Mepilex® Border Flex — results of an observational study in German specialist wound care centres

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This article describes the results of a retrospective, observational study that was undertaken at specialised wound care centres in Germany to evaluate the management of a variety of exuding wound types with an all-in-one self-adherent, silicone-coated foam dressing. The study collected data from 431 patients with 549 wounds that were considered appropriate for treatment with the dressing. Assessed parameters included wound size and status, periwound skin condition, exudate management, dressing wear time, pain associated with dressing change and ease of dressing change. Based on the clinical outcomes observed in this study, the wound dressing demonstrated an ability to handle exudate, provide an optimal moist wound-healing environment, promote healthy periwound tissue, minimise pain and minimise the risk of maceration. Further investigation is warranted to confirm these findings.

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Wound care has moved forward significantly over the past decade or so, leading to a range of wound dressing options, serving a variety of purposes. Wound dressings facilitate healing by providing an optimal healing environment. They do not heal the wound themselves (Bennett-Marsden, 2010), however, selection of the most appropriate dressing can be a challenge. As well as being appropriate for the wound's characteristics and stage of healing, a modern conformable dressing must be able to remain in place, for as long as needed, even on hard-to-dress body contours and while the patient moves about. For optimum patient comfort, the adhesive used in the wound contact layer of the dressing must be non-adherent (atraumatic) to the wound as, should adherence occur, dressing removal is likely to be very painful and may damage the fragile new tissue, leading to a longer healing time and scar tissue formation (White, 2005; Upton and Solowiej, 2012).

Older or very young patients or those with genetic skin conditions (e.g. epidermolysis bullosa) are particularly vulnerable to this type of skin damage. Studies have indicated that atraumatic dressings using Safetac® soft silicone adhesive technology (Mölnlycke Health Care, Gothenburg, Sweden) significantly reduce pain during wear, at dressing removal and after dressing change, compared with dressings with traditional adhesives (Meaume et al, 2004; White, 2008; Meuleneire and Rücknagel, 2013).

Mepilex® Border Flex

Mepilex Border Flex (Mölnlycke Health Care, Gothenburg, Sweden) is an all-in-one self-adherent soft silicone (Safetac) coated foam dressing *[Figure 1]* that effectively absorbs and retains exudate and maintains a moist environment (Feili et al, 2008; Wiberg et al, 2008; Mölnlycke Health Care [1], data-on-file). The dressing is designed to adapt to contours of the body and to distribute forces on the borders evenly, so that rolling is minimised, and conformability and ability to stay in place are increased. It offers the key features required to assist healing in a variety of wounds, for example, those caused by trauma, leg and foot ulcers, pressure ulcers and other secondary healing wounds. Furthermore, from a practical perspective, it comes in a variety of sizes.

The innovative Mepilex Border Flex dressing receives features from the Flex Technology with patterned perforations ('flex cut') in the absorbent pad allowing greater extensibility, flexibility and smooth movement with the patient's body (Mölnlycke Health Care [2], data-on-file); dressing wastage is likely to be reduced through its enhanced capacity to remain in the same place for as long as needed.

Table 1. Wound- and dressing-related parameters extracted from the digital wound documentation system for analysis.

Wound-related	Dressing-related
Type	Treatment duration
International Classification of Diseases (ICD-10)	Wear time/interval between dressing changes
Wound age at start of treatment	Ease of dressing changes
Anatomical location	Pain at dressing changes
Visual assessment (colour)	Reason for treatment discontinuation
Size	
Condition	
Exudate characteristics	
Signs of infection	
Periwound skin condition	

Table 2. Colour of wound tissue at baseline and at Final Visit. The most common colour of the wound tissues at baseline was yellow/red (highlighted) changing to a healthy pink at the Final Visit (highlighted).

Wound visual assessment	Baseline (n, %)	Final Visit (n, %)
Red	187 (34.06)	72 (13.51)
Yellow/red	199 (36.25)	98 (18.39)
Red/pink	113 (20.58)	94 (17.64)
Yellow	29 (5.28)	13 (2.44)
Pink	0 (0)	245 (45.97)
Black/yellow/red	17 (3.1)	10 (1.88)
Black	0 (0)	0 (0)
Black/yellow	4 (0.73)	1 (0.19)

From a patient's perspective, Mepilex Border Flex dressing is designed to minimise pain and trauma at dressing changes and its conformability enhances patient comfort and confidence in the dressing. Its unique Safetac adhesive technology is designed to form a gentle adhesion between the dressing and intact skin (reducing the risk for maceration) and minimises skin and wound damage (Dykes et al 2001; White et al 2005; Feili et al 2008; Wiberg et al, 2008; Waring et al, 2011).

