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Use of a new, flexible lipidocolloid dressing on acute and chronic wounds: results of a clinical study

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Use of a new, flexible lipidocolloid dressing on acute and chronic wounds: results of a clinical study

• **Objective:** To document the performance (efficacy, tolerability and acceptability) of Urgotul Flex, a new, more flexible version of the lipidocolloid dressing Urgotul, in the management of acute and chronic wounds. Efficacy was defined as the reduction in ulcer surface area after 4 weeks of treatment.

• **Method:** This open, non-comparative, multicentre clinical trial recruited patients from 11 centres, which included surgical, burns and rehabilitation units and paediatric, geriatric and dermatology wards. Inclusion criteria were non-infected wounds of any aetiology that were <120cm^2 in size. Ulcer surface area was assessed by tracing and planimetry. Acceptability parameters were: ease of dressing application; pain at dressing change; dressing adherence to wound bed and bleeding at removal; maceration of surrounding skin; these were all assessed qualitatively. Patients were followed up for a maximum of 4 weeks, or until they healed if this occurred first. Efficacy and tolerability were assessed by the physicians on a weekly basis, and acceptability by the nursing staff at each dressing change. All of the physicians/nurses had previously participated in clinical evaluations of Urgotul using the same outcomes and assessments, and so performed a retrospective assessment of the two dressings.

• **Results:** Forty-four patients from 11 investigating centres were included in the study. The mean baseline surface area at was 21cm^2 and 6cm^2 for the acute and chronic wounds respectively. Twenty wounds (17 acute wounds and three chronic wounds) healed. Of the remainder, the mean surface area reduction was 78% and 42% for the acute and chronic wounds respectively at the end of the 4-week treatment period. Only two local adverse events were reported, but these were not considered to be dressing related. Based on the 345 documented dressing changes, conformability of the new dressing was considered to be superior to that of Urgotul, particularly when used on acute wounds.

• **Conclusion:** These findings show that the efficacy and tolerability of Urgotul Flex is similar to that reported in previous observational studies on Urgotul. However, results show it is more flexible and thus more conformable, particularly when used on wounds in awkward locations, including paediatric wounds and hand surgery.

• **Conflict of interest:** This evaluation was sponsored by Laboratoires URGO, Chenôve, France.

wound contact flex; flexibility; awkward wounds; paediatric wounds; acceptability

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In many countries, acute and chronic wounds were for many years treated with (and in some cases still are) vaseline- or paraffin-impregnated gauze, as documented in a huge observational survey undertaken in France involving more than 5,000 patients.[1] These dressings are most frequently used in the proliferation stage of healing to promote granulation tissue formation and epithelialisation.[2,3] However, they often need to be changed every day as they adhere to the wound bed, which causes pain at dressing removal.[4,5] This pain, which can cause patients additional stress, has been linked to a delay in healing.[6] A dressing that does not cause pain and trauma has obvious benefits for patients (comfort) as well as clinicians, one of the latter being a potential reduction in healing time.[6]

Over 10 years ago, Laboratoires Urgo developed a non-adherent contact layer, Urgotul, as an alternative to vaseline and paraffin-impregnated gauze for acute and chronic wounds.[7-9] Urgotul is based on Technology Lipido-Colloid (TLC, or Triact as it is known in north America), in which hydrocolloid (carboxymethylcellulose) and petroleum jelly are impregnated into a fine polyester mesh. This lipidocolloid non-adherent dressing has some of the desirable benefits of hydrocolloids (less frequent dressing changes) without the drawbacks of paraffin gauze (pain and/or trauma at removal), which allows it to meet most of the requirements of an ideal dressing,[2] as defined by Thomas.[10]

The clinically efficacy of Urgotul has been demonstrated on paediatric wounds, which are often difficult to dress,[11,12] on acute wounds, when it was compared with vaseline or paraffin gauze or non-adherent dressings in controlled trials[2,7,13] and on chronic wounds, when it was compared with hydro-

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colloids.[14] The dressing has also been associated with high levels of patient and clinician satisfaction, again in relation to both acute and chronic wounds,[8,9,11,12,14,15-17] even when compared with other contact layers.[2,7,13]

