A prospective randomised controlled trial of the effectiveness of calcium alginate and retention dressings in split-thickness skin graft donor sites

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ABSTRACT

The type of dressing used to manage split-thickness skin graft (SSG) donor sites is variable, with limited evidence on the most effective dressing to use. We conducted a prospective randomised controlled trial comparing the effectiveness of calcium alginate and retention dressing (calcium alginate+Fixomull®) to Fixomull alone for the management of these wounds. Outcome measures included the proportion of healed donor sites, participant reports of pain and number of dressing changes.

A total of 56 elective surgical patients with skin graft donor sites were randomised. By day 15, significantly more participants treated with Fixomull alone had achieved 100% epithelialisation compared with those treated with calcium alginate+Fixomull (82% v 56%, p=0.04). Differences in mean pain scores between treatment groups were not discernible at day five clinic assessments. By day 15, Fixomull dressings were associated with less pain during the day (p=0.02) and during dressing changes (p=0.04). Participants who received Fixomull alone required significantly fewer dressing changes (p=0.009).

Retention dressings provide a simple, comfortable dressing that achieves acceptable time to healing for SSG donor site wounds. The popularity of retention dressings for the management of these wounds appears to be supported by our findings in respect to time to healing and comfort.

Keywords: donor wound, retention dressing, Fixomull®, Algisite M®, healing, patient comfort.

INTRODUCTION

A number of dressing products have been promoted for managing skin graft donor site wounds with healing, patient comfort, infection rates and cost-effectiveness being the most commonly evaluated outcomes[1,2]. Of the range of products available, calcium alginate appears to be the most widely used in Australasia and the United Kingdom (UK)[3,4]. A recent survey of UK practice reports that retention dressings are the second most commonly used dressing after calcium alginate[4]. Retention dressings are also used in Australasia[3].

A number of studies have compared calcium alginate with polyurethane[5], paraffin gauze[6-9], scarlet red[10], and bio-occlusive dressings (for example, Tegaderm®)[11,12]. Several of these report favourable results with calcium alginate in respect to healing and patient comfort[6,8,11,12]. Others, such as those comparing calcium alginate with polyurthethane[5], scarlet red[10] and bio-occlusive dressings[12] report lower healing rates with calcium alginate than the comparison product. However, polyurthethane[5] and bio-occlusive dressings[12] were associated with significantly higher leakage rates than calcium alginate, prompting more frequent dressing changes[5] which add to the cost of care.

Research to support the effectiveness of retention dressings is limited with only two randomised controlled trials (RCT) available. Both were conducted in the UK, and compared calcium alginate and retention dressings[13,14]. Their findings suggest that retention dressings provide greater patient comfort and better time to healing when compared to calcium alginate[13,14]. The dearth of studies examining the effectiveness of retention dressings may in part be due to the fact that these products were designed as a fixation tape rather than a primary dressing. Our positive experience with retention dressings in the management of partial-thickness burn injuries[15,16] led us to using these products in the management of donor site wounds which are surgically acquired areas of partial-thickness skin loss.

We compared the effectiveness of calcium alginate with retention dressing fixation with retention dressings alone in promoting wound healing and patient comfort for split-thickness skin graft (SSG) donor sites. The aim of our study was to investigate which of these commonly used options is superior for SSG donor wound management.

METHODS

This RCT involved a single plastic surgery service at one Australian university teaching hospital and was approved by the institution Human Research Ethics Committee (EC2008/041). Patients ≥18 years old, requiring a SSG and who would be reviewed at the plastic dressing clinic (PDC) were eligible for inclusion. Exclusion criteria are noted in Table 1. The study site provides a plastic surgery service

Table 1: Study exclusion criteria

Patient refusal
Physically or intellectually impaired and unable to respond to questions
Thermal burns greater than 10% of body area*
SSG ≤ than the size of a postage stamp
Known allergy to dressing product

SSG, split-skin graft
* criteria used for minor burns

for a broad range of patients in metropolitan and regional areas of Western Australia.

