150 patient experiences with a soft silicone foam dressing

Sharon Dawn Bateman
Pain, malodour and exudate from acute and chronic wounds can be catastrophic to the patient. Excessive exudate results in significant tissue damage to the wound bed and surrounding skin, reduces quality of life, and often requires costly specialist service input. Effective wound assessment and management including appropriate dressing choice is, therefore, paramount to ensure wound healing can take place in a timely manner. This observational evaluation explores 150 ward-based patients who presented with acute and chronic exuding wounds; it examines and evaluates the proposed benefits of the Cutimed® Siltec foam dressing range over a 4-month period in an acute hospital setting. The outcomes of the evaluation were exudate management, maceration reduction, atraumatic application and removal, non-adherence and patient experience. The evaluation highlights not only an overall positive improvement in exudate management and maceration reduction, non-adherence, atraumatic application and removal but also emphasises the importance of a positive patient experience in the wound-care journey.

Key words: Wound exudate ■ Peri-wound maceration ■ Absorbency and protection ■ Non-adherence ■ Atraumatic wound care ■ Patient experience

The body produces wound exudate as a response within the biological and chemical processes within the natural wound healing continuum, taking the wound through the key stages of inflammation, proliferation and maturation (Wounds UK, 2013). Wound exudate is responsible for ensuring a moist environment is maintained, providing essential elements and cell nutrients such as electrolytes, growth factors, inflammatory mediators, matrix metalloproteinase and key growth factors (White and Cutting, 2006; World Union of Wound Healing Societies, 2007). Where wounds are healing as expected, exudate levels tend to reduce over time along the wound healing continuum. Gardner (2012) states that when wounds are stuck within the chronic phase, excessive levels of exudate within the wound bed delays the healing process. This has a negative effect on the healing potential of cells when they are in the inflammation phase. Inappropriate levels of exudate can result from external and or internal events such as infection, pharmacology, and incorrect dressing product application which can have a detrimental effect on the vulnerable tissues such as increased maceration to the periwound skin, increased malodour and extension of wound borders through leakage (Cutting and White, 2002). Jones (2006) highlights the ‘falling off’ of dressing products, which can be an issue when wounds have excessive and high exudate levels increasing maceration, leading to inconvenience to the patient, reduced credibility for the manufacturer and financial burden on the healthcare provider.

According to Thomas (1994) when managing wound exudate, dressing products can be classified as adherent, low adherent or non-adherent, with many new dressing formulations now being promoted as ‘atraumatic’; providing increased protection to the periwound skin and wound bed (White, 2014). Skin tearing or ‘skin stripping’ caused by overly adherent dressing products is traumatic to patients and results in negative physical and psychological wellbeing, with pain and discomfort in product application and removal being common side-adverse events. This increases demands upon the clinician, patient, carer and diminishes healthcare resources (Wounds UK, 2013).

The avoidance of non-intentional damage to the patient’s wound and discomfort should be a priority, in order to reduce the negative impact on wound healing through resulting stress and anxiety (Upton and Solowiej, 2012).

Today’s advanced wound care products, such as the Cutimed® Siltec foam range, are manufactured with not only exudate containment in mind but also how the product adheres to the patient’s vulnerable skin, providing atraumatic removal without unnecessary trauma and stripping of the epidermis skin layer. Clinicians must therefore be mindful in ensuring that a robust assessment of the patient’s wound is undertaken in the first instance and that the product choice truly meets the needs of the patient and his or her wound to optimise wound healing (Bateman, 2014a).

Aim of implementation
This evaluation was undertaken at a large NHS Foundation Trust agreed between the lead nurse wound care, procurement team, consultant, and industry, for those patients who presented with exuding wounds that consented to be managed with the Cutimed Siltec foam range. The cohort included any ward-based patient that had an exuding wound who was referred to the wound care service over a 4-month period requiring optimisation

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of their wound status. The Cutimed Siltec foam range was chosen as the evaluation product because of positive outcomes from the trust’s own evaluation (Bateman, 2014). These evaluations reflect the key supporting evidence in respect to effective absorbency, non-adherence, atraumatic removal and its low price (Stephen-Haynes and Timmons, 2009). In conjunction with evidenced clinical efficacy, this evaluation aimed to gain insight into the patient experience, especially in regards to patient choice of product.

