Management of diabetic foot ulcers using dressings with Safetac®: a review of case studies

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Abstract

Background: Foot ulcers are a common occurrence in patients with diabetes. Like other types of chronic wounds, diabetic foot ulcers are often associated with pain. As part of the treatment of diabetic foot ulcers, consideration should be given to the use of dressings that prevent wound-related trauma, minimise pain on removal, and manage infection. Aims: To provide evidence in the form of case studies to demonstrate the benefits of dressings with Safetac adhesive technology in the treatment of diabetic foot ulcers presenting with a variety of clinical challenges. Methods: A number of different dressings with Safetac were evaluated in a series of case studies involving patients with diabetic foot ulcers. Results: All ulcers responded well to treatment, demonstrating minimal pain at dressing change, complete healing, and resolved infection. Conclusions: It is not generally recognised that patients with diabetic foot ulcers have painful wounds, although recent research indicates that more than 50% of such patients may experience wound-related pain. The findings of the case studies presented in this article show that dressings with Safetac can be used to address this problem and successfully treat diabetic foot ulcers. Conflict of interest: This study was supported by an educational grant from Molnlycke Health Care, Göteborg.

KEY WORDS

Diabetic foot ulcers
Atraumatic dressings
Soft silicone
Safetac

Ulcers and foot injuries are major causes of lower extremity amputations in patients with diabetes. Treatment of diabetic foot ulcers is aimed at preventing infection and providing an optimal wound healing environment. Vascular control of the disease (e.g. regulation of serum glucose levels and arterial risk factors such as hypertension and dyslipidaemia), combined with debridement, pressure off-loading, treatment of infection and the effective use of wound dressings are important factors in the care of patients with diabetes. In a recently undertaken cross-sectional survey of patients with neuropathic or neuroischaemic ulcers, it was observed that 53% of them had wound-related pain (Bengtsson et al, 2008). Hence, in addition to the cornerstones of treatment described above, the healing of diabetic foot ulcers is likely to benefit from the use of atraumatic dressings. A range of dressings with Safetac® adhesive technology (Molnlycke, Göteborg) has been developed which prevent trauma and minimise wound-related pain at dressing procedures for patients with all types of wounds. This article summarises the evidence which demonstrates that both the prevalence of diabetes and its associated treatment costs are increasing. It also outlines the standard treatment of diabetic foot ulcers, with an emphasis on wound care and the clinical benefits of dressings with Safetac. To highlight these benefits, a series of case studies are presented.

Diabetes mellitus, often referred to simply as diabetes, is a metabolic disorder that is characterised by chronic hyperglycaemia. The two main forms of diabetes mellitus are known as Type I and Type II. Type I diabetes mellitus, associated with diminished or total lack of insulin production, can affect both adults and children and, at present, accounts for the majority of diabetic cases in children. Type II diabetes mellitus, associated with a diminished cellular response to insulin, is most likely to occur in middle-aged and elderly patients, although there is considerable evidence that onset in patients under 30 years of age is becoming increasingly common. Although Type I diabetes remains the predominant form of the disease in children, it is likely that Type II diabetes will overtake it within the next 10 years, the main reason being the alarming increase in the prevalence of obesity in many developed countries (Alberti et al, 2004).

Diabetes is costly to health services. In a study involving more than 7,000 patients with Type II diabetes in eight European nations (Belgium, France, Germany, Italy, the Netherlands, Spain, Sweden and the UK), the total direct medical costs of the disease and its complications in those countries was estimated at €29bn (£22.54bn) per annum, with the cost per patient estimated at €2,834 (£22,203) per year. Hospitalisations accounted for the greatest proportion (55%, range 30–65%) of the costs (€15.9bn [£12.36bn] per annum) (Jonsson, 2002). Diabetes is the third leading cause of death after...
cardiovascular disease and cancer and it is predicted that the number of people with diabetes is set to rise from an estimated 171 million in 2000 to 366 million in 2030 (Wild et al, 2004).

Complications are associated with both forms of diabetes including coronary artery and peripheral vascular disease, stroke, diabetic neuropathy, amputations, renal failure and blindness (Williams et al, 2002). Ulceration of the foot is the most common cause of hospitalisation of patients with diabetes (Knuse and Edelman, 2006). Foot ulcers in patients with diabetes can result in severe infection, gangrene and amputation.

