



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	WoundExpress intermittent pneumatic compression device in people with hard to heal lower leg ulcers
Topic exploration report number:	TER291

Introduction and aims

WoundExpress is a device which promotes wound healing in people with 'hard to heal' venous leg ulcers or mixed leg ulcers (venous and arterial aetiologies) by using intermittent pneumatic compression. 'Hard to heal' is defined as a failure of the wound to progress towards healing (as indicated by a decrease in surface area). Intermittent pneumatic compression is the application of mechanical cyclical pressure through compressed air from an electronically operated pump attached to encircling garments. The resulting physiological effects contribute to wound healing. The WoundExpress device is a three-chamber thigh garment attached to a pneumatic compression pump, and is intermittently inflated in a patented sequence. The device is designed to be used for two hours per day in the hospital, community or home settings, and is an adjunct to current practice. It is worn on the thigh of the afflicted leg, away from the leg ulcer site below the knee. By contrast, traditional intermittent pneumatic compression devices (boot-like, zip-up garments) apply relatively high intermittent pressure over a wound site.

In current practice, people with leg ulcers receive static compression therapy using graduated, multi-layered bandaging, wraps or hosiery. However, some people are unable to tolerate continual high compression bandaging and a proportion of wounds do not heal.

Health Technology Wales researchers searched for evidence on WoundExpress, or other proximal intermittent pneumatic compression devices, used in the home setting, in people with hard-to-heal venous leg ulcers or mixed leg ulcers (of venous or arterial aetiologies) that have not responded or healed with standard treatment (graduated static compression therapy).

Summary of evidence

UK Guidelines and Guidance

The NICE Medtech Innovation Briefing (MIB) on WoundExpress to promote lower leg wound healing for people at home (MIB261, published June 2021) summarised evidence from six studies in total (n=121), including two observational studies (one pilot study) and four case series. All six studies were based in the UK. The MIB found that WoundExpress could improve the management of hard to heal lower leg wounds, and reported that the case series showed reduced wound size and pain. However, the MIB cautions that the evidence base is of low methodological quality with small patient numbers, noting that the studies are non-comparative. One ongoing randomised controlled trial (The IPCOTT study, ISRCTN77093550) highlighted in the MIB began recruitment in March 2021, and compares WoundExpress used in the home environment for two hours daily in addition to standard wound care, with standard wound care alone.

The MIB also gives detail on the cost of WoundExpress, which is £114 based on an 8-week rental period for the WoundExpress pump and a single garment. As WoundExpress is an adjunct to standard care, these costs would be in addition to other costs of chronic wound treatment, which the MIB reports can be as high as £13,500 per person per year for an unhealed venous leg ulcer.

The Health Service Executive (HSE) National Wound Management Guidelines (2018) state that compression bandages... are recommended as the initial treatment modality to promote healing in patients with a venous leg ulcer (evidence grade C). The guidelines further recommend the use of high compression pressures of at least 40mmHg at the ankle level (evidence grade C). The guidelines do not refer to WoundExpress, or intermittent pneumatic compression more generally, but are included here for completeness. However, the HSE 'Patient Safety Toolbox Talks' on Tissue Viability Leg Ulcer Assessment and Management lists intermittent pneumatic compression alongside multi-layer elastic or inelastic bandages and compression hosiery as a management strategy for venous ulcers.

The SIGN national clinical guideline on management of chronic venous leg ulcers (SIGN 120, published 2010) found that intermittent pneumatic compression did not improve healing rates when compared with standard compression bandaging alone, though healing rates were improved when compared with no compression bandaging. This was based on a Cochrane review of four small randomised controlled trials (updated in 2014, discussed below). The guideline considered that there was insufficient evidence on which to base a recommendation for intermittent pneumatic compression in chronic venous leg ulcer. WoundExpress was not included in the guideline.

Systematic Reviews

One Cochrane review, most recently updated in 2014, included nine randomised controlled trials which compared the effects of intermittent pneumatic compression with either sham treatment, no treatment or different intermittent pneumatic compression regimens in people with venous ulcers. The review concluded that intermittent pneumatic compression may improve healing when compared with no compression, but it is unclear whether it can be used instead of compression bandages. It found that 'there is some limited evidence that intermittent pneumatic compression may improve healing when added to compression bandages'. One included randomised controlled trial compared compression regimens and found that rapid was better than slow.