The primary endpoints for the study were the proportion of donor wounds that had healed and participant comfort. Healing was defined as 100% epithelial cover and was assessed at each clinic visit. Patient comfort was assessed by self-report using an visual analogue scale that provided a numeric pain intensity score from 0 to 10. A score of 0 indicated 'no pain' and 10 indicated the 'worst possible pain.' Participants were asked to score their donor site pain since their surgery (during the day, at night) and during dressing change.

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Information on pain management was provided for participants who reported pain to reinforce postoperative instructions. Secondary outcomes included the incidence of dressing slippage, number of dressing changes required, and the incidence of wound infection.

We calculated a priori sample size estimation for the study of 44 (Fixomull alone n=22, calcium alginate+ Fixomull n=22) to detect a difference in healing of three days which was considered clinically significant (α <0.05 and power [1-β] 0.8). This sample was calculated on the basis of an audit of previous SSG donor sites that indicated that the mean expected healing time was 21 days (SD+/– 3.5 days) from surgery[17].

Eligible participants were identified from upcoming theatre lists by investigators (LG/MY) and were informed of the study by mail. A telephone call prior to their admission date was made as a follow-up invitation and provided an opportunity to address any questions. Verbal consent was obtained at this time. Participants were allocated a dressing type using a sealed opaque envelope in which the treatment had been predetermined using block randomisation. A random ratio for randomisation had been used to prevent prediction of assignment. Theatre lists were not managed by any of the investigating team.

Table 2: Data collected

At baseline
Weight
Height
Donor site location
Dressing applied
Presence or absence of:
Type I or type II diabetes
Anaemia
Malignancy within past 5 years
Inflammatory bowel disease
Altered sensation
Limited mobility
Other key medical conditions
Medication use
Anticoagulant
Immunosuppressant
At each clinic visit
Wound healing (% of epithelialisation)
Pain at night, during the day and at the time of dressing change (using a 10-point numeric rating visual analogue scale)
Signs of infection **
Dressing slippage (yes/no)
Need for dressing change (and details if changed)

** According to the Australian Infection Control Association criteria for diagnosis of superficial surgical site infections and approved by Healthcare Associated Infections Advisory Committee[26]

Investigators responsible for assessing eligibility did not have access to clinical information other than the procedure listed on the theatre list. Potential participants who could not be contacted preoperatively were included in randomisation as both treatment options were routinely used in the management of donor sites at the study site. Written consent to participant in the study was obtained at the first PDC visit. For the duration of the study the type of calcium alginate used was Algisite M® and the retention dressing was Fixomull®.

Surgeons harvested the grafts using a Zimmer® dermatome which was set at 8 one hundredths of an inch. The surgical team and nursing staff followed a Standardised Surgical and Wound Care Protocol for all SSG donor sites. Calcium alginate was applied directly to the skin surface and covered with Fixomull without any interface dressing. Fixomull alone was applied directly to the wound. In both dressings, a 2cm adherent margin was maintained around the donor site. Dry gauze and crepe bandage were then applied over the primary dressing until the first PDC review.

Participants visited the PDC at days 5, 15 and 21 postoperatively, or until healing occurred. Individuals who had their theatre cancelled, did not proceed to having a donor site (that is, were able to have primary closure of wound), or declined to participate in the study were not included in follow-up. Follow-up was provided by a specialist plastic surgery nurse (LB) who recorded the data outlined in Table 2. The total number of clinic visits, the number of dressing changes and the date the donor site wound healed were also collected.

During the study, the primary dressings were changed only if clinically indicated due to slippage, excessive exudate, or infection. This avoided any unnecessary disturbance of the newly formed epithelium. The outer dressing and bandage were changed if seepage had occurred. An assessment of healing was performed at dressing change/removal or if the dressing had been shed. Dressings were expected to shed between day 14 and day 21. If the dressing had not shed by day 21, it was removed. Day 15 was used as the benchmark for comparison of time to healing as most SSG donor sites are expected to have healed by this time[4]. Blinding of the assessor was not possible given the obvious difference in the dressings' appearance. However, investigators performing analysis were not involved in the clinical management of participants or data collection.