Peripheral neuropathy can cause altered or complete loss of sensation in the foot and/or leg (Duby et al, 2004). Any cuts or trauma to the foot can go completely unnoticed for days or weeks in a patient with neuropathy (McIntosh, 2001). A common problem in diabetic patients is Charcot foot, which is a deformity that occurs as a consequence of decreased sensation (Fishman, 2002).

This can result in tissue ischaemia and necrosis, ultimately leading to plantar ulcerations (Giurini and Lyons, 2005). Microfractures in the bones can result in disfigurement, chronic swelling and bony prominences (Sommor and Lee, 2001). Additionally, microvascular disease (caused by narrowing of the small arteries) and macrovascular disease (caused by ailments affecting the larger arteries supplying the heart, brain, and the legs) are significant problems for patients with diabetes and can also lead to ulceration (Jeffcoate, 2003; Chan et al, 2006).

Infection has been described as an additional mechanism of injury in the diabetic foot and is an important factor that complicates ulceration with sometimes devastating consequences, e.g. amputation (Lysy et al, 2008). Patients with diabetes are more prone to infection than those without diabetes, with the rate of infection reflecting the level of blood glucose control (Burke et al, 1992). Pain is a common occurrence in patients with chronic wounds, including diabetic foot ulcers (Ribu and Wahl, 2004), and is generally regarded as the most devastating aspects of living with a venous leg ulcer (Hofman et al, 1997). Additionally, as mentioned earlier, recent work has highlighted that pain is also a significant problem in patients with diabetic foot ulcers (Bengtsson et al, 2008).

In addition to relieving pressure from plantar surfaces (‘off-loading’) to prevent further trauma, management of the diabetic foot ulcer follows the principles that are now universal in wound care practice, i.e. cleansing and debridement, controlling exudate thus protecting the wound from trauma, preventing infection and controlling pain (Frykberg, 2002). It is also important to consider that chronological ageing has cumulative and intrinsic effects which are intimately linked to dynamic changes in the skin (such as appearance, structure, mechanical properties and barrier function) that, in turn, may result in increased skin fragility over time (Waller and Maibach, 2006; Cutting, 2008). Such observations reinforce the need to preserve the integrity of aged skin by choosing dressings which areatraumatic and appropriate to local clinical conditions.

Dressings with Safetac technology rely on a patented adhesive technology involving the use of soft silicone, a material that adheres readily to intact dry skin but does not stick to the surface of a moist wound or to the surrounding skin. Hence, dressings with Safetac can be applied and re-applied without causing damage to newly forming tissue in the wound or skin stripping in the peri-wound region, as well as minimising pain at dressing removal (Cutting, 2008). The gentle but effective seal that forms between the intact skin and a dressing with Safetac inhibits the movement of exudate from the wound onto the surrounding area, thereby helping to prevent maceration of the peri-wound region (White, 2005).

A number of studies (Eager, 2001; Young, 2002; O’Neill, 2004; Misgavige, 2005; Khamiin, 2006; Spraul et al, 2006; White, 2008) have been undertaken to evaluate the use of dressings utilising Safetac in the management of diabetic foot ulcers. One study, which took the form of a retrospective review of data collated on patients with a variety of wound types (arterial ulcers, burns, diabetic foot ulcers, mixed aetiology ulcers, pressure ulcers, surgical wounds, traumatic wounds and venous leg ulcers) seen at an outpatient clinic, set out to compare Mepilex® (Mölnlycke, Göteborg) (an absorbent foam dressing with a Safetac wound contact layer) (n=87) with Allevyn (Smith & Nephew, Hull) (an absorbent foam dressing) (n=86). Patients treated with Mepilex had fewer peri-wound issues (i.e. dermatitis) (n=6) than those treated with Allevyn (n=11). Mepilex was also associated with a faster healing rate and a longer wear time than Allevyn (Eager, 2001).

