Performance of a silicone foam dressing in management of wounds in a community setting: a sub-analysis of the VIPES study

Objective: Managing the gap between the dressing and the wound bed can facilitate the healing of exuding wounds. A silicone foam dressing (Biatain Silicone; Coloplast A/S, Denmark) was developed for application to exuding wounds. A sub-analysis of the real-world, prospective, observational VIPES (Observatoire en Ville des Plaies ExSudatives) study was conducted to investigate the use and performance of the silicone foam dressing in a community nursing setting in France.

Method: The sub-analysis included patients from the VIPES study who received the silicone foam dressing as a primary dressing for an acute or hard-to-heal (chronic) wound. Epidemiological and wound healing outcomes were reported via a smartphone application.

Results: Overall, 64 patients were included in the sub-analysis. At baseline, most wounds (n=33/40; 82.5%) were in treatment failure (i.e., were stagnant, non-healing or had poor exudate management). At the last follow-up visit, a median of 22.5 (range: 3–151) days post baseline, 48.4% of wounds had healed and 25.0% were progressing towards healing. From baseline to the last follow-up visit, significant reductions in exudate level ($p<0.0001$) and exudate pooling ($p<0.0001$), and significant improvements in wound edges ($p\leq0.0001$) and periwound skin ($p<0.01$) were observed. A total of 62.3% of patients had re-epithelialising wounds at the last follow-up visit. The majority of nurses (88.3%) and patients (85.0%) reported that the wound had improved and, at most dressing removals (93.5%), nurses reported that the dressing conformed closely to the wound bed.

Conclusion: Overall, the data suggest that use of the silicone foam dressing in community practice supported the healing of wounds, illustrating the importance of exudate and gap management.

Declaration of interest: This study was funded by Laboratoires Coloplast S.A.S., France. Coloplast A/S designed the study in close collaboration with CEN Biotech Inc., Canada, which administered the research as a clinical research organisation. Data collected by nurses during the study were analysed by the CEN Biotech Inc. statistician, independent of the sponsor, after review of the data and photographs. Nurses received financial compensation for their participation in the study. Coloplast A/S funded the writing of the article and contributed to its content. Laboratoires Coloplast S.A.S. reviewed the article for scientific accuracy. HC is a member of the Coloplast Global Advisory Board and the local advisory board in France, and received an educational grant from Coloplast to provide scientific input to this publication. NA is a full-time employee of Coloplast A/S. APJ was an employee of Coloplast A/S when the article was written. RS is an employee of CEN Biotech Inc. FA was a full-time employee of Laboratoires Coloplast S.A.S. at the time of publication development. The authors have no other conflicts of interest to declare.

acute wound • chronic wound • exudate management • gelling fibre dressing • hard-to-heal • observational study • wound • wound care • wound dressing • wound healing

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Wounds are a common, yet often underestimated, public health issue.[1] In Europe alone, it is estimated that four million people develop a wound each year,[2] many of whom receive care from nurses in the community.[1,3] In France, the cost of managing leg ulcers and pressure ulcers (PUs) in the community totalled €965 million in 2011; funding for nursing staff accounted for >40% of the total expenditure.[4] Furthermore, French health insurance data show that wound dressings were the second largest expenditure category in 2022, totalling €732 million.[5]

Wounds are not only economically burdensome for healthcare systems,[6–11] but have a profound impact on patient health-related quality of life (HRQoL).[11–14] Wounds that are hard-to-heal (chronic) can prolong the pain, distress and anxiety experienced by the affected individual.[1,15] A systematic review documented the profound humanistic burden of hard-to-heal wounds, showing that, among other issues, pain and limited mobility were key for patients.[11] These observations are particularly concerning considering that the prevalence of hard-to-heal wounds appears to be increasing, as a consequence of ageing populations and the increasing prevalence of chronic disease (e.g., diabetes) at a younger age.[11,16–18] To reduce the prevalence of non-healing wounds, and to minimise their impact on the individual and society, proactive and appropriate management is essential.[15,18]

The effective management of exuding wounds is particularly challenging.[19,20] Exudate (fluid in the wound) is a natural and vital part of the healing process;[21] a key role of exudate is to maintain a moist environment,[22] which actively supports the healing

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process.[23] However, if produced in excess or with a harmful composition (e.g., with elevated levels of matrix metalloproteinases), which can occur in hard-to-heal wounds, exudate can delay healing,[12,24,25] with significant implications for patient HRQoL.[22] Excess exudate can pool in the wound bed, increasing the risk of infection and maceration of the periwound skin—factors that are known to compromise healing.[26,27] In recognition of the risks associated with exudate pooling in the wound bed, there is growing understanding of the importance of managing the gap between the wound bed and the dressing.[26,28,29] During a consensus process, 90% of international wound care specialists (n=85) agreed that gap management is the most important factor in promoting an optimal healing environment.[29] Healthcare providers consider a variety of factors when assessing and managing the gap, which can include the condition of the wound edges, the wound bed, periwound skin, and the characteristics of the exudate.[29]

Successful management of the gap between the wound bed and the dressing relies on the selection of an appropriate dressing.[29] Although high-quality evidence is limited, guidelines, consensus statements and position papers from international organisations and experts typically recommend the use of foam dressings for moderately to highly exuding wounds.[30–33] These recommendations can be attributed to the superior absorbency of foam dressings and their lower risk of adhesion to the wound bed compared with traditional textile dressings.[34] Specifically, French national guidelines recommend foam dressings for the management of highly exuding acute wounds throughout the healing process, and during the granulation phase for hard-to-heal wounds.[35] It has been suggested that foam dressings may also have utility in other wound profiles, including sloughy wounds.[22]

A real-world, observational study—the Observatoire en Ville des Plaies ExSudatives (VIPES) study—was conducted in France to describe the use and investigate the performance of two wound dressings (a silicone foam dressing and a gelling fibre) in the management of acute and hard-to-heal wounds in a community nursing setting.[36] Epidemiological findings from the full study population have been previously described.[36] The sub-analysis presented here focuses on the subset of patients who received the silicone foam dressing as a primary dressing.

