Use of topical negative pressure with a lipidocolloid dressing: results of a clinical evaluation


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The enclosed peer-reviewed journal article is provided in the interest of free exchange of truthful scientific information. Restore® wound care dressings* are intended for single use in the management of partial- and full-thickness wounds.

More than 40% of the treated wounds in this observational study were clinically infected. Restore Contact Layer Dressing may be used on infected wounds only under the care of a healthcare professional.

Warnings and Precautions: Do not re-use the dressing. Restore Contact Layer Dressing tends to stick to latex gloves. Moisten latex gloves with normal sterile saline prior to use. Store the dressing flat and at room temperature.

Contraindications: Restore Contact Layer Dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or one of its components.

* The product cited in this article – Urgotul® (Laboratoires URGO, Dijon, France) – is marketed in the U.S. by Hollister Wound Care LLC as Restore® Contact Layer Dressing with TRIACT™ Technology. (In the United States, lipidocolloid technology is known as TRIACT Technology.)

• The Instructions for Use (IFU) is attached. The full IFU – written in English, French and Spanish – is available at: www.hollisterwoundcare.com/products/ifus.html
Use of topical negative pressure with a lipidocolloid dressing: results of a clinical evaluation

**Objective:** To evaluate the protection and acceptability of Urgotul wound dressing in the local management of acute or chronic wounds receiving topical negative pressure (TNP) therapy.

**Method:** This was a prospective multicentre non-comparative open-label trial. At each dressing change the investigating physician clinically evaluated and photographed the wound. Planimetric measurement was undertaken and wound depth was assessed at the start and end of the treatment. Follow-up was undertaken until deemed clinically unnecessary by the investigator.

**Results:** Sixty-six patients were included (42 acute wounds and 24 chronic wounds) and followed up for an average of 17 days. Dressing changes were deemed entirely painless in 52% of cases (compared with 18% at baseline) and pain between two consecutive dressing changes was absent in 66% of cases (34% at baseline). Removal of the TNP-interface dressing combination was considered ‘very easy’ or ‘easy’ in 94% of cases and adherence to the wound was recorded as ‘absent’ in 88%. On average, the dressings were changed every 3.8 ± 1.1 days (all wounds were considered), and wound area and depth were reduced by 19% and 54% respectively by the end of the follow-up period.

**Conclusion:** Use of the interface dressing in combination with TNP substantially reduced the pain caused by dressing changes. It therefore makes more acceptable the use of this technique, which aims to optimise the management of wounds that are sometimes considered to be in a therapeutic impasse.

**Declaration of interest:** This study was sponsored by Laboratoires Urgo, Dijon, France.

Topical negative pressure therapy; pain; non-adherent interface dressing; clinical evaluation

To evaluate the protection and acceptability of Urgotul wound dressing in the local management of acute or chronic wounds receiving topical negative pressure (TNP) therapy.

Strategies recommended to reduce pain include use of a non-adherent dressing beneath the foam dressing, but no clinical evaluation has been conducted to demonstrate its advantages. In France practitioners familiar with topical negative pressure (TNP) often use a lipidocolloid non-adherent dressing (Urgotul, Laboratoires Urgo, Dijon, France) between the foam and wound. Its small mesh size prevents granulation tissue from migrating into the foam, reducing the risk of the buds being damaged. In clinical terms this translates as painless, or almost painless, removal of the foam dressing, and results in improved patient acceptability.

**Materials and method**

This multicentre clinical evaluation was conducted in eight French hospitals by departments of plastic and reconstructive surgery, vascular surgery, general surgery and dermatology. The main aim was to assess whether, when used with TNP, Urgotul can be removed without causing trauma to the wound bed, paying particular attention to its ability to reduce pain at dressing removal and its impact on patient acceptability of care procedures. Secondary aims were to evaluate the tolerance (occurrence of local adverse events) and efficacy of this combination.

Sixty-six patients whose wounds were being managed with TNP were included. Patients aged under 18, or who were pregnant or lactating were excluded. No other inclusion or exclusion criteria were used.

Patients’ mean age was 57 years (range 16–92). Follow-up, dressing changes and completion of treatment were determined by the investigators, based on their clinical judgement.

Wound-area tracings were recorded and photographs taken at the start and end of treatment. Wound depth was measured if subcutaneous tissue was involved. At each dressing removal, the physicians and nurses assessed the wound to determine whether the study goals had been reached.