More recently, a clinical evaluation has demonstrated the ability of dressings with Safetac to minimise pain at dressing change. This took the form of a multinational survey of 3,034 patients (White, 2008) presenting with a variety of different wound types including leg ulcers (arterial, venous or mixed aetiologies), burns, skin tears, pressure ulcers and 212 (7%) had diabetic foot ulcers. The impact of introducing dressings with Safetac — either Mepilex, Mepilex® Border (absorbent self-adhesive island foam dressing), Mepilex® Lite, or Mepilex® Border Lite — on the intensity of wound-related trauma and pain was assessed in comparison with previous treatment regimens involving advanced dressings with traditional adhesives (adhesive foams, hydrocolloids and others including films, surgical dressings and alginates). The dressings with Safetac demonstrably reduced trauma to wounds and peri-wound skin and were associated with significant (p=0.01) reductions in the levels of wound-related pain measured (by means of a visual analogue scale) before, during and after dressing change, compared with advanced dressings using traditional, but more aggressive, adhesives. Furthermore, when asked about dressing preference, more than 90% of patients surveyed indicated that they preferred the dressings with Safetac to their previous treatment regimens.
Other studies have specifically evaluated dressings with Safetac in the treatment of diabetic foot ulcers. For example, in a multi-centre study involving 77 patients with foot lesions, 64 of whom had diabetes, the performance of Mepilex Lite was evaluated in terms of the healing state of the wounds, the condition of the peri-wound skin, and the opinions of both patients and investigators. Forty-two percent of the diabetic foot ulcers were associated with wound-related pain and 16% were neuropathic. The objectives for treatment were met in 81% of cases with 88% of patients and 96% of investigators stating they would wish to use Mepilex Lite again. The high patient acceptance of Mepilex Lite was attributed to a number of factors including: its ease of application, comfort, pain-free removal; and that it was less bulky for footwear than other dressings (O’Neill, 2004). Mepilex Lite was also evaluated in a 10-patient study for the management of non-exuding or low-exuding diabetic foot ulcers that were Grade I or II on the Wagner Ulcer Grade Classification System (Wagner, 1981). Wound size decreased from a mean of 3.6 cm² to 0.85 cm² over the five-week treatment period with complete healing achieved in three patients. Dressings were atraumatic to the surrounding skin and were evaluated as good or very good by all patients and the investigator (Khramilin, 2006).

Misgavige describes how the introduction of Mepilex Border to the treatment of a painful diabetic foot ulcer decreased the patient’s level of pain, as well as providing additional padding and comfort to her diabetic shoes (without compromising the fit) and an environment conducive to healing (Misgavige, 2005).

Spraul et al (2006) reported on a case study involving the use of Mepilex Border Lite in a 70-year-old patient with diabetes and ulcers on the toes. Three of the four ulcers healed completely after 33 days of treatment and the remaining ulcer healed after three months. No maceration occurred. Of note is that Mepilex Border Lite stayed in place well in this difficult anatomical area for applying dressings (Spraul et al, 2006). Additionally, Young reports on the successful healing of a deep ulcer which showed little evidence of granulation and an inflamed and infected ulcer after the introduction of Mepitel (Mölnlycke, Göteborg) (wound contact dressing consisting of a flexible polyamide net coated with Safetac) and Mepilex, respectively (Young, 2002). The use of Mepitel helped to protect the new epithelisation tissue from trauma at dressing changes.

Using this evidence to inform treatment, a series of case reports were undertaken to evaluate the performance of dressings with Safetac in the management of wounds of patients with diabetes where traditional treatment regimens were failing. Patients with diabetic foot ulcers attending a specialist out-patient wound care centre in Belgium were recruited. Patients were selected if, in the opinion of the investigator, they had wounds that presented clinical challenges that could be overcome by using dressings with Safetac. The case reports are presented below.

**Case report 1**

**Clinical history**

A 77-year old man who had Type 1I diabetes for the previous 20 years as well as complicating cardiac problems, presented with an ulcer with a deep osteomyelitis on the digital interphalangeal joint of the second left toe. A digital interphalangeal arthroplasty was recommended by the orthopaedic surgeon. Subsequently, a post-operative cellulitis led to a necrotic wound that had a cavity tracking to the bone.

**Wound history**

The wound was a small inter-digital ulcer caused by pressure from the first toe rubbing against the second toe. Clinical signs of infection and a deep-seated osteomyelitis were observed. The infected bone was surgically removed but post-operative necrotic tissue and a cavity wound were subsequently identified as hindering the healing process. Autolytic/mechanical debridement was undertaken to remove the necrotic tissue. Previously povidone-iodine gauze had been used without success to treat the wound. This treatment regimen was disadvantageous in that it did not provide a moist wound environment, required frequent dressing changes, was complicated to apply, time-consuming for the nurse, and adhered to the wound.

