DermaWound®

NON-HEALING CONTAMINATED WOUNDS:

A MULTIDIMENSIONAL SOLUTION

INTRODUCTION AND BACKGROUND

The care of chronic wounds is expensive and becoming more difficult to address. One study indicated that more than one-third of chronic wounds are never fully healed, that more than 10% of chronic wounds take longer than 230 days to heal,[1] and current treatment options are often expensive and ineffective. DermaWound Original© is a new product designed to help overcome these difficulties. It is a simple solution that is applied to the wound, and no other interventions are necessary during treatment. A clinical observational study has shown evidence that treatment using DermaWound Original© heals wounds more effectively and faster than existing treatment options. DermaWound Original© is also more cost-effective and less labor intensive than existing treatment options. DermaWound Original© is transforming the way clinicians address the challenges of chronic wound care.

Wound Care Trends

The care of chronic wounds is a growing area of clinical concern. Chronic wounds cost the medical system in the United States an estimated $25 billion each year and affect 6.5 million patients annually.[2]

Wound care, as a field, has become increasingly more complex, with treatment complicated by the presence of more comorbid conditions as advances in medical science lead to increased longevity for patients with chronic illness. The prevalence of diabetes mellitus and its associated comorbidities has especially impacted the wound care field.

Outcomes in wound care are influenced both by comorbidities and by the treatments utilized to manage the wound. A 2014 study of a large section of data from the US Wound Registry showed that more than a third of chronic wounds within the data set did not heal, and that the average time for wound healing for the wounds that did heal was 105 days, with 10% of these wounds taking over 230 days to heal.[1]

Trends in Treatment

The growing prevalence of chronic wounds and the increased need to treat these wounds have resulted in a myriad of treatment options. The specific treatment option actually used for an individual wound usually depends on the characteristics of that wound and on provider preference. The patient's ability to provide payment and/or insurance status, as well as product cost, can also factor into treatment decisions.

Hyperbaric oxygen therapy is a wound treatment option that is sometimes used in the management of chronic wounds. In theory, hyperbaric oxygen promotes fibroblast proliferation, enhances immune function, and stimulates angiogenesis.[2] In reality, however, this form of therapy has not been consistently as effective as anticipated, and the treatments are expensive. Its role remains somewhat controversial.

Negative pressure wound therapy (NPWT) is a promising treatment option that has led to decreased healing times and reduced rates of infection. NPWT involves the application of continual negative pressure to the wound bed, thereby removing exudate and optimizing blood flow, while maintaining a moist environment that promotes epithelialization.

There are also multiple types of dressings used in wound care. Many available dressings are infused with a variety of products designed to help promote healing while reducing the risk of infection. Perhaps the most common form of dressing used is a moist occlusive dressing, providing a moist environment in which wound epithelialization is promoted while infection risk is somewhat reduced. One challenge is that although there are multiple dressing types available, many are applicable only to certain wound types, and each has its limitations, requiring a wound care practice to carry a large and often costly inventory to address many different wounds.

Surgical or enzymatic debridement of the wound bed is used to remove dead or damaged tissues and promote the development of healthy granulation tissues. There are several products that focus on this area of wound care, with varying levels of success.

Complications of Treatment

Complications that may be experienced during treatment of chronic wounds include permanent scarring, infection, increased length and cost of hospitalization or rehabilitation, and complications related to decreased mobility. In severe cases these complications can lead to amputation, further injury, permanent disability, or death.

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TRANSFORMATIONAL WOUND CARE

Background and Overview

DermaWound Original© was invented by David Dixon, MD and was first marketed in 2014. Because of the complexity and cost of existing products, Dr. Dixon recognized the need for a simple yet efficacious wound care product and developed DermaWound Original© in response to this need.

DermaWound Original© is a solution to the chronic wound care problem; it provides wound healing and is designed to be used in the treatment of chronic wounds. DermaWound Original© can be used either as an adjunct to other treatment modalities or as an independent treatment option, depending on the wound type.

