Management of split-thickness skin graft donor sites: A randomized controlled trial of calcium alginate versus polyurethane film dressing

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Abstract: Background: Split-thickness skin graft (STSG) donor sites sometimes cause more postoperative morbidity for patients than the wound covered with the graft. Yet, there is no consensus on which dressings are best suited to treat these donor sites. Objective: To evaluate two commonly used modern wound dressings in the postoperative healing of STSG donor sites in a prospective randomized controlled trial. Methods: 38 patients were randomly assigned to treatment of an STSG donor site with an alginate dressing or a polyurethane film dressing. The primary outcome measures were postoperative pain scores, secondary outcome variables were time to epithelialization, dressing changes and complications. Results: Postoperative pain on day 1 was significantly lower in the polyurethane film group (2.05 vs. 0.79, p = 0.035) as compared to the alginate group. This difference was not detected on day 5 (0.89 vs. 0.53, p = 0.52). Time to epithelialization did not differ significantly between the two dressing groups. There were more dressing changes in the polyurethane film group and problems with leakage. Conclusion: Whereas film dressings resulted in initially lower pain scores, alginate dressings caused fewer additional dressing changes and less leakage. © 2013 S. Karger AG, Basel.

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Management of Split-Thickness Skin Graft Donor Sites: A Randomized Controlled Trial of Calcium Alginate versus Polyurethane Film Dressing

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Key Words
Wound healing · Split-thickness skin graft · Donor site · Polyurethane film · Calcium alginate

Introduction
Split-thickness skin grafts (STSG) are a widely used procedure in dermatological surgery [1]. Postoperative defects after tumor excision as well as chronic wounds needing a stimulation of epithelialization are often covered with STSG. Furthermore, the procedure is extensively used by plastic surgeons to cover sometimes extensive defects (e.g. burns). Harvesting of the graft leaves a second, superficial wound; in the subjective perception of the patient this is often more disturbing than the site treated with the graft, due to pain, irritation and the discomfort caused by bulky or leaking dressings.

There is no consensus on what type of dressing is ideally suited to promote healing of the donor site. The main criteria in the choice of the donor site dressing are patient comfort, notably the reduction of wound pain and avoiding leakage of exudate, the speed of epithelialization and treatment costs. Ease of application and available resources/formularies are further aspects to consider. Many types of dressings have been studied for use in donor site wounds but none seem to fulfill all of these requirements ideally [2–12]. Furthermore, the results of these trials are not unanimous and sometimes even contradicting. A recent systematic review stipulates that no dressing is superior to another with regard to time to complete wound healing [13]. A majority of surgeons seem to use a calcium
alginate dressing as a standard dressing for donor sites [14]. Alginates are easy to apply, can absorb large amounts of exudate and have hemostatic properties which make them ideally suited for this type of superficial but sometimes heavily exuding wound. However, the gel formed by the alginate dressing with the wound exudate tends to dry out after a few days which can lead to some pain and discomfort [15]. There are indications in the literature that a more occlusive dressing which keeps the wound bed continuously moist may be associated with faster healing and less pain [16]. This led to the interest of examining the properties of a dressing such as polyurethane film which is known to maintain a high degree of moisture and thus to have the potential to reduce pain [17] in comparison with the current standard treatment. Therefore, we performed a randomized controlled trial comparing different outcome variables with these two dressings.

**Materials and Methods**

**Study Design**

Prospective randomized controlled trial comparing different outcome variables in the healing of superficial STSG donor site wounds of an alginate dressing (Kaltostat®) with a transparent polyurethane film (Opsite Flexigrid®). The study was approved by the ethics committee of the University of Zurich (KEK ZH No. 534).

**Material (Dressings)**

Kaltostat® (ConvaTec Ltd.), an alginate dressing, is produced from the calcium and sodium salts of alginic acid found in a family of brown seaweed (Phaeophyceae) [18]. Kaltostat® contains 80% calcium alginate and 20% sodium alginate. The alginates’ ability to absorb fluid up to 15–20 times their weight makes them suitable for highly exudative wounds. Furthermore, the calcium ions are exchanged for sodium ions in the blood upon contact, which activates the blood clotting cascade and thus exerts a hemostatic effect.