Method

Study design

The VIPES study was a prospective, observational, real-world study that described the use and investigated the performance of two wound dressings—a silicone foam dressing and a gelling fibre—in the management of complex wounds by nurses in real-world community care in France.[36] The present sub-analysis focuses on the subset of patients enrolled in the VIPES study who received the silicone foam dressing as a primary dressing.

Ethical approval and patient consent

The VIPES study was conducted between May 2020 and September 2021 in France as part of the National Observatory of Wounds and Wound Healing NursTrial study (Observatoire National des Plaies et Cicatrisations NursTrial).[37] The NursTrial study received favourable opinion from the French advisory committee on health data processing for research purposes (Comité Consultatif sur le Traitement de l'Information en Matière de Recherche dans le Domaine de la Santé) on 16 September 2015, and authorisation from the French data protection authority (Commission Nationale de l'Informatique et des Libertés) on 24 December 2015 (DR-2015-699). The study complied with the Declaration of Helsinki. As part of the nationwide NursTrial study, no additional authorisation was required for the VIPES study.

All patients gave verbal informed consent prior to participation in the study. To illustrate exudate pooling and the appearance of the dressing at removal, two photographs of patient wounds are included in this manuscript. In both cases, the patients are not identifiable from these photographs and patient/caregiver consent was obtained when the images were taken. Permission to use the photographs in this manuscript has been granted by the copyright holder.

Data collection

The baseline visit of the VIPES study was defined by the application of at least one of the two dressings as a primary dressing at the discretion of the nurse. The last follow-up visit was defined by the discontinuation of study follow-up or the discontinuation of the primary dressing (silicone foam dressing or gelling fibre), irrespective of the reason given by the nurse.

At each follow-up visit, the condition of the wound was assessed and documented using standardised photographs, taken at a 20cm distance with a graduated ruler next to the wound. Questionnaires developed specifically for the VIPES study were completed at least once per week by the nurse. The nurse also completed the Clinical Global Impression of Improvement (CGI-I) questionnaire, and the patient completed the Patient Global Impression of Improvement (PGI-I) questionnaire.[38] All data were recorded by nurses using the secure smartphone application, NursTrial (CEN Biotech Inc., Canada).

Silicone foam dressing

The silicone polyurethane foam dressing (Biatain Silicone; Coloplast A/S, Denmark) investigated during the VIPES study, and the focus of this sub-analysis, was developed for application to a wide range of exuding wounds. Combining the silicone foam dressing with 3DFit Technology (Coloplast A/S, Denmark) allows the dressing to conform to the wound bed (filling the gap), absorb fluid vertically and retain exudate. As shown in an in vitro study, the silicone foam dressing can retain bacteria, even under pressure.[39]

Patients

Patients eligible for inclusion in the VIPES study were: aged >18 years; were receiving treatment from community nurses for an acute or hard-to-heal wound for which nurses independently chose to apply the silicone foam dressing or the gelling fibre; and gave verbal informed consent to participate. No specific exclusion criteria were defined.

Outcomes

Epidemiological outcomes were recorded at baseline, including patient demographics, clinical characteristics (including details of conditions that have been associated with delayed wound healing) and wound management. During data analysis, wounds were categorised as acute or hard-to-heal based on their aetiology and according to the categories described in Beeckman et al.[40]

Wound healing outcomes comprised:

- The proportion of patients with healed wounds (consisting of 100% epithelial tissue) at the last follow-up visit
- For patients with non-healed wounds, the proportion of wounds progressing towards healing (consisting of >75% granulation tissue or >25% epithelial tissue, 0% necrotic tissue and <25% sloughy tissue) at the last follow-up visit
- The time from baseline to the last follow-up visit, i.e., time taken to heal for healed wounds and time to discontinuation of study follow-up or discontinuation of the silicone foam dressing for non-healed wounds
- The change in wound surface area (length × width) and wound depth from baseline to the last follow-up visit for all wounds and for non-healed wounds
- The change from baseline to the last follow-up visit in the Pressure Ulcer Scale for Healing (PUSH) score,[41] which was calculated for hard-to-heal wounds (excluding malignant wounds).

Although originally developed to monitor the healing of PUs, the validity of the PUSH tool has since been demonstrated for the assessment of a variety of hard-to-heal wounds.[41–43] The PUSH score was calculated during data analysis using three subscales assessing ulcer surface area (score 0–10), amount of exudate (score 0–3), and tissue type (score 0–4); higher total scores (maximum score: 17) indicate a lower probability of healing.[41]

Wound bed, wound edge and periwound skin outcomes comprised the change from baseline to the last follow-up visit in the following parameters, each described in terms of the proportion of patients: the level of exudate (none, low, moderate or high); the extent of exudate pooling (none, low, moderate or high); the condition of the wound edges (healthy, macerated, dry, thickened/rolled or undermining); and the condition of the periwound skin (healthy or unhealthy). Additional assessments comprised the change from baseline to the last follow-up visit in the proportion of tissue types (necrotic, sloughy, granulation and epithelial) present in the wound bed and in the proportion of patients with wounds showing local signs of infection (pain, erythema, oedema, heat and/or odour).