Cutimed® Siltec foam range

The Cutimed Siltec range of foam dressings is marketed as having a silicone wound contact layer providing:

- Atraumatic and pain-free dressing changes (Derbyshire, 2010)
- An open porous polyurethane foam core which allows excellent vertical absorption (Casu and Schubert, 2013) of even viscous exudate
- Super-absorbent particles above the foam core help to retain exudate and prevent maceration (Stephen-Haynes, 2010), making the dressings suitable for use under compression
- A highly breathable polyurethane top film that provides a high and dynamic moisture vapor transmission rate (Thomas, 2010) that reacts with the changing levels of exudate within the wound to provide a moist wound healing environment.

The silicone wound contact layer is available in either feather-tack or soft-tack silicone variants, which is unlike other dressings.

Clinical indications for this product are wounds with low to high exudate levels including pressure ulcers, venous or arterial leg ulcers, diabetic foot ulcers, skin grafts and surgical and trauma wounds, either as a primary or secondary dressing (Stephen Haynes et al, 2009). The dressings are also suitable for skin tears (Bateman, 2014b).

It is widely known that there many different super-absorbent and technologically advanced foam dressings available for exudate management, however, not all products suit all needs and it is therefore important that clinicians continue to ensure a holistic and informed approach to product choice is maintained.

Methods

A total of 150 patients, who were referred with low to high-exuding wounds, were recruited over a 4-month period through the trust’s wound care service. The inclusion criteria were that the patient had an exuding wound and was able to undertake independent consent to be involved in the evaluation (or had an appropriate carer that could on his or her behalf). The exclusion criteria referred to those patients who did not have an exuding wound, were unable to provide independent consent, or who did not wish to change their current dressing regimen. Patients were provided with verbal information by the lead nurse for wound care regarding the evaluation process, its aims and objectives and the choice to be involved or carry on with their current regimen. Due to the product being used in the organisation as part of the formulary review process and the review being an evaluation process, ethical approval was not required.

The 150 patients who were referred and had agreed to take part in the evaluation had their verbal/written consent

### Table 1. Patient demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>101</td>
<td>49</td>
<td>150</td>
</tr>
<tr>
<td>Age</td>
<td>2–93 years</td>
<td>6–99 yrs</td>
<td>Mean age 69</td>
</tr>
</tbody>
</table>

### Table 2. Wound summary

<table>
<thead>
<tr>
<th>Wound type</th>
<th>Incidence (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg ulcers (venous)</td>
<td>24</td>
<td>17</td>
</tr>
<tr>
<td>Leg ulcers (arterial)</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Pressure ulcers (grade 2, 3 and 4)</td>
<td>42</td>
<td>28</td>
</tr>
<tr>
<td>Surgical site infections</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>Skin tears</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>Burn</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Trauma/other</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Tracheostomy site</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

### Previous products used

- Silicone foams non-adhesive
- Silicone foams adhesive border
- Polyurethane non-silicone foam
- Surgical non-adhesive pads
- Gauze and tape
- Surgical gauze

*Designated absorbent foam products

### Figure 1. Exudate levels pre-evaluation

- None
- Low
- Moderate
- High

### Figure 2. Exudate levels at end of evaluation (4 weeks)

- None
- Low
- Moderate
- High
documented in the medical and nursing notes. Each patient and nurse at the onset of the evaluation were shown and conversed with regarding the tailored education document and dressing product; a copy of the education leaflet was placed in the nursing notes and a copy kept with the patient at the bedside. All care outside of the dressing regimen, analgesia, cleansing routine and surgical input was not changed outside of normal routine practice/care to maintain consistency. All patients remained in the evaluation either to the day-28 endpoint or to discharge from the service. There were no patient drop outs throughout the individual 4-week monitoring, adverse reactions or need to implement an alternative product.

The evaluation was undertaken over a 4-month period, with the monitoring of each patient recruited occurring over a 28-day span (due to the short-stay nature of the acute sector) or up to discharge by the lead nurse. All dressing changes, interventions and wound care charts were completed by the ward clinicians, registered general nurses and healthcare assistants, who would normally carry out such duties. Data collection related to patient demographics (Table 1), previous treatments used and wound status (Table 2) and patient/clinician experience of the product. The established product education leaflet used successfully within previous work (Bateman, 2014a) was provided to all patients as part of their normal care plan. All patients were asked the question ‘do you wish to continue with this product as part of your wound care?’, which was documented by the individual clinician at the midpoint (2 weeks) and endpoint (4 weeks) of the evaluation.

