

APWCA Case #3: A Unique Aggregating Powder Dressing



Here are some clinical applications for this wound care product.

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Introduction

Changes in wound care product design often follow paths leading to larger or smaller packages (2 x 2 vs. 4 x 4 squares) or alternate materials (foam vs. hydrating polymers). A new dressing is presented with a unique approach to mechanism of action, material construction, and presentation. Good science and engineering are essential in developing a new product, along with its chemical and physical properties, but clinical experience is the most critical component of under-

standing if a new wound dressing offers exclusive or added benefits over available treatment options.

There is a wide variety of wound types available to evaluate a treatment with a new product and small groups of case studies do not represent the data developed in controlled clinical studies; however, education about a new product

is an essential preliminary step to learning about clinical applications. Early clinical examples indicate that a dressing has been used as part of a treatment and can help guide research into best clinical practice and science to improve wound healing.

This dressing has been applied to over 8,000 wounds from numerous classifications. It is currently the subject of two randomized clinical trials: one in skin graft donor sites, and one in chronic leg ulcers. Preliminary experience has been published with the product as part of treatment involving limb salvage.¹

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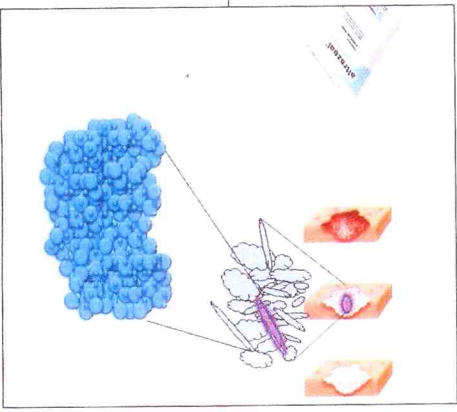


Figure 1: Cartoon showing application of the aggregating powder dressing to a wound surface with images showing magnification of the powder flakes and polymer spheres that make up the dressing material.

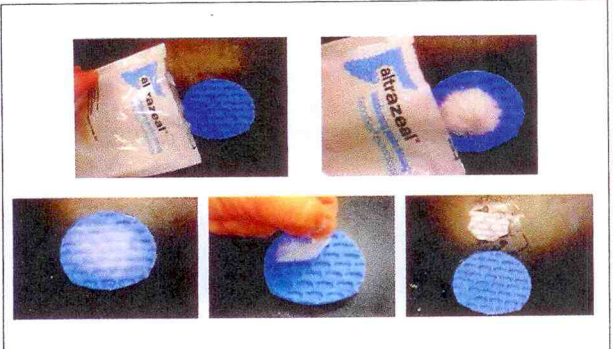


Figure 2: The aggregating powder dressing is applied to a sponge soaked in normal saline. The powder hydrates and aggregates and can be left in place or immediately removed.

New Concepts and Studies

“New Concepts” is a forum for the presentation of (1) new technologies and products which have been the subject of clinical study, and (2) new studies involving existing products. Readers should be aware that Podiatry Management does not specifically endorse any of the technologies, concepts, or products being discussed.



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Clinical cases demonstrating its use in wound management is presented with description of this dressing² along with tips for application.

Dressing Description

This dressing has the initial appearance of a powder resembling non-dairy coffee creamer. It is lightweight and is dispensed directly from the pouch onto a wound surface.

The powder flakes are composed of two polymers: poly-2-hydroxyethyl-methacrylate, and poly-2-hydroxypropyl-methacrylate, which are two hydrophilic polymers commonly used in contact lenses. The powder consists of small flakes of polymer with sizes between 100 and 500 micrometers (1/10 of a millimeter to 1/2 of a millimeter). Application of the dressing to wound exudates cause the polymer flakes to hydrate and irreversibly aggregate, transforming from individual polymer flakes into a flexible, moist dressing on the surface of a wound. Figure 1 shows a diagram of the powder applied to a wound and images of the powder flakes if magnified (Figure 1).

