Split-thickness skin graft donor site management: a randomized controlled trial comparing polyurethane with calcium alginate dressings

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ABSTRACT

Split-thickness skin grafting (SSG) is a common reconstructive technique for the treatment of patients with deep burns and other traumatic injuries. The management of the donor site after harvesting an SSG remains controversial because of a variety of dressings available for use. The aim of this randomized controlled trial was to compare the effectiveness of a polyurethane dressing, Allevyn™, to a calcium alginate, Kaltostat®. From August 2009 to April 2010, 36 patients were randomized to Allevyn™ or Kaltostat® for donor site management following split skin graft surgery. Pain intensity and adverse events were the primary outcomes assessed. Secondary outcome measures included time for wound healing, ease of application and removal and overall patient satisfaction. Time to first dressing change was earlier in those randomized to Allevyn™ compared with Kaltostat® (5·5 days versus 8·11 days, $P = 0{\cdot}014$). In patients randomized to Allevyn™, excessive exudate lead to a significantly increased number of dressing changes before day 10 (14 days versus 7 days, $P = 0{\cdot}018$). The total number of dressing changes applied was also greater in those with Allevyn™ compared with Kaltstat® ($P = 0{\cdot}007$). There were no significant differences between the two treatment groups with respect to time to wound healing, level of pain intensity, length of stay, staff and patient satisfaction levels. This trial showed Allevyn™ to be associated with increase demands on nursing time, increased cost of dressing products, medical consumables and wastes. Kaltostat® remains the dressing of choice for initial donor site dressing in this burns unit.

Key words: Clinics • Evidence • Infection • Wounds

INTRODUCTION

Split-thickness skin grafting (SSG) remains the primary management technique for the treatment of deep burns and other injuries resulting in a skin deficit (1). An SSG requires the formation of a secondary wound (donor

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site). The donor site wound is often painful, and if wound exudate is not contained by the dressing, then it is prone to infection (2). The optimal donor site dressing is yet to be determined (3). A recent systematic review of donor site dressing trials found no clear evidence to support the choice of a particular dressing (2). Nonetheless, there is agreement that the optimal dressing should maintain a moist environment and support rapid healing without adhering to the wound bed (4). It needs to be absorbent and easy to apply and remove. Patient and resource factors, such as pain, frequency of dressing changes, convenience and cost effectiveness are also relevant issues (2).

In our unit, a calcium alginate donor site dressing (Kaltostat®) is the preferred option because of ease of application and haemostatic properties. However, with reduction in exudate as time elapses after surgery, the gel initially created tends to dry out and the dressing becomes adhered to the healing wound (4). This can impede patient mobility, comfort and on removal cause damage to the wound bed.

We therefore identified an alternative polyurethane dressing that would not adhere to the healing wound, while maintaining a moist wound environment, and providing a barrier to the passage of fluid or wound exudate (5). Such dressings may also enhance the reepithelisation process. Allevyn™, Smith & Nephew, UK, is a multi-layered foam dressing consisting of three layers: the inner is a non adherent, polyurethane contact layer; the middle, an absorbent layer; and the outer, a water proof, polyurethane film, which prevents bacterial contamination, and is water resistant (5). As a result, we conducted a randomized control trial (RCT) comparing the effectiveness of this polyurethane dressing (Allevyn™) with the calcium alginate dressing (Kaltostat®) in order to determine the preferred donor site dressing in our unit.

MATERIALS AND METHODS

Study design

This RCT compared the effectiveness of Allevyn™ and Kaltstat® on the donor site wounds of 36 patients between August 2009 and April 2010. The study protocol was approved by The Alfred Hospital's Research and Ethics Committee. All patients provided written informed consent during a clinical consultation before undergoing any study procedures.

Participants

Eligible participants were those admitted to the Victorian Adults Burns Service (VABS) and Plastic Surgery Units at The Alfred Hospital who required an SSG procedure, and had the graft harvested from the thigh. Excluded patients were those with allergies to polyurethane film, those with injuries to the thigh and those with burn injuries larger than 20% of total body surface area. Patients with significant psychiatric conditions associated with psychotic or delusional symptomatology, significant drug and alcohol dependency or impaired conscious state were also excluded.