ANALYSIS

Descriptive statistics were used to provide a summary of sample characteristics. Continuous variables in normally distributed data were analysed using an independent t-test and Mann Whitney U test for non parametric data. A c^2 test (or Fisher's exact for small

samples) was used to compare categorical data. Height and weight data was used to calculate participant's body mass index (BMI) using the National Heart, Lung and Blood Institute online calculator and then classified as underweight (<18.5), normal weight (18.5–24.9), overweight (25.0–29.9) and obese (≥30)[18]. Differences in wound healing and pain were assessed on an intention to treat basis. All incidences of infection were reported. Statistical significance was set at $p<0.05$.

RESULTS

A total of 56 participants completed the study. One participant had two donor sites making the total number of donor sites 57. Five participants did not receive the allocated dressing postoperatively which left 52 participants who received the protocol treatment. A summary of sample characteristics is provided in Table 3 and the consort diagram for enrolment and analysis is provided in Figure 1.

Medical conditions for participants in each treatment group that may influence healing are outlined in Table 4. No participants were prescribed immunosuppressive therapy and 19 (33.3%) were on anticoagulants. Two participants who were prescribed anticoagulants received Fixomull alone instead of the randomised calcium alginate+Fixomull. The reason for this protocol deviation by theatre staff who applied the treatment dressing could not be determined. A Fisher's exact comparison found significantly more participants in the calcium alginate+Fixomull group (n=13) than in the Fixomull alone group (n=6) were prescribed anticoagulants (p=0.004).

Number of dressings required

The number of dressing changes required by participants in each treatment group to achieve 100% epithelialisation is summarised in Table 5. Participants who were randomised to receive a Fixomull alone dressing required significantly fewer dressings than those in the calcium alginate+Fixomull group (p=0.009). This difference remained significant when participants who required up to two dressings were compared (p=0.03).

Fifty nine per cent of participants (calcium alginate+Fixomull n=12, Fixomull alone n=22) did not require a dressing change before day 15. A further nine participants required a dressing change on day

Table 3: Sample characteristics

Characteristic	Calcium alginate + Fixomull (n=23)	Fixomull alone (n=34)	Group comparison
Median age in years (IQR)	77 (65–82)	70 (58–79)	p=0.09 [A]
Age group (yrs)			
<60	3 (13%)	8 (24%)	p=0.490 [B]
≥60	20 (87%)	26 (76%)	p=0.76 [B]
Male (%)	16 (69.6%)	24 (70.6%)	p=0.93 [C]
Mean BMI (SD)	28.2 (5.8)	27.9 (4.9)	p=0.86 [C]
BMI group			
18.5–24.9	6 (26%)	10 (29%)	
25.0–29.9	8 (31%)	10 (29%)	
>30	7 (27%)	11 (33)	p=0.91 [B]
Missing	2 (7.7%)	3 (9%)	
Donor site location			Total
L) anterior thigh	5 (21.7%)	9 (26.5%)	14 (24.6%)
L) posterior thigh	1 (4.3%)	0	1 (1.8%)
L) lateral thigh	3 (13.0%)	4 (11.8%)	7 (12.3%)
L) other	0	3 (8.8%)	3 (5.3%)
R) anterior thigh	10 (43.5%)	8 (23.5%)	18 (31.6%)
R) lateral thigh	3 (13.0%)	9 (26.5%)	12 (21.1%)
R) anterior thigh proximal	1(4.3%)	0	1 (1.8%)
R) inner arm	0	1 (2.9%)	1 (1.8%)
Mean donor wound size (length x width in mm)	6402	7970	p=0.38

A = Mann Whitney U test
B = χ^2 comparison or Fisher's exact test
C = Independent sample t-test
mm = millimetres
IQR=Interquartile range
SD=Standard deviation

