

Mepilex® Border Heel and the treatment of foot ulcers: a case series

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Article points

1. Diabetic foot ulcers on the heel are particularly challenging to manage; irregular shape, high exudate levels, poor perfusion in the heel and dressing displacement are common challenges in the management of these wounds.
2. In this case study series, Mepilex Border Heel was associated with improved wound healing outcomes and effective exudate management. Improvements in periwound condition were also noted.
3. Overall, clinicians and patients were highly satisfied with the wound dressing. Dressings generally remained in situ, providing high levels of patient comfort and minimal disturbance to the wound and surrounding skin.

Declaration of interest

This study was supported by an unrestricted educational grant from Mölnlycke Health Care

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Diabetic foot ulcers (DFUs) are a clinical challenge, in part due to their awkward location, risk of infection and high levels of wound exudate. This case study series set out to evaluate the effectiveness of an all-in-one foam dressing with soft silicone (Safetac®) technology, Mepilex Border Heel®, in the management of foot ulcers in terms of wound status outcomes and patient and clinician satisfaction. The use of Mepilex Border Heel was associated with improved wound healing outcomes, good exudate management, minimisation of periwound skin damage and patient comfort.

Diabetic foot ulcers (DFUs) are difficult to heal and foot ulceration is a common risk factor for lower extremity amputation, with the risk of amputation increasing in line with wound chronicity (Armstrong and Lavery, 1998; Aumiller and Dollahite, 2015). While infection is rarely a predisposing factor for DFU development, DFUs commonly become infected once the wound is established, resulting in pain, delayed wound healing, an increased risk of lower-limb amputation and, ultimately, reduced patient quality of life (QoL) (White, 2009; Richards and Chadwick, 2011).

The aetiology of DFUs is multifactorial and complex, with many risk factors associated with their onset. Neuropathy is an underlying factor which leads to the development of foot ulceration and ultimately amputation (Frykberg, 2002). However, research has suggested that pain can be associated with both neuropathic and neuroischaemic DFUs (Bengtsson et al, 2008), with dressing-related pain often associated with these wounds (Richards and Chadwick, 2011). Other underlying factors include ischaemia, callus formation and oedema (Frykberg, 2002). Patients with diabetes are particularly prone to ulceration on the heel since the fat pads in the heel are less pliable and cannot easily regain shape after impact, compared to those in people without diabetes (Wounds UK, 2013).

DFU management should include a thorough wound assessment and monitoring for the prevention

of foot complications, pressure relief, wound bed preparation, exudate management, and careful management of infection and pain (Armstrong and Lavery, 1998; Richards and Chadwick, 2011).

Heel ulcers are particularly challenging to manage due to their awkward location, tendency to be irregularly shaped, often high exudate levels, poor perfusion in the heel and dressing displacement (Wounds UK, 2013). Mepilex® Border Heel (Mölnlycke Health Care, Sweden) is a self-adherent, bordered dressing with soft silicone technology designed to fit the heel comfortably, with a five-layer design. The incorporation of Safetac® soft silicone technology on its wound contact surface allows the dressing to gently adhere to the surrounding skin without sticking to the wound bed, enabling easy and atraumatic dressing removal and prevention of wound exudate leakage.

Aims

The objectives of this study were to evaluate the performance of Mepilex Border Heel in terms of a number of in-use characteristics and clinical outcomes when used to manage foot ulcers.

Methods

The investigation was designed as a single-centre case series. Five participants attending the Salford Royal NHS Foundation Trust with foot ulcers who met the inclusion/exclusion criteria (both in- and out-patients)