![Image](Image)
Clinical RESEARCH/AUDIT

Lite was used to facilitate autolytic debridement and aid in the removal of the necrotic tissue. Mepilex was retained by Tubitron (surgical stockinette) and Mepitac (both Mölnlycke, Göteborg) to reduce the risk of damaging the fragile peri-wound skin. The wound infection was treated with systemic antibiotics.

Evaluation of dressings
Mepilex Lite dressings were conformable and easy to apply to the awkwardly located wound. They coped adequately with exudate and no leakage occurred. The patient had no pain during treatment or at dressing changes. No trauma to the wound or adjacent skin was identified throughout the course of treatment.

Clinical outcomes
The treatment regimen was associated with excellent debridement of the necrotic tissue and cleansing of the wound. The quality of healing was good in about eight weeks of treatment (Figures 1 a–d). The patient was satisfied that the dressing stayed in place, that it was comfortable and that it helped to heal his wound. Mepilex Lite was seen as a safe dressing that was easy to apply and remove, very comfortable for the patient, and provided an excellent environment for healing to proceed.

Case report 2
Clinical history
An 83-year-old woman, with diabetes but no other health-related problems, presented with a heel ulcer.

Wound history
The wound was a very painful deep pressure ulcer on the heel, with a low-grade infection and associated peri-wound erythema (Figure 2a). The wound was exuding moderately and there was some maceration of the surrounding skin.

Rationale for dressing use
The heel is a very difficult area of the body when it comes to applying and securing wound dressings. In this instance, Mepilex Heel was used because it conforms well to the shape of the heel, while its self-adhesive border ensures firm fixation (Figure 2b).

This dressing can also be used to adequately manage moderate levels of wound exudate. The patient was also experiencing severe wound pain so a dressing that would help to alleviate this was required. Off-loading strategies including the use of a cushion under the legs at night and open slippers during the day were also employed.

Clinical outcomes
Healing was qualitatively good, but slow (Figures 2a–d). The patient was very happy with the dressing when it had been applied and she did not complain of any side-effects associated with its use. Mepilex Heel proved to be very easy to apply to the awkwardly positioned heel ulcer. The dressing successfully managed exudate and aided in autolytic debridement of the wound, while providing good protection for neo-granulation tissue. No trauma due to skin stripping was apparent and good pain control was achieved.

Evaluation of dressings
The conformability of Mepilex Heel allowed it to be easily moulded to the shape of the heel. Application and removal of the dressing was quick and simple with no adherence causing further trauma to the wound or surrounding skin. Wound exudate was readily absorbed and the dressing’s adhesive border prevented exudate leakage. It was possible to retain Mepilex Heel in place for a period of up to five days, dependent upon exudate levels. The patient experienced no pain with the dressing in situ or at dressing changes.

Case report 3
Clinical history
A 62-year-old man with diabetes, presented with a traumatic wound.

Wound history
The wound was a superficial, traumatic lesion in the region of the left Achilles tendon. There were no signs of infection but the wound was extremely painful as a result of rubbing from the patient’s shoes. Previously, the wound had been treated with Vaseline-impregnated gauze, but these dressings dried out and delayed the healing process.

Rationale for dressing use
The wound required a protective dressing that could provide a cushion in the area of the Achilles tendon to prevent further trauma. As the wound and surrounding skin were tender, a dressing that could provide pain and trauma-free application and removal was required. For this reason, Mepilex was selected for use.

Evaluation of dressings
Mepilex dressings were found to be very easy to apply and remove from a difficult-to-dress area. The dressings stayed in place for a period of up to five days, dependent upon exudate levels. The patient experienced no pain with the dressing in situ or at dressing changes.
place under the shoe for a period of 4–7 days, affording the patient protection of the wound, freedom from pain and subsequent mobility. Mepilex did not adhere to the wound or surrounding skin and therefore successfully prevented re-traumatisation. Exudate was managed effectively with no evidence of maceration to adjacent tissue.

