

Cutimed®

**CUTIMED® EPIONA
IN-MARKET EVALUATION**

**Clinical Case Studies Show Rapid
Improvement in Chronic Wounds**

THERAPIES. HAND IN HAND.

www.bsnmedical.com



Cutimed® Epiona: When Other Therapies Fail for Healing of Chronic Wounds

Wounds that do not heal within three months are often considered chronic. Because they can take years to heal, or may never heal, chronic wounds generate high costs and use extensive resources within health systems. Chronic wounds cause severe physical and emotional distress for patients, and create a major financial burden for patients and the entire healthcare system. No wonder these types of wounds are the focus of intense efforts to improve healing outcomes. Today, in addition to traditional wound dressings, there are dressings made with specific types of collagen to treat chronic wounds with greater efficacy.

Why collagen?

A number of collagen-based materials have historically been proposed for this purpose. These more advanced, native collagen dressings can help prepare the wound bed to heal, but they often deliver limited benefits, so the healing process stalls and wounds do not close.

That is because there are multiple barriers involved with the healing of chronic wounds. These barriers include exudate levels that are too high, a large bacterial load, and high protease (inflammatory) levels. As a key molecule in the wound-healing process, collagen provides healing by secondary intention (wounds with separated edges). It plays an essential role at each phase of wound healing – reducing inflammation, providing a matrix so that new cells can granulate and epithelialize, and remodel, when wound contraction occurs.

A novel, collagen wound dressing

While BSN medical offers a wide range of treatment options for all stages of wound healing, our newest collagen-based dressing fills an important role in the therapy sequence for chronic wounds. With Cutimed® Epiona, we now have a dressing that contains 90% native collagen and 10% alginate that accelerates healing of chronic wounds.

Cutimed® Epiona provides a natural structure for enhanced cell growth; binding MMPs, the inflammatory factors that destroy the proteins and native collagen that are critical to healing. Its 3D structure allows fibroblasts seeded on the dressing to proliferate and grow exponentially. Early clinical observations of Epiona revealed improvements in both regranulation and revascularization.

Cutimed® Epiona optimizes and activates wound healing

Compared to dressing like Promogran® (a mixture of bovine collagen and 30% regenerated, oxidated cellulose), and Endoform® (a dressing with 10% ECM ovine forestomach), Cutimed® Epiona was found to be analogous to intact, native dermal collagen. It not only stabilizes and protects growth factors in wounds – it also promotes the ingrowth of dermal fibroblasts that lead to accelerated healing of stalled and stagnant wounds. Cutimed® Epiona reduces inflammation, protects growth factors, and stimulates new cell growth to heal chronic wounds when other treatments have failed.

Contents

How Cutimed® Epiona Works.....	4
The Integrated Use of a New Native Collagen Scaffold With Other Therapies to Manage Chronic Wounds	5
Cases #1 – #3: An Integrated, 2-Step Approach with DACC and Cutimed® Epiona.....	6–8
Case #4: Treatment of a Traumatic Wound with Cutimed® Epiona.....	9
Case #5: Healing of a Deep Wound with NPWT and Cutimed® Epiona.....	10
Case #6: Combination Therapies for Multiple Wounds—DACC, Standard Bandaging, Cutimed® Epiona and Cutimed® Sorbact®	11
Conclusion	12

How Cutimed® Epiona Works

How wounds become chronic

Chronic wounds typically exhibit from a degraded extracellular matrix (ECM) due to increased levels of inflammatory cells in response to increased levels of proteases. Excessive wound proteases lead to the degradation of newly formed ECM and other proteins, e.g. growth factors and receptors.

In wound healing, the major proteases are the matrix metalloproteinases (MMPs) and the serine proteases, e.g. elastase¹. In the normal wound-healing process, proteases break down the damaged ECM proteins and foreign material so that new tissue can form and wound closure can occur in an orderly fashion.

But when the level of protease activity is too high, the delicate balance between tissue breakdown and repair is disturbed¹. This damages the ECM and prolongs the inflammatory stage of healing that prevents the wound from progressing to the proliferative phase². MMPs effectively stall the healing process – and using only conventional healing methods can create chronic wounds.

Cutimed® Epiona “jump-starts” healing

This new native collagen wound dressing is a fenestrated substrate made of 90% bovine-derived collagen and 10% alginate – nearly identical to the human dermal structure. It creates a 3D matrix that acts as a scaffold to support tissue regeneration. The 10% alginate aids in exudate management, and the dressing neutralizes the excess MMPs that slow and stall wound healing. Then healing takes a leap forward:

- MMPs become attracted to and bound by the open, porous, 3D matrix of the collagen scaffold the dressing provides
- In this improved wound climate, fibroblasts rise up from the wound bed and migrate into the dressing
- Dermal collagen proliferates, and matrix proteins and growth factors occur, creating a 3D dermal substitute to emerge and stimulate Type IV collagen
- The native collagen dressing gets fully resorbed during the healing process

With its natural collagen structure, Cutimed® Epiona provides a scaffold for tissue growth. It neutralizes the MMPs that prevent healing from progressing, and it supports Type IV collagen, which is essential to the basal lamina, a layer of the ECM secreted by the epithelial cells.

