wound healing. Healing was further complicated by frequent recurrence of fungal/yeast infection on the periwound skin, which caused constant pruritus and inflammation. Patient complained of sleep loss due to itching and discomfort throughout the day. Initial goals in this case were to reduce wound drainage and edema.

Initial Wound Treatment:
In addition to triamcinolone, anti-fungal ointments and topical antibiotics, a variety of dressings were applied to the wound during the first four months of treatment, including foams, alginates, silver alginates, and polymeric membrane dressings. Unfortunately, the quantity and consistency of drainage from the wound did not change with application of any of these dressings. After 4 months of advanced wound care, the ulcer remained weepy and hypergranulated with raised wound edges above peri-wound skin level. Condition of the periwound skin was bright red, erythematous, edematous, and with scaly dry drainage adding to the pruritus (Fig. A).

Application of Enluxtra:
Prior to the first application of Enluxtra® Humifiber wound dressing, following debridement, the ulcer measured 4.0 x 4.0 x 0.5 cm. Topical antibiotics and anti-fungal ointment were applied. Enluxtra was placed over the ulcer, overlapping 2 to 3 cm onto intact skin, and secured with circumferential gauze wrap.

Wound Progression with Enluxtra:
Two weeks following initial application of Enluxtra, drainage was noticeably reduced, the periwound erythema was resolved, and the wound was granulating normally with only a small, slightly raised area (Fig. B). The dressing prevented transfer of exudate to the peri-wound skin, ending prolonged skin irritation and itching after only one week of Enluxtra.
After 4 weeks of Enluxtra, the wound bed was completely level with the periwound skin and re-epithelializing normally. The wound measured only 0.5 x 0.25 x 0.25 cm with no periwound edema (Fig. C). No dressing adjustment or cutting was required during course of wound healing. After 2 months, the wound was completely closed and re-epithelialized (Fig. D). Dressings were discontinued and the patient was released from care.

**User Experience:**
The patient was very satisfied with the Enluxtra dressing, particularly with respect to painless, non-adherent dressing removal and the rapid rate of erythema resolution and wound closure. Patient reported no dressing leakage or fluid strike-through. Itchiness stopped within one week of application, and the patient was relieved to finally sleep through the night. His wound that had been open and draining for 4 months was nearly closed within 1 month of Enluxtra use, allowing him to return to his normal daily activities.

**Clinical Outcomes/Conclusion:**
In this case, Enluxtra appeared to contain all the properties needed to reverse the impediments in ulcer healing that were evident during the previous four months, including edema, uncontrolled drainage, and moisture imbalances. Compared to all previous dressings used in this chronic ulcer, Enluxtra was the only dressing that facilitated effective and efficient wound closure.

Drainage was controlled, locked in and reduced with this dressing, resulting in edema reduction and optimal moisture balance throughout the wound and periwound skin. The dressing appeared to absorb exudate from the central area of the draining wound while maintaining moist wound edges, and to provide a moist healing environment during the low-/non-exuding final stages of wound healing. The final cosmetic appearance of the healed wound was excellent.

From a clinician’s perspective, Enluxtra greatly simplifies the tedious process of choosing appropriate wound care dressings, because this one dressing type is suited for the entire wound healing continuum and does not need to be switched according to changing wound conditions. Enluxtra was effective throughout all conditions and dimensions of the wound in this case.

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Case study 2: Basal cell carcinoma of the temporal region

Enluxtra® Wound Dressing Clinical Results

**Patient:**
A 62-year-old male presented with a nonhealing soft tissue radionecrosis wound of the left facial and temporal region following severe radiation damage post basal cell carcinoma. Patient’s medical history also included hypertension and stage II chronic kidney disease.

**Wound Description:**
Continual drainage from the exposed frontal sinus was contaminating and causing inflammation to the surrounding soft tissue, prolonging wound healing process. Wound healing was further complicated by desiccation of wound edges and non-exudative portions of the wound, as well as formation of necrotic tissue and biofilms.

**Initial Wound Treatment:**
A range of absorbent dressings, including hydrocellular and self-adherent polyurethane foams, were tried in the wound and were unsuccessful in controlling drainage of the sinus fluid and necrotic tissue formation. The wound required weekly debridements to remove necrotic tissue, which was increasing the wound size and traumatizing the wound edges, exposed bone, and the fragile thin tissue layer over the brain. Brain pulsating movement could be observed in the center of the wound. Continual debriding of this fragile area due to drainage deterred the healing process.

