

WoundExpress to manage lower leg wounds

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is WoundExpress. WoundExpress is an advanced wound therapy device, which uses intermittent pneumatic compression to promote lower leg wound healing for people at home.
- The **innovative aspects** are that, unlike with standard treatment, WoundExpress is placed on the thigh of the ulcerated limb, rather than the wound site. The company claims this improves circulation to the wound site without having to apply direct pressure to the wound bed.
- The intended **place in therapy** would be alongside current wound management for people with hard to heal lower leg wounds.
- The **main points from the evidence** summarised in this briefing are from 6 studies including 2 observational studies and 4 case series. They included a total of 121 adults, who were mostly at home. They suggest that WoundExpress could improve the management of hard to heal lower leg wounds.

- **Key uncertainties** around the evidence are that patient numbers are small and internal validity is weak, with no comparators in the studies, making it difficult to confirm the cause of the outcomes.
- **Safety issues** identified are that the device should not be used with several conditions, including severe peripheral artery disease (ankle brachial pressure index of 0.6 or less), suspected deep vein thrombosis, and significant limb oedema.
- The **cost** of WoundExpress is £114 per week, based on a recommended 8-week rental period. This includes the WoundExpress pump and a single garment. Quantity and duration discounts may apply. WoundExpress should be used alongside standard care.

The technology

WoundExpress (Huntleigh) is an advanced wound therapy device, which uses intermittent pneumatic compression to promote lower leg wound healing for people at home. The device has a specially designed 3-chamber garment that attaches to a pump, which has a patented timing cycle to augment venous and arterial blood flow. By inflating the garment in this special sequence, the company says that the flow of nutrient and oxygen-rich blood increases into the affected region, helping with wound healing.

Innovations

The company claims WoundExpress is unique because it's designed to go on the thigh of the ulcerated limb, rather than the wound site. Intermittent pneumatic compression is widely used, but the company claims this novel approach to positioning has the benefit of increasing arterial and venous circulation to the wound site without applying direct pressure to the wound bed.

Current care pathway

WoundExpress is intended to be used alongside standard care for hard to heal lower limb venous and mixed aetiology ulcers. Standard care involves cleaning and dressing the wounds with static compression therapy (bandages, or hosiery). The best dressing to use depends on things like wound size and depth, and amount of exudate.

More complicated wounds, for example surgical site infections, diabetic foot problems,

venous leg ulcers and pressure ulcers can result in chronic non-healing wounds and need more advanced care. Care of these types of wounds aims to promote healing and minimise the risk of further complications.

A professional with expertise in wound management (such as a district nurse or tissue viability nurse) should be involved in the person's holistic assessment. For venous leg ulcers this should include a general wound assessment, limb and vascular assessment, venous assessment and wound and surrounding skin assessment.

Vascular assessment can, using ankle brachial pressure index, identify whether arterial disease is present and so if compression therapy is appropriate. Before starting compression therapy, dressing choice is decided: compression bandages or hosiery. The amount of compression may vary, depending on what caused the wound.

The following publications have been identified as relevant to this care pathway:

- [NICE's clinical knowledge summary on venous leg ulcers](#)
- [The AHSN Network's lower limb recommendations](#)
- [NICE's guideline on peripheral arterial disease: diagnosis and management](#)
- [NICE's guideline on diabetic foot problems: prevention and management](#)
- [NICE's guideline on pressure ulcers: prevention and management](#)
- [NICE's guideline on varicose veins: diagnosis and management.](#)

Population, setting and intended user

WoundExpress is intended to be used alongside current wound treatment. It can be used to treat hard to heal lower limb venous and mixed aetiology ulcers that are not progressing significantly towards healing in people over 18.

WoundExpress is not appropriate for suspected deep vein thrombosis, pulmonary embolism, thrombophlebitis, severe congestive cardiac failure, symptoms of sepsis, pulmonary oedema associated with significant limb oedema, active metastatic disease affecting the limb, kidney failure, acute infections of the skin such as cellulitis, severe acute or chronic limb-threatening ischaemia and severe peripheral artery disease (ankle

brachial pressure index of 0.6 or less).

