Treating recalcitrant venous leg ulcers using a PHMB impregnated dressing: A case study evaluation

KEY WORDS

- ▶ Patient comfort
- ▶ Polyhexamethylene biguanide (PHMB) wound dressing
- >> Venous leg ulcer

This series of five case studies focuses on patients with nonhealing venous leg ulcers who were treated with CelluDress-PHMB (Medicareplus International), a sterile, moist wound dressing impregnated with a polyhexamethylene biguanide (PHMB) Antimicrobial Complex. In addition to chronic and lower leg wounds such as venous leg ulcers, the dressing is indicated for use in postoperative, superficial and deep wounds, first and second-degree burns, diabetic foot ulcers and pressure ulcers (category I and II) at risk of infection, with low to moderate exudate.

his series of five case studies focuses on patients with nonhealing venous leg ulcers (VLUs) who were treated with CelluDress-PHMB (Medicareplus International), a sterile, moist wound dressing impregnated with a PHMB) Antimicrobial Complex. The dressing has a three-layer structure. The outer layer (on either side) is non-adherent to prevent adherence to the wound and aid patient comfort. The middle layer is designed to function as a 'reservoir' for the antimicrobial solution as well as an 'absorption layer' for the bacterial and fungal pathogens in the wound.

ROLE OF PHMB IN WOUND MANAGEMENT

PHMB is a synthetic antiseptic agent that has been used for over 60 years in a wide range of applications. The compound is fast-acting at high concentrations and exhibits a broad spectrum of activity against Gram-positive and Gram-negative bacteria (Gilbert and Moore, 2005), viruses (Valluri et al, 1997) and even some parasites (Kim et al, 1999). In addition to efficacy against a wide range of microbes, PHMB has also been shown to reduce wound pain (Galitz et al, 2009; Sibbald et al, 2011), malodour (Daeschlein et al, 2007) and slough (Mueller and Krebsbach, 2008).

Research and testing have demonstrated that PHMB has a good safety record, has low toxicity to human tissue and is effective in reducing bacterial

load. PHMB is now widely used in the UK and has been shown to be an effective option for managing wounds at risk of infection and infected wounds (Wounds UK, 2010).

CELLUDRESS-PHMB

This new PHMB-impregnated dressing, recently made available on Drug Tariff, protects against the development of wound infection by absorbing and binding to the negatively charged microorganisms, decreasing the bacterial load in the dressing and preventing bacterial growth in the wound bed (Edwards-Jones et al, 2013). This easy-to-apply dressing can be used on wounds at different stages of healing to promote granulation, while providing antimicrobial protection and effective exudate management. It can be also be used under compression.

Because of these qualities, we sought to investigate the use of CelluDress-PHMB for treating venous leg ulcers (VLUs) that were either at risk of infection or already infected.

CASE STUDY 1

Background and treatment

Mr B, a 76-year-old man, had a history of recurrent infection and venous ulceration on both limbs for 20 years. He had experienced right and left deep vein thrombosis in 1997 and 1999, respectively, and in 2011 had a pulmonary embolism.

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Clinical Trials Manager, Wound Healing Research Unit, Cardiff University, Cardiff "With use of CelluDress-PHMB (Medicareplus International) and antibiotic therapy, the patient [Case 1] improved."

He presented with three VLUs of 6 months' duration on the lower left gaiter region of the leg: two anterior and one posterior (*Figure 1a*). The anterior wounds measured $0.4 \, \text{cm} \times 0.4 \, \text{cm}$ and $1.2 \, \text{cm} \times 1.4 \, \text{cm}$, and the posterior wounds measured $1.3 \, \text{cm} \times 1.4 \, \text{cm}$; all had no depth. Exudate level was low, and infection was not diagnosed.

Nurses had been changing and dressing the wounds twice weekly with an antimicrobial dressing comprising a primary wound contact layer (Atrauman*; HARTMANN) and a retention bandage (Tubifast™; Mölnlycke). The patient reported experiencing pain during dressing removal. At the time of presentation, based on the wound's duration and the patient's previous history of infection, CelluDress-PHMB was chosen for the wound contact layer (with Tubifast as a retention bandage) and applied to all three wounds.