DermaWound Original© has been shown to be highly effective in the treatment of chronic wounds and wounds that have been resistant to other forms of healing. DermaWound Original© has gone through clinical testing and has been shown to promote full wound healing.

One of the primary benefits of this novel wound treatment product is that it is far more cost-effective than most other available treatment modalities. The cost of a standard course of treatment using DermaWound Original© is 38% of the average cost of traditional wound treatment.

One of the greatest clinical benefits to DermaWound Original© is that treatment using this product requires minimal intervention. DermaWound Original© is designed to be applied during dressing changes two or three times a day and does not require advanced wound care beyond application of the treatment and a basic dressing. DermaWound Original© does not require debriding, and in fact, debriding is contraindicated. Because of the inherent proteolytic properties of this product to eliminate biofilm and dead tissue, invasive debridement techniques such as sharp debridement with a surgical instrument are simply unnecessary.

The ease of application decreases the time spent on wound care and dressing changes, thus making patient care more efficient. The ease of application also reduces discomfort to the patient during dressing changes and is much less distressing to patients than most wound care interventions. Another benefit of the ease of application is that it increases the chance of compliance by reducing discomfort and time needed for treatment.

Mechanism of Action

Active ingredient: The active ingredient in DermaWound Original© is povidone-iodine suspended in a unique matrix of a non-toxic carbohydrate substrate. This allows the bound iodine to be cytotoxic to microorganisms and to osmotically disrupt the biofilm yet provide a non-toxic healing environment for normal cells.[3] The use of povidone-iodine in wound care was extensively studied in 2017, and

several features make this substance particularly useful in wound management. Povidone-iodine is a broad-spectrum bactericidal that is effective against both gram-positive and gram-negative organisms. Povidone-iodine is thought to work by oxidizing bacterial membrane components that are essential to cellular respiration. The exact pathway for this process has not yet been elucidated.[4] Povidone-iodine has been found to be effective against a wide range of organisms and is capable of treating resistant organisms such as methicillin-resistant *Staphylococcus aureus* and *Candida albicans* when it is used in dilute concentrations. An added benefit of povidone-iodine is that it has not been found to be associated with the development of bacterial resistance.

Biofilm disruption: Treatment of chronic wounds is greatly affected by the development of a biofilm, an extracellular polymer protective matrix secreted by the unique flora with which the wound bed is colonized. More than 90% of chronic wounds have biofilms that contain bacteria and fungi. The biofilm leads to chronic inflammation in the wound bed, thus arresting wound healing and increasing the risk of septicemia.[5] Based on clinical experience with the healing of previously non-healing wounds, DermaWound Original© seems to disrupt the biofilms that are typically resistant to most therapeutic interventions. By disrupting this biofilm, natural healing mechanisms, such as autolytic debridement, angiogenesis, and granulation tissue development, are allowed to progress.[5]

Autolytic debridement: Autolytic debridement is the process through which phagocytic cells and proteolytic enzymes that are naturally present in the body soften and liquefy necrotic tissue, allowing it to be digested by macrophages. These enzymes are selective to necrotic tissues, reducing the pain and complications that can occur during wound healing. One of the greatest barriers to allowing this natural form of wound healing is the risk for infection, which interferes with the autolytic process.[6] The DermaWound Original© formulation provides a moist, infection-free environment in which the conditions for autolysis are optimized.

Wound bed oxygenation: By disrupting the biofilm, providing an environment conducive to healing, and providing essential nutrients, DermaWound Original© is thought to promote wound bed oxygenation by encouraging angiogenesis. This increased wound bed oxygenation promotes the development of granulation tissues and speeds the healing process.[7]

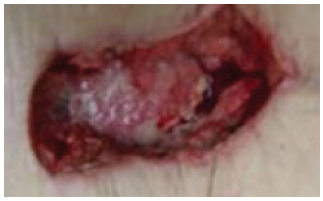
Odor reduction: The unique formulation of DermaWound Original© suppresses the development and diffusion of odors. The source of odor is suppressed by eliminating the source of wound odor production through promoting the eradication of bacteria and necrotic tissues. DermaWound Original© also provides a physical barrier between the wound bed and the external environment, thereby preventing the diffusion of odors.

