Evaluation of a lipidocolloid wound dressing in the local management of leg ulcers

• **Objective:** To evaluate the efficacy, tolerance and acceptability of Urgotul and DuoDERM E dressings in the local management of venous or mixed-aetiology leg ulcers.

• **Method:** This was a prospective multicentre randomised phase IV clinical trial conducted open-label in parallel groups. It involved 20 investigating centres, including hospital dermatology and vascular medicine departments, and private practices. Dermatologists and angiologists/phlebologists took part. Subjects were adult, non-immunosuppressed patients presenting with a non-infected, non-malignant leg ulcer of predominantly venous origin (ABPI >0.8). Ulcers were between 4cm^2 and 40cm^2 in size, with granulation tissue covering more than 50% of their surface area. Ulcer duration ranged from three to 18 months. Patients were followed-up by the investigating physician for eight weeks on a weekly basis; this included clinical examination, wound area tracings and photographs. Nurses (hospital or visiting) assessed exudate volume and clinical appearance at dressing changes.

• **Results:** Ninety-one patients were included: 47 in the Urgotul group and 44 in the DuoDERM E group. Baseline patient demographic data and wound characteristics were comparable in the two groups. After eight weeks of treatment wound surface area had reduced by a mean of 61.3% in the Urgotul group and 52.1% in the DuoDERM E group (NS); dressings were changed more frequently in the DuoDERM E group (2.54 ± 0.57 times per week versus 2.31 ± 0.45 in the Urgotul group, p=0.047). Thirty-three local adverse events were recorded in 27 patients: 10 in the Urgotul group and 23 in the DuoDERM E group (p=0.039). Nurses reported better acceptability for the Urgotul dressing, based on pain on removal, maceration and odour (p<0.0001).

• **Conclusion:** Both dressings showed similar efficacy for the local treatment of venous leg ulcers. Nevertheless, medical and nursing staff reported better tolerance and acceptability for the Urgotul dressing.

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

non-adhesive; hydrocolloid; outpatients; clinical trial; leg ulcer

The treatment of chronic wounds is based on the concept of moist wound healing, as described by Winter and Hinman in the early 1960s.[1,2] In the late 1970s the introduction of hydrocolloid dressings was a real step forward for wound management, and in the past two decades these dressings have clearly demonstrated their advantages for the local treatment of chronic wounds, particularly leg ulcers.[3-8]

Laboratoires Urgo has recently developed a non-adhesive dressing, Urgotul (a synthetic support impregnated with hydrocolloid particles — carboxymethylcellulose and vaseline), that is widely recognised for its capacity to heal both acute[9,10] and chronic wounds, particularly leg ulcers.[11,12]

This study, which was conducted in outpatient departments, compared the therapeutic efficacy, tolerance and acceptability of two wound dressings, Urgotul (Laboratoires Urgo) and DuoDERM E (Granuflex in the UK) (ConvaTec) in the local treatment of venous leg ulcers or mixed leg ulcers of predominantly venous origin.

DuoDERM E was chosen as the comparator dressing because it corresponds to the reference dressing (a dressing commonly used for these wounds in controlled trials) for the treatment of such chronic wounds.[13-16]

Method

This multicentre randomised controlled phase IV clinical trial was conducted open-label in parallel groups in 20 centres (hospital dermatology and vascular medicine departments and private practices).

Ninety-one adult outpatients were randomised to receive one of the two trial treatments as well as a class 3 compression bandage worn daily (this is the European classification for high compression — at least 35mmHg). These patients were followed up by the same investigating team for a maximum of eight weeks.

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Box 1. Characteristics of Urgotul

Urgotul lipidocolloid wound dressing is a non-adhesive, non-occlusive, hydrocolloid dressing (Laboratoires Urgo, Chenôve, France) comprising a polyester textile support impregnated with hydrocolloid and vaseline. Textile support is composed of a flexible, continuous yarn in an undistortable lattice.