Figure 1: Consort flow diagram

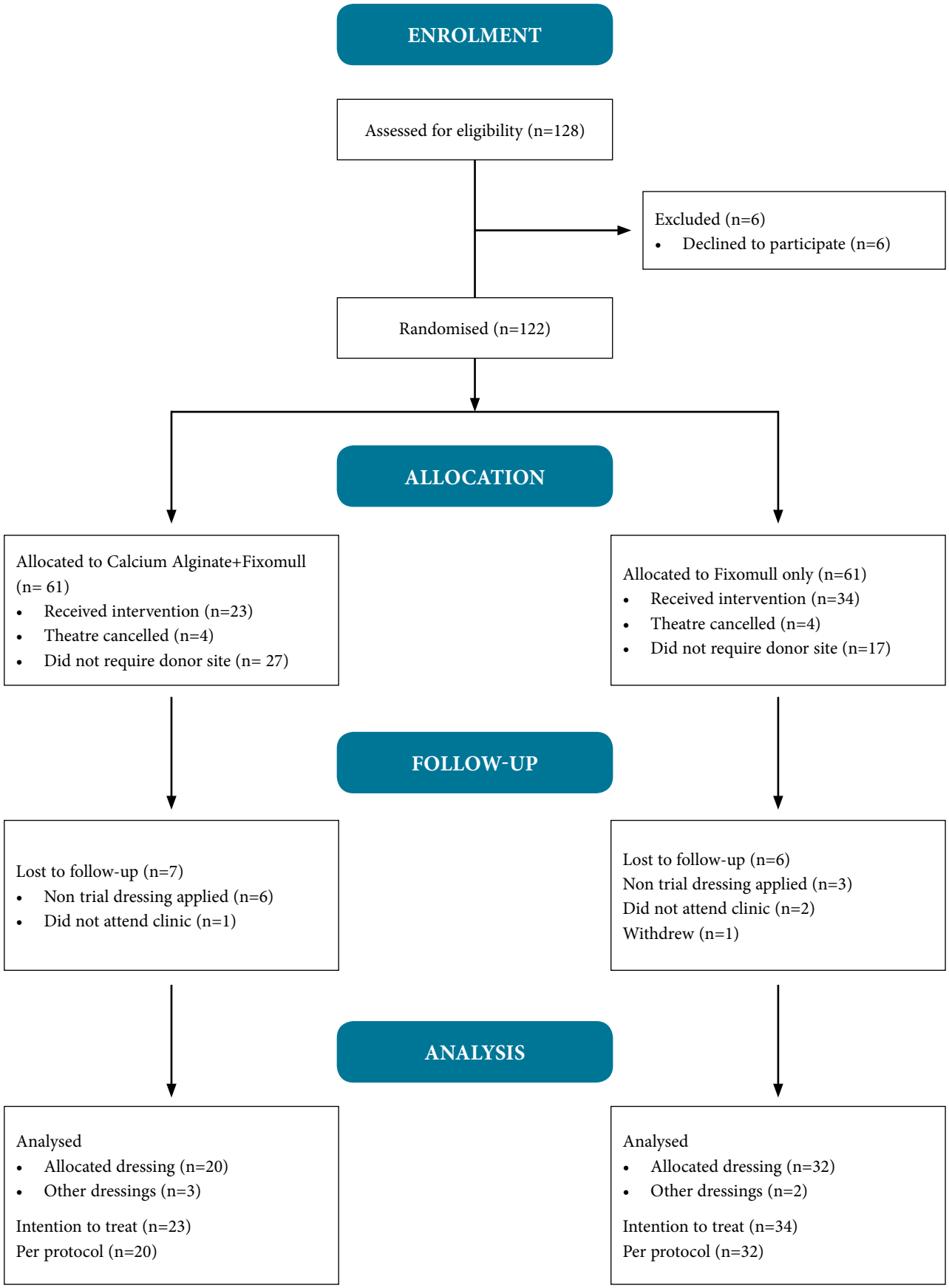


Table 4: Medical conditions

Condition	Calcium alginate+ Fixomull	Fixomull alone
Type I diabetes	1	2
Type II diabetes	5	7
Anaemia	1	1
Malignancy in past 5 years	3	12
Inflammatory bowel disease	–	2
Limited mobility	5	4
Altered sensation	1	1
Other medication conditions		
Autoimmune disorders	0	6
Kidney impairment	3	2
Chronic Obstructive Pulmonary Disease	1	1
Congestive Heart Disease	1	1
Atrial fibrillation	2	0
Rheumatoid disease	0	1
Dementia	1	0

COPD=Chronic Obstructive Pulmonary Disease
CHD=Congestive Heart Disease

15 (calcium alginate+Fixomull n=7, Fixomull alone n=2). Excessive exudate was the primary factor that prompted dressing change for participants dressed with calcium alginate+Fixomull. The two participants dressed with Fixomull alone had both pre-emptively removed their dressing prior to the clinic visit to facilitate review. As the site had not yet healed a new Fixomull dressing was applied.