Patients were made aware at the outset that they could stop product use and revert back to their previous regimen or start an alternative appropriate regimen at any stage of the evaluation process.

The following products were used in the evaluation according to wound requirement:
- Cutimed Siltec—non border, feather tack silicone WCL
- Cutimed Siltec B—adherent silicone border
- Cutimed Siltec Plus—non bordered with soft tack silicone WCL.

Assessment
Following entry into the evaluation, alongside information provision, each patient’s wound was cleansed as required before being dressed with the appropriate Cutimed Siltec product. The pre-evaluation wound care continuum (Gray et al, 2009) and dressing regimen were continued consistently; those wounds that required the foam as a secondary product would continue to deploy the same wound filler used before the evaluation, similarly with those wounds that were being managed with barrier films, creams, bandaging and compression therapy. It is essential in any evaluation to remove all variables that can affect outcomes (Mayer, 2004). The wound assessment documentation was reviewed at day 7 of each of the 4 weeks by the lead nurse to ensure accurate up-to-date data collection.

Results
Although the evaluation referred to a moderate-sized cohort (n=150), the results were extremely positive in terms of the key outcomes; this despite the variation and complexity of the patients’ wound types, patient demographics and

Table 3. Patient experience from data collection questionnaire

<table>
<thead>
<tr>
<th>Theme of comments</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Atraumatic application and removal</td>
<td>'Didn’t get on with the other dressing.'</td>
</tr>
<tr>
<td>2. Skin protection</td>
<td>'I don’t want to have any other dressings'</td>
</tr>
<tr>
<td>3. Good adherence with product remaining in place</td>
<td>'The leaflet will help me ask for this dressing from my GP'</td>
</tr>
<tr>
<td>4. Comfort of product in place</td>
<td>'Those dressings helped my mum’s legs in that they didn’t hurt here when the nurse took them off'</td>
</tr>
<tr>
<td>5. Patient trust and compliance</td>
<td>'It didn’t stick to my scabby areas which I was worried about at first'</td>
</tr>
<tr>
<td>6. Patient leaflet and verbal information positive</td>
<td>'It didn’t rip my skin when the nurse took it off'</td>
</tr>
<tr>
<td></td>
<td>'Didn’t curl up and leak like my other one'</td>
</tr>
<tr>
<td></td>
<td>'I could flex my hand and it stayed in place'</td>
</tr>
<tr>
<td></td>
<td>'Stayed on for 7 days'</td>
</tr>
<tr>
<td></td>
<td>'Feels soft and strong'</td>
</tr>
<tr>
<td></td>
<td>'It was comfortable around my chest drain and didn’t leak'</td>
</tr>
<tr>
<td></td>
<td>'No problem on my baby’s skin, so I was happy for the nurse to keep putting it on'</td>
</tr>
<tr>
<td></td>
<td>'Leaflet good for communication'</td>
</tr>
<tr>
<td></td>
<td>'I kept the paperwork and took it to my next ward which was helpful to the nurse there'</td>
</tr>
</tbody>
</table>
Comorbidities. The results regarding exudate containment, maintenance of a moist wound bed, periwound skin healing and protection through maceration reduction, atraumatic application and removal reflect the positive outcomes of other publications (Thomas, 2009; 2010; Norris, 2010; Bateman, 2014a) adding to the current weight of credible evidence for this product. Although not a pre-set outcome, there were clear positive results with longer wear time compared with the pre-evaluation regimen, with average wear time pre-evaluation being 0–24 hours compared with the evaluation wear time of 72 hours using Cutimed Siltec over the 4-week period.

With regard to exudate levels, there was a good representative cohort of wound types that clinicians find a challenge to manage in everyday healthcare settings; with pressure ulcers, leg ulcers, burns and surgical site infections being more prominent across the patients recruited. Each wound group produces variances in exudate viscosity, volume and pH levels, according to Vowden et al (2015), which increases the risk of periwound skin maceration, infection and wound extension (Ono et al, 2015).