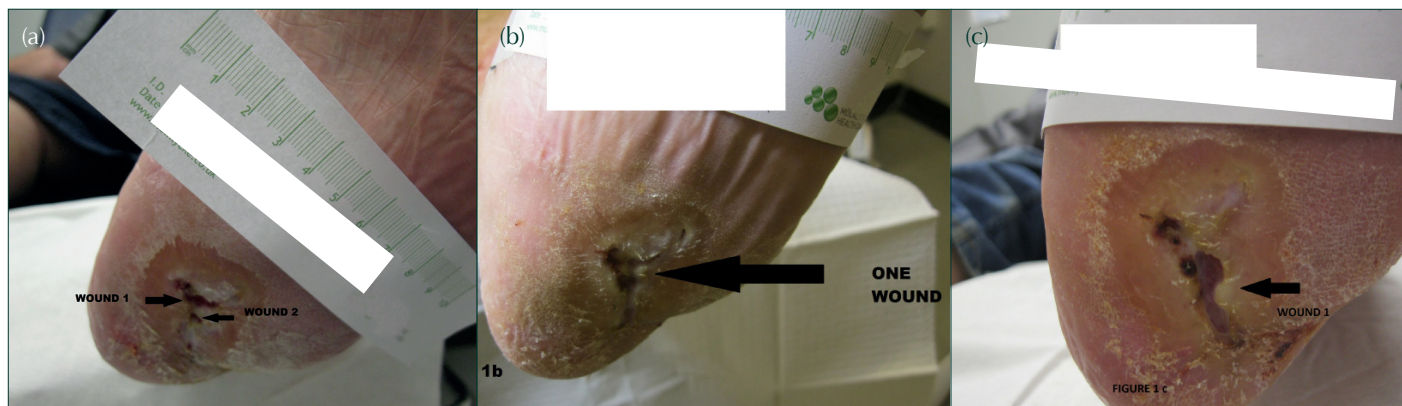


Figure 1. Case 1: (a) wounds at baseline; (b) wound at first follow-up visit (visit 2) (post-debridement); (c) wound at the final visit (visit 4) (post-debridement).

Key words

- Chronic wound
- Foot ulcer
- Mepilex Border Heel
- Wound dressing

(Table 1) and who were assigned to a treatment regimen that included the use of Mepilex Border dressings were included in the study. Each participant was treated according to local routine clinical practice and assessed over a treatment period of up to 12 weeks or until the wound(s) healed, whichever occurred first.

Ulcers were classified using Site, Ischemia, Neuropathy, Bacterial Infection, and Depth (SINBAD) classification (Ince et al, 2008). Assessments were made at dressing changes (baseline visit and follow-up visits), the frequency of which were determined by the condition of the wound and the judgement of the investigator. Table 2 lists the wound status variables that were assessed at visit 1 (baseline) and at subsequent follow-up visits (assessed before cleansing and/or debridement). All variables were assessed by visual qualitative assessment, apart from wound size, which was measured quantitatively.

Cleansing and debridement procedures performed were also documented. Traumatization to the wound and/or periwound region was recorded at each visit. Adverse events (AEs)/serious adverse events (SAEs) were also recorded. Digital photographs of the wound(s) were taken at each visit for each participant

to monitor wound progression throughout the course of the evaluation.

Table 3 lists the variables for the evaluation of the test dressing that were assessed at visit 1 and at subsequent follow-up visits. These were assessed qualitatively using a five-point scale from ‘excellent’ to ‘very poor’ by the clinician. Table 4 lists the variables for the patient evaluations.

Results

Five male participants met the inclusion criteria and were included in the evaluation. The five patients were recruited from July 2014 to February 2015. All five participants had diabetes (1 patient had type 1 diabetes; 4 patients had type 2 diabetes). Participants were aged between 25 years and 67 years. Coexisting medical conditions (other than diabetes) for each of the five participants are listed in Table 5. Baseline data for each participant and the target ulcer, and the target goals with the product under evaluation, are also outlined in Table 5. Current wound treatments are listed in Table 6.

