

WoundExpress: an advanced therapy for hard-to-heal venous leg ulcers

KEY WORDS

- ▶ Wound Express
- ▶ Hard-to-heal wounds
- ▶ Complex wounds
- ▶ Venous leg ulcers
- ▶ Adjunct therapy
- ▶ Intermittent pneumatic compression therapy.

Hard-to-heal wounds have a significant impact on patients, clinicians and healthcare systems. Wounds impose a substantial health economic burden on the NHS, and much of this cost can be attributed to the burden of non-healing (or hard-to-heal) wounds. The NHS manages an estimated 278,000 venous leg ulcers (VLUs) every year, of which 47% do not heal within 12 months (Guest et al, 2018), with UK costs £1.98 billion (Phillips et al, 2020).

A hard-to-heal wound has been defined as one that ‘fails to heal with standard therapy in an orderly and timely manner’ (Troxler et al, 2006). A wound can become hard-to-heal due to a variety of factors — both related to the wound and the patient — and early identification of these, followed by effective therapy targeted on the cause, will result in better outcomes, often having a hugely beneficial effect on patient quality of life. As such, there is a recognised need for advanced therapies in hard-to-heal wounds, in order to kickstart healing and improve outcomes.

WoundExpress™ (Huntleigh Healthcare Ltd) is an advanced wound therapy device, which has been found to promote healing in wounds that have not responded to previous treatments, particularly in hard-to-heal VLUs (Naik et al, 2019).

VENOUS LEG ULCERS: A CHALLENGE IN PRACTICE

Leg ulcers represent a common, and often challenging to treat, wound type. It is generally accepted that leg ulcers (of venous, arterial and mixed aetiologies) have a significant impact on costs to the NHS, to society and to patients themselves (Bishop and White, 2017). The annual cost of treating patients with leg ulcers in the UK has recently been estimated at £1.98 billion. (Phillips et al, 2020).

The precise UK prevalence of VLUs is unclear (Bishop and White, 2017). However, VLUs are believed to be the most common chronic wound in the UK (Wounds UK, 2019). Treatment is often ineffective, and the care of a patient with a VLU has been described as ‘palliative’ in many cases

(White et al, 2016), meaning that little or no clinical improvement is achieved. Treatment of VLUs poses a particular challenge, as they are often recurrent and may persist for months or years (Harding et al, 2015).

COMPLEXITY IN VENOUS LEG ULCERS

Wound complexity can make a wound hard-to-heal and increases the likelihood of the wound becoming chronic (Wounds UK, 2019). In VLU management, ‘complexity’ tends to refer to four key factors in VLU management (EWMA, 2008):

- ▶ Patient-related — e.g. comorbidities, medication, pain, concordance
- ▶ Wound-related — e.g. high exudate, infection (Vowden, 2005), biofilm (IWII, 2016)
- ▶ Healthcare professional-related — e.g. clinical skills and knowledge
- ▶ Resource/treatment-related — e.g. healthcare systems, availability, cost.

When considering wound complexity, it may be useful to determine the factors contributing to wound complexity and if the wound is:

- ▶ Hard-to-assess
- ▶ Hard-to-manage
- ▶ Hard-to-heal.

Recognising, understanding and addressing the factors that contribute to wound complexity will help to direct treatment and impact on healing progression (Wounds UK, 2019).

HARD-TO-HEAL WOUNDS

In most wounds, healing progress should be visible within a four-week period (Troxler et al, 2006).

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What is a hard-to-heal wound?

A chronic or hard-to-heal wound is defined as a wound that has not healed in 12 weeks, or if the wound has not improved — or not reduced in area by 40% — in 4 weeks of standard care following an appropriate leg ulcer treatment pathway (Wounds UK, 2016).

When a wound does not progress to healing in the expected timeframe, a wound can be considered hard-to-heal.

The more wound healing is delayed, the more it impacts on the patient (Vowden, 2011). The impact of hard-to-heal wounds on the patient (in terms of quality of life and psycho-social factors, as well as their physical health) can be considerable and in some cases ‘extreme’ (Pragnell and Neilson, 2010).

The challenge posed to the clinical team in terms of resource expenditure can also be considerable. Non-healing can additionally have a psychological influence on clinicians who are providing care, who may be emotionally overwhelmed by their inability to alleviate the patient’s suffering and achieve wound healing (Morgan and Moffatt, 2008).