Wound healing

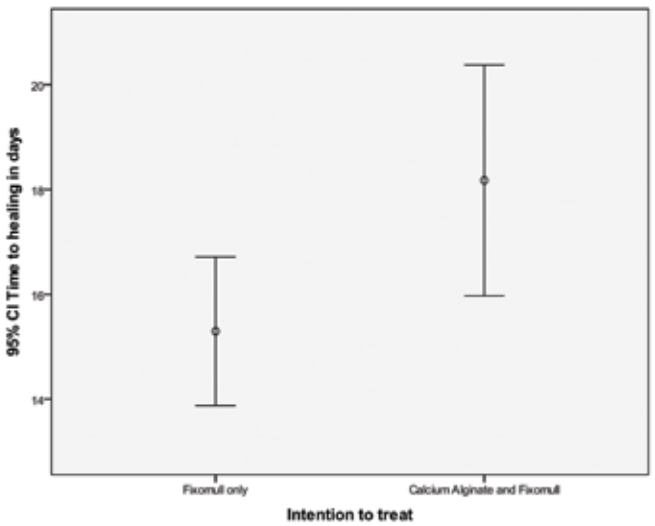
By day 15, 41 participants (71.9%) had achieved 100% epithelialisation (calcium alginate+Fixomull 56%, Fixomull alone 82%, χ^2 p=0.04). In those patients who had not healed by day 15, the use of prescribed anticoagulants was similar in both treatment groups (calcium alginate+Fixomull 63.7%, Fixomull alone 53.8%, χ^2 p=0.49). At day 21, 6 patients had wounds that had not yet healed (calcium alginate+Fixomull n=4, Fixomull alone n=2; Fisher's exact p=0.20). The longest time to healing was 29 days. This participant was 81 years old, with a BMI >30.

Table 5: Number of dressing changes required

Dressing changes (n)		Frequency (%)	Cumulative %
Fixomull alone	0	2 (6.0%)	0
	1	17 (50.0%)	55.9%
	2	13 (38.2%)	94.1%
	3	2 (5.9%)	100.0%
	Total	34 (100%)	
Calcium alginate +Fixomull	1	7 (30.4%)	30.4%
	2	9 (39.1%)	69.6%
	3	6 (26.1%)	95.7%
	4	1 (4.3%)	100.0%
	Total	23	

As some variability in the actual time to review occurred due to clinic scheduling, we also calculated time to healing by subtracting the surgery date from the date when 100% epithelialisation was documented in addition to the proportion of patients healed at each clinic visit. The mean number of days to achieve healing was 15.29 in the Fixomull only group (SD+/– 4.06) and 18.17 in the calcium alginate+Fixomull group (SD+/– 5.10). Figure 2 provides a comparison of mean time to healing (in days)[17].

Figure 2: Error bars comparing mean time to healing with 95% confidence limits



Incidence of infection

We recorded one case (#14) of wound infection during the study which was identified and confirmed at the day 15 clinic visit. This participant had no known comorbid risk factors and had received a calcium alginate+Fixomull dressing. The dressing was changed to Acticoat® on day 15, then to DuoDERM® on day 21. The wound was healed by day 28.

Pain

Differences in mean pain scores between treatment groups (Table 6) were not discernible at day five clinic assessments. By day 15, significant differences in pain scores for each treatment group were reported during the day (p=0.02) and during dressing changes (p=0.04). Differences in pain scores at night approached significance (p=0.06). Comparisons were not performed for day 21 as most participants' wounds had already healed.

