The use of modern dressings in managing split-thickness skin graft donor sites: a single-centre randomised controlled trial

Objective: To identify the most appropriate, most suitable and most efficient dressing for split-thickness skin graft (STSG) donor sites. Comparing the wound healing rate, pain severity and duration, as well as the dressing change frequency in four randomised patient groups.

Methods: A single-centre non-blinded randomised controlled trial was carried out during 2010–2014. All patients treated for skin defects/lesions (due to burns, trauma or ulcers) using STSG were included in the study. All patients were randomly allocated in four different donor site treatment groups; polyurethane (PU group, Mepilex); polyurethane with silicone membrane (PUSM group; Mepilex border); transparent, breathable film (TBF group; Mepitel film) and cotton gauze dressings (CG group) using Excel 2007. We evaluated: wound healing time, pain severity and duration, the frequency of dressing change, donor site re-epithelialisation, donor site complications (signs of inflammation or infection). Patients were assessed on postoperative days: 1, 3, 6, 9, 12, 15, 18 and 21.

Results: After random allocation of study participants the number of patients in each group were: PU group n=25; PUSM group n=24; TBF group n=24; CG group n=25. The groups were homogenous according to gender, age, main pathology, donor site area and wound size. The STSG donor site healing time varied from 9 to 21 days. The mean healing time in the CG group was 14.76 days, whereas in the PU, PUSM, and TBF group it was significantly shorter; 12.25 days, 11.63 days and 10 days, respectively. Patients in the TBF group demonstrated the most rapid healing time with 66.7% of STSG donor sites healed by postoperative day 9. The pain duration interval in modern dressing groups (PU, PUSM and TBF groups) was 0–9 days, whereas it was 6–18 day in the CS group. Pain intensity mean on postoperative day 1 was 2.21 in the PU group; 1.67 in the PUSM group; 1.46 in the TBF group and 3.04 in the CG group. The average pain duration in Group PU, PUSM, and TBF was 4.08 days; 2.5 days; 2.29 days, respectively. The average number of times each dressing was changed in each group was, 2.83 times in the PU group and PUSM group and 1.46 times in the TBF group. The CG dressing group were changed once when the donor site wound re-epithelialised. There was one patient in the PU group who experienced signs of infection, was treated accordingly and excluded from the study.

Conclusion: The fastest healing time was demonstrated by patients in the TBF group. The pain was not as severe and for a shorter period of time in modern dressing study groups. However, the pain was lightest and felt shortest in TBF dressing group. The modern dressings PU and PUSM had to be changed more frequently than TBF.

Declaration of interest: The authors have no conflict of interest.

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Methods
This study was designed as single-centre, prospective, randomised, non-blinded study and took place from 2010 to 2014. All of the patients treated for skin defects/lesions (due to burns, trauma or ulcers) having a STSG were included in the study. Before the study the protocol was approved by Kaunas Regional Biomedical Research Ethics Committee. The study was designed according to CONSORT guidelines.5

Inclusion criteria
The patients were recruited voluntarily after being introduced to the study. Inclusion criteria were:
- Willingness to participate
- ≥18 years old
- Treated using STSG in the Department of Plastic and Reconstructive Surgery, Lithuanian University of Health Sciences Kauno klinikos.
The exclusion criteria were:
- Refusal to participate
- Pregnancy
- Patients with metabolic diseases
- Patients with cardiovascular or other diseases that may affect wound healing
- Oncology patients treated with radiation therapy or chemotherapy.

Once patients provided informed consent, all of the study participants were randomly allocated in four donor site treatment groups using Excel 2007; group PU group (Mepilex, Mölnlycke Health Care, Goteburg, Sweden); PUSM group (Mepilex border, Mölnlycke Health Care); TBF group (Mepitel film, Mölnlycke Health Care); and the CG group.

Experimental and control groups interventions
The surgery was performed under general intravenous anaesthesia and surgical donor and recipient sites were prepared using antiseptic agents for skin preparation applying the standard technique.6 A STSG of 0.3mm thickness was harvested with Zimmer dermatome (Zimmer, Inc., Warsaw, US). The donor site was then temporarily covered with sterile gauze and the STSG positioning on recipient site, which was then dressed with paraffin gauze and sterile dressings. The temporary gauze was then removed from the donor site and the wound dressed according to the group the patient was randomised to.
The quantitative variables that satisfied the conditions for normality were described by presenting the mean, SD and the 95% confidence intervals (95% CI). Quantitative variables that did not satisfy the conditions for normality were described by presenting the median as well as minimum and maximum values. At times the mean was also presented for a clearer description of the data.