Reducing cost and resource expenditure (e.g. clinician time) while optimising quality of life for patients with hard-to-heal wounds should be considered of paramount importance.

THE NEED FOR ADVANCED THERAPIES

In managing hard-to-heal VLUs, treatment should form a two-pronged approach: ensuring that the basic principles of standard VLU care (i.e. an appropriate structured care pathway); and, in wounds that are not healing, using appropriate advanced therapies to encourage healing and improve outcomes (Wounds UK, 2019).

Advanced, or adjunctive, therapies may be considered following:

- ▶▶ Comprehensive assessment of the patient and the wound to identify/address known risk factors for delayed healing
- ▶▶ Clinical observation/documentation over a 3–4 week period, with failure to respond to standard therapy (Vowden, 2011).

The benefits of using advanced therapies include improved healing rates and a reduction of symptoms from a hard-to-heal wound, resulting in improved quality of life for the patient (Vowden, 2011). The introduction of advanced therapies can, if used appropriately, result in long-term savings — both financial and in terms of clinician time — despite initial increased treatment costs (Vowden, 2011).

The potential benefits of advanced therapies include:

- ▶▶ Earlier control of symptoms
- ▶▶ Promotion of wound closure
- ▶▶ Improved quality of life

- ▶▶ Reduced healthcare costs (Vowden, 2011).

For all patients with wounds, it is important to set treatment goals and monitor healing progress according to the treatment plan and the goals set.

THE POTENTIAL ROLE OF WOUNDEXPRESS

WoundExpress is an advanced wound therapy device, which has been found to assist in the healing of hard-to heal VLUs (Naik et al, 2019). WoundExpress therapy is delivered via a pump and garment, which operates by using low-pressure air to deliver therapeutic levels of compression. This is sometimes referred to as ‘intermittent pneumatic compression’ therapy.

The WoundExpress system has a specially designed three-chamber garment that attaches to the pump, which has a unique 4-minute timing cycle that increases venous and arterial blood flow (Figure 1). Unlike standard treatment, the WoundExpress garment has been designed to be placed on the thigh of the ulcerated limb and not on the wound site. A recent study has demonstrated that applying sequential compression to the thigh alone can produce positive haemodynamic effects in the calves of patients with chronic wounds (Morris et al, 2019).

The garment can be easily applied by the patient and is used for only 2 hours per day as an adjunct to standard treatment.