Urgotul must be used with a secondary dressing (gauze or an absorbent dressing, depending on the amount of exudate present). Therefore, absorbent gauze and Nylex bandages were provided for the purpose of this trial

Box 2. Characteristics of DuoDERM E

DuoDERM E hydrocolloid dressing — available in the UK as Granuflex (ConvaTec, BMS, Princeton, USA) — is composed of two layers: an external polyurethane layer and an inner layer of sodium carboxymethylcellulose, pectin and gelatine, which is intended for skin contact. A gel is formed when this comes into contact with exudate, which can be seen through the dressing in the form of a bubble. The dressing must be changed just before the bubble reaches the edge of the dressing.

DuoDERM E does not require a secondary dressing but it may be fixed in place with a bandage if necessary — in this trial this was left to the discretion of the investigating physician

On admission, each patient underwent a clinical examination involving wound-area tracing and photography. This was repeated at a frequency defined by the protocol: weekly for the first month (day 0, week 1, week 2, week 3 and week 4) and then every two weeks (week 6 and week 8) until the end of the second month.

Inclusion criteria

- Venous or mixed ulcer (ABPI over 0.8)
- Ulcer duration of two to 18 months
- Granulation tissue on 50% of the ulcer surface
- Ulcer size between 4cm^2 and 40cm^2
- Ulcer had no clinical signs of infection or malignancy.

Exclusion criteria

- Presence of progressive, malignant ulcers
- Immunosuppressant drug therapy
- Known hypersensitivity to carboxymethylcellulose.

Ethical approval

Approval was obtained from the Versailles Medical Ethics Committee (France), and the study was conducted in compliance with good clinical practice and the principles laid down in the Declaration of Helsinki.

Trial treatments

Patients meeting the inclusion criteria were randomised to one of the two therapeutic groups. Doppler examination verified ulcer aetiology — venous origin or mixed. Most ulcers (71.1% in the Urgotul group and 76.9% in the DuoDERM E group) (p=0.42) were of venous origin.

Boxes 1 and 2 outline the dressing characteristics. All of the investigators followed the manufacturers' instructions.

Dressing change frequency was decided for both products by the investigating physician alone; this was left entirely to his or her discretion. As a rough guide, it was recommended that both dressings should be changed every three to five days (or more often) on granulating wounds. This change frequency correlated with the volume of exudate and the clinical course of the wound.

Local wound care was to be conducted exclusively with saline solution, along with mechanical debridement if needed.

Some patients had used compression before entry. At the start of the trial, the sponsor therefore provided a strong, monolayer compression therapy (Dupraflex 3) for use with both treatments and for all patients. This ensured the compression, which is essential for venous ulcers, was homogeneous.

Endpoints

The principal endpoint used to evaluate dressing efficacy was the reduction in wound surface area after eight weeks of treatment: surface areas were reported in the form of wound (planimetric) tracings taken at inclusion. The investigators were given a protocol on planimetric tracing.

In addition to these tracings, the investigator performed clinical evaluations to assess granulation tissue, sloughy tissue and any local adverse events. They also photographed the wound throughout the follow-up period.

Secondary endpoints included tolerance (occurrence of local adverse events), as evaluated by the investigating physician during patient visits, and the acceptability of the trial dressing. Acceptability was evaluated by nursing staff during each dressing removal, either the investigating nursing team or visiting nurses when care was provided outside the hospital between two hospital evaluations. Acceptability included:

- Ease of dressing use
- Painful/painless nature of dressing changes
- Odour
- Maceration and leakage of exudate.

All were evaluated using qualitative methods.

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Statistical analysis

It was evaluated that this clinical trial needed a total of 80 patients (40 in each treatment group).

The results were analysed statistically by a company independent of Laboratoires Urgo and in concordance with the statistical analysis plan defined and approved by the parties involved in the trial.

Two analyses were conducted:

- One analysis was based on the intention-to-treat (ITT) principle. This considered all of the patients recruited (this amounted to 90 patients as one patient died before being seen at week 1)
- A second per-protocol analysis (PP) considered 77 patients (13 were excluded as they were not concordant with a major inclusion criterion — their initial wound surface area was not between 4cm² and 40cm²). Before the blind was broken, and therefore before the results were analysed, it was agreed with the trial coordinator that an error of not more than 20% would be tolerated with respect to this initial surface area criterion. The PP analysis therefore considered only ulcers with an initial surface area between 3.2cm² and 48cm².

