Received: 19 June 2024 | Revised: 13 September 2024 | Accepted: 13 September 2024

DOI: 10.1111/iwj.70074

ORIGINAL ARTICLE

IWJ WILEY

Clinical performance and cost-effectiveness of a Silicone foam with 3DFit™ technology in chronic wounds compared with standard of care: An open randomised multicentre investigation

David Voegeli[1] | **Malene Hornbak Landauro**[2] | **Trine Sperup**[2] | **Nayla Ayoub**[2] | **John William McRobert**[3]

[1]Faculty Health & Wellbeing, University of Winchester, Winchester, UK

[2]Coloplast A/S, Humlebaek, Denmark

[3]Unit 7, Pioneer, Wound Healing and Lymphoedema Centres, Sussex, UK

Correspondence
Malene Hornbak Landauro, Coloplast A/S, Humlebaek, Denmark.
Email: dkmhla@coloplast.com

Funding information
Coloplast

Abstract

The objective of the study was to show the clinical performance and cost-effectiveness of a Silicone foam dressing with 3DFit™ Technology compared to current standard of care. This was an open-labelled, two-arm, randomised controlled multicentre study conducted from February to December 2023. One hundred and two participants with an exuding, non-infected and chronic ulcer were randomised in a 1:1 fashion and treated with either a Silicone foam with 3DFit™ Technology or standard of care (a filler combined with a secondary dressing), stratified by venous leg ulcers and diabetic foot ulcers. After a 4-week study period, wound size and total costs were evaluated. After 4 weeks of treatment, a comparable percentage in wound area reduction was observed in both treatment arms with mean and 95% confidence interval of 54.3% (37.1%; 71.5%) and 43.0% (26.5%; 59.6%) for the investigational and comparator dressing, respectively. This corresponded to a mean difference of 11.3% ([−10.22; 32.86], $p = 0.299$). Total mean estimated costs were significantly lower for the investigational dressing (£14.3, 95% confidence interval [£9.6; £19.0]) compared to the two-dressing regime (£21.4 [£16.9; £26.0]), corresponding to a 33% price reduction ($p = 0.033$) after 4 weeks of treatment. With this RCT, a conforming Silicone foam dressing with 3DFit™ Technology was shown to be clinically comparable and a cost-effective alternative to using a filler and a secondary dressing at a significantly lower cost in both venous leg ulcers and diabetic foot ulcers up to 2 cm in depth.

Trial registration number: NCT05786612.

KEYWORDS
cost-effectiveness, dressing, exudate, wound healing, wound infection

Key Messages

- The growing demand of wound care in a time where healthcare resources are limited calls for increased focus on evidence- and quality-based treatments.
- Dressing selection has become a complex decision, affected by the plethora of continuously new dressings, where subjective preferences, habitual management and lack of training stand in the way of evidence-based choice of treatment.
- Changing the standard of care for exuding wounds from a two-dressing to one dressing regime provides a simplified and cost-saving solution by reducing number of wound fillers consumed and support self-management, known to increase patient's empowerment and life quality. This may translate into a positive health economic impact in terms of reduced costs and labour.
- When 102 patients with chronic wounds tested two different dressing regimens, the Silicone foam with 3DFit™ Technology was demonstrated to have an equally effective wound healing outcome at a lower cost compared to standard of care offering a one dressing solution and alleviating the need for a wound filler.

1 | INTRODUCTION

Chronic wounds are a debilitating health issue for patients worldwide and have become ever more prevalent, with an ageing population and the pandemic rise of the metabolic syndromes. A 71% increase in the annual wound prevalence was estimated in two 'burden of wounds studies' in the UK from 2012/2013[1] to 2017/2018,[2] corresponding to an 'annual growth rate' (AGR) of 11.4% ($AGR = ((3.8\text{ million} / 2.2\text{ million})^{(1/5)}) - 1$). If this trend persists, there will be 14.7 million wound patients in 2030 ($3.8\text{ million} \times (1 + 0.1137)^{12}$), nearly quadrupling the 2018 figure (3.8 million). This, coupled with a declining healthcare workforce, presents a significant resource challenge.[3]

The annual 8%–9% rise in wound care costs over the same 5-year period is projected to result in an increase to £18.1 billion, based on a 6.7% AGR.[1,2] Conclusively, these numbers are well in excess of the cost of £6.5 billion spend on obesity management[4] and illustrates the urgent need to find better ways for patient self-care in the era of inadequate resources.

A report on the operational productivity and performance in acute National Health Service (NHS) hospitals estimated cost savings of £5 billion following a number of proposed recommendations.[5] Among the proposals, an optimised use of the clinical workforce was recognised as the key cost driver, potentially saving £2 billion.[5] In 2018, the National Wound Care Strategy Programme (NWCSP) was commissioned by the NHS to address sub-optimal wound care with the aim to improve wound care for pressure ulcers, lower limb ulcers and surgical wounds, to the benefit of patients and to secure a significant financial and economic impact on the healthcare system.[6] Key proposals of the programme consisted of early and accurate diagnosis of the wound and its underlying cause, as well as increasing the availability of evidence-based care. In line with this, there is an increased awareness on value-based healthcare which is centred around the value gained (outcome) for patients relative to healthcare cost, shifting the focus away from merely quantity of costs.[7,8] A cost-effective analysis is therefore a strong tool to evaluate two treatments effects relative to their costs. For example, a higher healing rate of 74% was demonstrated when venous leg ulcer (VLU) patients received evidence-based care with compression therapy compared to a healing rate of only 32% with standard non-evidence-based care.[6]

The management of chronic wounds therefore necessitates a multidisciplinary professional effort, which includes a thorough understanding of various wound types to ensure the provision of appropriate treatment. This approach is essential for effective healing and recovery.[9] However, the spiralling nursing staff shortages lead to healthcare inconsistencies which impacts patient care quality and safety negatively within both hospital and

community settings.[3] Incoherent treatment plans, continuous nursing replacements and the use of different dressings introduce unwarranted variation in wound management. Potential consequences include delayed wound healing, increased risk of infection, pain, reduced QoL and negative impacts on healthcare costs.[10]

Excess exudate in chronic wounds can further complicate the healing process, causing pain, leakage, maceration of the periwound skin and wound edges, and significantly increase the frequency of wound dressing changes.[11] In addition, if a gap between the wound bed and dressing develops there is an increased risk for bacterial pooling and growth, precipitating further infection risk.[12,13] Therefore, an ideal dressing for chronic, exuding wounds must provide and maintain a moist environment, conform to the wound bed to fill the gap, absorb and retain excess exudate, reduce the risk of leakage and infection and support autolytic debridement.[14] Historically, Hydrofibers®, gelling fibres and alginate dressings have been the standard of care (SoC). However, these dressings typically require a secondary dressing to keep them in place.[15–17]

The Silicone foam with a 3DFit™ Technology is a bordered polyurethane foam dressing with a bacteria- and waterproof top film, which conforms to the wound bed, absorbs exudate vertically and retains exudate, eliminating the need for a filler. Therefore, the shift from a two-dressing regime to a simplified one-dressing regimen should reduce costs and labour, facilitate self-management and improve patient quality of life by decreasing the number of wound fillers used.[18]

In the scarcity of randomised controlled wound dressing studies,[19] the objectives of this study were to show the clinical performance and cost-effectiveness of a Silicone foam with 3DFit™ Technology compared to current SoC (a filler covered by a secondary dressing), used for the treatment of chronic wounds with a wound depth down to 20 mm which has been shown to be the typical depth in 80% of chronic wounds.[20] Additional data from a retrospective cohort sample of >150 000 patients with 312 744 wounds of all causes demonstrated wounds down to 20 mm to be prevalent in 99% and 99.9% of patients with diabetic foot ulcer (DFU) ($n = 59\ 464$) and VLU ($n = 81\ 560$), respectively.[21]

2 | MATERIALS AND METHODS

2.1 | Study design

In an open-labelled, two-arm, randomised controlled multicentre study, the performance and cost-effectiveness of a single Silicone foam dressing with 3DFit™ Technology for 4 weeks was assessed and compared to SoC in participants with a chronic and non-infected VLU or DFU. The study was conducted at 10 hospitals and research centres in the UK from February to December 2023, in accordance with the Declaration of Helsinki II (1964, as amended in Fortaleza, Brazil, October 2013), approved by the local Medical Research Ethics Committees and local authorities, and registered at ClinicalTrials.gov (NCT05786612, 18 January 2023).

