An open, prospective randomized pilot investigation evaluating pain with the use of a soft silicone wound contact layer, Mepitel® One, vs. Bridal Veil and staples used on split thickness skin grafts as a primary dressing

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INTRODUCTION

Burns are, unfortunately, a common injury with as many as 450,000 people in the United States of America suffering burns that require treatment. [American Burn Association, 2011] Superficial burns are easily treated, usually with a conservative approach by topical medication, or with some type of dressing or covering that promotes the natural course of healing. For deep dermal burns, a combination of excision and grafting is preferred [Ogull, 2009]. Areas of burn injury that initially appear more superficial can sometimes become deeper over a period of 48-72 hours, resulting in necrosis of the burn wound from infection or poor perfusion to the affected area [Fritz, 2008]. This resulting conversion to a deeper burn then requires excision and grafting.

Skin grafts are placed over excised areas of full thickness injuries and usually attached with sutures or staples [Fritz, 2008]. Staples are usually the preferred method of attachment because sutures take more time to do and require a higher level of skill [Meiring et al, 2019], while staples are useful in anchoring grafts in place, subjects often complain that they cause pain as wound healing progresses. The use of staples can also increase the risk of infection and scarring [Chughati et al, 2000; Smith et al, 2000; Mital et al. 2009]. Pulling and sticking are common complaints and there is the possibility that staples can become embedded in the graft. This leads to disruption of an otherwise healed area, increased pain, and anxiety for the subject as well as anxiety for the staff. Furthermore, wound-related pain can cause psychological stress which may, in turn, delay healing [Soliowey, et al, 2019]. Unfortunately the pain is often mismanaged and subjects suffer more pain than is necessary [Nagy, 1999]. Thus, there remains a need for less painful methods of fixing grafts to the wound bed. Other methods such as fibrin sealants are in use [Foster, et al 2008] and these alleviate the need for staples; however, successful use is dependent on appropriate technique. In some circumstances, the sealants can fail to adhere [Sierra et al 2008]; this is a particular problem with moist conditions. If fibrin sealants are applied too thickly wound healing is slowed down (O’Grady et al, 2000). When dressing changes require staple removal, patients experience varying degrees of pain and anxiety. Anxiety during dressing changes can sometimes be mistaken for pain, resulting in the potential for over-sedation, which is detrimental to the subject [Vanderbilt University, 2007]. Pain is subjective and anxiety often confounds a true pain assessment in subjects who are alert. The visual analog pain rating system is a reliable method for measuring pain in burn subjects and was used in this study [Choniere et al, 1994; Hickerson et al, 1994; Marvin et al, 1996].

METHODS

Four thirty patients who met the inclusion/exclusion criteria for the study (Table 1) were randomized to either Mepitel® One (Figure 1) or Bridal Veil and staples (Figure 2). Donor skin was harvested between 0.010 and 0.012 inch thickness. Skin was meshed at a 1:1 to 3:1 ratio. After the split-thickness skin graft was applied to the wound, Mepitel® One or Bridal Veil staples and was placed over the graft and over a margin of the surrounding healthy skin.

Evolution was performed at the initial consultation for baseline demographic data (age, gender, race, medical history) and the wound history was recorded (type of burn, site, date of injury, percentage total body surface area (TBSA), wound appearance, infection assessment).

Skin graft assessment was performed at Day 7 (+/- 1 day) and Day 14. (+/- 1 day) if the graft had > 95% take, before the 14 days, this was considered the end of the study.

The assessments included pain (prior, during and after product removal), dressing removal (time and pain medication or other treatments required), healing (percentage of graft take), peri-wound status, clinician input on handling, subject input on product, and adverse events.

The time and cost of staff were estimated by referring to www.indeed.com/salary for median salaries and the start and stop time of treatment was recorded in hh:mm:ss.

Cost data for the material used was estimated by collecting the quantities/ units used and estimating the unit cost from the GHX database (www.ghx.com), the manufacturers discount suppliers and from web vendors (the median value was reduced by 50% to more accurately reflect hospital costs).

Photographs were taken to record the treatment status.

OBJECTIVE

The primary objective of the Institutional Review Board-approved study was to compare pain at the time of dressing removal for the use of Mepitel® One versus Bridal Veil and staples on deep partial or full thickness burns requiring skin grafts. Secondary objectives were to investigate the overall costs, ease of use, adherence, tolerance, safety and efficacy of Mepitel® One.