The two treatment groups in both the ITT and PP analyses were compared using the Student's t-test for continuous variables (described by sample size, mean, standard deviation, median and minimum-maximum values), the Chi-square test (or Fisher's exact test) for unordered qualitative variables and the Cochran-Mantel-Haenszel or Wilcoxon test for ordered discrete variables.

Results

Baseline population and pathology

Ninety-one patients (47 in the Urgotul group and 44 in the DuoDERM E group) were included and followed up in this clinical trial conducted in the different investigating centres between 2001 and 2003. None of the patients was lost to follow-up, despite the fact that they were outpatients.

Parameters used to record the patient characteristics are listed in Table 1. No significant difference was observed at inclusion in the demographic characteristics of the two groups or in the phlebologic history of those included.

Numerous parameters describing trial pathology were evaluated at inclusion (Table 2). Ulcer characteristics at inclusion were similar in the two groups with regard to initial surface area and duration — the two major prognostic factors in the healing process.

Ulcers in both treatment groups were recurrent in approximately 40% of cases. Spontaneous pain was reported in one-third of patients, despite the ulcers' venous origin (confirmed by an ABPI that, on average, exceeded 1.0).

No significant difference was noted between the two groups for ulcer location (submalleolar in nearly 50% of cases) or in the circumference of the affected lower limb (values calculated for the calf and ankle).

Table 1. Baseline patient characteristics

	Urgotul group (n=47)	DuoDERM E group (n=44)	p value
Gender:			
• Female	32 (68.1%)	25 (56.8%)	0.27
• Male	15 (31.9%)	19 (43.2 %)	
Age (range)	70.7 ± 15.3 (22–93)	75.5 ± 9.1 (56–99)	0.25
Weight (kg) (range)	73.9 ± 19.4 (40–120)	78.1 ± 19.4 (43–134)	0.18
Height (cm) (range)	164.9 ± 8.1 (148–182)	167.4 ± 8.3 (150–185)	0.15
Venous disease history:			
• Phlebitis	27.7%	27.3%	0.97
• Stripping	25.5%	36.4%	0.26
• Sclerosis	14.9%	18.2%	0.67
• Familial venous disease history	34.0%	25.0%	0.34

PP analysis of both patient demographic and wound characteristics at inclusion produced very similar results to those presented above for the ITT analysis.

Principal endpoint: efficacy of trial treatments

The results reported below concern only the patients included in the PP analysis: 77 patients who were totally concordant with the inclusion criteria (38 patients in the Urgotul group and 39 in the DuoDERM E group) are considered.

It is nevertheless noteworthy that the ITT analysis produced very similar results to those of the PP analysis (for efficacy, tolerance and acceptability).

After eight weeks of treatment, ulcer surface area had reduced by a similar proportion in both groups (61.3 ± 39.7% in the Urgotul group and 52.1 ± 66.2% in the DuoDERM E group). These time-course changes in surface area are illustrated in Fig 1.

There was no significant difference between the two study groups with regard to the proportion of patients healed.

The mean time to healing was 33.3 ± 11.0 days in the Urgotul group and 29.8 ± 7.1 days in the DuoDERM E group.

The strong, mono-layer compression therapy was worn daily throughout the entire trial by 98.5% of patients in the Urgotul group and 96.9% in the DuoDERM E group. The exceptions were patients for whom this compression level was too high, and they instead wore bandages with a lower compression level, or compression hosiery.

