A Prospective, Multi-Centre, Post-Market Clinical Follow-Up Study to Evaluate the Safety and Effectiveness of a Three-Layer Silicone Adhesive Foam Dressing

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Introduction

Wound closure by secondary intention can be supported by a wide range of wound dressings designed specifically for this purpose. An ideal dressing must, at a minimum, provide the following: a barrier to exogenous contamination and infection; adequate management of wound exudate, and maintenance of a moist wound healing environment. Failure of a dressing to deliver these fundamental features will negatively impact wound progression. A dressing that meets the aforementioned needs is a three-layered, silicone adhesive composite dressing* consisting of a breathable top film[1,2], a foam absorbent layer and a perforated, silicone adhesive wound contact layer; designed to conform to body contours[3], stay in place even on awkward areas[4-8] and in turn, optimise patient comfort[4-8] and in addition provide an up to 7-day wear time[8-10]. The primary objective of this Post Market Clinical Follow-up (PMCF) study is to demonstrate the clinical performance of a three later silicone adhesive foam dressing as measured by reduction in the size of the wound area (cm^2) over a 4-week treatment period, in subjects with chronic and acute full-thickness, partial thickness, or shallow granulating, exuding wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, and dehisced surgical wounds.

Methods

A prospective, multicentre post-market, non-randomised, single arm clinical study was conducted between March 2019 and November 2021. Patients were eligible if they were over 18 years old and had a moderate to highly exuding wound, which was either a chronic wound of at least 6 weeks duration, including pressure ulcers, leg ulcers and diabetic foot ulcers, or an acute wound including dehisced surgical wounds or traumatic wounds. Patients were excluded from the study if they had a confirmed or suspected clinically infected wound, were undergoing treatment with compression therapy and had contraindications or hypersensitivity to the use of the specified three-layer silicone adhesive foam dressing*. Eligible patients were treated with the foam dressing*, applied by the investigators at the first study visit and continued for up to 4 weeks or until the patient exited from study participation. The study was performed in compliance with the ethical principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and International Organization for Standardization (ISO) 14155:2011. The study was approved by the relevant local independent Ethics Committee. All patients provided informed consent. The study was registered with ClinicalTrials.gov (NCT03877484). Relevant patient demographics and medical history were recorded. Primary and secondary endpoints were measured at assessment visits, including Day 0, with follow-up visits at days 7,14, 21 and 28 to assess wound healing progress. Wound photography was captured using the Silhouette Camera System (ARANZ Medical). Patients completed Patient Reported Outcome Measures ([PROMS), including the Cardiff Wound Impact Schedule (CWIS) and Patient Assessment Scales. The primary and secondary endpoints were summarised, for the modified Intention to Treat (mITT). The mITT population was used for the analysis of the primary and secondary endpoints. For the analysis of the distribution of wound sizes the median values were utalised due to required normality assumptions not being met and analysis by non-parametric Wilcoxon signed-rank test. The safety analysis set includes all patients who enrolled in the study and received the study treatment.

Results

Demographics, Co-Morbidities and Wound Characteristics

Table 1 summarises the patient demographics, baseline characteristics including relevant medical history and conditions, wound type, duration, area and exudate levels of the mITT (n=40). The most prevalent chronic wound type were leg ulcers (n=12 leg); compared to the acute wounds categorized as trauma wounds (n=8).

Primary and Secondary Endpoints

Wound area significantly reduced from baseline to day 28 (p=0.002). Furthermore, there was a statistically significant percentage reductions in wound dimensions for area (47%; p<0.001) and absolute reduction in median wound volume ($0.12cm^3$, p = 0.010). The mean dressing wear time was 4.3 day. This equated to a mean use of 6.5 dressings per patient over the 4-week study duration. The mean estimate of reduction in mBWAT score from baseline to day 28 was statistically significant (p<0.010).

