

Using a new lipidocolloid dressing in paediatric wounds: results of French and German clinical studies

- **Objective:** To evaluate the efficacy, tolerance and acceptability of a lipidocolloid dressing, Urgotul (Laboratoires Urgo), in the local treatment of acute and chronic paediatric wounds.
- **Method:** Two non-comparative multicentre prospective clinical studies were conducted using the same protocol in France and Germany. A total of 100 patients were recruited from 16 centres (11 in France and five in Germany), and followed up for four weeks. Seventy wounds (55 burns and 15 other wounds) from France and 30 from Germany (22 burns and eight other wounds) were evaluated by nursing staff at every dressing change and by the medical investigator on a weekly basis.
- **Results:** In the French study population, 86% of the burns (superficial and deep partial-thickness) and 53% of the other wounds healed completely within the four weeks. Figures for the German study population were 100% and 88% respectively. Pain was evaluated using pain scales adapted to the patient's age (objective pain scale, faces scale for pain and a visual analogue scale) at each dressing change. Dressing removal was non-traumatic, inducing very limited pain. Minor local adverse events were reported in four children.
- **Conclusion:** Urgotul is not only efficacious, but also well-tolerated and accepted by children with acute and chronic wounds. The dressing, therefore, might be an appropriate and highly promising alternative to conventional dressings.
- **Declaration of interest:** This study was sponsored by Laboratoires Urgo.

paediatric wound care; dressing removal; pain; burns

Most wounds in surgical paediatric wards are acute (mainly burns) and are treated with neutral or impregnated vaseline gauze or an equivalent. These can cause pain on removal, with sociopsychological consequences.¹⁻³

As pain in children is influenced by age and anticipation of pain,^{4,5} assessment is difficult. Therefore, pharmacologic and non-pharmacologic interventions should be combined to manage pain.⁶

Even though the efficacy of tulle-gras dressings has not been proven, they have long been used on wounds,⁷ particularly burns, surgical wounds and chronic wounds at the granulation and re-epithelialisation stages of healing. They need to be changed daily to avoid adherence to the wound bed and painful removal.

Hydrocolloid dressings contain carboxymethylcellulose, which maintains a moist environment at the wound surface, accelerating the healing process.⁸⁻¹⁰ Their efficacy has been demonstrated in controlled clinical trials involving patients with chronic wounds such as leg ulcers,^{11,12} pressure ulcers^{13,14} and acute wounds.^{15,16}

Recently, lipidocolloid technology has been developed.^{7,17} Hydrocolloid particles within the dressing hydrate on contact with exudate. Combined with petroleum, they form a lipidocolloid

interface, which does not adhere to the wound surface, enabling non-traumatic, pain-free removal.

The primary aim of this study was to evaluate the efficacy of a new lipidocolloid dressing, Urgotul (Laboratoires Urgo), in children with burns or other acute and chronic wounds. The secondary aims were to evaluate tolerance to and acceptability of the dressing, particularly at dressing removal.

Materials and method

Study design

Two open multicentre non-randomised prospective clinical studies were conducted: one in France (11 centres) and one in Germany (five centres).

Inclusion criteria

- Children (in- or outpatients) aged one to 12 years
- Acute or chronic wounds less than 200cm². If more than one wound was present, a single lesion was chosen for the study.

Exclusion criteria

- Cancerous lesions
- Donor sites for skin grafting
- Wounds with necrotic plaque
- Wounds with clinical signs of infection
- Hypersensitivity to the test dressing
- Previous inclusion in a clinical study.

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Table 1. Baseline characteristics of the studies' populations

