

Keragel™ and Keragel T™ Wound Dressings

Functional Keratin™ Advanced Wound Care Products

Keratin is a family of cytoskeletal proteins present in skin, hair, nails and a range of other tissue. Traditionally seen as primarily a physical structure in the skin, researchers at the Johns Hopkins University have determined that keratin proteins are also vitally important in the wound healing process.¹ While collagen protein has been used in wound care for many years, wound dressings and topical skin treatments have only recently been developed using keratin proteins. Functional Keratin™ is a proprietary technology that utilizes the structural and biologic elements of keratin in a range of wound care products. This technology has captured the keratin protein as a highly versatile biopolymer.

Functional Keratin™ wound care products have demonstrated clinical efficacy in:

- Acute wounds
- Chronic wounds
- Improving skin condition and quality of life in patients with Epidermolysis Bullosa

Keragel and **Keragel T** are keratin-rich gels designed for dry wounds and skin disorders. They function to provide moisture as well as a keratin-rich environment.

Keragel and **Keragel T** are suited for dry wounds requiring autolytic debridement, such as stage II and III pressure ulcers, arterial ulcers, venous stasis ulcers or wounds arising as a result of a surgical procedure.

Keratin research

Research has been conducted into the use of Keragel and Keragel T in the treatment of

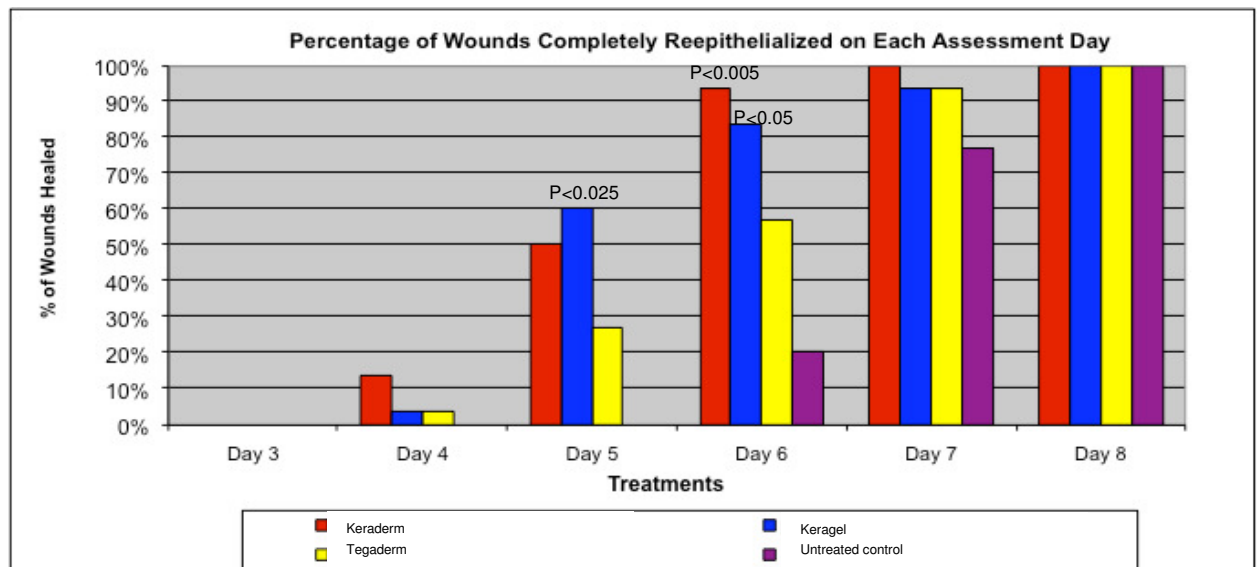
- Acute wounds
- Chronic wounds
- Wounds arising from the condition Epidermolysis Bullosa.