Patient Reported Outcomes Measures (PROMs)

All patients (n=40) completed the Cardiff Wound Impact Schedule (CWIS) questionnaire, at each study visit. **Figure 1** illustrates all domains improved or were maintained. During the treatment phase subjects completed an additional Patient Assessment Scale questionnaire, at each study visit, reported in **Figure 2**. Over all assessments, 49% of subjects rated their experience as a 10 for each questions, however only 23.5% of subjects rated their experience as 10 (mean score = 6.5) in relation to 'visible exudate' on the dressing. Study subjects reported their level of pain on dressing application, removal and during treatment. **Table 2** summarises the level of pain on dressing application, treatment and removal.

Safety Reporting

In total, 40 subjects were included in the safety analysis set; 15 Adverse Events (AE) were reported from 14 subjects. Four Serious Adverse Events (SAEs) from 4 subjects were reported. Four device-related non-serious events were reported from 3 subjects. No device related events required subject withdrawal from the study. Seventeen Device Deficiencies (DD) were reported from 7 subjects. One DD was associated with an Adverse Device Event (ADE) (maceration of the peri-wound). It was assessed that none could have led to a Serious Adverse Device Effect (SADE).

Table 1: Baseline patient and wound characteristics of mITT (n=40)

Variable	Study Population (n=40)
Age (years)	
Mean (SD); Median [Range])	69.6 (18.6); 75.5 [21-98]
Gender n (%)	
Female	18 (45)
Male	22 (55)
Race/Ethnicity n (%)	
Caucasian	38 (100)
Missing	2
Body Mass Index (Kg/m²)	
Mean (SD); Median [Range])	28.1 (6.1); 27.1 [16.8-40.5]
Any relevant medical and/or diseases or past surgeries n (%)	
Yes	39 (97.5)
No	1 (2.5)
Any relevant medical conditions that may affect wound healing n (%)	
Yes*	32 (80)
No	8 (20)
***Frail Skin**	4 (10)
***Anaemia**	4 (10)
***Stroke (CVA)**	3 (7.5)
***Peripheral vascular disease**	5 (12.5)
***Congestive heart failure**	4 (10)
***Rheumatoid arthritis**	1 (2.5)
***Osteoarthritis**	4 (10)
***Deep Vein Thrombosis (DVT)**	3 (7.5)
***Varicose veins**	6 (15)
***Steroid use**	2 (5)
***Hypertension**	17 (42.5)
***Neuropathy**	4 (10)
***Diabetes – Type 1**	1 (2.5)
***Diabetes – Type 2**	14 (35)
***Other**	7 (17.5)
Wound Type n (%)	
Acute	14 (35)
Chronic	26 (65)
Wound Duration (Days)	
Mean (SD); Median [Range])	158.3 (266.4); 49 [0-1334]
Wound Area (cm^2)	
Mean (SD); Median [Range])	11.9 (13.8); 7.8 [0.5-68.1]
Exudate Levels n (%)	
None	6 (15)
Scant	4 (10)
Small	17 (42.5)
Moderate	11 (27.5)
Large	2 (5)

Table 2: Patient pain VAS over all assessments

	Level of Pain on Dressing Application (n=252)	Level of Pain During Treatment (n=245)	Level of Pain on Dressing Removal (n=246)
Mean (SD); Median [Range]	1.1 (2.0); 0 [0-10]	1.9 (2.6); 0 [0-10]	1.1 (2.1); 0 [0=10]

Figure 1: Mean Patient Reported Outcome measures assessed as part of the Cardiff Wound Impact Scale in the clinical study at Baseline visit and Day 28 for the mITT Population (n=40).

