A random prospective non-controlled clinical study of Cutimed Sorbact® as a skin substitute for the treatment of partial thickness burn wounds in a South African adult burns unit

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Introduction
Cutimed Sorbact® was used in a Random Prospective Non-Controlled Product Clinical Study in 2013 previously which included 13 patients (57 wounds) to establish the comparability with silver containing products Acticoat® and Silverlon®.

Cutimed Sorbact® is marketed as a dressing containing antibacterial activity with a lipophilic active molecule DACC (dialkylcarbamoylchloride) that binds to bacterial cell walls. Cutimed Sorbact® provides a rapid and effective mode of action, where 1cm² of dressing binds 100 000 bacteria in 30 seconds, it is a broad spectrum antibacterial and antifungal, including MRSA and VRE with no bacterial or fungal resistance, and provides no risk of allergies, cytotoxic and contraindications. One of the findings of the pilot study was that the dressing was effective on early partial thickness burns suggesting a role as a skin substitute.

Since the results of the pilot study did not show any significant difference in comparison the controls, and that the patient sample numbers were small, it was decided to test Cutimed Sorbact® clinical efficacy in a larger number of patients on partial thickness burns as a skin substitute without controls.

No reports were found by online search and company representative consults of the dressing being used previously as a skin substitute.2-14

Material & Methods
The clinical follow-up part of the study included random selection of partial thickness burns without controls and microbiology testing. The study excluded Patients who were to go to theatre for an operation within less than three days.

After cleaning the partial thickness burns with Chlorhexidine and water (Hibitane®) and removing blisters and loose skin the Cutimed Sorbact® was applied. Secondary dressings were not specified and Cutimed Sorbact® would be applied alone in the facial sites. On the trunk of the patient some Telfa®/Melolin® were applied with soft Cling® bandages.

Wound Assessment: A photograph using an 5 megapixel camera was taken before each dressing and after removal of the dressing by the first author in all cases.

Outcome Parameters: Wound assessment was done by the first author in conjunction with the co-authors. The factors looked at on the wounds were wound bed appearance, slough, pus, biofilm, granulation, epithelium, smoothness and colour.

Ethics: The research was conducted in line with the Helsinki Ethical guidelines. All patients consented to the use of their photos for research purposes.

Statistical Analysis: The follow-up clinical study was for descriptive non-comparative analysis and therefore not requiring statistical analysis.

Results
27 patients were included in this study. The demographic data is presented in table 1.

The average age of the patients was 34 years old. The youngest patient was 2 years old and the oldest 65 years old. The average TBSA was 13.59 %. The number of females was 10 and the males 17 as shown in Figure 1.

The commonest mechanism of injury was hot water, then flame burns followed by chemical burns shown in Figure 2.

The average time to application of the dressing was less than one day after the burn (17/27 = 0.7 days). The commonest sites chosen were the face, neck and forearms or hands shown in Figure 3.

Figure 1: Gender distribution of patients
The clinical assessment data for the application of the dressing is presented in Table 2.

The assessment followed the recording of pain (patient interviewed), clinical observation for the need for a pus swab (visual site inspection), days noted for dressing change, observed complications and the final assessment for wound cleanliness, dryness with regard to slough, progression of depth of the burn from partial to full-thickness areas wound pink colour in regard to wound healing at epithelisation stage and resulting healing of the wound.

A summary of the wound factors assessed after application and removal, of the dressing and their incidence (as a %) is shown in Figure 4.

In Figure 4 it can be observed that most wounds appeared clean (59 %), dry (51 %) and pink (51 %). About a third (27 %) appeared healed and there was depth progression in 2 patients (< 10%).

The dressing was not associated with any subjective noticeable pain and therefore the pain assessment was stopped after 12 patients.

The average days after application for removal of the Cutimed Sorbact® dressing was day 4 (112/26) as shown in Figure 5 below.

The only complications related to the dressing were at removal there was punctate minor bleeding points in 5 patients (5/27; 18.5%) as shown in Figure 6.

It also appeared that in 2 patients there was progression of depth of the burn from partial to full-thickness areas (2/26; 7.6%). One patient developed an otitis externa unrelated to the dressing.
Clinical Study: A Random Prospective Non-controlled Clinical Study of Cutimed Sorbact® as a Skin Substitute

Discussion

Based on the initial 2013 findings of the Cutimed Sorbact® pilot study it seemed possible that Cutimed Sorbact® can be classified as a skin substitute. Cutimed Sorbact® has some similarity to Suprathel® which has antibacterial properties, in that upon removal of the dressing, most of the exudate and surface bacteria are stuck to the dressing and the wound bed is clean.15-17 Suprathel® is a skin substitute for the treatment of dermal wounds; especially with the wound care of scalds and burns, abrasions, as well as split-thickness skin graft donor sites and represents an absorbable, synthetic wound dressing with properties of natural epithelium.