**Evaluated treatments**

Topical negative pressure therapy aids healing by:

- Maintaining a warm, moist environment
- Draining exudate and reducing bioburden
- Mobilising interstitial fluid
- Improving blood circulation, dermal perfusion

**Declaration of interest:** This study was sponsored by Laboratoires Urgo, Dijon, France.
Table 1. Rationales for use of TNP*

<table>
<thead>
<tr>
<th>Rationale</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promote growth of granulation tissue</td>
<td>54 (81.8)</td>
</tr>
<tr>
<td>Drain exudate</td>
<td>38 (57.5)</td>
</tr>
<tr>
<td>PENDING surgery</td>
<td>28 (42.4)</td>
</tr>
<tr>
<td>Infected wound</td>
<td>25 (37.8)</td>
</tr>
<tr>
<td>Therapeutic impasse</td>
<td>4 (6.0)</td>
</tr>
</tbody>
</table>

* More than one response could be selected

Table 2. Patients’ medical histories

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High blood pressure</td>
<td>28 42.4</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>27 40.9</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>16 24.6</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12 18.2</td>
</tr>
<tr>
<td>Smoking</td>
<td>28 42.4</td>
</tr>
</tbody>
</table>

References


Results

As TNP is not widely used in France, investigating physicians (10 in the eight centres) were asked to select a TNP system and indicate their rationale for its use for each patient treated (Table 1).

Baseline population and pathology

Sixty-six patients were included and followed up. Forty-five patients were male and 21 female; mean age was 57 years (range 16–92). Patients’ medical histories are given in Table 2. In total, the sample received 1145 days of treatment and underwent 320 documented clinical evaluations and local care procedures. On average, the dressings were removed every 3.8 ± 1.1 days (for all wounds) and the mean treatment duration was 17 days (range 17.4 ± 10.1).

Nearly 42 wounds (64%) were acute. Most were postoperative and had been present for an average of 16 days. The remainder (n=24, 36%) were chronic; these were mainly pressure ulcers and had been present for an average of 226 days.

Measurements made at the initial visit showed that the treated wounds were on average 111cm² in area and 35.8mm deep (calculated on the basis of 54 wounds involving subcutaneous tissue).

More than 40% of the treated wounds were clinically infected. In most cases (82%) this prompted administration of oral antibiotics. Other baseline wound characteristics are presented in Table 3.

Prior to treatment with the TNP and interface dressing combination, pain was noted in 82% of care procedures, including sharp debridement performed without general anaesthesia. At baseline, pain was also noted between two consecutive dressing changes in 66% of the patients, even though nearly 60% were prescribed oral analgesics (these qualitative data were obtained using an oral questionnaire). The characteristics of this pain at baseline are presented in Table 4.

Principal endpoint

Pain was evaluated and documented during each care procedure and between two consecutive dressing changes throughout the follow-up period. As this was not a comparative evaluation, it was documented qualitatively.

The results (Table 4) formed the basis for the evaluation of whether or not the interface dressing caused trauma on its removal, thereby necessitating pain relief. They were also used to indicate the acceptability of the TNP system to the patient.

Removal of the TNP-interface dressing combination was considered to be very easy by patients in 123/319 (39%) cases, easy in 178/319 (56%), difficult in 17/319 (5%) and very difficult in 1/319 (0.3%). The dressing combination adhered to the wound in 39/311 cases (12%); there was no adherence in the remaining 272 cases (88%). There was

Care procedure

After cleansing the wound with saline and/or local antiseptic (routine practice in the department), the interface dressing was applied to the wound bed. The TNP foam dressing was cut to match the wound size and positioned on top. The entire assembly was covered with a polyurethane film to make it air tight.

A starting negative pressure of 100 or 125mmHg was applied either continuously or intermittently, as considered suitable by the investigator.

Statistical analysis

A descriptive statistical analysis of all the patients followed up was performed. The tolerance analysis considered all patients who received at least one care procedure with this treatment. Continuous data were described by sample size, mean, standard deviation, median and range.
no adherence of the interface dressing to the wound in 199/316 cases (63%), minor adherence in 98/316 (31%) and moderate adherence in 19/316 (6%). No bleeding at dressing removal was noted in 169/318 cases (53%), minor bleeding in 121/318 (38%) and moderate bleeding in 28/318 (9%). Maceration was absent in 108/318 dressing removals (34%), minor in 104/318 (33%), moderate in 81/318 (25%) and nauseating in 25/318 (8%).

Dressing application was reported as very easy in 49/274 cases (18%), as easy in 200/274 (73%) and difficult in 25/274 (9%).

