

Management of Epidermolysis Bullosa using Keragel T™ Case study summary

Background

Keratin is a family of proteins present in skin, hair, nails and a range of other tissue. Traditionally seen as primarily a physical structure in the skin, recent research has determined that keratin proteins are also vitally important in the wound healing process.

Functional Keratin proteins developed by Keraplast Technologies have been shown to be able to activate keratinocytes present in the wound and to stimulate them to quickly enter a hyperproliferative phase, an essential phase for wound healing. In many cases, proliferation and migration of keratinocyte cells is the limiting process for epithelization and wound closure and the activation and stimulation of keratinocytes achieved by the Functional Keratin proteins increases or accelerates epithelization and results in good wound healing. Key indicators of activated and stimulated keratinocytes include increased synthesis of a range of key proteins responsible for healthy skin structure such as collagen IV, collagen VII and keratin 17. Consistent improvements in epithelization rates in wound healing and improved skin robustness in studies in which Keragel T™ has been used by people with various forms of the condition epidermolysis bullosa can be attributed to this mechanism.

Keragel T™ is an aqueous gel product available from Keraplast Technologies. Keragel T™ is rich in keratin protein and has been designed as an easy to apply low viscosity gel for convenient application to very fragile skin.

Recessive Dystrophic Epidermolysis Bullosa

Case 1

A 11 year old girl with recessive dystrophic Epidermolysis Bullosa, had required extensive wound dressing treatment daily since birth. Dressing changes were painful and some of the dressings uncomfortable to wear. Dressings and coverings worn around the back of the neck led to the patient feeling extremely “overheated” which was described by the patient as being a more persistently distressing symptom than pain because it lasted throughout the day and night, whereas pain was principally present during dressing changes only. This affected the patient's ability to attend and concentrate at school as well as her general appearance. The dressings used to protect the neck were Mepilex Lite as a primary dressing and Melolin as the secondary dressing coated with silicone 555 cream to avoid friction to the skin and covering. Previous attempts at treatment had included liquid honey

Keragel T™ was applied daily to the back of the neck at dressing change. A progressive and sustained improvement occurred leading to almost complete healing over a 9 month period. After 3 months of treatment, covering

dressings that had been required since the age of three years were no longer required. This effectively eliminated the patient's perception of feeling very hot and significantly improved patient comfort, overall appearance and happiness. The neck area subsequently remained healed with no sign of relapse for a further 3 months. Occasional blisters that form are lanced and treated with Keragel T™



Blistering on fragile skin on the nape of the neck before treatment was started. This area had required protection with a secondary dressing which had to be



After 9 months of daily Keragel T™ application (including 6 months without a secondary dressing) the skin can be seen to be much more robust with greatly

Case 2

An 8 month old infant boy, diagnosed with recessive dystrophic epidermolysis bullosa was treated over a 6 month period with Keragel T™. The left foot and left hand were treated and the right hand and right foot were control areas. The gel was applied at each dressing change and thoroughly rubbed in and covered the whole treated area. Identical secondary dressings were used on the treated and control areas. For the hands, Mepitel was wrapped around the fingers. For the feet, both treated and control areas had Mepilex heel as a secondary dressing which was wrapped around the foot and made into a boot shape. Over a 6 month period progress was documented by the nurses on a log sheet after each dressing change. Documentation indicated numbers of blisters, ease of application, comfort and pain level. The wounds were imaged weekly with a high resolution digital camera.

Wound care nurses reported that the Keragel T™ dressing was easy to apply. It was noted that the area seemed slightly uncomfortable for a matter of seconds if applied to a fresh lanced blister, but healing appeared accelerated compared to the control areas. There were no adverse events noted. Twice the gel treatment was stopped due to infection and recommenced once the infection had been resolved using antimicrobial treatment.

The perceptions of the mother, nurses and carers that attended to dressing changes were that Keragel T™ healed acute wounds quickly.

During the trial both hands were accidentally injured, at different points in time, when an older sibling stood on them when the patient was crawling. The photos presented show the impact of the traumas and subsequent healing. Treatment had been applied to the treated hand for 6 months prior to the accident. The treated hand appeared to be much more robust and able to withstand the trauma compared to the control hand. Subsequent healing following the injury was significantly quicker for the treated hand compared to the control hand. This may have arisen due to a stronger dermal-epidermal junction in the treated hand. It is not certain that the traumas were of identical severity, however, they were sufficiently similar that the difference observed in response is believed to be significant.