Opsite Flexigrid® (Smith & Nephew Healthcare Ltd.) is a thin polyurethane film without any exudate absorption capacity [19]. It is a semipermeable film with a moisture-vapor transmission rate of 621.2 g/m²/24 h which holds back a considerable part of the exudate and creates a moist wound environment that has been shown to accelerate wound healing [20].

**Patients and Randomization**

A power analysis was performed to detect an expected difference in healing time of 3 ± 2 days with statistical significance (p < 0.05). Thirty-eight patients who received a STSG at the Department of Dermatology of the University of Zurich were randomized into two groups. Randomization took place by blinded allocation of treatment instructions; 19 patients were randomized into each group.

**Primary outcome variables were pain on the first and fifth postoperative days as well as during dressing removal. Secondary outcomes were time until re-epithelialization, number of dressing changes and the occurrence of complications.**

**Inclusion Criteria**

Patients who were hospitalized at the Dermatology Department of the University Hospital of Zurich, gave written consent to participate in the study and who had an STSG donor site area of 12–300 cm² were included in the study.

**Exclusion Criteria**

Patients who had already received an STSG during the recruiting period or who could not give adequate responses about pain and comfort of the procedure due to mental deficiencies were excluded from the study. Furthermore, patients with contraindications to one of the dressings studied, such as allergies to the dressings or one of their components, were excluded.

**Technique**

All 38 STSG were taken from the lateral thigh with an electrical dermatome (Aesculap, Tuttlingen, Germany) at a depth of 0.2 mm (8/1,000 inch) including all of the epidermis and parts of the dermis (fig. 1). Prior to the removal of the graft, the chosen area was anesthetized with lidocaine (0.5%) and epinephrine (10 mg/ml). Hemostasis was achieved by covering the donor site with a gauze soaked in physiological saline solution for 15 min before applying the allocated dressing.

The surgical procedure was performed by 2 experienced dermatological surgeons of the Department of Dermatology of the Zurich University Hospital (S.L., J.H.). A picture was taken of the donor site, and the width and the length of the wound were measured with a sterile ruler. The allocated dressing was then applied.

All patients received their routine medications and standard care independently of the type of wound dressing applied. The nursing staff was instructed to leave the dressing on the wound until it could be removed easily following full epithelialization or if it shifted, leaked or was uncomfortable to the patient.

**Postoperative Management and Follow-Up**

Study visits took place on the first and fifth postoperative days and after full epithelialization of the donor site, i.e. when the dressing could be removed easily and epithelialization was completed. Full epithelialization was defined as a continuous coverage with epidermis.

During the first visit (first postoperative day), pain was assessed during the procedure (i.e. application of local anesthesia, and during the removal of the STSG) and the current pain of the donor site. Pain was assessed using the VAS® (visual analog scale, Hayes and Patterson, 1921) on a scale from 0 to 10, where 0 indicates no pain at all and 10 indicates maximum imaginable pain.

On the second visit (fifth postoperative day) the patient was asked to grade the pain of the donor site again using the VAS. Every change of dressing was noted including the date, the reason and the pain (VAS) recorded during removal of the old dressing.

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After complete epithelialization, the patient was once again asked to grade the pain during the final removal of the dressing, and the date of epithelialization was recorded. The day of full epithelialization was determined as the day when the dressing could be removed without relacerating the newly formed epithelial layer (fig. 2). Other additional dressing changes since the last visit were noted again including the above-mentioned parameters. After epithelialization had been achieved, the wounds were dressed according to local customs, usually with dry gauze or petrolatum-impregnated gauze to provide some mechanical protection for the newly formed epithelium.

### Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (IBM, USA, 2011). Since the collected data did not conform to normal distribution, the statistical evaluation was done with the Mann-Whitney U test for nonparametric variables. Significance was defined as $p < 0.05$.

### Results

Thirty-eight patients fulfilled the inclusion criteria and were included in the study (27 females, 11 males). Their mean age was 75 years (35–95 years). The skin defects covered by the skin graft were due to venous leg ulcers in 12 patients, leg ulcers of other etiologies in 16 patients (3 arterial ulcers, 6 mixed venous-arterial ulcers, 6 hypertensive ischemic leg ulcers, 1 vasculitic ulcer) and the removal of skin tumors in 9 patients. Typical for patients in this age group, there was a wide range of comorbidities and medications in both groups. There were 5 smokers (2 in the alginate group, 3 in the polyurethane film group). The size of the donor site wounds ranged from 12 to $300 \text{ cm}^2$ with a mean size of $58 \text{ cm}^2$ and did not differ between the two groups ($p > 0.05$) (table 1).