Case study 1

Case 1 was a 60-year-old male with type 2 diabetes. At baseline, the patient had two 2-year-old neuropathic heel plantar ulcers which measured 10mm (length) by 5mm (width) and 3mm (length) by 2mm (width), respectively (Figure 1a). The wounds contained 40% non-viable tissue (defined as necrotic, fibrinous and/or sloughy) and were producing a moderate level of clear/serous exudate. The wounds had a SINBAD score of 4, indicating a potentially poor outcome. There was no traumatization to the wound or the surrounding skin during the initial dressing change. At the first follow-up visit (visit 2),

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Subject with a foot ulcer deemed by the investigator to be suitable for treatment with the product being evaluated.	Subject not expected to follow the evaluation procedures.
	Subject with known or suspected sensitivity to any of the components of the product being evaluated.
	Subject included in other case study series evaluation or clinical investigation at present or during the last 30 days.

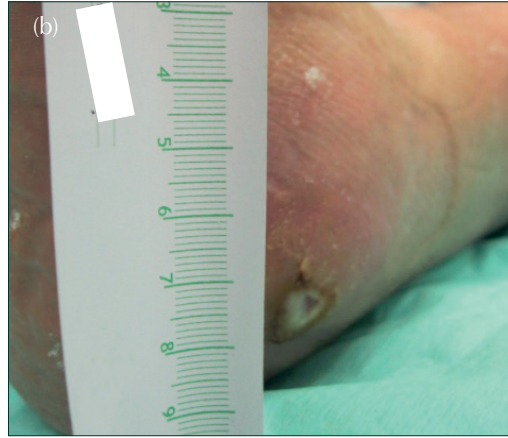
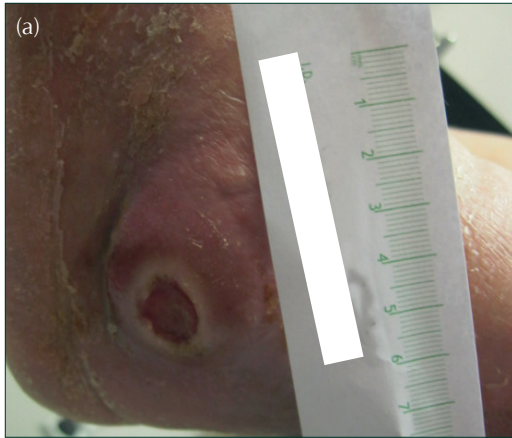


Figure 2. Case 2: (a) wound at baseline (Visit 1); (b) wound at final visit (visit 5).

the two wounds had become one. Signs of maceration and excoriation to the surrounding skin had decreased from 'moderate' to 'mild' (Figure 1b). By the second follow-up visit (visit 3), these signs of unhealthy surrounding skin had resolved. Some clinical signs of infection were noted at baseline (oedema, increased exudation, delayed healing). However, at the first follow-up visit oedema had been resolved. By the second follow-up visit, increased exudation and delayed healing were no longer documented. Pain between dressing changes was recorded as 'mild' at the first follow-up visit but by the second follow-up visit pain between dressing changes was no longer reported and this was maintained throughout the rest of the investigation. While the wound had slightly increased in size by the study end, the wound contained 100% viable tissue by the final visit. Furthermore, the exudate level had reduced by the end of the study. Figure 1c shows the wound at the final visit (visit 4).

At the final visit, the clinician rated each of the variables as 'excellent' (Table 3). The clinician's overall impression of the dressing at the final visit was 'excellent' and it was noted that the dressing 'went on easily' and 'fit well'. In terms of comfort, ability to stay in place during wear and overall impression of the dressing, the patient rated it as 'good'.

Case study 2

Case 2 was a 67-year-old male with Charcot foot (left foot). The patient had a neuropathic wound to the lateral aspect of the ankle, measuring 15mm in length and 11mm in width (Figure 2a). The wound had been present for 5 months prior to the initiation of the study and was given a SINBAD score of 3. The wound contained 100% non-viable tissue (defined as

necrotic, fibrinous and/or sloughy) and was producing a moderate level of clear/serous exudate.