	France (n=70)		Germany (n=30)	
	Burns (n=55)	Other wounds (n=15)	Burns (n=22)	Other wounds (n=8)
Sex				
Male	35 (64%)	9 (60%)	9 (41%)	5 (63%)
Female	20 (36%)	6 (40%)	13 (59%)	3 (37%)
Age				
≤3 years	38 (69%)	4 (27%)	12 (55%)	1 (13%)
4-6 years	9 (16%)	2 (13%)	5 (23%)	2 (25%)
>6 years	8 (15%)	9 (60%)	5 (23%)	5 (63%)
Body weight (kg)	16.9 ±10.5	31.2 ±18.7	18.0 ±10.3	31.3 ±13.7
Minimum; maximum	6.0; 69.0	7.0; 63.0	8.0; 48.0	10.0; 50.0
Height (cm)	98.1 ±21.2	129.3 ± 32.8	104.5 ±26.9	135.1 ±26.8
Minimum; maximum	76.0; 166.0	70.0; 182.0	72.0; 158.0	80.0; 165.0
Wound duration (days)	3.8 ±5.7	15.4 ±21.1	1.7 ±1.3	13.3 ±20.8
Minimum; maximum	0.0; 28.0	0.0; 70.0	0.04; 5.0	0.04 ; 56.0
Location				
Face	5 (9%)	1 (7%)		
Hand	12 (22%)	1 (7%)	1 (5%)	4 (50%)
Superior limb	19 (35%)	2 (13%)	9 (41%)	1 (13%)
Lower limb	7 (13%)	8 (53%)	5 (23%)	1 (13%)
Other	12 (22%)	3 (20%)	7 (32%)	2 (25%)
Previous treatment				
None	20 (36%)	2 (13%)	2 (9%)	3 (38%)
Greasy dressing	22 (40%)	11 (73%)	14 (64%)	3 (38%)
Other	13 (24%)	2 (13%)	8 (36%)	2 (25%)

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Ethics

Approval was obtained from the University of Nantes national ethic committee in France and the local ethic committees of each investigation centre in Germany. The studies were conducted according to European regulations under Good Clinical Practice.¹⁸ Written informed consent was obtained from parents or guardians before enrolment.

Treatment and follow-up

The children's medical and surgical histories, and the origin, duration and characteristics of their wounds were recorded at inclusion.

Wounds were cleaned with saline, and the Urgotul dressing was then applied directly to them. A secondary dressing (gauze pad) was secured with adhesive tape. No other interventions were undertaken, unless manual debridement was indicated.

Dressing change frequency was decided by the investigator, based on clinical need. Use of analgesics was permitted before dressing change, again according to the investigator's practice. Less than 20% received this, mainly as paracetamol. The fact

Table 2. Wound characteristics

	France (n=70)	Germany (n=30)
	No. (%)	No. (%)
Burns	55 (79)	22 (73)
• Superficial partial thickness	15 (27)	7 (32)
• Deep partial thickness	40 (77)	15 (68)
• Thermal origin	53 (96)	22 (100)
Other wounds	15 (21)	8 (27)
Acute wounds		
• Post-surgery	4	1
• Traumatic	4	5
• Recent pressure under plaster	1	-
• Post-surgery necrosis	1	-
Chronic wounds		
• Burn sequelae	5	1
• Other	-	1

that this may have reduced pain levels at dressing changes was considered when evaluating the results on the level and character of pain.

Clinical evaluation, wound-area tracing and photographic follow-up were performed weekly until healing occurred or for a maximum of four weeks.

Wound area was traced using transparent film in line with a protocol provided by the sponsor.

Nurses evaluated dressing acceptability at each dressing removal. This included ease of application and removal, odour, bleeding, dressing conformability and adherence to the wound bed. Nurses were trained by the lead investigator at the site on the use of the various pain scales and on how to assess dressing acceptability.

Pain was assessed using one of two paediatric pain assessment scales, depending on the child's age.^{19,23}

- The faces scale, which is designed to assess pain in children aged over three years — children choose one of a range of faces, 'smiling', 'indifferent', 'weeping' or 'sobbing', to reflect the intensity of their pain
- A visual analogue scale (VAS) for children aged over six years — this is a 100mm non-hatched line where 0 = no pain and 100 = worst imaginable pain.

In addition, the investigators and/or nurses evaluated pain in children aged one to six years. This involved using the objective pain scale, which has four items (crying, motion, restlessness and verbal and non-verbal expression) scored 0-2 for each parameter. The VAS was also used (same as above).

The investigators and nurses evaluated pain in the younger children to get an objective view as very young patients may have difficulty communicating their scores. Nurses evaluated the pain level at each dressing change using different scales, depending on the patient's age. The investigator evaluated this at their weekly assessments.

Local adverse events were also monitored at each assessment.

Data processing and statistical analysis

Efficacy and tolerance (occurrence of local adverse events) were analysed on the intent-to-treat population (all patients recruited).

The primary outcome measure was predefined as the number of children with full wound healing (100% re-epithelialisation).