Nutritive and regenerative properties: In addition to its active ingredient, the DermaWound Original© formulation contains ingredients that combine to promote a moist and nutrient-rich environment conducive to wound healing. By fostering optimal conditions for healing, DermaWound Original© provides the best circumstances for high-quality, rapid wound healing.

Clinical Research

Background: Observational studies were performed in a wound care practice setting on the clinical efficacy of DermaWound Original© by David M. Barbara, MD between February 2018 and January 2019. The efficacy of DermaWound Original© was tested on 20 wounds in 16 patients. The average wound area, estimated by multiplying wound height and width, was 40.8cm2, with a range of 2.1 to 184.5cm2. The average wound depth was 2.7cm, with a range of 0.4 to 5.2cm. The locations of the wounds were diverse, and the wounds were primarily post-operative wounds or pressure ulcers. For 16 of these wounds, DermaWound Original© was a secondary treatment after traditional treatments had been unsuccessful.

Results: Of the 20 wounds included in this small observational study, all 20 wounds experienced full healing with use of the DermaWound Original© formula and remained healed for at least six months following treatment. The average time to healing was 68 days, with a range of 21 to 91 days, with the exception of an outlier, an 87-year old woman with a stage 3 pressure ulcer. This older patient had multiple, significant comorbidities, including atherosclerotic cardiovascular disease, peripheral vascular disease, hypertension, anemia, and frail status. She still did ultimately experience complete wound healing of her two wounds after 164 days of treatment.



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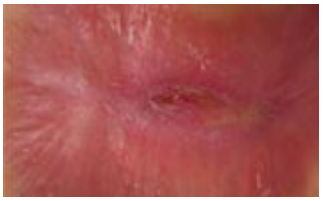

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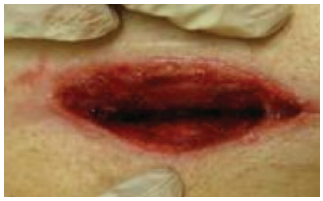

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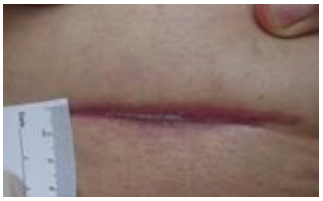

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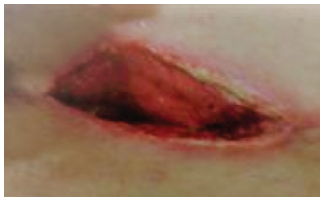

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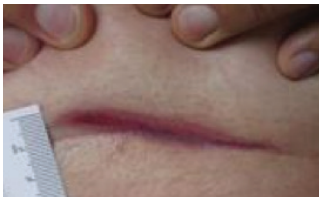
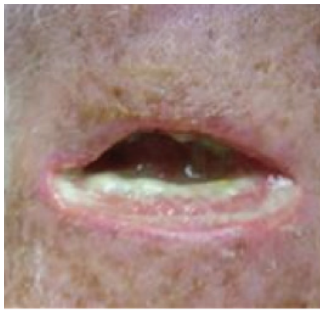