Treated hand following trauma



Untreated hand following trauma

Conclusions - RDEB

Regular use of Keragel T™ for the management of acute wounds and on undamaged skin for patients suffering from recessive dystrophic epidermolysis bullosa appeared to provide improvements in wound healing rates for blisters when they formed and a reduction in blister frequency. Improved skin robustness may be indicative of strengthening of the dermal epidermal junction. The two patients presented continue to use Keragel T™ as part of daily wound care.

Epidermolysis Bullosa Simplex

Case 1

A 28 year old women had suffered from EB Simplex (Kobner, confirmed by histology and electron microscopy) since childhood. This caused painful blisters on the plantar aspect of both feet accompanied by a burning sensation which she described as 'like standing on hot coals'. The blistering was accentuated by 1) heat, e.g. hot weather, 2) friction and 3) pressure., e.g. standing/walking or the application of wound dressings. The patient typically had 5 blisters on each foot and each lasting for approximately a week. The pain and heat symptoms restricted her ability to work (due to the need to stand/walk) and her overall quality of life.

The patient applied 20g of Keragel T™ to her right foot daily, and the left foot was untreated. The gel was rubbed in gently and thoroughly but without excessive force. The gel was allowed to dry for 10 minutes before socks were put on. Within a week of the commencement of treatment, the patient's current wounds healed and she observed less new lesions appearing. Subjectively the patient noted "Not as much skin shedding as before, can work longer without burning or blistering as much."

After a month, reduction in blistering was visually apparent as noted in the photos presented. This is consistent with the patient's own assessment of 1) reduced pain from the treated foot, 2) significantly reduced propensity to blister. No such improvement took place on the untreated (control) left foot.



Right foot before treatment started



Treated right foot 1 month after treatment started

Case 2

An 8 month old baby with the condition Epidermolysis Bullosa Simplex (Dowling Meara) applied Keragel T™ daily to the plantar and palmar aspects of the right foot and left hand. The left foot and right hand were untreated. Nurses who attended to the baby's dressing changes 3 times a week lanced fresh blisters and then applied Keragel T™ after each bath. This was massaged into the foot and left several minutes to dry before putting dressings or socks on. The parents also applied the Keragel T™ every evening before putting the baby to bed.

On alternate days of the dressing changes the parents would pull the dressing back and apply the gel twice a day. Initially the Keragel T™ was applied and then a secondary dressing of Mepilex Lite was placed over top. As the baby's wounds healed and the weather got warmer it was found that the Mepilex Lite dressings were detrimental to wound healing, which is common in the Dowling Meara condition, so the Keragel T™ was applied, left to dry a little and then a sock placed on the baby's foot. The hands had the Keragel T™ massaged into the hands, but no dressings were applied at all. The wounds were photographed with a high resolution digital camera for evidence and effectiveness of the areas treated.

Regular evidence in the form of a log entry was gathered from the mother. The baby made significant improvement on her treated hand and foot in the early days of treatment. The baby's mother reported that putting the Keragel T™ on fresh blisters healed them quickly and prevented further re-blistering occurring in these areas. In addition, Keragel T™ was found easy to apply, no adverse events occurred and no wound infections were reported.

Two months into the trial, the baby's mother stated she "could not help herself and I am now using the Keragel everywhere".

The areas which were initially wounded or became wounded were treated and subsequently healed. The consensus was that healing was better than would have been expected without treatment.

Tackiness of the Keragel T™ was reported as difficult and it was not always possible for the baby to be kept still for long enough for the gel to dry sufficiently to avoid sticking to socks.



Left foot, blisters present before the start of treatment



Treated foot now looks much improved though new blisters have formed in a different place.

Conclusion – EB simplex

Regular use of Keragel T™ for the management of acute wounds and on undamaged skin for patients suffering from epidermolysis bullosa simplex appeared to provide improvements in wound healing rates for blisters when they form and a reduction in blister frequency associated with more robust skin. The patient presented in case 2 continues to use Keragel T™ as part of daily wound care.

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