Despite these positive results, Urgotul sometimes demonstrated a lack of conformability in some specific clinical situations. Laboratoires Urgo therefore decided to develop an improved version of the contact layer dressing, giving it greater conformability than before. The new dressing (Urgotul Flex, or Restore Contact Layer Flex as it is known in north America) incorporates the same lipidocolloid technology as in Urgotul, but its polyester mesh is thinner than in the previous version and more extensible. According to the manufacturer, Urgotul Flex is therefore suitable for difficult anatomical areas, such as postoperative or traumatic wounds, digital surgery and paediatric wounds. Like Urgotul, it is indicated for granulating or epithelialising acute or chronic wounds. The dressing is non-adhesive and non-absorbent and so should be covered with a secondary dressing and held in place with a bandage (or tape). It needs to be changed every 2–4 days on average, although it may be left in place for longer if appropriate.

This is the first clinical evaluation to assess the clinical performance (efficacy, acceptability and tolerability) of Urgotul Flex in the local management of acute and chronic wounds in hospitalised patients and outpatients. This evaluation also describes a retrospective comparison of Urgotul and Urgotul Flex undertaken by the investigators.

Table 1. Baseline patient demographics

	Acute wounds (n=32)	Chronic wounds (n=12)
Gender:		
• Female	17 (53.1%)	6 (50.0%)
• Male	15 (46.9%)	6 (50.0%)
Age (years) Mean ± SD (range) median	36.3 ± 30.4 (1–98) 36.5	61.3 ± 31.5 (7 months–94) 74
Body weight (kg) Mean ± SD (range) median	52.3 ± 29.9 (10–125) 58.5	59.3 ± 27.0 (7–102) 60.3
Height (cm) Mean ± SD (range) median	146.5 ± 36.2 (78–184) 164.0	149.6 ± 33.3 (68–180) 157.5
Hypertension	6 (18.8%)	4 (33.3%)
Cardiac disease	4 (12.5%)	5 (41.7%)
Diabetes mellitus	3 (9.4%)	1 (8.3%)

Table 2. Baseline wound characteristics

	Acute wounds (n=32)	Chronic wounds (n=12)
Wound type		
	Postoperative: 13 (40.6%) Traumatic: 2 (6.3%) Amputation stump: 2 (6.3%) Burn: 15 (46.9%)	Pressure ulcer: 6 (50.0%) Leg ulcer: 2 (16.7%) Other 4: (33.3%)
Wound duration (days) : (Mean ± SD) (range) (median)	13.0 ± 19.0 (0–71) 4.5	135.3 ± 122.3 (30–390) 60.0
Location: n (%):		
• Upper limb	12 (37.5%)	—
• Lower limb	12 (37.5%)	9 (75.0%)
• Abdomen	2 (6.3%)	—
•)Others	6 (18.7%)	3 (25.0%)
Surface area (cm^2): (Mean ± SD) (range) (median)	21.15 ± 23.79 (1.63–78.54) 11.14	6.61 ± 3.12 (2.19–13.40] 6.05
Condition of the peri-wound skin n (%):		
• Healthy	18 (56.3%)	4 (33.3%)
• Altered	14 (43.7%)	8 (66.7%)

Method

This was an open, non-controlled, multicentre (11 active centres) clinical evaluation. These settings comprised surgical, burns or rehabilitation units and paediatric, geriatric and dermatology wards. Two of the surgical units specialised in hand surgery. The centres treated both inpatients and outpatients.

Patients (adults and children) presenting in these units with an acute or chronic wound were included in the study. Inclusion criteria were wounds with no signs of clinical infection or malignancy that were <120cm^2 in size. The wounds had to be indicated for a wound contact layer — that is, they were granulating or epithelialising. Those that were partly or wholly covered with necrotic tissue were therefore excluded. Other exclusion criteria were progressive neoplasic lesions, known hypersensitivity to carboxymethylcellulose, and radiotherapy, chemotherapy or immunosuppressive drugs.

