

ASSESSMENT OF A NEW CONTACT LAYER IN THE LOCAL MANAGEMENT OF PEDIATRIC WOUNDS: RESULTS OF A EUROPEAN CLINICAL STUDY

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INTRODUCTION

The great majority of the wounds we treat in pediatric plastic surgery and burn units are represented by acute wounds, mainly burns. Therapeutic strategies are quite limited: these wounds are usually treated by dry or impregnated petrolatum gauze.

This poster describes the results of a European clinical study (France and Germany) to evaluate the efficacy, tolerance and acceptability of a new contact layer dressing in the healing process of pediatric wounds.

MATERIALS AND METHODS

A non-comparative multicenter prospective clinical study, using a new contact layer (a polyester net impregnated with petrolatum formulation and hydrocolloid particles), was conducted in 16 centers. Subjects were followed for a period of 4 weeks.

Subjects consisted of 100 children, ages 1 through 12. Seventy wounds (55 burns and 15 other wounds) were evaluated on a weekly basis (clinical and photographic records). Nursing staff rated the acceptability of the product at every dressing change

RESULTS

Baseline characteristics of the sample and wounds are summarized in Table 1. 90% of the burns and 60% of other wounds healed completely within the 4 weeks. Details of the efficacy results are shown in Table 2. Pain was evaluated using pain scales adapted to the patient's age (objective pain scale, faces scale and visual analogue scale (VAS)) at each dressing change. (Table 3). Details of the acceptability are summarized in Table 4.

Table 1: Baseline Characteristics of Patients and Wounds

	Burns		Other Wounds	
	France (n=55)	Germany (n=22)	France (n=15)	Germany (n=8)
Gender				
Male	35 (64%)	9 (41%)	9 (60%)	5 (63%)
Female	20 (36%)	13 (59%)	6 (40%)	3 (37%)
Age				
3 years	38 (69%)	12 (55%)	4 (27%)	1 (13%)
4-6 years	9 (16%)	5 (23%)	2 (13%)	2 (25%)
> 6 years	8 (15%)			
Wound duration (days)	3.8	1.7	15.3	13.3
Mean surface area (cm²)	41.9	46.0	9.1	8.2
Min; Max	(3; 188)	(1.3; 26.7)	(2; 37)	(1.2; 28.3)

Table 2: Clinical Results

	Burns		Other Wounds	
	France (n=55)	Germany (n=22)	France (n=15)	Germany n=8
Healed Patients	47	22	8	7
Mean healing time (days)	12.4 ± 5.5	14.4 ± 6.3	13.3 ± 4.2	19.7 ± 4.2
Min; max	(4; 28)	(7; 28)	(7; 21)	(13; 26)
Removal Frequency (days)	2.7 ± 1.1	2.6 ± 1.0	2.8 ± 1.1	3.1 ± 1.4
Min; max	(1; 8)	(1; 7)	(1; 7)	(1; 8)

Table 3: Pain Evaluation

		France	Germany
FACES 3-6 year old children	Smiling	62.3%	58.7%
	Indifferent	24.6%	28.3%
	Weeping	8.2%	13.0%
	Sobbing	4.9%	—
VAS (mm) Over 6 year old children	Mean	6 ± 11.3	4.8 ± 10.7
	Min; Max	0; 50	0; 45

Table 4: Acceptability

	Burns		Other Wounds	
	France (n=55)	Germany (n=22)	France (n=15)	Germany (n=8)
Easy or very easy application	88%	99%	100%	94%
Easy or very easy removal	97%	94%	100%	98%
None or slight adherence	95%	94%	100%	100%
None or slight bleeding	95%	99%	97%	100%

**Case 1 Initial injury****Case 1 After 6 days treatment with a new contact layer**



Case 2 Initial injury



Case 2 After 14 days treatment with a new contact layer



Case 2 Results 3 months after injury

CONCLUSION

This clinical study seems to confirm the efficacy, the good tolerance and acceptability in children suffering from acute and chronic wounds. This new contact layer dressing represents an appropriate and highly promising alternative to conventional dressings.

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