**Application of Enluxtra:**
Ten weeks after the patient initially presented to our clinic, the wound measured 10.0 x 13.0 x 1.0 cm with exposed bone (Fig. A). Debridement was performed, and Enluxtra was placed on the wound, overlapping 2 to 3 cm onto intact skin, and secured with non-woven cotton tape at the first dressing change. On follow-up visit, additional folded gauze was added to the outer Enluxtra dressing and cotton tape to ensure wound bed contact with the Enluxtra and aid drainage absorption and biofilm elimination.

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Fig. A. Chronic soft tissue radionecrosis wound prior to use of Enluxtra is filled with necrotic tissue and contaminated with sinus fluid
**Wound Progression with Enluxtra:**

Two weeks following initial placement of Enluxtra, the wound displayed marked signs of improvement. Drainage was controlled and isolated within the dressing, and healthy pink tissue was present in the wound bed and on wound edges (Fig. B).

Exudate containment and maintenance of correct moisture balance throughout the entire wound led to a drastic reduction in sharp debridements and associated trauma to the exposed bone and healing tissues. The layer of tissue covering brain tissue continuously retained its moisture, and appeared strengthened within one month of Enluxtra use (Fig. C).

After 3 months of Enluxtra, wound size was decreased, sinus fluid remained contained, and granulation buds were present throughout the wound bed (Fig. D).

**User Experience:**

The patient reported increased comfort with the dressing, particularly with respect to painless dressing removal, leak-free dressing and decreased debridement frequency. Other dressings applied prior to Enluxtra leaked drainage into the eye and inner ear, requiring frequent debridement and use of antibiotic eye drops for inflammation and irritation.

**Clinical Outcomes/Conclusion:**

All areas of this complex soft tissue radionecrosis wound responded positively underneath the Enluxtra dressing throughout the 12-week application period. Improved moisture balance and considerably reduced necrotic tissue and biofilm formation were observed with application of Enluxtra, compared to previous dressings used in this wound. Enluxtra appeared to assist in autolytic debridement, which greatly decreased the need for sharp debridement and allowed the underlying healthy tissue to consistently remain on a positive wound-healing trajectory.

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Case study 3: Fourth metatarsal head following amputation

Enluxtra® Wound Dressing Clinical Results

**Patient:**
A 67-year-old male presented with a diabetic wound of the right foot fourth metatarsal head following toe amputation. Patient was a healthy, insulin-dependent diabetic with hypertension.

**Wound Description:**
Patient with a diabetic wound of the right foot fourth metatarsal had been unsuccessfully treated by a local physician for 1 month. Patient was admitted to a local hospital for amputation of foot and intravenous antibiotics. Patient sought second opinion from our wound clinic and it was determined that amputation of only the fourth digit was necessary. Three days after amputation, the incision dehisced and the wound began producing copious amounts of drainage. At initial presentation post dehiscence, wound edges were macerated and erythematous, due to the uncontrolled wound drainage.

**Application of Enluxtra:**
Following debridement, the ulcer measured 3.0 x 1.5 x 1.0 cm with exposed bone (Fig. A). A small piece of Enluxtra was cut and placed between the toes and over the wound, overlapping 2 to 3 cm onto intact skin (Fig. B), then secured with gauze wrap. The aim of the dressing was to absorb and reduce wound drainage as well as facilitate recovery of the macerated periwound skin.

**Wound Progression with Enluxtra:**
The drainage was well absorbed by the dressing. After one week of Enluxtra application, drainage was reduced and maceration around the wound was decreased (Fig. C). The periwound area was healthy and completely recovered at week 3 (Fig. D).

After 6 weeks of Enluxtra, edema and erythema were no longer present and the wound appeared optimally moist. The wound was smaller (0.5 x 0.5 x 1.0 cm) and well-granulated, including over previously exposed bone (Fig. E). The wound was

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Fig. A. Diabetic wound post amputation and debridement with copious drainage and wound edge maceration

Fig. B. Enluxtra dressing applied between toes and overlapping onto intact skin

Fig. C. After 1 week of Enluxtra, wound edge maceration is resolving due to dressing absorption capabilities. Slight erythema is present at the wound
completely closed after 4 months of Enluxtra application (Fig. F), and the patient was discharged from wound care services.