End of treatment

Select case study 1 (G.K., age 59, male): G.K. presented with three chronic abdominal wall wounds secondary to infected mesh. He initially had a ventral hernia repair on 3/18/14. G.K.'s comorbidities included atherosclerotic cardiovascular disease, hypertension, previous myocardial infarction, obstructive sleep apnea, and gout. At 31 months after his first surgery, on 10/20/16, inflammation at the incision was noted. Exploratory surgery was performed four days later, and a probable mesh infection was found. Four surgical procedures were performed over the next two and a half years, with each operation involving explantation and replacement of mesh, with multiple mesh products used. The dates of the surgical procedures were 12/09/16, 05/16/18, 06/07/18, and 06/11/18. On 07/13/18, the wounds were explored and debrided, and NPWT was started. NPWT did initially cause some improvement in wound depth, but the response then rapidly plateaued, and further healing was arrested. NPWT was discontinued on 08/07/18. On 08/14/18, treatment using DermaWound Original© was started. At the beginning of DermaWound Original© therapy, G.K. had three anterior abdominal wall wounds, one at the epigastric region that was 9.5 × 5.1cm and 3.3cm deep, one at his right upper quadrant that was 8.7 × 2.0cm and 2.8cm deep, and one at his left upper quadrant that was 7.2 × 2.4cm and 3.5cm deep. The midline abdominal wound was fully healed without any documented complications in 84 days, and the right upper quadrant and left upper quadrant wounds both fully healed in 49 days without any documented complications.



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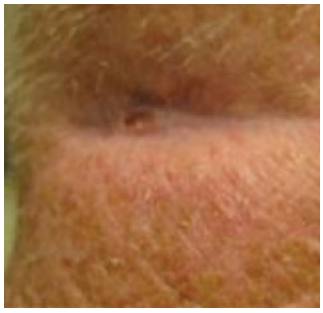
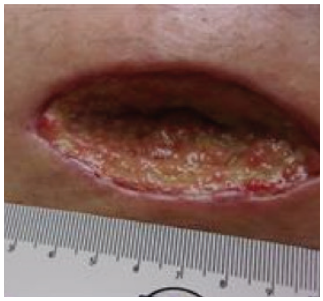


End of treatment

Select case study 2 (R.K., age 73, male): R.K. presented with an open wound on the posterior neck at the C3 level that was caused by excisional debridement of a necrotizing abscess. R.K.'s comorbidities included type 2 diabetes mellitus, atherosclerotic cardiovascular disease, coronary artery disease, hypertension, and stage 3 chronic kidney disease. The onset of the wound was documented to be 06/20/18, and conventional methods of wound treatment were not effective. Treatment using DermaWound Original© was started on 07/03/18, almost two weeks later. The posterior neck wound was 6.0 × 3.0cm and was 5.0cm deep when DermaWound Original© treatment was started. The wound completely healed without any documented complications with 63 days of DermaWound Original© treatment. No other wound care interventions were used during this treatment period.



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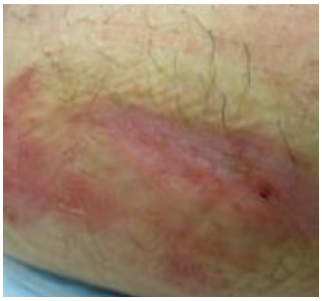
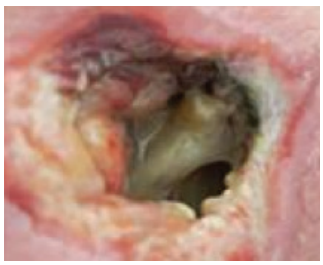


End of treatment

Select case study 3 (D.T., age 57, male):
D.T. presented with a right lower quadrant abdominal wound that was caused by debridement of necrotizing fasciitis. D.T. had several significant comorbidities, including morbid obesity (body mass index >50 kg/m2), type 2 diabetes mellitus, obstructive sleep apnea, atherosclerotic cardiovascular disease, hypertension, and asthma. The initial onset of the wound was documented to be 07/09/18, and treatment with DermaWound Original© was started more than a month later on 08/21/18, after conventional treatment attempts had proved ineffective. The right lower quadrant abdominal wall wound was 6.5 × 3.1cm and was 2.5cm deep. The wound healed rapidly once DermaWound Original© treatment was started and was completely healed in 28 days without any documented complications or any other treatment interventions.