2.2 | Participants

Participants were recruited from participating site hospitals, outpatient clinics, community collaborations or from advertisement. Adult participants who had signed the informed consent form were eligible in the study if they had either a non-infected VLU or DFU, present with a wound duration between 8 weeks to 24 months, and their wound had a maximum wound depth of 20 mm relative to its wound diameter, because the expansion of the dressing when exposed to fluid (i.e., the conformability) varies with the wound diameter[22] (Table S1). Wound infection was defined according to the IWGDF/IDSA guideline for DFUs[23] (Table S2). For VLUs, no similar validated scoring system currently exists. Therefore, an infected VLU was defined as two or more clinical signs of infection defined as new or altered pain in the wound area, malodour, increased ulcer area, maceration, delayed or non-healing, erythema or increased temperature.[24]

Additionally, to be eligible, wounds were required to be exuding and require a filler and a secondary dressing. In line with local standards[23,25] and to ensure optimal conditions for wound healing, compression therapy, for example, compression bandage, socks or other, was a requirement for participants with a VLU and off-loading, for example, bed rest, wheelchair, crutch-assisted gait, total contact casts, felted foam, half shoes, therapeutic shoes or removable cast walkers, was a requirement for those with a DFU. Additionally, for participants with diabetes, there was an HbA1c requirement of ≤10% or ≤86 mmol/mol, measured within the last 3 months prior to inclusion. Participants with wounds larger than 10 × 10 cm; wounds exposed with tendons, bones or fistulas, or wounds with a cavity; participants with ankle-brachial pressure index below 0.8; and participants receiving chemotherapy or enrolled in another wound care device investigation were excluded from the investigation.

2.3 | Randomisation and blinding

After eligibility assessment and signed informed consent at Visit 1 (week 0), block randomisation with

stratification based on wound type (VLU or DFU) was completed and centralised using Medidata Rave (Rave RTSM, version 2021.2.1, delivered by Medidata Solutions Inc.), assigning participants to one of two intervention groups, in block sizes of four. Participants and the trial investigator were unblinded to the assigned treatment, whereas the trial statistician was blinded until database lock.

2.4 | Interventions

During the investigational period, study participants attended weekly clinic visits where their wound was assessed and either the investigational dressing or the comparator dressing was applied according to the randomisation scheme. The use of compression and offloading for VLU and DFU, respectively, were performed across both randomised groups.

The investigational dressing, Biatain® Silicone (Coloplast A/S, Denmark), is a hydrophilic and hygroscopic foam with porous open cell structures that act like small capillary tubes which absorb and retain aqueous fluids. This results in efficient mass transportation and absorption of fluid (e.g., pool of exudate) when in contact with the foam.[26] The capillary action enables liquid to spontaneously flow into narrow spaces, capillaries and porous materials and even move vertically upwards, against gravity, defined as the capillary rise.[27,28] The hydrophilic polyurethane open cell foam with 3DFit Technology mediates this vertical capillary action and fluid absorption when in contact with water or an aqueous fluid. Consequently, the Silicone foam with 3DFit™ Technology allows the dressing to conform to the wound bed (filling the gap), absorb fluid vertically and retain exudate using a single dressing.[29] This dressing is indicated for low to highly exuding wounds, including both acute and chronic wounds and has a wear time up to 7 days.[29]

The comparator dressing regime included a separate filler combined with a secondary dressing on top. The filler was AQUACEL® EXTRA™ Hydrofiber® Dressing (Convatec Inc., UK), a non-woven pad dressing, composed of sodium carboxymethylcellulose and regenerated cellulose fibres which absorb and conform to a variety of acute and chronic wounds. The secondary dressing was Mepilex® Border (Mölnlycke Health Care, Sweden). A polyurethane foam dressing with a waterproof top layer which provides a barrier to external contaminants, keeps the Hydrofiber in place and maintain a moist environment.[30] This dressing is indicated for a wide range of exuding acute and chronic wounds.[31]

After randomisation at visit 1 (week 0), baseline information was collected, the wound was cleaned according to SoC and debridement was performed if needed. A photo of the wound was uploaded to Medidata Solutions Inc.'s eCOA solution which is a digital photo-planimetric software system that enables wound area measurements from the photos and were assessed by a blinded reviewer. Furthermore, the wound condition was assessed by the healthcare professional (HCP) based on an adapted version of the Triangle of Wound Assessment Form (Figure S1), and the relevant dressing of either the investigational or comparator product was applied according to the randomisation scheme. Study participants were provided with additional randomised dressings to use at home if needed between visits.

At each subsequent clinic visit (weeks 1–4), one every week, the number of dressing changes since the last scheduled visit and product accountability (i.e., correct handling of product and relevant details regarding product application) were recorded; the cleansing of the wound and debridement, if necessary, was performed according to protocol. Wound size was assessed with the digital photo-planimetric software system, and wound depth and dressing conformability were evaluated by HCP and recorded. Overall wound condition was assessed by the HCP with the Triangle of Wound Assessment Form. Any changes in wound dressings used, concomitant medications and any adverse events, device deficiencies and protocol deviations were registered. For the last termination visit in week 4, study participants were instructed to revert to their routine care.

2.5 | Assessments

The Triangle of Wound Assessment Form is a guide for clinicians and practitioners to assess all aspects of the wound before a specific wound management plan is prepared. This ensures that the wound bed, wound edge and periwound skin are thoroughly assessed with specific attention to level and type of exudate, debridement (removal of non-viable tissue), bacterial burden and right level of moisture.[32]

2.6 | Endpoints

The primary endpoint was percentage of wound area reduction (WAR) during the investigational test period of 4 weeks. The wound area was measured from the photographed wound border with a wound measurement ruler next to the wound for calibration,[33–35] and the size

difference between the wound sizes measured at the first and the last scheduled clinic visits was calculated.

The secondary endpoint, total costs, was employed to assess the cost-effectiveness of the investigational product compared to SoC. This was evaluated by the mean difference in total treatment costs between the two treatments over the course of the study period, based on the number of products used and the unit price of the dressing at the time of last patient out.

Exploratory endpoints included the percentage wound depth reduction; dressing conformability; visual assessment of the wound bed, wound edge and peri-wound skin; the number of responders, defined as participants reaching ≥30% wound area reduction and the number of wounds healed within the 4 weeks treatment period.