A significantly greater proportion of participants treated with Fixomull alone compared with those treated with calcium alginate+ Fixomull reported no pain at day 15 during the day (94% v 65%;

p=0.0115) and at night (94% v 65%; p=0.0115) with differences in proportions also approaching significance during dressing changes (93% v 71%; p=0.05). Comparative analysis of participant pain levels that considered anticoagulant use at day 15 was not conducted as there were too few patients who were taking prescribed anticoagulants and who reported pain to enable any inference to be made.

Dressing slippage

There were two reported cases of dressing slippage (one for each dressing type) and these were reported at the day five clinic visit. Both involved donor site wounds to the thigh.

DISCUSSION

Although calcium alginate is the preferred plastic surgical dressing in Australia and the UK[3], retention dressings such as Fixomull, have been used for many years. Only two other studies[13,14] that evaluated the effectiveness of retention dressings in the management of donor sites were found. These UK studies were conducted in the same organisation, with the second undertaken to extend the study sample. Both studies used calcium alginate as the comparative treatment and provide a benchmark for wound healing and patient comfort outcomes which were the primary outcomes in our study. These factors have been identified as important to plastic surgeons when selecting a dressing[3,4].

Accurately measuring healing times in a practice setting is difficult unless the patient attends hospital for daily dressing changes. However, this is impractical and unless dressing change is clinically indicated, its removal may prolong the healing process by unnecessarily disturbing newly formed epithelium. Our patients had scheduled periodic follow-up but some variation in time to review occurred due to the logistics of scheduling. This is not uncommon in practice[12]. To account for variation in actual review times, we report time to healing as well as the proportion of wounds healed at periodic reviews. The inclusion of both measures provides a comparison to previous studies[6,12,19,20] beyond the two RCTs evaluating calcium alginate and retention dressings.

We found that at 18 days (SD 5.10), the mean time to healing in calcium alginate+ Fixomull group was similar to the 21 days (range 8–23) reported by Terrill *et al.*[12]. Healing in the Fixomull alone group (15 days SD 4.06 days) was significantly shorter (p=0.03), occurring on average three days earlier than those dressed with calcium alginate+Fixomull. These times were longer than some previous reports[21], though within the 'expected range' for healing reported in a survey of plastic surgeons[4]. The periodicity of our wound reviews was limited by clinic schedules (5, 15 and 21 days) and are likely to have extended the reported time to healing. As such, our findings are a conservative measure of time to healing.

Table 6: Mean pain scores for each treatment group

Clinic visit	Treatment randomisation	N	Mean	SD	Independent sample t-test
Day 5					
Day	Fixomull alone	31	0.90	1.5	
	Calcium alginate+ Fixomull	22	1.86	2.6	p=0.09
Night	Fixomull alone	31	0.74	1.4	
	Calcium alginate+ Fixomull	22	1.59	2.4	p=0.112
Dressing	Fixomull alone	22	1.32	2.2	
	Calcium alginate+ Fixomull	18	2.11	2.7	p=0.309
Day 15					
Day	Fixomull alone	32	0.16	0.6	
	Calcium alginate+ Fixomull	23	1.13	1.8	p=0.02
Night	Fixomull alone	32	0.22	0.9	
	Calcium alginate+ Fixomull	23	0.87	1.5	p=0.06
Dressing	Fixomull alone	30	0.13	0.6	
	Calcium alginate+ Fixomull	21	1.00	1.8	p=0.04

SD = standard deviation

We found that by day 15, 82% of participants treated with Fixomull alone had achieved 100% epithelialisation compared with 56% of those treated with calcium alginate+Fixomull. This is a clinically important difference and is consistent with those of Horbrey *et al.*[14] and Giele *et al.*[13] who found that by two weeks post surgery, 91% of participants treated with Fixomull had achieved healing compared to 62.5% of participants treated with calcium alginate dressing. As Horbrey *et al.*[14] and Giele *et al.*[13] do not provide baseline characteristics for their sample, we are unable to establish similarities or differences in our participants. Participants in our sample had a number of systemic (for example, age, BMI[22] and comorbid risks) factors that may influence healing[22-24] and are prevalent in populations requiring SSG. With the exception of anticoagulant use, risk factors were equivalent between groups. We found no differences in anticoagulant use between groups for patients not healed by day 15.