An economical solution for chronic wounds

Cutimed® Epiona can be applied repeatedly until epithelialization occurs. It's indicated for the treatment of chronic wounds that include, but are not limited to, pressure, venous and diabetic foot ulcers.

1) International consensus. The role of proteases in wound diagnostics. An expert working group review. London: Wound International, 2011. 2) Gibson D, Cullen B, Legerstee R, et al. MMPs Made Easy. Wounds International 2009; 1(1).

The Integrated Solutions Approach Using Native Collagen Scaffold with Other Therapies to Manage Chronic Wounds

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

Introduction

There are many obstacles that can affect the cascade of normal wound healing. These same obstacles present formidable challenges in managing chronic wounds in the clinical setting, not the least of which is preparing the wound bed.

Wound-bed preparation has been defined as the management of the wound to accelerate endogenous healing, or to facilitate the effectiveness of other therapeutic measures. Two of the factors that must be addressed in preparing the wound to heal are 1) treating inflammation and bacterial bioburden with topical agents, and 2) managing unbalanced protease activity, which can lead to degradation of the intact extracellular matrix (ECM). Controlling bacterial levels in the wound presents biofilm formation and reduces excess matrix metalloproteinases (MMPs), thus creating a favorable environment for the formation of granulation tissue, reepithelialization and, ultimately, wound closure.

Methods and materials

In the first 3 cases that follow, an integrated, two-step approach with dialkylcarbamoil chloride (DACC) technology and a new, native collagen dressing scaffold was used. The three patients that presented to the clinic with chronic wounds included two poorly controlled diabetics with dehisced first-ray and hallux amputations, and a noncompliant diabetic with PVD and open left TMA.

DACC is a fatty acid derivative that manages bacteria through hydrophobic interaction. It binds to the cell walls, rendering them inert and thereby controls the bacterial load and reduces infection and inflammation.

The new native collagen dressing scaffold was used to reduce MMPs by acting as a sacrificial substrate to protect the intact ECM, allowing for new collagen deposition and neovascularization (granulation) to proceed. The native collagen dressingscaffold is a fenestrated, bovine, native collagen that is 90% Type I, III and V collagen and 10% alginate.

In cases 4–6, the native collagen dressing scaffold was used in combination with standard wound care and other common therapies, including negative pressure wound therapy (NPWT).

Results

As shown on the next pages, all patients responded to an integrated approach, with no secondary infection. Using DACC to control bacterial burden and inflammation – together with the native collagen dressing scaffold to control excess MMPs – addressed two major challenges to chronic wound healing.

The native collagen dressing scaffold also proved to jump-start healing in cases 4, 5 and 6. The collagen attracts healthy cells to the wound and provides a substrate for new tissue growth. It ultimately provides an optimum environment for wound closure.

References

Schultz GS, et al. Wound Repair Regen. 2003; 11(suppl 1) S1-S28.
Sibbald RG, et al. Ostomy Wound Manage. 2003;49(11): 24-51.
Ljungh A, et al. J Wound Care. 2006;15(4): 175-180.

Case #1 – Surgical Wound

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

History

Female, 50 years old, with medical history significant for Type II diabetes, PVD, end-stage renal disease, and partial first-ray amputation. Post-operative course complicated by dehiscence of the surgical incision, resulting in a large, necrotic and non-healing wound.

Treatment

The initial treatment consisted of hyperbaric oxygen therapy, sharp debridement and negative-pressure wound therapy (NPWT). Patient responded well with significant improvement in wound volume and depth, but progress eventually stalled. The patient's wound was then treated with a native collagen dressing scaffold in conjunction with a DACC bacteria-binding layer, initially applied every 2-3 days to accommodate exudate level.

Result

There were notable improvements in granulation tissue quality and wound dimensions within two weeks. Migration of the wound edge was restored. As healing progressed, the collagen and DACC dressing were replaced every 5-7 days until there was no need for an advanced wound dressing.



Case #2 – Diabetic Foot Ulcer

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

History

Male, 48, with poorly controlled Type II diabetes. Right hallux infection with osteomyelitis resulted in toe amputation. His incision dehiscenced distally and responded poorly to local wound care. He was referred for hyperbaric oxygen therapy and more aggressive wound care to prevent secondary infection, hospital re-admission or additional tissue loss.

Treatment

Wound debridement to remove biofilm and slough was done. Silver alginate was packed in the wound every other day. Wound did not progress as expected with this treatment for two weeks. New wound-care regimen began, using a combination of native collagen dressing scaffold with DACC bacteria-binding contact layer. A transformative foam was used for exudate control.

Result

Wound bed improved steadily as the native collagen scaffold encouraged repair of the ECM, neovascularization, and granulation tissue formation. DACC layer prevented biofilm reformation. Transformative foam allowed for extended dressing-change intervals. Once the wound ECM was fully repaired, the native collagen dressing promoted epithelial cell migration across healthy granulation tissue, and the wound completely epithelialized.