Categorical variables were described using frequencies and percentages. Continuous variables were summarised using frequencies, means, standard deviation, medians and extremes. No statistical tests were performed, and the results were calculated separately for each clinical study.

Collected data were analysed using SAS 6.12.

Results

Patients and wounds

Seventy children were enrolled in 11 centres in France between May 2000 and July 2001 and 30 children in five centres in Germany between September 2002 and May 2003. Baseline characteristics of patients and wounds are given in Tables 1 and 2.

Efficacy results: the French study

• **Burns** Forty-seven out of 55 burns (86%) healed during the study (range: four to 28 days; median: 12 days). Mean time to healing was shorter in superficial partial-thickness burns than in deep partial-thickness wounds (9.5 ±4.2 days versus 13.8 ±5.6 days).

One burn was grafted after the third week of follow-up. Two burns had not completely re-epithelialised at week four. Overgranulation occurred in three patients, who were withdrawn from the study. Two patients were lost to follow-up.

• **Other wounds** Eight out of 15 children (53%) healed within seven to 21 days (median: 13 days; mean: 13.3 ±4.2 days). In six patients the wound had not healed completely at week four.

An adverse event (infection of the wound bed) caused one child to be withdrawn from the study and another child's investigation to be stopped prematurely.

Efficacy results: the German study

• **Burns** All 22 burns (100%) healed within seven to 28 days (mean: 13 days). Mean time to healing was shorter in superficial partial-thickness burns than in deep partial-thickness wounds (10.6 ±3.0 days versus 16.1 ±6.7 days).

• **Other wounds** Seven out of eight children (88%) healed within 13–26 days (median: 21 days; mean: 19.7 ±4.2 days). One patient's wound had not healed at week four.

Healing rates reported here are the same as reported for Urgotul in the literature.¹⁷ Table 3 gives differences in wound surface area in wounds at inclusion and after four weeks.

Table 3. Wound surface area (cm²) at inclusion and four weeks

	France		Germany	
	Burns (n=55)	Other wounds (n=15)	Burns (n=22)	Other wounds (n=8)
Surface area (cm ²) at inclusion	41.9	9.15 ±10.93	46.0 ±59.9	8.2 ±13.4
Minimum; maximum	5; 170	1.70 ±37.30	1.3; 226.7	1.2; 28.3
Surface area (cm ²) after four weeks	–	1.59 ±2.21	–	0.3 ±0.8
Minimum; maximum		0; 7.11		0; 2.4

Table 4. Dressing acceptability*

	France (355 changes)		Germany (174 changes)	
	Burns (n=262)	Other wounds (n=93)	Burns (n=120)	Other wounds (n=54)
Dressing application				
No. of changes	237	67	117	53
Easy or very easy	208 (88%)	67 (100%)	115 (98%)	50 (94%)
Difficult or very difficult	29 (12%)	0 (0%)	2 (2%)	3 (6%)
Dressing removal				
No. of changes	261	74	120	51
Easy or very easy	252 (97%)	74 (100%)	113 (94%)	50 (98%)
Difficult or very difficult	9 (3%)	0 (0%)	7 (6%)	1 (2%)
Odour				
No. of changes	260	74	120	52
None or moderate	250 (96%)	71 (96%)	120 (100%)	52 (100%)
Important or nauseating	10 (4%)	3 (4%)	0 (0%)	0 (0%)
Bleeding				
No. of changes*	261	74	120	52
None or slight	247 (95%)	72 (97%)	119 (99%)	52 (100%)
Moderate or important	14 (5%)	2 (3%)	1 (1%)	0 (0%)
Dressing conformability				
No. of changes	222	67	117	53
Good or very good	198 (89%)	61 (91%)	115 (98%)	37 (70%)
Poor or very poor	24 (11%)	6 (9%)	2 (2%)	16 (30%)
Adherence to wound bed				
No. of changes	258	74	119	52
None or slight	246 (95%)	74 (100%)	112 (94%)	52 (100%)
Moderate or important	12 (5%)	0 (0%)	7 (6%)	0 (0%)

*Results of nurse assessment. In the French study, certain data were not complete because the initial dressing application may have been made by the investigator on the visit at inclusion

