

## A clinical evaluation of Urgotul® to treat acute and chronic wounds

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A study was conducted to evaluate the use of the novel wound dressing Urgotul® in the management of acute and chronic wounds across primary and secondary care during 2001–2002. This was the first non-comparative, descriptive clinical trial of the product in a single site in the UK. A total of 22 hospital and community patients completed the study which lasted 4 months from October 2001 to February 2002. This article describes the conduct of the study and study results.

### TRADITIONAL DRESSINGS

Historically, tulle-type dressings, containing soft paraffin, were used routinely for donor sites, burns and leg ulcers because of their perceived advantage of non-adherence to the wound surface (Thomas, 1990). In practice, these dressings were greasy and therefore semiocclusive, sometimes causing problems with skin and wound maceration beneath them (Thomas, 1990). Today, tulle dressings are available that act as carriers for other substances, such as anaesthetic agents, sulphonamides, antibiotics, honey and vitamins (Thomas, 1990).

A common problem associated with tulle dressings in practice is that as the exudate and/or blood dries out, the dressing strongly adheres to the wound causing bleeding, trauma and pain on removal (Thomas, 1990). More seriously, if the dressings are left in place for too long, granulation tissue grows through the open weave of the dressing, again causing disruption of the newly formed epithelial tissue on removal.

Newer 'non-adherent' dressings have been developed to try to address the problem of adherence, such as Melolin (Smith & Nephew) and Telfa (Kendall). In practice there may still be a problem with adherence to the wound surface with these dressings, as frequently observed by the authors (Morgan, 2000).

### Abstract

*This article describes the first UK clinical open study of Urgotul®, a new dressing, in the management of acute and chronic wounds. A single-centre, qualitative, descriptive, non-comparative study was carried out to evaluate the tolerance, acceptability and efficacy of Urgotul® in practice. Urgotul® comprises a new concept in wound management: lipido-colloid technology. It is a class IIb medical device and takes the form of a non-occlusive, thin-sheet, lipido-colloid dressing. Twenty-two out of 27 hospital inpatients who were selected by the tissue viability nurse and vascular nurse completed the study. Informed written consent was obtained before inclusion and photography of the wounds. Wounds were photographed and traced on entry, at each dressing change and on exit. The clinical report forms were completed weekly until wounds healed, or up to a maximum of 4 weeks. Patient and nurse acceptability was documented weekly and on exit from the study. The results were very positive regarding ease of application, conformability and non-adherence, absence of trauma, pain and bleeding on removal, with minimal maceration of the surrounding skin and odour. The study involved a limited sample of patients but demonstrated good efficacy, tolerance and acceptability of the dressing in a wide range of acute and chronic wounds.*

### URGOTUL®

Urgotul® is a new concept in wound management known as lipido-colloid technology. It is a sterile, EC class IIb medical device developed and produced by Urgo Laboratories in Dijon, France, and is available through the UK subsidiary, Parema Medical Ltd.

Urgotul® is a non-occlusive, thin-sheet, lipido-colloid dressing comprising a 100% polyester net with non-deformable filaments impregnated with hydrocolloid particles dispersed in a petroleum jelly matrix (*Nurses' Index of Medicines and Products*, 2003). This combination provides the optimal wound environment of moisture, protection and warmth (Winter, 1962). Limited informal evaluations conducted in the UK by the author and other UK tissue viability nurses before the clinical study had shown that Urgotul® is non-greasy to the touch, non-adherent and comfortable (Benbow, 2002).

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Accepted for publication: September 2003



**Table 1. Mean wound surface of the acute and chronic wounds during one month of treatment**

Acute wounds	Mean wound surface (cm <sup>2</sup> )	
	Week 0	Week 4
Mean	84.4	12.6
Minimum	1.35	4.73
Maximum	290.0	38.2
Chronic wounds	Mean wound surface (cm <sup>2</sup> )	
	Week 0	Week 4
Mean	26.8	7.0
Minimum	3.5	2.1
Maximum	59.0	11.9