Study protocol

A computer-generated randomization sequence developed by an external agency assigned the patient to either the polyurethane dressing or the standard calcium alginate dressing. Allocation of the dressing regime was carried out using the opaque-sealed envelope technique, in which an envelope containing a card assigning a treatment regimen was allocated to a patient on the day of surgery. In the operating theatre, a split skin graft was harvested from the thigh, using a Zimmer® dermatome set at 0·010 in (0·254 mm). The donor sites were covered with saline adrenaline-soaked gauze packs (concentration 1:500 000) for 7 minutes before dressing application. The donor site was then dressed with either Allevyn™ or Kaltostat® according to the randomization protocol. If a patient required both thighs to be harvested, one dressing product was applied to both donor sites. Owing to the nature of intervention, patients and staff were not blinded to the treatment allocation.

Donor site wound monitoring

Our current donor site management protocol entailed leaving the dressing intact for 7–10 days, unless there was evidence of exudate strike through. If there was evidence of exudate leakage from the Allevyn™ dressing, the dressing was removed. The wound site was assessed and the surrounding skin cleansed and a new Allevyn™ dressing applied. If the Kaltostat® secondary dressing of cotton gauze

Key Points

- a recent systematic review of donor site dressing trials found no clear evidence to support the choice of a particular dressing
- in our unit, a calcium alginate donor site dressing (Kaltostat®) is the preferred option because of ease of application and haemostatic properties
- however, with reduction in exudate as time elapses after surgery, the gel initially created tends to dry out and the dressing becomes adhered to the healing wound
- as a result, we conducted a randomized control trial (RCT) comparing the effectiveness of this polyurethane dressing (Allevyn™) with the calcium alginate dressing (Kaltostat®) in order to determine the preferred donor site dressing in our unit

and crepe bandage showed evidence of strike through, it was removed and replaced with cotton gauze and bandage. If the Kaltostat® came away from the donor site when the outer dressing was being removed, it was replaced with a new Kaltostat® dressing. At dressing change, the site was cleansed with diluted Cetrimide Shampoo (20%) and redressed with the same dressing product. If the donor site was assessed as potentially infected and requiring an antimicrobial dressing, this was recorded in the medical record and the area was treated as per burn unit protocol for clinically infected wounds.

Primary and secondary outcome measures

The primary outcome measure was pain intensity. In this instance, patients scored pain at their SSG donor sites between 0 (no pain) and 10 (worst pain possible) daily using the numerical rating scale (NRS). The NRS was chosen as it showed not only a greater responsiveness in detecting improvements associated with pain treatment (6), but was also used across a number of previous donor site trial studies (5,7). For each dressing change, a series of secondary outcome measures using an NRS were also collected. They included the following:

Ease of dressing application; including flexibility and conformity. Staff evaluated the application and removal of the dressing using an NRS adapted from Caruso(8). The anchor points were: 0 = not at all, 1 = not very, 2 = somewhat, 3 = very and 4 = extremely. The number of required dressing changes before day 10 was also noted.

Patient perception and satisfaction (Patient assessment). Patient comfort, ease of movement whilst wearing dressing and ease of dressing removal was graded using NRS adapted from Caruso (8) and Terrill(4). The patients were assessed using anchor points 0 = not at all, 1 = not very, 2 = somewhat, 3 = very and 4 = extremely. Feelings of anxiety, at commencement, during and completion of the dressing changes were recorded using an NRS with anchor points 0 = no anxiety to 10 = worst possible anxiety.

Adverse effects. Adverse effects, such as infection, haematoma and excessive exudate were identified and managed as per trial protocol. Excessive exudate was defined as exudate leaking from the dressing or, in the case of Allevyn™, when exudate collected under the dressing and lifted it from the wound bed.

Dressing changes, time to wound healing and length of stay. Time of first dressing change and number of subsequent dressings required until complete healing occurred was recorded. Time to wound healing was assessed on the day of donor site dressing removal and defined as reepithelisation with no adherent dressing. Recording of total length of stay was also obtained.

Data analysis. A minimum of 18 patients per group were required to have an 81% power to show a statistical difference equivalent to 1 SD on the primary outcome measure with a two-sided P value of 0·05. For all outcomes that were assessed by rating scales, mean and SD were calculated for the two treatment groups. Independent t-test statistics were performed to assess differences between these groups at the 0·05 level. Pearson's chi-square statistics were calculated to assess the differences in the incidence of adverse effects and the number of dressings required between treatment groups.

