

Advancing the management of hard-to-heal wounds: a prospective, multicenter study of a next-generation multi-layered foam dressing

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Introduction

- Hard-to-heal wounds present a significant healthcare challenge, due to their complex etiology, impact on health-related quality of life, and large economic burden¹
- The global prevalence of hard-to-heal wounds has been estimated as 2.21 per 1000 population and is predicted to increase with the ageing population²
- For the management of hard-to-heal wounds, guidelines recommend the use of a basic dressing that will provide a moisture-balanced wound healing environment, absorb excess wound exudate and protect the peri-wound skin; in addition to being cost-effective^{3,4}

Objective

To assess the efficacy and performance of next-generation advanced multi-layered foam dressings* in the management of indicated hard-to-heal wounds

Methods

- Prospective, multicenter, interventional, non-comparator, open-label study (NCT05632250)
- Patients were recruited from seven sites, six in the United States and one in Chile
- Eligible wounds: venous leg ulcer, arterial leg ulcer, diabetic foot ulcer or pressure injury (stage 2 or higher) classified as hard-to-heal for the purpose of this study (present for ≥30 days and ≤18 months)
- Dressings were applied according to the IFU and weekly in-clinic visits were conducted for up to 12 weeks
- Primary endpoint: percentage change in study wound area at 4 weeks
- Secondary endpoints:
 - Satisfactory clinical progress (40% reduction in study wound area at 4 weeks)
 - Percent change in target wound area at 12 weeks
 - Complete wound closure (100% epithelialization of the wound surface)
- Safety: adverse events (AEs) and device related AEs

Table 1. Baseline characteristics

Parameter	Value
Patients, N	
Screened	92
Completed	73
Country, N Subjects (%)	
Chile	30 (33)
United States	62 (67)
Age, years	
Mean (SD)	66.0 (14.1)
Median	67.0
Q1, Q3	56.5, 76.0
Min, Max	27, 95
Age, years, N (%)	
< 65	42 (46)
65-79	35 (38)
80+	15 (16)
Sex, N Subjects (%)	
Female	32 (35)
Male	60 (65)
Study wound Type, N (%)	
Arterial Ulcer	3 (3)
Diabetic Ulcer	34 (31)
Pressure Injury	10 (9)
Venous Ulcer	64 (58)

Results

Patient characteristics

- 92 patients (111 hard-to-heal wounds) were enrolled (intent-to-treat population; Table 1)
- Endpoint analysis was conducted on the full analysis set (FAS) which included 90 patients (109 wounds)
- 19 patients were discontinued from the study, 73 patients completed the study
- Most patients presented with one wound (83%) with the most prevalent wound being venous ulcers (58%) followed by diabetic ulcers (31%; Table 1)
- A breakdown of dressing types utilized for each wound type are presented in Figure 1

Percentage change in wound area (n=109 wounds)

Week 4:

- Statistically significant median percentage change in wound area of -47.9% from baseline at week 4 (interquartile range (IQR) Q1, Q3: -73.5%, -17.3%; p<0.0001; Figure 2)
- Stratified by wound type: median percentage changes in wound area of 9.4% for arterial ulcers, -48.5% for diabetic ulcers, -33.5% for pressure injuries and -49.4% for venous ulcers were reported

Week 12:

- Statistically significant median percentage change in wound area of -93.8% from baseline at week 12 (IQR Q1, Q3: -100.0%, -44.4%; p<0.0001)
- Stratified by wound type: median percentage changes in wound area of -26.2% for arterial ulcers, -83.3% for diabetic ulcers, -86.0% for pressure injuries, and -99.5% for venous ulcers were reported

Satisfactory clinical progress (n=109 wounds)

- Sixty-one wounds (56.0%) experienced satisfactory clinical progress at week 4 (95% CI: 46.6%, 65.3%; p<0.0001; Figure 3)
- Stratified by wound type: one arterial ulcer (33.3%), 19 diabetic ulcers (57.6%), six pressure injuries (60.0%) and 37 venous ulcers (58.7%) achieved satisfactory clinical progress by week 4

Complete wound closure (n=109 wounds)