The transforming aggregation

that the powder undergoes when applied to a wound is not a chemical reaction but is the polymer spheres and flakes rapidly hydrating and falling out of suspension as a swollen hydrogel material. Aggregation occurs in microseconds at the wound surface and is not exothermic (producing heat). Aggregation is an irreversible process with no mechanism for the intact dressing to revert back to powder flakes. The process can be seen in

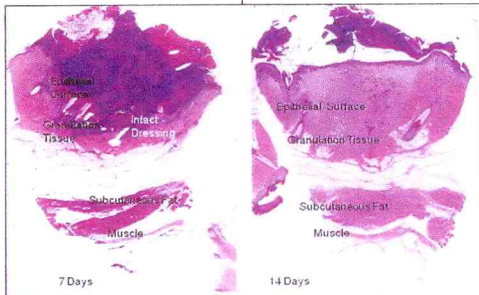


Figure 3: Biopsies from full thickness porcine wound study using the aggregating powder dressing taken at 7 and 14 days.

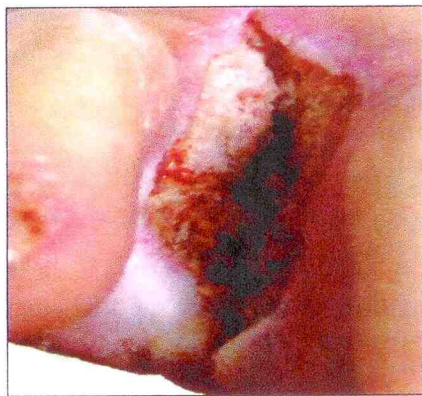


Figure 4: Post surgical amputation of the second metatarsal following NPWT.



Figure 5: Post surgical amputation wound following three weeks of weekly dressing.

the images shown (Figure 2). Here the powder is applied to a simulated wound which is a sponge soaked in saline. Note in the last photograph in Figure 2, the detail of the sponge is reproduced in the dressing that was removed.

The intact dressing is a primary dressing that is in direct contact with the wound bed. Cells and tissue do not move into the dressing and the material rests directly on the cell and extracellular matrix of the granulation tissue. Figure 3 shows a punch

biopsy of a porcine wound with the dressing in place. (Figure 3) In Figure 3, the biopsies are cross-sections of tissue from a wound with the slide oriented so that the epithelium is up and the subcutaneous fat and muscle is down. For these wounds, the defects were formed surgically and the dressing was applied without a secondary covering and left in place without changing until harvest. In the first image of a biopsy taken at seven days, the dressing is the mass of stained material taking up the bowl-shaped

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tissue defect near the top center of the image. There is no gap between the granulation tissue underlying and surrounding the dressing and the dressing itself. In the slide of a biopsy taken from a wound allowed to heal for 14 days, there is a keratinocyte layer in place seen as a dark, narrow band beneath the dressing and the dressing has detached from this new epithelium while a mature bed of undifferentiated tissue lies beneath that keratinocyte layer.

Maintaining a Moist Environment

While in place on a wound, the dressing maintains a moist wound environment with continuous total moisture content of 68% at the wound surface. The design of the material was not intended to simply absorb exudates but to manage exudate flow. Once the dressing has aggregated, the polymer spheres are oriented so that capillary channels of pores 4-10 nanometers in diameter honeycomb the dressing structure. This network of pores produces a capillary flow from the moist wound surface through the dressing where the moisture is driven off as a vapor. The moisture vapor transpiration rate for this dressing is roughly 10 times that of a typical moist wound dressing which provides some measure of fluid management when it is in place on a wound.²

The product has been tested for toxicity in chronic and sub-chronic models, sensitization, irritation, particle migration, and bacterial impermeability, and has passed all

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of these tests for biocompatibility and performance.

Case Studies

The reported cases do not represent controlled clinical data but rather show general application of the dressing to a wound surface and results of wounds that have healed while the dressing was in place.

Case 1

A 72 year old male presented with a necrotic diabetic foot ulcer necessitating amputation of the second metatarsal. The patient had Type II diabetes mellitus. The resulting wound after amputation had underlying osteomyelitis and was treated with gentamycin sulfate-impregnated beads and negated to negative pressure wound therapy (NPWT) for four weeks. During this time, significant granulation tissue had formed within the wound bed; however, little change in wound area or volume was noted. The wound was approximately 2.5 cm long, 1 cm. wide and 1-2 cm deep after NPWT and shows the irregular surface and shape of the wound that is typical of this type of metatarsal amputation.