RESULTS

A total of 36 patients were enrolled in this study, with characteristics shown in Table 1. One patient was excluded from the trial on day 3 after returning to the operating theatre for dressing removal.

Table 1 Patient characteristics by dressing product

	Allevyn™ (n = 18)	Kaltostat® (n = 18)	Total (N = 36)
Gender			
Male	6	10	16
Female	12	8	20
Patient category			
Burns	10	8	18
Plastics	8	10	18
Area of injury			
Lower limb	9	10	19
Upper limb	4	6	10
Back/Flank	4	0	4
Abdomen/Chest	1	2	3

Table 2 Overall mean numerical rating pain scale scores by dressing product

NRS scores	*n**	Allevyn™, Mean (SD)	*n**	Kaltostat®, Mean (SD)	*P*
Day 1	18	1·33 (1·68)	18	2·11 (2·08)	0·226
Day 2	18	1·61 (1·91)	18	1·67 (1·68)	0·927
Day 3	17	1·24 (1·39)	18	1·39 (1·15)	0·723
Day 4	17	1·56 (1·98)	18	0·89 (1·18)	0·230
Day 5	17	1·62 (1·93)	18	1·44 (2·41)	0·817
Day 6	17	1·71 (2·54)	18	1·17 (1·58)	0·454
Day 7	17	1·18 (2·11)	18	0·75 (1·14)	0·458
Day 8	13	1·27 (1·51)	16	1·25 (1·65)	0·974
Day 9	11	2·64 (3·38)	10	0·80 (1·32)	0·125
Day 10	8	0·88 (1·36)	10	0·10 (0·32)	0·154

NRS, numerical rating score.

*Reduced according to patients still having a dressing at the time.

Numerical rating pain scale scores

The NRS scores for pain recorded at daily time points for Allevyn™ and Kaltostat® are shown in Table 2. The variation in the number of patients assessed on each day was because of dressing removal and changes resulting from adverse events or wound healing. No statistical differences in mean pain scores between the two patient groups were observed on any day.

Staff satisfaction

Table 3 illustrates the staff assessment of the application and removal and the patient assessment of comfort, satisfaction and restrictiveness. Staff consistently reported that the Kaltostat® dressing was easier to apply than the Allevyn™ dressing. However, there were no significant differences in patient perceptions of the dressing or staff perception of ease of dressing removal. Table 3 also illustrates that overall patient anxiety with the donor wound dressing was similar for the Allevyn™ and Kaltostat® groups. There was no difference in anxiety scores before, during or after the dressing between those receiving Allevyn™ and Kaltostat®.

Table 3 Staff, patient perception and product satisfaction by dressing product

	Allevyn™, Mean (SD)	Kaltostat®, Mean (SD)	*P* (*t* statistic)
Ease of application (staff)	2 (0)	3 (0)	*
Ease of removal (staff)	2·33 (1·41)	2·22 (1·06)	0·79
Patient comfort	2·17 (1·25)	2·06 (1·26)	0·79
Patient satisfaction	2·39 (1·29)	2·39 (0·61)	1·00
Dressing restrictiveness	1·06 (0·94)	0·96 (1·11)	0·86
NRS score: pre-dressing	2·22 (2·80)	1·89 (2·78)	0·722
NRS score: during dressing	2·83 (3·29)	2·78 (2·76)	0·957
NRS score: post-dressing	0·94 (1·00)	1·17 (1·86)	0·658

NRS, numerical rating score.

*t cannot be computed because standard deviations of both groups are 0.

Adverse effects

Table 4 shows no incidence of haematoma in either product. The incidence of excessive exudate was significantly greater in the Allevyn™ compared with the Kaltostat® dressings. Clinical observation of infection occurred in five donor wounds, which were swabbed for microscopy and culture. Organisms identified were methicilin-resistant *Staphylococcus aureus* (MRSA), ($n = 2$), *Pseudomonas aeruginosa* ($n = 2$) and *Alcagenesis* species ($n = 1$). No organism was specific to either product.