To compare the values between groups the non-parametric Kruskal-Wallis test and paired comparisons were employed. Values of qualitative variables were compared using the Chi-squared test of homogeneity (Fisher’s test or the exact Chi-squared test were employed in the case of insufficient frequency values) and described by providing the frequencies and the relative frequencies (%). The correlation between quantitative variables was used to determine sample size was mean time to complete re-epithelialisation. After carrying out the pilot study it was found that the time of complete re-epithelialisation for cotton gauze dressing was 15 days while modern dressing ranged between 10 and 12 days. When comparing gauze and modern dressings using PS software it was estimated that 11 subjects would be needed in each group in order to detect statistically significant differences, \( \alpha = 0.05 \), power 90%, standard deviation (SD)=3. While comparing between the three modern dressings we estimated that 24 participants were necessary in each group (\( \alpha = 0.05 \), power 90%, SD=2).

Primary and secondary outcome measurement
We evaluated wound healing time, pain intensity and duration, the frequency of dressing change and donor site complications (signs of inflammation or infection). Patients were assessed on postoperative days: 1, 3, 6, 9, 12, 15, 18 and 21, or until the wound was fully healed.

The wound healing was assessed visually by identifying the epithelialisation surface area in groups 1–3. Dressings were changed as needed, including if the maximum capacity of the dressing was exceeded, and a dressing change was noted as removal. On the first follow-up of TBF dressing any excess fluid was aspirated from under the dressing. The donor site wound was considered healed upon achieving full surface re-epithelialisation. In the CG group the wound dressing would be removed only once when the donor site was completely healed.

The pain severity was evaluated using Visual Analogue Scale (VAS) (numeric pain rating scale values from 0=no pain; 10=worst possible pain). The pain duration was measured from day 1 postoperatively until the last day the patient expressed feeling pain. The dressing and the signs of infection or inflammation were evaluated on all assessment days.

Statistical data analysis
Sample size was determined using PS – Power and Size Calculation Version 3.0 software. The main outcome

Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Recruited patients</th>
<th>Donor site dressing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing</td>
<td>PU (n=24)</td>
</tr>
<tr>
<td>Female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 (50.0%)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 (50.0%)</td>
</tr>
</tbody>
</table>

Chi-squared=1.183; p=0.0757

| Burn               |           |             |           |           |             |
|                   | 8 (33.3%) | 9 (37.5%) | 8 (33.3%) | 12 (48.0%) | 37 (38.1%)  |
| Trophic ulcer      |           |             |           |           |             |
|                   | 12 (50.0%) | 12 (50.0%) | 12 (50.0%) | 11 (44.0%) | 47 (48.5%)  |

Chi-squared=3.903; p=0.922

| Other              |           |             |           |           |             |
|                   | 4 (16.7%) | 3 (12.5%) | 4 (16.7%) | 2 (8.0%)  | 13 (13.4%)  |

Chi-squared=3.903; p=0.935; PU–polyurethane; PUSM–polyurethane with silicone membrane; TBF–transparent, breathable film; CG–cotton gauze

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evaluated by using the Spearman correlation coefficient, while the links between qualitative variables were calculated using the Kramer coefficient. The differences were considered statistically significant p<0.05. The statistical data analysis was carried out using the IBM SPSS Statistics 22.0 package.

### Results

**Patient characteristics**

The number of patients recruited was 98. After study participant randomisation the number of patients in each group was: PU group n=25; PUSM group n=24; TBF group n=24; CG group n=25. During the study one patient was excluded due to surgical site infection (SSI), hence 97 participants completed the study (Fig 1). The average patient age was 59.55 (SD=14.86; [95% CI: 56.55–62.54]) and 49.5% (n=48) were male and 50.5% (n=49) female. The mean donor wound sizes were 108.54 (35.59) cm$^2$ in the PU group, 99.79 (30.84) cm$^2$ in the PUSM group, 104.58 (40.96) cm$^2$ in the TBF and 110.56 (56.32) cm$^2$ in the CG group. The donor site wound surface area varied the most in the CG group between 24–250 cm$^2$, whereas the lowest wound surface area variation was noted in the PU group, 42–176 cm$^2$. However, there was no statistically significant difference in wound size between the groups (p=0.843). The most common sites chosen for STSG were the left (n=42, 43.3%) and right thighs (n=42, 43.3%), whereas upper arm was chosen in 13 (13.4%) cases.