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Alginate group</th>
<th>Polyurethane film group</th>
<th>Significance level ($p \leq 0.05$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>72.1 (35–95)</td>
<td>78.6 (46–96)</td>
<td>0.92</td>
</tr>
<tr>
<td>Gender (female/male)</td>
<td>14/5</td>
<td>13/6</td>
<td></td>
</tr>
<tr>
<td>Size of STSG, cm$^2$</td>
<td>47.2</td>
<td>68.8</td>
<td></td>
</tr>
<tr>
<td>Pain score day 1 (VAS)</td>
<td>2.05 (0–7, SD 2.17)</td>
<td>0.79 (0–5, SD 1.47)</td>
<td>0.035</td>
</tr>
<tr>
<td>Pain score day 5 (VAS)</td>
<td>0.89 (0–3, SD 1.15)</td>
<td>0.53 (0–4, SD 1.02)</td>
<td>0.52</td>
</tr>
<tr>
<td>Time to epithelialization, days</td>
<td>18.8 (13–36)</td>
<td>21.9 (14–41)</td>
<td>0.49</td>
</tr>
</tbody>
</table>
Perioperative pain during the infiltration of local anesthesia and the harvesting of the graft was perceived with a mean pain score of 1.92 and did not differ significantly between the polyurethane film group (1.42; range 0–5; SD 1.86) and the alginate group (2.42; range 0–6; SD 2.10; p > 0.05). Mean postoperative pain scores recorded on day 1 were significantly less for the polyurethane film group (0.79; range 0–5; SD 1.47) than for the alginate group (2.05; range 0–7; SD 2.17; p = 0.035). There was no significant difference (p = 0.52) in pain scores on day 5 between the polyurethane film group (0.53; 0–4; SD 1.02) and the alginate group (0.89; 0–3; SD 1.15).

**Time to Epithelialization**

Time to epithelialization did not differ significantly between the two treatment groups. The mean time to full epithelialization was 18.8 days (range 13–36 days; median = 16.5) in the alginate group and 21.9 days (range 14–41 days; median = 20 days) in the polyurethane film group (p = 0.49).

**Assessment of Dressing Changes and Complications**

In the alginate group, dressings had to be changed once before epithelialization in 3 patients. Reasons for the premature dressing changes were wound pain in 2 patients and smelling exudate with clinical suspicion of superficial wound infection in 1 patient. This patient was then treated with the additional application of a local antiseptic (eosin 0.5%). In the polyurethane film group, dressings had to be changed before epithelialization in 8 patients. In 3 patients, several dressing changes were necessary, causing a total of 12 premature dressing changes. These additional dressing changes in the polyurethane film group occurred both in patients with small (min. 12 cm²) and large (max. 130 cm²) donor sites. Reasons for the dressing changes were leakage of excess exudate in 7 patients and a skin blister formation at the wound edge due to the tension of the film dressing in 1 patient. In 3 additional patients, the excess exudate could be removed by puncturing the film dressing.

**Discussion**

STSG are a widely performed and very useful procedure in dermatological surgery. However, STSG donor sites may be the source of significant postoperative problems. To date, there is no consensus regarding the surgical technique or the best postoperative management of STSG and its donor site. In order to standardize the technique for this randomized controlled study comparing polyurethane film with alginate dressings for STSG donor sites, the harvesting of the skin graft was performed under local anesthesia, and the graft was taken with a thickness of 0.2 mm (8/1,000 inch) as described in the protocol. Although the final thickness of the graft is also influenced by other factors than the settings on the dermatome (such as dermatome speed and pressure when harvesting, lubrication, skin tension) [21], this technique creates fairly uniform wounds, as the operation was performed by the same two surgeons with the same equipment.