Dressing changes

Table 5 shows that ten patients randomized to Allevyn™ required more than one dressing change before day 10. Time to first dressing change in days was earlier among patients receiving the Allevyn™ dressing (Allevyn™,

Table 4 Incidence of adverse effects at site of dressing (data for first dressing, $N = 36$)

	Allevyn™, *n* (%)	Kaltostat®, *n* (%)	*P* (chi square)
Haematoma	0	0	–
Excessive exudate	10 (55·6)	3 (16·7)	0·015
Infection	2 (11·1)	3 (16·7)	0·630

Table 5 Number of dressing changes before day 10 according to dressing product

	Allevyn™, *n* (%)	Kaltostat®, *n* (%)	*P* (chi square)
Dressing change before day 10	14 (77·8)	7 (38·9)	0·018
Number of dressings applied per patient, posttheatre			
1	8	16	0·007
2	5	2	
3	5	0	

Key Points

- we found no difference in the primary outcome (pain) between the two products that were tested
- we did not show any difference between the two products with respect to patient satisfaction, time to healing or adverse events
- neither product reliably absorbed exudate from the donor site without leakage or breakthrough, which required dressing change within 10 days
- later drying out of both dressings was noted in the event that early dressing change was required
- this was associated with adherence to the wound bed, and difficulty of dressing removal
- although our study did not analyse the cost for both products, use of Allevyn™ is associated with possible increase in theatre time, increase in nursing time and the accumulated cost of frequent dressings
- Allevyn™ was presented to our unit as a donor site wound management product, which would decrease wound pain, could be left on a wound for up to 10 days and required reduced number of dressing changes, which reduced costs associated with nursing time and medical consumables and waste
- in this trial, it was not found in our unit to be superior to Kaltostat

mean = 5·50 days versus Kaltostat®, mean = 8·11 days, $P = 0·014$). Time to wound healing and total length of stay show no significant difference in either product groups.

DISCUSSION

There are many products available that potentially address the requirements for an optimal donor site dressing. However, none is definitely shown to be superior, and choice of dressing currently depends largely on clinician preference (1,2). The effect of a dressing on healing is of primary importance; however, the way in which a product can be applied and used, patient and staff satisfaction and resource implications are also significant considerations.

This trial compared two different dressing products. Both dressings are designed to be occlusive and promote moist wound healing. Such dressings have previously been associated with decreased levels of wound pain and protect the wound from dehydration, contamination and mechanical trauma (1,2,9). We found no difference in the primary outcome (pain) between the two products trialled. This contrasts with an earlier comparison study with Kaltostat® showing Allevyn™ to be associated with decreased pain levels (10). Nor did we show any difference between the two products with respect to patient satisfaction, time to healing or adverse events.

Allevyn™ was rated lower by surgeons in the ease of application, possibly because of their familiarity with Kaltostat®, and also because the technique used of taping the edges of Allevyn™ to the skin was found to be awkward and time consuming. This technique was found to be associated with a 'tenting' effect, which allowed the product to lift off the wound bed and may have decreased absorptive capacity.

Neither product reliably absorbed exudate from the donor site without leakage or breakthrough, which required dressing change within 10 days. Our study protocol was to leave the dressing intact for 10–14 days unless there was leakage or the need to examine the wound for clinical reason; however, other studies examining donor site dressings dictate a protocol of much earlier 'elective' dressing change, as early as day 2 (1,7,9). Thus, leakage is avoided, possibly at the expense of more frequent dressing changes. Later drying out of both dressings was noted in the event that early dressing change was required. This was associated with adherence to the wound bed, and difficulty of dressing removal.

Other studies on donor sites show a preference for Allevyn™ use, despite the lack of difference in overall statistical findings (5,10). However, one study found the use of Acticoat®, preferable over Allevyn® in their unit, indicating that many dressings can be appropriate for the donor site depending on the units' preference (1). Although our study did not analyse the cost for both products, use of Allevyn™ is associated with possible increase in theatre time, increase in nursing time and the accumulated cost of frequent dressings.

Allevyn™ was presented to our unit as a donor site wound management product, which would decrease wound pain, could be left on a wound for up to 10 days and required reduced number of dressing changes, which reduced costs associated with nursing time and medical consumables and waste. In this trial, it was not found in our unit to be superior to Kaltostat®.

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