Nurse- and patient-reported outcomes comprised: nurse opinion across all visits (i.e., all dressing removals) on the ease of dressing removal, and the adhesion and conformability of the dressing to the wound bed; the change over time in patient-reported pain during the dressing change, measured on a visual analogue scale (VAS) from 0 (no pain) to 100 (severe pain);[44] and nurse and patient opinion of wound improvement at the last follow-up visit assessed using the CGI-I and the PGI-I questionnaires, respectively.[38] The questionnaires asked the patient/nurse to provide their assessment of wound improvement on a seven-point scale ranging from 'very much worse' to 'very much improved'.

The safety of the dressing was also assessed through reported adverse events (AEs).

Fig 1. Patient disposition. *Validated questionnaires were defined as forms that were submitted by the user with all fields completed; †Patients were excluded if the photograph showed deviations from the study protocol, for example, if the photograph did not show a wound, or if the wound differed from that reported in the questionnaire; ‡Deviations were defined as a change in the dominant treatment regimen and a discontinuation of follow-up

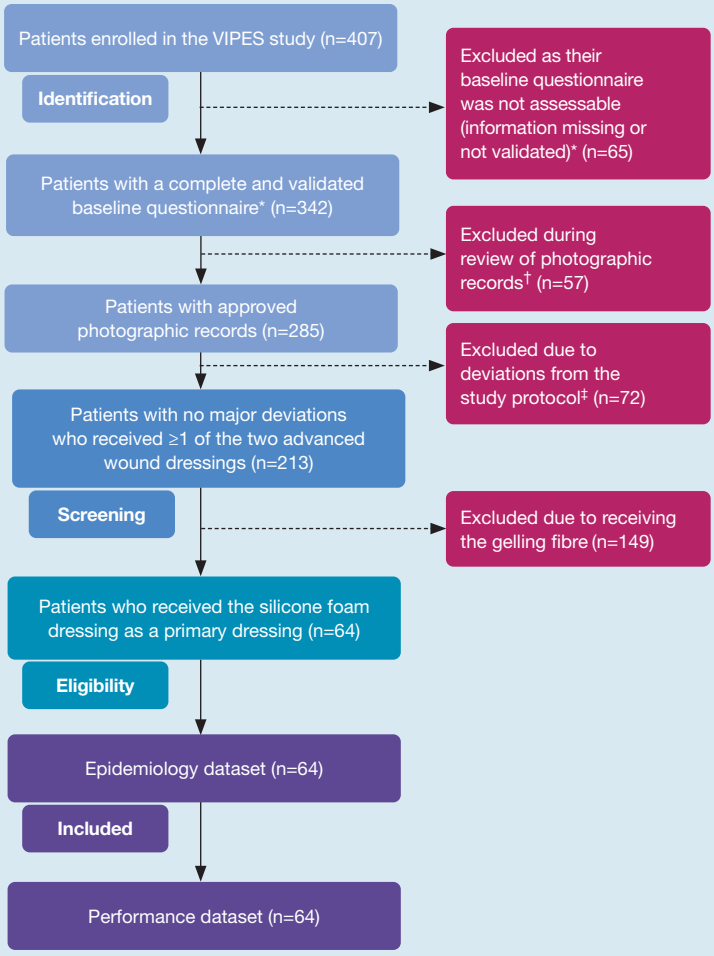


Table 1. Baseline demographics and clinical characteristics

	Silicone foam dressing population (n=64)
Demographics	
Male, n (%)	21 (32.8)
Age, years	
Mean±SD	72.8±21.7
Median (range)	82.5 (18–96)
Patients ≥70 years of age, n (%)	44 (68.8)
BMI, kg/m²	
Mean±SD	25.5±6.4
Median (range)	24.8 (15.6–55.1)
Clinical characteristics	
Medical history	
Patients with at least one condition associated with delayed healing, n (%)	50 (78.1)
Conditions associated with delayed healing, n (%)	
Venous insufficiency	29 (45.3)
Immobility	16 (25.0)
Malnutrition	13 (20.3)
Obesity (BMI ≥30 kg/m²)	10 (15.6)
Diabetes	10 (15.6)
PAD	7 (10.9)
Peripheral neuropathy	6 (9.4)
Immunodeficiency	2 (3.1)
Systemic corticosteroid therapy	1 (1.6)
Other	18 (28.1)
Current smoker, n (%)	3 (4.7)
Wound characteristics	
Acute, n (%)	**27 (42.2)**
Traumatic wound*	18 (28.1)
Burn	1 (1.6)
Surgical (pilonidal cyst)	4 (6.3)
Surgical (dehiscence)	3 (4.7)
Surgical (non-sutured post-surgical wound)	1 (1.6)
Hard-to-heal, n (%)	**37 (57.8)**
Ulcer†	21 (32.8)
Pressure ulcer	10 (15.6)
Neoplastic/malignant ulcer	4 (6.3)
Diabetic foot ulcer‡	2 (3.1)

Data processing and statistical analysis

Datasets

In this sub-analysis, two datasets were defined. The 'epidemiology dataset' included all patients who received the silicone foam dressing as a primary dressing at the baseline visit, and for whom baseline data (wound type, surface area and tissue types) were collected and no major deviations were identified during review of the baseline photographic and questionnaire data. The 'performance dataset' included all patients in the epidemiology dataset who had at least one outcome assessment for the silicone foam dressing and for whom no major deviations were identified during review of the photographic and questionnaire data collected at follow-up visits. Deviations were defined as a change in the dominant treatment regimen and a discontinuation of follow-up.

