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

KEY WORDS
- 3D Fit Technology®
- Dressings
- Case series
- Silicone foam

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Background: The annual NHS cost of managing wounds was reported to be £4.5–5.1 billion (Guest et al, 2017). **Aim:** The authors conducted this case series to determine if they could offer the same quality of service while reducing associated costs. This case series considers the clinical effectiveness, patient satisfaction and potential health economic benefits of a silicone foam with 3DFit Technology® across a variety of wound aetiologies. **Method:** A convenience sample of 49 patients was selected across primary and secondary care settings. A variety of wound types were included. Silicone foam with 3DFit Technology® was used at the discretion of the clinician in all cases. Ten evaluation parameters were recorded utilising a 5-point Likert scales. These included: ease of application and removal; conformability to the wound bed; ability to manage exudate; ability to stay in place; condition of the wound bed; wound edge and periwound skin. **Results:** Results of the evaluation parameters are graphically represented, as well as the patient and clinician's feedback on the overall dressing performance compared to the previously used dressing regimen. There are a large number of wound types and care providers represented in this series across a variety of care settings. Despite many variables in this case series, the overall consensus is that this product has shown to be versatile across a wide number of wound types. **Conclusion:** The findings have shown that silicone foam with 3DFit Technology® has the potential to be a useful dressing for all types of wounds given the clinical improvements observed.

Biatain Silicone is a foam dressing with 3DFit Technology® that conforms to the wound bed to minimize the creation of dead space, therefore, reducing exudate pooling for optimal healing conditions. The conforming nature of the dressing reduces the need for primary contact layers and secondary dressings.

METHODS

The study design was a case series. A convenience sample of individuals attending wound clinics with wounds which fitted the criteria in *Table 1* were invited to participate. In total, 49 patients agreed to participate. The primary objectives were to assess the clinical effectiveness of and patient and clinician satisfaction with a silicone foam dressing with 3DFit Technology®. We wanted to assess whether this single dressing could replace our current regimen of using a primary and secondary dressing. An agreed evaluation tool was developed *(Table 2)*. Evaluation took place over a maximum of 8 dressing changes. To examine health economics, data were collected on previous dressing regimen used, frequency of dressing change, cost of previous regimen versus cost of new regimen.

With consent, the clinicians invited individuals who attended wound care clinics in Ireland to participate. A total of 49 patients took part.

Table 1. Criteria for inclusion and exclusion	
Wounds included	**Wounds excluded**
Any wound treated with a wound contact layer and secondary dressing up to and including 2 cm in depth	Necrotic wounds
Presents as low, moderate or high exudate levels	Wounds with undermining or tunnelling

Table 2. Evaluation tool

A 5-point Liker scale was used to assess all parameters, with 1 being poor and 5 being excellent. Clinicians and patients were asked to evaluate the product compared with their previous regimen. Patient comments were also collected. The parameters upon which the clinicians and patients based their appraisal of the products performance were as follows

- Ease of application
- Ease of removal
- Conformability to the wound
- Managing exudate
- Improvement in condition of the wound bed
- Improvement in condition of the wound edge
- Improvement in condition of periwound skin
- Ability to stay in place
- Performance versus previous dressing
- Patient comfort level

Figure 1. Wound type

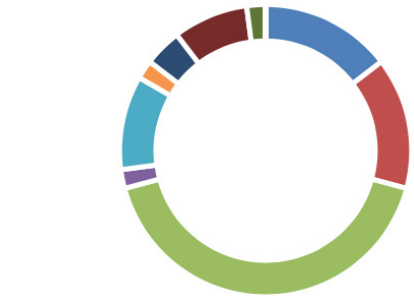


Figure 2. Wound location

RESULTS

Results are displayed in graphs and also by percentage. Percentages expressed represent scores of 3, 4 and 5 on the Likert scale, which equates to dressing performance as average, very good or excellent compared with previous regimens.