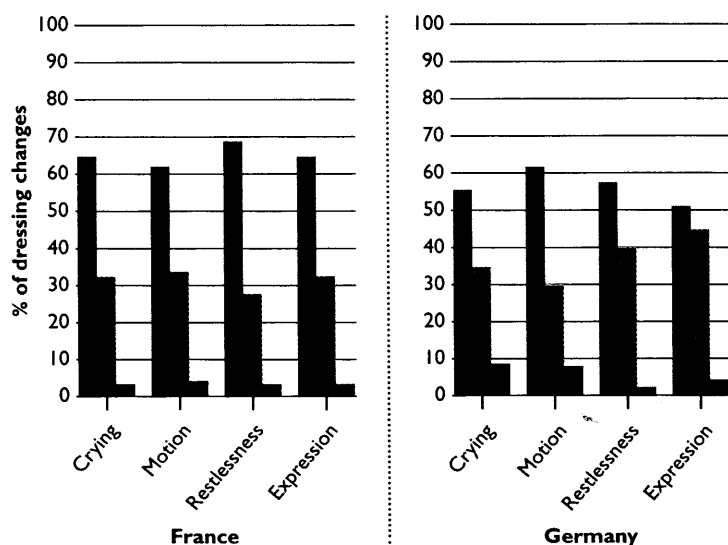
Dressing-change frequencies

Mean time between dressing changes for burns was 2.7 days (range: one to eight days) and 2.6 days (range: one to seven days) in the French and German studies respectively. For other wounds, this was 2.8 days (range: one to seven days) and 3.1 days (range: one to eight days) in France and Germany.

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Fig 1. Objective pain scale (children from one to six years)



Crying	■ None
	■ Child crying but may be consoled
	■ Child crying and inconsolable
Motion	■ None
	■ Intermittent
	■ Continuous
Restlessness	■ None
	■ Intermittent, moderate
	■ Continuous
Verbal or non-verbal expression	■ Peaceful or sleeping child
	■ Moderate disturbance, restless
	■ Immoderate and intense disturbance, may hurt him/herself

Dressing acceptability

Nurses documented 355 dressing changes in France and 174 in Germany. Results are given in Table 4.

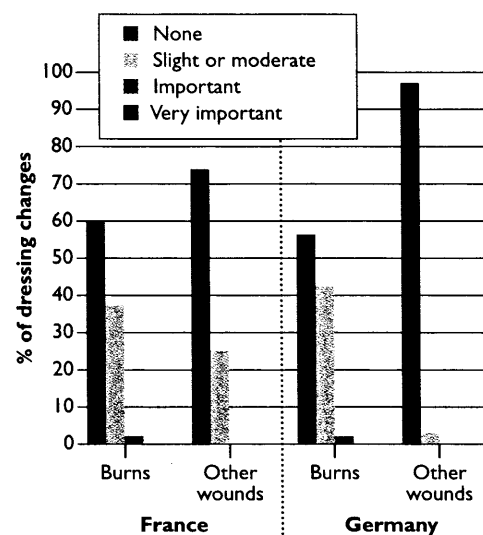
Pain evaluation during nursing care

• **Assessment by the children** The faces scale, used by children aged over three to demonstrate the level of pain, was completed at 61 dressing changes in the French study and in 92 dressing changes in the German one. In the French study 60% of the children with burns and 73% of those with other wounds selected smiling faces. In the German study this was 35% and 80% respectively.

The VAS scale, used by children aged over six years, was completed at 96 dressing changes in France and at 58 dressing changes in Germany.

• **Assessment by the investigator and nurses** In France the objective pain scale was used during 235 dressing changes for burns and 35 for other wound types. In Germany this was 104 and 16 respectively. (There were significantly more burns than other wound types.) Results are in Fig 1.

Fig 2. Pain (qualitative evaluation by investigators)



Nurses completed 352 VASs for both burns and other wound types after dressing changes in France and 122 in Germany in children aged over six. Again, numbers reflect sample sizes. Results are in Table 5.

Pain was considered totally absent in 60% (burns) and 74% (other wounds) of the dressing changes in France, and in 57% and 97% respectively in Germany. Results are in Fig 2.

Prescription of analgesia

In France analgesia was given before 27% of dressing changes. Of children under six years, 96% received non-morphine analgesia and 56% morphine.

In Germany only 16% of burns and 1.6% of other wounds received analgesia before dressing changes. Morphine was used in less than 1% of changes.