The groups were homogenous according to gender (p=0.757), age (p=0.752), main diagnosis (p=0.922), donor site area (p=0.935) and wound size (p=0.843) (Table 1).

**Primary outcome: wound healing**

The wound improvement was assessed visually by identifying the epithelialisation surface area in the PU, PUSM and TBF groups and in group CG upon full healing of the wound, when the dressing would detach from the wound. The healing time varied from 9–21 days. In modern dressing groups (PU, PUSM, TBF), the wounds

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**Table 2. Donor site wounds re-epithelialised on postoperative days 9, 12 and 15**

<table>
<thead>
<tr>
<th>Postoperative day</th>
<th>Donor site dressing number of wounds healed; n (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PU (n=24)</td>
<td>PUSM (n=24)</td>
</tr>
<tr>
<td>9</td>
<td>4 (16.7%)</td>
<td>6 (25.0%)</td>
</tr>
<tr>
<td></td>
<td>18 (75.0%)</td>
<td>21 (87.5%)</td>
</tr>
<tr>
<td>15</td>
<td>24 (100.0%)</td>
<td>24 (100.0%)</td>
</tr>
</tbody>
</table>

Chi-squared=45.869; p<0.001; PU—polyurethane; PUSM—polyurethane with silicone membrane; TBF—transparent, breathable film; CG—cotton gauze

**Table 3. Dressing change frequency distribution in modern dressing groups**

<table>
<thead>
<tr>
<th>Dressing change frequency</th>
<th>STSG donor site dressing n (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PU (n=24)</td>
<td>PUSM (n=24)</td>
</tr>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>4 (16.7%)</td>
<td>4 (16.7%)</td>
</tr>
<tr>
<td>3</td>
<td>20 (83.3%)</td>
<td>20 (83.3%)</td>
</tr>
</tbody>
</table>

Chi-squared=28.391; p<0.001; STSG—split-thickness skin graft; PU—polyurethane; PUSM—polyurethane with silicone membrane; TBF—transparent, breathable film; CG—cotton gauze
would heal within 9–15 days, whereas in the CG group the wounds healed within 12–21 days. Assessment on day 9 revealed that in the PU group 16.7% of the wounds were healed, in the PUSM group 25% and the TBF group 66.7% were re-epithelialised. On day 15 all of the patient wounds were healed in the PU, PUSM and TBF groups and 85% of wounds were healed in group CG (Table 2).

We noted a statistically significant difference in wound healing time between the groups (p<0.001). Median time to healing for group PU was 12 days (9–15; mean: 12.25 days), the results were similar in group PUSM where median was also 12 days (9–15 days; mean: 11.63). The median in CG group was 15 days (12–21; mean: 14.76), whereas in the TBF group median time to complete epithelisation was 9 days (9–12; mean: 10) (Fig 2). The Kruskal–Wallis test revealed that the CG group healing time was significantly longer compared with TBF (p<0.001), PUSM (p <0.001) and PU (p=0.01). The modern dressing wound healing time comparison using the same test demonstrated that in the TBF group wound healing time was significantly shorter compared with the PU group (p<0.001) (Fig 3).

We aimed to identify other factors, that may have influence wound healing time. Without considering the dressing choice, the grouped wound healing time did not depend on the patient age (rSpearman=0.09; p=0.932) or donor site wound size (rSpearman=0.07; p=0.521). However, patients grouped according to their wound healing time in each intervention group demonstrated a statistically significant correlation between the dressing used and grouped wound healing time (rKramer=0.523; p<0.001). Within 9 days the majority of the wounds were completely healed in the TBF dressing group, n=16 (66.7%), whereas in the PU group 4 wounds were healed (16.7%) and 6 (25%) in the PUSM group. The only group that did not require healing time longer than 12 days was the TBF dressing, whereas in the CG group the majority of the wounds (72%) required more than 12 days to heal. In the PU and PUSM groups the number of patients requiring longer than 12-day healing time was low (Fig 4).