Table 2. Baseline wound characteristics

	Urgotul group (n=47)	DuoDERM E group (n=44)	p value
Ulcer duration (months) (range)	7.9 ± 5.6 (2–18)	7.0 ± 5.3 (2–18)	0.47
Recurrent nature of ulcer (%)	38.3	40.9	0.8
Surface (cm^2) (range)	11.71 ± 12.27 (0.42–73.69)	9.95 ± 7.02 (1.32–31.71)	0.40
ABPI measurement (range)	1.1 ± 0.1 (0.8–1.4)	1.1 ± 0.3 (0.8–2.1)	0.37
Aetiology:			
• Venous	33 (70.2%)	34 (77.3%)	
• Venous post-phlebitis	10 (21.3%)	5 (11.4%)	0.40
• Mixed (arterial and venous)	4 (8.5%)	5 (11.4 %)	
Presence of peri-ulcer oedema	15 (31.9%)	12 (27.3%)	0.63
Trophic disorders on the opposite limb	26 (55.3%)	22 (50.0%)	0.61
Spontaneous pain:			
• None	19 (40.4%)	16 (36.4%)	
• Slight	11 (23.4%)	13 (29.5%)	0.91
• Moderate	14 (29.8%)	13 (29.5%)	
• Severe	3 (6.4%)	2 (4.5%)	
Condition of peri-ulcer skin:			
• Healthy	8 (17.0%)	5 (11.4%)	0.44
• Inflammatory	24 (51.1%)	16 (36.4%)	0.16
• Oedematous	10 (21.3%)	6 (13.6%)	0.34
• Eczematous	11 (23.4%)	5 (11.4%)	0.13
• Irritated by wound dressings	4 (8.5%)	3 (6.8%)	1.00
• Other	5 (10.6%)	10 (22.7%)	0.12
Granulation tissue:			
• 51–75% of the wound bed	22 (46.8%)	22 (50.0%)	
• >75% of the wound bed	17 (36.2%)	18 (40.9%)	0.53
• On the whole wound bed	8 (17%)	4 (9.1%)	
Circumference of the lower limb (cm):			
• Calf (range)	34.6 ± 6.0 (23.5–49.0)	34.7 ± 4.4 (25.1–43.0)	0.89
• Ankle (range)	23.4 ± 3.1 (18.0–31.0)	23.9 ± 3.3 (16.0–31.5)	0.3
Nature of the previous treatment:			
• Greasy gauze	16 (34.0%)	11 (25%)	0.34
• Hydrocellular	10 (21.3%)	5 (11.4%)	0.20
• Hydrocolloid	6 (12.8 %)	6 (13.6%)	0.90
• Alginate	2 (4.2 %)	6 (13.6%)	0.14
• Other	13 (27.7%)	16 (36.4%)	0.37

Secondary endpoints

The investigating physician documented tolerance to the two trial dressings during the weekly visits scheduled in the protocol: 33 adverse events were reported for the two groups:

- Ten for the Urgotul group (nine patients)
- Twenty-three for the DuoDERM E group (18 patients) (p=0.039).

These local adverse events prompted eight premature withdrawals from the study:

- Three in the Urgotul group, which were due to pain and eczema
- Five in the DuoDERM E group — peri-wound ulceration, pain, eczema and secondary infection.

The local adverse events are described in Table 3.

By the end of the trial 33.3% of the patients in the Urgotul group presented with healthy peri-ulcer skin, compared with 22.7% in the DuoDERM E group. Only 3.7% of the patients who received Urgotul, compared with 18.2% in the DuoDERM E group, presented with irritated skin at the end of the follow-up period.

Nurses documented the acceptability of the trial dressings at each dressing change throughout the entire trial duration. Table 4 presents the comments for each of the evaluated parameters.

A significant difference was observed in favour of the Urgotul group for most of the evaluated parameters evaluated (ease of removal, pain on removal, maceration, odour and leakage of exudate). Nurses nevertheless considered that the DuoDERM E dressing was significantly easier to apply than Urgotul (p<0.0001).

Significantly fewer dressing changes were made per week in the Urgotul group than in the DuoDERM E group: 2.31 ± 0.45 changes per week compared with 2.54 ± 0.57 for the DuoDERM E group (p=0.047).

The values for the dressing changes given by the ITT analysis were virtually identical: 2.28 ± 0.42 for the Urgotul dressing compared with 2.49 ± 0.56 for the DuoDERM E group (p=0.048).