WoundExpress is applied at home by the user for a total of 2 hours every day. People who have problems with dexterity or cognitive impairment may need a family member or carer to help them put it on. People may need some basic advice on how to use the technology.

Costs

Technology costs

Standard care using wound dressing and static compression therapy is expected to take place before and alongside WoundExpress.

- WoundExpress pump: £90 per week rental (quantity and duration discounts may apply). The pump has an expected lifecycle of up to 7 years. It needs to be serviced every 2 years, which costs £106.
- Single patient garment: £195, single patient use, guaranteed to last up to 16 weeks of daily use.
- In total WoundExpress costs £114 per week, including disposables and service, based on the recommended 8-week rental period.

Costs of standard care

Different dressings are available for standard care of non-healing wounds. Individual dressing costs are:

- soft polymer dressing £3.49 to £17.91
- hydrocolloid fibrous dressing £0.99 to £10.58
- antimicrobial dressing £0.18 to £48.08
- if appropriate, PICO negative pressure wound dressing kits cost between £20.15 to £129.60
- high compression bandages £2.52 to £6.24

- multilayer compression bandaging (Ultra Four, Profore) £4.19 to £12.38.

Chronic wound treatment is not a single treatment. It is a treatment process over time. Total wound care costs over a year are reported as £698 to £3,998 per person for a healed wound, and £1,719 to £5,976 per person for an unhealed wound ([Guest et al. 2017](#); [Andriessen and Eberlein 2008](#)). The annual cost of a venous ulcer is reported as £3,000 per person for a healed ulcer, and up to £13,500 per person for an unhealed venous leg ulcer ([Guest et al. 2018](#)).

Resource consequences

The company estimates that around 265,000 people per year could be eligible for the technology in the UK (based on [Guest et al. 2020](#)). WoundExpress is to be used alongside standard care for hard to heal wounds, so initial costs are higher than standard care. However, the company claims that, because it improves healing outcomes, it reduces the resource burden of chronic non-healing and complex wounds. The company says WoundExpress does this by improving healing, reducing length of care and the need for further interventions, improving service efficiency, and potentially allowing resources to be reallocated.

Because the technology is used alongside standard care, organisational changes are not likely to be needed. Healthcare professionals using WoundExpress are trained by the company for free, although there will be a cost for staff time when they are introduced to it. The device is sent with clear instructions and there is comprehensive support online. It can be managed at home by people and carers. The person will need a power source near to where they have their treatment in their home. Appropriate storage of the device and its parts needs to be taken into account, as well as its delivery and return between user and clinic.

Regulatory information

WoundExpress is a CE marked class IIa (or In Vitro Diagnostic Devices Directive [IVDD] device for self-testing, or In Vitro Diagnostic Regulation [IVDR] class B).

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful

discrimination, and fostering good relations between people with particular protected characteristics and others.

WoundExpress is intended to be used by people with venous leg ulcers and hard to heal wounds. Older people, people with diabetes and people with restricted mobility are more likely to have peripheral arterial disease, chronic or non-healing wounds. People with obesity, varicose veins and a history of deep vein thrombosis are more likely to be affected by leg ulcers. Age and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology.

Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 6 studies summarised in this briefing, including a total of 121 people. Two studies are observational, 1 of which is a pilot study. Four are case series. Davies and Dunn (2021) is an extension to the Kettley and Turner-Dobbin study.

The company sponsored a [consensus article on the benefits of intermittent pneumatic compression and how to use WoundExpress in practice](#).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence base for the technology is of low methodological quality and the studies are small in terms of patient numbers. All studies are based in the UK and generalisable to clinical practice in the NHS. The observational studies both suggested that using WoundExpress could improve hard to heal wounds. Case series also showed reduced

wound size and pain. Further evidence is needed from larger sample sizes with comparator arms and improved internal validity. Both observational studies received funding from Huntleigh Healthcare and the former company Arjo (now ArjoHuntleigh Healthcare).

Morris et al. (2020)

Study size, design and location

Prospective observational study of 33 people (including 20 healthy volunteers) in Wales.