2.7 | Statistics

2.7.1 | Sample size

The sample size calculation was based on assumptions from a previous meta-analysis of randomised controlled trials using a bordered Silicone foam dressing with silver which has the same 3DFit™ Technology properties as the dressing in the current study without silver, in hard-to-heal VLU with normally distributed data, assuming a similar standard deviation (SD) of wound area reduction of 43%.[36] To account for an assumed 20% dropout rate, a sample size of 50 participants in each arm was required. With this sample size, the power to obtain a 95% confidence interval for the difference in mean WAR within the limits of ±21% was 80%.

2.7.2 | Study populations

Two study populations were predefined for the statistical analyses. An intention-to-treat (ITT) population was defined as the full analysis set including all randomised participants with valid informed consent who had been exposed to at least one product. Additionally, a per protocol (PP) population was defined with the aim to identify a treatment effect under optimal conditions and support the validity of the findings with the ITT population. The PP population was a subset of the ITT population with a predefined criteria which included participants who fulfilled the inclusion/exclusion criteria, did not use other dressings than the randomised dressing during the study, did not shift therapy during the study and/or did not have a wound infection during the study.

2.8 | Analyses

The primary endpoint, the *percentage wound area reduction* (WAR) after 4 weeks of treatment, was evaluated by an analysis of variance with treatment and wound type (VLU and DFU) as fixed effects and wound area at baseline as covariate. The mean WAR for each treatment group and the corresponding 95% CI were estimated, and the differences in mean including the 95% CI between the two treatments were determined.

The secondary endpoint, *total treatment cost*, was calculated as the number of products used during the investigational period multiplied by the unit price of the product which was extracted from the Drug Tarif Part IXA[37] on the date of 'Last Patient Out'. The mean cost for each treatment and corresponding 95% CI was estimated based on a linear model with treatment as a fixed effect assuming cost data to be normally distributed. It was tested on a 5% test level if the difference in mean cost between the two treatment arms was significant, and the difference was presented as a reduction compared to the estimated cost for SoC.

The exploratory endpoints included percentage wound depth reduction, which was analysed by the same model as described for the primary endpoint but with wound depth at baseline as a covariate. Finally, the number of responders, defined as a subject reaching ≥30% wound area reduction, and the number of wounds healed within the 4-week investigation period were analysed by a logistic regression model with treatment and wound type (VLU or DFU) as fixed effects and wound area at baseline as covariate. Dressing conformability, visual assessment of the wound bed, wound edge and peri-wound skin were summarised by treatment group.

Finally, adverse events and device deficiencies were listed and summarised using descriptive statistics. Continuous variables were presented as mean, SD, minimum and maximum and as numbers and percentages for categorical variables. All analyses were performed using SAS 9.4 software (SAS Institute Inc., Cary, NC, USA).

3 | RESULTS

A total of 103 participants with either a VLU or a DFU were assessed for eligibility. One participant was excluded due to a screening failure, leaving 102 for randomisation with 51 participants in each treatment arm as part of the ITT population (Figure 1).

All 102 participants were part of the ITT population, whereas only a subset of the ITT population constituted the PP population. The 25 participants not part of the PP population (29% and 20% from the investigational

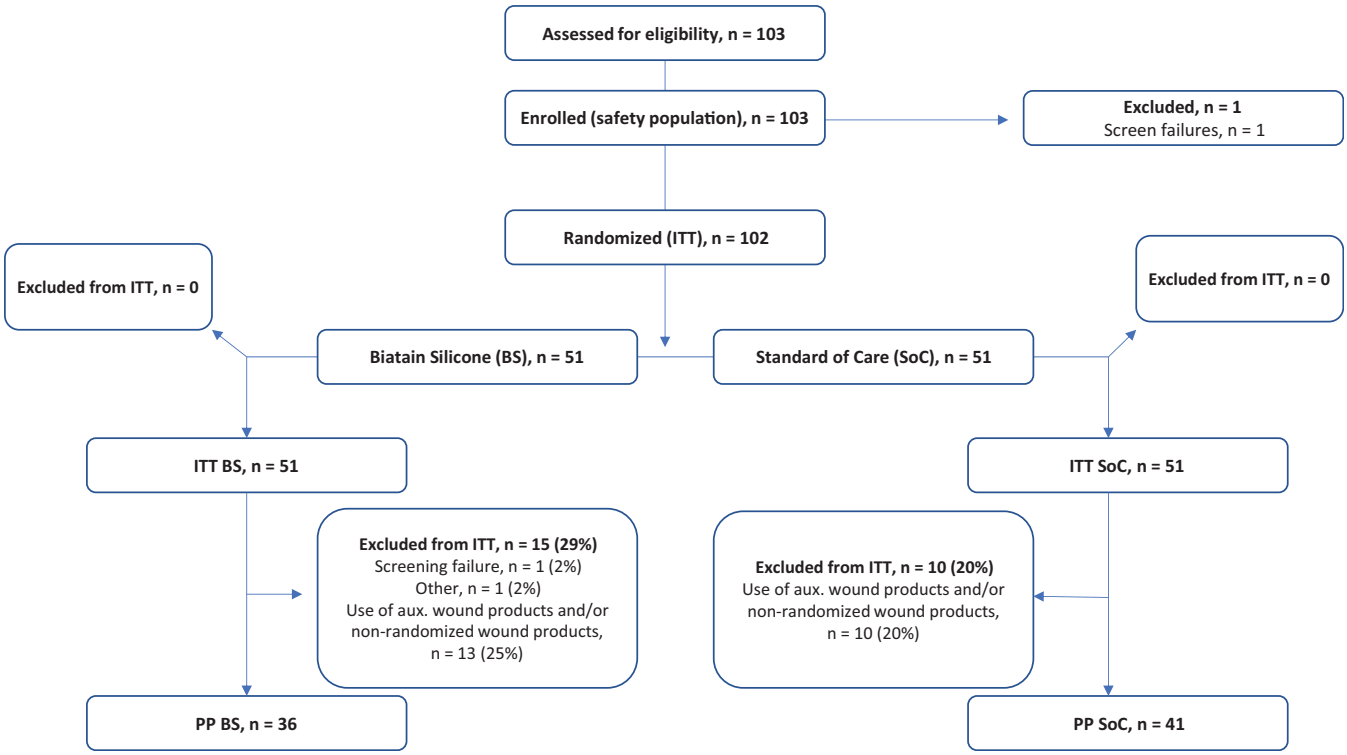

FIGURE 1 Study flow chart. ITT, intention-to-treat; PP, per protocol.

dressing group and SoC group, respectively) were excluded if they did not fulfil the inclusion/exclusion criteria, had used other dressings than the investigational test product(s) during the study period, had a wound infection during the study period or shifted therapy during the study period. This left 77 study participants for the PP analyses, 36 in the investigational dressing group and 41 participants in the SoC group (Figure 1).

3.1 | Baseline patient characteristics

As presented in Table 1, all baseline characteristics were similar between the intervention and control group. There was a higher percentage of men (56.9%), mean age was 71.6 years and mean body mass index was 30.4 kg/m^2. Furthermore, there was a higher number of participants with VLU, $n = 79$ (77.5%), compared to DFU, $n = 23$ (22.5%), and almost all female participants enrolled had a VLU compared to DFU (42 vs. two participants). Comorbidities primarily reflected the underlying wound cause. Hence, all participants with a VLU (100%) had venous insufficiency and all participants with DFU (100%) had diabetes. In addition, cardiopulmonary conditions (52.2%) and peripheral artery disease (47.8%) were most common among patients with DFU, whereas other comorbidities (27.5%) and cardiopulmonary conditions (24.4%) were more prevalent among VLU patients (Table 1). A higher number of patients in the intervention group were smoking compared to the control group (17.6% vs. 7.8%).