RESULTS

The study included 43 patients in the clinical investigation, of which three were considered either lost to follow up or withdrawn. The “intention-to-treat” (ITT) population included those patients (n = 42) for whom post-treatment randomization data pertaining to the primary objective were recorded. Patient demographics and burn type are summarized in Table 2. There were no significant differences between the treatment groups in terms of the extent of burn injuries at baseline (Table 3).

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TABLE 1: Inclusion/exclusion criteria for the study

Inclusion criteria

• Subjects presenting with 1% - 25% total body surface area (TBSA) deep partial or full-thickness burns requiring skin graft

• At least 1% -10% TBSA available for grafting that could be considered for study site selection (exact, healthy peri-wound area around entire portion of this burned site)

• Both genders with age ≥ 18 years but < 70 years

• Signed informed consent

Exclusion criteria

• Subjects with chronic wounds, dermatologic skin conditions, or necrotizing disorder

• Subjects on mechanical ventilation

• Diagnosed underlying disease(s) (HIV/AIDS, cancer and severe anaemia) judged by the investigator to be a potential interference in the treatment

• Subjects treated with systemic glucocorticosteroids, except subjects taking occasional doses or doses less than 10 mg prednisolone/day or equivalent

• Use of immunosuppressive agents, radiation or chemotherapy within the previous 30 days

• Known allergy/hypersensitivity to any of the components of the investigational products

• Subjects with physical and/or mental conditions that were not expected to comply with the investigation

• Participation in other clinical investigation(s) within 1 month prior to start of the investigation

• Pregnancy

TABLE 2: Patient demographics and burn type

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mepitel® One (n=21)</th>
<th>Bridal Veil and staples (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>38.0 (19.0)</td>
<td>42.3 (16.0)</td>
</tr>
<tr>
<td></td>
<td>30.0 (19.0;77.0)</td>
<td>39.0 (19.0;70.0)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>16 (76.2%)</td>
<td>18 (85.7%)</td>
</tr>
<tr>
<td></td>
<td>(5.28%)</td>
<td>(3.14%)</td>
</tr>
<tr>
<td>Type of burn injury</td>
<td>Flame</td>
<td>Scald</td>
</tr>
<tr>
<td></td>
<td>10 (47.6%)</td>
<td>3 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>8 (38.1%)</td>
<td>2 (9.5%)</td>
</tr>
<tr>
<td></td>
<td>9 (42.9%)</td>
<td>6 (29.0%)</td>
</tr>
</tbody>
</table>

For categorical variables, n(%) is presented. For continuous variables, mean (standard deviation) or median (minimum; maximum) are presented.
PAIN

Pain was measured using a visual analog scale (VAS) ranging from 0 (no pain) to 100 (worst possible pain) and was compared between the Mepitel® One group and the Bridal Veil and staples group at post-op day 7 (+/- 1 day). Pain level was obtained at the beginning of the dressing change and there was no significant difference between the groups (p=0.1690). Pain level at the mid-point of the dressing change and there was no significant difference between the groups (p=0.1449). Graft take for Mepitel® One was 99%.

Table 3: Burn injury assessment at baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mepitel® One (n=21)</th>
<th>Bridal Veil and staples (n=21)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% TBSA</td>
<td>7.27 (5.61)</td>
<td>5.83 (4.38)</td>
<td>0.3828</td>
</tr>
<tr>
<td>% partial</td>
<td>3.49 (5.38)</td>
<td>3.26 (2.99)</td>
<td>0.6706</td>
</tr>
<tr>
<td>% deep partial</td>
<td>1.25 (2.32)</td>
<td>0.38 (0.95)</td>
<td>0.2287</td>
</tr>
<tr>
<td>% full thickness</td>
<td>2.33 (2.33)</td>
<td>2.19 (2.94)</td>
<td>0.4402</td>
</tr>
<tr>
<td>Median VAS (Median)</td>
<td>20.00 (0.00; 14.00)</td>
<td>20.00 (0.00; 14.00)</td>
<td></td>
</tr>
</tbody>
</table>

Of the 43 subjects enrolled, 12 were pre-medicated prior to removal of dressings and study product. There were 10 subjects pre-medicated in the Bridal Veil + staples group and 2 subjects pre-medicated from the Mepitel® One group. In at least 4 cases, titration of intravenous medication was necessary to complete the dressing change for the staple removal. This would imply that the pain levels during this procedure were so high that an extra dose of pain medication was necessary in order to tolerate the entire procedure with some level of relief from pain.