**User Experience:**
The patient appreciated the ease of application and removal of the Enluxtra dressing, and was encouraged at each dressing change by consistent progress toward closure.

**Clinical Outcomes/Conclusion:**
The diabetic foot ulcer showed steady progression toward closure at each dressing change with use of Enluxtra, and was completely closed at 4 months. Drainage and edema were decreased and periwound maceration was eliminated with this dressing. Enluxtra appears to be a viable, simplified dressing option for diabetic wounds due to its effectiveness over different tissue types and throughout the wound healing continuum.

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Case study 4: Diabetic foot ulcer secondary to gout

Enluxtra™ Wound Dressing Clinical Results

**Patient:**
A 60-year-old female presented with a diabetic foot ulcer secondary to gout and neuropathy on the lateral side of her right foot great toe. Patient is morbidly obese with an existing diabetic plantar ulcer of 7 months’ duration. Patient comorbidities include type 2 diabetes mellitus, gout, arthritis, venous insufficiency, hypertension, neuropathy, and Charcot foot disease.

**Wound Description:**
Upon presentation to the clinic, the wound was copiously draining, and inflammation extended to the periwound areas. The periwound skin was erythematous, edematous and warm to the touch.

**Initial Wound Treatment:**
Patient restarted allopurinol dosages and started on topical antibiotic and IV daptomycin. Sharp debridement was performed and continued weekly. The wound measured 2.0 x 4.0 x 1.0 cm with undermined edges (Fig. A).

**Application of Enluxtra:**
Enluxtra was placed over the ulcer, overlapping 2 to 3 cm onto intact skin, and secured with circumferential gauze wrap. Dressing changes were ordered once daily and performed by a family member.

**Wound Progression with Enluxtra:**
One week after initial application of Enluxtra, drainage was drastically reduced and the periwound erythema was largely resolved. Wound margins and undermining were reduced, and debridement of devitalized tissue revealed exposed tendon (Fig. B).

After 2 weeks of Enluxtra, the wound size was reduced to 1.5 x 3.0 x 0.25 cm and the wound bed was 100% granulated over tendon (Fig. C). Periwound redness was no longer present, drainage was slight, and the wound edges remained optimally moist.

After one month of Enluxtra, wound edges remained moist and approximating. The wound measured 1.0 x 1.0 x .25 and was re-epithelializing.
normally (Fig. D). At 2 months post initial Enluxtra application, the wound was fully re-epithelialized and dressings were discontinued (Fig. E).

**User Experience:**
No dressing adjustment or cutting was required during course of wound healing. The patient was very satisfied with the Enluxtra dressing, particularly with respect to drainage containment, the rapid rate of erythema resolution and wound closure. Enluxtra contained the large amount of drainage early on, decreasing exacerbation of the peri-wound area and facilitating healing.

**Clinical Outcomes/Conclusion:**
During application of Enluxtra in this case, edema and drainage were reduced, and an optimal wound healing environment was maintained, despite multiple patient co-morbidities. After 2 weeks with the Enluxtra dressing, the wound was 100% granulated over exposed tendon, and within 2 months, the wound was closed without further complications. Enluxtra maintained effectiveness throughout all stages of healing in this diabetic foot ulcer.

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At 1 month after initial presentation, wound edges are approximating; periwound is healthy with no edema.

After 2 months of Enluxtra dressings, the wound was fully re-epithelialized and the dressings were discontinued.
Case study 5: Chronic lower extremity venous stasis ulcer

Enluxtra® Wound Dressing Clinical Results

Patient:
A 49-year-old female presented with a draining venous stasis ulcer on her right shin. Patient’s medical history included coronary bypass graft surgery, hypertension, hyperlipidemia and coronary disease. Pyoderma was suspected but not diagnosed.

Wound Description:
This venous stasis ulcer had been present for 6 months, and appeared weepy and edematous at the initial clinic visit. Areas of wound edges were raised with undermining. Peri-wound skin was red and erythematous, and exhibited multiple scabs due to patient scratching and spreading contact dermatitis. The wound area was warm, and the patient complained of itchiness and pain. Initial goals in this case were to reduce wound drainage and edema, and to resolve wound edge erythema.

