

Thigh-administered IPC for the treatment of lower limb ulcers

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This case series evaluation assessed the efficacy of WoundExpress™ (Huntleigh Healthcare), a novel IPC device, which applies compression to the thigh of the afflicted leg for the management of hard-to-heal leg ulcers. Eleven wound treatment centres or wound care specialists undertook WoundExpress evaluations. Eligible and willing patients (n=61), with a 'hard-to heal' leg ulcer used the WoundExpress device for two hours a day, in addition to continuing to receive their standard wound care for a 16-week period. Fifty-three participants completed the evaluations. Thirty-three percent (n=19) of all ulcers healed within the 16-week study period; the mean time to healing was 10 weeks. A further 60% of ulcers (n=35) progressed towards healing within the 16-week period, with a mean surface area reduction of 56% (23cm²). The evaluation concluded that thigh-administered IPC is an effective adjunctive treatment, that aids healing and reduces pain, for patients with hard to heal leg ulcers.

KEYWORDS:

- Intermittent pneumatic compression (IPC)
- Hard-to-heal wounds
- Compression therapy
- Pain
- Improved healing rates

Leg ulceration, a significant and growing problem in the UK, causes immense suffering for those afflicted by the condition and also represents a substantial burden to the NHS. A recent paper by Guest et al (2020) estimated that the prevalence of venous leg ulcers (VLUs) in the UK more than doubled from 2012/13 to 2017/18 (increasing from 278,000 to 560,000). Furthermore, ulcers of mixed and arterial aetiology also increased from 24,000 to 102,000 (+325%) and 9,000 to 31,000 (+244%) respectively over the same time period (Guest et al, 2020). While these increases in prevalence may, in part, be attributed to improvements in diagnosis, it is likely that factors such as an aging population with increasing levels of obesity, both of which are associated with the development of leg ulcers, mean that these figures do represent a significant increase in real terms.

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Static compression therapy is widely accepted as the treatment of choice and gold standard therapy for the prevention and management of VLU (National Institute for Health and Care Excellence [NICE], 2019; Wounds UK 2019). Some ulcers heal successfully within a few weeks, however, a proportion of wounds do not progress towards healing despite receiving this gold standard treatment and furthermore, some patients cannot tolerate wearing continual high compression bandaging (Young et al, 2021). Guest et al (2018) showed that of 440 patients with VLUs who were in gold standard compression, 48% had not healed within 12 months.

Intermittent pneumatic compression (IPC) is an adjunctive treatment modality which has been shown to be effective in the treatment of leg ulceration (Nelson et al, 2014). Pressure and inflation cycles vary and compression can be applied to the entire limb, or region of the leg (Naik et al, 2019). In 2014, a Cochrane review

found that there was some limited evidence that showed that IPC may improve healing of venous leg ulcers when added to compression bandaging (Nelson et al, 2014).

The aim of this case series evaluation was to assess the efficacy of WoundExpress™ (Huntleigh Healthcare), an IPC device designed to apply compression to the thigh of the afflicted leg, not the wound site, to increase blood flow, for the management of hard-to-heal ulcers.

METHOD

Eleven wound treatment centres or wound care specialists undertook to evaluate WoundExpress on patients with hard-to-heal leg ulcers over a 16-week period — England (n=9), Wales (n=1) and Sweden (n=1). Eligible and willing patients with a 'hard-to heal' leg ulcer and no contraindications to use of the WoundExpress provided written consent to participate. Hard-to-heal was defined as 'failure of the wound to progress in the opinion of the responsible wound care specialists'. Participants were asked to use the WoundExpress device for two hours a day in addition to continuing to receive their standard wound care for the 16-week period.



WoundExpress

The WoundExpress device has a specially designed three-chamber garment that attaches to a lightweight, portable and quiet pump, which has a patented timing cycle (two hours) that augments venous and arterial blood flow. Unlike standard treatment, the WoundExpress universal garment has been designed to be placed on the thigh, not the wound site (Roberts, 2019).