Statistical analysis

Epidemiological outcomes are reported for the epidemiology dataset using descriptive statistics. All other outcomes were assessed in the performance dataset.

Mean wound surface area at baseline and at the last follow-up visit were compared using a paired Student's t-test. Evolution of wound depth over time was analysed using a Wilcoxon signed rank test. Change in the mean PUSH score (for hard-to-heal wounds) from baseline to the last follow-up visit was analysed using a Student's t-test. Levels of exudate, the extent of exudate pooling and the condition of the wound edges were compared between baseline and the last follow-up visit using Wilcoxon signed rank tests. Changes in the condition of the periwound skin and in local signs of infection between baseline and the last follow-up visit were analysed using McNemar comparison tests. Changes in the proportions of necrotic, sloughy, granulation and epithelial tissue between baseline and the last follow-up visit were analysed using paired time comparison tests.

For all comparisons, p-values <0.05 were considered statistically significant. No adjustments were made to account for missing data. All analyses were conducted using SAS software version 9.4 (SAS Institute Inc., US).

Results

Patient disposition

A total of 407 patients were enrolled in the VIPES study. Of the 213 patients who received at least one of the two dressings, 64 (30.0%) received the silicone foam dressing as a primary dressing and were included in the present sub-analysis (Fig 1). All 64 patients were included in the epidemiology and performance datasets.

Epidemiological outcomes

Baseline demographics and clinical characteristics are summarised in Table 1. The population of 64 patients included predominantly older adults (68.8% were aged ≥70 years) and the majority of patients (78.1%) had at least one condition associated with delayed healing. At baseline, 28/64 (43.8%) wounds had a moderate or high

level of exudate and, for most wounds (n=45/51; 88.2%), the exudate had an aqueous consistency. Exudate pooling (see example, Fig 2) was observed in 45/64 (70.3%) wounds. A total of 33/64 (51.6%) wounds had unhealthy edges and 19/64 (29.7%) had unhealthy periwound skin.

Details of prior wound management recorded at the baseline visit are presented in Table 2. Most wounds (n=33/40; 82.5%) were in treatment failure (stagnant/non-healing or had poor exudate management) before study inclusion. Mechanical debridement was performed on one of the three necrotic wounds, none of the eight sloughy wounds, and on 3/36 (8.3%) granulating wounds. Regarding the use of supportive measures for specific types of wounds, compression was used for 7/16 (43.8%) patients with venous/mixed ulcers, preventive support was used for 6/10 (60.0%) patients with PUs, and offloading was used for one of two (50.0%) patients with diabetic foot ulcers.

Wound healing outcomes

At the last follow-up visit, wounds were considered healed in 31/64 (48.4%) patients and were progressing towards healing in a further 16/64 (25.0%) patients. Consequently, 16/33 (48.5%) non-healed wounds were progressing towards healing. Patients were followed for a median duration of 22.5 (range: 3–151) days. Wounds that were considered healed at the last visit had a longer median duration of follow-up than wounds that were not healed: 28.0 (range: 3–151) days versus 18.0 (range: 3–88) days, respectively.

Across all wounds, there was a significant mean±standard deviation (SD) wound area reduction (WAR) of 6.1±17.6cm^2 from baseline to the last follow-up visit ($p<0.01$). A significant WAR of 5.4±13.1cm^2, corresponding to a 33.3% median improvement, was also observed in the group of 33 patients whose wounds were not healed at the last follow-up visit ($p<0.05$). Of the 33 patients with non-healed wounds, 28 were followed for at least eight days (median: 26.0 days) and showed a WAR of 3.8±6.4cm^2, corresponding to a 41.3% median improvement. WARs were accompanied by significant reductions in wound depth over time ($p<0.05$). For 31 hard-to-heal wounds, the mean±SD PUSH score significantly improved, decreasing by 3.2±3.3 points from baseline to the last follow-up visit ($p<0.0001$).

Wound bed, wound edges and periwound skin outcomes

Significant reductions were observed in the level of exudate ($p<0.0001$) and in the extent of exudate pooling ($p<0.0001$) from baseline to the last follow-up visit (Fig 3a, b). On an individual level, the proportion of patients with moderate or high levels of exudate decreased by 69.2% from baseline to the last follow-up visit. Within the same timeframe, all patients with a moderate or high level of exudate pooling at baseline experienced reductions in exudate pooling by the last follow-up visit.