At the first follow-up visit (visit 2), signs of eczema, excoriation and maceration to the surrounding skin noted at baseline had resolved. By the final follow-up visit (visit 5), erythema was no longer noted (Figure 2b). Gradual improvements in the clinical signs of infection noted at baseline were recorded including a decrease in oedema, exudation and heat. In line with the improvements in the condition of the wound and

Table 2. Wound status variables that were assessed at visit 1 and at subsequent follow-up visits (assessed before cleansing and/or debridement).

Wound Status Variable	Measurements
Clinical signs of infection	Measured on a four-point scale from 'none' to 'severe'; pus; pain between dressing changes; oedema; increased exudation; lymphangitis/adenitis; erythema; malodour; increased heat; delayed healing
Wound tissue appearance	Percentage viable and non-viable (necrotic, fibrin, slough) tissue
Exudate nature (if present)	Clear/serous; yellow/green; brown/blood; serosanguinous/blood; purulent
Exudate amount	Low; moderate; high
Condition of surrounding skin	Healthy, intact; not healthy
Condition of surrounding skin	Measured on a four-point scale from 'none' to 'severe': eczematous; erythema; rash; macerated; excoriated; blistered; other
Type of surrounding skin	Dry; flaky; normal; oily; cracked; moist; other
Odour from dressing	Yes; No
Wound size	Length; Width (mm)

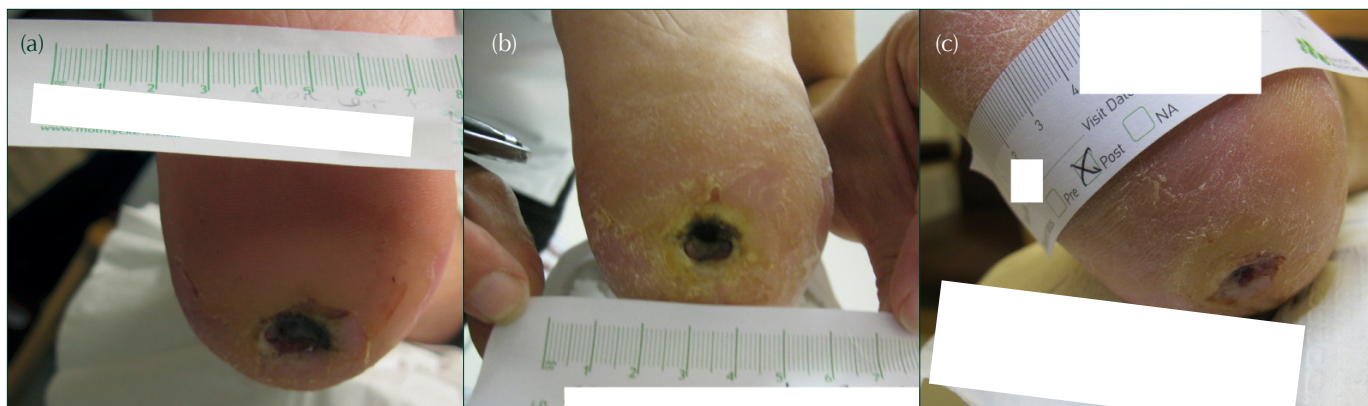


Figure 3. Case 3: (a) one of the two wounds at the first follow-up visit (Visit 2); (b) one of the two wounds at the final visit (visit 3) pre-debridement; (c) one of the two wounds at the final visit (visit 3) post-debridement.

surrounding skin, there was a steady decrease in wound size throughout the study period. By the final visit the wound was filled with 100% viable tissue and the exudate level had reduced.

At the final visit, the clinician rated each of the eight dressing variables as ‘excellent’ despite the area being difficult to dress. The clinician’s overall impression of the dressing at the final visit was ‘excellent’. The patient rated the dressing as ‘excellent’ in terms of comfort, ability to stay in place during wear and overall impression. The patient reported that Mepilex Border Heel was the first dressing to have stayed in place.

