Excellent Exudate Management in Acute Wounds with a Next-Generation Advanced Multi-Layered Foam Dressing: Prospective, Multi-Center Study

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Introduction

- Acute wounds require prompt and effective management to optimize healing outcomes and prevent complications[1]
- Dressings play a pivotal role in acute wound care by creating an optimal environment conducive to tissue repair[2]
- While a moist environment is key in wound healing,[2] inappropriate exudate management can result in peri-wound maceration, pain, and poor patient wellbeing[3]
- A next generation advanced multi-layered foam dressing* is indicated in traumatic and surgical wounds
  - Unique construction of layers designed to synergistically provide enhanced absorption, retention, and fluid handling[4,5]
  - **Hydrofiber layer**: absorbs exudate, forming a cohesive gel to reduce dead space where microorganisms can grow, while retaining its harmful constituents[6–8]
  - **Superabsorbent fiber layer**: rapidly absorbs and retains exudate under compression[9,10]
  - **Silicone layer (where applicable)**: large, evenly distributed pores that enables fast fluid uptake[9,10]

Objective

To assess the efficacy and performance of a next generation advanced multi-layered foam dressing* in the management of surgical and traumatic wounds

Methods

- A prospective, multicenter, interventional, non-comparator, open-label study (NCT05632276)
- Eligible patients received the foam dressing in accordance with its Instructions for Use (IFU) for up to 4 weeks, with scheduled visits every 7 days until final wound assessment (Day 28 ± 2)
- **Primary endpoint:** excellent exudate management, defined as no strikethrough and no maceration of the peri-wound skin
- **Secondary endpoint:** excellent exudate management in dressings that were used for the maximum 7-day wear time
- **Safety endpoints:** adverse events (AEs) and device-related AEs

Results

Patient and Wound Characteristics

- A total of 52 patients with traumatic (*n*=28; 54%) or surgical wounds (*n*=24; 46%) were enrolled in the study (**Table 1**)

Dressing Utilization

- A total of 268 dressings were applied with a mean of 5.2 dressings (range, 1–32) per patient (**Figure 1**)
- Forty-seven (90%) patients completed treatment, 5 (10%) discontinued (four were lost to follow-up, one was withdrawn)

Table 1. Baseline Characteristics

	Patients (*n*=52)
Median (range) age, years	51 (27–76)
Female, n (%)	29 (55.8)
Mean (SD) BMI, kg/m²	31.6 (6.5)
Wound type, n (%)	
Surgical	28 (53.9)
Traumatic	24 (46.2)
Baseline wound area, cm²	
Mean (SD)	5.45 (9.86)
Median	0.80
Min, max	0.50, 6.65
Tissue type, n (%)	
Eschar	1 (30.0)
Slough/fibrin	4 (36.3)
Healthy granulation	14 (80.0)
Epithelial	41 (95.2)
Exudate volume, n (%)	
Medium	5 (9.6)
Low	14 (26.9)
None	33 (63.5)
Exudate type, n (%)	
Pink/red	15 (25.9)
Thin/watery	4 (7.7)
No exudate	33 (63.5)

Exudate Management

Patient level:

- Of 47 patient patients who completed treatment, 81% (*n*=38) had excellent exudate management (90% CI, 71–90%; p=0.1540) (**Figure 2**)

Dressing level:

- 93% of dressings (209/224) achieved excellent exudate management (95% CI, 90–97%) (**Figure 2**)

7-day wear time:

- 65 dressings were used up to the maximum 7 days duration per IFU; of these, 63 (97%; 95% CI, 93–100) had excellent exudate management

Figure 1. Dressings Applied

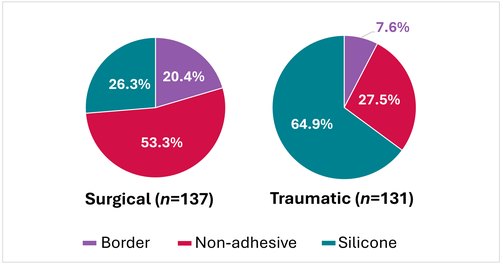
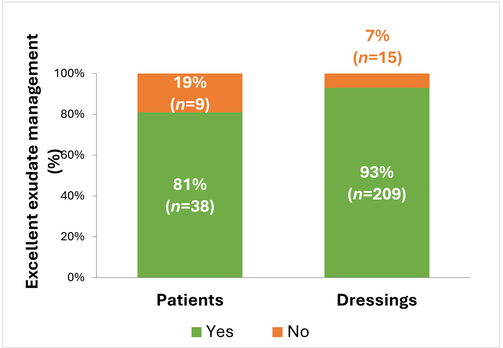


Figure 2. Excellent Exudate Management



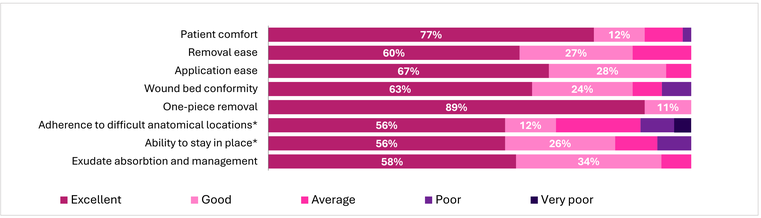
Utility Questionnaire and Pain Score

- A high percentage of patient and healthcare provider satisfaction was reported (**Figure 3**)
- Median patient-reported pain score on dressing application was 0 (‘no pain’) per Numerical Rating Scale

Healing Rate and Safety

- A total of 32 wounds (61.5%) had healed at the end of study
- There were a total 12 AEs in 12 patients, none of which were device-related or serious AEs; the most common AEs were wound bleeding (n=2) and wound dehiscence (n=2)

Figure 3. Utility Questionnaire



Discussion

- In this prospective, multicenter study, treatment of surgical and traumatic wounds with next-generation multilayered foam dressings for up to 4 weeks was associated with excellent exudate management
- A high proportion of wounds with excellent exudate management was observed for dressings that were worn for the maximum 7 days
- Nearly 90% of subjects rated the comfort of their dressing as "above average"
- The findings suggest that the carboxymethyl cellulose fiber layer in the dressing may play an important role in exudate management

Conclusion

The assessed next-generation multilayered foam dressings* are safe and effectively manage exudate in acute wounds

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*ConvaFoam™ Silicone, ConvaFoam™ Border and ConvaFoam™ Non-adhesive

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