Secondary endpoints

- **Local tolerance** The evaluating physician documented tolerance throughout the follow-up. Three local adverse events were reported, two cases of eczema and one of intolerance, all attributed to the polyurethane membrane, so TNP was discontinued.

- **Efficacy** This was evaluated on the basis of wound size and depth. At the end of the follow-up period the average wound area was 72.1cm² (mean reduction 19%) and the average depth was 22.7mm. (mean reduction 54%).

When acute and chronic wounds were considered separately, acute wounds had reduced by 33.5% and 53% in area and depth respectively over a mean treatment period of 15 days, and chronic wounds by 9% and 52% over a mean treatment period of 21.4 days. Time between two dressing removals was 3.8 and 3.7 days for acute and chronic wounds respectively.

At the end of the evaluation (after a mean treatment duration of 17 days), 11 wounds (17%) were still considered by the investigating physician to be clinically infected (n=28, 42.4% at baseline); five wounds (4%) were treated with oral antibiotics.

**Discussion**

Topical negative pressure therapy has been adopted by many clinicians, and clinical trials have demonstrated its advantages in wounds that were difficult or even impossible to manage with traditional methods. Its use may be restricted by often painful dressing removals, but application of a non-adherent dressing under the foam may be a solution.
It was decided not to conduct this clinical evaluation in a comparative manner because of the difficulty in recruiting homogeneous populations and the variety of wounds suitable for TNP. The design therefore is close to a cross-over study; after considering the baseline evaluation of pain experienced without the non-adherent interface dressing, patients were treated with the TNP-interface dressing combination and an indirect ‘comparison’ was made. This is a study limitation.

Despite its non-comparative design, this evaluation — for which more than 320 care procedures were documented by nursing staff — clearly demonstrated that dressing changes were less painful when the TNP was used with the interface dressing. This is probably because no granulation tissue became attached to the foam dressing as the tight mesh of the interface dressing denied it access.

This lack of adherence is similar to that observed with the lipocolloid dressing in patients with burns and in fragile populations such as children or patients suffering from congenital epidermolysis bullosa skins lesions. These painless or almost painless removals meant care procedures were better accepted and even improved quality of life.

The condition of the periwound skin also improved. Such improvements have been reported with the interface dressing when used on leg ulcers, where the skin condition is often altered.

For all wounds the average interval between dressing changes was 3.8 days, with no difference between acute or chronic wounds. Dressing changes have been reported to take place every two or three days. Were it to be established that this extended interval is due to the use of the interface dressing beneath the TNP foam, this would doubtless have an economic impact, reducing the overall cost of treatment.

As expected, the reduction of the surface area was greater for acute wounds (but no difference in reduction in depth was observed between the two groups); mean treatment time was also shorter for the acute wounds (15 versus 21.5 days for the chronic group).

The initial results reported both in the literature and in this evaluation, which was conducted in a larger cohort of patients, indicate TNP should be used with a non-adherent interface dressing to render it more acceptable — that is, to substantially reduce pain during dressing changes.

<table>
<thead>
<tr>
<th>Table 4. Pain during care procedures and between two consecutive dressing changes: at baseline and follow-up</th>
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</thead>
<tbody>
<tr>
<td><strong>Baseline (%)</strong></td>
</tr>
<tr>
<td><strong>During care procedures</strong></td>
</tr>
<tr>
<td>Absent</td>
</tr>
<tr>
<td>Minor</td>
</tr>
<tr>
<td>Moderate</td>
</tr>
<tr>
<td>Marked</td>
</tr>
<tr>
<td><strong>Between two consecutive dressing changes</strong></td>
</tr>
<tr>
<td>Present</td>
</tr>
<tr>
<td>Absent</td>
</tr>
<tr>
<td><strong>If present between two consecutive dressing changes, pain intensity</strong></td>
</tr>
<tr>
<td>Minor</td>
</tr>
<tr>
<td>Moderate</td>
</tr>
<tr>
<td>Marked</td>
</tr>
<tr>
<td><strong>If present between two consecutive dressing changes, pain frequency</strong></td>
</tr>
<tr>
<td>Occasional</td>
</tr>
<tr>
<td>Frequent</td>
</tr>
<tr>
<td>Constant</td>
</tr>
</tbody>
</table>

**Remarque Contact Layer avec la Technologie TRACT, Non-Adherent Dressing**

**Description**
La Remarque Contact Layer est un pansement non-adhérant, non-adhérant conçu pour être parfaitement intégré à l’interface de la couche de la peau et à la couche de la peau. Il est spécialement conçu pour être utilisé dans les situations de soins où une couche de protection est nécessaire pour éviter l’adhérence de la peau et la cicatrice postopératoire. Il est également conçu pour être utilisé en conjonction avec d’autres pansements pour assurer une couche de protection maximale.