Case study 3

Case 3 was a 25-year-old male with type 1 diabetes. At baseline, the patient had two neuropathic wounds on the heel which had been present for 1 week. The wounds had a SINBAD score of 3 and measured 14mm (length) by 13mm (width) and 10mm (length) by 10mm (width), respectively. The wounds contained 40% non-viable tissue (defined as necrotic, fibrinous and/or sloughy) and the wounds were producing a moderate level of clear/serous exudate.

There was no traumatization to the wound bed or the surrounding skin during the initial dressing change. No pain was recorded throughout the evaluation due to neuropathy. Figure 3a shows the wounds at the first follow-up visit (visit 2).

By the final follow-up visit (visit 3) maceration to the surrounding skin had resolved. Moderate eczema, erythema and mild excoriation were recorded at the first follow-up visit (visit 2), however, these signs of unhealthy surrounding skin had improved or resolved by the final follow-up visit (visit 3) (Figure 3b/c). Clinical signs of infection noted at baseline

resolved or remained at a low level by the final visit. While moderate pus, oedema and malodour were first noted at the first follow-up visit (visit 2), these signs of infection had improved or had resolved by the final visit (visit 3). However, at the final visit mild pain (between dressing changes) and erythema were noted. Despite the wounds containing 40% non-viable tissue at the final visit, there was a decrease in wound size throughout the study period for both wounds and the exudate level had diminished (Figure 3b/c).

At the final visit, the clinician rated each of the eight dressing variables as ‘good’ or ‘excellent’. The clinician’s overall impression of the dressing at the final visit was ‘excellent’. The patient rated the dressing as ‘good’ in terms of comfort, ability to stay in place during wear and overall impression.

Case study 4

Case 4 was a 47-year-old male with type 2 diabetes. The patient had previously undergone debridement on the right first toe due to osteomyelitis. At baseline the patient had three neuropathic ulcers to the plantar aspect of the left heel which had been present for 1 week (Figure 4a). The wounds had a SINBAD score of 4 and measured 15mm (length) by 12mm (width), 4mm (length) by 5mm (width), and 6mm (length) by 2mm (width), respectively. The wounds contained 80% non-viable tissue (defined as necrotic, fibrinous and/or sloughy) and were producing a moderate level of serosanguinous/blood exudate.

There was no traumatization to the wound beds or the surrounding skin during the initial dressing change. Pain during the dressing change regime was a particular problem for this patient, despite the presence of neuropathy.

Table 3. Investigator evaluation variables of the test dressing (measured on a five-point scale, from ‘Excellent’ to ‘Very Poor’) (assessed at each visit).

Variables
Ease of handling at application
Ease of application
Ease of repositioning
Conformability
Flexibility
Ability to stay in place during wear
Ability to handle exudate
Ease of removal
Overall impression of the dressing

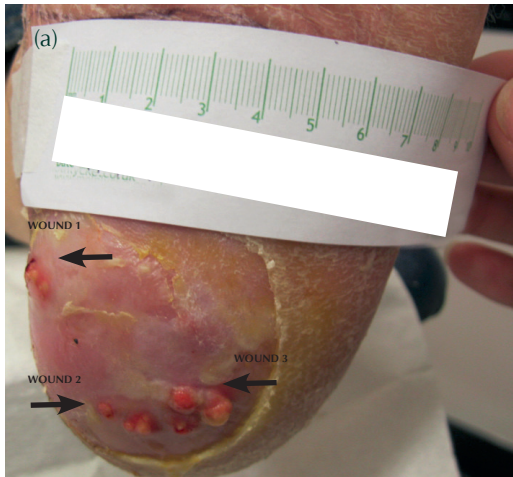


Figure 4. (a) Case 4: (a) wounds at baseline (visit 1); (b) wounds at the final visit (visit 3).

By the final follow-up visit (visit 3), all of the signs of poor wound and periwound status had resolved (Figure 4b). Furthermore, by the final visit the issues with pain had been resolved (Figure 5). Improvements in all of the clinical signs of infection were recorded at the first follow-up visit (visit 2) and all signs of infection were absent by the final visit (visit 3). There was a steady decrease in wound size throughout the study period for each of the three wounds and all wounds had healed by the final visit (visit 3). The wounds contained 100% viable tissue and were not producing exudate (Figure 4b).