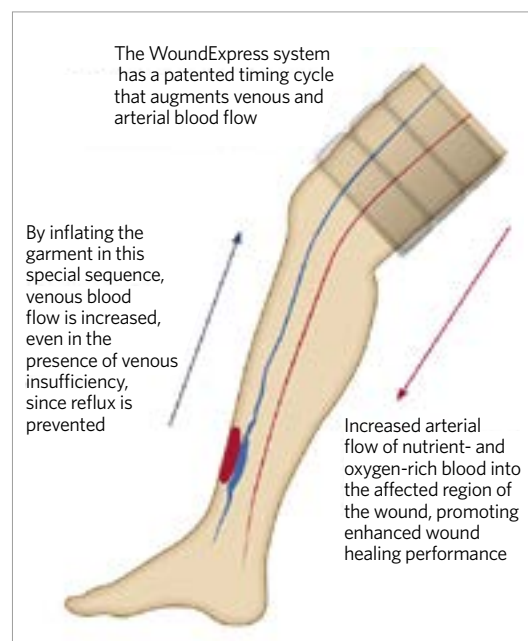


Figure 1. How WoundExpress works

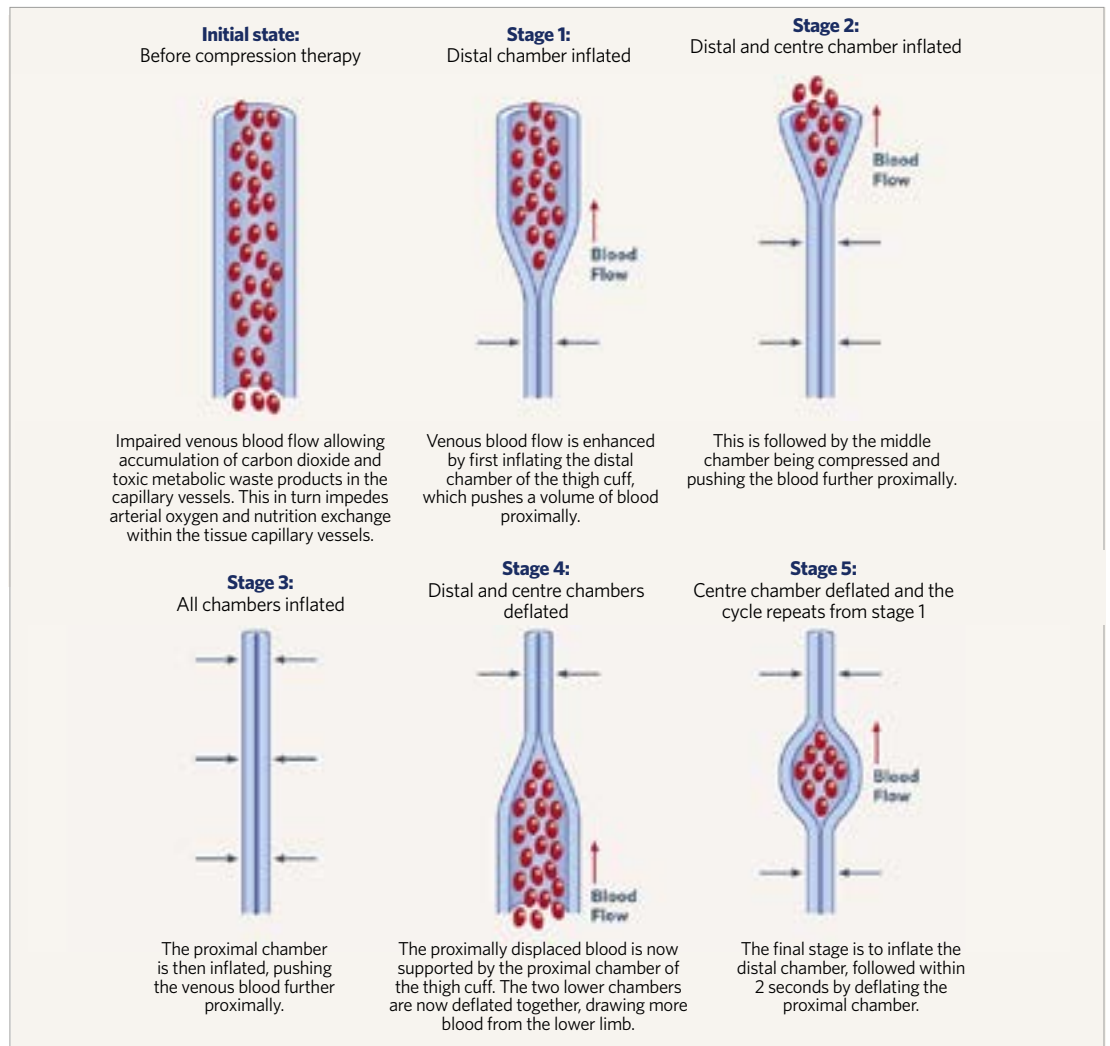


Figure 2. The process of intermittent pneumatic compression therapy

HOW WOUNDEXPRESS WORKS

The garment is inflated to 60mmHg in a peristaltic action, which draws the venous blood from the wound site. By inflating the garment in this sequence, venous blood flow is increased, even in the presence of venous insufficiency, since reflux is prevented. This effect reduces the venous and interstitial pressure and increases the pressure gradient across the arterial venous pathway, distal to the garment (Figure 2).

The result is the removal of high levels of accumulated carbon dioxide and metabolic waste products from the wound site. The arterial inflow to the leg subsequently increases and encourages the flow of nutrient and oxygen rich blood into the affected region of the wound, promoting enhanced wound healing performance.

BENEFITS OF WOUNDEXPRESS

A recent clinical study has demonstrated that WoundExpress is highly effective in reducing the size of hard-to-heal leg ulcers (Naik et al, 2019). In the 21-patient study, average reduction in wound size was 44% after 8 weeks of therapy. Most of these wounds had been present for more than 1 year prior to commencing WoundExpress advanced therapy, and had not responded to standard treatment. 48% of the leg ulcers treated were of mixed aetiology and 52% were VLUs. The average VAS pain score also reduced from 34 to 15, with 5% of patients reducing their level of analgesics (Naik et al, 2019).

