A New "Smart" Wound Dressing to Control Moisture Content and Reduce Pain

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THERAGAUZE™
Absolutely Non-Stick Moist Wound Care

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Introduction

Controlling moisture content is a critical challenge in wound healing. Dry, desiccated wounds rapidly lead to necrosis and diminished angiogenesis. Conversely, wounds which are too moist will show localized maceration, which leads to separation of dermal layers and increases the risk of skin slough and infection. The problem most commonly encountered when trying to control fluid content is that every wound requires a different amount of moisture control. Ideally, a dressing that continually adapts to existing conditions would be able to provide optimal moisture content to enhance healing.

The topic of this paper is a new dressing material, which consists of a proprietary polymer sheet, marketed under the trade name, TheraGauze™, which is designed to either release or absorb moisture based on conditions at the wound's surface. This product represents a new class of smart dressings which are capable of dynamically adapting to existing conditions at the wound surface (in an almost instantaneous fashion) and to different needs across the wound surface.

TheraGauze™ and SMRT Polymer Technology

The SMRT (Skin Moisture Rebalancing Technology) polymer is what allows TheraGauze™ to regulate moisture so precisely. TheraGauze™ consists of a proprietary inert polymer which is integrated into a non-woven polyester/rayon substrate (Figure 1a). During the manufacturing process, release of alcohol in a specially controlled environment creates a vertically oriented matrix of hundreds of thousands of microscopic channels that decrease in a fractal pattern and are bordered by millions of vertically oriented polymer chains (Figure 1b).

A materials analysis of this dressing has characterized the TheraGauze™ polymer as "biomimetic"; a man-made substance that simulates a natural process. This configuration begins to explain how TheraGauze™ is able to dynamically absorb or release fluid differentially across the wound surface.

The sets of vertically oriented polymer chains are only a few microns in diameter– smaller than the individual cells making up the surface of the wound. As a result, TheraGauze™ can extract or deposit fluid to surface cells that are close together. In other words, TheraGauze™ can provide moisture differentially across the wound as demanded by different areas within the same wound.

Although the polymer itself is very good at regulating moisture over small areas, there needs to be a more coordinated mechanism to add or remove fluid from the area, once the contact areas have filled (or emptied). This is where the "canals" separating the polymer chains come in. This network works like a capillary bed, dividing up into finer and finer extensions, in order to move fluid into the dressing (Figure 1d-1f). This coordinated movement of fluid allows the surface moisture content to be maintained perfectly, while managing the ingress and egress of larger volumes of fluid just off the wound surface.

It is interesting to consider how this differs from a strictly absorbent dressing. Absorbent dressings are designed to draw materials out of the wound bed like a sponge. As a result, exudates which may contain growth factors, natural enzymatic debriders, and other nutrients critical to wound healing end up lodged within the dressing. Absorption is in a single direction

away from the wound surface until the dressing becomes saturated. At this point, the moisture simply amasses at the wound surface, and can ultimately lead to maceration.

Conversely, dressings that are occlusive do not promote any type of dynamic exchange. They simply hold materials at the wound surface in place. No moisture regulation occurs, and the dressing functions primarily to protect the wound from the external environment while preserving fluid. These types of dressings can also contribute to maceration.

In its current formulation, the SMRT (Skin Moisture Rebalancing Technology) TheraGauze™ polymer is also hydrated with propylene glycol (PG). As a humectant, it moderates the delivery of moisture to and from the SMRT Polymer. In addition, PG, which has been used in other dressings, and in cosmetic preparations for years, lubricates the contact layer, which, along with the polymer, virtually eliminates adherence to the wound bed when dressings are changed.

Clinical Experience with TheraGauze™

Since its development in 2003, TheraGauze™ has been successfully used on over 1000 patients. We have found it to be a versatile dressing, in which the pumping action can be utilized to control moisture content. In addition, its non-stick properties virtually eliminate pain during dressing changes.