The two subjects medicated in the Mepitel® One group tolerated the entire procedure with some level of relief from pain. This would imply that the pain levels during this procedure were so necessary to complete the dressing change for the staple removal.

PERI-WOUND STATUS

Peri-wound status was assessed at the time of grafting and at the time of dressing removal (post-op day 7 (+/- 1 day). Variables assessed were turgor, dryness, flakiness, maceration, blistering, erythema and warmth. With the exception of one subject who developed an infection of the skin graft (Bridal Veil and staples), all other subjects maintained a healthy peri-wound status. Some dryness and flakiness were reported in the majority of subjects in both groups, but this is to be expected with normal graft healing. No maceration, erythema or blistering occurred in either group with the exception of the subject that developed infection and this subject had mild erythema and warmth of the peri-wound skin.

GRAFT TAKE AND HEALING

Graft take was defined as >=95% take and was assessed at post-op day 7 (+/- 1 day) after the removal of the dressing. There was no significant difference noted in graft take assessment between the two groups (p=0.1449). Graft take for Mepitel® One was 100% and for Bridal Veil and staples 99%.

CLINICIAN INPUT

Clinician input was given on the dressing’s conformity to the grafted site, ability to stay in place, ease of use, transparency, and the overall experience with the dressing. This input was gathered at the time of grafting, and post-op day 7 (+/- 1 day), and post-op day 14 (+/- 1 day), if applicable. Both groups had similar evaluations for most categories, with some categories being more favorable for Mepitel® One (Figure 5). In terms of overall experience, Mepitel® One was rated as ‘good’ and ‘very good’ in 39% and 61% of assessments, whereas Bridal Veil and staples were rated as ‘good’ and ‘very good’ in 75% and 5% of assessments.

OVERALL COSTS

For the total of all costs, including time and unit costs, there were no statistically significant difference between the two treatment groups. However, there was a trend for lower costs with Mepitel® One (p=0.1719).

There was a highly significant difference for the total staff costs in favor of Mepitel® One (p=0.0044).

The time required for dressing application was comparable for both the Mepitel® One and Bridal Veil and staples treatments (p=0.3152). Less time was used for Mepitel® One for dressing removal. There was a statistically significant difference in favor of Mepitel® One from the time dressing removal started to the time dressing removal ended (minutes) (p=0.0095). Bridal Veil and staples required 75% more time to remove than Mepitel® One.

Figure 1: Mepitel® One used on a split thickness skin graft. Graft take was excellent, the peri-wound skin remained intact and healthy, and the dressing was easily removed without any adherence.

Figure 2: Bridal Veil and staples used on a split thickness skin graft. Despite the use of staples, Bridal Veil easily bunched in places. The staples pulled and tugged at the netting, causing discomfort.

Figure 3: Pain of dressing removal 7 days post-operative measured using the VAS system.

Figure 4: Separation of graft from wound bed.
This study set out to evaluate the pain experienced at dressing removal for Mepitel® One compared to Bridal Veil and staples when used as a primary dressing over split thickness skin grafts. The performance of the dressings was also assessed by both the clinicians and patients.

- Mepitel® One was shown to be less painful than the common standard of care (Bridal Veil and staples) at the time of dressing removal, and this difference was statistically significant (p=0.0188).
- The results of this study indicate that Mepitel® One should be considered as a clinically acceptable primary dressing for placement over skin grafts in the treatment of burns. Mepitel® One demonstrated less pain, better ease of use and a better overall experience for patients than the comparator treatment involving the use of staples. When the total costs were evaluated, Mepitel® One was also less expensive and took much less time to remove, a major benefit to both patient and clinician.

**CASE STUDY 1: Mepitel® One**

- Graft application
- Post-op Day 7 prior to removal
- Mepitel® One application
- Post-op Day 7 removal

**CASE STUDY 2: Bridal Veil and Staples**

- Graft application
- Bridal Veil application
- Post-op Day 7 prior to removal
- Post-op Day 7 removal
REFERENCES:


Collin A. Use of Mepitel One dressing following hand surgery: a case study series. Poster presentation at Wounds UK Conference, Harrogate, United Kingdom, 2009


Meuleneire F. Using a soft silicone-coated net dressing to manage skin tears. J Wound Care 2002 Nov;11(10): 365-9