Case #3 – Diabetic Foot Ulcer

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

History

Male, 50 years old, smoker with medical history significant for poorly controlled Type II diabetes, PVD, ESRD, recurrent foot ulcer, and amputations on both feet. The left-foot amputation dehisced; the patient continued to smoke and refused to modify his diet, resulting in continued elevated blood glucose levels.

Treatment

Debridement and silver alginate packing successfully cleared wound bed of gross debris and biofilm. To reduce wound depth and prevent biofilm from reforming, the native collagen dressing scaffold and DACC dressing combination was used. The patient remained noncompliant with his hyperbaric and wound-care treatment regimen, and often skipped 2-3 clinic appointments per week.

Result

Despite the patient's poor compliance, the native collagen dressing rapidly reduced the stump-wound volume, as it provided the necessary scaffold to repair the ECM and promote wound contraction. The DACC contact layer provided extended bacteria-binding coverage and prevented biofilm reformation when dressing changes were delayed. The open stump wound closed in less than 30 days, and the patient achieved complete closure and limb preservation.



Case #4 – Traumatic Wound

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

History

Female, 85 years old, with end-stage renal disease, on dialysis. In mid-May 2015, the patient sustained a blunt injury from a car door to her lower right leg. She was observed in the emergency room for other reasons and was found to have a contusion, which was treated expectantly, but resulted in a full-thickness necrosis by end of June.

Treatment

An I&D revealed some purulence. Patient was referred for vascular surgery and had an angiogram and angioplasty in her lower right leg. Marked improvement in her noninvasive arterial studies followed these procedures. She was referred to the wound center for ongoing management of the wound in her right leg. Review of systems other than those related to her wounds, a prior fall and the patient's end-stage renal disease did not contribute and were not relevant to wound treatment.

Result

Application of the native collagen dressing began on 15 September 2015. It provided the scaffold needed to repair the ECM and contract the wound. By 5 January 2016, the wound was less than half its original size than when treatment began.



Case #5 – Pressure Ulcer

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

History

Female, 64 years old, with right hip decubitus ulcer.
History of previous CVA and left-side weakness/
paralysis.

Treatment

Due to the patient's immobility, negative-pressure wound therapy (NPWT) via mechanical device (SNAP) was used. The native collagen dressing was added to speed the formation of granulation tissue.

Result

The deep wound filled in just 3 weeks.



Case #6 – Traumatic Wounds

Christopher L. Barrett, DP, CWS
The Center for Wound Healing
Crozer-Chester Medical Center
Chester, PA 19013

History

Female, 88 years old, sustained traumatic wounds to her left lower leg while gardening in May 2015. The wounds had not healed. Her past medical history was significant for osteoporosis and a fractured left hip, which she refractured in the past year, and then recovered well from that surgery. She also had mild peripheral edema, chronic venous stasis changes, but no history of phlebitis or chronic venous disease, along with mild hypertension on occasion. She is extremely active and involved for her age.

Treatment

Starting 7 August 2015, the patient was treated with a combination of therapies, including DACC, standard bandaging, the new native collagen dressing, and Cutimed® Sorbact®.

Result

Over a period of 3 months, both of the patient's wounds completely healed.



CUTIMED® EPIONA IN-MARKET EVALUATION

Conclusion

Chronic wounds can persist for months, even years, with some never healing. Most of these wounds resist healing due to severity, the patient's often aggravated health status, and frequently limited mobility. These types of wounds are particularly troublesome for patients, physically and emotionally. The repeat treatments also tax resources within health systems and create a financial burden on the entire healthcare system.

While there are a variety of collagen-based treatments that do assist with the healing of chronic wounds, many of these wounds will not heal without a jump-start that allows for reducing the MMPs that create persistent inflammation and wound stagnation in the wound bed.

As seen in the cases outlined here, the addition of BSN medical's new, native collagen dressing scaffold delivers that additional "leap" that chronically stalled wounds need in order to heal. Cutimed® Epiona provides a natural structure to enhance cell growth. It captures the MMPs that inflame and destroy the proteins and native collagen essential to healing. Its unique and flexible 3D structure acts like an ECM scaffold that allows fibroblasts to attach to the dressing, and then grow quickly and exponentially. This enhances rapid tissue regeneration, and complete wound healing, unlike Promogran® or Endoform® dressings that do not offer the 3D structure within their types of collagen.

Cutimed® Epiona can be applied repeatedly until full healing is achieved. It transforms into a flexible, moist gel covering when exposed to wound exudate or blood, and is completely resorbed into the wound. In laboratory studies, it was found to perform most like intact, native dermal collagen.

BSN medical's new Cutimed® Epiona reduces inflammation, enhances growth factors, and helps new, healthy cells proliferate more rapidly than other available collagen-based dressings. As our case studies have shown, it heals chronic wounds when other treatments have failed.

Promogran® is a trademark of Systagenix Wound Management IP Co B.V.
Endoform® is a trademark of Mesynthes Limited.

BSN medical Inc. 5825 Carnegie Blvd. Charlotte, NC 28209-4633
Tel. 704 554 9933 Fax 704 358 4558 www.bsnmedical.com
To order toll-free: BSN medical 800 552 1157

62461 RN ©2016 BSN medical Inc. REV 01/16