To date, the dressing has worked well for treatment of diabetic foot ulcers, venous stasis ulcers, vasculitis, skin grafts, burns, and surgical incision sites. Importantly, TheraGauze™ has also been found to successfully regulate moisture when used as a cover to living skin equivalents and advanced biologic dressings, thereby increasing success rates with these therapies.

The first randomized TheraGauze™ clinical trial began in 2006, and was designed to compare treatment of foot ulcers in patients with diabetes to otherwise identical treatment using saline wet to dry dressings as the standard-of-care modality. Complete data from this study is expected in July, 2008, but preliminary results are extremely positive in favor of the use of TheraGauze™ for these difficult to heal wounds.

Case Studies using TheraGauze™

Case #1: Patient CB is a 29 year old male with sudden onset of disseminated intravascular coagulation (DIC) following septicemia. He presented with a milieu of complicated conditions requiring continuous monitoring of his limb-threatening wounds. Most notable was the fact that he has severely macerated wounds adjacent to gangrene tissues. He also had severe and intractable pain which required dosing with intravenous morphine prior to all dressing changes. After admission to our service, all dressings were switched to TheraGauze™ on his feet and legs.

Beginning with the first dressing change after 24 hours, there was immediate improvement. Most notable was the total absence of pain during dressing changes. Additionally, it was immediately observed that the maceration present upon admission was improved within 24 hours, and was virtually eliminated within 72 hours. Reduction in pain medication was also clearly documented. The patient commented that the TheraGauze™ had a soothing sensation as well, and we have found this to be a consistent anecdotal finding among all patients who typically have pain associated with their wounds. Following treatment with the TheraGauze™, patient went on to close midfoot wounds, with no loss other then gangrenous areas of toes and forefoot.

Prior to treatment with TheraGauze™. Note the exposed tendon, macerated wounds, and erythema. Exposed deep fascia (FHL tendon) is especially prone to dessication.

TheraGauze™ is applied to the wounds.

Dressings are easily removed without pain, and there is apparent decrease in erythema and maceration, while no dessication occurred in the deep, exposed tendon.

Case #2: 69 year old female with diabetes presented to our clinic with a Wagner, grade 1 ulcer measuring approximately 1 cm x 0.8 cm, at the sulcus of the left foot, just proximal to the 4th toe. The wound had an excellent granular base, and patient had strong dorsalis pedis and posterior tibial pulses. Wound had been present for approximately 3 weeks when she presented. Treatment consisted of TheraGauze™ and offloading. Dressings were changed daily. Total closure was achieved in 1 week.

Pre-treatment

Healed wound after 1 week

Case #3: A 67 year old female with diabetes presented with a chronic fissure along the medial aspect of her right first metatarsal phalangeal joint. Saline-moistened dressings were attempted for approximately 1 month with no improvement. Occlusive dressings were also attempted, and this resulted in maceration along with increase in wound size. She was treated with TheraGauze™ for 2 weeks and the fissure was completely eliminated. She has not had a recurrence in approximately 10 weeks.

Although fissures are not impressive to look at, they are often difficult to close due to complex nature of dry skin surrounding a moist wound. Untreated fissures frequently progress to full ulcerations, as was the case with this patient.

After 2 weeks of treatment with TheraGauze™, the fissure completely resolved.

Case #4: This is a 51 year old male with severe type 1 diabetes and with peripheral ischema. He has a chronic wound along the lateral aspect of his right foot, at the metatarsal head, that has been present for approximately 4 months. He has chronic serrous drainage, and has failed enzymatic debridement and treatment with silver-based dressings. He frequently gets maceration in the periwound region, and has been hospitalized twice in the last year for cellulitis to the right foot. He is neuropathic and reports no pain in the area at all. Treatment was initiated with TheraGauze™, changed twice per week. Full epithelialization and wound closure was achieved in approximately 5 weeks.

Initially, wound had a complex mix of exudate and fibrous necrosis.

After treatment with TheraGauze™, wound is healed without periwound maceration, and with natural enzymatic debridement.

