

TECHNOLOGY UPDATE:

Biatain® Silicone dressings: A case series evaluation

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A multicentre case series was performed as a product evaluation of two new silicone wound dressings, Biatain® Silicone and Biatain® Silicone Lite (Coloplast A/S, Humlebaek, Denmark). This addressed the dressings' overall usability (focusing on comfort for the patients and dressing handling for the healthcare practitioners) in a total of 39 patients who fulfilled the evaluation criteria. All investigators rated Biatain Silicone better than previously used products. The case series found that Biatain Silicone offers patients a comfortable treatment option with optimal exudate management for all evaluated wound types, and the dressings were very easy to apply and remove and stayed in place during wear.

Chronic wounds often produce copious amounts of exudate, which can have a significant impact on patients' quality of life and place increased demands of healthcare resources.^[1,2] Excess moisture from exudate can damage the periwound skin, leading to maceration. This can increase the risk of infection and friction-related damage, with the potential for wound enlargement and delayed healing.^[3] The increased proteolytic activity of chronic wound exudate can further inhibit healing by damaging the wound bed and surrounding skin.^[4]

Absorbent dressings are the main option for managing exudate at wound level. Numerous dressings exist and these can vary in their fluid handling capabilities. Characteristics of an ideal wound dressing include maintaining moisture balance while effectively removing excess fluid from the wound bed.^[2] Effective exudate management can reduce time to healing, prevent exudate-related problems such as periwound maceration and infection, reduce dressing change frequency and improve patient's quality of life.^[2,5-7]

Biatain® Silicone and Biatain® Silicone Lite (Coloplast A/S, Humlebaek, Denmark) are two new wound dressings that combine the absorbent foam technology of Biatain foam dressings^[8] with a soft silicone adhesive.

They can be used on a broad range of exuding wounds.

In this article, the authors report the findings of a case series performed as a product evaluation in which both patients and healthcare practitioners (HCPs) assessed the dressings, by means of questionnaires, to determine the usability (focusing on comfort for the patients and dressing handling for the HCPs) of these two Biatain Silicone dressings.

METHOD

Test dressings

Biatain® Silicone and Biatain® Silicone Lite are new silicone wound dressings for moist wound healing and exudate management. Biatain Silicone is a flexible absorbent multi-layered foam dressing with a soft silicone adhesive. It is designed to expand and conform to the wound bed to facilitate absorption of exudate [Figure 1].

Biatain Silicone Lite is a thinner, more flexible version of the dressing, which can provide a closer anatomical fit to the wound and body for increased mobility.

Study design

The product evaluation took place in seven clinics or hospitals in the following countries: France, Italy, Spain and the UK. Approximately

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“The study was initiated with a questionnaire that focused on the handling of the dressing (Biatain® Silicone; Biatain® Silicone Lite) and was completed with an evaluation addressing overall dressing performance.”

Figure 1. Biatain® Silicone showing the characteristic conformable ‘bubble’ after absorption of exudate.



10 participants were recruited from each country (mean six patients per site).

The study was initiated with a questionnaire that focused on the handling of the dressing and was completed with an evaluation addressing overall dressing performance. The study ran for two weeks or six dressing changes after first application of Biatain Silicone (12.5 × 12.5 cm) or Biatain Silicone Lite (12.5 × 12.5 cm) dressings [Figure 2]. The questionnaires included questions on:

- Patient history
- Inclusion characteristics
- Wound assessment
- Experience with the dressings (all questions apart from one were for the HCPs):
 - “To what extent was the dressing easy to apply?”
 - “To what extent was the dressing capable of handling the amount of exudate (ability to absorb)?”

- “How do you experience the dressing’s ability to absorb exudate compared to the patient’s previously used dressing?”
- “How well did the dressings stay in place during the product evaluation?”
- “How do you rate the dressing’s ability to conform to the wound bed during use?”
- “To what extent was the dressing easy to remove?”
- “How was the dressing to wear?” (This question was for the patients.)

Questions on experience with the dressings and those in the closing evaluation were answered on five-point rating scales (e.g. very good – good – average – poor – very poor).