**Secondary outcomes: pain duration**

The average pain duration between the dressings was statistically significantly different (p<0.001) varying from 0 to 18 days. The longest pain duration was noted in the CG group, statistically significant when compared with the modern dressing groups (p<0.001). We also noted that the pain duration was significantly shorter in the TBF group when compared with the PU group (p=0.001) and the PUSM group (p=0.007) (Fig 5). Grouped pain duration comparison aimed at identifying other factors that may effect the time the patient felt pain showed that patient age (p=0.963) and wound surface area...
research

(p=0.121) did not significantly differ among the groups. However, the pain duration correlated with the modern dressing choice (r(kramer=0.36; p=0.001) and main diagnosis (r(kramer=0.23; p=0.036) (Fig 6).

Secondary outcomes: pain intensity
On postoperative day 6 we identified the number of patients still expressing pain in the study groups: group TBF 0%; group PUSM 4.2%, group PU 33.3% and group CG 52%. Complete and the most rapid pain relief was achieved in the TBF group on postoperative day 6. The average pain intensity on the postoperative day 1 was 2.21 in group PU, 1.67 in group PUSM, 1.46 in group TBF, and 3.04 in group CG. Analysis of postoperative day 6 pain intensity average in group CG was 1.76, group PU 0.33; group PUSM 0.04 and group TBF 0 (Fig 7).

Secondary outcomes: dressing change frequency
The CG group dressing was changed once when the wound was completely healed and the dressing would easily peel off the wound with the superficial epithelial layer. The modern dressings usually required 3 changes (65.3%), while in 20.8% of the cases the dressings were changed twice (Table 3). When comparing the dressing changing frequency between the modern dressings groups there was a statistically significant difference (p<0.001). In group TBF the dressing had to be changed on average 1.46 times, which was less compared with group PU (2.83) and group PUSM (2.83).

Adverse events
There was one complication noted during the study. A patient in PU group developed an infection and so that was excluded from the study.

Discussion
Based on published data, CG is considered to be a cheap, but not the best choice when considering other relevant factors. What is more, some authors suggest that CG dressings should be discontinued as they are likely to cause infections.\(^7,^8\) We did not observe infection in our study, however, we believe that CG dressings are obsolete and do not provide satisfactory primary outcome, as they demonstrate the longest wound healing time of all groups. Similar results have been demonstrated in other studies with Muanman et al.\(^9\) reporting 14 days and Poonyakariyagorn et al.\(^10\) 17.84 days. However, others found that CG dressings may have an average wound healing time of 11.3 days.\(^11\) Lawrence et al.\(^12\) found that 84% of STSG donor site wounds would heal on postoperative day 10. In our study, we found that none of the donor site wounds were healed on postoperative day 9, and 84% of wounds were healed on postoperative day 15.

The modern dressing group overall demonstrated faster wound healing time when compared with CG. A relatively longer healing time in the modern dressing group was noted in wounds that were dressed with PU dressing (median: 12, average: 12.25). The healing time was even longer in other studies and reached 14 days in Terill et al.\(^13\) The PUSM group demonstrated a shorter healing time (median: 12, average: 11.63), however, the difference between the PU and PUSM groups was not statistically significant.

Based on our findings we have identified that the shortest healing time was in the TBF group (median: 9 days, average: 10 days). Our results are in line with those published by Rakel et al.\(^14\) of 9.47 days; Poonyakariyagorn et al.,\(^10\) 10.44 days, Melandri et al.,\(^15\) 10–13 days and Horch and Stark,\(^16\) 12.5 days. Even shorter healing times were noticed by Fernandez et al.\(^11\) (8.2 days) and Wang et al.\(^17\) (6–7 days). The fact that TBF dressings are made of a variety of materials (polyurethane, polyethylene, cellulose) and have different permeability and moist permeability properties may have resulted in variety of findings in different studies. Regardless, the dressing demonstrates faster healing time compared with the others tested.

The varying results of wound healing time in different studies may be due to differences in the STSG thickness chosen by the surgeons. The currently recommended thickness is 0.2–0.4mm, however, we have not found any studies identifying the STSG thickness effect on wound healing.