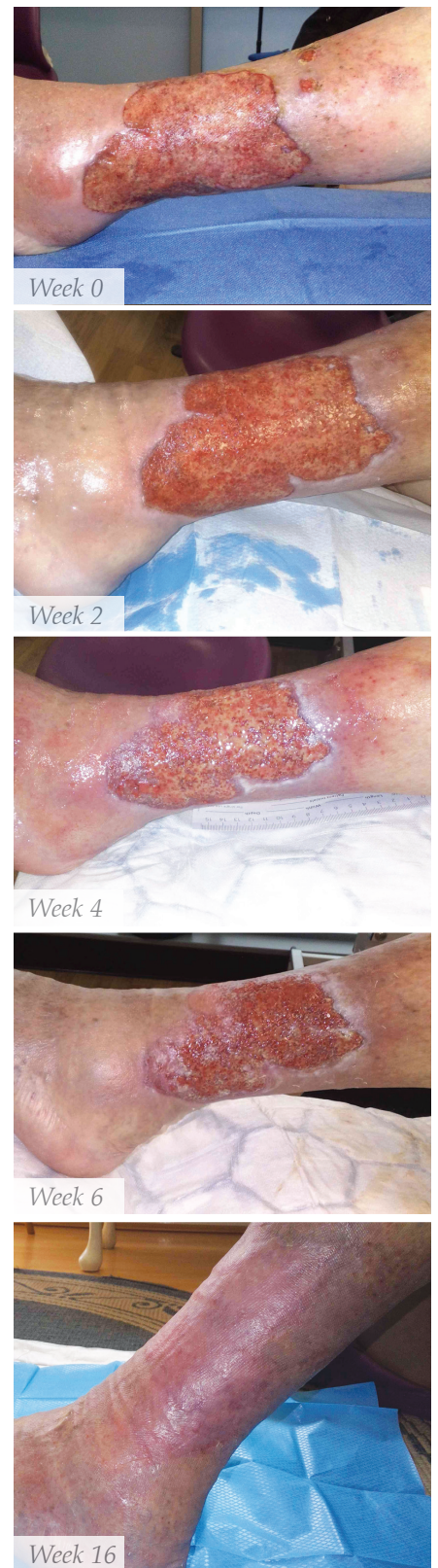
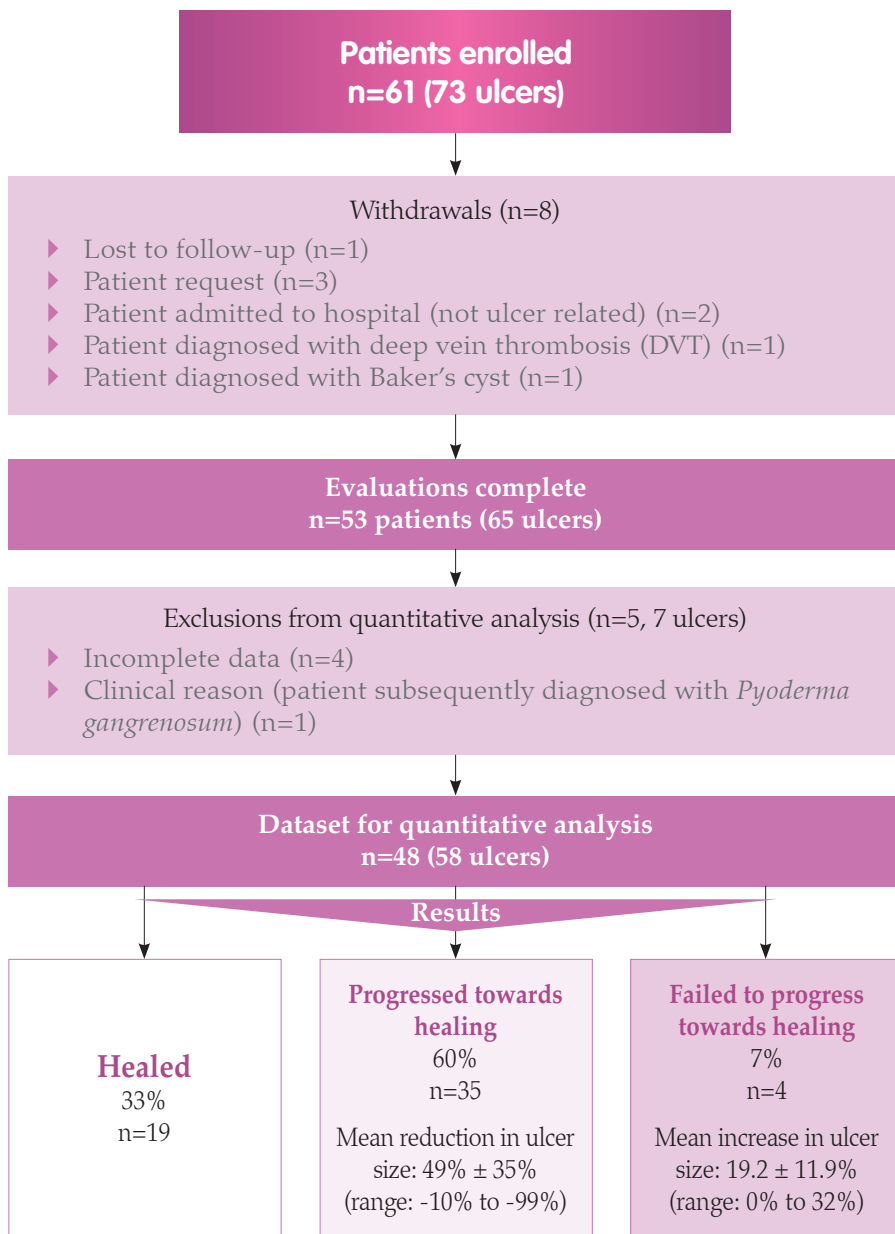


Figure 2. Leg ulcer progressing to healing over 16-week treatment period with WoundExpress.