Exudate was strictly assessed in accordance with the wound care continuum (Gray et al, 2009) with categories of low, moderate and high exudate levels being recorded (Figure 1). Pre-evaluation, only 3% of patients (n=4) were deemed to have no exudate but they were included in the evaluation as surgical debridement of necrotic tissue was to be undertaken before the evaluation’s first dressing application, which resulted in moderate levels being produced. It is imperative that non-viable, dead tissue be removed from the wound bed where possible if healing optimisation is to be achieved, due to the toxic effects this dead tissue has on new tissue growth and to reduce incidence of infection (Dowsett et al, 2015). High levels of exudate represented 24% (n=36), moderate levels 52% (n=79) and low levels 21% (n=31) of the cohort’s wounds, resulting in 77% (n=115) of patients being at high risk of tissue maceration, increased pain levels and delay in wound healing, according to Vowden et al (2015).

After the 4-week evaluation period, the final exudate assessments demonstrated a positive reduction in wound exudate levels representing progression along the wound healing continuum according to White and Gray (2009). Figure 2 highlights an almost complete turnaround with regard to the cohort’s levels of exudate with less than 1% (n=1) with high exudate, 21% (n=32) with moderate exudate, 56% (n=84) with low exudate and 22% (n=33) with no exudate.

All of the recruits had no incidences of periwound skin maceration throughout the 4-week period, alongside no comments by the patients or the clinicians in the evaluation documents regarding incidences of leakage. Product wear time was dictated by the levels of exudate and dressing change accommodated accordingly in the assessment and re-evaluation processes.

The wound groups in the evaluation had a good representation of those types that have a known tendency to adhere to dressing products, particularly those of skin tears (11%, n=16) surgical site (20%, n=30) and burns (8%, n=12). Pressure ulcers and leg ulcers are well known to have higher incidences of wound pain and discomfort requiring high-level analgesia within the management regimens (Beldon, 2008; Newton, 2010). A high representation of these wound groups were evaluated with venous leg ulcers in 17% of patients, arterial leg ulcers in 5% and pressure ulcers 28%. This meant that just over a quarter (28%) of the cohort were at
higher risk of product adherence and a complete third (33%) were at risk of increased pain in their own wound groups.

Adhesive dressings have been shown to cause skin trauma and pain with both application and removal, according to Waring et al (2011), alongside increased epidermal sensitivity and potential adverse reactions. Before the evaluation 78% (n=118) of the wounds had been using a designated adherent/non-adherent absorbent foam dressing product, which 100% of the patients preferred not to change back to.

Pain scores were assessed at each dressing change using the McGill pain assessment tool (Melzack, 1975). Pain scores were assessed and documented pre-, peri- and post-evaluation as is normal standard practice to allow comparison at start and end points. More than 98% of patients (n=148) had a pain score of between 1 and 10 at the stage of preparation for the first Cutimed Siltec dressing application, showing some degree of pain. At first dressing change 85% (n=129) had a level of 0 (no pain) with 15% (n=21) having pain scores of 1–3. At second change 100% (n=150) demonstrated a pain score of 0. It is worth noting that no changes to any pharmacological analgesia were implemented in the time frame and all normal care plans put in place before the evaluation started were adhered to.

Interestingly, although not a pre-set outcome, the emerging data demonstrated a clear increased wear time overall within the evaluation period compared with previous regimens (Figure 3). Increased wear time is an essential criterion in choice of product for wound exudate management, according to the Wounds UK (2013) best practice statement. Reduction in dressing changes reduces pain, wound bed disturbance and risk of infection occurrence (Gardner, 2012).

When reviewing the data of wounds over a 2-week period prior to the evaluation and comparing these figures to the first 2 weeks of use of the Cutimed Siltec foam range, there was a positive difference regarding wear time across the majority of patients. Average wear time prior to evaluation of the group was collated as 6–24 hours and at 2 weeks into the evaluation average wear time was reduced to 24–48 hours. This clearly has an important impact on patient care, clinical resources and financial budgets and requires further economic evaluation in its own right.

Regarding patient experience, when all of the patients were asked if they wished to continue with the Cutimed Siltec range within their wound care regimen there was an outstanding 100% ‘yes’, they would continue with the product and did not wish to revert back to their previously used dressings (Table 3). Comments from patient and carers were collated into general themes to enable a more insightful perspective to be gleaned to aid understanding of decision making and choice. Although not a pre-set primary outcome in this evaluation, many of the participants felt that the education leaflet and verbal explanation for product use was a welcome addition. The product information leaflet and dressing regimen travelled with the patient throughout the various departments and discharge destinations within and beyond the evaluation period.

