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THERAGAUZE™
Moisture Regulating Wound Care

Precise Moisture Control Enhances Wound Healing with Advanced Biologics and Living Skin Equivalents

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Abstract

This is a pilot study to determine the optimal way to maintain and regulate moisture in complex wounds treated with advanced biologic materials such as living skin equivalents and collagen bioscaffolds. We evaluated the use of TheraGauze, a new smart dressing capable of precisely adjusting and regulating moisture content to varying degrees, over the entire surface of a wound. Based on this preliminary study, we feel that precise moisture regulation will enhance the incorporation and survival of the advanced biologic materials. Furthermore, this study demonstrates that precise moisture control may be an effective method to reduce wound care costs by decreasing the number of advanced biologics needed to achieve wound closure.

Introduction

Advanced Biologics such as living skin equivalents (Apligraf, Dermagraft) and collagen bioscaffolds (Primatrix, GraftJacket, Pegasus, Oasis) are used in the treatment of chronic and difficult wounds. During the application process, the materials will experience a dramatic change in environment, and as a result, are prone to destruction.

One of the most fundamental aspects of wound care is the control of moisture. Excessive fluid within the wound bed can result in maceration, tunneling and separation of the tissue planes, and elevation of the advanced biologic material off the wound bed. Conversely, a dry wound can easily kill living skin equivalents, and prevent both collagen bioscaffolds and living skin equivalents from attaching to the wound bed.

FIG. 1: Precision moisture regulation is achieved with TheraGauze. This advanced polymer dressing is capable of absorbing or releasing fluids, such as saline, simultaneously and differentially across the wound bed, as needed.

We propose to examine the effect of precise moisture regulation on the uptake and incorporation of living skin equivalents and collagen bioscaffolds in the presence of difficult wounds. This study represents a pilot study designed to gain a better understanding of the methods of application and utilization of a significant new wound dressing, TheraGauze, which is designed to actively regulate and adjust moisture content across the entire surface of a wound.

Hypothesis

We hypothesized that:

a. Precision moisture control will result in more rapid and frequent uptake of advanced biologics such as living skin grafts and collagen bioscaffolds.

b. Better incorporation of living skin equivalents and collagen bioscaffolds will occur when wound moisture content is precisely controlled.

Materials and Methods

Patients with ulcers of at least 4 weeks duration were eligible to participate in this study, regardless of depth or location of the wound. All participants were required to use either a living skin equivalent or a collagen bioscaffold product, applied to the surface of the wound, and backed with TheraGauze moisture regulating dressing.

TheraGauze is one of the first new generation of smart dressings, which is able to precisely control the quantity of saline present over the entire wound surface. Its unique structure allows it to either release or absorb fluid to different degrees, over the entire surface of the wound.

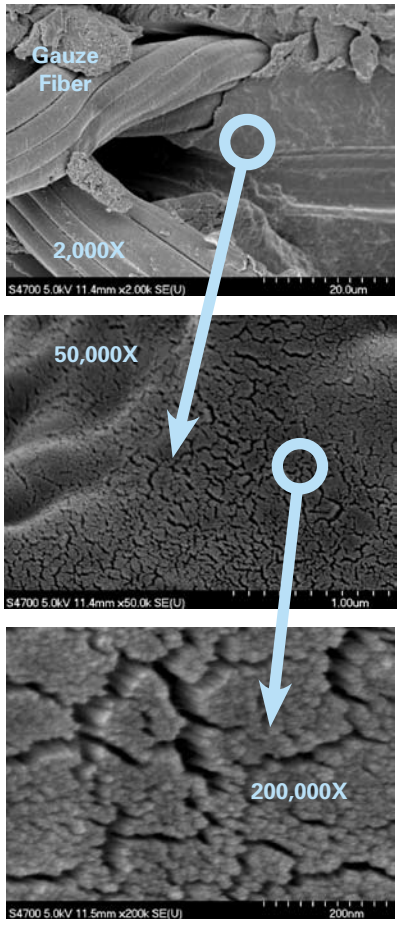

Fig 2: Electron Micrographs illustrate the unique structure of TheraGauze. The polymer dressing appears to be a biomemetic material – it contains a series of tube-like structures and canals which enable the dressing to regulate moisture at the cellular level across the wound interface.

All wounds were photographed and measured prior to treatment. Records were examined to determine the number of biologics applied to the wound surface in order to achieve closure. We observed the response to precise moisture regulation with Apligraf, Primatrix, Oasis, Biostep, Prisma, and Integra. Dressings were applied to the wound with the biologic in direct contact with the wound, and then backed with TheraGauze. This was then backed with Profore compression dressing for venous leg ulcers, or gauze and Kling if diabetic ulcer. Dressings were left in place for 5-7 days.