3.2 | Baseline wound characteristics

Participants' wound age ranged from 2 to 23 months with a mean of 5.4 months and a mean wound depth of 2.5 mm (Table 1). Mean wound area was 5.8 cm^2 for the entire population, ranging between 0.07 and 40 cm^2 with the investigational dressing and 0.13–26 cm^2 with the SoC dressing.

The assessment of the wounds at baseline demonstrated an overall equal appearance and balance in terms of the wound condition (Table S3). In summary, most wounds were moderately exuding, the consistency primarily of the watery/thin type, and none with purulent exudate.

At baseline however, the investigational dressing group showed greater wound friability, with 28% of wound exudate appearing pink/red and only 10% appearing clear. This was in contrast with the SoC group, where only 15.7% of the wounds' exudate were pink/red and 21.6% were clear. Additionally, for the periwound skin, a smaller proportion of wounds in the investigational dressing group was assessed as 'nothing abnormal', with slightly more callus and dry skin, macerated and

TABLE 1 Baseline characteristics for patients in the intention-to-treat population.

	Investigational dressing ($n = 51$)	SoC dressing ($n = 51$)	Total ($n = 102$)
Wound type (stratification factor) (n, %)			
VLU	39 (76.5)	40 (78.4)	79 (77.5)
DFU	12 (23.5)	11 (21.6)	23 (22.5)
Gender (n, %)			
Female	21 (41.2)	23 (45.1)	44 (43.1)
Male	30 (58.8)	28 (54.9)	58 (56.9)
Age [years], mean (SD)	69.7 (12.0)	73.5 (12.0)	71.6 (12.1)
Min; max	40; 89	49; 94	40; 94
BMI [kg/m^2], mean (SD)	30.4 (7.8)	30.4 (9.6)	30.4 (8.7)
Min; max	16; 58	19; 61	16; 61
Comorbidities (n, %)			
Diabetes	16 (31.4)	16 (31.4)	32 (31.4)
Venous insufficiency	41 (80.4)	43 (84.3)	84 (82.4)
Peripheral arterial disease	5 (9.8)	8 (15.7)	13 (12.7)
Cardiopulmonary conditions	19 (37.3)	13 (25.5)	32 (31.4)
Immune deficiencies	2 (3.9)	3 (5.9)	5 (4.9)
Other	12 (23.5)	14 (27.5)	26 (25.5)
Substance use			
Smoking, n (%)	9 (17.6)	4 (7.8)	13 (12.7)
Alcohol, n (%)	14 (27.5)	16 (31.4)	30 (29.4)
[Units/week], mean (SD)[a]	7.0 (6.0)	7.3 (8.6)	7.1 (7.3)
Wound age [months], mean (SD)	5.1 (4.4)	5.7 (4.8)	5.4 (4.6)
Min; max	2; 22	2; 23	2; 23
Wound depth [mm], mean (SD)	2.3 (2.0)	2.7 (2.3)	2.5 (2.2)
Min; max	0; 11	1; 10	0; 11
Wound area[b] [cm^2], mean (SD)	6.1 (8.8)	5.6 (6.1)	5.8 (7.5)
Min; max	0.07; 40	0.13; 26	0.07; 40

Abbreviations: BMI, body mass index; DFU, diabetic foot ulcer; SD, standard deviation; SoC, standard of care; VLU, venous leg ulcer.
[a]Mean and (SD) for participants who drink, only.
[b]Subtracted islands.

excoriated, compared to the wounds in the SoC group (48.0% vs. 68.6%) (Table S3). Finally, the proportions of wound edges defined as 'nothing abnormal' were similar in both groups (62% and 66.7% for the investigational and SoC group, respectively), whereas ~24% of the wound edges were macerated for both groups.

3.3 | Wound dressing performance

After 4 weeks of treatment, the investigational dressing resulted in a mean WAR and 95% CI in the ITT population of 54.3% (37.1%; 71.5%) compared to 43.0% (26.5%; 59.6%) with the SoC dressing and a mean difference of 11.3% (−10.2%; 32.9%) ($p = 0.299$). There was neither a significant difference in WAR between the two stratification groups (DFU ($n = 23$, mean = 47.0% [24.1%; 70.0%]) and VLU ($n = 79$, mean = 50.4% [38.2%; 62.6%])) nor a significant effect of wound area at baseline (covariate) ($p = 0.697$). Results on WAR for the PP population supported these results (Table 2).

Similarly, a slightly larger mean wound depth reduction (WDR) of 72.0% was observed after 4 weeks of use with the investigational dressing compared to 60.7% with the SoC dressing. The mean difference in percentage points was 11.4% (4.8–27.5), which was not statistically significant ($p = 0.165$). Results were supported by the analysis in the PP population (Table 2).

Progression to healing was evaluated in a responder analysis for those where WAR after 4 weeks was more

TABLE 2 Wound reduction estimates and differences between the investigational dressing and SoC dressing.

	Investigational dressing, mean estimate (95% CI)	SoC dressing, mean estimate (95% CI)	Mean difference (95% CI)	*p*-value
% WAR—ITT	54.3% (37.1; 71.5)	43.0% (26.5; 59.6)	11.3% (−10.2; 32.9)	0.299
% WAR—PP	54.6% (30.7; 78.6)	37.9% (15.4; 60.5)	16.7% (−8.8; 42.2)	0.195
% WDR—ITT	72.0% (59.5; 84.5)	60.7% (48.3; 73.0)	11.4% (−4.8; 27.5)	0.165
% WDR—PP	65.2% (50.5; 79.8)	56.8% (42.1; 71.6)	8.3% (−8.0; 24.6)	0.311

Abbreviations: CI, confidence interval; ITT, intention-to-treat; PP, per protocol; SoC, standard of care; WAR, wound area reduction; WDR, wound depth reduction.

than or equal to 30%. This applied to 76% (59%; 87%) of the wounds with the investigational dressing compared to 71% (55%; 84%) with the SoC dressing with an estimated odds ratio = 1.24 (0.49; 3.14) ($p = 0.643$). The difference in responder analyses was not affected by the stratification groups, DFU and VLU ($p = 0.626$) nor the wound area at baseline (the covariate) ($p = 0.361$).

For the investigational dressing, 8 out of 47 wounds had healed after 4 weeks (17%) and 12 out of 50 wounds (24%) had healed with the SoC dressing. Wound size at baseline had a significant effect on the results ($p = 0.004$) in the analysis of healed wounds after 4 weeks, whereas the analysis was not affected by the stratification groups (DFU and VLU) (p-value = 0.204). With an estimated odds ratio = 0.52 (0.17; 1.59) ($p = 0.251$), the difference in proportions was not significant.

In terms of the ability of the dressing to fill out the entire wound bed, the dressing conformability was evaluated on a five-point scale by the PI. To ensure that the assessment was evaluated for participants who had only used the randomised dressing, results were based on the PP population. After 4 weeks of treatment, 38% of the remaining participants applying the investigational dressing ($n = 29$) had a very good conformability, 52% had a good conformability and 10% had an acceptable conformability compared to 39%, 55% and 7% in the SoC group ($n = 31$). None of the dressings had poor nor very poor conformability (Figure 2).