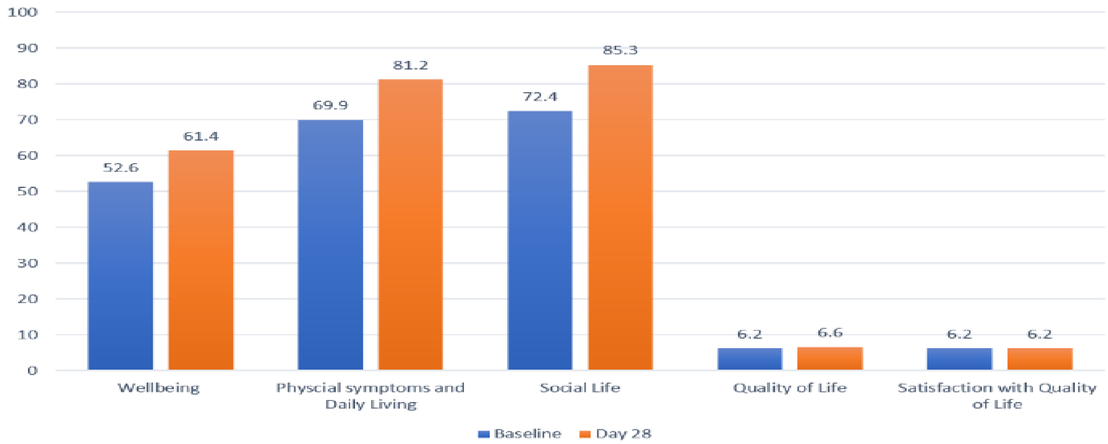
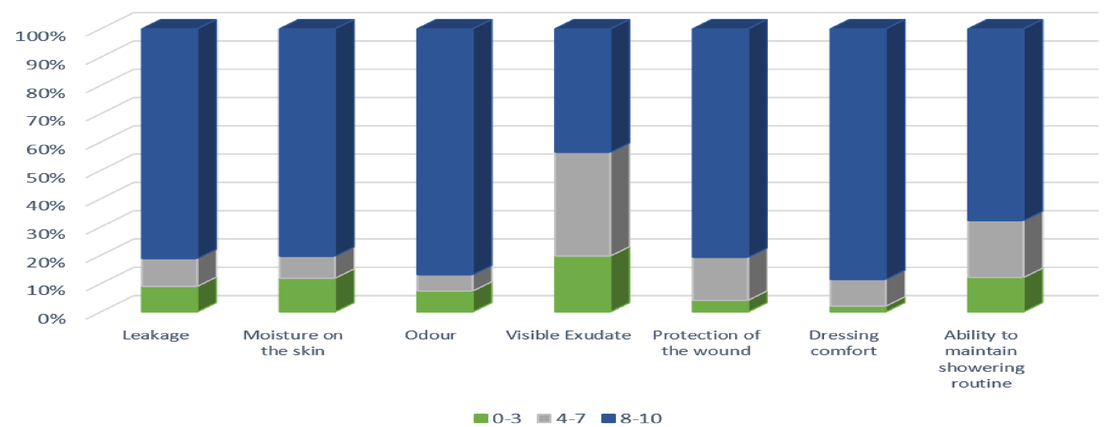


Figure 2: Figure 10: Patient Assessment Scale ratings over all assessments for the mITT Population (n=40).



Discussion & Conclusion

The clinical efficacy and safety of a three-layer silicone adhesive foam dressing* for the management of both acute and chronic exuding wounds has been demonstrated by this PMCF study. Statistically significant reductions from baseline to day 28 were reported across all wound dimensions. In addition, the reported PROMS highlighted the maintained improvement in patient scoring throughout the study period. However, patients' perception of visual exudate scored lower compared to other domains, raising an interesting further research question on visible exudate being perceived by patients a less desirable and concerning to patients. Whereas from a clinical mode of action viewpoint, exudate collection within a foam dressing, demonstrates its effectiveness at removing exudate from the wound Overall, this foam dressing* can be used to manage exudate, providing a suitable moist wound healing environment, conform to awkward and challenging anatomical areas, and provide patient comfort allowing for a positive impact on the patients' day-to-day living and overall quality of life; for the duration of their wound management treatment.

*ALLEVYN◇ Gentle Border, Smith and Nephew, Hull, UK.
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This clinical study was Sponsored by Smith and Nephew

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