Local tolerance

Four local adverse events were reported in France and warranted withdrawal from the study: three wounds overgranulated (burns) and there was one local infection (other wound). These were not attributed to the dressing as they are caused by a wide range of factors.

No local adverse events were noted in Germany.

Patient outcomes

In the French study treatment was discontinued in seven patients before the four-week follow-up for reasons other than healing. Six of these patients had burns: causes of discontinuation were overgranulation (n=3); skin grafting (n=1) and being lost to follow-up (n=2). The seventh patient, who had another wound type, had a local wound infection.

No patients were withdrawn in Germany.

Discussion

The efficacy of Urgotul has been demonstrated in adult outpatients with leg ulcers, traumatic wounds, second-degree burns¹⁷ and epidermolysis bullosa.²⁴

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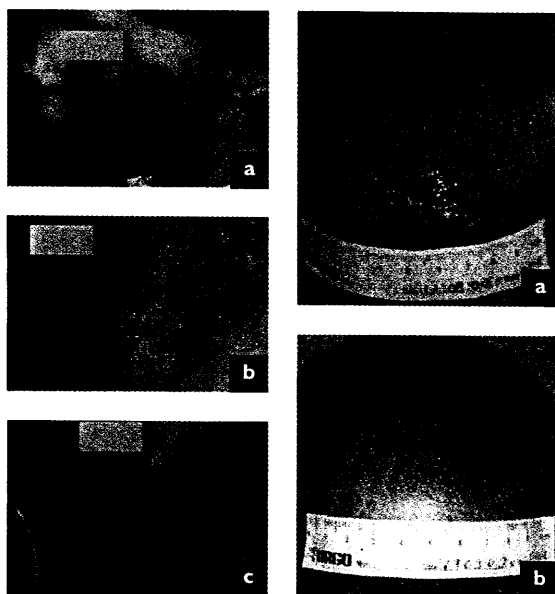


Fig 1. Young girl with cheek burn: at day 0 (A), day 14 (B) and after three months (C)

Fig 2. Young boy with forehead wound: day 0 (A) and at day 14 (B)

Table 5. Pain assessment using the VAS

	France		Germany	
	Burns	Other wounds	Burns	Other wounds
Children				
No. of changes	50	46	25	33
Mean	8.5	3.3	10.1	0.9
Minimum; maximum*	0.0; 50.0	0.0; 45.0	0.0; 45.0	0.0; 15.0
Nurses				
No. of changes	271	81	60	62
Mean	6.7	4.0	6.0	1.1
Minimum; maximum*	0.0; 69.0	0.0; 37.0	0.0; 52.0	0.0; 28.0

*0 = no pain, 100 = maximum pain

In the last study, in the 20 patients studied (nine children and 11 adults), healing was observed in a mean time of 8.7 days without adherence or bleeding at dressing removal (more than 200 documented dressing changes), with no apprehension apparent in the paediatric population.²⁴

In the present studies, baseline characteristics of the populations and their wounds were very similar: burns represented the great majority of wounds (78% and 73%), particularly in children under three.

The study appears to confirm Urgotul's efficacy as 86% and 100% of the burns and 53% and 88% of the other wounds healed completely in the French and German studies respectively.

The efficacy of non-adherent dressings has been studied in children.²⁵⁻²⁸ However, these studies had selected populations (paediatric scalds or skin-graft donor sites). The present study includes children with wounds of any origin.

Acceptability parameters reported by the nurses show that Urgotul is easy to apply and remove, and is conformable and non-adherent. Moreover, attention was paid to pain at dressing change. All the

assessments, both by children and practitioners, were concordant and showed either no pain or minor pain requiring little analgesia. However, children with burn injuries did require analgesia, confirming that these wounds are the most painful.²⁹

Finally, reported data confirm that Urgotul can be left in place for several days. The mean time between two dressing changes was almost three days in the two studies, with a maximum of eight days. In both studies the wounds showed no signs of maceration or odour when changed at this frequency. Reducing the number of dressing changes is cost-effective — neutral-type tulle-gras dressings often need to be changed daily.

Urgotul's pain-free removal could result in significant time savings and decrease the need for analgesia. Less time was needed to remove the dressing from the wound bed, and less than 20% of the children needed analgesia, principally paracetamol.

The two studies confirm the efficacy and safety of Urgotul, which offers patient comfort and clinical benefits, enhancing both concordance and parental satisfaction. ■

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