- Forty-three wounds (39.5%) experienced complete wound closure by week 12 (95% CI, 30.3%, 48.6%; p<0.0001; Figure 4)
- Stratified by wound type: one arterial ulcer (33.3%), 12 diabetic ulcers (36.6%), two pressure injuries (20.0%), and 28 venous ulcers (44.4%) achieved complete wound closure by week 12

Safety

- There were two AEs related to the study dressings in the 2,935 dressing applications
 - One skin tear and one periwound skin irritation

Figure 2. Median percentage change in wound area at 4 weeks

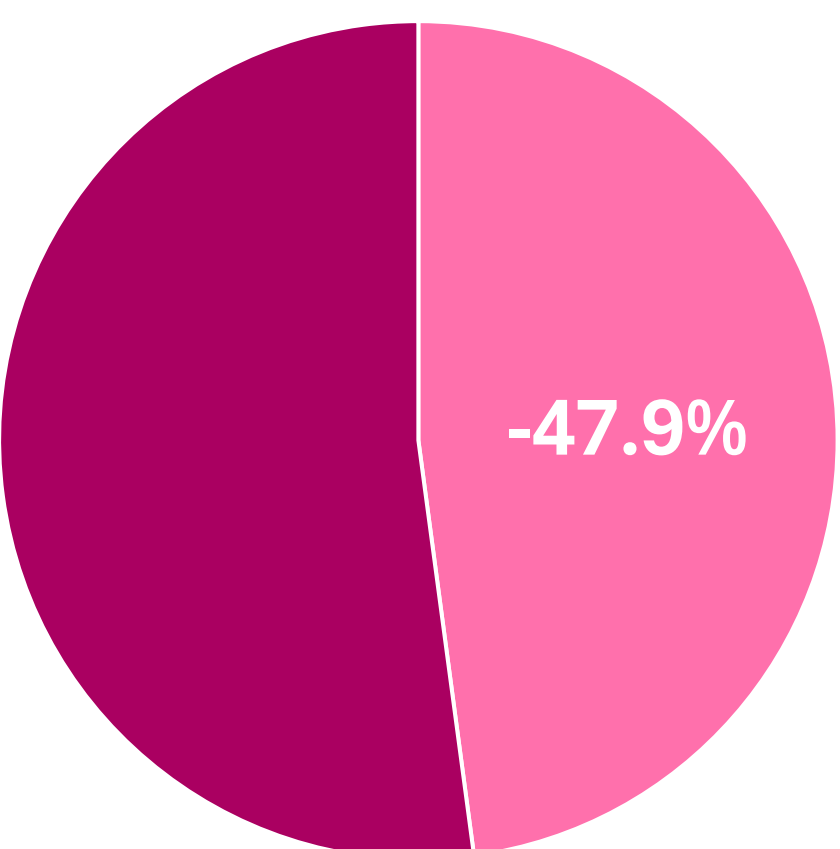


Figure 3. Percentage of wounds that demonstrated satisfactory clinical progress at 4 weeks