Clinical evidence supporting Mepilex Border Flex

WZ-WundZentren GmbH operates 15 specialised wound care centres throughout Germany. At the time of this analysis, there were 12 specialised wound care centres. These centres operate to the same standard of care and use a digital wound documentation system. The study described here is observational and is based on wound and dressing parameters that were entered into a central database *[Table 1]* over 5 months (September 2017 to January 2018).

The study collected data from 431 patients (42% women, 58% men) with 549 wounds that were considered appropriate for treatment with Mepilex Border Flex. Patients were excluded if their wounds had no exudate at the beginning of wound care treatment. Mean patient age (standard deviation, SD) was 67.12 years (19.07 years) with a mean wound duration (SD) of 65.19 days (151.18 days). Concomitant medications used by patients during the study included: anti-coagulants (*n*=93; 21.58%), analgesics (*n*=92; 21.35%), diuretics (*n*=42; 9.74%), anti-diabetics (*n*=32; 7.42%), antibiotics (*n*=30; 6.96%), laxatives (*n*=16; 3.71%), glucocorticoids (*n*=15; 3.48%), chemotherapeutic agents (*n*=1; 0.23%) and other (*n*=159; 36.89%). Diseases of the circulatory system and of the endocrine, nutritional and metabolic systems were the most common conditions among the patients. Mobility of the participating patients was rated as mobile (*n*=234; 54.29%), mobile with assistance (*n*=155; 35.96%), immobile (*n*=38; 8.82%), and not recorded (*n*=4; 0.93%). A total of 132 wounds (24.04%) at baseline and 151 wounds (27.55%) at the final visit were undergoing concomitant use of compression therapy.

Patients had a variety of wound types, with venous leg ulcer, pressure ulcer and exogenous ulcer (defined here as a surgical wound or self-inflicted wound) making up 68% of all wound types *[Figure 2]*. The foot, leg and sacrum were the most common anatomical areas where wounds were found. The size of the wound (area in cm^2) was tracked regularly (approximately every 2 weeks) throughout the study and was compared at t0 (baseline) and at the final visit. At baseline, the mean wound area (SD) was 1.95 cm^2 (3.42 cm^2) and at the final visit, was 1.25 cm^2 (4.10 cm^2) (excluding outliers).

A visual inspection of the wounds was also conducted (approximately every 2 weeks); the type, colour, level of moisturisation and exudate type of the wounds were assessed and recorded at baseline with Mepilex Border Flex and at the final visit *[Table 2, Figures 3 and 4]*. At baseline, the most common colour of the wound tissues was yellow-red (36.25%) or red (34.06%), changing to pink at the final visit in almost half of the wounds (45.97%), as the wounds progressed towards healing. Signs of local infection were present in 55.74% of wounds at baseline and in 30.22% of wounds at the final visit. Invasive infection with extensive symptoms was recorded for 2.19% of wounds at baseline and for 1.68% of wounds at the final visit. At baseline, 42.08% of wounds were without infection, increasing to 68.1% at the final visit.

Exudation was assessed, together with the dressing's ability to deal with different types and volume of exudate and the effect this had on