Acute wound care

Studies conducted at the University of Miami on deep partial thickness wounds in a porcine model demonstrated statistical significance in wound reepithelialization when compared to a transparent film comparison dressing. Wounds treated with Keragel typically reepithelialized 1 day faster than with the comparison dressing and 2 days faster than the untreated control group.²

¹ Kim, S., Wong, P. and Coulombe, P.A. "A keratin cytoskeletal protein regulates protein synthesis and epithelial cell growth", Nature. 2006 May 18;441(7091):362-5

² S Davis, R Perez, Y Rivas, J Gil, J Valdes, and R Kirsner, The effect of a keratin based dressing on the epithelialization of deep partial thickness wounds, Journal of the American Academy of Dermatology March 2009 (Vol. 60, Issue 3, Supplement 1, Page AB201)



Rate at which acute wounds completely heal in a porcine model. p measured relative to Tegaderm® (transparent film)

Related analysis of protein expression indicated that keratinocytes in the treatment group entered the activated phase and migratory phase sooner than the comparison treatment group. Both of these events are critical in the wound healing process.³

Chronic wound care

Clinical evaluations of Functional Keratin™ dressing use in chronic wound care have been conducted at the Nurse Maude Wound Clinic in New Zealand. Wound size reduction, confirmed by planimetry and wound photography, was seen in a variety of problematic, non-healing chronic wounds, most notably in refractory venous leg ulcers that failed to respond to previous compression therapy. A case series of 22 patients (mean age 74 yrs; mean wound duration 5.2 yrs) with chronic, long term non-healing venous leg ulcers was completed. Three Functional Keratin dressings were evaluated, including Keragel™, over a 4 month period. 91% of nurses and 86% of patients indicated a preference for the Functional Keratin™ dressings over their previous treatments. 77% of patients improved during the treatment period. 71% of wounds categorized as non-healing by established independent criteria, (>6month duration, >5cm² size) achieved wound closure confirmed by planimetry and wound photography, compared to a historical expectation of 13% for this wound type.^{4, 5}

³ R Perez, R Kirsner, J Gil, J Valdes, S Davis, Evaluation of the effects of two keratin formulations on wound healing and keratin gene expression in a porcine model, SAWC conference presentation, April 2009 in press

⁴ M Than, C Hammond, RA. Smith, C Marsh, R Kelly, P Rohricht, RS Kirsner, "A Prospective Pilot Study of Keratin Dressings: Effectiveness on Refractory (Large and of Long Duration) Venous Leg Ulcers" SAWC, April 2010, Orlando, Florida.

⁵ D Margolis, J Berlin, B Strom, Which Venous Ulcers Will Heal The American Journal of Medicine, 2000, 109, 15-19.

Treatment of Epidermolysis Bullosa (EB)

Epidermolysis Bullosa simplex and recessive dystrophic epidermolysis bullosa are severe skin disorders characterized by substantial and sustained skin blisters. Regular application of Keragel T™ over a several month period has resulted in positive outcomes for patients suffering from EB.

Caregivers of EB patients have observed that once healed, the skin appears more robust and the tendency to blister is significantly reduced.⁶



Blistered neck area of a dystrophic EB patient prior to keragel T treatment. Blisters had been present for approximately 10 years. Substantial secondary dressings were required daily.

⁶ R Kirsner "Use of topical keratin gel by patients with epidermolysis bullosa", Journal of the American Academy of Dermatology, March 2009 (Vol. 60, Issue 3, Supplement 1, Page AB202)



Neck area of dystrophic EB patient following 9 months of daily keragel T treatment. Secondary dressings were no longer required after 3 months of treatment. The skin continued to improve and quality of life has changed substantially

Mechanism of Action

Keragel™ and Keragel T™ help create a moist wound environment which promotes autolytic debridement and supports the wound healing process.

Keragel™ and Keragel T™ are designed for dry wounds and are highly hydrophilic, which means that they keep the wound moist but are able to absorb light amounts of exudate.

Regulatory Status

Functional Keratin™ wound care products have received (510K) clearance from the U.S. Food and Drug Administration. These products have also received the CE mark for sale in Europe and related countries and are listed by Medsafe in New Zealand. Functional Keratin™ devices are designed to ISO 13485 standards, manufactured in certified facilities in New Zealand, and supported with the standard safety testing demanded by global regulatory agencies.

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