WOUND TYPE AND WOUND LOCATION

Wounds were varied in their aetiology *(Figure 1)* and anatomical position *(Figure 2)*. By chance, twenty of the wounds (41.6%) were diabetic foot ulcers.

EASE OF APPLICATION AND REMOVAL FROM THE WOUND BED

Clinicians assessment of ease of application indicated that 98% found the product easy to apply *(Figure 3)* and 100% felt the product was easy to remove *(Figure 4)*.

CONFORMABILITY AND ABILITY TO MANAGE EXUDATE

Ninety-eight per cent of the clinicians assessed the dressing as being highly conformable to the

Figure 3. Ease of application

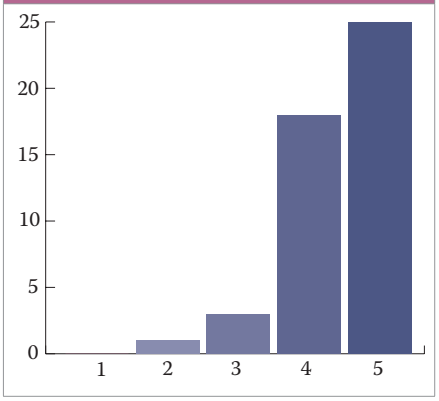


Figure 4. Ease of removal

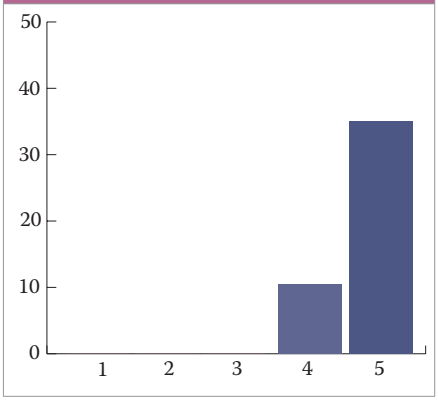


Figure 5. Conformability to the wound bed

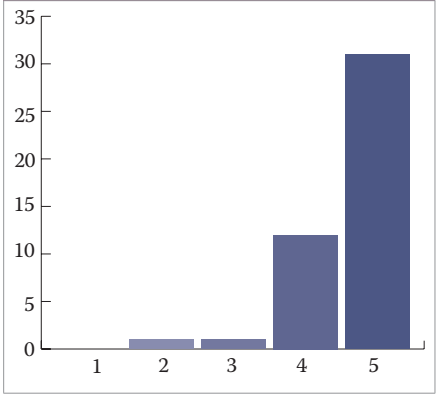


Figure 6. Ability to manage exudate

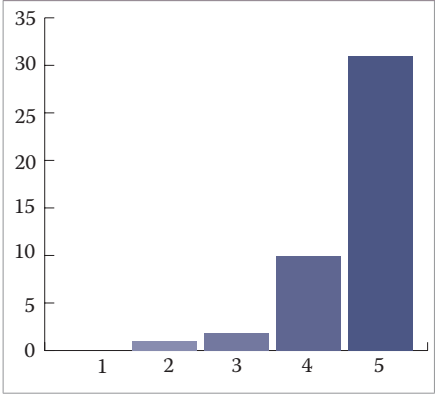


Figure 7. Improvement it wound bed

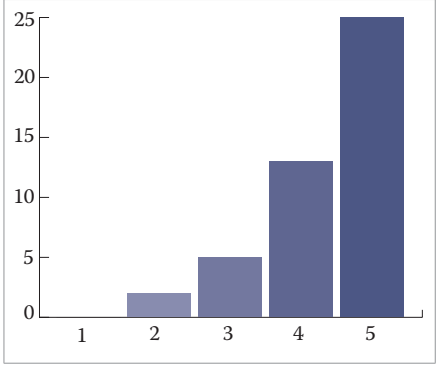


Figure 8. Improvement in wound edge

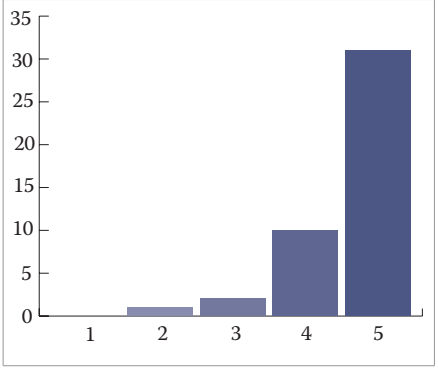


Figure 9. Improvement in periwound skin

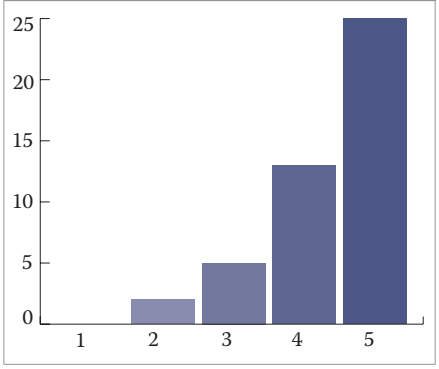
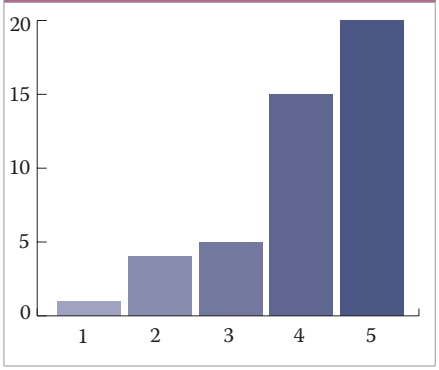


Figure 10. Ability to stay in place



wound bed *(Figure 5)*. Ninety-eight per cent rated the dressings ability to manage exudate equal to or better than previous regimens *(Figure 6)*.

IMPROVEMENT IN WOUND BED, EDGE AND PERIWOUND SKIN