Intervention and comparator

WoundExpress, no comparator.

Key outcomes

Measured the haemodynamic potential of a thigh-only approach to intermittent pneumatic compression. The average peak velocity caused by the intermittent compression was 11.6 cm/s, which was greater than for the previous group of healthy volunteers (Mann–Whitney U, $p=0.1$, 2-tailed). The mean of the approximate correlate of the volume of venous blood (multiplication of the mean peak velocity and the mean duration of venous blood flow) was 8.2 cm, which was greater than for the healthy volunteers (Mann–Whitney U, $p=0.3$, 2-tailed).

Strengths and limitations

The small number of patients and heterogenous disease conditions in the ulcer group make it difficult to draw firm conclusions. Scans were not available, so some differences in effect may have been caused by underlying vascular conditions. Arjo (now ArjoHuntleigh) provided funding to support the work.

Naik et al. 2019

Study size, design and location

Prospective observational pilot study of 21 patients in the UK.

Intervention and comparator

WoundExpress, no comparator.

Key outcomes

Wounds progressed towards healing in 20 patients, with the median wound area at 8 weeks post intervention significantly lower than at recruitment ($Z=-3.980$, $p<0.000$). Pain scores significantly reduced in 15 patients ($Z=-2.905$, $p<0.036$).

Strengths and limitations

This was the first pilot study of WoundExpress. The main limitation was that it was not a controlled study, with the potential for selection bias. Regression to mean bias is also not addressed, however the author argues that it is unlikely given the population of hard to heal wounds. Huntleigh Healthcare sponsored and funded the study.

Davies and Dunn 2021

Study size, design and location

Case series including 61 patients with hard to heal leg ulcers recruited across 11 wound treatment centres or wound care specialists in the UK.

Intervention and comparator

WoundExpress, no comparator.

Key outcomes

Fifty-three out of 61 participants completed the evaluations. Thirty-three per cent ($n=19$) of all ulcers healed within the 16-week study period; the mean time to healing was 10 weeks. Sixty per cent of ulcers ($n=35$) progressed towards healing with a mean surface area reduction of 56% (23 cm^2). Seven per cent ($n=4$) did not progress towards healing.

Strengths and limitations

Eight participants withdrew from the study and 5 were removed from the analysis. Without

a control the progression towards healing cannot be attributed to WoundExpress. However the authors note that the population's hard to heal wounds had a mean duration of 50 months before entry into the study.

Kettley and Turner-Dobbin 2020

Study size, design and location

Case series abstract including 27 patients recruited across 6 sites in the UK.

Intervention and comparator

WoundExpress, no comparator.

Key outcomes

In Wales 8 out of 11 patients completed the 16-week evaluation using WoundExpress. All 8 progressed towards healing, with a mean wound surface area reduction of 63%. In England 13 out of 16 patients completed the 16-week evaluation with 12 progressing towards healing, with a mean surface area reduction of 66%. In England 2 patients' wounds had complete epithelisation and in Wales this was 5.

Strengths and limitations

This study is reported in abstract form only, so detail is limited.

Ivins et al. 2020

Study size, design and location

Case studies of 2 patients.

Intervention and comparator

WoundExpress, no comparator.

Key outcomes

The first patient's wound surface area reduced by 71.5%, and their pain reduced by 65% after 4 months using WoundExpress. The second patient's pain score reduced from 5 to 4 out of 10 after 6 weeks. The wound completely healed at week 16 and the patient said they were no longer in pain.

Strengths and limitations

This was a narrative article with 2 case studies. It was limited in methodological detail and generalisability.

Ivins et al. 2020

Study size, design and location

Case series of 4 patients in Wales.

Intervention and comparator

WoundExpress, no comparator.

Key outcomes

Patients used WoundExpress for 16 weeks. Two patients' wounds reduced by 64% and 72%, and the wounds of the other 2 patients completely healed. Their pain scores reduced after treatment. Patients said the device was easy to apply and remove.

Strengths and limitations

This study is reported in poster abstract form only, so detail is limited.