Figure 1. Origin of data and key results.

For the majority of participants (92%), standard wound care comprised adequate and appropriate static compression therapy in line with current leg ulcer guidelines/recommendations. Eight percent of participants could not tolerate the recommended level of static compression and hence received a reduced level or no compression at all.

The primary outcome assessed was percentage change in ulcer size. Measurements and photographs were taken/recorded at several time points throughout the evaluations in line with the patients' usual clinical reviews. One participating centre (Welsh Wound Innovation Centre [WWIC]) also provided data in relation to wound-

related pain levels throughout the evaluations.

POPULATION

Sixty-one participants, aged 71 ± 12 years, with a total of 73 ulcers, consented to take part, of which 53 completed the 16-week evaluation (Figure 1). Data from five evaluations (with a total of seven ulcers) were excluded from the analysis (reasons shown in Figure 1).

The WoundExpress is primarily indicated for ulcers of venous or mixed aetiology, hence the majority of ulcers included were venous (81%, $n=47$) or mixed venous/arterial (8.6%, $n=5$). The Swedish wound treatment

centre included rheumatoid ulcers ($n=2$), traumatic wounds ($n=2$) and Martorell's ulcers ($n=2$). The mean ulcer duration before inclusion in the evaluations was 50 ± 87 months (median: 24 months).

Table 1: Population statistics with comparison of healed and non-healed ulcers

	All (n=58)	Healed (n=19)	Not healed (n=39)	P
Age (years)	69.9 ± 13.3 (range: 27–92)	72.8 ± 11.6 (range: 50–92)	68.5 ± 14 (range: 27–92)	0.4*
Gender (M:F %)	60:40 (35:23)	63:37 (12:7)	59:41 (23:16)	0.78*
Wound duration (months) Mean ± SD range	50 ± 87 (range: 3–600)	18 ± 17 (range: 3–60)	66 ± 102 (range: 3–600)	0.002*
Baseline area (cm ²) Mean ± SD range	36.9 ± 60.7 (range: 0.01–362)	24.7 ± 59.1 (range: 0.6–252.7)	42.7 ± 64.1 (range: 1.52–362)	0.002*
Change in wound size (cm ²) Mean ± SD range	-20.8 ± 38.5 (range: -252–2.2)	-24.7 ± 59.1 (range: 0–252.7)	-18.9 ± 23.2 (-110–2.2)	0.27*
Change in wound size (%) Mean ± SD range	-65 ± 37 (range: -100–32)	-100%	-49 ± 35 (range: -99–32)	

*Mann Whitney U test

Table 2: Comparison of concordant and non-concordant participants

	Concordant (n=54)	Non-concordant (n=4)	P
Age (years)	69.9 ± 13.3 (range: 27–92)	70.2 ± 11.1 (range: 27–83)	0.78
Gender (M:F %)	61:39 (33:21)	50:50 (2:2)	1.0
Wound duration (months) Mean ± SD range	49 ± 89 (range: 3–600)	30 ± 63 (range: 3–132)	0.84
Baseline area (cm ²) Mean ± SD range	32.6 ± 57 (range: 0.1–362)	88.22 ± 110.2 (range: 24–252)	0.07
End area (cm ²) Mean ± SD range	16.4 ± 40.6 (range: 0–252)	8.16 ± 6.31 (range: 0–14.5)	0.7
Healed (Y:N) %	33:67 (18:36)	25:75 (1:3)	1.0
Change in wound size (cm ²) Mean ± SD range	-16.1 ± 21.9 (range: -110–2.2)	-80 ± 115.59 (range: -12.7–252.7)	0.04*
Change in wound size (%) Mean ± SD range	-65 ± 39 (range: -100–32)	-74 ± 21 (range: -100– -47)	0.82

*Mann Whitney U test

As said, standard care for all participants included adequate and appropriate static compression therapy, with the exception of four participants who were unable to tolerate such treatment.

RESULTS

At the end of the 16 weeks, wound size had significantly decreased from an average of 36.9 ± 60.7 cm² to 15 ± 37.9 cm² (p<0.001). Thirty-three percent (n=19) of all ulcers healed within the 16-week study period — the mean time to healing was 10 weeks. A further 60% of ulcers (n=35) progressed towards healing with a mean surface area reduction of 56% (23cm²). Only three ulcers increased in size, two of which were rheumatoid ulcers. In addition

to this, one ulcer remained static (no change in wound surface area). Analysis of the healed versus non-healed group (Table 1) demonstrates that wound duration (p=0.002) and baseline area (p0.002) were significantly smaller in the healed compared to the non-healed group (Table 1).