Improvement in wound skin was 95% for wound bed *(Figure 7)*, 95% for wound edge *(Figure 8)* and 87% for periwound skin *(Figure 9)*. Thirty-nine patients had improvement in the periwound skin. Only four wounds saw deterioration in the periwound skin. In one patient, periwound evaluation was described as non-applicable as the skin was healthy prior to the observation period and did not change during the study. One patient had a known sensitivity to adhesives.

ABILITY TO STAY IN PLACE

Eight-nine per cent found the dressing stayed in place as well as or better than previous dressing products *(Figure 10)*. Ninety-three per cent of clinicians felt the dressing performed equal to better than previous dressings used *(Figure 11)*.

PATIENT COMFORT LEVEL

The majority of the patients (91.9%) graded the product as very good or excellent *(Figure 12)*.

FEEDBACK FROM PATIENTS AND CLINICIANS

"Patient changing dressings between appointments, finds it easy to self-care."

"Very comfortable dressing, hardly noticed it."

"Lovely dressing, does not pull on the skin when walking."

"Patient liked the way it was applied, she had only one finger on one hand and was still able to apply dressing."

DIFFERENT DRESSING TYPES AND DRESSING CHANGE FREQUENCY

Information on the types of dressings used was collected *(Figure 13)*. *Figure 14* shows the frequency of dressing changes.

The majority of nurses applied two different dressing products, however, in eight patients, three different products were used and in one patient, four different dressing products were used *(Figure 15)*.