Clinical outcomes
No pain was experienced by the patient when the dressing was in place, or when the dressing was changed. Healing progression was rapid over the 15 days that it was evaluated, producing good qualitative results with granulation tissue and re-epithelialisation and no signs of infection (Figures 3a–d). The patient wished that he had been treated with Mepilex earlier, and was surprised that the dressing stayed in place for so long. With little exudate from the wound, Mepilex could be retained in place for relatively long periods of time (up to seven days). The cushioning effect of the dressing allowed it to protect the wound and support the growth of granulation tissue and re-epithelialisation.

Case report 4
Clinical history
A 66-year-old man with diabetes presented with a foot ulcer:

Wound history
The wound was an ulcerated lesion under a callous on the first toe that was caused by pressure due to foot deformation resulting from limited joint mobility. Povidone iodine and cotton gauze swabs had previously been used to treat the wound.

Rationale for dressing use
Because of the location of the wound, a thin conformable dressing that could be applied completely around the region of the toe was required. Mepilex Border Lite was used in conjunction with an off-loading dressing (a piece of felt cut to size) as a pressure-relieving device, secured with Hypafix adhesive tape (Smith & Nephew, Hull).

Evaluation of dressings
Mepilex Border Lite dressings were found to be easy to apply to the wound and around the toe due to their conformable nature. There was no dressing adherence to the wound and no pain associated with their use at any time.

Clinical outcomes
After the wound had been debrided, healing occurred very quickly in approximately four weeks (Figures 4a–d). No maceration occurred. The patient was pleasantly surprised that the dressing stayed in place for between 3–5 days and that he had experienced no discomfort with the dressings. Overall, Mepilex Border Lite allowed extended wear time in this low-exuding wound.

The dressing provided an atraumatic and painless treatment of the wound with no adherence to the wound or adjacent skin.

Case report 5
Clinical history
A 68-year-old man, who had had Type II diabetes for more than 15 years, presented with a foot ulcer:

Wound history
The wound was a diabetic foot ulcer (grade 1, Wagner Ulcer Grade Classification System, 1981) on the patient’s first toe that had been caused by pressure. The wound was not painful due to neuropathy, but was producing low levels of exudate. Additionally,
evidence of leakage or maceration of surrounding tissue.

Clinical outcomes
The wound healed within a month of starting treatment with Mepitel (Figures 5a–d). This was perceived as very quick in relation to the usual progress of a diabetic foot ulcer. The patient stated that he thought that Mepitel was a comfortable dressing because it was not necessary to remove it every day. Mepitel was also good to use in combination with topical antiseptics. It was cost-effective and could be maintained in place for prolonged periods. There was an improvement in the appearance of the wound bed and adjacent edges.

Case report 6
Clinical history
A 71-year-old woman, with a 10-year history of diabetes, venous and cardiac insufficiency with retinopathy presented with a leg ulcer. Previously the patient had had deep vein thrombosis with recurrent hard-to-heal venous leg ulcers, although arterial flow was satisfactory.

Wound history
The wound, present for three days, was the result of breakdown of atrophy blanche skin. It was very painful, and was exuding heavily and was easily damaged. The wound had previously been treated with Fucidin gauze dressings (Leo Laboratories, Bucks) without success.

Rationale for dressing use
There was a need for a dressing that could be used under compression therapy while also providing exudate management and would not be painful especially at the times of dressing changes. Mepilex Transfer, a thin, conformable dressing with Safetac that conforms closely to the wound and the surrounding skin, even where the surface is uneven, was used under compression with cotton gauzes and a cotton gauze bandage for fixation.

Evaluation of dressings
Mepilex Transfer was found to be easy to apply and remove without causing trauma or tissue damage. Exudate management was very good even under compression therapy and no leakage or tissue maceration was observed with this dressing in situ.

Clinical outcomes
Previously, the wound had been associated with very slow healing, however, complete healing was achieved within two weeks of starting treatment with Mepilex Transfer (Figures 6a–d). No infection was observed and pain control was very good. The patient was delighted with the pain control that Mepilex Transfer provided. Venous leg ulcers in association with diabetes can be problematic. In order to treat such wounds, appropriate compression therapy with an optimal dressing choice

Figure 5a. Blistered toe of a patient with diabetes
Figure 5b. Treatment with Mepitel shows excellent conformability of dressing
Figure 5c. Wound healing progressing well after eight days of treatment
Figure 5d. Wound almost completely healed after 17 days of treatment

Figure 6a. Venous leg ulcer of diabetic patient
Figure 6b. Demonstration of dressing application
Figure 6c. Wound healing progression after one week of treatment
Figure 6d. Wound completely healed after two weeks of treatment
such as, in this case, Mepilex Transfer; is necessary to aid wound healing.

