KEY PERFORMANCE CHARACTERISTICS OF A NEW 5-LAYER SILICONE FOAM DRESSING IN A RANDOMIZED, CONTROLLED, PROSPECTIVE, HUMAN VOLUNTEER TRIAL

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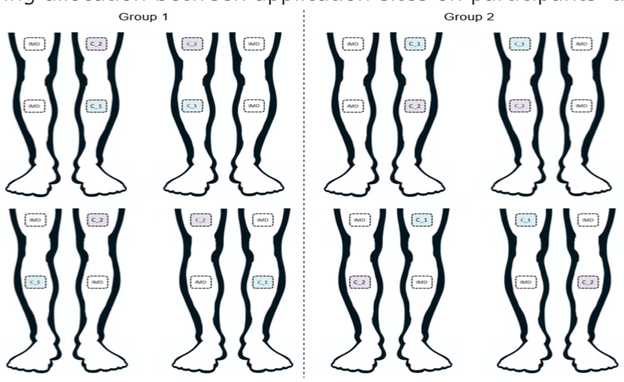
Introduction

- Wound dressings are integral to effective wound management and can also be used on intact skin as part of a pressure injury prevention protocol in at-risk individuals; however, in order to be effective, the dressing must stay in place for an appropriate length of time.
- Assessment of foam dressing clinical performance using standardized laboratory tests has limitations. Volunteer studies are a robust method to assess dressing presence during wear [1,2]. This large volunteer trial evaluated a new, 5-layer foam dressing against two marketed 5-layer foam dressings to ensure comparable performance using stringent assessment criteria.

Methodology

- A single-centre, open-label, prospective, randomized volunteer study evaluated three, 5-layer silicone foam dressings over 7 days (EUDAMED: CIV-24-02-046076).
- Conducted at a Contract Research Organization (CRO), in Germany, between January and March 2025. Ethical approval was granted by an Independent Ethics Committee (IEC; Ref: 015/24).
- Each participant received 2 of the Prototype dressing (Dressing 1*), and 1 each of the commercially available dressings (Dressings 2† and 3‡). The applied dressings were randomized over four body locations (thighs and shins). Participants were allocated to one of two groups, with the dressing randomized to either the left or right thigh/shin in a 1:1 ratio (Figure 1).

Figure 1. Dressing allocation between application sites on participants' thighs and shins



IMD = Dressing 1; C_1 = Dressing 2†; C_2 = Dressing 3‡*

- The primary outcome measure assessed was Acceptable Dressing Presence (ADP) following 7 days of wear. ADP was defined as dressings present with no border lift reaching the pad and no pad exposure.
- The primary endpoint was the non-inferiority comparison of the prototype dressing (Dressing 1*) to the commercially available dressings (Dressings 2† and 3‡), in terms of ADP at day 7. A post-hoc analysis, comparing ADP at day 7 between the evaluated dressings, was conducted. A generalized linear mixed model with binomial distribution was applied, that included all three evaluated dressings.
- Secondary outcome measures included dressing presence, participant reported dressing comfort, and participant reported pain on dressing removal.

Results

- 120 participants were randomized in the investigation (Full Analysis Set (FAS; n=120), Per Protocol (PP; n=110)). The majority of participants were female (78.3%). The mean age of participants was 52 years (range, 19-70 years).
- For the Per Protocol population, ADP following 1, 3 and 7 days of wear with the new 5-layer silicone foam dressing (Dressing 1*) was 93.20%, 85.00%, and 73.60%, respectively. The percentage ADP, at each timepoint, for all evaluated dressings are presented in Table 1.

Table 1. Acceptable Dressing Presence following 1, 3, and 7 days of wear

	Day 1 (%)	Day 3 (%)	Day 7 (%)	
	PP; n=110	PP; n=110	PP; n=110	FAS; n=120
Dressing 1*	93.20%	85.00%	73.60%	72.90%
Dressing 2†	96.40%	90.90%	82.70%	83.30%
Dressing 3‡	90.00%	77.30%	66.40%	65.00%

- The post-hoc analysis indicated that for the FAS population, Dressing 1* had a significantly higher rate of ADP than Dressing 3‡, following 7 days of wear (p=0.03).
- Following 1, 3 and 7 days of wear ≥95% of Dressing 1* remained in place. Figure 2 details the percentage of dressings present at days 1, 3 and 7 for all evaluated dressings.