In an evaluation of WoundExpress in hard-to-heal wounds (mean duration prior to inclusion was 45 months), 21 patients were assessed over 16-weeks. Of these, 95% progressed towards healing, with a mean surface area reduction of -66% (range: -16% to -100%);

Benefits of WoundExpress

- Kickstarts healing
- Effective in healing hard-to-heal wounds that have not responded to standard treatment
- Reduced pain and improved patient quality-of-life
- Simple for patients to apply and only has to be used for 2 hours per day
- Long-term savings in cost and clinician time.

33% ($n=7$) achieved complete re-epithelialisation and reduced pain was reported in 80% of patients (Kettley and Turner-Dobbin, 2020)

Long-term financial benefits were also observed, with the annual cost of a non-healing ulcer estimated at £13,500 per year (Guest et al, 2018). The cost of WoundExpress was £675 for 8 weeks of treatment, creating an ongoing cost saving as the wounds went on to heal (Naik et al, 2019).

CASE STUDY 1 (Nicky Ivins and Kirsty Kettley)

This 74-year-old woman presented with a VLU measuring 63.8cm² that had been present for 3.5 years. The wound had been prone to repeated infection, requiring hospitalisation twice in the previous two months; additionally, she had allergies to most types of antibiotics and, therefore, needed to be managed conservatively with suitable dressings and early detection of infection. Due to her past medical history, which included hypertension, fibromyalgia, arthritis, asthma, depression, a left total hip replacement and right knee surgery, she had difficulty in mobilising and relied on aids to assist her in walking. Her pain levels were moderate-severe and almost continuous

(her reported pain measured 91/100 on the visual analogue scale), causing problems with wearing compression therapy, as often her wound was too painful to endure it for long periods, and this also affected her overall wellbeing and mood.

The wound bed consisted of granulation tissue, slough and fibrin, with static wound edges and moderate exudate levels. The peri-wound skin was oedematous, dry/flaky and eczematous, with signs of haemosiderin staining (Figure 3).

It was agreed to use the WoundExpress device as an adjunct therapy with her compression wrap, with fortnightly assessment over a 16-week period.

At the week two assessment visit, after using WoundExpress on average for 2 hours per day, the wound surface area had reduced to 57.5cm². The wound bed was mostly slough with some granulation tissue (Figure 4). The patient's reported pain levels had reduced to 73/100, enabling her to tolerate her compression wrap for longer periods. WoundExpress was reported as comfortable and easy to apply and remove.

At week four, the wound surface area had reduced further to 54.6cm². The wound bed appeared unhealthy, consisting of dark granulation tissue and

