Clinical evaluation of a charged, fiber-based dressing for support of debridement of slough on wounds at risk/with clinical signs of infection: results of a prospective, multicenter study in pediatric patients.

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METHODOLOGY

- **Study design:** Prospective, non-interventional, multicenter study in Germany
- **Evaluated dressing:** Supercharged, polyacrylate dressing*
- **Inclusion period:** Between September 2016 and September 2017
- **Follow-up:** Maximum duration of 4 weeks or a maximum of 3 documented visits
- **Number of active centres:** 81
  - Physicians: GPs and specialists
- **Number of patients analysed:** 2270, including 77 minors
  - 10 patients per center (median value, IQR 5 – 25)
- **Follow-up:**
  - Intermediate visit: 11 ± 8 days (median 10 days, IQR 7 – 14)
  - Final visit: 22 ± 13 days (median 21 days, IQR 14 – 28)

PRODUCT DESCRIPTION

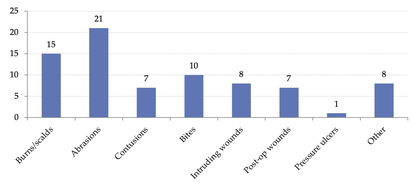
- A supercharged, polyacrylate fiber dressing with TLC-Ag matrix (lipido-colloid technology with silver salts)

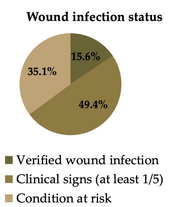
- Provides a combined antimicrobial & continuous cleaning action to fight against local infection and support continuous debridement while managing exudate

RESULTS

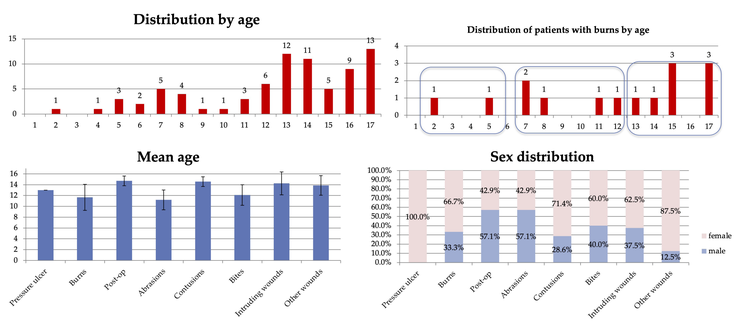
Pediatric Patient Characteristics

- 77 patients including by 16 centres (mean number of patients per centre: 5 ± 7)
- Follow-up: 18 ± 8 days (intermediate visit: 9 ± 4 days)

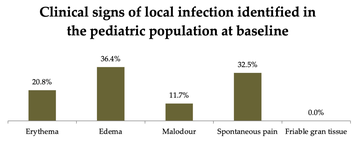


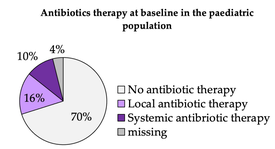


Demographics	n = 77	
Mean age	12.6 ± 3.8	[Min 2 – Max 17]
Sex Male / Female, n(%)	31 (40.3%) / 46 (59.7%)	



Clinical signs and conditions at risk of infection





Conditions at risk of wound infection in the paediatric population	N = 77	(100.0%)
Contaminated or dirty wound	40	(51.9)
Critical wound surface or depth, possibly with direct contact with organ	12	(15.6)
Worsening or stagnating wound	10	(13.0)
Haematological or cancer affection	6	(7.8)
Immunosuppressive condition	4	(5.2)
Prolonged hospitalization (>3 weeks)/Post-surgical wounds	3	(3.9)
Extreme age/Very young patients	1	(1.3)

Patients' Anamnesis

- 36 patients (46.8%) with a comorbidity or a current treatment that could alter the wound healing process

Anamnesis	n = 77
Malnutrition	18 (23.4%)
Severe obesity	3 (3.9%)
Type I Diabetes	2 (2.6%)
Current infection (not wound-related)	5 (6.5%)
Immunodeficiency	4 (5.2%)
Respiratory insufficiency	1 (1.3%)
Systemic steroid treatment	1 (1.3%)