Case #5: In this case, patient underwent a cadaveric skin graft (Graftjacket®; Wright Medical, Inc.) for a chronic ulceration on the medial aspect of his foot. This was done in conjunction with a distal vascular bypass. The TheraGauze™ was used to retain moisture within the graft site. The TheraGauze™ was changed weekly for 4 weeks. At that point, the remaining unincorporated Graftjacket® was removed, and the wound was treated with TheraGauze™ as the contact layer and dry gauze as the outer layer. The TheraGauze™ was changed weekly until full closure, which occurred 3 weeks later. It was noted upon each dressing change that the non-adherent nature of the TheraGauze™ caused minimal lifting and disruption of the skin graft.

Initial application of skin graft following vascular bypass surgery and wound debridment.

TheraGauze™ dressing is applied over skin graft site.

After 3 weeks, there has been dramatic improvement in the wound, and the site has maintained a complex balance of moisture retention centrally, and drying of exudate peripherally.

After 6 weeks, the wound is nearly completely closed. This wound went on to full closure at week 7.

Photographs courtesy of Dr. Thomas Roukis, Director of the Limb Salvage Service, Madigan Army Hospital, Tacoma, WA.

Case #6: Patient presents with a chief concern of venous stasis dermatitis. In addition to chronic drainage, patient was experiencing itching and chronic edema. Patient was treated exclusively with TheraGauze™ dressing for 3 weeks, resulting in rehydration of the skin, closure of sores, and dramatic reduction in dermatitis.

Prior to treatment, patient has multiple petechial hemorrhages, and erythema extending from above the ankle to just below the knee. Multiple, scaly areas of skin slough are also apparent.

Following 3 weeks of treatment with TheraGauze™, the contrast between the treated area on the left side of this picture and the untreated area to the right is dramatic. The left side of the picture shows smooth, non-scaly skin with near total resolution of petechial hemorrhages.

Photographs courtesy of Dr. Thomas Roukis, Director of the Limb Salvage Service, Madigan Army Hospital, Tacoma, WA.

Case #7: This case demonstrates a patient who underwent split-thickness skin graft , in which the bolster dressing and subsequent topical dressings were all performed with TheraGauze™. The patient went on to complete closure in 4 weeks. It is particularly notable that the healed skin graft site retained its flexibility and suppleness, a result which has been previously attributed to healing of skin grafts in a moist environment.

Split Thickness Skin Graft is applied to dorsum of the left foot.

After 4 weeks of TheraGauze™ dressings changed weekly, the wound is completely healed, and has a supple, flexible feel. Note the adjacent incision where the vascular graft was performed. This adjacent site was simply dressed with gauze, and is much more ropy and firm, as compared to the skin graft site.

Photographs courtesy of Dr. Thomas Roukis, Director of the Limb Salvage Service, Madigan Army Hospital, Tacoma, WA.

Case #8: Patients undergoing split thickness skin grafts often complain most about pain associated with the donor site, typically on the thigh or calf. These sites have raw nerve endings, and drain profusely as they heal. In the case presented here, the patient underwent a split thickness skin graft, and had pain primarily from his donor site. He was switched to TheraGauze™ as the contact layer, and pain was dramatically reduced within 24 hours.

Donor site from split thickness skin graft is frequently raw and painful with sloughy exudate.

Graft site covered with TheraGauze™ resulted in very rapid relief of sensitivity and provides an optimal moist environment to minimize scarring in this area.

Case #9: TheraGauze™ makes an ideal dressing for use with living skin equivalents such as Apligraf® (Organogenesis, Inc.). This is a 66 y.o. female with a chronic heel ulcer of 3 months duration. She underwent a single treatment with Apligraf®, kept moist with TheraGauze™. The result was total closure in just one week.

Apligraf® is applied to the prepared wound surface, and covered directly with the TheraGauze™. The TheraGauze™ is then backed with a saline-moistened gauze. This will keep the Apligraf® moist without causing maceration.