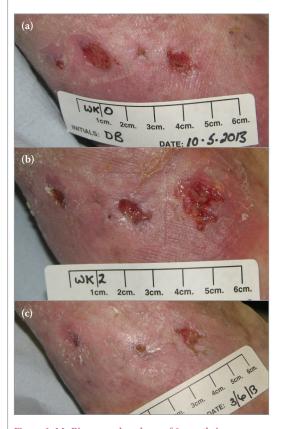


Figure 1. Mr B's venous leg ulcers of 6 months' duration (a) at presentation, (b) 2 weeks following the commencement of CelluDress-PHMB, and (c) at week 4, by which time the largest anterior wound had 100% granulation tissue, while the other two wounds had partially epithelialized.

Week 1

The patient reported no pain on dressing removal. Granulation tissue had increased 100%, and wound sizes had decreased: the anterior wounds measured 0.4cm × 0.4cm (no depth) and 0.9cm × 0.7cm × 0.1cm, and the posterior measured 1.0cm × 0.6cm × 0.1cm. Exudate remained consistent with baseline. The nurse reported high satisfaction with the dressing and rated its performance "good" in all areas. Because of the reduced pain, increased granulation tissue and continued absence of infection, the dressing change regimen with CelluDress-PHMB was continued.

Week 2

Level of exudate remained the same, but erythema had increased, as had reported pain (to 2 on a visual analogue scale [VAS] of 1–10). All three wounds had enlarged (Figure 1b): the anterior wounds measured 0.5 cm \times 0.4 cm and 1.4 cm \times 0.7 cm. \times 0.2 cm, and the posterior wound measured 1.3 cm \times 1.6 cm \times 0.3 cm. The nurse thought the overall dressing performance was good and the patient was started on oral antibiotic therapy of Augmentin* (GlaxoSmithKline) 625 mg three times daily. CelluDress-PHMB was continued with twice-weekly dressing changes.

Week 3

The level of pain reported decreased to 0 on a VAS of 1–10. The size of the small anterior wound remained the same; the other anterior wound had decreased to 1.1 cm \times 0.6 cm, with no depth. The posterior wound had changed shape, but decreased size overall, measuring 1.5 cm \times 1.0 cm (no depth). The nurse considered the dressing's overall performance to have been very good during week 3 and continued to find the dressing easy to use. The dressing regimen plus antibiotic therapy were continued into week 4.

Week 4

Exudate remained at the same level as previously recorded, but the largest anterior wound presented with 100% granulation tissue, and the other two had partially epithelialized (*Figure 1c*). Mr B reported no pain, and remained on oral antibiotics to complete the course of treatment.

Outcome

Overall, with use of CelluDress-PHMB and antibiotic therapy, the patient improved. The nurse rated the

dressing performance as good, reporting that it was easy to apply and remove, conformed to the wound bed and did not cause the patient discomfort.

CASE STUDY 2

Background and treatment

Mr T, a 49-year-old man, had a history of asthma, anxiety attacks and five episodes of deep vein thrombosis. Mr T had several episodes of infection that had been treated with systemic antibiotics. Pain had also been a problem during these periods of infection.

He presented with a VLU measuring 3.6 cm × 3.6 cm (no depth) on the left limb (*Figure 2a*); the wound had been present for 18 months. The wound had been treated with Inadine* PVP-I nonadherent dressing (Systagenix), Promogran™ (Systagenix) and a two-layer compression bandage system (Coban™; 3M). At the beginning of the evaluation, the patient scored pain as 3 on a VAS of 1−10, but did not require analgesia. The wound was considered infected at presentation.

CelluDress-PHMB was used as the primary wound dressing with Atrauman, and two-layer compression bandaging (Coban) was continued. Dressing changes were planned for twice weekly.

Week 1

The patient reported the dressing as comfortable to wear, but pain reported at dressing change remained a 3 (VAS 1–10). Signs of infection had improved and the wound bed appeared cleaner. Granulation tissue covered 50%–75% of the wound bed, and wound size had reduced to $2.7\,\mathrm{cm}\times2.1\,\mathrm{cm}$. CelluDress-PHMB was continued for a further week.