The aggregating powder dressing was applied to the surface of the wound and was left uncovered,

without a secondary dressing. The dressing was applied for this type of wound using a tongue blade to press the powder into place. The patient was off-loaded and the dressing was changed weekly. Figure 5 shows the wound after three weeks of off-loading and coverage with the powder dressing changed weekly (Figure 5).

The wound measured 1 cm. in length, approximately 1 mm. in depth and 2 mm. in width at the widest point. Figure 6 shows the wound after four weeks of treatment involving off-loading and weekly dressing changes with the powder dressing. In this case, the healing endpoint cannot be directly attributed to any properties of the powder dressing; however, it was possible to leave the dressing in place without a secondary covering for intervals of seven days. The dressing did cover the wound during these intervals and the wound surface beneath the dressing was moist at each dressing change. The dressing required no adhesive to remain in place and the patient did not complain of discomfort.

Case 2

A 38 year old female with vascular insufficiency and varicose veins presented with a six year old wound that had been treated with surgical grafting, NPWT, and numerous conservative dressing treatments over the

wound history. Figure 7 shows the wound after sharp debridement (Figure 7). The wound was debrided and a pinch graft was taken and expanded. The graft was carefully put in place on the wound and no su-



Figure 6: Post surgical amputation wound healed after antibiotic treatment, NPWT, and off-loading with aggregating powder dressing applied and changed weekly for final four weeks of treatment.



Figure 7: Venous ulcer after sharp debridement prior to pinch graft treatment.



Figure 8: The wound after application of the expanded pinch graft and prior to the powder dressing application.

tures or staples were used to fix the graft on the wound surface. Figure 8 shows the graft after application on the wound (Figure 8). The aggregating powder dressing was applied over the graft and pressed into the wound bed between interstitial spaces on the expanded graft as shown in Figure 9.

The dressing was the only fixative for the graft and was not removed during treatment. A non-adhesive wound contact layer was applied over the aggregated dressing followed by a flexible wrap compressing bandage. At each weekly assessment, additional powder was applied to the graft surface if it appeared that the wound could benefit from further coverage. The dress-

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ing was assessed but not changed for a period of six weeks, which is beyond the manufacturer recommendation of 30 days; however, additional dressing was applied weekly to ensure adequate coverage. With this treatment regimen, the wound healed at week six as shown in Figure 10. In this case, the product did perform as a graft fixation material and primary dressing beneath a compression dressing.

Discussion

These cases demonstrate clinical applications of several techniques used to aggressively treat a complex, non-healing wound. Successful wound healing is dependent on numerous factors including accurate wound assessment and good clinical practice. They demonstrate the ability of the powdered dressing to maintain a clean wound with

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good moisture healing. The application



Figure 9: dressing



Figure 10: pinch graft with aggregating powder dressing applied to the wound surface.

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good moisture balance and timely advancement of healing. The dressing was well-tolerated by the patient. The application of this product was easy to learn and



Figure 9: Application of the powder dressing to the graft.



Figure 10: Healed venous ulcer after pinch graft treatment and pressure wrap with aggregated powder dressing as graft fixation and primary dressing.

met the needs of these commonly encountered wounds. Further information to assist the practitioner in application of this product will follow.

The aggregating powder dressing can be applied to any wound; however, certain wound preparation should be followed for best clinical results.³ There should be a clean wound bed that is free of necrotic tissue and eschar and should not show signs of infection or significant contamination. Wound size and shape is not a critical issue to Altrazeal™ application. The wound bed should show some sign of exudates. Dry wounds are not suitable for this dressing as some moisture is required to hydrate and transform the powder. Occasionally, wounds with low exudate levels can be moistened with sterile saline and then covered with the powder. Significant exudates or blood shown as pools of fluid should be blotted prior to applying this dressing.

For most wounds, the powder can be applied by pouring onto the wound surface. The powder can be transferred to a sterile container, and for vertical or upside down wounds, we have found that a tongue blade or 4 x 4 gauze square can be used to press the powder in place. The powder should be smoothed to form a layer between 1 and 2 mm. thick over the wound surface. Figure 11 shows several spreading techniques that have been used successfully to disperse the powder over a wound after it has been applied.