After just one week, the dressing is removed to reveal total take of the Apligraf® and full wound epithelialization. Because the TheraGauze™ is non-adherent, it will not disturb the graft.

Case #10: TheraGauze™ makes an excellent dressing for a skin graft. It keeps the graft moist, without maceration, greatly enhancing the take rate of the graft. This case involves a split-thickness skin graft, applied to the dorsum of the 1st metatarsal phalangeal joint region.

After application of the split-thickness skin graft, the excess material is trimmed away and the graft is stitched in place.

Stent dressing with TheraGauze™ as the contact layer is applied.

The graft was kept moist throughout the healing process with TheraGauze™. Here, you can appreciate the near total take of the graft.

The TheraGauze™ is applied directly to the surface of the wound, and is used as a stent dressing to apply uniform pressure to the wound and graft surface.

At the first dressing change, you can appreciate the non-stick nature of the TheraGauze™. The underlying graft looks pristine, and is well adhered.

An added advantage of moist wound healing is scar reduction. Notice how smooth the graft site is. Also, since the surface of the TheraGauze™ is dense, there is virtually no granulation tissue trapped in the dressing, further helping to develop a smooth and supple wound.

Case #11: In this case, TheraGauze™ is used to deliver an antibiotic solution to the surface of a wound which has dehisced as a result of a post-operative infection. The TheraGauze™ dressing was saturated with antibiotic just prior to application, and changed every other day for 1 week. The patient went on to full recovery without the loss of any portion of the infected toe.

Patient presented with deep MRSA infection and dehiscence of his wound following hammertoe repair.

TheraGauze™ saturated with antibiotic solution was applied to the wound and changed every other day, for 1 week.

At the end of the first week, the wound is clean, without maceration or dessication.

Final closure is achieved without loss of the toe.

Case #12: Woman with type 1 diabetes presented with a chronic ulcer following a forefoot amputation. She underwent a skin advancement flap (V to Y skin plasty) to cover a distal wound. TheraGauze™ was implemented immediately after surgery in order to minimize scarring and achieve moisture balance. Time of surgery to full closure is 6 weeks with essentially no scarring.

V to Y skin plasty to cover the distal wound.

TheraGauze™ dressing is applied over skin flap.

TheraGauze™ dressing prior to dressing change.

After 6 weeks, the wound is fully closed with essentially no scarring.

Controlled Delivery of Medication

Based on the cases presented here, as well as additional clinical experiences, numerous new applications have been considered. Because of the unique SMRT polymer technology incorporated into TheraGauze™, we have recently begun to use this smart dressing to deliver medications to the wound site. The standard sizes of TheraGauze™ are 4.125”x 4.125” and 2” x 2”. Using the current polymer configuration, this size will hold approximately 5.5 cc’s and 1.5 cc’s, respectively, of saline. Because we can predict the amount of fluid held by the TheraGauze™, we can also dose delivery of medications such as liquefied antibiotics, analgesics, and steroids.

Having a known absorption capacity also helps us to predict how often dressing changes will need to be performed. A highly exudative wound may require that the TheraGauze™ be fenestrated and backed by a more absorbent material such as gauze, foam, or ABD pad to wick away drainage. It is apparent that there are many new avenues to explore when considering the quantitative aspects of this new dressing material.

Conclusions

TheraGauze™ represents the first of what will probably be a new wave of "Smart Dressings", which are capable of being tuned to either dispense or extract moisture from a wound, and which can act simultaneously to control moisture to a different extent in adjacent sites, even within the same wound bed. Furthermore, because the absorptive character of the dressing occurs primarily within the proprietary polymer component, it can act to deliver a specific quantity of medication, or can be used to absorb a measured amount of fluid discharged from a wound.

Historically, certain types of wounds have been difficult to close due to a mixture of factors. Some areas are too wet, while other areas are too dry. Sometimes, it is difficult to even gauge what the complication is that prevents wound closure. TheraGauze™ brings another tool to clinicians, which allows them to dispense or absorb wound exudate or medication precisely where it is needed. The SMRT dressing acts to normalize moisture at all points of contact with the wound.