The Parisian medical ethics committee approved the study, which complied with the rules of Good Clinical Practice and the principles of the Declaration of Helsinki.[18]

Written informed consent was obtained from all patients, and from both parents of the children recruited into the evaluation.

Assessment

Patients were followed up for a maximum of 4 weeks, or until the wound healed fully, whichever occurred first. (Full healing was defined as complete

epithelialisation with no further need to apply the dressing.) The primary outcome was to evaluate the efficacy of the dressing, which was defined as the reduction in wound surface area after 4 weeks of treatment.

Ulcer surface area was measured at baseline and at each weekly assessment. The ulcers were traced onto a transparent film in accordance with a predefined and standardised protocol, and the ulcer area was then calculated using planimetry. The investigator also performed clinical evaluations to assess peri-wound skin, in terms of whether it was oedematous, eczematous, erythematous or inflamed. The wounds were also photographed throughout the follow-up period to help validate the findings.

Secondary endpoints were tolerability (occurrence of local adverse events) and acceptability (patient comfort and ease of use).

The investigating physician fully documented any observed local adverse events at each assessment.

Acceptability parameters comprised:

- Ease of dressing application and removal
- Pain at dressing change
- Conformability
- Adherence of the dressing to the wound bed and bleeding at removal
- Maceration of surrounding skin.

These parameters were recorded qualitatively (for example, a visual analogue scale was not used to evaluate pain) and documented by the nursing staff during each dressing change.

In addition to the test dressing, all patients received treatment for the underlying aetiology of their wound — for example, those with venous leg ulcer had compression therapy and those with pressure ulcers used pressure-redistributing mattresses.

Retrospective assessment

In addition, the investigators and nursing staff were asked to retrospectively compare the new dressing (Urgotul Flex) with the original version (Urgotul) in terms of conformability, ease of use and the time taken to complete the procedure. To make the comparison between these two products meaningful, the same investigators who had participated in previous clinical evaluations of the original version of the dressing[9,11,14] also participated in the present one. All of these previous evaluations had the same primary and secondary outcomes, which were assessed in the same way as described here. Parameters assessed were conformability, ease of application, time taken to complete the procedure and ease of handling.

Statistical analysis

Results are presented descriptively as means, medians, standard deviations and percentages. No statistical tests were performed. Results are given for all patients recruited into the study. All of the patients recruited into the trial were included in the analysis.

Table 3. Results for acceptability, reported at dressing change

	Acute wounds (n=206)	Chronic wounds (n=139)
Ease of application:		
• Very easy	28.8%	25.9%
• Easy	58.5%	61.2%
• Difficult	12.7%	12.9%
• Very difficult	—	—
Conformability:		
• Very good	42.2%	53.3%
• Good	51.0%	32.1%
• Poor	6.9%	13.1%
• Very poor	—	1.5%
Ease of removal:		
• Very easy	60.9%	73.3%
• Easy	36.0%	26.7%
• Difficult	2.5%	
• Very difficult	0.5%	
Pain at removal:		
• None	86.7%	88.0%
• Minimal	9.2%	6.0%
• Moderate	3.6%	3.0%
• High	—	3.0%
• Very high	0.5%	—
Adherence to the wound bed:		
• None	76.1%	78.5%
• Moderate	21.3%	19.3%
• High	2.0%	2.2%
• Very high	0.5%	
Bleeding at removal:		
• None	91.9%	91.9%
• Moderate	8.1%	8.1%
• High	—	—
Maceration:		
• None	80.7%	61.7%
• Moderate	19.3%	35.3%
• High	—	3%

Results

Patients

Forty-four patients were recruited into this clinical evaluation. Of these patients, 15 were children recruited from three paediatrics centres, including plastic and reconstructive surgery, burns or rehabilitation centres; a large majority of the wounds (in both the sample as a whole and in its paediatric sub-

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Table 4. Results for the retrospective comparison

	Acute wounds (%)	Chronic wounds (%)
Conformability to wound:		
• Better	79.3%	58.8%
• Identical	17.1%	36.8%
• Worse	3.6%	4.4%
Ease of application:		
• Better	61.0%	44.1%
• Identical	32.6%	51.5%
• Worse	6.4%	4.4%
Time of the care:		
• Shorter	25.0%	14.7%
• identical	71.4%	82.4%
• longer	3.6%	2.9%
Handling:		
• Easier	68.8%	66.2%
• Identical	25.5%	29.4%
• more difficult	5.6%	4.4%

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population) were acute. Baseline patient demographic details are given in Table 1. There was an equal distribution of male and female patients in the acute and chronic wound groups.