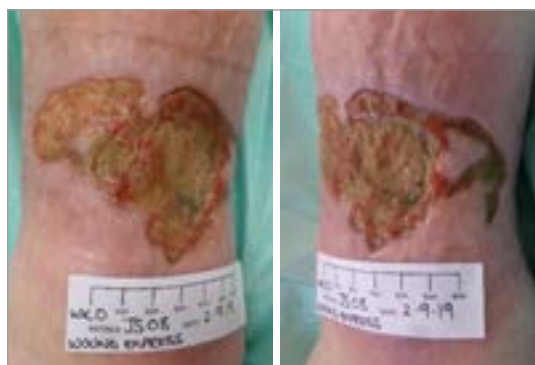


Figure 3. The wound at baseline



Figure 4. After 2 weeks of WoundExpress as an adjunct therapy

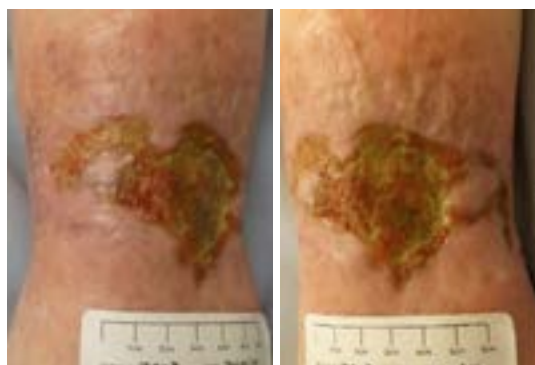


Figure 5. After 4 weeks of WoundExpress as an adjunct therapy



Figure 6. After 6 weeks of WoundExpress as an adjunct therapy



Figure 7. After 8 weeks of WoundExpress as an adjunct therapy

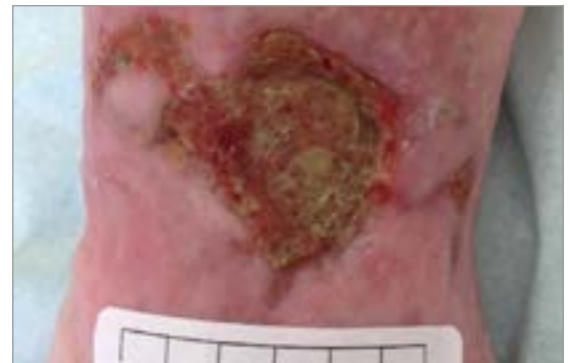


Figure 8. After 11 weeks of WoundExpress as an adjunct therapy

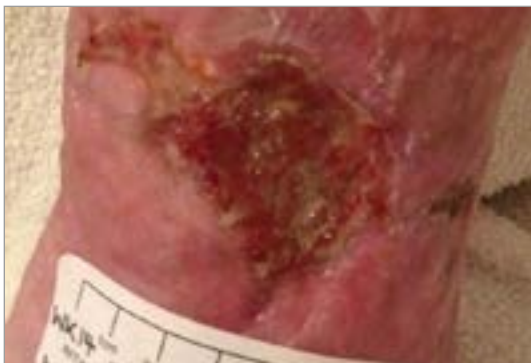


Figure 9. After 14 weeks of WoundExpress as an adjunct therapy

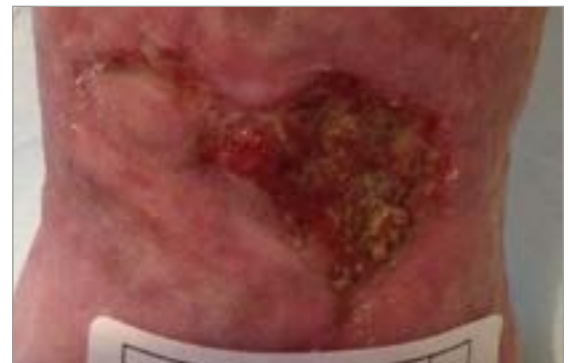


Figure 10. After 16 weeks of WoundExpress as an adjunct therapy

mostly fibrin (*Figure 5*). The patient's reported pain was slightly higher this week at 86. This was probably due to localised infection at the wound bed and also cellulitis in the patient's right leg.

At the week 6 assessment visit, the wound surface area measured 47.5cm². The wound bed was still unhealthy but improving (*Figure 6*). The patient's reported pain levels had reduced again to 74/100, and she was able to tolerate her compression wrap. She was happy with WoundExpress and could start to see that it was making a difference to her wound size.

At the halfway assessment point, the wound surface area had reduced to 38.5cm², almost a 40% reduction from baseline. The wound had now bridged into two separate wounds, with epithelial tissue growing between the two (*Figure 7*).

The patient's reported pain level had reduced to 62/100. At this point in the evaluation, the patient could see that WoundExpress was helping her, not only to tolerate her compression therapy by reducing pain levels, but to heal her wound. Although the patient was still wearing the device on average for 2 hours daily, she had missed some days in the last two weeks due to a family bereavement. However, her

wound was still progressing. She reported that the device was comfortable to use, and she was able to fit it into her daily routine with no problems. From a clinician point of view, the device was clearly aiding in healing the wound and reducing pain levels — a pattern that had been observed in other case studies.

The patient was next seen at week 11. The wound surface area now measured 31.4cm², (*Figure 8*). The patient's reported pain was 51/100; however, the patient had said she didn't believe that WoundExpress had changed her pain levels, even though her reported pain had reduced from 91 at baseline. At this point, the patient rated the effectiveness of WoundExpress as 'moderate', and the clinician rated it as 'very good' considering the reduction in wound size and pain.

At week 14, the wound measured 26cm², with a healthy wound bed consisting of 50% slough and 50% granulation tissue (*Figure 9*). The wound edges continued to epithelialise, with exudate level recorded as 'light'. The patient reported a pain level of 59/100, which was a slight increase from the week before, but the patient did not see this as significant and reported pain levels as 'about the

same'. Her usage of the device had been variable over the past two weeks due to general ill health, but she had managed to wear it most days for an average of 2 hours.