The results overall demonstrated that the Cutimed Siltec foam range had a 100% success rate of non-adherence with no documented evidence of increasing pain levels in the 4-week evaluation period; with all 150 recruits being pain-free before or at week 2. It therefore offered a protective, atraumatic, non-adherent dressing layer to the vulnerable wound bed tissues. At 2 weeks and 4 weeks, 100% (n=150) of the cohort was assessed as having not had any adverse reactions, making this product safe to use for a wide variety of patients and skin integrity states.

Case Studies: Patient B
A 44-year-old male with a 48-hour grade 2 pressure ulcer to right heel from walking boots. Polyurethane non-silicone adhesive foam dressing required daily changes and had to be soaked off due to strong adhesion border.

Day 1. Moderate exudate levels, moderate pain (5/10) and macerated periwound skin

Day 1. Dressing application, 4-day wear time, pain 3/10 post dressing

Day 7. Second dressing change, 7-day wear time, pain free (0/10)

Patient healed at day 14
There was an outstanding overall positive response regarding the use of the Cutimed Siltec foam range from patients, with all wishing to continue with the product within and outside of the evaluation period. Comments received demonstrated a good experience relating to the key outcomes evaluated through emerging generated themes alongside the education leaflet and continued care into other areas outside of the remit of this study. Increased wear time was a welcome unexpected outcome, which would require further exploration as to its significance in the management of exuding wounds using this product range.

Limitations
The cohort group represented a moderate number (n=150) of patients who presented in an acute trust and who were assessed as having exuding wounds requiring absorbent dressing products in their management regimen. The benefits of the Cutimed Siltec foam range in other settings—such as the patient’s home and community and the wider wound care population—have not been represented and therefore not commented on. However, the benefits highlighted in this evaluation acknowledge a wide variation in age groups, and typical exuding wound groups that require exudate management and could therefore be transferable to other settings. There were no patient drop outs, the data were collated and cross-checked by the author producing positive results relating to set outcomes that duplicates the clinical efficacy shown in current available evaluation and study literature referenced here. Positive patient experience, although explored at a basic level in this work, could benefit from a detailed clinician or carer viewpoint to enable the generation of a holistic insight into the experiences of others regarding the Cutimed Siltec foam range.

Conclusion
The key focuses of healing a highly exuding wound are adequate absorption of exudate, non-adherence, the protection of surrounding tissues and the provision of an appropriate wound environment. Patient comfort, quality of life, education and adverse-reaction reduction are all key elements when ensuring the wound care journey is as effective and efficient as possible. High on the healthcare agenda is the active involvement of both patient and carer in day-to-day clinical care, with wound care practice being no exception. Patients and carers, where possible, must have a loud voice within clinical wound care decisions, choice of products and care environment if a truly holistic approach is to be achieved. This in turn will result in best-practice provision and resulting outcomes.

This moderate sized cohort evaluation of an absorbent foam product, alongside patient informed choice in regards to their product use and direction of care, is an innovative addition to the many tools that clinicians have access to. Increasing the availability of evaluated products based on the above principles provides the clinician with the evidence base on which to provide appropriate care.

Conflict of interest: BSN medical provided the author with the dressings for the evaluation

Bateman S (2014a) Improving the holistic wound care experience and integrating an education regimen. Wounds UK 10(2): 70–9

Case Studies

Patient C
A 71-year-old female with a 3-month-old grade 3 pressure ulcer to right elbow

Day 1. Haematoma, severe pain, dry and scaly periwound skin, moderate exudate. Due to a chronic psoriasis skin condition this lady was unable to keep adhesive dressings in situ on her elbow for more than 24 hours. Clinicians had used several adhesive products including soft silicone with little success. Pain score 9/10

Day 1. Cutimed Siltec adhesive border in situ – 3-day wear time for 2 weeks then 5-day wear time for evaluation duration. Pain 5/10

Category 3 pressure ulcer healed at day 35 outside of evaluation data collection, pain free (0/10) day 11.

Conflict of interest: BSN medical provided the author with the dressings for the evaluation
KEY POINTS

- Pain, malodour and exudate from acute and chronic wounds can be catastrophic for patients.
- Effective wound assessment and management by clinicians is key to ensuring the right patient receives the right dressing at the right time.
- Involvement of the patient and carer from the outset of any wound product choice is essential to promote a positive wound-care experience.
- Soft silicone foam dressing such as Cutimed Siltec provides a highly absorbent, atraumatic and effective management product agreeable with a wide range of patient wound needs.