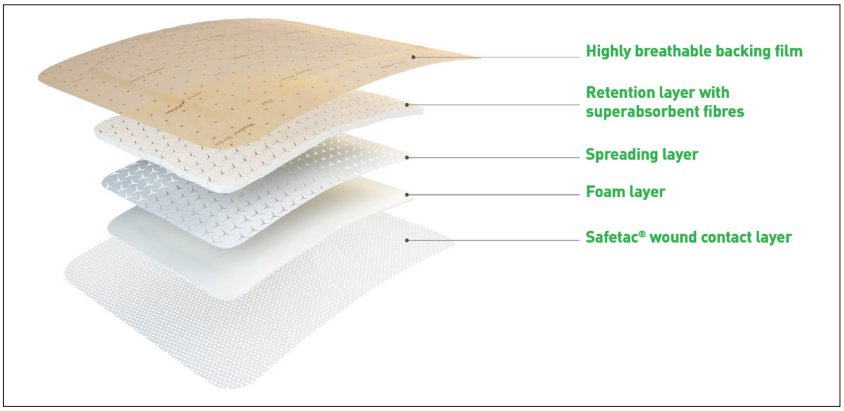


Figure 1. Composition of Mepilex Border Flex

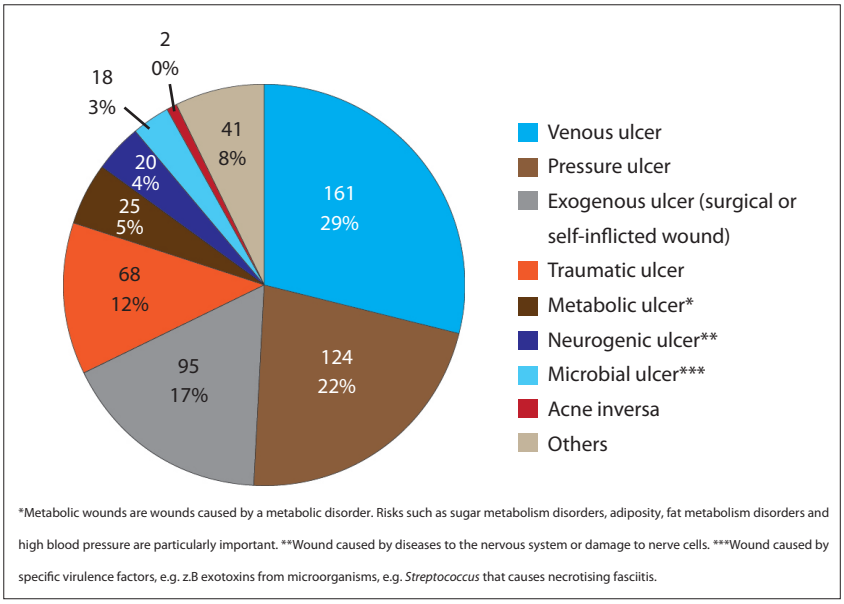


Figure 2. Wound types treated with Mepilex Border Flex (n, %). Note: In some cases, the wound was defined under more than one wound type.

wound healing. At baseline, wounds were mostly exuding slightly (63.93%) or were moist (33.52%), and this was similarly the case at the final visit: 59.72% and 31.94% for slightly exuding and moist, respectively *[Figure 3]*. In terms of exudate type, at baseline, the exudate was mostly serous (68.12%) or murky (26.23%) and this remained the case at the final visit (58.97%, serous and 27.66%, murky) *[Figure 4]*. For those wounds that were producing enough exudate to assess in terms of viscosity, the majority had thin exudate at both baseline (95.99%) and final visit (52.05%), with the remaining recorded as thick exudate. Mepilex Border Flex's ability to handle exudate and protect the wound and periwound skin to improve overall healing by providing an optimal moist wound-healing environment (Bond, 2015), was also assessed, based on clinical assessments. In relation to the periwound skin condition (flaking, maceration), at baseline, >95% of wounds had either no flaking (41.13%) or slight flaking (55.39%); this was similarly the case at the final visit (no flaking, 42.62%, slight flaking, 52.58%). At baseline and at the final visit, most of the wounds (81.93% and 89.14%, respectively) had no maceration. Hence, Mepilex Border Flex was shown, based on the clinical data from this observational study, to be able to handle exudate effectively. A dressing's ability to handle exudate is also known to impact on dressing wear times (Evans, 2014). The median (range) total treatment duration with Mepilex Border Flex was 33 days (6 days to 149 days). Dressing wear time ranged from 1 to 7 days, with a mean of 4.5 days (median 4 days) at the first dressing change (*n*=522). However, in line with local protocol, wounds were required to be examined at least once per week.

Mepilex Border Flex was easily removed at dressing changes throughout the study; respondents said that the dressing was "easily removed" in 458 wounds (83.42%) at the first dressing change, a figure that increased up to 100% over the 12 weeks. Mean pain score/severity (SD) (assessed using a 10-point visual analogue scale (VAS), ranging from 0 (no pain) to 10 (intolerable pain)) at dressing change (sought from 47 and 49 patients at baseline and the final visit, respectively, i.e. only those patients who had pain) was 2.95 (1.99) at baseline and 3.29 (2.01) at the final visit. Pain levels at dressing change and overall ease of dressing change are important to patients and can influence their acceptance of, and confidence in, a specific dressing (White, 2008). Furthermore, stress as a result of pain has been associated with delayed wound healing (Coulling, 2007). The most common reason for termination of treatment with Mepilex Border Flex was that the wound had healed, *n*=231, 42% (however, at the time of this analysis, 263 wounds (48%) were still being treated).

Conclusions

This retrospective, observational study, conducted in Germany, provided wound and dressing data from 431 patients with 549 wounds. The data show that Mepilex Border Flex is a highly effective dressing for exuding wounds that may be present in a challenging anatomical location, even wounds of relatively longstanding duration (>20 weeks). While further investigation is necessary, based on the clinical outcomes observed in this observational study, Mepilex Border Flex demonstrated an ability to handle exudate, provide an optimal moist wound-healing environment, promote healthy periwound tissue, minimise pain and minimise the risk of maceration.