Figure 11. Performance compared with previous dressing regimen

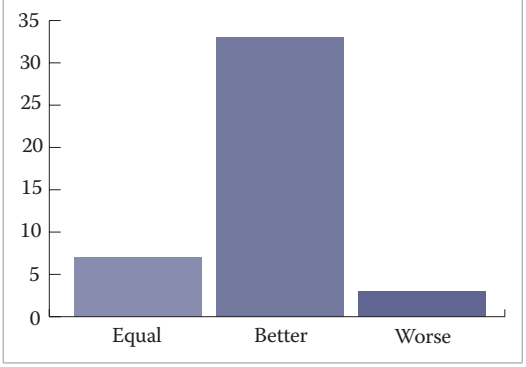


Figure 12. Patient comfort level

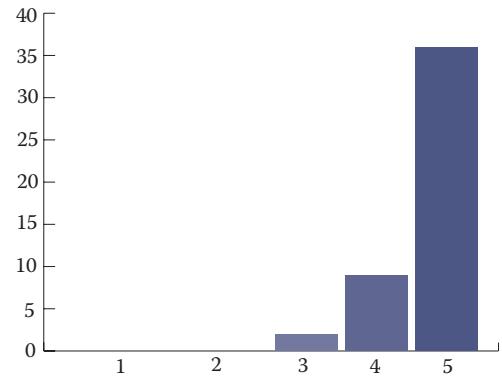


Figure 13. Type of dressing/product

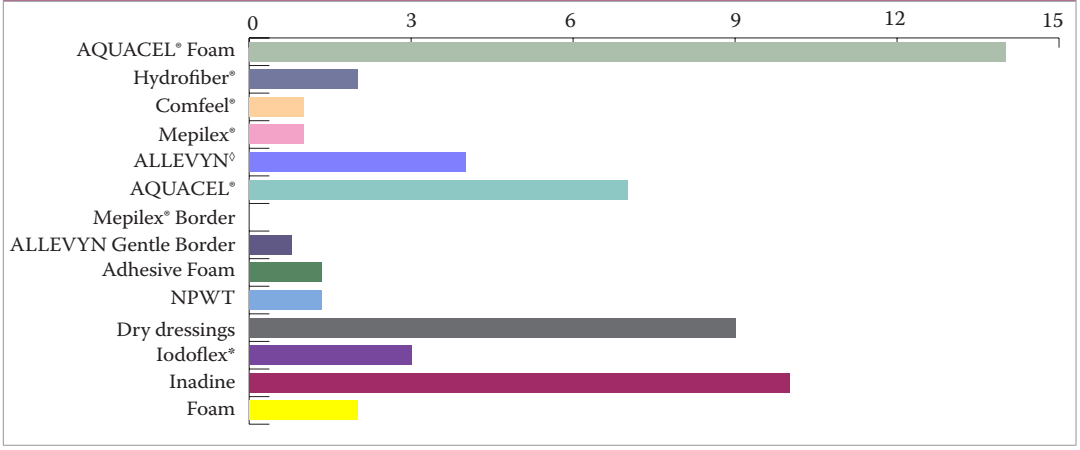


Figure 14. Frequency of dressing change

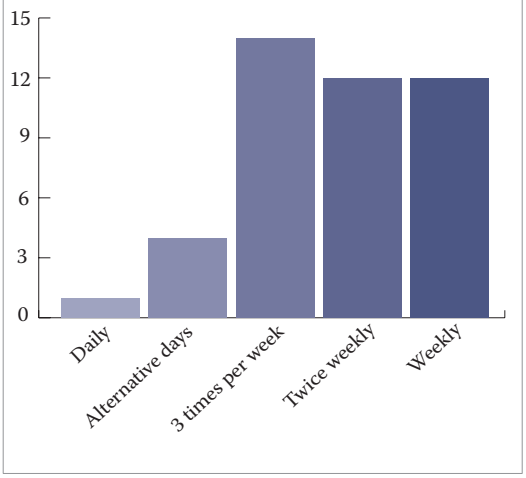
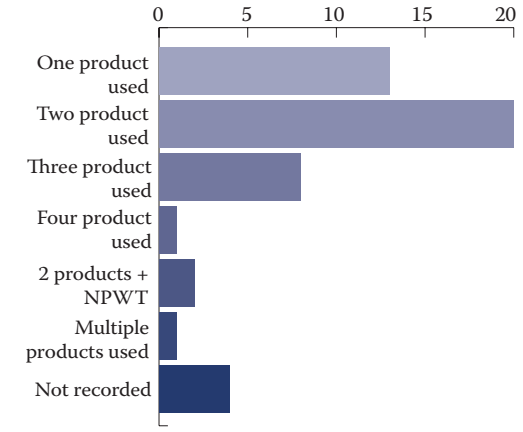