Another factor that may have a significant effect on wound healing time is donor site wound infection. A number of authors have found that infectious complications may be present in 3–20% of the cases,\(^18,^19\) and most of the studies indicate that the use of occlusive dressings decreases the risk of infection by presenting a barrier to potential pathogens when compared with standard treatment methods (cotton gauze, paraffin gauze dressing).\(^18,^20\) These findings are not yet supported by systematic reviews. Our study revealed a low complication rate (1%).

The most rapid healing time, 66.7% of the wounds within 9 days postoperatively, was in the TBF group and could be due to better fluid handling properties compared with the other dressings. TBF moisture...
permeability is 900g/m² 24 hours, whereas in PU it is 1340g/m² 24 hours and PUSM 2360g/m² 24 hours. With increasing moisture permeability, the wound healing time also increases. Lower moisture permeability allows faster wound healing, as optimal humidity is maintained in the wound bed. Moist environment not only seals in natural wound fluid to prevent dehydration of the wound bed but also promotes migration of keratinocytes to the wound and re-epithelialisation.\(^{21}\)

When analysing the secondary outcomes we noted similar tendencies that were favourable to the TBF group. The pain duration varied significantly among the groups. Pain relief in the CG group would usually be achieved only on day 9 postoperative, whereas in the modern dressing group (PU, PUSM, TBF) patients would not express pain on day 3 postoperative. These findings can be explained by looking into dressing characteristics. CG upon application on wound attaches to it and becomes solid and has no elastic properties. Thus a slightest movement of the patient that results in tension on the skin surrounding the wound causes the pain.

When comparing the modern dressings the pain duration varies from 0 to 9 days, the average time to pain relief differed: PU group 4.08 days; PUSM group 2.5 days; TBF group 2.29 days. When we grouped the patients into sub-groups according to their pain relief time (0–1 days; 3 days; >3 days), we identified statistically significant correlation between the dressing choice and pain duration. The results revealed that TBF dressings allowed patients to relieve the discomfort faster, i.e. up to 3 days. The pain intensity demonstrated a similar pattern. This could be explained by the fact that the modern dressings are elastic, do not attach to the wound bed and create a moist environment, all of which reduces the nerve ending irritation and causes less pain when the patient moves. The difference between the modern dressings could be related to different moisture permeability of the dressings.

We would only change the CG dressing once when the wound had completely healed. The frequency of dressing change in the modern dressing group varied. In the TBF group the dressing had to be changed on average 1.46 times, which was fewer than the PU and PUSM groups. One of the major TBF dressing disadvantages in the literature is the need of frequent changes due to exudate accumulation under the dressing that may lead it to become detached from the wound. This can be solved by either using another dressing over perforated TBF or by repeated aspirations to remove the fluid collection that was seen under the TBF dressing. We applied the latter method in our study, and this allowed for a reduced dressing changing frequency. In 41.7 % of the cases in the TBF group, the dressing was changed only once, whereas in the PU and PUSM groups it had to be changed more frequently. Aspiration of fluid may have helped with less frequent dressing change in the TBF group, however this is unlikely as it was performed in only a few cases. We believe the transparency of the dressing and ability to see the condition of the wound influenced dressing change numbers a lot more.

Limitations

Our study had some limitations, as it was unblinded and the assessment period was short (up to 21 days). The study sample was relatively small and this may have some impact on results of the study.

Conclusions

The analysis of collected data demonstrates the superiority of applying a TBF dressing for managing STSG donor site wounds. TBF dressing promotes an optimal environment for faster wound healing, causes less discomfort for the patients as they experience lower intensity pain for a shorter period of time postoperatively. TBF usage should be considered as a cost-effective treatment method as it allows faster wound healing, enables the treating doctor to evaluate the wound healing daily easily and requires fewer times of dressing change.

References

3 Barrit D, Birke-Sorensen H. Dressings for split thickness skin graft donor sites: a comparison of three options. EWMA Journal 2014; 14 (2):15-20

Reflective questions

- What is your standard dressing for split-thickness skin graft donor site?
- What aspects should be/ do you considered when choosing a dressing for split-thickness skin graft donor site?
- Would transparent breathable films which have the ability to assess the wound without taking off the dressing be valuable in your practice and why?