No other systematic reviews were identified which were published after the Cochrane review in 2014.

Primary studies

As the NICE MIB261 may not have searched for evidence relating to intermittent pneumatic compression devices other than WoundExpress, HTW researchers looked for primary studies, other than those primary studies which were included in MIB261, which were published after the Cochrane review in 2014.

One study (Dolibog et al, 2014) (n=147) randomised between five types of compression therapy (intermittent pneumatic, stockings, multi-layer, two-layer short stretch bandages and Unna boots) in people with venous leg ulcers. The study found that the healing rate was highest in the intermittent pneumatic compression group. An earlier publication by the same group was included in the Cochrane review.

One randomised controlled trial (Marston et al, 2020) compared treatment with a pneumatic compression device (the ACTitouch adaptive compression therapy system, (n=26)) and multi-layered bandaging (n=30) in people with venous leg ulcers, but was halted early. Subsequent to randomisation, ten patients withdrew from the ACTitouch group, due to skin or wound problems related to the ACT device (n=5) and because of the inconvenience of using the device (n=5). The trial was therefore halted so that improvements could be made to the device. Data from 42 patients showed similar rates of wound healing between groups, with a larger size reduction in the ACTitouch group compared with the multi-layered bandaging group.

One randomised study (Harding et al, 2016) compared an adaptive compression therapy which combines intermittent and sustained pneumatic compression therapy (n=38) with a four-layer bandage system (n=52) over 12 weeks of treatment. The study found similar rates of ulcer healing, adverse events and patient-rated comfort between the two treatments. It concluded that adaptive compression therapy is as effective as four-layer bandage systems for ulcer healing but is better accepted by patients, who report higher quality of life scores.

One retrospective case series (Arvesen et al, 2017) described the use of intermittent pneumatic compression in combination with negative pressure wound therapy in people with ulcers (experienced for 2-6 months). The relevance of this study may be limited due to the short history of ulcers in this population, as the population of interest for this topic exploration report is 'hard to heal'. The study found that all wounds improved and oedema was reduced during the study period.

Other evidence

Evidence supplied by the topic proposer included those studies which were already included in NICE MIB261, and an additional health economic analysis which is currently in press. The topic proposer states that a cost-utility analysis was constructed which compared WoundExpress in addition to standard care with standard care alone in people with hard to heal venous leg ulcers. The costs and QALYs of the two strategies were compared over a 24 week time horizon. The topic proposer reports that QALYs were 0.02 higher in the intermittent pneumatic compression group. The incremental cost was reported to be £17 higher for standard care alone, if the use of the device is stopped after 6 weeks in non-improving wounds.

Areas of uncertainty

The standard of care in Wales for first line and second line (hard to heal) wounds is uncertain. It is unclear whether the standard of care is static compression therapy using graduated, multi-layered bandaging, wraps or hosiery. In addition, it is not known whether traditional intermittent pneumatic compression devices (boot-like, zip-up garments applied over the wound site) are used in current practice. There may be other relevant comparators, such as negative pressure wound therapy or sustained compression devices.

The topic proposal alternately describes the population as 'venous leg ulcers' and 'venous leg ulcers...which have not responded or healed with standard treatment'. The latter seems to reflect the populations of the studies included in NICE MIB261, including the ongoing randomised controlled trial. Should such evidence exist, it is unclear whether evidence in the first-line population is relevant.

There may be other wound types which should be included in the population (hard to heal leg ulcers or mixed leg ulcers (venous and arterial aetiologies)). It is unclear whether there is one generally accepted definition of 'hard to heal'. If not, populations considered within the evidence identified may vary in the length and severity of their wounds.

Conclusions

A MIB published in June 2021 found that WoundExpress could improve the management of hard to heal lower leg wounds, but that the evidence base was limited in terms of patient numbers and quality. Other UK guidelines did not refer specifically to WoundExpress specifically. SIGN concluded that there was insufficient evidence to make recommendations on intermittent pneumatic compression in 2010.