Patients who were non-concordant with static compression therapy

Four patients were considered 'non-concordant with compression', as they were unable to tolerate the optimal level of static compression therapy in the form of bandages, wraps or hosiery. These patients were receiving either low levels of compression or no compression at all. This small subset did not report any problems tolerating WoundExpress therapy, with a healing

rate of 25% and a mean reduction in ulcer size of 65% for those that did not heal within the study period. Participants who were non-concordant with static compression therapy experienced a significantly greater reduction in wound size than those who were concordant: -80 ± 115.59 compared to -16.1 ± 21.9 respectively (p=0.04) (Table 2).

Ulcer-related pain

Out of the 19 WWIC patients who reported pain scores, three patients were free of ulcer-related pain at baseline and remained pain-free throughout the study. Of the remaining patients, 31% (n=5) reported complete resolution of their ulcer-related pain. A further 63% (n=10) reported a reduction in their wound-related pain with a mean reduction of 47%. Only one patient (6%) reported an increase in their wound-related pain (an increase of 16%).

DISCUSSION

All wounds with the exception of the rheumatoid ulcers and two venous leg ulcers responded well to the addition of WoundExpress therapy to their standard treatment regimens. Ninety-three percent of wounds within the reported evaluations progressed towards healing (as indicated by reduced wound surface area), with 33% of wounds healing completely within the 16 weeks of WoundExpress treatment. This progression towards healing cannot conclusively be attributed to the use of the WoundExpress, as there was no control in this case series evaluation. However, as these wounds were considered 'hard to heal' with a mean duration of 50 months before inclusion in the study, it is reasonable to infer that achieving healing, or progression towards healing after the 16-week period was at least partly due to the addition of WoundExpress therapy to standard wound care.

Findings from this case series evaluation concur with the results of a prospective observational pilot study by Naik et al (2019), which evaluated the same thigh-administered IPC device (WoundExpress). Twenty-one participants with hard-to-heal venous or mixed leg ulcers used the WoundExpress for two hours a day for an eight-week

period, in addition to receiving their standard wound care (hard to heal was defined as failure of the wound to progress in the opinion of the treating clinician and a wound that was observed for an eight-week period before recruitment). Ninety-five percent of participants progressed towards healing and pain scores decreased in 83%.

A lab-based study conducted by Morris et al (2020) provided some insight into how thigh-administered IPC may assist healing. They assessed how WoundExpress affected distal arterial and venous blood flow in 20 healthy volunteers and 14 patients with leg ulcers of various aetiologies. They found that arterial blood flow velocity increased in the dorsalis pedis artery after periods of compression, and that venous blood flow velocity increased when the lower chambers of the cuff deflated. These effects were similar in the healthy volunteers and the patients with leg ulcers. These results thus demonstrated that the device resulted in positive effects on venous and arterial blood flow distal to the compression site, but proximal to wound sites.

Non-concordance with static compression therapy is a frequent issue in relation to VLU treatment. Indeed, Young et al (2021) reported that up to 80% of patients in some studies fail to be concordant with wearing sustained compression bandages and hosiery, due to the challenges of donning and removing hosiery, pain, wound leakage, skin irritation and discomfort. Within the evaluations outlined here, patients (n=4) who could not tolerate static compression therapy also achieved positive results after starting WoundExpress therapy. On average, these patients had larger wounds at baseline but achieved greater reductions in wound size than those who were receiving optimum levels of static compression.

A review of the literature reveals a paucity of evidence examining the efficacy of IPC as a stand-alone or primary form of compression for leg ulcers. One trial (n=80) reported specifically on pneumatic compression therapy compared to no compression therapy. The pneumatic compression regimen consisted of one hour sessions,

five days a week for up to six months using sequential pressure of 50mmHg at the ankle and 40mmHg at the thigh. Significantly more VLUs healed when pneumatic compression was used (p=0.004) (risk ratio 2.27, 95% CI 1.30–3.97) (Nikolovska et al, 2005). Sixty-three percent healed in the IPC group versus 27.5% in the control group.

This case series evaluation supports the notion that thigh-administered IPC may be a useful alternative for those who cannot tolerate static compression; although a larger scale study is needed to investigate this further.

CONCLUSION

Leg ulceration is a significant and growing problem in the UK. There is an urgent need to optimise treatment regimens to minimise patient suffering and reduce the burden on increasingly stretched healthcare resources. Findings from this case series evaluation suggest that thigh-administered IPC is an effective adjunctive treatment, that aids healing and reduces pain, for patients with hard-to-heal leg ulcers. A large scale, multicentre, randomised control trial (RCT) is currently in progress to further evaluate the efficacy of the WoundExpress (ISRCTN: 77093550).

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