We found no difference in participant reported levels of pain early in the treatment course (day 5). Other studies[13,14] comparing calcium alginate and retention dressings have reported significant differences in comfort levels in favour of Fixomull alone. These studies assessed pain at 24 and 72 hours post surgery when operative pain due to harvesting of the graft may have been more prevalent. Donor site pain is said to become more prevalent as operative pain diminishes[13,14] but often persists for 10 or more days. As the first assessment of pain in our study occurred at day 5, this is more likely to reflect donor site pain. A major difference between our study and others[13,14] was that we secured the calcium alginate dressing with Fixomull, rather than using bandages. As thigh wounds are prone to slippage[25], this approach to affixing dressings may have improved participant comfort and freedom to perform daily activities.

By day 15 clinic visit, participants who had received calcium alginate+Fixomull dressing reported significantly higher mean pain scores during the day and at dressing change than those in the Fixomull alone group. A difference was also found for night time pain levels but this only approached statistically significant levels. A possible reason for this is that alginate assists to achieve haemostasis, but as the dressing dries the alginate may adhere to the wound, causing discomfort. Alternatively, even if not adhered, dried blood in the dressing may create a stiff mass of material that irritates the donor site as the patient moves. Fixomull may be more comfortable for participants as it conforms to body contours. We were unable to explore potential differences in patient comfort due to anticoagulant use because of the small number of participants receiving this therapy in our sample. Further research is required to guide dressing selection in this subgroup of patients.

It is worth noting, that overall both dressings we compared provided high levels of participant comfort, though the proportion of participants who reported no pain (during the day, at night or during dressing changes) was higher in the Fixomull alone group when compared to the calcium alginate+Fixomull group. The high proportion of patients in the Fixomull alone group who had achieved healing by day 15 would account for this result.

While healing and patient comfort are of primary importance, the frequency of dressing changes and incidence of infection are also important to consider when determining the suitability of a dressing as they impact on the cost of care. We found participants treated with Fixomull alone required fewer dressings than those treated with calcium alginate+Fixomull. Although we did not perform a full economic evaluation, fewer dressing changes, along with a lower initial cost when Fixomull was used as the primary dressing make Fixomull a more cost-effective option than calcium alginate in the management of SCG donor wounds. The low incidence of dressing slippage (one in each dressing group) and wound infection (n=1)

suggest these issues were not problematic. No inference can be drawn in relation to either dressing option for these outcomes.

Our findings, along with those of Giele *et al.*[13] and Hormbrey *et al.*[14] extend the evidence in support of Fixomull in managing donor site wounds. Our findings suggest that retention dressings should be considered in the management of donor site wounds as they achieve healing times and comfort levels that were better than, or at least equivalent to calcium alginate, while requiring fewer dressings. A key benefit of retention dressings as a primary dressing, is that they allow participants easier mobility and require less nursing care[14] to many other dressings currently used for the management of donor site wounds. This combination of factors builds a case for the wider adoption of Fixomull in practice. Retention dressings also provide an appropriate cover over a calcium alginate dressing, as they reduce the incidence of dressing slippage.

A recent systematic review found no clear evidence to support the choice of dressing in donor site management[1]. This was largely due to the heterogeneity of dressings reviewed. By focusing on dressing options that are commonly used in practice, we hoped to provide a comparison of products that would be meaningful to clinicians.

There were limitations to this study. Our study involved a single plastic surgery service and a small sample. Larger, multisite studies are required to generalise findings. Participant reports of pain reflected the individual's experience over the days preceding clinic review. Some recall bias may have occurred, though this would have influenced each group equally. Analgesic use was not compared; however, patients who reported pain were advised how to optimise their pain management using simple analgesics. Patient satisfaction and quality of life were not examined in this study. These outcomes are important to include in future studies.

CONCLUSION

Retention dressings provide an appropriate donor site dressing whether used as the primary wound cover or in conjunction with calcium alginate. We found the popularity of retention dressings for the postoperative management of donor site wounds across Australia to be supported by benefits in respect to time to healing, patient comfort and the number of dressing changes required.

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CONFLICT OF INTEREST

None identified.

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