

Excellent Exudate Management in Acute Wounds with a Next-generation Advanced Multi-layered Foam Dressing: Prospective, Multi-centre Study

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Introduction

- Acute wounds require prompt and effective management to optimize healing outcomes and prevent complications¹
- Dressings play a pivotal role in acute wound care by creating an optimal environment conducive to tissue repair²
- While a moist environment is key in wound healing,² inappropriate exudate management can result in peri-wound maceration, pain, and poor patient wellbeing³

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- Forty-seven (90%) patients completed treatment, 5 (10%) discontinued (four were lost to follow-up, one was withdrawn)

Figure 1. Wound types

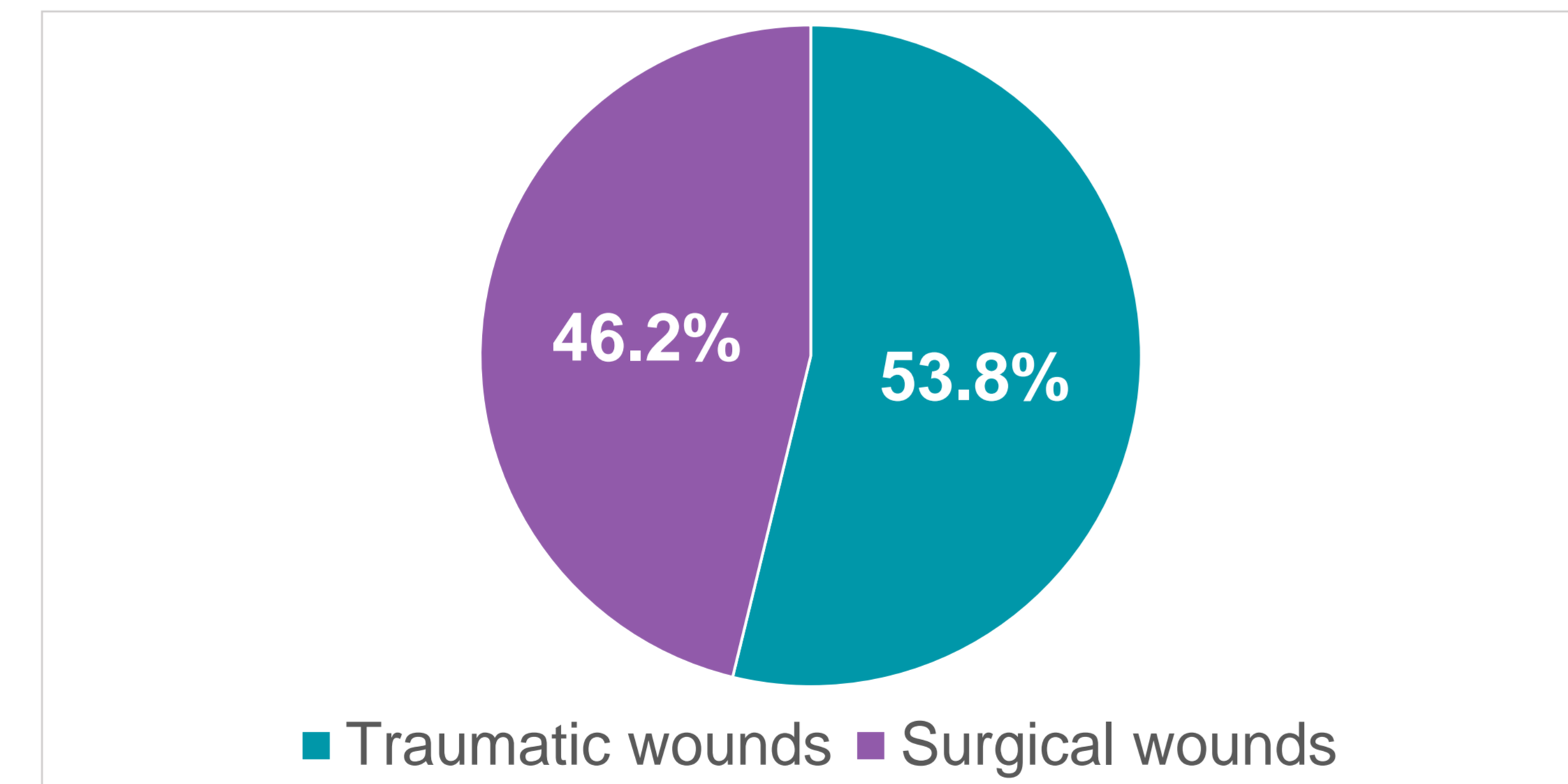


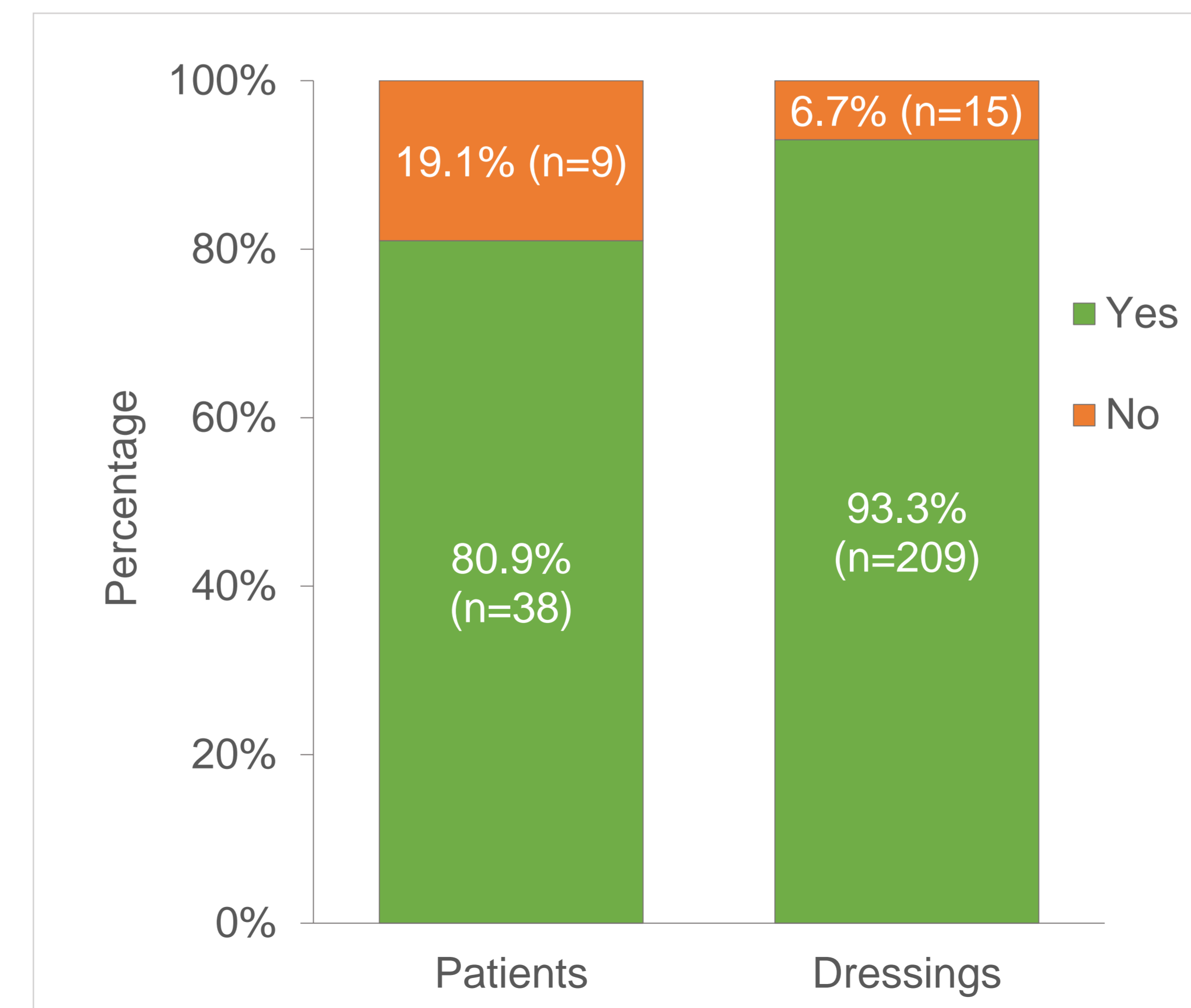
Table 1. Baseline characteristics

Characteristic	Value
Total dressings applied	268
Border version	38 (14.2%)
Non-adhesive version	109 (40.7%)
Silicone version	121 (45.2%)
Total subjects	52
Completed treatment	47 (90%)
Number of dressing per subject (mean, range)	5.2 (1, 32)
Sex	
Male	23 (44.2%)
Female	29 (55.8%)
Age (mean, range)	48.2 years (20, 76)

Exudate management

- Patient level:**
 - 80.9% of patients (38/47) had excellent exudate management (90% CI, 71.4–90.3%; p=0.1540) (Figure 2)
 - Eight patients experienced at least one episode of strike-through, but only one of these was associated with peri-wound skin maceration
- Dressing level:**
 - 93.3% of dressings (209/224) achieved excellent exudate management (95% CI, 90.0–96.6%) (Figure 2)
 - 14 were associated with strikethrough, but only one was associated with peri-wound skin maceration

Figure 2. Excellent exudate management



7-day wear time:

- 65 dressings were used up to the maximum 7 days duration per IFU; of these, 63 (97%; 95% CI, 92.7–100.0%) had excellent exudate management
- Two dressing performance evaluations were associated with dressing strikethrough, one of which was also associated with maceration of the peri-wound skin

Safety:

- There were no dressing-related AEs

Discussion

- This prospective, multicenter study of the 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
- 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

References

- Nicks BA, et al. *Int J Emerg Med*. 2010 Aug 27;3(4):399-407;
- Mir M, et al. *Prog Biomater*. 2018 Mar;7(1):1-21;
- Shultz G, et al. WUWHS consensus document: Wound exudate, effective assessment and management. Wounds International. 2019.

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