At the final visit, the clinician rated each of the eight dressing variables as 'excellent'. The clinician's overall impression of the dressing at the final visit was 'excellent'. The patient also rated the dressing as 'excellent' in terms of ability to stay in place during wear and 'good' in terms of comfort and overall impression of the dressing.

Case study 5

Case 5 was a 64-year-old male with type 2 diabetes. At baseline, the patient had a two-week-old neuropathic wound with a bursa overlying the inner longitudinal arch area of the foot. The wound had a SINBAD score of 3 and measured 35mm (length) by 15mm (width) and the wound contained 80% non-viable tissue (defined as necrotic, fibrinous and/or sloughy) (Figure 6a/b). The wound was producing a high level of brown, serosanguinous/blood exudate and had a mild odour.

There was no traumatisation to the wound bed or the surrounding skin during the initial dressing change. No pain was recorded throughout the evaluation due to neuropathy.

By the third follow-up visit (visit 4), all of the signs of poor wound and periwound status had resolved (Figure 6c). Improvements in all of the clinical signs of infection were noted throughout the study and all signs of infection were absent by the final visit (visit 5). At the final visit the wound contained 100% viable tissue and the wound was producing a low amount of clear/serous exudate. In line with the improvements in wound status there was a steady decrease in wound size throughout the study period.

At the final visit, the clinician rated each of the eight dressing variables as 'excellent'. It was highlighted that, although the wound was not located on the heel, the dressing covered the area and performed very well. The clinician's overall impression of the dressing at the final visit was 'excellent'. The patient also rated the dressing as 'excellent' in terms of ability to stay in place during wear, comfort and overall impression of the dressing.

Figure 5. Case 4: pain before, during and after dressing removal (100mm pain scale).

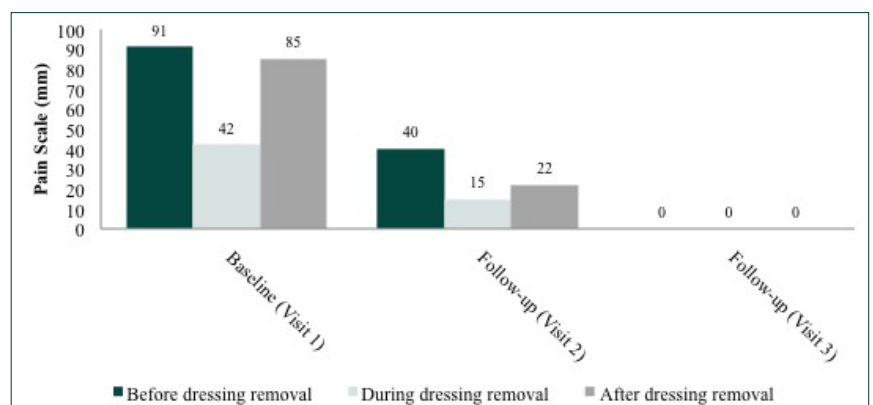




Figure 6. Case 5 (a) dressing in situ at the first visit; (b) wound at baseline; (c) wound at follow-up visit 3 (visit 4).

Discussion

The findings of the present study suggest that Mepilex Border Heel can effectively manage the signs and symptoms of poor periwound status. While case studies cannot demonstrate the efficacy of a product or intervention, case study series can highlight the benefits of management strategies when used in the ‘true’ clinical setting and can show how clinical challenges relating to a specific wound type can be overcome.

The advantages of an atraumatic wound dressing in the optimisation of wound healing have been frequently reported, particularly in the treatment of those patients with fragile, friable skin. In addition to the protection offered to the surrounding skin during dressing removal, the gentle adhesion offered by dressings with soft silicone technology ensures the retention of wound exudate, preventing periwound skin maceration by providing a seal between the dressing and the intact skin (White, 2005). A gradual reduction in the signs of poor wound and periwound status were recorded for each of the study participants throughout the study period. In line with this, exudate levels were

effectively managed for each case. A previous study which compared Mepilex Border with Tielle found that tissue damage and maceration were minimised with the use of Mepilex Border (Meaume et al, 2003).