Possible multiple answers

Wound Characteristics

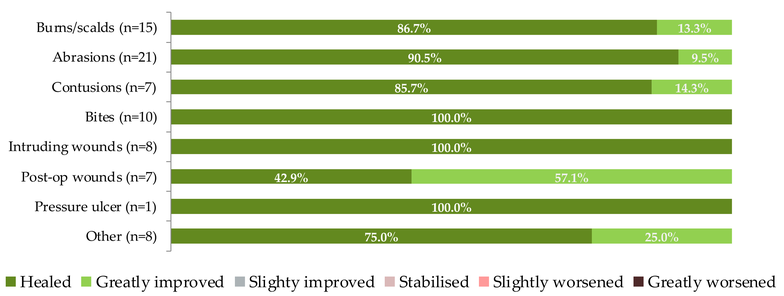
	Paediatric patients (N= 77)	
Median wound duration, days (IQR)	5	(3 ; 7)
Median wound area, cm² (IQR)	3.9	(1.6 ; 8.1)
Wound healing stage		
Granulation stage, n (%)	16	(20.8)
Debridement stage, n (%)	50	(64.9)
missing or implausible	*11*	*(14.3)*
Level of exudate		
High/moderate exudate, n (%)	37	(48.1)
Few/no exudate, n (%)	39	(50.7)
missing	*1*	*(1.3)*
Peri-wound skin condition score		
Healthy skin, n (%)	23	(29.9)

Wound Healing Outcomes

By the final visit:

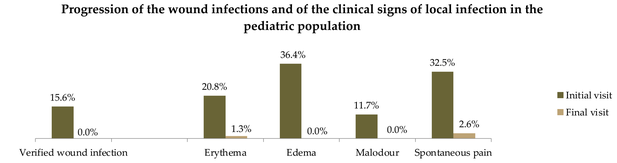
- **85.7%** of the wounds **healed** (66/77) – Mean time to heal: 13 ± 8 days
- And **14.3%** had **greatly improved** (11/77)
- **Rate of Wound Area Reduction of the non-healed wounds** (n=11): **71.4% ± 17.7%** [min 25.0% - max 92.5%] Median value: 75.0% (IQR 67.7% - 80.6%)

Wound healing progression at the final visit in the paediatric population



- 2 burns not healed at the last visit (71 and 126 cm² at baseline, 15 and 17 years old), but 83.3% and 68.8% of RWAR
- Median RWAR of the 4 non healed post-op: 78.3% (IQR 59.9% ; 86.9%)

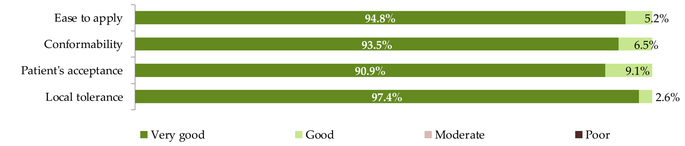
Wound Infection Outcomes



- **All the verified wound infection were resolved by the final visit**
- **Reductions of all the clinical signs of local infection throughout the study period:** in particular
  - No more edema or malodour by the final visit
  - Erythema and spontaneous pain still reported in only one and two patients respectively.

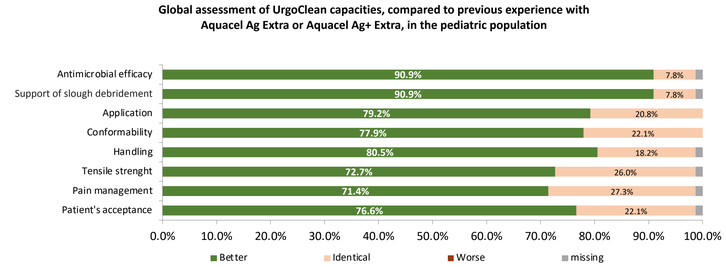
Acceptability

- **Dressing change per week:** 2 ± 1 [min 1; max 7]



- Dressing changes have been judged **painless in 75.3%** of the cases (n=58), associated with slight short pain in 20.8% of the cases (n=16), or with slight persistent pain in 2.6% of the cases (2.6%) (1 missing data).
- The supercharged, polysorbent dressing has been judged **extremely useful in 92.2%** (n=71) of the cases and useful (n=4) in 5.2% of the cases (2 missing data).
- **The supercharged, polysorbent dressing was very well accepted and tolerated in the paediatric population**

Comparison with Aquacel Ag Extra



- **According to the physicians' point of view and based on their experience, the supercharged, polysorbent dressing capacities were judged better than Aquacel Ag Extra's in the management of wounds at risk or with clinical signs of local infection in paediatric population.**

CONCLUSION

The results of this clinical study of cohort of 77 minor patients demonstrates through clinical evidence that Urgo Clean Ag Dressing with poly-absorbent fibers promotes good healing properties and good safety profile in the management of wounds at risk or with clinical signs of local infection, regardless of the age of the patients.. The supercharged, polyacrylate dressing reduces the clinical signs of infection, promotes wound healing in acute and chronic wounds at risk or with clinical signs of infection and is very well tolerated and accepted, rated highly by both clinicians and patients.

Based on their previous experiences with other antimicrobial dressings, the physicians involved in this study expressed their preference for this new dressing.

**UrgoClean Ag, Urgo Medical North America,*

Produced with support from Urgo Medical North America