

Gregory A. Bohn, MD FACS, Medical Director,
Trinity Center for Wound Care and Hyperbaric Medicine, Bettendorf, IA
Sid Sharma DPM FAPWCA, All County Podiatry PC, NY, NY
Gianni Persich DPM FAPWCA, All County Podiatry PC, NY, NY
John V. St. John, PhD, ULURU, Inc. Addison, Texas

Properties of a Novel Powder Wound Dressing and Clinical Experience in Diabetic Foot Ulcers

Introduction

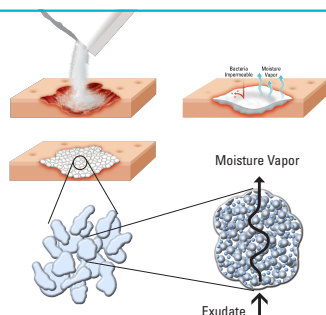
Purpose — The purpose of this presentation is to show the physical and chemical characteristics of a unique powder wound dressing and to demonstrate the use of this dressing in the treatment of diabetic foot ulcers (DFU's).

Method — We report on the properties of a novel powder dressing formulated of polymer particles, and clinical experience in the treatment of diabetic foot ulcers with and without contact casts.

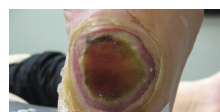
Results — The physical properties of this powder wound dressing are unique when compared to other dressing materials. When the powder interacts with wound exudate, an instantaneous and irreversible aggregation of the powder particles occurs. This aggregation is a physical transformation from powder form into a solid, non-resorbable, porous moist wound dressing. The structure of the intact dressing provides intimate contact to surface irregularities at the sub cellular level sealing the wound in a manner that is not possible with other dressing materials. The intact moist dressing makes use of capillary forces inherent to the aggregated particles to provide a strong adhesion to the wound surface. This adhesive force coupled with the sealing properties result in a primary dressing that in most cases requires no secondary covering to remain in place and isolate the wound from exogenous bacteria. We report on four separate clinical cases of diabetic foot ulcers treated with this wound dressing. Two cases involved the powder wound dressing applied to heel or Achilles DFU's with coverage of the aggregated dressing using a veil and gauze pads then offloading during healing. Two cases used the powder wound dressing on plantar surfaces with total contact casts applied over the dressing. In all four cases, the DFU's were followed to healing.

Nanoflex Technology

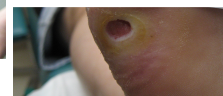
Nanoflex technology is the basis for a powder wound dressing product. The dressing components consist of polymer particles. The polymer particles are composed of 85% poly-2-hydroxyethylmethacrylate (pHEMA) and 15% poly-2-hydroxypropyl methacrylate (pHPMA). The polymers pHEMA and pHPMA are both non-resorbable, non-degradable, hydrophilic crosslinked polymers that are in the ratio of 85:15 by weight and maintain a fluid content of approximately 68% by weight of the matrix. The powder aggregates (coalesces) immediately and irreversibly from polymer particles into an intact dressing. There is no chemical reaction during dressing formation. The dressing binds together physically and not chemically and remains bound together with the wound exudate through hydrophilic/hydrophobic interactions, hydrogen bonding and Van Der Waal forces. An illustration of the dressing displaying the mechanism of action is shown.



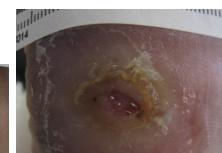
Patient 1: 47 yo Insulin dependent Diabetic Male maintained on Humulin R presented with a diabetic Wagner grade 2 lesion on the plantar surface of the fifth metatarsal phalangeal joint. Non-smoker. Current wound present for 24 weeks, starting as a blister. Wound volume stalled after treatment with tissue substitute. Powder wound dressing applied and dramatic improvement occurred with healing by week 4 of dressing treatment with weekly dressing changes.



DAY 0

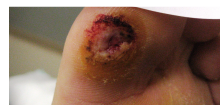


WEEK 2

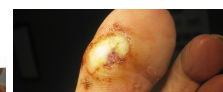


WEEK 3

Patient 2: 53 yo insulin dependent diabetic male with past history of planter Neuropathic ulcers presented to the wound clinic with a new Wagner grade three lesion to the plantar surface of the left great toe. Powder wound dressing applied and covered with veil. Wound healed by week four.



DAY 0



APPLICATION 1



WEEK 3

Patient 3: 58 yo male with history of DM, HTN. Wound is a DFU on the lateral aspect of his left heel. On initial consult (week 1) Pt. had one ulcer measuring 1.0x0.4x0.2cm. He had hyperkeratotic tissue surrounding the wound, no undermining, no probing to bone. Both wounds were debrided with a #15 blade, cleansed with sterile saline. The powder dressing was applied to the wound and covered with wound veil. The wound was covered with non-stick pad, king and coban. At week 2 the patient developed a second adjacent ulcer. Pt. had the first ulcer measuring 0.6x0.3x0.1cm and the second wound measured 0.3x0.2x0.2 cm. At week 3, the patients newly developed ulcer 2 was closed. At week 4, the first ulcer had closed.



DAY 0



WEEK 1



WEEK 3

Patient 4: 64 year old female with history of DM, HTN. Wound was surgical and result of achilles repair and was present for four weeks. The wound was debrided with a #15 blade, and cleaned. The powder dressing was then applied to the wound and then covered with Smith and Nephew's wound veil. Using a spray device, the saline was sprayed on the wound veil allowing the altrazeal to set in. The wound was then covered with Johnson & Johnson 2x3inch non-stick pad, king and coban. A Posterior splint was also applied to the patient due to protect the tendon repair. Patient was offloaded with crutches. At followup one week after the initial application the wound was closed.



DAY 0



WEEK 1

This study was sponsored by ULURU, Inc. All wounds were treated with Altrazeal™ Transforming Powder Dressing.

Conclusions

A novel powder wound dressing was evaluated as a treatment option for the coverage, healing and protection of DFU's. For the cases presented, the dressing was applied by pouring the powder onto the moist wound surface. The powder aggregated into a uniform dressing with the use of saline. In all four cases, the aggregated dressing was covered with a veil and the patient was instructed to offload the ulcer. For each presented case, the dressing was removed weekly and all wounds were followed to closure. This novel powder dressing can be applied to diabetic foot ulcers and held in place with a porous veil for periods of up to one week and the wound can be treated to closure.