Initial Wound Treatment:
In addition to topical antibiotics, a range of dressings, including hydrocellular and hydropolymer foams, were applied to the ulcer during the first 6 months of treatment. However, the wound continued to drain copiously and the condition of the peri-wound skin remained red and irritated throughout treatment, even with daily dressing changes (Fig. A). The patient continued to complain of discomfort during dressing changes, and requested a dressing that could be changed less frequently than daily. A decision was made to apply Enluxtra® Humifiber wound dressing.

Application of Enluxtra:
Prior to the first application of Enluxtra and following debridement, the ulcer measured 5.5 x 7.0 x 0.5 cm with exposed tendon (Fig. A). Topical antibiotics were applied. Enluxtra was placed over the ulcer, overlapping 2 to 3 cm onto intact skin, and secured with circumferential gauze wrap. Daily dressing changes were ordered initially. However, after 3 days, dressing could be left in place for up to 2 days.

Wound Progression with Enluxtra:
Two weeks following initial application of Enluxtra, drainage and peri-wound erythema were decreased. Edema was considerably reduced, wound edges were no longer raised, and the wound bed was level with the peri-wound skin. Healthy granulation buds appeared over the tendon (Fig. B). The patient reported no itching and less pain during or between dressing changes. Dressing change frequency was further reduced to every 3-4 days.
After 2 months of Enluxtra, the wound was approximately 85% granulated and erythema in peri-wound was nearly resolved (Fig. C). At 12 weeks, use of Enluxtra was discontinued due to original time limits set forth in the clinical trial. The wound bed was 100% granulated and re-epithelializing normally. Peri-wound erythema remained controlled and the wound size was decreased to 3.5 x 5.0 x 0.25 cm (Fig. D).

**User Experience:**
The patient described the Enluxtra dressing as having a “soothing and cooling effect” on her wound, and was particularly satisfied with the rapid decrease in drainage, pain, and itchiness that resulted with the dressing. Because the patient was uninsured, the reduction in dressing change frequency with Enluxtra had huge cost benefits for her.

Non-adherent dressing changes every 3-4 days were well tolerated by the patient. Patient reported no dressing leakage or fluid strike-through. Exudate containment, wound size reduction and increased comfort allowed the patient to return faster to normal daily activities. Clinicians appreciated ease of dressing removal and longer 2-year shelf life of dressing.

**Clinical Outcomes/Conclusion:**
Compared to prior dressings used in this wound, use of Enluxtra resulted in a decreased frequency of debridements and dressing changes—both of which favorably impacted healthcare costs for this patient.

Use of Enluxtra facilitated conversion of this stalled chronic ulcer to a wound that showed positive wound healing progression at every dressing change. The dressing was effective in controlling exudate removal throughout all phases of wound healing, ending prolonged skin irritation and itching within 2 weeks of Enluxtra use.

Enluxtra appeared to maintain a positive moisture balance throughout the wound and peri-wound skin for the duration of its use, resulting in a well-granulated venous stasis ulcer in a patient with considerable co-morbidities.

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Case study 6: First metatarsal head following amputation

Enluxtra® Wound Dressing Clinical Results

**Patient:**
A 75-year-old male presented with a diabetic wound of the left foot first metatarsal head following toe amputation performed prior to presentation at our clinic. Patient’s past medical history significant for insulin-dependent diabetes, hypertension, neuropathy, and mild chronic obstructive pulmonary disease treated with prednisone.

**Wound Description:**
The patient was referred to our clinic with a dehisced incision over the first metatarsal head. The wound was edematous with copious drainage and maceration to the periwound area. Initial goals in this case were to reduce wound drainage and edema.

**Initial Wound Treatment:**
Culture-specific topical antibiotics, as well as numerous dressings and grafts were applied to this amputation wound during the first 7 months of treatment. Dressings applied to the wound included hydropolymer foam and oxidized regenerated cellulose/collagen matrix. Human fibroblast-derived dermal substitute was applied 5 times, and tissue-engineered skin was applied 6 times. Despite the wide array of advanced wound care products used, the ulcer continued to drain on to the peri-wound area, causing severe maceration of wound edges and loss of surrounding tissue. After 7 months of care, the wound had a foul odor and was covered with a thin biofilm layer (Fig. A). A decision was made to apply Enluxtra® Humifiber wound dressing to contain the drainage and maintain moisture balance throughout the wound and peri-wound.