**Table 2. Rate of healing and healing time of the acute and chronic wounds during one month of treatment**

Acute wounds (n=12)	Healed	Not healed
	7 (58%)	5 (42%)
<i>Healing time (day): 15.5 ± 5.0</i>		
Chronic wounds (n=10)	Healed	Not healed
	1 (10%)	9 (90%)
<i>Healing time (day): 10</i>		

Urgotul® is indicated as a primary dressing for a wide range of acute wounds including superficial burns, abrasions, traumatic wounds and chronic wounds, such as pressure ulcers, leg ulcers and dehisced wounds (Meaume et al, 2002). It is supplied in three sizes — 10 cm x 10 cm, 15 cm x 20 cm and 10 cm x 40 cm — with each dressing individually wrapped.

Adherence to the wound surface is prevented by hydration of the hydrocolloid particles with wound exudate producing a lipido-colloid interface (Urgotul® Product File: Laboratoire Urgo). This allows the dressing to remain in place for extended periods without sticking to the wound surface and causing trauma on removal. The maximum wear time locally was found to be 14 days, when a patient missed an appointment, but is routinely 5–7 days. The dressing is not absorbent but allows drainage of exudate through its fine, constantly open mesh into an outer absorbent dressing, as observed during the study. This avoids any build-up, occlusion or maceration of the wound and surrounding skin. Newly formed granulation tissue is prevented from migrating through the dressing

by the small opening diameter of the mesh that, in turn, prevents trauma, bleeding and pain on removal.

## METHOD

The aims of the study were to evaluate patient tolerance and overall efficacy of the product, patient and nurse acceptability and dressing performance. Patients were recruited into the study following approval from the local research ethics committee.

Subjects were selected from referrals made to the tissue viability nurse and vascular nurse from within the hospital trust who matched the criteria set for inclusion into the study. The inclusion criteria stated that the patient must be adult and capable of giving written consent, have an acute or chronic wound suitable for use of Urgotul®, as judged by clinical assessment. Urgotul® is indicated for local care of acute and chronic wounds at the granulation and epithelialization stages.

The product was assessed during the trial for a maximum of 4 weeks, or until the wound healed, if less than 4 weeks. Subjects originating in the hospital were followed up in the community following discharge.

Twenty-seven subjects were recruited between October 2001 and February 2002. Of the subjects, 22 completed the study, as five patients were lost to the study as a result of loss of contact. The 22 patients included nine males and 13 females. The age of the subjects ranged from 23 years to 86 years.

A wide range of wound types were included in the study. The chronic wounds were:

- Pressure ulcers on the sacrum (three)
- Venous/arterial leg ulcers (five)
- Diabetic foot ulcer (one)
- Traumatic haematoma on the shin (one)

The acute wounds were:

- Burns to the shoulders, legs and arms (five)
- Postoperative abdominal wounds (two) — these were being treated with vacuum-assisted closure (VAC) therapy and Urgotul® was used to line the cavities to prevent ingrowth of granulation tissue
- Traumatic wounds (three)
- Cellulitis (two).

Before inclusion in the study, the study requirements were explained to the potential subjects. Informed, written consent was obtained from subjects for inclusion in the study and for photography of their wounds.



Consent from the respective consultants and chief executive was also obtained for the study.

The patients and their wounds were assessed for suitability for inclusion. At each dressing change, the wound assessment and area tracing were documented and photographs were taken with a digital camera. The time between dressing changes varied from 3 to 7 days in the patients with acute wounds and from 6 to 7 days in the patients with chronic wounds. Patient and nurse observations were also documented to evaluate acceptability at each dressing change and at the end point of treatment. Secondary dressings were applied at the clinician's discretion according to the site of the wound and general assessment. For some low-exudate wounds a vapour-permeable film was adequate; for others, e.g. heavily exuding leg wounds, padding and a bandage were necessary.

The wound assessment data were recorded on a clinical report form on entry to the study, at every dressing change and on exit from the study. The data were statistically analysed using the SAS system. The parameters measured were ease of application, ease of removal, the degree of adherence on removal, bleeding on removal, pain on removal, odour, maceration and conformability to the wound bed. The size of the wound was documented and improved, even healing noted. The progress of the wounds during the 4 weeks of treatment can be seen in Tables 1 and 2. During the weekly assessment the two researchers were required to assess subjectively the level for each parameter and record the finding at each stage. For example, ease of removal was assessed and recorded as very easy, easy or difficult.