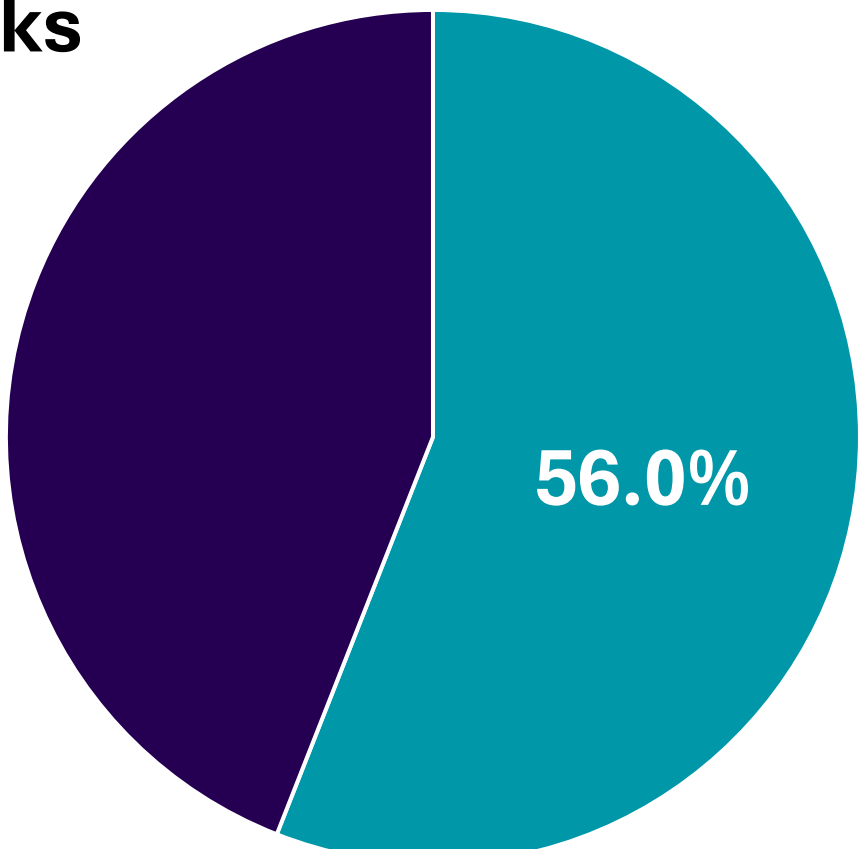


Figure 4. Percentage of wounds that experienced complete wound closure by week 12