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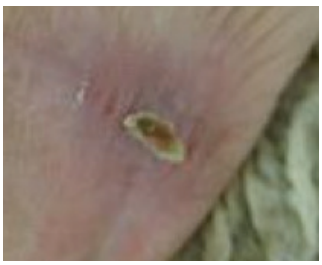

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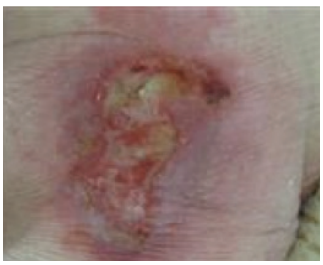

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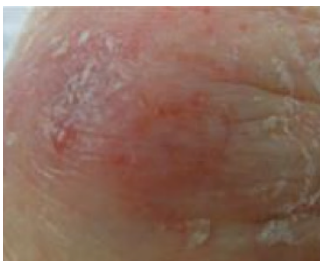

End of treatment

Select case study 4 (G. F., age 87, female):
G.F. presented with a stage 3 right buttock pressure ulcer and a stage 3 left lateral ankle pressure ulcer. G.F.'s comorbidities included atherosclerotic cardiovascular disease, peripheral vascular disease, hypertension, hyperlipidemia, anemia, and overall frail status. The date of onset of the buttock wound was documented as 2/19/18, and the wound bed was full of necrotic tissue. The date of onset of the ankle wound was documented as 1/29/18, and the wound was increasing in size at the time DermaWound Original© treatment was started. DermaWound Original© treatment was started for the buttock wound on 4/3/18 and on 2/27/18 for the ankle wound. The right buttock wound was 4.5 × 2cm and was 2cm deep with necrotic tissues covering the wound base. The left ankle wound was 2.1 ×1.0cm and was 1.1cm deep, with the wound size increasing at the time DermaWound Original© treatment was initiated. The right buttock wound completely healed after 164 days of DermaWound Original© treatment, and the left ankle wound completely healed after 140 days of DermaWound Original© treatment.

CONCLUSION

DermaWound Original© has been shown to have several significant advantages over existing wound treatment options. These advantages include a high rate of wound healing, increased speed of wound healing, and decreased cost and labor.

With current wound treatment modalities, less than two-thirds of chronic wounds experience full healing.[1] DermaWound Original© was shown in an observational study (discussed in the previous section) to promote healing in a much greater percentage, with 100% of patients experiencing complete healing. These results occurred in a small sample, and although 100% efficacy cannot reasonably be expected in larger populations, the results of this study indicate that the success rate for DermaWound Original© is likely to be much higher than that of traditional treatment options.

The average time for wound healing using DermaWound Original© was 68 days, with a range of 21 to 164 days. This data set includes a patient who was a significant outlier, and the longest time for wound healing without this outlier was 91 days. When the average of a 68-day healing time with DermaWound Original© is compared with the 105-day average healing time with traditional treatment modalities,[1] it can be reasonably inferred that the length of healing with DermaWound Original© is 65% of current treatment methods. Ten percent of chronic wounds that are treated using traditional methods take longer than 231 days to heal,[1] and the longest time for a patient to heal using DermaWound Original© was just 70% of that time frame. Although the sample size for this clinical study was small, it seems reasonable to infer a much faster healing time for chronic wound treatments using DermaWound Original©.

In addition to the increased success rate and speed of healing, DermaWound Original© is also much easier to use than many existing treatment modalities and provides a significant cost reduction when compared with the expense of existing treatment options.

Given its high success rate, increased speed of healing, and reduced cost of treatment, DermaWound Original© has been shown to be superior to many existing treatment modalities and will likely have a significant influence on the future direction of wound treatment.

Try DermaWound© for yourself—contact a representative today to request a sample of DermaWound© to test in your facility or practice. 1-520-490-5115, contact@dermawound.com.

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