Photos were taken on Day 1 and at completion of the product evaluation (as well as at each dressing change for some participants).

Study endpoints

The primary study endpoint was to investigate the HCPs’ experience with the handling of the dressing. The secondary endpoint was to understand the participants’ experience with wearing the dressing.

Study population

Individuals aged 18–85 years with various wound aetiologies including leg ulcers, pressure ulcers, diabetic foot ulcers or donor site wounds were recruited to the study. The exclusion criteria were wound infection, treatment with radiotherapy or chemotherapy (current or in previous 2 months), and systemic or local (in the periwound area) treatment with steroids (current or in previous month).

RESULTS

Patient demographics and disposition

Between 29 April and 1 August 2013, a total of 43 participants meeting the eligibility criteria were recruited to the study. Of these 43 participants, four discontinued, three due to adverse events (of which one was deemed related to the dressing) and one due to non-completion of the questionnaire. Therefore, the study population consisted of 39 participants: 21 female and 18 male, mean age 69 (range 23–89) years old.

Patient treatment history

Of the 39 participants in the study population, 16 had leg ulcers, 12 had donor site wounds, nine had diabetic foot ulcers and two had pressure ulcers [Figure 3]. At study inclusion, alginate/Hydrofiber® and foam dressings

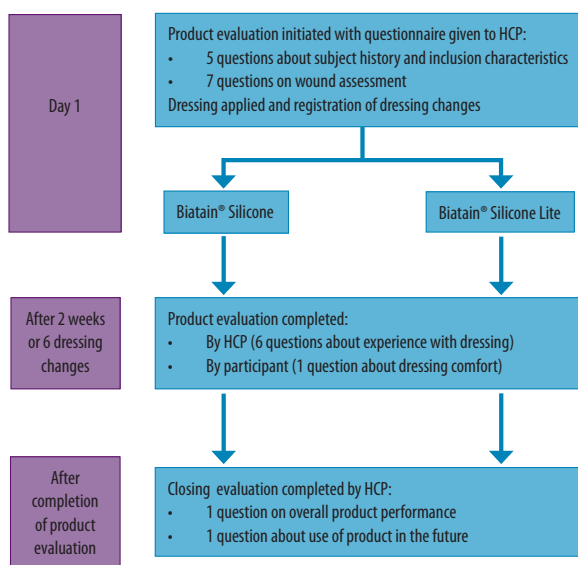
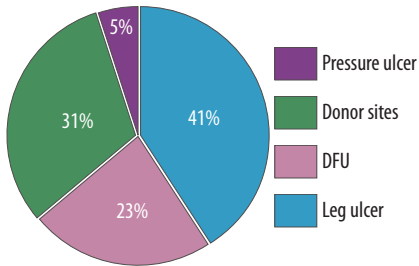


Figure 2. Study design schema. HCP, healthcare practitioner.

Figure 3. Distribution of wound types at study inclusion.



were the preferred choices (in nine and ten participants, respectively) [Figure 4]. Alginate/Hydrofiber® dressings were the most commonly used in participants with leg ulcers, while foam dressings were most common among those with diabetic foot ulcers. Among participants with pressure ulcers, treatments were equally split between alginate/Hydrofiber and foam dressings. Among participants with donor site wounds, no dressing was applied at study inclusion.

Wound assessments

At study entry, 81% of leg ulcers and 100% of pressure ulcers had been present for >6 months and 78% of diabetic foot ulcers had been present for 4–6 months.

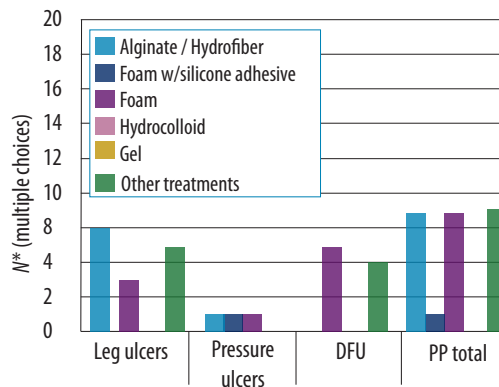
The number of dressing changes for the dressings used at study inclusion were two per week for pressure ulcers (n=2), two to three per week for leg ulcers (n=16) and an average of three per week for diabetic foot ulcers (n=9).

