Biatain® Silicone with 3DFit Technology: a clinically effective, cost-saving alternative to two-dressing regimes

The increasing prevalence of chronic wounds and the rising costs associated with treating them have prompted the healthcare industry to identify ways of improving the cost-effectiveness of chronic wound care, without adversely affecting treatment outcomes. Because it replaces the two-dressing regime with a simplified, one-dressing approach, a silicone foam dressing with 3DFit Technology should reduce costs and labour associated with chronic wound treatment.

THE STUDY

A first-of-its-kind clinical trial

We embarked on the first randomised controlled clinical trial comparing a single wound dressing (Biatain Silicone) with the Standard of Care (an Aquacel® Extra filler combined with a Mepilex® secondary dressing).[1] The goal of the study was to compare the clinical performance and cost effectiveness of a single wound dressing with the two-dressing standard.

How the study was designed

- The study was conducted in 10 hospitals and research centres in the United Kingdom, from February to December 2023.
- The study had 102 participants with an exuding, non-infected, chronic venous leg ulcer or diabetic foot ulcer, with a wound depth down to 20 mm.
- The study evaluated results after a four-week period.

What the study measured

The study measured two endpoints. The first was how much the wound area was reduced during the four-week test period. And the second was the total treatment costs during the study period.

THE RESULTS

Comparable reduction in wound area and depth in both groups

In the full intention to treat (ITT) population[2], participants with Biatain Silicone experienced a 54.3% reduction in wound area, compared with a 43% reduction for participants on the standard, two-dressing regime (p-value=0.299[2]). The same group experienced a 72% decrease in wound depth with Biatain Silicone, compared to a 60.7% decrease for participants using the Standard of Care dressing (p-value=0.165).

Significant cost reduction when using Biatain Silicone

Using Biatain Silicone resulted in significant cost reduction of 33%* (p-value=0.033) compared to the Standard of Care. Furthermore, the mean number of products was significantly lower for participants applying Biatain Silicone (5.6 products vs 10.6 for the Standard of Care), corresponding to a 47% reduction in products used.

The HCP evaluated Biatain Silicone conformability to the wound bed and found that it was as effective as the two-dressing regime, a finding which further demonstrates the cost-savings potential of a single dressing regime.

Same clinical effectiveness at a lower cost

The results show that Biatain Silicone's clinical performance was just as effective as the two-dressing regime**. This simplified one-dressing treatment regime reduces costs*, as it requires fewer products per patient and frees up time and costs associated with dressing changes. This benefits patients, healthcare providers and the environment.

1. 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).
2. Two study populations were predefined for statistical analysis. The Intention to treat (ITT) population was the full analysis set, including all randomised participants with valid, informed consent, who had been exposed to at least one product. The per protocol population was a subset defined for the purposes of identifying a treatment effect under optimal conditions to validate the findings with the ITT population. 2.A p-value of >0.05 means that the difference is not statistically significant. Thus, the results are comparable.
*Based on UK pricing data.
** In wounds up to 2 cm in depth.

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Clinical performance and cost effectiveness of a silicone foam dressing with 3DFit Technology in chronic wounds compared with standard of care: An open randomised multi-centre investigation.

A multi-centre study[1] comparing the clinical performance and cost-effectiveness of Biatain® Silicone to the current Standard of Care – an Aquacel® Extra filler combined with a Mepilex® Border secondary dressing – showed that the Biatain Silicone was equally effective[2], while being significantly more cost-efficient[3], than the two-dressing regime over a four-week study period.

Baseline *(n=102)*

77.5% venous leg ulcers

22.5% diabetic foot ulcers

43.1% female

56.9% male

Mean wound age: **5.4 months**

Mean wound depth: **2.5 mm**

Mean wound area: **5.8 cm²**

Comparable levels of conformability to the wound bed

"Very good" or **"good"** conformability to the wound bed (after four weeks):

Biatain Silicone – **89.7%**

Standard of Care – **93.5%**

Clinical performance comparison

Wound area reduction

Intention to treat population[4]:

54.3% Biatain Silicone

43% Standard of Care

Mean difference: **11.3%** p-value=0.299[5]

Wound depth reduction

Intention to treat population[4]:

72% Biatain Silicone

60.7% Standard of Care

Mean difference: **11.4%** p-value=0.165

Cost comparison

Estimated total costs (mean)

Significant cost reduction of **33%**[3] (p-value= 0.033) when using Biatain Silicone

Biatain Silicone – **£14.3**

Standard of Care – **£21.4**

Number of products (mean)

47% product reduction when using Biatain Silicone

Biatain Silicone – **5.6**

Standard of Care – **10.6**

Higher proportion with normal periwound skin

Biatain Silicone:
The number of participants with normal periwound skin after four weeks increased by: **24%**

Standard of Care:
The number of participants with normal periwound skin after four weeks decreased by: **14%**

Discussion

The results show that the Biatain Silicone's clinical performance was just as effective as the two-dressing regime[2].

Conclusion

This simplified one-dressing treatment regime reduces costs, as it requires fewer products per patient and frees up time and costs associated with dressing changes. This benefits patients, healthcare providers and the environment[3].

1. 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). 2. In wounds up to 2cm in depth. 3. Based on UK pricing data. 4. Two study populations were predefined for statistical analysis. The Intention to treat (ITT) population was the full analysis set, including all randomised participants with valid, informed consent, who had been exposed to at least one product. The per protocol population was a subset defined for the purposes of identifying a treatment effect under optimal conditions to validate the findings with the ITT population. 5. A p-value of >0.05 means that the difference is not statistically significant

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