Table 1. Baseline demographics and clinical characteristics (continued)

	Silicone foam dressing population (n=64)
Clinical characteristics (continued)	
Wound age, days	**[n=62]**
Mean±SD	72.7±157.6
Median (range)	18.0 (1–1095)
Wound surface area, cm²	
Mean±SD	9.7±21.4
Median (range)	2.6 (0.1–120.0)
Wound depth, mm	
0–5	52 (81.3)
6–10	9 (14.1)
11–20	3 (4.7)
21–30	0 (0.0)
31–40	0 (0.0)
≥41	0 (0.0)
PUSH score (hard-to-heal wounds only)	**[n=33]**
Mean±SD	9.7±3.5
Median (range)	9.0 (4.0–16.0)
Wound bed tissue (tissue covering >75% of the wound),§ n (%)	
Necrotic	3 (4.7)
Sloughy	8 (12.5)
Granulation	36 (56.3)
Epithelial	0 (0.0)
Exudate level, n (%)	
None	0 (0.0)
Low	36 (56.3)
Moderate	22 (34.4)
High	6 (9.4)
Exudate pooling prior to debridement, n (%)	
None	19 (29.7)
Low	34 (53.1)
Moderate	10 (15.6)
High	1 (1.6)
Type of exudate, n (%)	[n=51]
Aqueous	45 (88.2)
Viscous	6 (11.8)

Table 1. Baseline demographics and clinical characteristics (continued)

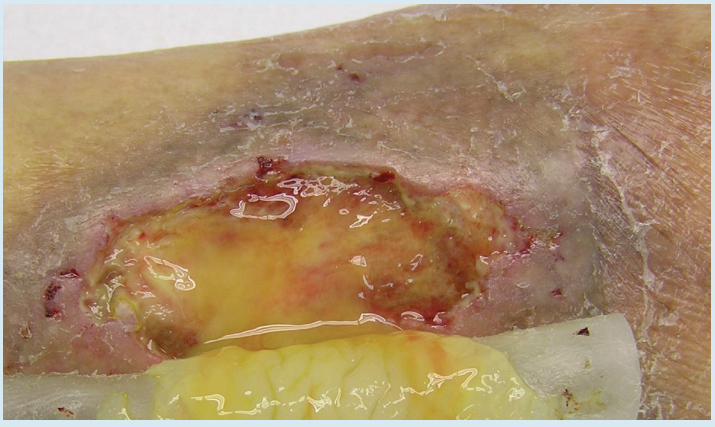
	Silicone foam dressing population (n=64)
Clinical characteristics (continued)	
Condition of the wound edges, n (%)	
Healthy	31 (48.4)
Macerated	17 (26.6)
Dry	9 (14.1)
Thickened/rolled	4 (6.3)
Undermining	3 (4.7)
Condition of the periwound skin, n (%)	
Healthy	45 (70.3)
Unhealthy‖	19 (29.7)
Local signs of infection,¶ n (%)	6 (9.4)
Local signs of infection requiring antibiotics, n (%)	3 (4.7)

Data are presented for the epidemiology dataset.*Comprised skin tear (n=9), skin abrasion (n=3), bite (n=1), other (n=4) and missing (n=1); †categorised as venous (n=13), arterial (n=2) and mixed (n=6); ‡both cases categorised as neuropathic (perforating ulcer of the foot); §the percentage for each category was calculated out of the total number of patients (n=64); ‖comprised maceration (n=5), erythema (n=3), stasis dermatitis, ochre dermatitis, desquamation, excoriations, blister, dryness and psoriasis (all n=1), and missing (n=4); ¶any number and combination of pain, erythema, oedema, heat, and odour; BMI—body mass index; PAD—peripheral arterial disease; PUSH—Pressure Ulcer Scale for Healing; SD—standard deviation

The condition of the wound edges improved significantly from baseline (p≤0.0001) with healthy edges observed in most patients (82.0%) at the last follow-up visit (Fig 3c). Similarly, significant improvements in the condition of the periwound skin were observed (p<0.01) and the proportion of patients with unhealthy periwound skin decreased by more than half from baseline to the last follow-up visit (29.5% versus 11.5%, respectively; Fig 3d).

Regarding the tissue composition of the wound bed, there were significant decreases from baseline to the last follow-up visit in the proportions of patients with necrotic (p<0.01), sloughy (p≤0.0001) or granulation tissue (p<0.0001). These decreases were accompanied by a significant increase in the proportion of patients with epithelial tissue (p<0.0001); 62.3% of patients had re-epithelialising wounds at the last follow-up visit (Fig 4).

Fig 2. Example of exudate pooling (copyright Coloplast A/S, Denmark)



During the study period, a significant reduction was observed in the proportion of patients with local signs of infection (p<0.05). Of the six patients with local signs of infection at baseline, three were receiving systemic antibiotic therapy. At the last follow-up visit, one patient had persistent local signs of infection but did not use antibiotics. No patients developed new local signs of infection during the study.

Nurse- and patient-reported outcomes

A total of 220 silicone foam dressing removals were performed for the 64 patients. Overall, 216/217 (99.5%) dressing removals were considered 'easy' by the nurse and most dressings had not adhered to the wound bed (162/214; 75.7%). Where adhesion had occurred, bleeding upon dressing removal was absent, very mild or mild in most cases (47/49; 95.9%); a high level of bleeding was observed in only two cases of adherent dressing removal. Across all 220 dressing removals, the mean±SD VAS score for patient-reported pain was 7.6±15.8 points.

In general, nurses reported that the dressing conformed closely to the wound bed (see example, Fig 5), with no, or a minimal, gap between the wound bed and the dressing in 203/217 (93.5%) cases.

Regarding wound improvement, at the last follow-up visit, most nurses and patients believed the wound had improved during the study (Fig 6). No nurses or patients thought that a wound had significantly or substantially worsened.

Safety outcomes

No AEs were reported during the study.