Exudate levels were assessed according to level (low, moderate or high), with high and moderate levels of exudate requiring more frequent dressing changes. Overall, 67% had moderately exuding wounds (69%, 78% and 67% among leg ulcers, diabetic foot ulcers and donor site wounds, respectively). Twenty percent of all participants had low-exuding wounds (50% among pressure ulcers) and 13% had high-exuding wounds (50% among pressure ulcers) [Figure 5].

The state of the surrounding skin was assessed in all participants (n=39) and was normal in 14, fragile in 14, irritated in nine, macerated in eight and painful in two participants (note that multiple choices for each case were allowed).

Upon entry into the product evaluation, 74% of cases received the standard Biatain Silicone product. The distribution according to wound type was Biatain Silicone among 75% of leg ulcers, 50% of pressure ulcers, 44% of diabetic foot ulcers and 100% of donor site wounds, while the remaining received Biatain

Figure 4. Dressings used at study inclusion. *Multiple choices were allowed. †“Other treatments” were antimicrobial dressing, honey dressing, gauze and film.



Silicone Lite. During the study, participants received Biatain Silicone dressings (Standard or Lite) for two weeks or six dressing changes. Overall, the mean wear time was 4.1 (range 1–11) days with a majority of dressing changes being routine dressing changes.

HCP experience with the Biatain Silicone dressings

When asked, “To what extent was the dressing easy to apply?” the HCPs rated the application as very easy or easy to apply in 92% of the cases, while in 8% of cases it was rated as average. No one rated the application as difficult or very difficult [Figure 6].

Evaluation of the dressings’ ability to absorb exudate showed that in 90% of the cases, the HCPs found them to be very good or good [Figure 7]. When comparing with previously

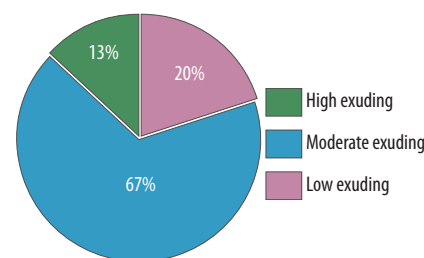


Figure 5. Distribution of wound exudate levels at study inclusion.

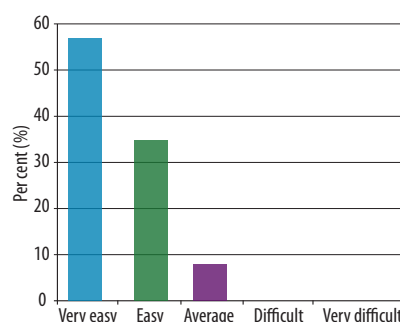
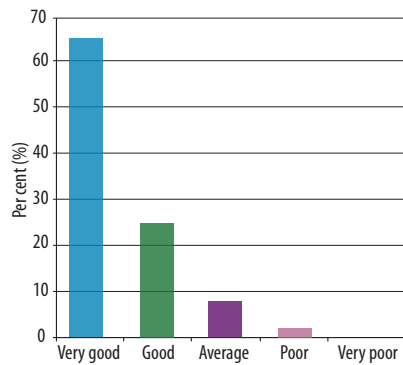


Figure 6. Ease of product application.

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Figure 7. Ability of product to handle (absorb) exudate.



used dressings, 77% of responders ($n=27$) rated the Biatain products as much better or better at absorbing exudate (note that the donor site wounds had no previous dressings, thus were considered non-responders). Twelve percent of the responders rated the Biatain products as the same, while 8% rated them as worse than previously used dressings [Figure 8].

Response to the question, "How well did the dressings stay in place during the product evaluation?" was "very good" or "good" in 87% of the cases, with no HCP rating them as poor or very poor. The ability of the dressings to conform to the wound bed was considered very good or good in 92% of the cases, with none rating them as poor or very poor. All HCPs rated the products very easy or easy to remove.