One Cochrane review of intermittent pneumatic compression devices was published in 2014. Since the Cochrane review (and in addition to the studies included in the MIB), two randomised controlled trials of adaptive compression therapies and one later publication of a randomised controlled trial were published, as well as a prospective study and a case series. One of the randomised controlled trials was halted early.

The topic proposer highlighted that a cost-utility analysis (WoundExpress) is currently in press. Recruitment began in March 2021 for a randomised controlled trial comparing WoundExpress for two hours daily in addition to standard wound care, with standard wound care alone.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source
Health Technology Assessment Group	<ul style="list-style-type: none"> Health Service Executive. National Wound Management Guidelines. Published date: 2018. https://healthservice.hse.ie/filelibrary/onmsd/hse-national-wound-management-guidelines-2018.pdf Health Service Executive. Patient Safety Tool Box Talks © Effective Care and Support Tissue Viability Leg Ulcer Assessment and Management. Published date: Not available. https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/pressureulcerszero/tissueviabilitylegulcermanagement.pdf
Health Information and Quality Authority	We did not identify any relevant evidence from this source
EUnetHTA	We did not identify any relevant evidence from this source
International HTA Database	We did not identify any relevant evidence from this source
UK guidelines and guidance	
SIGN	<ul style="list-style-type: none"> Healthcare Improvement Scotland. Management of chronic venous leg ulcers A national clinical guideline (SIGN 120). Published date: 2010. https://www.sign.ac.uk/media/1058/sign120.pdf
NICE	<ul style="list-style-type: none"> National Institute for Health and Care Excellence. WoundExpress to manage lower leg wounds Medtech innovation briefing [MIB261]. Publication date: 01 June 2021. https://www.nice.org.uk/advice/mib261
Secondary literature and economic evaluations	
Cochrane library	<ul style="list-style-type: none"> Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database of Systematic Reviews 214, Issue 5. Art. No.: CD001899. DOI: https://doi.org/10.1002/14651858.CD001899.pub4
Medline (via Ovid-date limit applied: published since 2014)	We did not identify any relevant systematic reviews from this source
Primary studies	
Cochrane library <i>Only include primary studies if there is insufficient secondary evidence</i>	<ul style="list-style-type: none"> Dolibog P, Franek A, Taradaj J, Dolibog P, Blaszcak E, Polak A, Brzezinska-Wcislo L, Hrycek A, Urbanek T, Ziaja J, Kolanko M. A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. Int J Med Sci. 2013 Dec 14;11(1):34-43. doi: https://doi.org/10.7150/ijms.7548 Harding KG, Vanscheidt W, Partsch H, Caprini JA, Comerota AJ. Adaptive compression therapy for venous leg ulcers: a clinically effective, patient-centred approach. Int Wound J. 2016 Jun;13(3):317-25. doi: https://doi.org/10.1111/iwj.12292

<p>Medline</p>	<ul style="list-style-type: none"> • Marston WA, Kirsner RS, Tallis A, Hanft JR, Walters J, Farber A, ACTitouch Investigators. Economic benefit of a novel dual-mode ambulatory compression device for treatment of chronic venous leg ulcers in a randomized clinical trial. J Vasc Surg. 8(6):1031-1040.e1, 2020 11. doi: https://doi.org/10.1016/j.jvs.2020.03.004 • Arvesen K, Nielsen CB, Fogh K. Accelerated wound healing with combined NPWT and IPC: a case series. Br J Community Nurs. 2017 Mar;22 Suppl 3(Sup3):S41-S45. doi: https://doi.org/10.12968/bjcn.2017.22.sup3.s41
<p>Other</p>	
<p>Evidence provided by the topic proposer</p>	<ul style="list-style-type: none"> • Guest, J., Staines, K. & Murphy, N. Potential cost-effectiveness of using Intermittent Pneumatic Compression to manage hard-to-heal venous leg ulcers in the UK. In press (accepted for publication in Journal of Wound Care, June 2021)

<p>Date of search:</p>	<p>June 2021</p>
<p>Concepts used:</p>	<p>WoundExpress, Wound Express, Intermittent Pneumatic Compression, Compression Pump, Proximal Compression, intermittent compression, Leg Ulcer, non-healing wound Intermittent Pneumatic Compression Devices/ Varicose Ulcer/ or Leg Ulcer/</p>