Discussion

Managing the gap between the wound bed and the dressing is crucial for controlling the level of exudate and reducing the risk of infection; thereby, facilitating the healing process.[29] A silicone foam dressing was developed for application to a wide range of exuding wounds and included 3DFit Technology to allow the dressing to conform to the wound bed. The ability of this silicone foam dressing to minimise the gap and manage exudate levels was investigated as part of the sub-analysis of the observational VIPES study presented here.

At the last follow-up visit, 48.4% of wounds had healed and, of the wounds that had not healed, 48.5% were progressing towards healing, which is reflected by a significant increase in wound re-epithelialisation during the study (p<0.0001). The progression of wounds towards healing is also supported by the 41.3% WAR among patients with non-healed wounds who were followed for at least eight days (median: 26.0 days). International consensus suggests that a 40–50% WAR

over a period of four weeks is an accepted marker for progression to wound closure.[45] These clinical findings are further supported by the CGI-I and PGI-I scores, with nurses and patients reporting high and comparable levels of wound improvement following treatment with the silicone foam dressing. As previously shown in the epidemiological analysis of the VIPES study population,[36] the wounds assessed in this sub-analysis were, generally, complex, with many patients enrolled due to the failure of prior treatment, i.e., a stagnant/non-healing wound or poor exudate management. Most patients also had risk factors associated with the development of hard-to-heal wounds, such as venous insufficiency, immobility and poor nutrition.[8,36,45] Consequently, it is highly encouraging that the combined proportions of healed wounds and wounds progressing towards healing in this sub-analysis is consistent with wound healing/improvement rates of ~50–70% reported in previous observational studies in broad patient populations.[46–48]

Furthermore, information gathered via the baseline questionnaire suggested that wound improvements with the silicone foam dressing were achieved despite suboptimal management of the wounds, and the underlying clinical causes, in community practice. Although mechanical debridement (removal of non-viable tissue) is widely advised in the care of necrotic or sloughy wounds,[30,32,33,49,50] debridement was rarely performed for these types of wounds in the present subset of patients. Furthermore, debridement was inappropriately performed for some granulating wounds.[32,33] Supportive care for venous/mixed ulcers was also used inconsistently, despite the known benefits for exudate reduction.[22] Suboptimal management could, potentially, be a consequence of outdated guidance; the existing French guidelines are old and, therefore, may not account for more recent advances in wound management and dressing technology.[35,49] Ensuring that guidelines are regularly updated and providing additional training in wound management may improve wound care in community nursing practice.

Although key principles in wound care were not consistently followed, application of the silicone foam dressing was associated with significant reductions in exudate level ($p<0.0001$) and in exudate pooling ($p<0.0001$). These findings suggest successful management of the gap between the silicone foam dressing and the wound bed across exuding wounds at various stages of the healing process. These reductions were accompanied by significant improvements in the condition of the wound edges and the periwound skin, which may be due to a reduction in exudate leakage.[22] The 'triangle of wound assessment' framework highlights the importance of improving the condition of the wound bed, wound edges and the periwound skin in order to optimise wound healing.[26] Consequently, the findings from this analysis imply that focusing on gap management using a dressing that conforms to the wound bed may be an effective approach to facilitate the healing process.

Table 2. Wound management prior to inclusion in the study

	Silicone foam dressing population (n=64), n (%)
Dressing	
Wound dressed at baseline	48 (75.0)
Previous primary dressing	**[n=46]**
Foam dressing, excluding 3DFit Technology	19 (41.3)
Foam dressing with 3DFit Technology	13 (28.3)
Hydrocolloid dressing	4 (8.7)
Contact layers	3 (6.5)
Alginate dressing	2 (4.3)
Superabsorbent foam dressing	1 (2.2)
Hydrofibre dressing	1 (2.2)
Hydrogel dressing	1 (2.2)
Other	2 (4.3)
Main reason for switching to silicone foam dressing	**[n=40]**
Stagnant, non-healing wound	28 (70.0)
Poor exudate management	5 (12.5)
Damaged periwound skin	2 (5.0)
Pain at removal for the patient	1 (2.5)
Dressing removal trauma to skin/periwound skin	1 (2.5)
Adhesive intolerance	1 (2.5)
Excessively frequent dressing changes	1 (2.5)
Other	1 (2.5)
Wound preparation at the baseline visit	
Mechanical wound debridement performed	6 (9.4)
Mechanical wound debridement according to primary wound type (tissue covering >75% of the wound)	
Necrotic [n=3]	1 (33.3)
Sloughy [n=8]	0 (0.0)
Granulating [n=36]	3 (8.3)
Wound cleansing performed	55 (85.9)
Type of wound cleansing*	**[n=55]**
Saline	30 (54.5)
Antiseptic	14 (25.5)
Water and mild soap	12 (21.8)
Water	4 (7.3)
Prontosan	1 (1.8)

Table 2. Wound management prior to inclusion in the study (continued)