Figure 15. Number of products previously used per dressing change



COSTINGS

Although 75% or respondents reported that the performance of Biatain Silicone was better than their previously used dressing products, no change in dressing wear time was observed as clinicians maintained their habitual dressing changing regimens during the evaluations.

The unit cost analysis was carried out to compare the purchase cost of Biatain Silicone with the ten cases using a filler (eight using AQUACEL®

and two using Hydrofiber®) and a secondary dressing (nine using various types of foam and one using a hydrocolloid) combination. Based on March 2019 pricing from a community setting, the average cost of two dressings (filler and secondary dressing) was €5.06 compared with the cost of Biatain Silicone of €2.58, representing a price difference of 49%.

DISCUSSION

In this study, the authors evaluated the clinical effectiveness, patient satisfaction and potential health economic benefits of the product. In the overall assessment, the dressings properties translated to tangible clinical benefits.

Wounds of more than 2 cm in depth were excluded from this study. The rationale for this decision was based on a study of 1,009 chronic wounds, where Braunwarth et al (2017) found that the majority of the wounds reviewed (80%) were less than 2 cm in depth, on average the wounds were 0.77 ± 1.44 cm deep. This confirmed the results of a previous audit of 4,772 patients across five NHS Trusts (Ousey et al, 2013).

The clinicans used one dressing rather than two, based on the findings of an *in vivo* experiment conducted by Braunwarth and Müller (2014), which demonstrated that Biatain dressings can conform up to 2 cm towards the wound bed. To confirm these findings, Braunwarth and Von Hallen (2018) conducted a retrospective study of 104 patients with a variety of chronic and acute wounds. The study examined conformability to the wound bed using a foam dressing with 3DFit Technology® (the Biatain range of dressings). In all cases, the foam dressing conformed to the wound bed with sufficient vertical absorption. The authors also noted that there was no maceration of the wound edges and periwound skin and neither exudate pooling nor gap was observed (Braunwarth and Von Hallen, 2018). Young et al (2018) found in a cohort of patients with wounds of different aetiologies, the overall the performance of the Silicone foam was either better than or equivalent to the previous dressing products where two or more dressings were used in 80% of cases.

The results of these studies reassured the authors that they could use one dressing to replace the previous regimen of two or more dressings.

Clinical effectiveness was assessed by the clinicians' observations of the wound bed, wound edge and periwound skin. Over the observation period, assessment was made at each dressing change by comparing the dressing to the previous regimen. All parameters measured, results indicate that in the most cases, the dressing performed as well as or better than the previous dressing regimen. There was an overall 76% improvement compared with the previous dressing regimen.

Periwound skin

Observation of changes in the periwound skin is as important as examining changes in the wound bed. Clinicans saw improvement in the periwound in the majority of their patients.

Patient satisfaction and self-management

In terms of patient satisfaction, comfort is paramount. In this study, 91.6% of patients reported that the dressing was very comfortable.

An incidental finding from patient feedback was that, as there was only one dressing to apply rather than two, for those who self-managed, they felt the dressing was easy to apply. The authors felt this was important information as self-management, where appropriate, can have benefits for both the patient and the healthcare organisation.

Poole et al (2016) reported on how one NHS Trust's adult community nursing teams supported self-management for wound care. The NHS text-messaging technology was used to extend self-management guidance to patients between face-to-face contacts. Their findings were similar to ours in that, patient experiences were positive. Additionally, and importantly, the number of nursing contacts was reduced, allowing the team to focus on patients with more complex needs.