During the final assessment visit at week 16, the wound surface area had reduced to 18.2cm² (Figure 10). This was a 71.5% reduction in wound surface area within 4 months.

The patient's reported pain had reduced to 26/100, a 65% reduction in pain levels from baseline. The pain was now mild-moderate and more manageable. Throughout the evaluation, the patient remained largely infection-free to the target limb and did not require any oral antibiotics for this wound. The patient was able to wear her compression wrap effectively and with little pain; her discomfort was reduced, and her tolerance levels increased.

As a result, she became more optimistic that her ulcer would heal. The physical changes had an impact on her wellbeing, and she had a more positive outlook. At week 16, she said that WoundExpress was effective in healing her wound and reducing pain levels. She reported it as being comfortable and easy to apply and remove. She found the machine was easy to use, as it just consists of an on/off switch and she was able to use the device when she was sitting down watching TV or reading. This patient had a positive experience of using WoundExpress for the 16-week evaluation, and both patient and clinician would recommend its use.

The patient was followed up at the outpatient clinic 2 months after the evaluation had finished, and her wound had continued on a healing trajectory. The wound surface area was 2.5cm² and her reported pain was minimal. She was thrilled that the wound had continued healing, and she had also remained infection-free.

CASE STUDY 2 (*Karen Staines and Hayley Turner-Dobbin*)

This 87-year-old lady presented to the multi-disciplinary team (MDT) clinic with a VLU measuring 252cm² that had been present for 5 months with a rapid deterioration. She had a past medical history of bradycardia and hypertension, but had been independent in her activities of daily living. Since the VLU developed, she had become depressed and became unable to go out independently, relying on support from her son. She was not sleeping well at night due to increased pain.

She had a recent history of chronic venous insufficiency, with dermatitis and reduced mobility due to pain. Different compression bandage systems had been tried without success; due to unmanaged pain they had to be removed. Clobetasol was commenced topically for dermatitis with simple dressings and retention bandage. She was allergic to opiates and paracetamol, and was taking ibuprofen for pain relief.

On her first assessment within the MDT, her pain was described as neuropathic (shooting pains) at a moderate level (5/10 on the pain scale). It was noted that multiple courses of antibiotics had been prescribed, with little effect on healing the ulcer. Her ankle brachial pressure index (ABPI) score was 0.88 to the left leg.

On examination, this lady presented with an almost circumferential leg ulcer to the gaiter region of the left leg (Figure 11). The wound bed to the lateral aspect of her leg had greater depth and presented with a thin layer of slough (60%) and 40% granulation tissue. Oedema was noted to the leg, which was hypersensitive to touch, with dermatitis to the surrounding skin.

She agreed to re-try compression therapy, along with a change of analgesia to manage the neuropathic