At the last visit, the *Triangle of Wound Assessment Form* was completed for 39 participants with the investigational dressing and 38 participants with the SoC dressing. Despite an overall similar assessment, the proportions of periwound skin defined as 'nothing abnormal' at week 4 had exchanged, so that a higher proportion of patients with the investigational dressing ($n = 28/39$, 71.8%) was now defined as 'nothing abnormal' compared to baseline ($n = 24/50$, 48%), whereas for the SoC dressing, a smaller proportion of the periwound skin was assessed as 'nothing abnormal' after 4 weeks ($n = 21/38$, 55.3%) compared to baseline (35/51, 68.6%),

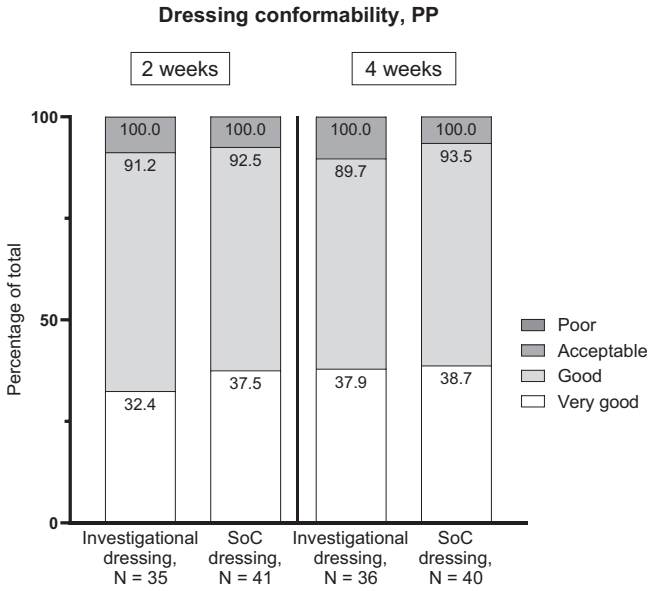

FIGURE 2 Accumulating percentage of total PP population with wound bed conformability of the dressing evaluated by principal investigator after 2 and 4 weeks on a five-point scale: White, very good; light grey, good; dark grey, acceptable; very dark grey, poor and black, very poor. N, number; SoC, standard of care.

corresponding to an increase of 24% points and a decrease of 13% points, respectively (Figure 3, Table S4).

3.4 | Dressing costs

The total costs were calculated only for those participants who completed the study ($n = 47$ with the investigational dressing and $n = 50$ with the SoC dressing) in the ITT population. However, completed participants in the ITT population also included participants who used other non-randomised wound dressings during their dressing change (corresponding to seven dressing changes with the investigational dressing and 25 with the SoC dressing) as depicted in Figure 1. For 19 out of these 32 non-randomised dressing changes (seven with the

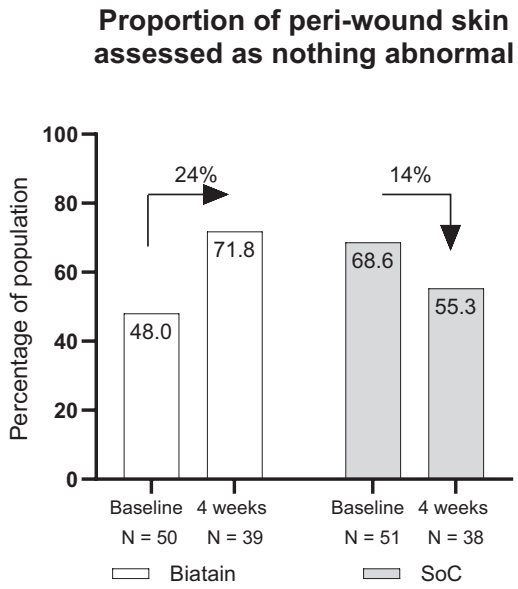

FIGURE 3 Assessment of the periwound skin as 'nothing abnormal' based on the Triangle of Wound Assessment Form at baseline and at week 4 in the intention-to-treat population. SoC, standard of care.

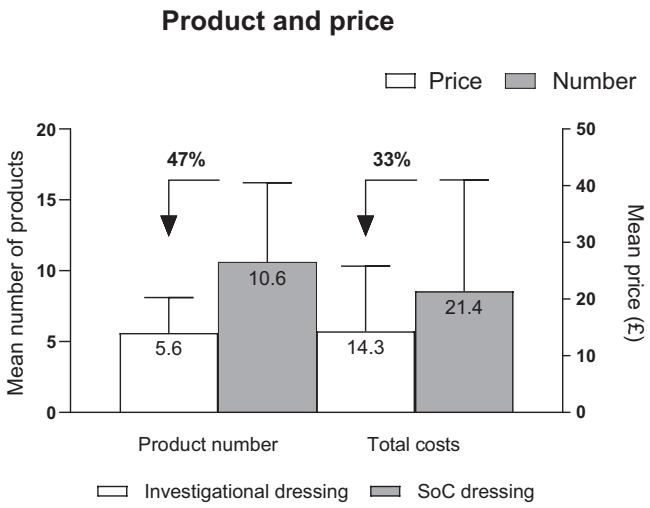

FIGURE 4 Mean number of dressings and total costs (SD) during the 4-week study period in $N = 47$ participants with the investigational dressing and $N = 50$ with the standard of care (SoC) dressing for the intention-to-treat population.

investigational dressing and 12 with the SoC dressing), the price was unknown, and therefore, the cheapest investigational dressing was applied (£1.59) instead.

As depicted in Figure 4, the mean of the estimated total costs and 95% CI for the 4-week study period was £14.3 (£9.6; £19.0) for participants using the investigational dressing compared to £21.4 (£16.9; £26.0) for participants using the SoC dressing, corresponding to a significant mean difference of £7.11 (£−13.64; £−0.57) ($p = 0.033$) and a cost reduction of 33%. When only participants using the randomised dressings were included, and no auxiliary wound care products impacting wound healing were allowed (i.e., the PP population), total costs were similarly reduced by 38% ($p = 0.028$).

The mean number of products used in the 4-week treatment period was 5.6 (SD = 2.5) for those applying the investigational dressing and 10.6 (SD = 5.6) with the SoC dressing, corresponding to a 47% product reduction (see Figure 4). The product consumption in the PP population correspondingly led to a 49.5% reduction. Hence, the number of products used and total costs were independent of the use of auxiliary wound care products expected to impact wound healing (Figure 1).

3.5 | Adverse events

There were two serious adverse events (AE) not related to test products and 11 related AEs which were similar in the two groups, all mild or of moderate severity.

4 | DISCUSSION

This is the first randomised controlled clinical trial comparing a single wound dressing, a Silicone foam with 3DFit™ Technology, with SoC (a filler combined with a secondary dressing). Results showed that the clinical performance of the investigational dressing was equally effective, while costs were significantly lower than SoC dressing over a 4-week study period.