Considering the bigger picture and challenges within health care, self-management and empowering patients to become partners in the decisions about their care is essential in the current health care environment. Supporting people to lead healthy and independent lives is a key initiative of UK and Irish governmental health strategies (The Irish Department of Health Statement of Strategy (2016–2019), Health Education England (2014); Healthcare Improvement Scotland (2014); NHS Wales 1000 Lives Plus (2018)).

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Health economics

Wound care has a significant financial burden on healthcare budgets. A recent health economic calculator was developed to assess the potential cost savings of adopting 3DFit Technology® on wounds up to 2 cms in depth. The calculator was adjusted to simulate this evaluation and assumed:

- 100% wounds under 2 cms
- No undermining
- 64.58% filler consumption.

The calculator predicted that the total number of dressing units used to treat 1,000 wounds is 1,646 (filler and secondary dressing). 646 wounds could potentially save on the use of a filler and estimated a total treatment cost using a filler and a secondary dressing of €4,392 compared to €2,580 with Biatain Silicone representing a saving of 41% (Jensen et al, 2019).

The combination of physical properties offered by a silicone foam dressing with 3DFit Technology® is unique. It's ability to conform to the wound bed and eliminate dead space made it a good alternative to the previous dressing regimens, where two or more dressings were being used in combination. In terms of health economics, Biatain Silicone was able to substitute the wound filler in a group of ten patients using both a filler and a secondary dressing at the beginning of the trial. When applying unit prices from a community setting to product consumption in this subpopulation it translates to cost savings of 49%. This reduction comes from savings in product consumption alone. Factoring in reduction in time spent on staff workload by excluding wound fillers from the treatment pathway, would likely lead to further savings.

Reducing the cost of dressings is important but other elements of wound care need to be taken into consideration when we look at the true cost of wound management.

The annual NHS cost of managing wounds was estimated to be £4.5–5.1 billion (Guest et al, 2017). Within the study period, the cost per healed wound ranged from £698 to £3,998 per patient and that of an unhealed wound ranged from £1,719 to £5,976 per patient.

In Wales, researchers interrogation of the SAIL database produced a prevalence rate of 6% of people with chronic wounds in Wales and an expenditure of £3,28.8 million, which equated to an average of £1,727 per head (Phillips et al, 2015)

Both studies highlighted the costliest part of wound care was District Nurse visits. As a measure to reduce the financial burden, Guest et al (2017) suggest enhanced support for safe patient self-care.

Young et al (2018) noted feedback from clinicans and patients suggesting that the increased wear time and intuitiveness of the product's 3-piece non-touch application system may facilitate increased patient self-management. The comments the authors collected for this case series study agree with these findings. In health economic terms, the potential to reduce nursing visits may help to reduce the cost of managing wounds.

Limitations

Further research would be needed but when nursing intervention is required, replacing two products with one may assist with appropriate allocation of staff, allowing Tissue Viability Specialists to delegate dressing changes to non-specialist staff in patients with wounds of up to 2 cm in depth and no undermining, allowing the specialist to focus on patients with complex needs. Having just one dressing, takes away the risk of inappropriate use of primary dressing, and over use of dressings, making the decision framework or wound care pathway less complicated for staff.

In this case series, dressing wear time did not change; however, a study conducted in the North of England found wear time could be increased. On average, the number of days between dressing changes of their previous regimen was 3.42 days compared with 4.21 days using the silicone foam with 3DFit Technology®, representing a 23% increase in wear time (Young et al, 2018). The authors' data is limited in terms of wear time and patient self-care, and the changing face of health care prompts the need for more research in these areas.

CONCLUSIONS

While the authors acknowledge that there is no one dressing for every wound, the properties of this dressing make it a useful addition to the current portfolio of products.

The case series has shown that silicone foam with 3DFit Technology® has the potential to be a useful dressing given the clinical improvements and health economic benefits observed. WUK