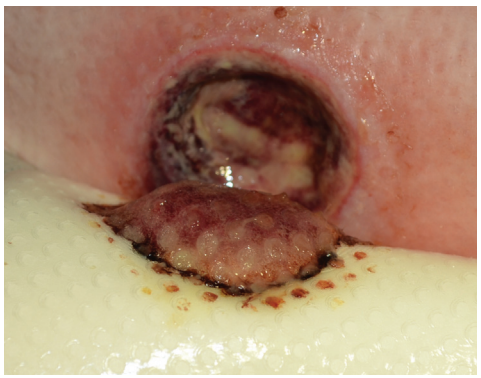
"The study was initiated with a questionnaire that focused on the handling of the dressing (Biatain® Silicone; Biatain® Silicone Lite) and was completed with an evaluation addressing overall dressing performance."

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 extend 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).

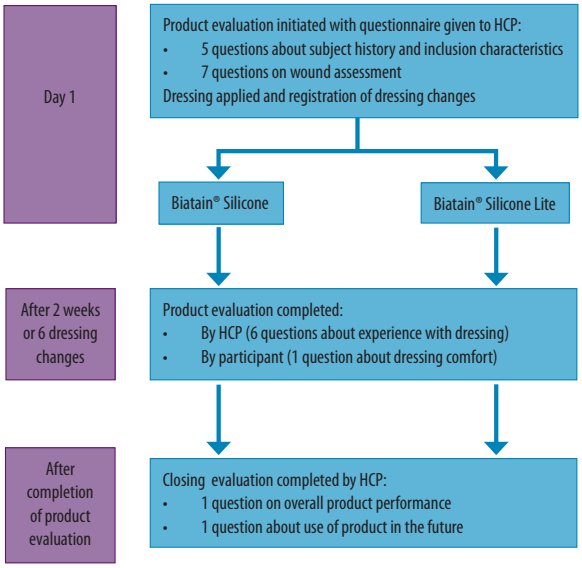


Figure 2. Study design schema. HCP, healthcare practitioner.

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