Week 2

The patient reported no pain at dressing change. Although signs of infection and wound size (2.8 cm × 2.0 cm) remained static, the wound bed had improved (*Figure 2b*). It was decided to continue with CelluDress-PHMB and the dressing regimen continued unchanged.

Week 3

Signs of infection had further improved, wound size remained the same ($3.0\,\mathrm{cm} \times 1.9\,\mathrm{cm}$), and granulation tissue covered 25%–50% of the wound (*Figure 2c*). The nurse rated the dressing performance as excellent and planned to continue with CelluDress-PHMB

Figure 2. Mr T's venous leg ulcers of 18 months' duration (a) at presentation, (b) 2 weeks following the commencement of CelluDress-PHMB, and (c) at week 3. Note that by week 3 the wound had reduced in size and the infection had been cleared.



based on the signs of healing. The dressing regimen continued unchanged.

Outcome

The ulcer size reduced and infection was cleared. The nurse reported "good" dressing performance and satisfaction with its ease of use, noting it conformed to the wound bed and remained in place during wear. The patient reported the dressing was comfortable to wear and did not cause pain upon removal.

CASE STUDY 3

Background and treatment

Mr W, an 89-year-old man, had recurring bilateral venous ulceration for 8 years. He had a history of hypertension and osteoporosis, and was taking morphine sulfate (Oramorph*; Boehringer Ingelheim), bendroflumethiazide, tramadol, and a vitamin D3 chewable tablet (Calcichew*; Shire).

He presented with a VLU on the left medial malleolus, which had initially presented spontaneously 8 years prior (*Figure 3a*). The wound measured 4.4 cm × 2.5 cm and had been treated with silver sulfadiazine (Flamazine™; Smith & Nephew) and three-layer compression bandaging, with twiceweekly dressing changes.

The wound was critically colonised; malodour had been present for several days. The patient reported distressing pain (6 on a VAS of 1–10). CelluDress-PHMB was chosen as the primary wound dressing. Due to the patient's fragile skin, N-A* Ultra (Systagenix) was chosen for the secondary dressing. Three-layer compression was continued, and dressing changes were planned for twice weekly, to be conducted by the practice nurse.

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Figure 3. Mr W's venous leg ulcers of 8 years' duration (a) at presentation, (b) 2 weeks following the commencement of CelluDress-PHMBthe wound increased in size, and (c) at week 4, when CelluDress-PHMB was discontinued due to wound-bed deterioration.



Week 1

Signs of infection and slight malodour remained, and the patient reported slightly greater pain on dressing removal (7 on a VAS of 1–10). Wound size had reduced to 4.4 cm × 2.4 cm, and granulation tissue covered 0%–25% of the wound. The nurse reported no signs of healing/improvement; however, she considered the dressing's overall performance very good and was satisfied with its ease of use. As the wound looked unhealthy, and it was too early to consider changing the dressing, the wound was redressed with CelluDress-PHMB. Atrauman was used as a secondary dressing, and dressing changes were planned for twice weekly.

Week 2

The patient reported less pain during dressing change (2 on a VAS of 1–10). Although the wound size had increased to $5.0\,\mathrm{cm} \times 3.0\,\mathrm{cm}$, granulation tissue coverage was still 0%-25% (*Figure 3b*). Signs of infection, including malodour, remained. The nurse was satisfied with the dressing, and the wound care regimen continued, unchanged.

Week 3

The patient reported more pain during dressing removal (6 on a VAS of 1–10), and the wound bed had increased to 8.0 cm × 4.4 cm. Malodour and signs of infection remained. Due to wound-bed deterioration, CelluDress-PHMB was discontinued. Mr W's leg was redressed with Flamazine and Aquacel* (ConvaTec) to try to clean up the wound bed.

Outcome

Recalcitrant wounds in older patients can be challenging to manage. In this case, the dressing failed to ameliorate infection or prevent wound-bed deterioration. Because the wound failed to improve, CelluDress-PHMB was discontinued.