Due to their chronic nature, wound management is today largely handled in the community setting[2,10,38] delivered by 'generalist' nurses with limited experience in wound care and wound care training.[2] Consequently, wound management outside the specialised field often result in non-evidence based choice of products which may become rooted in general practice and in the community setting[7,39] at the expense of true evidence-based and value-based treatment.[8] For example, the costs of an unhealed wound are 4.5 times greater than the costs for managing a healed wound, which outlines the importance of specialised wound care training as a mean to reduce complications that maintain wounds in a chronic or non-healing state.[10,40]

To ensure a successful and value-based wound management in the community, increased focus on specialised wound care for physician, nurses and patients, and understanding of the technical properties of the plethora of available dressings, is an essential requirement. This view is supported by several wound associations, for example, The American College of Wound Healing and

Tissue Repair (ACWHTR), The American Board of Wound Management (ABWM), European Wound Management Association (EWMA) and The Wound Ostomy and Continence Nurses (WOCN) Society.[41] Hence, various instruments such as the T.I.M.E framework,[42] the Triangle of Wound Assessment[32] and the Wound Care Pathway[43] have been devised. These serve as practical guides for comprehensive and continuous evaluation of a patient's wound and comorbidities and facilitate an appropriate management strategy.

4.1 | Dressing variation and cost implications

Healthcare consumables, including wound dressings, expenditure of auxiliary wound care products, management procedures during dressing change and time spent by the caregiver, are some of the main drivers of hospital budgets which may affect disinvestment of expensive products, introducing cheaper and low-value products at the expense of high-value products which are more expensive on the short run but with better investment on the long run.[7,19]

However, dressing selection has become a complex decision, affected by the plethora of continuously new dressings, either alone or used in combination. In 2020, Guest and co-workers reported that only 1% of patients from the UK Health Improvement Network (THIN) database were prescribed the same dressing for the duration of their wound. Instead, the average patient was prescribed a mean of eight different dressing types.[2] Similar dressing variations were observed in a convenience sample of 49 patients across primary and secondary care settings with low to highly exuding wounds of different aetiologies. Seventy-two percent used more than one dressing, 45% used two dressings and 27% used three or more dressings,[16] which clearly highlight an unwarranted practice variation with little consistency and standardisation of care.[2]

Hydrofiber and other gelling fibres have been the SoC in the treatment of exuding acute and chronic wounds ever since its market entrance in the 1990s. Due to its technical abilities, this product has been established as the first dressing choice to handle excess amounts of exudate in both hospital and community settings.[19,44] In addition, this dressing is often preferred over an alginate dressing, due to its easy application and removal, longer wear time and decreased costs.[45] However, these fibres typically require a secondary dressing to keep it in place. Therefore, a simplified dressing regime with only one dressing, to avoid handling of multiple dressings, can potentially support self-management, when possible. Beyond saving expensive nursing hours, patients potentially have more freedom to handle their own wounds which is known to increase patients' empowerment and life quality.[18]

In the current study, the use of the Silicone foam dressing with a 3DFit™ Technology compared to SoC demonstrated a 33% cost reduction which was likely associated with the lower consumption of product used in the investigational group compared to the SoC group. The confirmation of results in the PP population demonstrated that the reduced cost was independent of the use of auxiliary wound care products, which could otherwise have impacted healing. Therefore, the use of Silicone foam with 3DFit™ Technology entails a cost-saving opportunity in chronic wounds compared with SoC which is in line with results from a previous case series study.[16] Similarly, a budget-impact model has previously demonstrated cost reductions between 18% and 48% when wound filler consumption was minimised and replaced by the Silicone foam dressing with 3DFit™ Technology.[46]

4.2 | Healing outcomes

Wound closure as a performance criterion is the internationally agreed golden standard for evaluating wound dressing effectiveness. This is especially true for acute wounds, whereas for complex and hard-to-heal wounds, the percentage of healing, pain reduction and slough are more relevant outcomes.[47] However, due to the heterogeneity of wounds and their healing trajectories as well as the length of time and large number of participants required for a trial to measure complete wound healing, other outcomes and proxy measures using shorter healing rate outcomes have been proposed.

These surrogates include gross area reduction, percentage wound area reduction (WAR) and wound margin advance (WMA).[48] Percentage WAR has been used in a multitude of RCTs[11,49–52] and can be used to describe the extent to which an otherwise non-healing wound off-tracks its current trajectory.[48] Hence, when healing trajectories were compared in a group of VLU patients ($n = 232$) between those that healed completely and those with non-complete wound healing, there was a statistically significant difference between the trajectories of the two groups.[51] In addition, within the first 4 weeks, the trajectory of percentage WAR follows a linear curve and therefore provides valuable information about the early healing process to identify hard-to-heal wounds that fail to respond to SoC. WAR can therefore be an efficient way to compare treatments and reduce the burden for both the patient and for the healthcare system as early as

possible. When wound healing of VLU was measured with two different dressings after 6 weeks and in a subgroup after 24 weeks, wounds consistently advanced inwardly over time, showing the largest reduction at week 4 and 6 and a slower inward advance at week 24.[11] This supports the notion that hard-to-heal wounds can be distinguished from wounds that are healing in their early trajectories.[51]

In the current study, % WAR and % WDR over 4 weeks were comparable between the two treatment arms and consistent for both the PP and the ITT population, with a slightly larger reduction for those using the investigational dressing. These results demonstrate how a single Silicone foam dressing with the 3DFit Technology™ performs equally well to the SoC with a filler and a secondary dressing.

Moreover, a responder analysis was performed as an additional indicator of wounds which responds to treatment in the initial treatment phase. A percentage area reduction of less than 20%–40% has previously been suggested as a reliable indicator of wounds not responding well to the initial treatment,[53] hence the decision in the current study to use a value of 30%. After 4 weeks of treatment, more than 70% of the wounds responded to treatment and the proportion of wounds in each treatment group was comparable. A number of characteristics, indicative of hard-to-heal ulcers, applied for those patients who did not meet the responder criteria ($n = 16$ in the investigational dressing group and $n = 16$ in the SoC group, ITT) that were age, wound age and number of comorbidities.

During conduct of the investigation, several dressing changes (47% and 45% in the investigational dressing group and the SoC dressing group, respectively) unexpectedly involved a variety of other wound care products (not specified nor prohibited in the protocol). An external medical wound specialist was consulted to discuss the implication of these products. Most of these changes involved products with no effect on wound healing, for example, barrier film and rinse free cleanser which were used in combination with the randomised dressing. Participants who had used these products were therefore eligible for the PP population. However, for 17 participants (10 in the investigational dressing group and 7 in the SoC dressing group), a number of auxiliary wound care products were applied which were likely to impact wound healing and hence the primary endpoint. These included activated charcoal dressing, hydrophobic microbe-binding wound dressings, gel/alginate dressings with antimicrobials, iodine containing dressings and antimicrobial dressings with silver. Participants who had used these products or otherwise had violated the PP criteria were therefore not eligible for the PP population (Figure 1). Nonetheless, results in the PP population confirmed the results from the ITT population and thereby demonstrated independence from use of auxiliary wound care products which were indicative of habitual tendencies.

Moreover, when the HCP evaluated the conformability, which is a key criterion for effective dressings,[14] both dressing regimens were assessed comparable in both the ITT and the PP population. This assessment confirms that the 3DFit™ Technology is as effective as a filler and is a validation of the investigational dressing's ability to manage exudate and to minimise the gap between the wound bed and the dressing.[54] These findings underscores the cost-saving potential of this single-dressing regimen, as it eliminates the need for a filler.

Healing outcomes were supported by the Triangle of Wound Assessment, as depicted in Figure S1. Although the initial assessment of the wound bed, exudate, wound edge and periwound skin was comparable, wounds with the investigational dressing were assessed slightly worse at baseline and slightly better at end of treatment. This trend led to a greater positive change for those applying the investigational dressing compared to the development observed from baseline to end of trial with the SoC dressing (Figure 3). However, Figure 3's depiction of this trend does not consider wounds that have healed. Moreover, there was no noticeable difference in the progression of exudate levels or the condition of the wound bed and results indicated that both dressing regimens were effective in managing and reducing exudate as well as slough as detailed in Table S4.