**Application of Enluxtra:**
Prior to the first application of Enluxtra® Humifiber wound dressing, following debridement, the ulcer measured 5.0 x 3.0 x 0.5 cm. A topical, culture-specific antibiotic solution was applied, then Enluxtra was placed over the debrided area, overlapping 2 to 3 cm onto intact skin, and secured with a gauze wrap.

**Wound Progression with Enluxtra:**
After 3 weeks of 3-times weekly dressing changes with Enluxtra, peri-wound maceration was greatly reduced. Wound odor and signs of biofilm in the wound bed were no longer present. The wound bed was healthy, beefy red and epithelializing (Fig. B).

Diabetic foot ulcer with severe peri-wound maceration after 7 months of advanced wound care and prior to Enluxtra application.

Three weeks following initial use of Enluxtra, maceration is considerably decreased, and the wound odor and signs of biofilm are no longer present.

After 6 weeks of Enluxtra, ulcer area was reduced by greater than 60% with minimal drainage.
A sheet of tissue-engineered skin was applied to the ulcer, over which the Enluxtra dressing was applied. Dressing change frequency was reduced from 3 times to 1 time per week.

After 6 weeks of Enluxtra dressings, the wound was considerably smaller and re-epithelializing normally (Fig. C). Tissue-engineered skin and Enluxtra were re-applied. At 8 weeks, skin islands were visible within the wound bed, indicating that the tissue-engineered skin graft was successful (Fig. D). Wound edges appeared moist, even over calloused skin of the patient who refused to offload or wear a boot.

After 12 weeks of Enluxtra dressings and tissue-engineered skin grafts, the wound bed remained optimally moist, and was 100% granulated. The wound size had been reduced to 1.5 x 1.5 x 0.25 cm (Fig. E). Use of Enluxtra was discontinued due to the 12-week time limit for the clinical evaluation. The patient subsequently lost home health services due to non-compliance and was lost to follow-up.

**User Experience:**

Patient preferred the Enluxtra dressing over all previously used dressings due to the dramatically decreased peri-wound maceration and reduction in dressing change frequency facilitated by the dressing. Clinicians reported excellent moisture control with Enluxtra, as the wound remained optimally moist without peri-wound maceration or leakage. Patient was also able to change his own dressing and provider care was cancelled.

**Clinical Outcomes/Conclusion:**

During use of Enluxtra, this previously stalled diabetic wound progressed to a clean, well-granulated wound that showed consistent size reduction at each weekly visit. The dressing maintained good contact with the wound and peri-wound areas, facilitating moisture control throughout, despite the patient’s refusal to off-load his foot. Reduction in dressing change frequency with Enluxtra also led to cost savings and increased patient satisfaction.

Compared to all dressings previously used in this wound, Enluxtra provided the most optimal moist wound healing environment needed to progress the wound and maximize the effectiveness of tissue-engineered grafts.

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Utilizing the Self Regulating Moisture Control of a Self-Adaptive Dressing to Manage a Single Complex Wound

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Abstract of presentation at The Symposium on Advanced Wound Care (SAWC) Spring 2012

Chronic wounds are often complex and have clearly been shown not to be homogeneous. The wound biofilm which covers the vast majority of the chronic wound shows significant differences in the constituent microbes at different locations within the wound. This heterogeneity of wound biofilm combined with the different tissue types that are often contributing to the wound bed along with different degrees of degradation of the host tissue can present significant problems for most traditional dressings. Certain areas, such as the wound edge that struggles with active wound biofilm producing marked inflammation and therefore exudate, have different moisture control needs versus areas of exposed bone or low inflammation.

Currently, available dressings tend to be engineered to solve a single problem, such as too much exudate (absorption) or wound desiccation (hydration), which can limit their overall effectiveness in a complex wound. Complex wounds with areas of different properties therefore may benefit from a self-regulating dressing.

An Enluxtra advanced wound dressing has a unique feature of self-adjusting its material properties in response to specific moisture conditions encountered within the wound. This material is able to simultaneously sequester large amounts of exudate over highly exudative regions and donate moisture to prevent desiccation of nondraining portions of the wound. The use of self-adaptive dressings simplifies wound care by assuring optimal moisture balance for the ever changing wound conditions within the complex chronic wound.

* Enluxtra™ Wound Dressing, OSNovative Systems, Inc., BASF, Inc.