For the closing evaluation, forms were received from six of the seven sites. In this questionnaire, HCPs were asked of the overall performance of the Biatain products in comparison with previously used dressings. HCPs from sites treating donor site wounds ($n=12$) could not respond as these wounds were all new, but for the remaining HCPs treating leg ulcers and diabetic foot ulcers ($n=25$), all rated the performance as better than that of previous dressings [Figure 9]. In response to the question, "Would you use Biatain Silicone again?", all six HCPs said "yes".

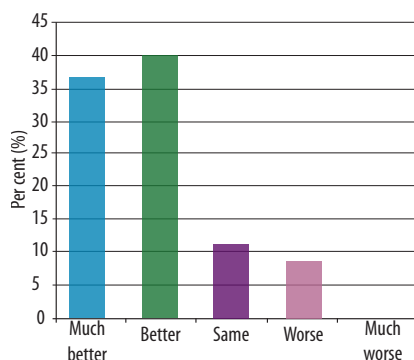


Figure 8. Ability to absorb exudate compared with previously used dressings.

Reasons given as to why the HCPs would use the Biatain products again included:

- "Excellent results, it sticks well, no pain at removal, short healing time"
- "Good comfort for the patients with optimal exudate management. Optimal periwound skin management in almost all cases treated"
- "The dressing handles donor site wound exudate very well. First dressing change could be done after five days, and the dressing was not saturated. After only two changes (less than 15 days) wounds in donor sites were healed. Cosmetic features of the scar were satisfactory. Dressing is very easy to use (to apply and to remove). Patients refer very, very low level in pain in change dressing"
- "Very conformable. Patients liked it"

Patient experience with the Biatain Silicone dressings

When asked, "How was the dressing to wear?," 62% of participants responded that the Biatain Silicone (Standard or Lite) product was "very comfortable" (highest rating on the five-point scale). Overall, 87% rated the Biatain Silicone dressings as very comfortable or comfortable, and one participant rated them as uncomfortable. No one rated them as "very uncomfortable" (lowest rating).

Adverse events

Adverse events occurred in three of the recruited patients (these were not included in the final study population as a result of discontinuation or death). Two adverse events were serious adverse events owing to hospitalisation (one case died); these were not considered related to the study product.

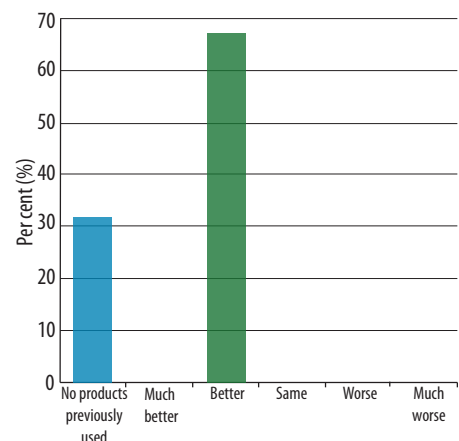


Figure 9. Comparison of the performance of Biatain Silicone dressings with previously used dressings.

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In the third case, adverse events (described as rise of exudate, erythema, and rise of pain) were considered related to the dressing.

DISCUSSION

In this study, a total of 39 patients were treated with Biatain Silicone or Biatain Silicone Lite for two weeks or six dressing changes. To evaluate these products, patients and HCPs were given questionnaires to determine their experiences with the products. Overall, all the HCPs felt that these products performed better than previously used dressings [Figure 9] and that they would use them again. The majority of the patients (87%) considered the product to be very comfortable or comfortable to wear, and only one rated it as uncomfortable. The HCP also rated the dressing worse than the previous dressing on this particular patient. The patient was a 75-year-old lady who had a mixed arterial/venous leg ulcer and was dressed with a Biatain Silicone Lite dressing. On consideration, the standard Biatain Silicone dressing might have been a better choice as it is better suited for moderate- to high-exuding wounds.