Of the 32 acute wounds, 15 (46.9%) were burns, 13 were postoperative (40.6%), two (6.3%) were traumatic and two (6.3%) amputation stumps. Thirteen of these 32 acute wounds (40%) occurred in the children, and were mostly burns on the hands/fingers. Postoperative hand surgery wounds in adults represented 12.5% (n=4) of the total number of acute wounds.

The chronic wounds constituted six pressure ulcers (EPUAP categories 2 and 3), two leg ulcers and four other chronic wounds, including two chronic burns in children (burns present for >6 weeks).

The wound characteristics for the sample as a whole are given in Table 2.

The patients in the acute and chronic wound groups were hospitalised in 68.8% and 66.7% of cases, respectively.

The acute wounds had been present for an average of 13 days, and an equal number were located on the upper and lower limbs (37.5% each). The other wounds were located on the pelvis, abdomen and thorax. At inclusion, the acute wounds had a mean surface area of 21cm² and 43% (n=14) had altered peri-wound skin. Almost half (47%) had been treated with a wound contact layer or paraffin or vaseline-impregnated gauze prior to inclusion in the evaluation.

The chronic wounds had been present for an average of 135 days (4.4 months) and had a mean surface area of 6.6cm², with altered peri-wound skin in 66% of the cases. The majority of these wounds (66.7%) (n=8) had been treated with hydrocellular, hydrocolloid or alginate dressings prior to inclusion in the evaluation.

Healing rate

Four patients did not complete the study: one because of an adverse event; one was lost to follow-up; two patients' wounds were grafted. In total, 20 wounds (45.5%) healed by the end of the 4-week period. These comprised 17 acute wounds (53%), mainly burns and traumatic wounds, which healed in a mean of 14.2 days (range 6–29), and three chronic wounds (25%) (one category 3 pressure ulcer and two chronic burns), which healed in a mean of 26.3 days (range 23–28).

The mean reduction in wound surface area at the end of the 4-week treatment period was 78.2% (range -71.45 to 100%) for the acute wounds and 41.9% (range -45.21 to 100%) for the chronic wounds (Fig 1). The mean time for which the test dressing was used was 19 and 24 days for the acute and chronic wounds respectively.

Local tolerance

Two local adverse events were reported for the acute wounds, and none for the chronic wounds. The two local adverse events were documented as 'infection' and, although the investigators did not consider them to be dressing related, in one case it resulted in the dressing being discontinued and a silver dressing being used instead, along with antibiotics.

The investigators also reported that the condition of peri-wound skin improved during the study period. By the end of the 4-week treatment, the peri-wound skin was considered to be 'healthy' in 86.2% (n=25) and 40.0% (n=4) of patients presenting with acute and chronic wounds respectively (56% [n=18] and 33% [n=4] at baseline).

Dressing changes

In total, 345 dressing changes were documented in the course of the trial for both groups (206 and 139, in the acute and chronic wound groups respectively). These corresponded to 826 cumulated days of treatment: 539 days for the acute wounds and 287 for the chronic wounds.

The mean dressing change frequency was 2–3 days. This probably reflects the large number of postoperative wounds, burns and pressure ulcers, which require frequent dressing changes (for regular assessment in the case of the surgical wounds/burns, and because of incontinence in the case of the pressure ulcers). The results for acceptability are given in Table 3.

Dressing application was considered 'very easy' or 'easy' at the vast majority of dressing changes per-

formed and documented by the nursing staff. Dressing conformability to the wound bed was considered 'very good' or 'good' in more than 93% and 85% of the acute and chronic wounds respectively.