## RESULTS

Chronic wounds accounted for 45% (10) and acute wounds 55% (12). There was a total of 500 days of treatment and 71 dressing changes carried out mainly by the tissue viability nurse, vascular nurse or a suitably trained first-level ward or community nurse.

The average initial surface area in the acute wound group was 84.36 cm<sup>2</sup> (range 1.35–290 cm<sup>2</sup>). Seven (58%) wounds healed completely, with a mean healing time of 15 days (range 7–20 days) and a dressing change frequency of 7.3 days within the 4-week period. Three (25%) wounds showed improvement and one wound remained

static. One wound deteriorated and the patient was removed from the study.

In the chronic wound group the average initial wound surface area was 26.68 cm<sup>2</sup> (range 3.54–59 cm<sup>2</sup>). One wound healed after 10 days and the dressing change frequency was 6.7 days. Nine of the chronic series remained unhealed but showed marked reduction in size during the 4 weeks of the evaluation. The initial surface area for acute wounds was 84.4 ± 119.3 cm<sup>2</sup> [1.35–290.0] and the final surface area was 12.6 ± 16.5 cm<sup>2</sup> [4.73–38.2]. For chronic wounds the initial surface area was 26.8 ± 28.8 cm<sup>2</sup> [3.5–59.0] and the final surface area was 7.0 ± 6.9 cm<sup>2</sup> [2.1–11.9]. Figure 1 shows a wound on entry to the study and Figure 2 shows the wound after 4 weeks of treatment with Urgotul®. Table 3 shows the acceptability of Urgotul® as evaluated by this study.

### Ease of application

Throughout the evaluations there was total agreement among a number of nurses who undertook the 71 dressing changes that Urgotul® was very easy to apply. This was because of its flexibility and conformability



Figure 1. On entry to study.



Figure 2. After 4 weeks of treatment with Urgotul®.



to the wound area. The only minor problem encountered was that if the operator's gloves were dry, the dressing tended to stick to the gloves. This was easily remedied by moistening the glove-covered fingers with sterile saline before handling the dressing.

**Table 3. Acceptability of Urgotul®**

Parameter measured	n	%
<i>Ease of application (n=71)</i>		
Very easy	71	100
Easy	-	-
Difficult	-	-
Very difficult	-	-
<i>Ease of removal (n=71)</i>		
Very easy	71	100
Easy	-	-
Difficult	-	-
Very difficult	-	-
<i>Adherence on removal (n=71)</i>		
None	71	100
Minimal	-	-
Moderate	-	-
Important	-	-
<i>Bleeding on removal (n=70)</i>		
None	70	100
Minimal	-	-
Moderate	-	-
Important	-	-
<i>Pain on removal (n=71)</i>		
None	71	100
Minimal	-	-
Moderate	-	-
Important	-	-
<i>Odour (n=70)</i>		
None	55	79
Minimal	5	7
Moderate	6	9
Offensive	4	6
<i>Maceration (n=71)</i>		
None	68	96
Minimal	2	3
Moderate	1	1

**Table 4. Local adverse events (n=3)**

Nature	Intensity	Duration (day)	Evolution	Relation to treatment
Pseudomonal infection	Severe	2	Disappearance	Excluded
Hypergranulation	Moderate	3	Disappearance	Excluded
Hypergranulation	Severe	4	Disappearance	Excluded

### *Ease of removal*

Again there was total agreement that Urgotul® was very easily removed. Comments such as 'even after 5 days Urgotul® falls off the wound' were made by the nurses involved. There was never any need to soak the dressing off even in the one case where it had been left for 14 days because the patient had missed an appointment. Patients were pleased that they did not have to suffer the pain of having a dressing sticking to their wounds. At no time was any bleeding associated with dressing removal observed.

Pain was assessed as none, minimal or moderate during dressing changes. Owing to the totally non-adherent nature of Urgotul®, patients did not suffer any pain when dressings were removed.