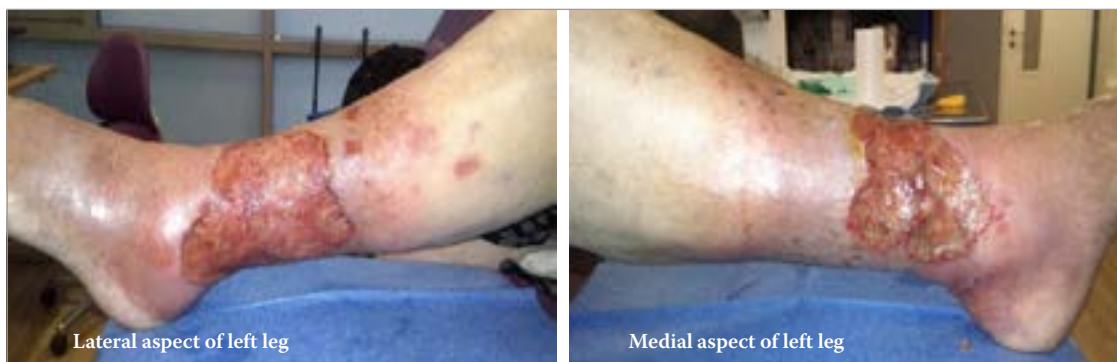


Figure 11. The wound at baseline

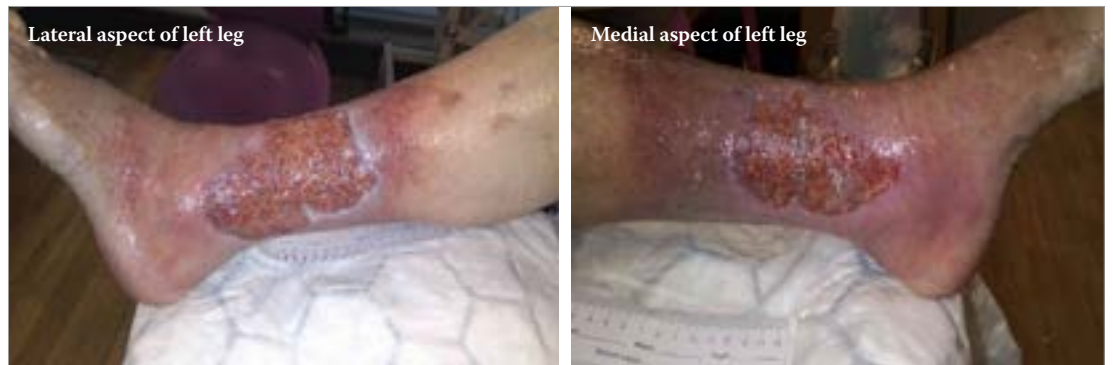


Figure 12. After 4 weeks of WoundExpress as an adjunct therapy

pain, and was commenced on a paste bandage and a single layer of short-stretch bandaging. As part of the MDT assessment, she was seen by the mobility and gait expert, who noted her reduced ankle range of motion and advised the use of a TheraBand with specific exercise as part of her treatment. WoundExpress was discussed and commenced as an adjunct therapy. The device was to be used 2 hours daily for a total of 16 weeks or until healing. This lady was seen three times weekly for dressing change and review.

By week 4, pain had reduced to 4/10 and she was now sleeping at night (reduction of pain was noted by the patient in her diary as early as day 5). The anterior aspect of the wound was now bridged, with epithelial tissue now creating two separate wounds; both wounds combined now measured 153cm² (Figure 12). The lateral wound measurement alone was 117cm².

Although pain had reduced, the compression had been applied more loosely by her local team and she had not been able to carry out TheraBand



Figure 13. After 6 weeks of WoundExpress as an adjunct therapy

exercises, but was able to use WoundExpress, for 1–1.5 hours a day. Dressing changes now reduced to twice weekly.

Week 6 was this lady's last visit to complex clinic due to the COVID-19 pandemic; local district nurses then continued to visit. The wound was measured, but only to the lateral side of the leg at 91.3cm² (Figure 13). Her pain score remained 4/10 and she reported being happy with the progress to date.



Figure 14. After 16 weeks of Wound Express as an adjunct therapy


During weeks 8–16, fortnightly telephone consultation reviews were continued, and pictures were sent in for reference. This lady confirmed that she continued to have single-layer short-stretch compression, and used WoundExpress for 1–2 hours a day, which were split between afternoon and evening sessions to fit in with her lifestyle. By week 14, district nurse visits had reduced to once weekly.

At week 16 (*Figure 14*), a home visit was arranged by the complex clinic team, in order to complete evaluation documentation and collect the machine. This lady had kept a diary and her final report noted: ‘feeling much happier, not so miserable, gradually back to normal, no wounds or leaking, no pain. Never thought I would reach this; obviously due to the WoundExpress and all the help from the nurses.’

She was measured for hosiery and will remain in single-layer short-stretch bandage until hosiery arrives. Patient and clinician feedback rated WoundExpress at 5/5 for effectiveness and overall use, with both parties expressing that the WoundExpress made a positive impact on the speed of healing and reduction in pain, thus greatly improving this lady’s quality of life.

CONCLUSIONS

Meeting the challenge of managing hard-to-heal wounds poses a real challenge in clinical practice. The burden of unhealed wounds is significant and growing (Guest, 2018) and can have a huge impact on the person living with the wound and their quality of life.

WoundExpress is an advanced therapy that has been shown in early studies to offer significant benefits to both the patient and the clinician. Its use in VLU is promising, particularly in kickstarting healing in long-term hard-to-heal VLUs that have not responded to previous standard treatment. 

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