

EVALUATION OF THE EFFICACY AND ACCEPTABILITY OF LIPIDO-COLLOID DRESSING* IN PUBLISHED LITERATURE.

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INTRODUCTION

Developed at the end of the nineties, the Lipido-Colloid Technology (TLC) is based on a non-adhesive non-occlusive dressing composed of a 100% polyester mesh impregnated with hydrocolloid particles (carboxymethylcellulose) and vaseline. Keeping a moist environment and then promoting the healing process, the TLC products have been developed to answer the different needs of the health care professionals in their daily management of acute and chronic wounds. The benefits of the **non absorbent TLC dressing*** have been documented in European clinical trials which involved few hundreds patients. The main objective of this review was to combine efficacy and acceptability data issued from these clinical trials in order to get an overall vision of the clinical impact of this dressing.

MATERIALS AND METHODS

This analyse included publications issued from clinical trials carried out on the **lipido-colloid dressing***, excluding the epidemical cohort surveys and publications of clinical case studies. Herein we report:

- Number of complete healed wounds
- Number of dressing changes over the total follow-up period with evaluation of the acceptability
- Reporting of local adverse events

Finally, eight open clinical studies have been selected. 3 of 8 were controlled (2 randomised and 1 non-randomised clinical studies) and 5 other were not controlled. These studies have been conducted in France, UK, Germany and Hong Kong (**Table 1**).

RESULTS

The combined healing rate was 90.7% for burns, 64.8% in other acute wounds and 12.5% in chronic wounds. This low percentage is explained by the short follow-up period (3-8 weeks) and the small sample size. No statistically significant difference were detected in the **lipido-colloid interface*** versus hydrocolloid dressing comparative study. Healing rate was significantly better compared to daily gauze dressing in the treatment of digital wounds (**Table 2**).

Overall, more than 2000 dressing changes have been evaluated by medical staff in these studies. Dressings were changed every 2 to 3 days in average. Easy/very easy dressing removal and no adherence to the wound bed was noted in more than 80% of the cares. Maceration, bleeding or pain at dressing removal was exceptionally reported. Combined with TNP procedure, this dressing decreased substantially pain at foam removal and its adherence to the wound bed. In all selected studies, local dressing tolerance was carefully monitored. Out of the 378 included patients, unexpected local adverse events were notified in 28 cases (7.4%). The peri-lesional skin irritation was the most frequently reported event (11 cases) followed by hypergranulation (7 cases). The events were more frequently observed in chronic wounds (16 cases) and were exceptional in burns (2 cases) (**Table 3**).

Table 2 : Complete Healing Rates (HR)

	BURNS		ACUTE WOUNDS		CHRONIC WOUNDS	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Meaume 2002	19/20	95% (75.1% - 99.9%)	11/34	32.4% (17.4% - 50.5%)	5/38	13.2% (4.4% - 28.1%)
Letouze	69/77	89.6% (80.6% - 95.4%)	15/23	65.2% (42.7% - 83.6%)		
Bendow			7/12	58.3% (27.7% - 84.8%)	1/10	10% (0.3% - 44.5%)
Blanchet			19/20	95% (75.1% - 99.9%)		
Ma			16/16	100% (79.4% - 100%)		
TOTAL	88/97	90.7% (83.1% - 95.7%)	68/105	64.8% (54.8% - 73.8%)	6/48	12.5% (4.7% - 25.2%)

Other results : **Burton** More favorable HR with lipido-colloid dressing but no figures provided in publication
Meaume 2005 Mean wound area regression at 8w: 61 ± 40%
Téot Mean wound area reduction of 19% after a mean 17 ± 10 days of Follow-Up

Table 1 : Treated Wounds

AUTHORS	YEAR	COUNTRY	DESIGN	CONTROL GROUP	FOLLOW-UP	BURNS	ACUTE WOUNDS	CHRONIC WOUNDS	TOTAL
Meaume	2002	F	O, NC	-	4w	20	34	38	92
Letouze	2004	F, G	O, NC	-	4w	77	23		100
Burton	2004	UK	O, C, NR	4 types of non-adherent dressings	2w		15		15
Bendow	2004	UK	O, NC	-	4w		12	10	22
Meaume	2005	F	O, R, PG	Hydrocolloid dressing	8w			47	47
Blanchet	2005	F	O, NC	-	4w		20		20
Ma	2006	HK (China)	O, R, PG	Daily gauze dressing	Up to healing		16		16
Téot	2006	F	O, NC	-	2-3w		42	24	66
Total						97	162	119	378
% of Total						25,7%	42,9%	31,5%	100%

O : Open
 NC : Not Controlled
 C : Controlled
 NR : Not Controlled
 NR : Not Randomized
 R : Randomized
 PG : Parallel Groups

7 clinical studies were conducted on the adult patients and one trial (Letouze) included a paediatric population. Overall, 378 wounds (97 burns, 162 acute and 119 chronic wounds) were managed over 2 to 8 weeks. All these wounds were quite completely debrided at baseline. Two trials included special wounds: digital wounds (Ma), epidermolysis bullosa lesions (Blanchet-Bardon) and one trial (Téot) evaluated the **lipido-colloid interface*** in complex wounds treated with TNP procedures.

CONCLUSION

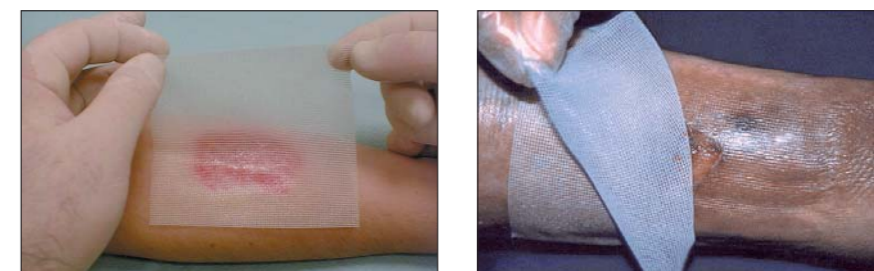
This review confirms the excellent acceptability and tolerance of the lipido-colloid dressing*. This dressing is very easy to use in a large variety of wounds both in children and adults. It can be used as an interface during TNP procedures to limit pain and risk of adherence of the foam to wound bed. Wound and peri-lesional skin tolerance to this dressing has been considered very good.

Table 3 : Local adverse events

	BURNS	ACUTE WOUNDS	CHRONIC WOUNDS	TOTAL
Peri wounds pb	1	4	2	7
Eczema			4	4
Hypergranulation		3	4	7
Pain	1		2	3
Bleeding		1		1
Infection		1	4	5
Fluid leakage		1		1
TOTAL	2	10	16	28

Overall prevalence of local adverse events **28/378**
7.4% (95% CI: 5.0 - 10.5%)

Use of the lipido-colloid dressing*



* Urgotul® trademark by the Laboratoires URGO (France), in Europe / Restore® Contact Layer (with TRIACT Technology) trademark by Hollister Wound Care LLC in the Northern America.

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