Results

Fig. 3: This diabetic heel ulcer was present for several months. Wound was treated with Apligraf, with TheraGauze as the backing material. Entire wound was fully epithelialized after only 2 weeks. Survivability of the Apligraf was excellent, and only a single treatment was needed to achieve closure.

Fig. 4: Following an extensive incision and drainage this patient dehisced and showed no progress in wound closure other then the development of granulation tissue, following 1 month with negative pressure wound therapy. At this point, the negative pressure wound therapy was discontinued, and the wound was treated with Primatrix fetal bovine collagen strips (TEI, Inc., Boston, MA). The collagen was backed with TheraGauze. Full closure was achieved in 7 weeks, after 3 applications of collagen and continuous dressing with the precision moisture regulating dressing.

Fig. 5: This patient had a severe Charcot deformity, and a persistent midfoot ulceration of 1.5 years in duration. Wound was treated with BioStep (S+N) and TheraGauze, in order to provide optimal moisture regulation. Immediately, there was noted to be significant improvement, and total absence of maceration. Although patient had been previously using saline-moistened gauze, progress was not seen until the combination of BioStep and TheraGauze was used.

Fig. 6: This 95 yo diabetic developed a serious decubitus ulcer following an extended stay in a nursing facility. He could not undergo a partial calcanectomy due to other health risks. Treatment consisted of Apligraf (1 application), and Primatrix fetal bovine collagen (1 application). In each case, TheraGauze was chosen as the cover dressing in order to provide precise moisture control. The initial ulcer, which began as a Wagner 2-3, measuring 7cmx5cm, closed completely in 11 weeks. During this time, excellent incorporation of both Apligraf and Primatrix was observed.

Fig. 7: This patient developed a deep, tunneling wound of 1 month duration following resection of his second toe. The wound was very highly exudative. In this case, Integra Flowable collagen was used to fill the void, and Integra collagen sheet was used to cover the ulcer site. The entire area was then covered with TheraGauze, in order to achieve precise moisture control. Within 1 week, the wound had stopped showing signs of maceration, and was completely closed in 2 weeks.

Discussion

The concept of moist wound healing is not a new one. Previous studies have demonstrated that moist wound healing will improve closure rates, and prevent desiccation. The new generation of advanced wound products, such as living skin equivalents and collagen bioscaffolds have given the clinician a whole new set of tools to battle ulcerations. However, there does not seem to be the same consideration given to dressing materials as there is for the use of the advanced biologic. Logic would tell us that a living skin equivalent would require optimal moisture regulation in the wound, just as it does in a tissue culture dish in the laboratory. Similarly, it is obvious that excessive moisture would cause peri-wound maceration and detachment of the graft from the wound bed. This also holds true for the collagen bioscaffold products which rely on intimate contact between the wound bed and bioscaffold in order to achieve incorporation.

Conclusions

Although this study represents a series of cases, using a variety of products, several trends have emerged. Our observations indicate that the incorporation of advanced biologics, and overall success rate in achieving wound closure, has improved with precision moisture control. We have observed higher rates of graft incorporation, less scarring, faster closure, and a better outcome with these advanced products.

Several manufacturers of advanced biologics have cautioned against the use of petroleum based products like Adaptic or Xeroform, due to the effect that these materials have on the living cell tissues and due to the incidence of maceration. (Oil and water do not mix!) However, the non-adherent aspects are critical in order to avoid damage to the delicate graft materials. This leaves us with old standbys like Owens silk, which won't stick, but also does nothing to regulate moisture content.

Over the last 2 years, smart dressings such as TheraGauze have become available. These highly versatile dressings allow one to precisely regulate moisture within the wound, providing for either hydration or absorption, and can vary the effect from location to location across the entire span of the wound. As a result, maceration or desiccation is greatly reduced, leading to more rapid and frequent uptake of these advanced biologic ulcer treatments.

Our normal treatment regimen is to apply the biologic and back with TheraGauze. This particular smart dressing is ideal for this application because it comes pre-loaded with normal saline, is non-adherent to the wound bed, and is relatively inexpensive. We have also used this with split thickness skin grafts, and find that scarring is diminished and that uptake of the graft is improved significantly.

Although this study clearly demonstrates the benefits of moisture regulation, it was not powered to be the definitive study in this area. Future studies will undoubtedly demonstrate the benefits of this new technology.

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