Discussion

Many factors including venous hypertension, endothelial cell alterations and increased capillary permeability may contribute to the onset of the trophic disorders represented by leg ulcers,[17] where compression therapy is still the aetiological treatment of choice.[18] It is nonetheless important to choose an appropriate primary wound dressing as this must create optimal conditions for reducing healing times and be well tolerated.[19]

It follows that the main objective of this randomised controlled clinical trial was to evaluate the efficacy, tolerance and acceptability of Urgotul and DuoDERM E wound dressings in the treatment of venous or mixed-aetiology leg ulcers of predominantly venous origin.

The trial was conducted in France in 20 hospital and private-practice centres, primarily in dermatology and angiology-phlebology departments. Eighty percent of the study sample was concentrated in 12 out of the 20 centres (with at least six patients from each of these centres).

Each patient had a weekly medical evaluation for a maximum of eight weeks. Each dressing removal was documented by the investigating centre's nursing team or by a visiting nurse when care was administered between the two hospital visits scheduled in the protocol.

DuoDERM E adhesive dressing was chosen as the comparator dressing because it is the reference dressing for the local management of leg ulcers.[13-16]

Since Urgotul is a non-adhesive dressing, to be included in the trial wounds had to have peri-ulcer skin that was suitable for an adhesive dressing.

Randomisation then ensured that two comparable groups were formed at inclusion, both in terms of patient demographics and ulcer characteristics.

Compression therapy was provided by the sponsor for all patients in the study to ensure they received the same aetiological treatment for their venous disease. The majority wore high compression, although in the few cases where this was too high, a lower level compression hosiery was worn.

As wound size is a major prognostic factor for healing time,[20,21] two statistical analyses were performed: ITT, which considered all 91 patients included in the trial, and PP, which considered the 77 patients who met the inclusion criteria for initial ulcer size. However, the ITT and PP analyses produced very similar results for efficacy, tolerance and acceptability, and for the number of dressing removals per week of treatment. Accordingly, only the results of the PP analysis are discussed here.

At the end of the eight-week treatment period, ulcers treated with Urgotul showed a greater reduction in the wound surface than those in the DuoDERM E group (61.3% versus 52.1%), although this was not significant.

The size reductions observed in the DuoDERM E group are similar to those reported in two papers[22,23] and slightly better than demonstrated in other trials involving hydrocolloid dressings.[15,24]

In addition, the clinical results observed here with Urgotul corroborate those obtained by Meaume et al.[9] using single-layer compression therapy.

In vitro studies have reported that Urgotul does not have toxic properties when compared with other dressing interfaces[25] and that it promotes fibroblast proliferation, unlike neutral paraffin gauze.[26]

It is tempting, therefore, to draw a parallel between these recent *in vitro* results and the clinical efficacy observed in this trial, which considered wounds during the granulation phase, when fibroblasts are mainly involved.

Local tolerance, evaluated on the basis of the onset of local adverse events, was deemed to be better in the Urgotul group. Of the 33 local adverse events reported, 10 concerned the Urgotul group and 23 the DuoDERM E group (p=0.039).

The large number of adverse events reflects the fact that all adverse events were reported, regardless of their relation to the study dressings.

Published studies[11,12] have reported that Urgotul is well tolerated in this regard, even when left in place for seven days under multilayer compression therapy. The tolerance of the DuoDERM E dressing, considered good in numerous randomised clinical trials,[3,4] has been deemed rather mediocre in others when compared with the test dressing because of the frequent occurrence of local adverse events.[27,28]

Overall, Urgotul was better accepted than DuoDERM E. When considering parameters such as pain on removal, ease of removal, maceration, odour (none in 82.7% of cases compared with 50.1% for the DuoDERM E group), the Urgotul dressing was significantly superior. The exception was application, which was significantly easier for DuoDERM E than Urgotul.