We have also observed that maintenance of this uniform fluid layer has the added benefit of reducing pain associated with some types of wounds. The SMRT polymer in TheraGauze™ acts to eliminate the adherence of dressings to the wound bed, so that we can move away from the use of occlusive petroleum products found in more traditional non-adherent wound dressings.

Based on our experience with TheraGauze™, we believe that we have a breakthrough technology for the treatment of complicated wounds. Furthermore, as we begin to explore the benefits of topical medication, and reduction of pain from this non-occlusive, and non-macerating dressing, we anticipate that the applications will increase dramatically.

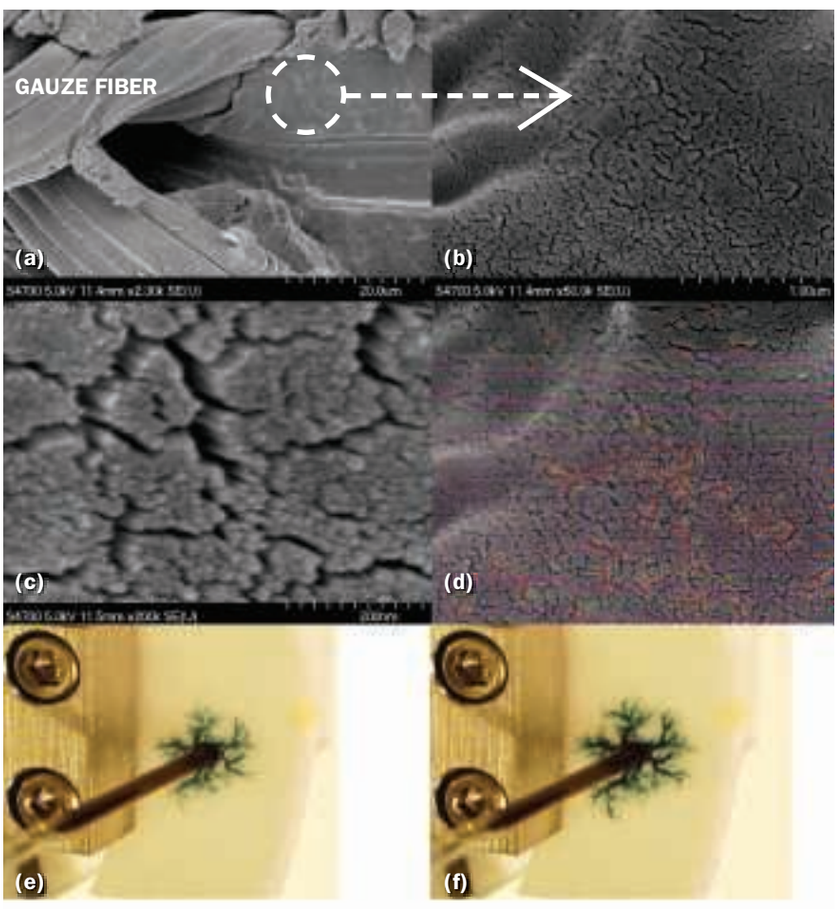

FIGURE 1: Scanning Electron Micrographs demonstrate how the TheraGauze™ polymer acts as a biomimetic. (a) Polymer is seen adjacent to polyester gauze substrate used to add strength to the polymer. (b) Increased magnification shows how the surface actually has a series of canals traversing it surface. (c) The canals are lined by pillars resembling a wheat field. (d) These pillars draw fluid into the polymer, and when saturated, shunt the fluid into the larger crevices that traverse the polymer (red lines). When a dye is added to the surface of the TheraGauze™ (e and f), you can see how the dye travels through the material, similar to the pattern one would see if you tracked the course of capillaries through skin.

SEM micrographs and photos courtesy of The College of William and Mary, Applied Research Center, Materials Characterization Laboratory, Newport News, VA.

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