The final aggregated dressing is a shiny, translucent material that covers the surface of the wound. After aggregation, observe the wound surface for any areas lacking in coverage where additional powder can be applied to the already formed dressing in layers to form a uniform dressing structure (Figure 12).

The product can be used without a secondary dress-

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ing; however, because of contact with other surfaces or on load-bearing areas, or highly draining wounds, use of a secondary dressing is needed. The best dressings are porous or highly fenestrated, non-adhesive dressings and do not contain petroleum-based products within the materials.

The intact dressing initially has a translucent appearance similar to waxed paper. On wounds with contamination or with high exudate flow, the dressing will begin to change appearance from translucent to opaque with color changes ranging from brick red for wounds with blood to yellow or tan for wounds with significant contamination or high exudate flow. The change in color and appearance is normal and is the result of proteins, cellular debris, and salts being deposited at the surface of the dressing as moisture is pulled through and transpires as a vapor at the dressing surface. It is common for chronic wounds with an initial treatment of powder for the dressing to require changing after the first two to three days as the material becomes filled with proteins and eschar materials that drastically reduce the moisture vapor transpiration for the dressing. After this initial period, the dressing typically

maintains the translucent, shiny appearance and is typically left in place for periods from 7-14 days between changes.

Conclusion

The preliminary evaluation of this aggregating powder dressing resulted in the development of several early best clinical practices including methods of application, methods of hydrating the dressing, appearance of the dressing on the wound, and determination of some secondary dressing choices suitable for covering the dressing if necessary. For the cases described, the dressing remained in place without adhesive for periods ranging from 7 to 42 days on a wound surface. The dressing is currently the

subject of several controlled scientific clinical studies and could be a promising component of wound management treatment regimens as more clinical data is developed and

best clinical practice is further refined. ■

References

¹ Fitzgerald, R.; Bharra, M.; Mills, J. A. Armstrong, D. A. Use of a Nanoflex powder dressing for wound management following debridement for nectrotising fasciitis in the diabetic foot. *International Wound Journal*. 2009, 6 (2), 133-139.

² Altrazeal Transforming Powder Dressing MVTR determined using ASTM Method ASTM F2298-03 with a measured value of

11.8 kg/m² in 24 hours. A compared woven cellulose dressing had a MVTR of 1.2 kg/m² in 24 hours determined with the same method.

³ Enoch, S.; Harding, K. Wound Bed Preparation: The Science behind the revoval of barriers to healing. *Wounds*. 2003;15(7)



Figure 11: Three application techniques. Best results are to apply 1-2 mm thick; however, wounds that are narrower and deeper can require a thicker layer of the powder dressing in early treatment as the granulation bed is built up beneath the wound.

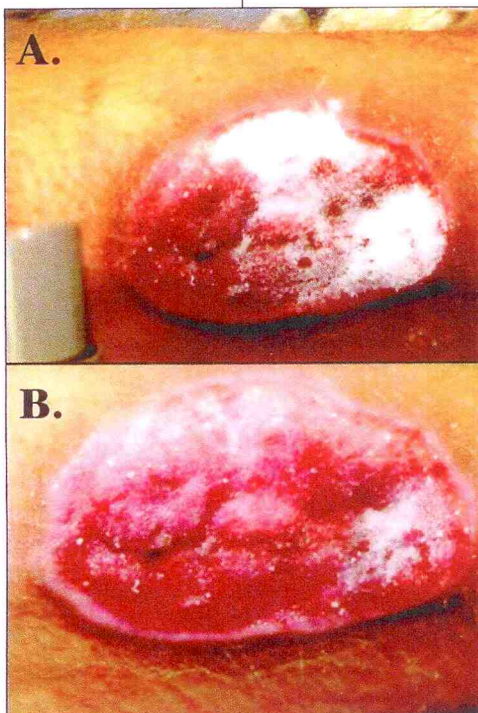


Figure 12 A and B: A—The dressing can be wetted with normal saline, which will speed the transformation from powder to dressing. The application of the saline can be performed by dripping or using a spraying device. B—Transformation using sterile normal saline sprayed from a misting bottle.

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