Fig 1. Mean percentage decrease of wound surface area, from baseline to week 8

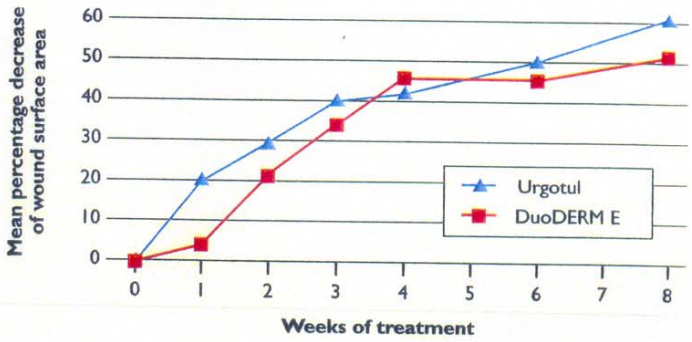

Table 3. Nature of the local adverse events

	Urgotul group (n=9)	DuoDERM E group (n=18)
Hypergranulation	1	4
Pain	2	2
Erythema	–	3
Eczema	2	7
Secondary infection	2	2
Pruritus	–	1
Peri-wound ulceration	1	2
Erysipelas	1	1
Maceration	1	1
Total	**10**	**23**

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Table 4. Wound dressing acceptability

	Urgotul group (n=453 changes)*	DuoDERM E group (n=415 changes)*	p value
Ease of removal:			
• Very easy	90.7%	73.0%	<0.0001
• Easy	9.3%	26.0%	
• Difficult	0.0%	1.0%	
• Very difficult	0.0%	0.0%	
Ease of application:			
• Very easy	71.3%	81.9%	
• Easy	25.8%	18.1%	<0.0001
• Difficult	2.9%	0.0%	
• Very difficult	0.0%	0.0%	
Pain at removal:			
• None	95.0%	82.5%	
• Slight	5.0%	12.9%	<0.0001
• Moderate	0.0%	4.6%	
• Severe	0.0%	0.0%	
Maceration:			
• None	71.0%	26.2%	
• Slight	14.7%	38.7%	<0.0001
• Moderate	10.0%	26.4%	
• Severe	4.3%	8.7%	
Odour:			
• None	82.7%	50.1%	<0.0001
• Slight	13.5%	43.9%	
• Moderate	3.2%	3.9%	
• Severe	0.7%	2.2%	
Leakage of exudate:			
• No	68.6%	56.3%	0.0002
• Yes	31.4%	43.7%	
Mean number of dressing removals, per treatment week (range)	2.31 ± 0.45 (1.50–3.25)	2.54 ± 0.57 (1.20–4.00)	0.047

* Five patients withdrew from the DuoDerm E group because of adverse events in the early stages of the trial. The three withdrawals from the Urgotul group occurred closer to the end of the follow-up period. More dressings changes, therefore, took place throughout the study period in the Urgotul group. However, analysis showed that statistically fewer dressing changes took place in this group when compared with the DuoDERM E group

These results corroborate those reported in the literature for Urgotul, which is recognised for its excellent acceptability due to its lack of adhesiveness to the wound bed.[9,10,29]

Smith et al.[12] recently reported that Urgotul remained non-adherent after seven days *in situ* under multilayer compression therapy for the treatment of leg ulcers of the same aetiology.

With regard to dressing-change frequency, a significant difference was observed between the two treatment groups: fewer dressing changes were made per week in the Urgotul group than in the control group — 2.31 ± 0.45 changes per week compared with 2.54 ± 0.57 DuoDERM E (p=0.047). In other words, Urgotul was left in place longer than DuoDERM E (on average, 3.06 days compared with 2.73 days).

Exudate levels were the same in both groups; Urgotul was used in combination with an absorbent pad.

Usually removed twice a week for up to seven days, the changing frequency for the DuoDERM E dressing in this trial is identical to that described by Thomas et al.:[15] on average, every 2.7 days when treating ulcers of the same aetiology, although smaller.

Conclusion

This randomised trial involving 91 patients showed that Urgotul and DuoDERM E dressings, although different in nature, were similar in terms of efficacy in the local management of leg ulcers.

Local tolerance, which was evaluated by the occurrence of local adverse events, was deemed to be better in the Urgotul group, which was also superior to DuoDERM E in terms of its acceptability, notably in relation to pain on removal, maceration and odour.

These two factors — tolerance and acceptability — are essential criteria for both medical and nursing staff when choosing the appropriate treatment for the management of chronic wounds. ■

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