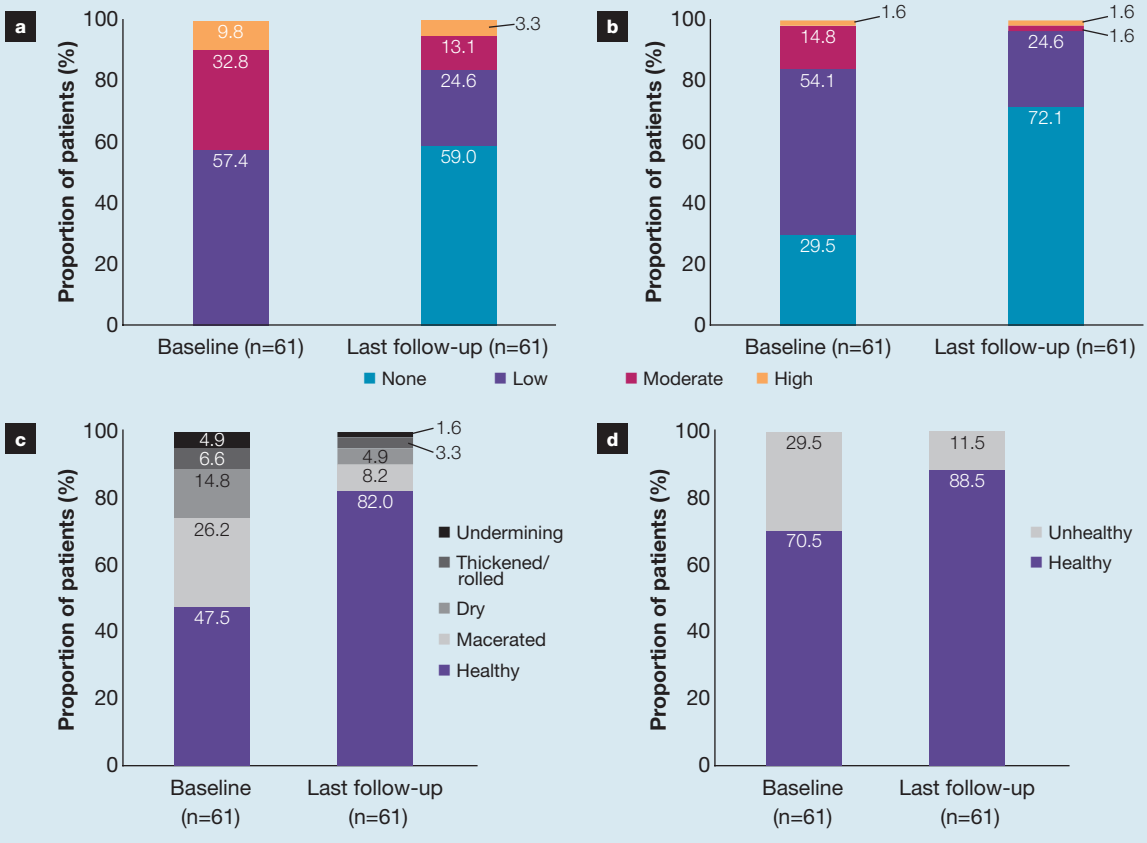
	Silicone foam dressing population (n=64), n (%)
Supportive measures	
Venous/mixed ulcers	[n=16]
Compression/containment	7 (43.8)
Pressure ulcers	[n=10]
Preventive support surface	6 (60.0)
Diabetic foot ulcers	[n=2]
Offloading foot or toes	1 (50.0)

Data are presented for the epidemiology dataset. *Multiple options could be selected

An additional benefit of gap reduction and exudate management is the reduced risk of infection.[26,29] Of the six patients with local signs of infection at baseline, five had no signs at the last follow-up visit, and no new infections were observed. It is important to highlight that only a small number of patients in this analysis presented with infections and half of these patients were receiving antibiotic treatment at baseline. It is not possible to draw conclusions on the effects of the silicone foam dressing on infection risk from this observational study. Nonetheless, an in vitro study has shown that the silicone foam dressing absorbed and retained a significantly higher quantity of bacteria than an alternative silicone foam dressing and a gauze control.[39] Further investigation is required to confirm that the combination of gap reduction, exudate management, and the absorption and retention of bacteria by this dressing can help to reduce infection risk.

While clinical assessments of wound condition and improvement are crucial when evaluating dressing performance, people living with a wound often have different priorities.[51] Pain management is essential for patient wellbeing—pain can be exacerbated by infection, treatment and physical activity, and the debridement and re-dressing of wounds.[52,53] The present analysis shows that, on average, the patient-reported VAS pain score across all silicone foam dressing removals was <10 (on a VAS of 0 (no pain) to 100 (severe pain)). According to an analysis that investigated the interpretation of VAS ratings in pain research,[44] an average score of <10 suggests that most patients experienced very mild pain

Fig 3. Level of exudate **(a)**, extent of exudate pooling **(b)**, condition of the wound edges **(c)** and condition of the periwound skin **(d)** at the baseline visit and at the last follow-up visit. Data are presented for the performance dataset for patients with data available for the baseline and last follow-up visits; data are missing for three patients. Exudate pooling was assessed prior to debridement



when the dressing was removed. This is consistent with the results of a survey-based study, which suggested that the preferential use of dressings with soft silicone adhesive technology over traditional adhesives may reduce the risk of pain and trauma to the wound bed during their removal.[53]

The main strength of the present analysis is its assessment of a broad population of people living with a wound. Real-world data has become increasingly important to practising clinicians and regulators, providing evidence of an intervention's effectiveness in clinical practice.[54] The present analysis adds to existing real-world data investigating the management of wounds,[55–57] and provides specific insights on the use of the silicone foam dressing. Using the NursTrial application, the study also assessed patient-reported outcomes including a VAS for pain assessment and the PGI-I. Patient-reported outcomes provide vital information for decision-making in healthcare, by reporting the status of a patient's health condition without clinician interpretation.[58] Consequently, the patient-reported data presented in this analysis directly illustrate the positive patient experience with the silicone foam dressing, complementing clinical assessments of dressing performance.