Overall, the HCPs rated the Biatain Silicone dressings better than previously used products. From the case study findings, the authors conclude that these dressings offer patients a comfortable treatment option with optimal exudate management for all evaluated wound types. In addition, they were very easy to apply and remove and stayed in place during wear.

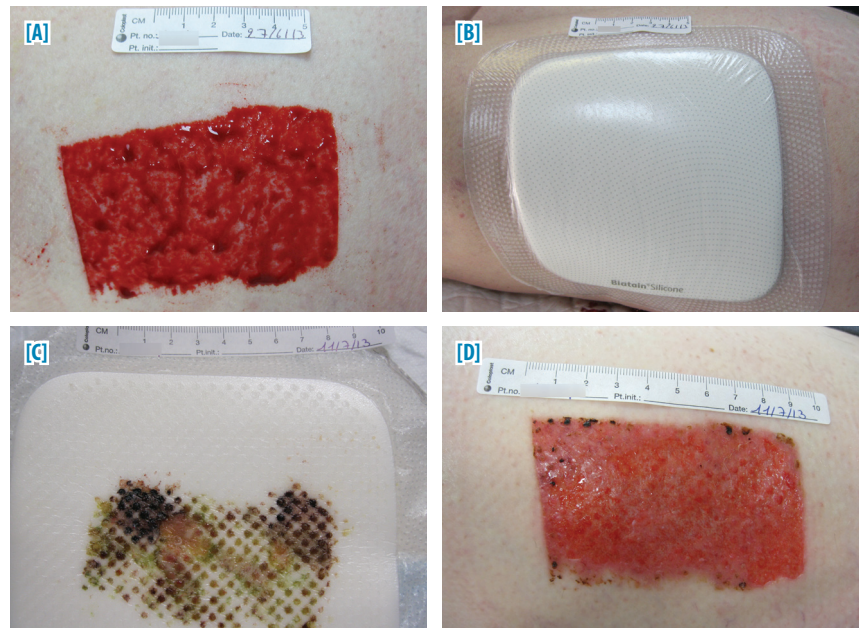
CASE REPORTS

The study evaluated the usability of the Biatain Silicone products; questions on clinical parameters such as wound progress and changes in condition of periwound skin were not included in the questionnaire. However, as photos were taken, we have included three case study examples using data included in the participants' healthcare records, and these are described below.

Case study 1 – donor site wound

This was a 66-year-old woman with a high-exuding donor site [Figure 10A]. After grafting, Biatain Silicone dressing was applied [Figure 10B]. The dressing showed very good absorption of exudate [Figure 10C]; this was worn for three days (mean wear time was 3.75 days). All dressing changes were routine and pain free. The dressing was easy to remove and did not leave any fibres in the wound bed. After two weeks of treatment the wound was improved with evidence of 30% granulation

Figure 10. Case study 1 – donor site wound. [A] Donor site at baseline, [B] after application of Biatain® Silicone, [C] dressing after 3 days wear and [D] donor site after 2 weeks of treatment.



tissue and 70% epithelialisation [Figure 10D]. The dressing was very easy to apply, conformed well to the wound bed and stayed in place during wear time. The patient found the dressing very comfortable.

Case study 2 – diabetic foot ulcer

This was a 45-year-old man with a moderately exuding diabetic foot ulcer [Figure 11A]. The duration of the ulcer was six months and the periwound skin was fragile with signs of skin