Mepilex Border Flex is likely to be highly acceptable to patients, as it is easy to apply, remove and wear, with either no or very low level pain at dressing change. A relatively rapid progression of the wound towards healing, combined with the very low

*Figure 3. Wound exudate level at baseline (n=549) and at the final visit (n=288) following initiation of treatment with Mepilex Border Flex. *Note: There was missing documentation in some cases.*

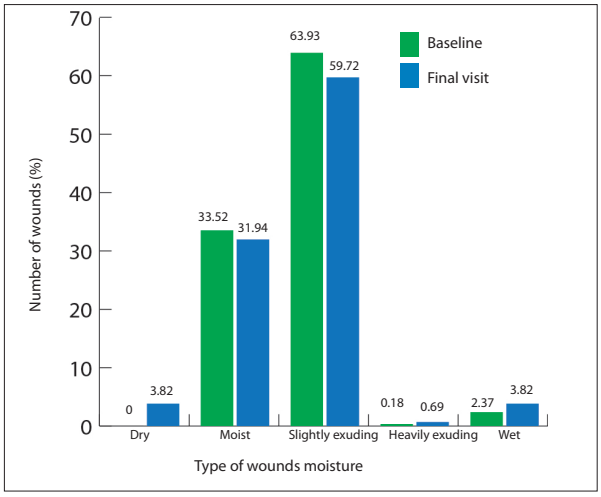


*Figure 4. Wound exudate type at baseline (n=549) and at the final visit (n=329) following initiation of treatment with Mepilex Border Flex.*Note: There was missing documentation in some cases.*

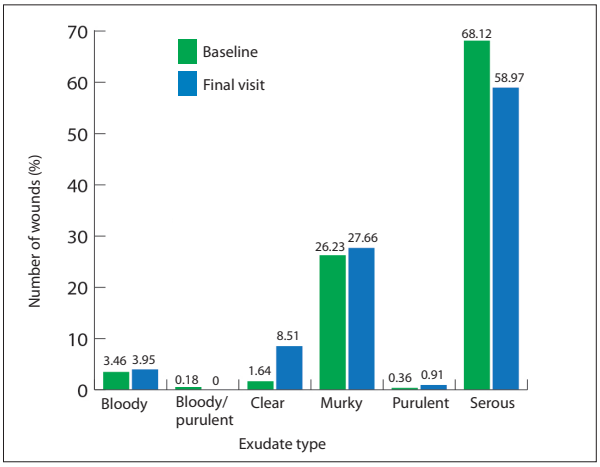
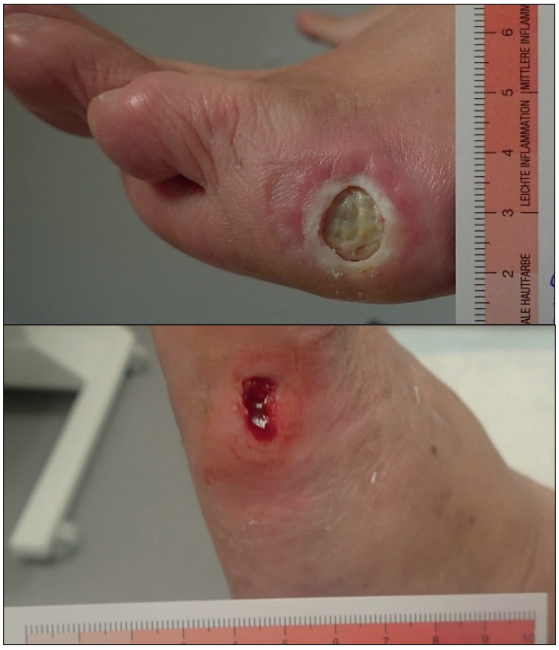


Figure 5 (top). Case study: wound at baseline

Figure 6 (below). Case study: wound at final visit (following a total of 18 weeks and 1 day of treatment), following surgical debridement.



pain levels, mean that patients are likely to be highly compliant with Mepilex Border Flex treatment. In addition, the dressing can be worn for up to 7 days on non-infected wounds; while the wear time of the dressing must be evaluated in a suitably designed study, long wear times speak for cost benefits.

Case Study

The patient was a 73-year-old male with mal perforans (neurotrophic ulcer in diabetes mellitus) on the lateral aspect of the left foot. The patient had atherosclerosis to the extremities. The wound measured 1.11 cm^2 and had 3 mm circular undermining *[Figure 5]*. Wet-to-dry dressings were used prior to debridement with a ring curette. The wound management procedure included active periodic wound cleansing with a wound cleansing solution, use of a wound filler (hydrofiber), wound edge protection and application of Mepilex Border Flex; this wound management procedure was performed three times per week. After 10 weeks and 5 days of treatment, the wound had reduced in size to 0.65 cm^2. At day 109 (15 weeks and 4 days), the wound measured 0.39 cm^2. After a total of 18 weeks and 1 day, the wound measured 0.2 cm^2 following surgical debridement *[Figure 6]*. WINT

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