CASE STUDY 4

Background and treatment

Ms N, a 65-year-old woman, was diagnosed with scleroderma and Raynaud's syndrome in 2004 (9-year history). She presented with a VLU on the left medial malleolus that she had sustained 4 years ago, after a traumatic injury. The wound had a history of recurrent infection.

The wound measured 6.4 cm × 4.9 cm and had been previously dressed using an antimicrobial

dressing (Kendall™ AMD Antimicrobial Foam Dressing; Covidien) and a compression layer (CliniGrip), with dressing changes twice weekly.

The patient reported pain (4 on a VAS of 1-10), and the wound was considered colonised. CelluDress-PHMB was applied with a secondary nonadherent dressing (N-A Ultra) and a compression layer (CliniGrip). The dressings were changed twice weekly by the nurse, with interim changes performed by the patient.

Week 1

The wound showed signs of healing: fibrin was evident in the wound bed; granulation tissue was estimated to cover 25%-50%; wound size had reduced to $4.1\,\mathrm{cm}\times5.5\,\mathrm{cm}$; and infection was not present. However, exudate was slight, erythema was evident in the surrounding tissue, and pain was reported as 8 on a VAS of 1-10. The dressing regimen was continued due to visible signs of improvement, the history of recurrent infection and the patient's preference. She reported that it was easy to handle, conformed well to the wound site, and remained *in situ* during dressing changes, letting her apply the remaining wound care products with ease and less stress.

The dressing choice and regimen remained unchanged. The dressing was cut to the size of the wound, and the patient was advised to change the dressings daily between nurse visits, to prevent dressing adherence to the wound bed and pain on removal.

Week 2

Granulation tissue increased to 40% of the wound, which remained free of infection. Exudate level was moderate and erythema of the periwound tissue persisted. Although wound size had increased to $7.0\,\mathrm{cm}\times4.2\,\mathrm{cm}$, the nurse was satisfied and rated the dressing performance as good. The patient rated pain as 5, and was happy with the dressing and confident regarding signs of improvement. CelluDress-PHMB was continued for a further week.

Week 3

There was no change in the wound size, wound bed, exudate level or pain score. The patient and nurse were happy to continue with no changes to the dressing care plan.

Week 4

The wound had not changed in size, erythema or exudate status. Granulation tissue had increased to 50% of the wound, the pain score had dropped to a 4, and infection was not present. The nurse reported high satisfaction with ease of use, overall performance, and the patient's ability to perform daily dressing changes while the nurse was on holiday.

Week 7

The patient was seen again 3 weeks later. Although the wound measured $7.4\,\mathrm{cm} \times 4.6\,\mathrm{cm}$, it looked healthier, was not infected and showed signs of healing, with granulation tissue covering 50%-75% of the wound bed. Exudate level was reduced and no erythema was present. The patient reported she was pain-free at dressing changes, despite the dressing having dried out and become hard, which necessitated daily changing. As a result, CelluDress-PHMB was discontinued in favour of a simple non-adhesive dressing (Atrauman), with Tubifast, and gauze swabs as a secondary dressing.

Outcome

In this case, CelluDress-PHMB helped maintain low bacterial burden. The patient and nurse were pleased with the dressing's performance, particularly in light of the patient's history of recurrent infection. The patient was experienced in dressing changes and caring for her wound, and was pain-free, so the ongoing management plan included that she apply increased compression, to aid venous return, and apply CelluDress-PHMB when necessary.

CASE STUDY 5

Background and treatment

Ms G, a 72-year-old woman, had a 7-year history of VLU with recurrent infection. Osteoarthritis was present in both knees and she had been managing back pain for 33 years (since 1970).

She presented with a recurring ulcer on the left lateral lower leg of 18 months' duration that had resulted from trauma ($Figure\ 5a$). The wound measured $5.6\,\mathrm{cm} \times 2.6\,\mathrm{cm}$, and was considered colonised. She reported a low level of pain from the wound (2 on a VAS of 1–10). Previous treatments included Aquacel*, Aquacel* Ag (both ConvaTec) and two-layer compression bandaging. Dressings and compression were being reapplied twice weekly by nurses.