STSG donor sites are ideal wounds for the study of wound healing. The procedure removes the epidermis and superficial parts of the dermis and thus creates uniform wounds which need to epithelialize. There is a general consensus that wounds epithelialize better if the wound healing environment is moist. This fact is accepted since the observations by Winter [20] that superficial wounds heal faster under intact blisters and was confirmed in many studies showing that a moist environment leads to less intense and less prolonged inflammation [22], more rapid keratinocyte proliferation and migration [23], earlier keratinocyte differentiation, leading to faster restoration of the cutaneous barrier function [24], increased fibroblast proliferation [25], increased collagen synthesis [26], earlier full-thickness wound contraction [27] and earlier, less prolonged angiogenesis.

A moist wound healing environment can be achieved with semiocclusive or occlusive dressings or with dressings that absorb some of the exudate whilst maintaining...
a moist layer between the wound and the dressing. This moist wound healing environment is achieved with both dressings used for this study. In our randomized controlled trial, the wounds took slightly longer to heal with the polyurethane film dressing but the difference was not significant. This could be due to the fact that alginites with their highly absorbing capacities, which can cause some desiccation of the wound bed, are still leaving a moist layer between the dressing and the wound for some time, favorable for wound healing. Film dressings on the other hand allow the accumulation of proteolytic substances under the polyurethane film, and they can macerate the newly formed epithelium (fig. 3). The results of another study comparing the efficiency of the combination of an alginate dressing with a film dressing versus a dry environment with a nonocclusive paraffin gauze dressing underscore the fact that excess moisture is not favorable for fast wound healing: there was no significant difference in healing time in that study either [28].

Several studies and extensive review articles comparing the influence of different dressings on wound healing in acute and chronic wounds have found that the type of dressing does not have a significant influence on the speed of healing time of the wound [29]. Many of these studies have methodological shortcomings and do not consider realistic study end points – clinical end points which are often more important for the patient are factors such as pain, patient comfort, exudate leakage and treatment costs [30]. For a majority of patients, pain is their most important concern [31]. In this study, patients felt only moderate pain during the infiltration of local anesthesia and the harvesting of the skin graft. Wounds dressed with a polyurethane film had significantly lower pain scores on the first postoperative day. This difference was not significant anymore on day 5. Whilst the difference in pain scores on day 1 was statistically significant, it was a relatively small difference with questionable clinical significance. With regard to patient comfort and exudate leakage, there were clearly more dressing changes and problems related to exudate leakage in the polyurethane film group; this has also been observed by other authors [32]. The same is true of other occlusive dressings such as hydrocolloid dressings [2]. The fear of exudate leakage with ensuing soiling of clothes and bed linens was a relevant problem to most patients as expressed in their comments about the treatment. Therefore, the advantage of slightly lower pain scores with the polyurethane film dressing was offset by the additional dressing changes and the reduced patient comfort with regard to exudate leakage.

At the time of the study, the recommended retail price for the polyurethane film was CHF 4.40 (Opsite® film, 12 × 20 cm). The cost of the alginate dressing was CHF 9.20 (Kaltostat®, 7.5 × 12 cm). The lower cost of the film dressing was unfortunately offset by the additional premature dressing changes in 9 patients with a total of 12 additional dressing changes, resulting in comparable dressing costs for these patients as well as increased nursing costs and time.

This study has several strengths and limitations. The randomized controlled design and the standardized technique allow a valid statement for a very uniform type of wound. However, the results are not necessarily valid for other types of wounds, especially chronic wounds. For the latter, treatment of underlying factors impeding wound healing is often more relevant than the choice of dressing. A further limitation is the difficulty to establish the precise date of complete epithelialization. It was measured when the dressing could be removed without sticking to the wound and the wound bed was fully covered with epithelium. As not all patients could be seen every day by their caregivers, this may have occurred in some cases 1 or 2 days before the recorded day which leads to some imprecision. However, this was true for the entire study population. The size of the donor sites and the demographic variables and influencing factors did not differ significantly between the two study groups. In order to minimize such possible differences, a study comparing 2 dressings on 2 donor sites of the same patient would be interesting.

**Conclusion**

This study shows that there is no significant difference in healing time of STSG donor sites between two commonly used dressings, an alginate dressing and a polyurethane film dressing. However, there are some important differences between the two dressings with regard to pain and exudate leakage: the patients with the polyurethane film dressings had lower pain scores on the first postoperative day but exudate leakage and dressing changes were more frequent in this group. Larger multicentric randomized controlled trials with different protocols according to local customs would be desirable to corroborate the findings of this study.
References


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