In conjunction with the improvements noted in periwound condition, there was a trend for wound size reduction throughout the study for four out of the five participants. In one case (case 1), the patient’s wounds did not reduce in size by the end of the study period, however, both wounds contained 100% viable tissue by the final visit and exudate levels had reduced by the end of the study. Although four of the five study participants had neuropathic wounds, the patient whose pain was an issue at baseline reported improvements in pain before, during and after dressing removal throughout the study period.

In general, both clinicians and patients reported high satisfaction with the dressing under evaluation. Dressings generally remained in situ throughout the study, promoting patient comfort and minimal disturbance to the wound and surrounding skin. While more in-depth clinical trials are needed to substantiate the results from this case study series, the study has clearly highlighted the benefits of the Mepilex Border Heel dressing in terms of managing complex DFUs and providing a positive patient experience.

Conclusion

This case study series has demonstrated the effectiveness of Mepilex Border Heel in the management of DFUs. Ulcers treated with the heel dressing as part of their wound management regimen demonstrated overall improvements in wound healing and improved periwound skin condition. The dressing also provided effective management of exudate. The dressings remained in place during the study and

Table 4. Variables for patients’ evaluations of the test dressing (assessed at each visit).	
Variable	Measurement
Comfort	Measured of a five-point scale, from ‘Excellent’ to ‘Very Poor’
Ability to stay in place during wear	Measured of a five-point scale, from ‘Excellent’ to ‘Very Poor’
Overall impression	Measured of a five-point scale, from ‘Excellent’ to ‘Very Poor’
Pain	Measured on a continuous scale from ‘no pain’ to ‘most intense pain imaginable’ (before dressing removal, during dressing removal and after dressing removal).

Table 5. Coexisting participant medical conditions and participant/target ulcer data at baseline (visit 1).

Case Number	Condition	Major Surgery	Palpable foot pulse (baseline)	SINBAD score (baseline)	Location of wound (baseline)	Duration of wound (baseline)	Target goals with product under evaluation (baseline)
1	Chronic kidney disease; myocardial infarction	No	No	4	Left heel (plantar)	2 years	Promote healing/closure; Manage exudate; Protect tissue; Minimise pain
2	Renal disease	No	Yes	3	Ankle (lateral)	5 months	Promote healing/closure; Manage exudate; Protect tissue; Other (other dressing slipping)
3	N/A	No	Yes	3	Left heel	1 week	Promote healing/closure; Manage exudate; Protect tissue; Provide palliative care
4	N/A	Osteomyelitis debridement (right first toe)	Yes	4	Heel (plantar, left)	1 week	Manage exudate; Protect tissue; Minimise pain; Improve patient quality of life
5	Charcot neuropathy, mental illness (psychosis)	No	Yes	3	Right inner longitudinal arch	2 weeks	Promote healing/closure; Manage exudate; Protect tissue; Improve patient quality of life

Table 6. Current wound treatments (all wounds had sharp debridement at each visit, apart from Case 4 whose wounds had sharp debridement at baseline only).

Case Number	Skin Protection used	Dressing used	Other treatment used	Offloading device used	Specialty mattress used
1	No	Yes (Inadine)	No	Yes (off-loading shoe and insole)	No
2	No	Yes (Allevyn Adhesive)	Yes (Co-amoxiclav)	Yes (total contact cast)	No
3	No	Yes (Allevyn Adhesive)	No	Yes (soft cast protector)	No
4	No	Yes (Allevyn Gentle Border)	Yes (Clindamycin; Ciprofloxacin)	Yes (sandal)	No
5	No	Yes (Melolin)	Yes (Clindamycin)	Yes (shoe and insole)	No

patients felt that the dressings were comfortable, prompting positive feedback from the patients and clinicians. ■

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