It was decided to use CelluDress-PHMB, with Atrauman as a nonadherent secondary dressing under compression, with dressing changes twice weekly.

Week 1

Signs of infection were considered reduced, granulation tissue increased and islands of epithelium were visible. Wound size had reduced to $5.0\,\mathrm{cm} \times 2.4\,\mathrm{cm}$. Pain at dressing change remained a 2. The nurse and patient were highly satisfied with the dressing's ease of use and performance. It was decided to continue the dressing regimen, unchanged for a further week.

Week 2

The wound had decreased to $4.8\,\mathrm{cm} \times 1.2\,\mathrm{cm}$ and remained infection-free. Granulation tissue

Figure 5. Ms G's venous leg ulcers of 18 months' duration (a) at presentation. (b) Three weeks following the commencement of CelluDress-PHMB granulation tissue was estimated to cover 95% of the wound bed. (c) Progress towards healing had continued at week 5.





Figure 4. Ms N's venous leg ulcers of 4 years' duration at (a) 1 week following the commencement of CelluDress-PHMB showed signs of healing and was not infected. (b) By week 2, granulation tissue had increased to 40% of the wound, which remained free of infection (c) at week 4, when CelluDress-PHMB was discontinued due to wound-bed deterioration.

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had increased to cover approximately 80% of the wound bed, and surrounding tissue showed less erythema. Serous exudate was present, along with oedema in the surrounding area. Because the patient remained infection-free and requested to continue with CelluDress-PHMB, the regimen remained unchanged.

Week 3

Although the wound size had increased slightly, to $4.8\,\mathrm{cm} \times 1.7\,\mathrm{cm}$, signs of healing were present, with granulation tissue estimated to cover 95% of the wound bed (*Figure 5b*). The dressing regimen was continued, with the dressing left in place for a week, as the patient was away for a few days.

Week 4

The wound continued to progress towards healing, with slight exudate and no reported pain. Wound size was $4.3\,\mathrm{cm}\times1.7\,\mathrm{cm}$, with no depth. However, the dressing had adhered to the wound bed and had to be soaked off. Dressing changes were returned to twice a week, as the patient wanted to continue with the same dressing regimen.

Week 5

Progress towards healing continued, as the wound now measured $4.3\,\mathrm{cm}\times0.9\,\mathrm{cm}$, with no depth (*Figure 5c*). Exudate remained slight and the patient remained pain free. Based on the patient's history of infection, she continued with CelluDress-PHMB after the dressing evaluation was completed.

Outcome

CelluDress-PHMB was used for 5 weeks and the wound remained infection-free. Ms G also experienced a reduction in pain at dressing change to zero by week 3. The nurse rated the dressing's overall performance as very good, but noted that exudate was a challenge. Three weeks after the evaluation had ended, the patient's wound became locally infected, and use of CelluDress-PHMB was discontinued.

CONCLUSION

All patients treated with CelluDress-PHMB had recalcitrant leg ulcers that were at high risk of reinfection. Despite this, patient 1's wounds improved with signs of healing. Signs of infection were cleared in patient 2 and wound size reduced.

Infection was prevented in patient 4's wound, who had a history of infection. And the fifth patient remained infection free, with reduced pain, during the observation period. CelluDress-PHMB was discontinued only in patient 3. However, it is important to remember that recalcitrant wounds in older patients pose a particular management challenge. Even in this patient, there was significant pain reduction between weeks 1 and 2.

Overall, nurses rated the dressing performance as good, reporting that it was easy to apply and remove, conformed to wound sites and did not cause patients discomfort on removal or during wear. Patients said they liked that it was comfortable and conformed to the wound site – even, in one case, staying in place so the patient could manage dressing changes herself between nurse visits. The clear improvements in patient comfort and, therefore, quality of life should make CelluDress-PHMB a consideration when selecting a dressing in patients whose wounds are at risk of infection/are infected.

DISCLAIMER

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