Figure 2. Dressing Presence following 1, 3, and 7 days of wear (PP; n=110)

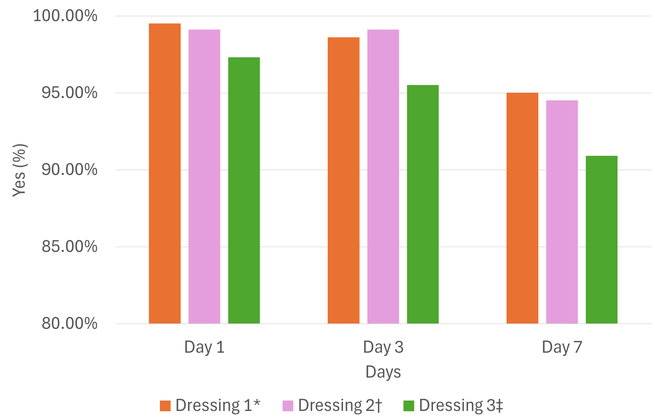
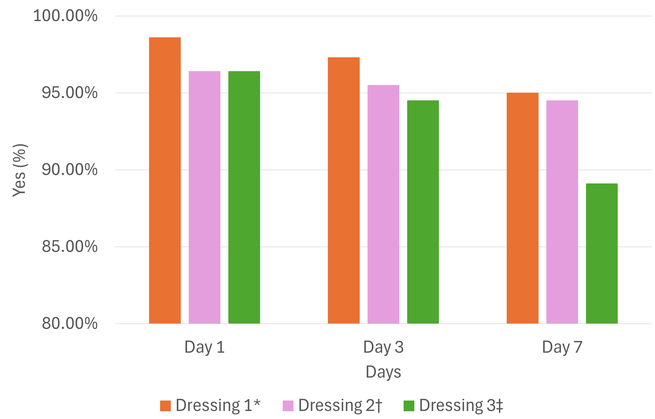


Figure 3. Participant reported dressing comfort following 1, 3, and 7 days of wear (PP; n=110)



- Dressing 1* was reported to be comfortable by ≥95% of participants following 1, 3 and 7 days of wear. Figure 3 shows participant reported dressing comfort at days 1, 3 and 7 for all evaluated dressings. Where dressings were not present, comfort could not be assessed and were included as a missing response.
- At day 7, all participants reported either 'None' or 'Mild' pain upon dressing removal, for all evaluated dressings.

Discussion & Conclusion

- This new 5-layer foam dressing performed well in key performance characteristics; dressing presence was comparable with marketed dressings and participant reported pain scores were low.
- Application of stringent clinical performance criteria can highlight differences versus conventional endpoints.

References
1. Waring M, et al. Wounds UK. 2011;7(3):14-24.
2. Rippon MG, et al. Wounds UK. 2015;11(1):45-54.

Abbreviations
ADP; Acceptable Dressing Presence. CRO; Contract Research Organization. IEC; Independent Ethics Committee. FAS; Full Analysis Set. PP; Per Protocol.

Acknowledgements
The authors would like to acknowledge all the volunteers who participated and the clinical team at SGS proderm GmbH, Schenefeld/Hamburg, Germany, where the study was conducted.

AWM-AWC-50026. Poster presented at SAWC Spring, April 08-12, 2026. Charlotte, NC, USA.

FOOTNOTED BRAND NAMES
*ALLEVYN◇ COMPLETE CARE Foam Dressing (10x10cm; Smith+Nephew)
†ALLEVYN◇ LIFE Foam Dressing (12.9x12.9cm; Smith+Nephew)
‡Mepilex™ Border Flex dressing (10x10cm; Mölnlycke Healthcare)