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Keratin-based products for effective wound care management in superficial and partial thickness burns injuries

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ABSTRACT

This $n = 40$ cohort study on superficial and partial thickness burns compares novel keratin-based products with the standard products used at our facility. The keratin products are found to facilitate healing with minimal scarring, be well tolerated with minimal pain and itch, be easy to use for the health professional and be cost effective for the health care provider. For these reasons they are being adopted into use at our facility.

1. Introduction

Superficial and partial thickness burns account for the majority of burn presentations in the hospital setting and patient management with topical dressings and outpatient followup is often appropriate. An ideal product meets the needs of the wound, the patient, the health practitioner and the healthcare provider. The wound requires protection from external infection and trauma, and something to promote rapid epithelialisation and scar minimisation. The patient seeks comfort and a rapid return to activities of daily living (ADLs); the practitioner seeks ease of use and the provider, minimal cost and use of limited health resources.

We report a cohort study comparing a range of keratin-based products (a thick keratin gel (keragel®), a thin keratin gel (keragelT®), and a keratin matrix (keramatrix®), from the Replicine® range (Keraplast Technologies LLC, www.keraplast.com)) with standard care. The aim of the study was to determine the effectiveness of these keratin-based products in the management of superficial (where only the epidermis is damaged) and partial thickness (where the epidermis and part, but not all, of the dermis is damaged) burns by comparing their ability to meet the above requirements against current standard care.

Potential fitness-for-purpose of the keratin-based products was supported by pre-clinical animal studies [1] and a clinical randomised control trial (RCT) on partial thickness donor site wound healing [2] and scar management [3]. The keratin in this range of products has been shown to stimulate keratinocyte activity [4] increasing migration and proliferation rates, and up-regulating the expression of key basal membrane proteins (types IV and VII collagens). This mechanism is consistent with results observed in the clinical trials described above and is well aligned to the needs for the classes of burns being studied. The ease of product use was confirmed in a clinical case study series on venous leg ulcers [5] and in clinical studies of patients with Epidermolysis Bullosa [6,7]. This is the first systematic clinical trial of keratin-based products for burns patients.

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2. Methods

The study was approved by the institutional review board (Upper South B Regional Ethics Committee, New Zealand). The inclusion criteria for the patient cohort was: burns presenting at Christchurch Hospital Emergency Department (ED) within 24 h of injury and involving less than 10% total body surface area (TBSA). The exclusion criteria were: infected burns (burn where the bioburden was likely to impede healing, as assessed by the duty plastic surgery team based on a combination of pain, swelling, pus and erythema), full thickness burns (as assessed by the duty plastic surgery team) and any burns not expected to heal by conservative approaches within approximately 14 days and likely to require skin grafting.

Patients in the treatment group ($n = 40$) presented at the ED and were consented to enroll in the study. For burns with low exudate, if they were judged not to need a secondary dressing for protection (e.g. on the face), the thin keratin gel alone was used as this would dry quickly. For burns with low exudate, if they were judged to need a secondary dressing for protection, the thick keratin gel was used and then covered with a non-adherent dressing such as Mepitel®, Silflex® or similar and then a Tegaderm™ film dressing was applied to secure, waterproof and for ease of performing ADL's. For burns with moderate exudate the thick keratin gel was again used and covered with a non-adherent dressing, cotton gauze and then a Tegaderm™ film dressing. For burns with high levels of exudate (typically on the trunk/legs), the keratin matrix dressing was used and covered with a non-adherent dressing, an absorbent pad dressing such as Melolin® or Mesorb® or similar and then a Tegaderm™ film dressing. In some cases hydration of the keratin matrix dressing with saline prior to application ensured increased compliance of the matrix and assisted with body contour moulding. Finally, for burns where exudate level for the subsequent 2 days was unpredictable, the thick keratin gel was applied and covered with a keratin matrix and Tegaderm™. The choice of keratin dressing to use was made by the duty plastic surgery team. Subsequent treatment was provided in the community by the same independent community nurse. Again the choice between thin gel, thick gel or matrix was based on exudate management and secondary dressing needs. Intact blisters were typically left for 2 days (unless these were over joints and would restrict movement) then debrided and all non-viable tissue was debrided. Overall, a moist wound healing approach was taken avoiding excess free liquid but not allowing the wound to dry. Oral analgesics were available to patients for dressing changes.

Digital photographs were taken at presentation and at each dressing change every 2–4 days. During dressing changes, patients' levels of itch and pain and their ability to resume ADLs were recorded in the clinical notes. Patients were clinically discharged once epithelialisation was complete and any not discharged were assessed in a hospital outpatient clinic by the same Plastic Surgeon 12–14 days after injury. At time of wound epithelialisation, patients were provided with the thin keratin gel to apply daily for 1 month to assist with scar management. Patients' scars were inspected by the same community nurse at 6 and 12 months after injury, and a Patient Observer Scar Assessment Scale (POSAS) measurement was recorded and digital photographs were taken at these time points.

A control group ($n = 40$) of patients was retrospectively identified. They had burns that met the inclusion criteria and presented during the same time period that patients were being enrolled into the treatment group. These patients were treated with protocols representing Standard Care for the Plastics Department. This includes Acticoat™, Biobrane® and an assortment of non-adherent dressings and topical liquids. All cohort patients had burn data recorded at presentation including cause of burn, TBSA and depth of burn. Healing times and oral antibiotic use were attained from patient clinical notes.

For each patient in both the treatment and control groups, resource utilisation data and associated costs were collected from hospital patient management records. The costs were categorised as: Emergency Department, Operating Theatre, Inpatient, Outpatient, Medical Staff, Support Staff and Other. In our facility's cost accounting system, nursing costs are included in either inpatient, outpatient or emergency department costs (as appropriate). The cost of consumables is excluded and no corrections were made for inflation. To statistically compare measurements from treatment and control groups, ANOVA or χ^2 test, as appropriate, was used to determine if differences are statistically significant with $P < 0.05$.

3. Results

Forty patients with 61 distinct burn wounds were enrolled to treatment, including 32 Caucasian, 7 Maori or Pacific Island and 1 Asian patient ethnicity, with an age range of 7 months to 69 years. The majority of the burn wounds healed rapidly with only 2 (4%) taking more than 10 days. Fig. 1 provides a Consort Diagram; 36 patients with 49 burn wounds were analysed.

Localised infection was noted in two burn wounds on the first three patients enrolled. Following outpatient treatment with oral antibiotics and a silver-based dressing, they healed with no further complications. Subsequently, the treatment method was revised to that described in the methods section and intact blisters were retained for 2 days, and then debrided to decrease the infection risk. The choice of secondary dressings was also revised to provide more absorption and avoid 'pooling' and the subsequent 37 patients showed no signs of clinical infection. The three patients enrolled prior to the method change have been excluded from the analysis as described in the CONSORT diagram, Fig. 1.

One patient presented with a scald burn, it was predicted that she would start to epithelise within 14 days and she was enrolled into the treatment group. After 14 days she had not started to epithelise and so she followed our facility's protocol and received debridement and split skin grafting at that time. Hence, she has been treated as 'discontinued intervention' and excluded from the analysis.

POSAS assessments of mature scars were conducted on 29 of the 36 patients in the treatment group, inclusive of 41