Sustainability

The company claims the technology could reduce environmental impact if patients have to travel less to appointments. There is no published evidence to support these claims.

Recent and ongoing studies

Intermittent pneumatic compression of the thigh for the treatment of lower limb wounds.
Trial identifier: ISRCTN77093550. Status: recruiting to start March 2021. Indication: lower limb wounds. Devices: WoundExpress. Countries: Wales, England, Germany and Sweden.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 4 experts had used this technology before.

Level of innovation

All 4 experts agreed that WoundExpress is novel in that it is designed to apply intermittent pneumatic compression away from the wound site, and because patients can use it themselves at home. Three experts said the device was a major innovation in care and had the potential to change clinical practice. One felt it would not shift practice but would instead be another treatment option for patients if standard care did not work for them or they could not tolerate it. Experts said the placement of the device eased application and removal and reduced pain and discomfort because there was no need to apply direct pressure to the wound site.

Potential patient impact

Three experts said that WoundExpress could mean better outcomes for people with lower limb oedema and lower limb ulceration when used together with standard care. Two experts said their patients had very positive experiences with it, with reduced pain and wound size. The other 2 experts also said healing rates were better, which can improve outcomes and quality of life, and reduce the need for clinic visits.

Two experts highlighted the benefits of home use: people can independently manage their therapy at their convenience, and take ownership of their long-term condition, which can improve outcomes. One expert said the position of the technology away from the wound site reduced pain and made it easier to apply and remove the device. One expert also said

that early intervention with the device could heal venous lower leg ulcers more quickly.

Two experts said that the device could particularly benefit people who cannot use standard compression therapies because of pain. Two said the device can only be used by people with a thigh circumference of up to 73 cm because of the cuff size.

Potential system impact

All experts said that WoundExpress could reduce clinic visits for wound care because people can self-manage at home, and that it could improve healing rates and reduce length of care. Two said nurse time and consumables needed could also reduce because of a quicker healing time and because chronic wounds could be avoided. Two experts said treatment is likely to cost more because of the initial capital investment in equipment and thigh garments on top of standard care costs.

One expert said a potential infrastructure barrier was single patient thigh cuff garments being made available to buy on prescription. They said another barrier was funding arrangements to buy or hire the devices and whether it would be appropriate for devices to be bought by the user in the future, which is not currently the case. One expert said storage would be needed for the devices and disposable bandages, as well as a system to supply and collect the devices in the community. All experts agreed that the technology is simple and straightforward to use, and minimal training is needed to use it safely and effectively. None of the experts was aware of any safety issues or adverse incidents.

General comments

All experts said there were gaps in the research on this emerging technology. Two said they would like to see longer-term follow-up research to find out if ongoing support is needed, and if there is an increased risk of re-ulceration and oedema when WoundExpress therapy has finished. One expert said more studies were needed to show the device being used independently by the patient. Two experts also said more research was needed in different wounds with different causes, such as diabetic foot ulceration, mixed arterial venous leg ulceration and arterial lower leg wounds. One expert said that because WoundExpress was to be used alongside standard care, the cost benefits were unclear. They suggested that more evidence was needed on the system impacts of the device.

Expert commentators

The following clinicians contributed to this briefing:

- Karen Staines, director of education and research/clinical lead for wound care, Accelerate CIC. Did not declare any conflicts of interest.
- Alison Schofield, tissue viability clinical nurse specialist, Northern Lincolnshire and Goole NHS Trust. Received an honorarium for involvement in best practice statement.
- Dr Leanne Atkin, vascular nurse consultant at The Mid Yorkshire Hospitals NHS Trust. Received an honorarium for involvement in reviewing a patient leaflet about the device as well as for an advisory board meeting relating to venous disease involving WoundExpress.
- Nicky Ivins, clinical director, Welsh Wound Innovation Centre. Received financial reimbursement for conference attendance, completed a pilot study through a research unit funded by Huntleigh Healthcare and received research funding from Huntleigh Healthcare for an evaluation study.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement for medtech innovation briefings](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Update information

July 2021: We corrected an error in the total patient numbers in the published evidence section.

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