Finally, even though smoking is generally considered a risk factor for complex wound healing,[2,35] smoking did not seem to affect healing rates in the current study. Eleven of the patients with an unhealed wound were smokers (14%), and two out of the 20 participants with a healed wound were smokers (10%).

4.3 | Environmental impact

Deciphering the life cycle assessment (LCA) of the overall environmental impacts, caused by wound care products, from its raw material acquisition, its production, use and waste, will be increasingly important to demonstrate potential CO_2 reductions. For example, improved healing rates and recurrence rates will reduce the total number of wound products used and the volume of waste produced when wound care management is evidence-based. This, in turn, will have a positive environmental impact.[55] Accordingly, healthcare systems around the world are increasingly evaluating environmental, social and corporate governance (ESG) factors in their medical device,

wound care purchasing and procurement decisions. Initiatives such as the 'gap challenge' which uses one dressing instead of a filler and secondary dressing in wounds up to 20 mm depth have previously reported the environmental benefits by reducing plastic, packaging, distribution and manufacturing resources.[56] Hence, when switching from SoC (a filler combined with a secondary dressing) to the Silicone foam with a 3DFit™ Technology dressing, gelling fibre usage was reduced by 22 200 over a 12-month period, which in turn saved raw manufacturing materials and packaging.[56]

4.4 | Strength and limitations

This is the first randomised controlled clinical trial comparing a single wound dressing, Silicone foam with a 3DFit™ Technology, with a two-dressing regime (a filler combined with a secondary dressing). The study was performed at multiple sites applying digital planimetric imaging which has been proposed as an accurate and reliable method to measure wound size.[34,57]

To account for potential necrotic tissue and underlying inflammation beneath the scab which could have made the wound area appear larger, debridement prior to wound measurement was performed and islands/bridges of epithelised tissue were subtracted from total wound area. Moreover, despite a potential risk of size variability depending on the angle of the photo taken, a prior validation study showed a high level of consistency in the wound measurements evaluated from photos between the two blinded tissue viability nurses. The measured wound areas are therefore expected to present a consistent and true area of the wound.

Even though wound closure is the internationally agreed gold standard for evaluating the effectiveness of wound dressings, a clinical trial with complete wound healing as an endpoint is a lengthy and costly endpoint, given the length of time and large number of participants required. Therefore, WAR over 4 weeks has been shown as a reliable and well-established indicator for progression to healing.[48,53]

Finally, despite the aim of a more balanced enrolment of VLU and DFU patients, most participants had a VLU. An equal enrolment would have allowed powerful subgroup analyses and insights into healing patterns based on wound type.

5 | CONCLUSION

With this RCT, the Silicone foam with a 3DFit™ Technology has been shown to be a cost-effective dressing, with a comparable effectiveness for wound healing for both VLU and DFU, at a significantly lower cost compared to SoC.

This simplified one-dressing treatment regime entails a cost-saving approach, requiring fewer number of products per patient, freeing up time and costs associated with dressing change which is an added benefit to the patients, the healthcare providers and the environment.

ACKNOWLEDGEMENTS

The authors would like to thank the clinical team, Helle Doré Hansen for the statistical analyses and Paddy Markey for his scientific review of the manuscript.

CONFLICT OF INTEREST STATEMENT

This study was sponsored by Coloplast. Faculty Health & Wellbeing, University of Winchester and Pioneer Wound Healing and Lymphoedema Centres were paid a fixed price by Coloplast A/S to conduct the study. However, Professor David Voegeli (DV) and Clinical Director John McRobert (JMR) have not received compensation for their involvement in this publication, and their contribution to the manuscript was based on a strictly scientific collaboration. Nayla Ayoub (NA), Trine Sperup (TS) and Malene Hornbak Landauro (MHL) were Coloplast A/S employees during the study, and all took part in the interpretation and writing of the manuscript.

DATA AVAILABILITY STATEMENT

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

ORCID

David Voegeli https://orcid.org/0000-0003-3457-7177
Malene Hornbak Landauro https://orcid.org/0000-0003-4479-428X

REFERENCES

1. Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that wounds impose on the National Health Service in the UK. *BMJ Open*. 2015;5(12):e009283.
2. Guest JF, Fuller GW, Vowden P. Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013. *BMJ Open*. 2020;10(12):e045253.
3. Committee HoCH. The Nursing Workforce-Second Report of Session 2017–19: HC353. 2018.
4. Griffith R. In: IfFSaUo M, ed. *The Costs of Obesity*. Economic and Social Research Council; 2023.
5. Carter MJ, Fife CE, Walker D, Thomson B. Estimating the applicability of wound care randomized controlled trials to general wound-care populations by estimating the percentage of individuals excluded from a typical wound-care population in such trials. *Adv Skin Wound Care*. 2009;22(7):316-324.