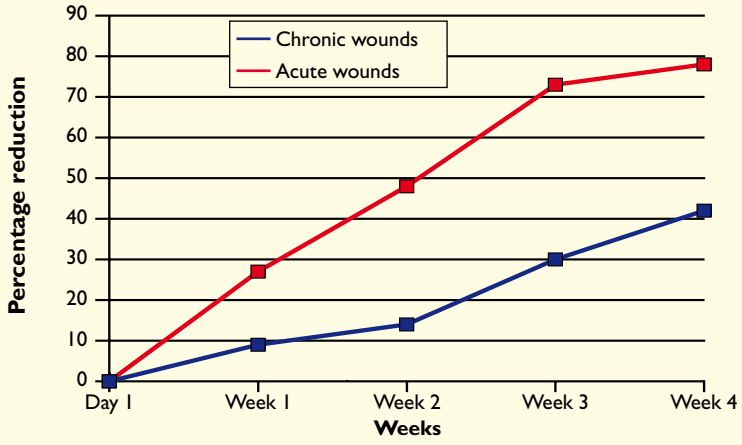
No pain was reported during removal in nearly 90% of all the dressing changes, both acute and chronic, due to lack of adherence to the wound bed.

Retrospective analysis

The documented comments made by the practitioners when asked to compare the test dressing with the previous version are given in Table 4. The dressing was considered more conformable than the previous version (79%) in the majority of dressing changes and easier to handle and apply in 68% and 61% of dressing changes respectively. However, positive results for these parameters were more likely to be recorded for the acute wounds than for the chronic ones.

Within the two groups of acute and chronic wounds, no difference between the two dressings was noted with regard to dressing time needed to do the care.

Fig 1. Percentage reduction of surface ulcer area during the follow-up period: acute versus chronic wounds



Discussion

These findings show that the mean percentage reduction in wound surface area (78% and 42% for acute and chronic wounds respectively) was similar to that reported for Urgotul (76% and 44% respectively) in a previous evaluation which had a similar patient population, wounds and protocol.[9] The occurrence of local adverse events was also similar: only two were documented compared with four in two in trials on Urgotul.[9,11]

As with previous trials on TLC products,[14,19,20] the present study also noted an improvement in the peri-wound skin.

Results for 'pain at removal' and 'ease of removal' reported at the 345 dressing changes undertaken in this study were very similar for those previously reported for Ugotul,[9] probably because both products contain TLC.

However, the present study yielded better results for 'conformability' and ease of application compared with previous studies on Urgotul.[9,11,14] The investigators in the current evaluation (who also participated in previous studies) considered the new dressing to be more comfortable than Urgotul, particularly when used on acute wounds. This is probably due to the greater flexibility of the test dressing, which was used in paediatric wounds (13/32) and digit/hand (4/32) wounds, representing 53% of the acute wounds in this trial.

Compared with Urgotul, this new dressing seems to be more adapted for paediatric wounds, which due of their small size or awkward location are often difficult to dress, as they conform to the convex irregular surfaces of the digits and hands. A highly conformation dressing is needed for this wound type.[5,6] However, this improved flexibility does not really affect the ease of application on chronic wounds, probably because these wounds are rarely located in awkward locations.

Study limitations

This open non-controlled clinical evaluation shows that the new, more flexible, version of Urgotul wound contact layer can adapt better to some wounds locations or indications. However, it should be borne in mind that these findings are subjective as they are based on a retrospective comparison by the same nurses who participated in studies on the earlier version of the dressing.

It was not possible to present data by wound type because the small sample size meant that such subgroup analysis was not viable.

Finally, the subjective/qualitative nature of the acceptability data reduced the likelihood of inter-rater and intra-rater reliability. For example, the fine line between 'minimal' and 'moderate' when assessed subjectively meant it was possible for nurses to report that adherence was moderate but that pain at removal was minimal.

Conclusion

While the efficacy and tolerability of Urgotul Flex appear to be similar to that of Urgotul, nurses involved in the study considered its conformability to be superior, especially for acute wounds.

Based on the results of this evaluation, Urgotul Flex will be added to the existing range of TLC products as it meets the needs and expectations of clinicians when managing irregular wounds, or wounds in awkward locations, paediatric wounds, or postoperative hand surgery. ■

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