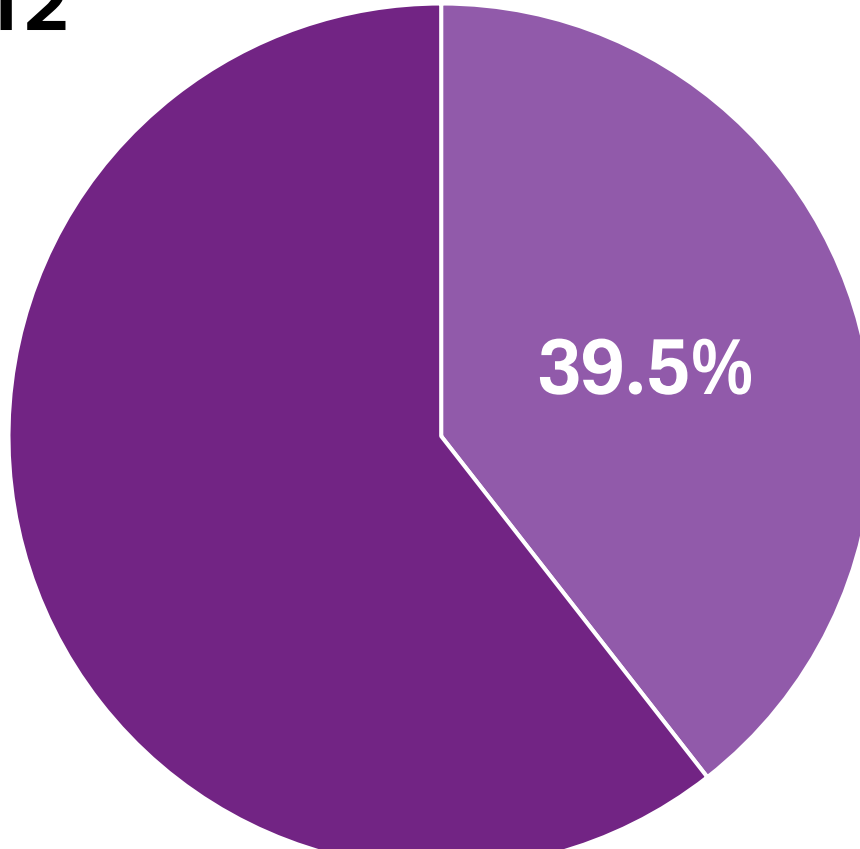
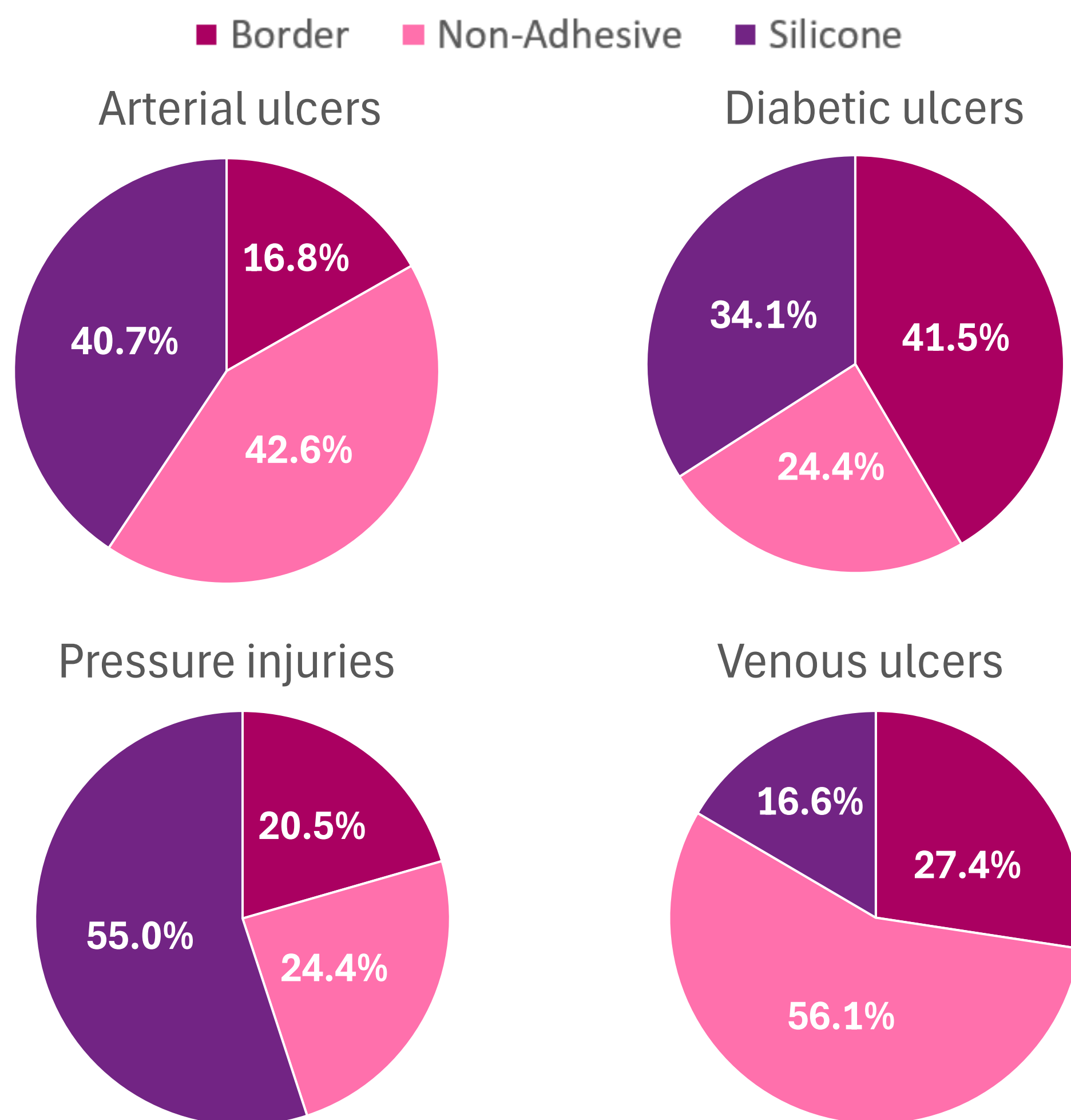


Figure 1. Dressing utilization by wound type



Discussion

- Hard-to-heal wounds treated with the next-generation multilayered foam dressings* were associated with clinical progression of wound healing, demonstrating a statistically significant median percentage area reduction of 48% at 4 weeks
- The dressings were shown to be safe, with only two dressing related-AEs reported out of 2,935 dressing applications
- Despite the broad population of the patients included in the study, the results were favorable and can be generalized to real world clinical practice

Conclusion

The next-generation advanced multi-layered foam dressings* were shown to be safe and effective in the management of hard-to-heal wounds

1. Rice JB et al. *Diabetes Care* 2014;37(3):651–658; 2. Martinengo L et al. *Ann Epidemiol* 2019;29:8–15; 3. Schaper NC, et al. *Diabetes Metab Res Rev* 2024;40:e3657; 4. Lavery LA, et al. *Wound Repair Regen* 2024;32:34–46.

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