**Instructions d’Usage**
Pour utiliser la Remarque Contact Layer, suivez les étapes suivantes :
1. Nettoyez et désinfectez la zone à panser.
2. Appliquez un pansement stérile sur la zone à panser.
3. Appliquez le Remarque Contact Layer sur le pansement stérile.
4. Appliquez d’autres pansements stériles pour assurer une couche de protection maximale.

**Avantages**
- Non-adhérant : garantit une couche de protection maximale.
- Convient à la surface de la peau.
- Facile à appliquer et à retirer.
- Convient à la surface de la peau.

**Contre-indications**
- Ne convient pas aux peaux sensibles ou à suer abondamment.
- Ne convient pas aux peaux qui ont une tendance à l’irritation ou à l’eczéma.

**Mémo**
La Remarque Contact Layer est idéal pour les situations de soins où une couche de protection est nécessaire pour éviter l’adhérence de la peau et la cicatrice postopératoire. Il est également conçu pour être utilisé en conjonction avec d’autres pansements pour assurer une couche de protection maximale.
Restore Interface avec la Technologie TRACT, Non-Adherent Dressing

DESCRIPTION
L'interface TRACT est un pansement non-adhésif, non-invasif, constitué d'une fibre polyelectrolyte imprégnée de particules hydrophiles (parasympathicotropiques), de polymère et de gaze.

INDICATIONS
L'interface TRACT est indiquée dans le traitement du décollement des fines écoulements, notamment à travers les suture de contrôle.

MÉTHODE D'EMPLOI
- L'interface TRACT est disponible dans deux tailles : 4 x 5 cm (30 x 12 cm) et 8 x 10 cm (50 x 20 cm).
- Chaque bâtonnet contient 10 interfaces.
- Cette méthode est indiquée initialement sous couche de gaze ou de couche de décollement.
- Cette méthode est utilisée sur certaines zones inflamatoires, par exemple en présence de gaz ou de couche de décollement.
- Usage unique.

REF: 500196 4 x 5 cm (30 x 12 cm)
500198 8 x 10 cm (50 x 20 cm)

Ref: 500196

Instructions/Mode d'emploi/Instructions

Contact Layer, Non-Adherent Dressing

Interface, Pansement non-adhérant

Cape de contact, Aposéto no aderente

STERILE

ÉTHERIL

INSTRUCTIONS DE Usage

1. Limiter le nombre de couches de soin.
2. Sélectionner un tampon adapté pour le dépôt d'une couche de soin.
3. Protéger les limites de contact avec le traitement préalable.
4. Appliquer directement sur le soin et le décollement de la couche de soin.
5. Éviter des apports excessifs de soins et l'exposition à une couche de sel.
6. Exclure des apports excessifs de soins et le dépôt d'une couche de sel.

MÉTHODE D'EMPLOI
- Retirer la couche de soin et le dépôt d'une couche de soin.
- Protéger les limites de contact avec le traitement préalable.
- Appliquer directement sur la couche de soin et le décollement de la couche de sel.
- Éviter des apports excessifs de soins et le dépôt d'une couche de sel.

Ref: 500196

Contact Layer, Ahesive, Non-Adherent Dressing

TRIACT

INSTRUCTIONS/Mode d'emploi/Instructions

Contact Layer, Non-Adherent Dressing

Interface, Pansement non-adhérant

Cape de contact, Aposéto no aderente

STERILE

ÉTHERIL

INSTRUCTIONS DE Usage

1. Limiter le nombre de couches de soin.
2. Sélectionner un tampon adapté pour le dépôt d'une couche de soin.
3. Protéger les limites de contact avec le traitement préalable.
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5. Éviter des apports excessifs de soins et l'exposition à une couche de sel.
6. Exclure des apports excessifs de soins et le dépôt d'une couche de sel.

MÉTHODE D'EMPLOI
- Retirer la couche de soin et le dépôt d'une couche de soin.
- Protéger les limites de contact avec le traitement préalable.
- Appliquer directement sur la couche de soin et le décollement de la couche de sel.
- Éviter des apports excessifs de soins et le dépôt d'une couche de sel.

Ref: 500196