Limitations

This sub-analysis has limitations. Firstly, the VIPES study was observational and did not include a control group, which is due to the restrictions imposed by the NursTrial study. Secondly, due to the observational design of the study, the dressing was discontinued before wound healing in 33 patients, meaning that their final treatment outcome is unknown; nevertheless, the CGI-I and PGI-I scores indicate that most wounds were improving at the last follow-up visit. Thirdly, the number of patients treated with the silicone foam dressing as a primary dressing was relatively small (n=64/213). It is important to note that the brand of gelling fibre assessed in the VIPES study was new to the market at the time of data collection, adding to the range of gelling fibres available in France. Therefore, nurses may have been influenced by the novelty of the brand and inclined to use it over other dressings, resulting in a small sample of patients who received the silicone foam dressing. Finally, the study was conducted in a community practice setting in France—further research is needed to determine whether these findings can be replicated in other countries.

Conclusion

This sub-analysis suggests that the silicone foam dressing supported the healing of complex, exuding wounds in the community by effectively managing the gap between the dressing and the wound bed. Considering that key principles in wound care were not consistently followed, updating management guidelines and delivering regular training could further optimise wound care in community nursing practice. JWC

Fig 4. Proportion of patients with necrotic, sloughy, granulating and re-epithelialising wounds at the baseline visit and at the last follow-up visit. Data are presented for the performance dataset for patients with data available for the baseline and last follow-up visits; data are missing for three patients. Wound type (necrotic, sloughy, granulating or re-epithelialising) is defined by the tissue covering >75% of the wound surface area

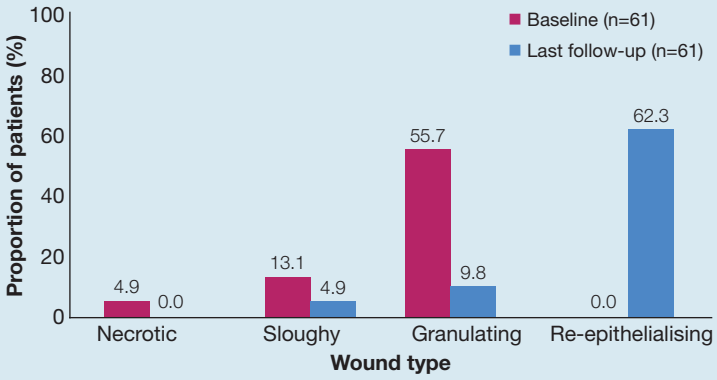


Fig 5. Example of silicone foam dressing conforming to the wound bed (copyright Coloplast A/S, Denmark)

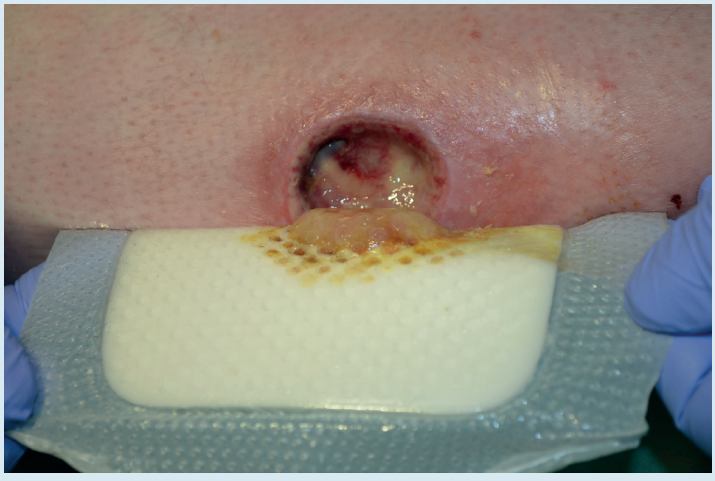
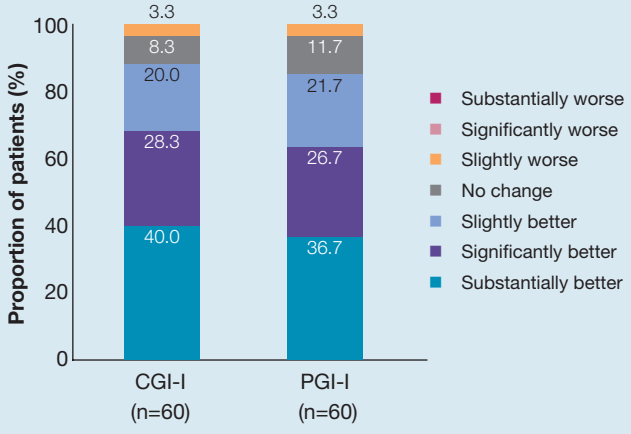


Fig 6. Nurse and patient opinion of wound improvement at the last follow-up visit. Data are presented for the performance dataset. Data are missing for four nurses and four patients. CGI-I—Clinical Global Impression of Improvement; PGI-I—Patient Global Impression of Improvement



Reflective questions

- Why is it challenging to manage an exuding wound effectively?
- What are the benefits of minimising the gap between the dressing and the wound bed?
- What outcomes were observed in patients with a complex exuding wound who received treatment with the silicone foam dressing?

Data availability statement
The data that support the findings of this study are available from the corresponding author upon reasonable request.

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