6. Programme NWCS. Preventing and improving care of chronic lower limb wounds implementation case. 2020.
7. McInnes E, Harvey G, Hiller JE, Phillips R, Page T, Wiechula R. Factors affecting procurement of wound care products: a qualitative study of hospital managers and clinicians. *Aust Health Rev*. 2021;45(1):66-73.
8. Posnett J. Value-based procurement in wound care. *Wounds UK*. 2022;18(1):42-49.
9. Caroline Dowsett CH, Keast D, Greenstein E, et al. Paving the way for effective wound care education for the non-specialist—developing five evidence-based wound type specific pathways. *Wounds Int*. 2023;4(3):34-42.
10. Drew P, Posnett J, Rusling L. The cost of wound care for a local population in England. *Int Wound J*. 2007;4(2):149-155.
11. Joergensen B, Blaise S, Svensson AS. A randomised, open-label, parallel-group, multicentre, comparative study to compare the efficacy and safety of Exufiber® with Aquacel® Extra™ dressings in exuding venous and mixed aetiology leg ulcers. *Int Wound J*. 2022;19:22-38.
12. Santamaria N, Woo K, Beeckman D, et al. Clinical performance characteristics for bordered foam dressings in the treatment of complex wounds: an international wound dressing technology expert panel review. *Int Wound J*. 2023;20(9):3467-3473.
13. Wiegand C, Tittelbach J, Hipler U-C, Elsner P. Clinical efficacy of dressings for treatment of heavily exuding chronic wounds. *Chronic Wound Care Manag Res*. 2015;2:101-111.
14. (WUWHS) WUoWHS. Wound exudate-effective assessment and management. 2019. www.woundsinternational.com
15. Ousey K, Stephenson J, Barrett S, et al. Wound care in five English NHS Trusts: results of a survey. *Wounds UK*. 2013;9(4):20-28.
16. Wilson PSH, Concannon F, Skerritt L, et al. A case series to consider the clinical effectiveness, patient satisfaction and potential health economic benefits of a silicone foam with 3DFit Technology® in the management of wounds. *Wounds UK*. 2019;15(3):54-60.
17. Braunwarth H, Von Hallern B. Conformability of a foam dressing - clinical experience based on 104 cases. Poster presented at Wounds UK Conference, Harrogate, 13–15 November 2017. Accessed April 15, 2024. https://tinyurl.com/3jpctpeb
18. Kapp S, Santamaria N. The effect of self-treatment of wounds on quality of life: a qualitative study. *J Wound Care*. 2020;29(5):260-268.
19. Sood A, Granick MS, Tomaselli NL. Wound dressings and comparative effectiveness data. *Adv Wound Care*. 2014;3(8):511-529.
20. Braunwarth H, Forster J, Schmitt M, et al. Wound depth and the need of a wound filler in chronic wounds. Poster presentation at Wounds UK Conference, Harrogate, 13–15 November 2017. Accessed April 15, 2024. https://tinyurl.com/yc5k6a2z
21. Wilcox JR, Carter MJ, Covington S. Frequency of debridements and time to heal: a retrospective cohort study of 312 744 wounds. *JAMA Dermatol*. 2013;149(9):1050-1058.
22. Brennan MR, Keast DH, Bain K, Bain M, Lorentsen B, Ayoub N. Defining wound bed conformability: a new testing methodology to assess the relative swelling rise of foam dressings. *J Wound Care*. 2024;33(5):312-323.
23. Monteiro-Soares M, Russell D, Boyko EJ, et al. Guidelines on the classification of diabetic foot ulcers (IWGDF 2019). *Diabetes Metab Res Rev*. 2020;36(Suppl 1):e3273.
24. Bui UT, Finlayson K, Edwards H. The diagnosis of infection in chronic leg ulcers: a narrative review on clinical practice. *Int Wound J*. 2019;16(3):601-620.
25. Alavi A, Sibbald RG, Phillips TJ, et al. What's new: management of venous leg ulcers: treating venous leg ulcers. *J Am Acad Dermatol*. 2016;74(4):627-640.
26. Mills N. *Polymer Foams Handbook: Engineering and Biomechanics Applications and Design Guide*. Elsevier; 2007.
27. Hiemenz PC, Rajagopalan R. *Principles of Colloid and Surface Chemistry, Revised and Expanded*. 3rd ed. CRC Press; 1997.
28. Richard M, Pashley MEK. *Applied Colloid and Surface Chemistry*. John Wiley & Sons, Ltd; 2004.
29. Coloplast AS. Biatain Silicone Instruction for Use. 2021.
30. Inc. C. Instruction for Use-AQUACEL® ExtraTM Hydrofiber® Dressing. 2016.
31. AB MHC. Mepilex Border Instructions for Use. 2019 (40337–08).
32. Caroline Dowsett BvH. The Triangle of Wound Assessment: a holistic framework from wound assessment to management goals and treatments. *Wounds Int*. 2017;8(4):34-39.
33. Gethin G, Cowman S. Wound measurement comparing the use of acetate tracings and Visitrak digital planimetry. *J Clin Nurs*. 2006;15(4):422-427.
34. Oien RF, Håkansson A, Hansen BU, Bjellerup M. Measuring the size of ulcers by planimetry: a useful method in the clinical setting. *J Wound Care*. 2002;11(5):165-168.
35. Guo S, Dipietro LA. Factors affecting wound healing. *J Dent Res*. 2010;89(3):219-229.
36. Leaper DMC, Meaume S, Scalise A, et al. The use of Biatain Ag in hard-to-heal venous leg ulcers; meta-analysis of randomised controlled trials. *PLoS ONE*. 2013;8(7):e67083.
37. Drug Tariff. NHS Business Service Authority. 2023. https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff
38. Nussbaum SR, Carter MJ, Fife CE, et al. An economic evaluation of the impact, cost, and medicare policy implications of chronic nonhealing wounds. *Value Health*. 2018;21(1):27-32.
39. Wiegand C, Hipler U-C, Elsner P, Tittelbach J. Clinical efficacy of dressings for treatment of heavily exuding chronic wounds. *Chronic Wound Care Manag Res*. 2015;2015(1):101-111.
40. Phillips CJ, Humphreys I, Thayer D, et al. Cost of managing patients with venous leg ulcers. *Int Wound J*. 2020;17(4):1074-1082.
41. Sen CK. Human wound and its burden: updated 2020 compendium of estimates. *Adv Wound Care*. 2021;10(5):281-292.
42. Schultz GS, Sibbald RG, Falanga V, et al. Wound bed preparation: a systematic approach to wound management. *Wound Repair Regen*. 2003;11(Suppl 1):S1-S28.
43. Caroline Dowsett KB, Hoffmann C, Brennan MR, et al. The wound care pathway–an evidence-based and step-by-step approach towards wound healing. *Wounds Int*. 2021;12(3):78-85.
44. Guest JF, Ruiz FJ. Modelling the cost implications of using carboxymethylcellulose dressing compared with gauze in the management of surgical wounds healing by secondary intention in the US and UK. *Curr Med Res Opin*. 2005;21(2):281-290.
45. Robinson BJ. The use of a hydrofibre dressing in wound management. *J Wound Care*. 2000;9(1):32-34.
46. Jensen L, Karlsmark T, Forster J, Brennan M. PMD35 potential cost savings in treatment of chronic wounds with first wound

bed conforming wound dressing. *Value Health*. 2019;22:S222-S223.
47. Brölmann FE, Eskes AM, Sumpio BE, et al. Fundamentals of randomized clinical trials in wound care: reporting standards. *Wound Repair Regen*. 2013;21(5):641-647.
48. Bull RH, Staines KL, Collarte AJ, Bain DS, Ivins NM, Harding KG. Measuring progress to healing: a challenge and an opportunity. *Int Wound J*. 2022;19(4):734-740.
49. Dolibog P, Franek A, Taradaj J, et al. A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. *Int J Med Sci*. 2014;11(1):34-43.
50. Hämmerle G, Strohal R. Efficacy and cost-effectiveness of octenidine wound gel in the treatment of chronic venous leg ulcers in comparison to modern wound dressings. *Int Wound J*. 2016;13(2):182-188.
51. Steed DL, Hill DP, Woodske ME, Payne WG, Robson MC. Wound-healing trajectories as outcome measures of venous stasis ulcer treatment. *Int Wound J*. 2006;3(1):40-47.
52. Waycaster CR, Gilligan AM, Motley TA. Cost-effectiveness of becaplermin gel on diabetic foot ulcer healing changes in wound surface area. *J Am Podiatr Med Assoc*. 2016;106(4):273-282.
53. Flanagan M. Wound measurement: can it help us to monitor pregressin to healing? *J Woundcare*. 2003;12:189-194.
54. David H, Keast KB, Christoffer Hoffmann T, et al. Managing the gapto promote healing in chronic wounds — an international consensus. *Wounds Int*. 2020;11(3):58-63.
55. Morton N, Adderley U, Lee R. How can we reduce the environmental impact of wound management? *Nurs Times*. 2022;118:8.
56. Coloplast AS, ed. *Environmentally Conscious Wound Care. How Can Simplification of Wound Care Help the NHS Meet its Sustainability Targets?* Wound Care Today; 2021.
57. Wendelken ME, Berg WT, Lichtenstein P, Markowitz L, Comfort C, Alvarez OM. Wounds measured from digital photographs using photodigital planimetry software: validation and rater reliability. *Wounds*. 2011;23(9):267-275.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Voegeli D, Landauro MH, Sperup T, Ayoub N, McRobert JW. Clinical performance and cost-effectiveness of a Silicone foam with 3DFit™ technology in chronic wounds compared with standard of care: An open randomised multicentre investigation. *Int Wound J*. 2024;21(12):e70074. doi:10.1111/iwj.70074