Some of the differences of Cutimed Sorbact® in comparison to Suprathel® would be the mechanism of action. Sorbact® is a bacterial adhesive via the lipophilic DACC molecule versus Suprathel's® bactericidal effect associated with its low pH of 5.5 in vivo.18 Cutimed Sorbact® doesn't stick to itself and it is extremely cheap and therefore highly cost-effective.

Clinical results before and after are shown in Figure 7.

Figure 4: The wound factors assessed and their incidence (%) is shown

Figure 5: The average days for removal of the dressings (blue); also are showing the first 13 days average (red) and the last 14 days average (green)

Figure 6: The incidence of minor punctate bleeds are shown

Table 2: Clinical data assessment

<table>
<thead>
<tr>
<th>Pain</th>
<th>Need for pus swab</th>
<th>Dressing change</th>
<th>Complications</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>No</td>
<td>D4</td>
<td>None</td>
<td>depth progression</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D7</td>
<td>None</td>
<td>clean, dry, healed</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D4</td>
<td>Small minor punctate bleeding</td>
<td>pink, healed</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D3</td>
<td>Dry cornea-refer Ophthalmologist</td>
<td>pink, healed</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D4</td>
<td>Small punctate red areas</td>
<td>pink, clean</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D3 arms; D7 Face</td>
<td>Dressing shifted from wound, O.E</td>
<td>arms open areas progression depth; face healed &amp; dry crusts</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D4</td>
<td>Small proximal bleeds</td>
<td>clean, pink, red</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D4</td>
<td>None</td>
<td>all pink &amp; epithelialized; some dry yellow crusts on forehead</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D3</td>
<td>None</td>
<td>clean &amp; pink</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D3</td>
<td>None</td>
<td>clean, pink epithelium</td>
</tr>
<tr>
<td>None</td>
<td>No</td>
<td>D4</td>
<td>None</td>
<td>clean &amp; dry</td>
</tr>
<tr>
<td>Stopped</td>
<td>No</td>
<td>D5</td>
<td>None, Dry &amp; Crusting</td>
<td>dry &amp; crusting</td>
</tr>
<tr>
<td>No</td>
<td>D4</td>
<td>None</td>
<td>Pink &amp; dry</td>
<td>pink &amp; dry</td>
</tr>
<tr>
<td>No</td>
<td>D5</td>
<td>None</td>
<td>Clean &amp; dry</td>
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</tr>
<tr>
<td>No</td>
<td>D3</td>
<td>None</td>
<td>Clean</td>
<td>clean &amp; pink</td>
</tr>
<tr>
<td>No</td>
<td>D8</td>
<td>None</td>
<td>Clean</td>
<td>clean, dry, some areas with thick slough</td>
</tr>
<tr>
<td>No</td>
<td>D5</td>
<td>None</td>
<td>Clean</td>
<td>clean, some deeper areas</td>
</tr>
<tr>
<td>No</td>
<td>D2</td>
<td>None</td>
<td>Clean &amp; pink</td>
<td>clean &amp; pink</td>
</tr>
<tr>
<td>No</td>
<td>D3</td>
<td>Spots of bleeding from dry areas</td>
<td>clean &amp; dry</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>D4</td>
<td>None</td>
<td>Pink &amp; healed, tiny dry crusts.</td>
<td>pink &amp; healed, tiny dry crusts.</td>
</tr>
<tr>
<td>No</td>
<td>D4</td>
<td>None</td>
<td>Pink &amp; clean, dry</td>
<td>Pink, clean, dry</td>
</tr>
<tr>
<td>No</td>
<td>D7</td>
<td>None</td>
<td>Pink &amp; clean</td>
<td>pink &amp; clean</td>
</tr>
</tbody>
</table>
dressing on the area (mostly in faces it was left open) allowing it to dry out more. The pink (51%) appearance which was also a common finding was an encouraging observation showing good early epithelialization. The fact that there was depth progression in 2 patients (<10%) one cannot directly say if it was related to the use of the Cutimed Sorbact® because of the relatively small numbers. Depth progression of the burn wound could have happened anyway given the many possible contributing factors like latent heat in the tissue or local edema or constriction with bandages.

The Cutimed Sorbact® dressing upon application and during its use was not associated with any subjective noticeable pain and therefore the pain assessment was stopped after 12 patients (and previous 13 patients in the pilot study). There was however some minor discomfort associated with the removal of the dressing if it was very dry.

The average days after application for removal of the Cutimed Sorbact® dressing initially was early (3.5 days) and as confidence grew it was left on longer (average days for the last patients increased to 4.5 days. The exact duration for leaving it on a partial thickness burn we don’t know. Fora psychiatric the dressing left in place for longer than 11 days without any problems.

There were no significant complications which was a positive sign. The minor bleeding points in 5 patients (5/27; 18.5%) were of no serious clinical consequence because it only required temporary pressure and cleaning of the wound.

Conclusion
Cutimed Sorbact® is a useful addition to the available skin substitutes and if it remains cost-effective will help revolutionize the primary care of burns especially in resource limited third world countries.

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References


Pending Peer Review process