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A randomised controlled pilot study comparing Mepitel® and SurfaSoft® on paediatric donor sites treated with Recell®

S.D. Campanella [a,b], P. Rapley [b,c], A.-S. Ramelet [d,e,*]

[a] Princess Margaret Hospital for Children, Perth, Western Australia, Australia
[b] School of Nursing and Midwifery, Curtin University, Perth, Western Australia, Australia
[c] Sir Charles Gairdner Hospital, Perth, Western Australia, Australia
[d] Institute of Higher Education and Nursing Research, Centre Hospitalier Universitaire Vaudois and University of Lausanne, Switzerland
[e] University of Applied Sciences, Western Switzerland, Switzerland

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ABSTRACT

This randomized controlled pilot study examined the effects of a silicone net dressing (Mepitel®) and a monofilament polyamide woven dressing (SurfaSoft®) on the rate of epithelialisation and epidermal maturation, pain, and ease of dressing removal on paediatric donor sites treated with epithelial cell suspension (ReCell®). Fifteen children (1–15 years) admitted for acute or reconstructive burns procedures in a tertiary referral hospital in Australia were randomly assigned to the experimental group, Mepitel® ($n = 8$) and to the control group, SurfaSoft® ($n = 7$). All donor sites were treated with ReCell® and covered with the assigned dressing. Measurements of rate of epithelialisation and epidermal maturation, pain, and ease of dressing removal were recorded every two days until the wound was healed. Results showed that there was no difference in the rate of epidermal maturation between the two groups. Less pain and force to remove the dressing was shown in the Mepitel® group when compared to SurfaSoft®. The rate of epithelialisation was found to be an unreliable measure.

Although additional research is required to support the results of this study, these results suggest that Mepitel's® pliable, self-adhesive and atraumatic properties may improve healing of ReCell® treated donor sites with less pain at dressing changes. This pilot study provides a strong base for further research in this area.

1. Introduction

Burn injuries in children can leave disfiguring scars and can be incredibly painful during the acute phase of treatment. Novel therapies for epidermal cellular replacement (ECR), including the use of cultured autologous cells in suspension (ReCell®), have provided alternative treatment options, particularly for patients with large burn injuries [1–3]. The appropriateness of dressing selection, based on wound healing principles is essential to minimize complications and promote healing [4–6]. Donor sites treated with ReCell® have traditionally been dressed with SurfaSoft® (Toreon, Rotterdam, The Netherlands), a monofilament nylon dressing that limits cell loss from the wound surface [7]. However, this type of dressing can adhere to the skin surface and cause trauma to the healing wound upon removal [6].

Advancements in silicone dressing technology may provide an alternative to the previous choices available for sites treated with ReCell®. Mepitel® (Mölnlycke Health Care,

* *Corresponding author at*: César Roux 19, 1005 Lausanne, Switzerland. Tel.: +41 21 316 8108.
E-mail address: aramelet@hecvsante.ch (A.-S. Ramelet).
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Gothenburg, Sweden) is a silicone-based wound contact dressing that incorporates a non-adherent polyamide mesh bound with a silicone gel [8]. It has pores that are 1.2 mm in diameter at a rate of 14 pores per cm^2, making it a fairly open structure and one, in which exudate can freely pass through to secondary dressings away from the wound bed [9]. It was showed to improve wound healing in rats with more epithelialization and granulation tissue formation, and less inflammatory cell infiltration and necrosis, when compared to vaseline gauze [5]. A recent literature review showed that Mepitel® was used in various types of wounds and skin injury, including skin grafts fixation, management of donor site, and burns [8]. It was used in finger tip injuries as a non-adherent dressing interface to solve the problems of dressing adhesion and has been noted to cause fewer disturbances to the healing wound bed during dressing changes [10]. Mepitel's® non-adherent property has also been shown to significantly reduce pain in patients having skin grafts fixation and burns [8,11]. However and to our best knowledge, the effect of Mepitel® on donor sites treated with ReCell® has not been demonstrated.