Odour was assessed and documented by the researchers as none, minimal or moderate. At the first dressing change evaluation, one patient's chronic wound was reported as having minimal odour and one as having moderate odour. It can be assumed that the odour was not dressing-related but associated with the wound being colonized/infected in the final analysis as the wounds were swabbed.

There were few reports of wound maceration during the study. Two patients were found to have wound maceration assessed as minimal and one patient had a moderate degree of maceration. As Urgotul® is not absorbent, it allows the passage of exudate through into the outer absorbent dressings. These were burn wounds on the shoulders and groin where the exudate levels increased after the application of a low-absorbent film dressing. At the next dressing change absorbent gauze was placed over the Urgotul® before applying the vapour-permeable film dressing which solved the problem.

Conformability was assessed and documented as very good, good or poor. In all subjects conformability was very good. This is excellent considering that the wounds treated varied in type, depth, shape and part of the anatomy. One patient receiving VAC had a very deep, full-thickness abdominal wound following wound infection and breakdown after Caesarian section. The base and sides of the wound were carefully and easily lined with Urgotul® to support healing, but mainly to prevent the ingrowth of granulation tissue into the VAC foam dressing (a commonly encountered problem in practice).



In spite of there being moderate amounts of exudate present in 12 wounds, maceration of the surrounding skin (not of the wound) was reported in only one case. The Urgotul® dressings were described by nurses as being easy to remove from the packaging and patients reported them to be comfortable when in place. Several of the patients with chronic wounds had painful experiences of dressings sticking to their wounds previously.

## Tolerance

There were three local adverse events recorded in this clinical evaluation (Table 4). Two wounds (leg ulcers) over-granulated at weeks 2 and 3, one of which was withdrawn and one leg ulcer became grossly infected at week 4 (although this was not thought to be associated with the dressing because of the underlying pathology and swab results).

## DISCUSSION

This was the first single-centre clinical study in the UK to evaluate the use of Urgotul® in a limited sample of patients. The results are very encouraging in terms of testing for efficacy, acceptability and tolerance. The key feature of non-adherence was a significant issue compared with older, traditional dressings, such as tulle and gauze-type dressings. Urgotul® can thus be considered an alternative to the older style dressings which are still in regular use.

The wear time of a dressing is a significant factor relating to its effectiveness and cost-effectiveness. This was not a distinct parameter tested in this study but, as can be seen from the results, Urgotul® dressings were left in place for 6–7 days on average, thus reducing nursing time and interference with the healing wound. If necessary and appropriate, the outer, absorbent secondary dressings were changed inbetween the weekly reassessments by ward and community nurses.

Following the study, the nurses caring for the study patients were given a choice as to whether they wished to continue using Urgotul®. The researchers, in their trust roles, continued to advise but data were not collected on study patients after 4 weeks of local treatment.

Staff and patients tolerated the dressing very well, it conformed to the wound surface, there was no pain, trauma or bleeding on removal and little odour and maceration. These results confirm those already published

on this wound dressing (Meaume et al, 2002). The results show improvement in terms of tolerance and acceptability compared to traditional dressings. This is not a comparative study and no comparison in terms of healing rates is acknowledged.

## CONCLUSION

Although the sample size in this study was limited, the results demonstrate that Urgotul® is a versatile product worthy of consideration for both chronic and acute wounds for its non-adherent, atraumatic properties. The dressing was observed to reduce the potential for trauma through atraumatic, pain-free removal, and it proved to be easy to use and comfortable for the patients.

More work is needed to explore issues relating to comparative healing times, optimum dressing wear time and the appropriateness of secondary dressings for different wound types. **BJN**

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## KEY POINTS

- Traditional tulle dressings should be used with caution in granulating and epithelializing wounds.
- Wound healing should not be compromised by traumatic dressing removal.
- Pain at dressing change should not be tolerated.
- Dressing comfort and reduced apprehension at dressing change should improve patient compliance to treatment.
- The non-adherent lipido-colloid wound dressing Urgotul® is pain free and atraumatic at dressing removal.