Case report 7
Clinical history
An 85-year-old man with chronic obstructive pulmonary disease and diabetes, presented with an ulcerated wound.

Wound history
The wound was a three-week-old post-operative lesion that had ulcerated after two amputations of the fifth toe on the right foot and had a cavity to a depth of 5mm. Clinical signs of infection were apparent as the wound demonstrated moderate levels of exudate, redness and oedema with a high level of pain.

Rationale for dressing use
There was a need for a dressing that could be used to treat the ongoing infection, but would also be able to reduce the level of pain that the patient was suffering. Mepilex Ag (silver-containing absorbent foam dressing with Safetac) addresses both of these issues as silver has been clinically proven as a highly effective topical antimicrobial agent in the management of infected wounds (Woo et al, 2008).

Evaluation of dressings
The challenge of cavity wounds is that dressings generally have to be cut to size before application. This was done with Mepilex Ag to good effect. Mepilex Ag was good in this indication because it could be cut to size and it has instant and sustained, broad-spectrum antimicrobial activity (Taherinejad and Hamberg 2008) and, as a result of it incorporating Safetac technology, prevents trauma to the wound and surrounding skin when it is removed.

Clinical outcomes
Within 10 days of starting treatment with Mepilex Ag, the wound infection was under control and the patient was subsequently discharged from hospital. Healing was initiated early on in the treatment process and complete healing was achieved within two months (Figures 7a–d). Both patient and investigator were pleased with the reduction of pain at dressing changes and the rapid antibacterial action associated with the use of Mepilex Ag.

Discussion
The wounds of patients with diabetes present a number of clinical challenges to healthcare workers who are responsible for their treatment. These challenges are not unique to this patient group but confounding factors, such as neuropathy leading to loss of sensation and physical malformations such as Charcot foot, may enhance the problems. The following problems are typically encountered when treating wounds of diabetic patients:

- The location of the wounds, especially with regards to digit amputations, makes application of dressings difficult. Heel wounds, generally occurring as a result of excessive pressure, also require highly conformable or specialist heel dressings to mould to the shape of the heel
- There is a relatively high incidence of infection in the wounds of patients with diabetes. Infected wounds require dressings that have an antibacterial action: infection usually goes hand-in-hand with moderate-to-high levels of exudate that also have to be managed
- Neuropathic disease leads to degeneration of nerves and results in loss of cutaneous sensation. If the skin is damaged or subjected to continuous trauma, e.g. friction from wearing shoes, then wounds may develop that go unnoticed by the patient. In these cases, treatment involves off-loading in association with the use of appropriate wound dressings.
- Although many patients with diabetes are neuropathic and may have a loss of sensation, many do in fact feel pain in their wounds or surrounding skin. Dressings aimed at reducing trauma and pain are therefore required to reduce the suffering of these patients.

Dressings with Safetac have been developed to address the specific problems of trauma and pain that may be associated with dressings that use aggressive adhesive components. Safetac technology has been used in a variety of different dressings that have ultimately been used to successfully treat many different types of both acute and chronic wounds (Bugmann et al, 1995; Dahlstrom, 1995; Platt et al, 1996; Gotschall et al, 1999; O’Donovan et al, 1999; Eager, 2001; Meaume et al, 2003; Zillmer et al, 2006; Woo et al, 2007; White 2008). Although the evidence presented in this article refers to case studies, and not to high level randomised controlled trials, the findings show how that in ‘real life’ situations, the clinical challenges presented by these patients can be successfully overcome with dressing regimens that utilise Safetac technology.

Conclusion
Patients with diabetes present with wounds that may be difficult to treat with traditional dressings. A series of case studies has demonstrated how such wounds can be successfully treated with a range of dressings that uses soft silicone dressings.
Wound-related pain is underestimated in patients with diabetic foot ulcers. J Wound Care 17(10): 433–5