The objectives of this study was, therefore, to compare the effectiveness of a silicone net dressing (Mepitel®) and a monofilament polyamide woven dressing (SurfaSoft®) on the rate of epithelialisation and epidermal maturation, pain, and ease of dressing removal on paediatric donor site wounds treated with epithelial cell suspension (ReCell®). Another aim of this pilot study is to determine the feasibility of the study protocol.

2. Materials and methods

2.1. Participants and setting

Children were recruited from the 9-bed total care burn unit (TCBU) at a tertiary referral hospital for children in Western Australia between September 2007 and March 2008. Eligible children were aged from 1 to 18 years, had sustained acute burn injury or were electively booked for reconstructive burn scar revision surgery and who required a split skin graft. Exclusion criteria included a medical condition that impaired sensation to their lower limbs, an acute burn injury equal to or greater than 20% of total body surface area, a known sensitivity to either of the dressings, a known underlying local or systemic condition that would influence wound healing (e.g. sepsis). The study was approved by the Human Research Ethics Committee of the hospital and the university. Written consent was obtained from parents and assent from children over seven years of age.

2.2. Procedure and instrumentation

A pilot single blind randomized control trial was designed to compare the effectiveness of a Mepitel® dressing with SurfaSoft® on split thickness donor site wounds treated with ReCell® in children. A computer-generated simple randomization was used to assign participants to the allocated treatment. The researcher informed the surgical team as to which study group the participant was randomized into, immediately prior to surgery. The participants were blinded to treatment assignment for the total duration of the study.

The standard epithelial cell suspension procedure was performed by the burns plastic surgeon on duty. The procedure consisted of taking an appropriate size split skin graft to a depth of 6/1000 in. with a Zimmer® dermatome (Zimmer, IN, USA) from the thigh or buttock and a portion of this skin graft being reapplied to the site in the form of epithelial cell suspension. Depending on treatment allocation, the surgeon applied either the current standard dressing, SurfaSoft® or the experimental dressing, Mepitel® and paraffin impregnated gauze. All donor sites were covered with secondary dressings of wrung-out betadine soaked gauze and dry gauze. The sites were then wrapped in a soft cotton bandage and a crepe bandage to secure. At completion of the epithelial cell suspension procedure, the participants were transferred back to the TCBU.

Dressing on donor sites were changed by experienced registered nurses on duty at day-2 post-surgery and repeated every second day thereafter for fourteen days or until the wound was considered healed. The participants were given analgesia one hour prior to the dressing change as per unit protocol and a baseline pain measure was taken prior to dressing change. Measurements of epithelialisation rate, surface electrical capacitance, and pain were performed after the primary dressing had been lifted. The wound was redressed with the secondary and outer dressings and a third pain measurement was taken five minutes after the dressing change was completed. To minimize measurement error, all measurements were taken by the same researcher.

All measurements were taken by the researcher at the time the outer and secondary dressings were removed.

The rate of epithelialisation was measured using VisiTrak™ (Smith & Nephew Pty Ltd., Australia), a portable, digital, self-calibrating device. Although not tested on wound sites treated with ReCell®, VisiTrak™ has been reported as a reliable and valid instrument that allows the user to make repeat tracings of a wound to determine the size and the healing progress [12,13].

Epidermal maturation was measured by skin surface electrical capacitance using a NOVA dermal phase meter (DPM)™ with standard 6 mm probes (NOVA DPM 9003; Nova Technology Corp., Gloucester, MA, USA). This self-calibrating instrument measures the surface electrical capacitance of the healing wound and indicates the maturity of the epidermis and stratum corneum. A newly formed wound would register high capacitance levels due to the absence or immaturity of the stratum corneum. As the wound healed, it registered lower capacitance levels as the epidermis differentiates and the stratum corneum develops.

Pain was measured using four pain scales, each of them validated for the participants' different age groups. These included the Children and Infants Postoperative Pain Scale (CHIPPS) for children aged 0–3 years [14], the Face, Legs, Arms, Crying, Consolability (FLACC) pain scale for ages 4–7 years [15], the Faces Pain Scale-Revised (FPS-R) for ages 8–12 years [16], and the Visual Analogue Scale (VAS) for children 12 years and older [17]. All pain instruments included a standardised 0 (no pain)–10 (maximum pain) pain scoring system. The analgesia and sedation administered prior to dressing change was