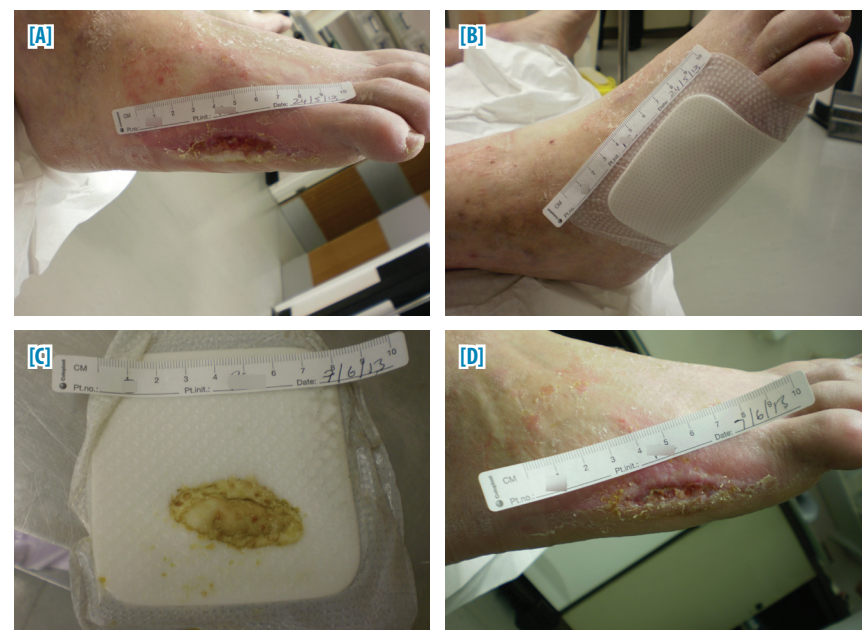


Figure 11. Case study 2 – diabetic foot ulcer (DFU). [A] DFU at baseline, [B] Biatain® Silicone Lite dressing in situ, [C] dressing on removal, [D] DFU after 2 weeks of treatment.

“The majority of healthcare practitioners were highly impressed with the Biatain® Silicone dressings in terms of ease of application, ability to absorb exudate, ability to stay in place, ability to conform to the wound bed and ease of removal.”

irritation, including inflammation, redness and raised edges. Ulcer size was 41 × 9 mm at inclusion. During this study the patient received Biatain Silicone Lite dressing [Figure 11B]. He found the dressing very comfortable to use. The dressing showed good absorption of exudate [Figure 11C]; this was worn for two days and all dressing changes were routine. After six dressing changes, the wound showed evidence of reduced inflammation and redness of the surrounding skin had improved [Figure 11D]. The dressing was very easy to apply and stayed in place during wear time. The dressing conformability was very good and the dressing was very easy to remove. At the final evaluation, the patient said he would like to continue using this dressing.

Case study 3 – leg ulcer

This was a 76-year-old woman with a moderately exuding mixed venous/arterial leg ulcer. The wound duration was 10 weeks and it measured 37 × 28 mm at baseline [Figure 12A]. The base of the ulcer showed the partial presence of fibrin and the periwound skin was normal. The patient received Biatain Silicone [Figure 12B] and graduated, multilayer compression bandaging. All dressing changes during the study period were routine. After two weeks of treatment the wound showed good progress with a reduction in size from 37 × 28 mm to 34 × 25 mm and the wound bed was 100% granulating. At three weeks the wound had further reduced in size to

28 × 18 mm [Figure 12C]. The wound continued to heal after the conclusion of the study and was completely healed at seven weeks. The dressing was very easy to apply and remove, had good absorption capacity [Figure 12D] and conformed very well to the wound bed. The patient found the dressing very comfortable.

CONCLUSION

In this case series study based on a product evaluation of Biatain Silicone and Biatain Silicone Lite dressings, the primary endpoint (understanding HCPs' experience with handling the product) and secondary endpoint (understanding patient experience of wearing the dressing) were achieved.

The seven HCPs assessing a total of 39 study participants with leg ulcers, pressure ulcers, diabetic foot ulcers or donor site wounds all found that the overall performance of the Biatain products was better than that of previously used dressings (which were mainly alginate/Hydrofiber and foam). The majority of HCPs were highly impressed with the Biatain Silicone dressings in terms of ease of application, ability to absorb exudate, ability to stay in place, ability to conform to the wound bed and ease of removal. In addition, the patient experience was shown to be good with 87% responding that they found the dressing very comfortable or comfortable to wear. All HCPs stated that they would use the Biatain Silicone dressings again. ■

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Figure 12. Case study 3 – leg ulcer. [A] Wound at baseline, [B] after application of Biatain® Silicone, [C] after three weeks of treatment, with evidence of wound healing and [D] dressing removal.